The impact of a group intervention to promote nutritional improvement and behaviour change for women following treatment for breast cancer

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My research project was looking at the effects of a group lifestyle intervention that we run at Worcester University for women who have had treatment for breast cancer. During the 12 weekly sessions, the group members share recipes, try new foods and discuss healthy food choices in line with the World Cancer Research Fund recommendations; they also try different physical activities such as power walking, tai chi, Pilates and circuits. The research project considered whether this programme addresses people's lifestyle concerns, improves wellbeing and influences behaviour change in the short and long term and investigated how this might have occurred.

Abstract

Many women live with a history of breast cancer. Breast cancer diagnosis and treatment can have ongoing consequences for health and wellbeing while lifestyle improvement can mitigate some of these effects. The focus of this study was to contribute evidence about how behaviour change might best be facilitated. The University offers a physical activity and healthy eating programme for breast cancer survivors. This doctoral study aimed to find out whether this intervention was beneficial, how it might work and how it could be improved. This study focused on the impacts on nutritional health and capacity for behaviour change.

The design of this study was informed by the Medical Research Council (MRC) guidance for developing and evaluating complex interventions together with the principles of realist evaluation. The intervention was refined, a feasibility study was carried out, and it was subsequently trialled to investigate its impact. The trial was carried out within a pragmatic paradigm using a convergent parallel mixed methods approach and a quasi-experimental design. Forty-three participants were recruited and attended one of three 12-week intervention groups. Data were collected at baseline, at intervention start and end, and after 12 months. Data collection included evaluation and interview data, measures of dietary intake and physical health and ratings of self-efficacy, concerns and wellbeing.

This research study found that the intervention led to reduced mean intakes of energy, carbohydrate and reduced daily glycaemic load together with a reduction in mean body weight and body mass index. The intervention also led to improvements in mean self-efficacy, wellbeing and a reduction in concerns. The intervention was found to have exerted its effects by a complex interplay of mechanisms including increased knowledge and understanding, improved confidence and motivation, skill rehearsal and increased peer support. The impact of the intervention on individuals was affected by contextual factors including personal experiences of treatment, previous lifestyle and health, intervention timing within the patient journey and support from family and friends.

This study found that the group lifestyle intervention was acceptable and feasible for participants to attend. It was beneficial as it addressed and reduced key concerns raised by group members and promoted the capacity of participants to initiate and maintain behavioural changes including improved nutritional quality. This research study gave a voice to research participants and identified behaviour change mechanisms that could provide the basis for an iterative process of intervention development. These findings were likely to be transferable to other similar contexts.

Acknowledgements

Firstly, and most importantly, I would like to thank the participants who attended the lifestyle programme and were so generous with their time; it was my absolute privilege to work with you. I would also like to thank clinic staff for a productive collaboration.

I would like to acknowledge the unfailing support of my supervisors Dr Rosie Erol and Dr Allain Bueno. It has been a real pleasure to meet regularly with you to mull over the minutiae of research theory and practice from either side of the methodological divide. You have both been tremendously wise and encouraging; thank you for making the whole process so enjoyable. I would also like to thank Mr Steven Thrush for acting as an advisor for my project, and Dr Penney Upton for initial supervision and for introducing me to complex intervention research.

I would also like to thank Richard Dilworth and colleagues for leading the physical activity sessions. I would particularly like to acknowledge the contribution of Alison Benbow, who ran the nutrition sessions at short notice when I was unable to do so; I am so grateful.

Thanks are also due to the many other people have helped and encouraged me over the past seven years. I would particularly like to thank Martin for the best ever writing retreat. It turns out that days at sea are ideal for analysing data and writing thesis chapters. Thanks also to Nathan and Daniel for IT support and discussions about exercise physiology and statistical analysis.

Last, but not least, I must thank Brian for endless patience, encouragement, interest, understanding, proofreading, cooking and all-round support. I can assure you Brian, this is absolutely my last and final thesis.

Table of Contents

List of Tables

List of Figures

Chapter one: Introduction

1 Introduction

1.1 Overview and context

Cancer occurrence has been increasing worldwide due to factors including population growth, increased life expectancy, urbanisation and associated lifestyle, and delayed parenthood (World Cancer Research Fund International, 2014; Torre *et al.*, 2015). The incidence rate for cancer overall varies between countries; in developed countries it is double that of developing countries. However, developed countries have better screening and treatment so mortality rates are only 8-15% higher (Torre *et al.*, 2015).

Breast cancer is the most common cancer in women worldwide (World Cancer Research Fund International, 2014); the incidence was nearly 1.7 million in 2012 (World Cancer Research Fund/American Institute for Cancer Research, 2017). Worldwide breast cancer incidence is also rising; it increased by 20% between 2008 and 2012 (World Cancer Research Fund International, 2014). The regional incidence of breast cancer is very varied, being three times higher in developed countries such as the United States of America (USA) (92 per 100,000 population) compared to developing regions such as Middle Africa and Eastern Asia (27 per 100,000 population) (World Cancer Research Fund/American Institute for Cancer Research, 2017). Breast cancer incidence is lower in developing countries though it is the leading cause of cancer mortality in women, while in developed countries, it is the second leading cause of cancer mortality, after lung cancer (Torre *et al.*, 2015). Breast cancer survival rates have improved globally and in many countries 5 year survival for stage I/II breast cancer is 80-90% (World Cancer Research Fund International, 2014).

Breast cancer is the most common cancer in women in the United Kingdom (UK); there were nearly 55,000 invasive breast cancer diagnoses in 2015 (Cancer Research UK, 2018). The breast cancer annual incidence rate in UK women is rising; it has risen by 6% over the last 10 years and by 25% since the 1990s **Figure 1:1** (Cancer Research UK, 2018).

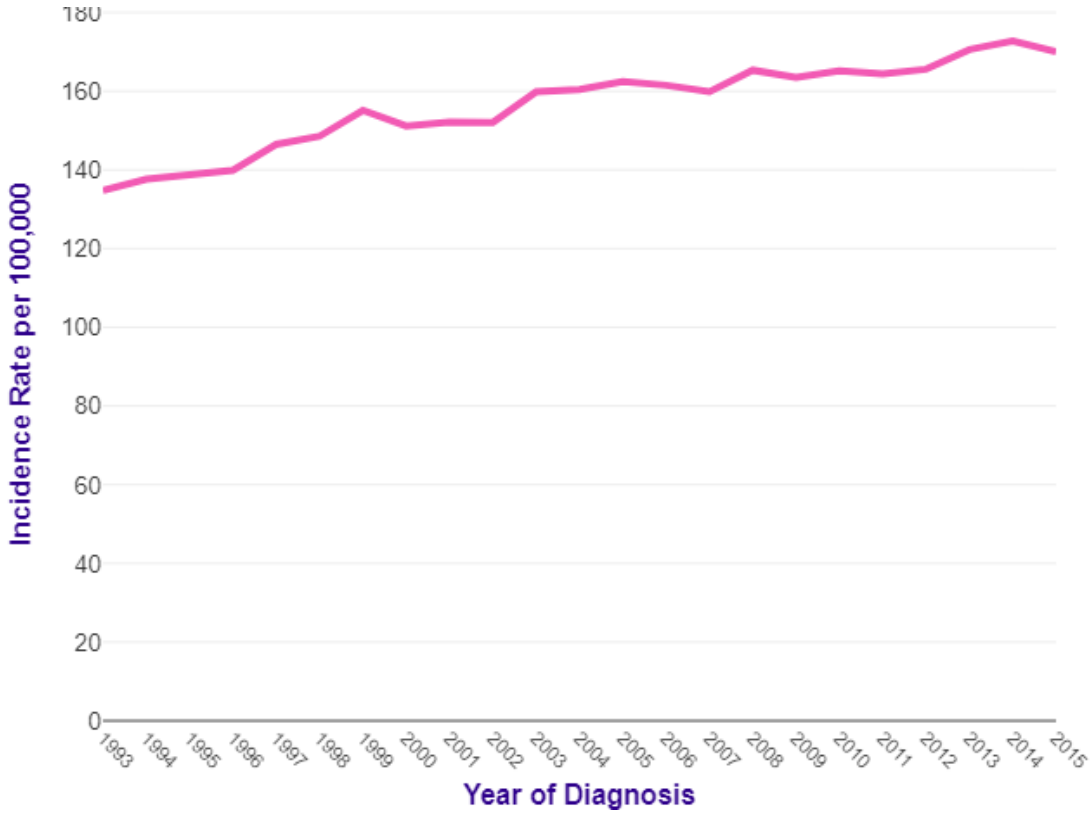

Figure 1:1 European age-standardised incidence rates of breast cancer in women in UK (Cancer Research UK, 2018)

Although UK breast cancer incidence in women is rising, breast cancer mortality has fallen and is less than that of lung cancer (Maddams *et al.*, 2009). UK breast cancer mortality rates have decreased by around a third (32%) since the 1970s, and by about 17% between 1999 and 2009; though they are higher for women living in the most deprived areas (Maddams *et al.*, 2009). As mortality rates reduce, so women with breast cancer are living longer; the 10-year survival rates for England and Wales almost doubled between 1971 and 2011 increasing from about 40% to just under 80% **Figure 1:2** (Cancer Research UK, 2018).

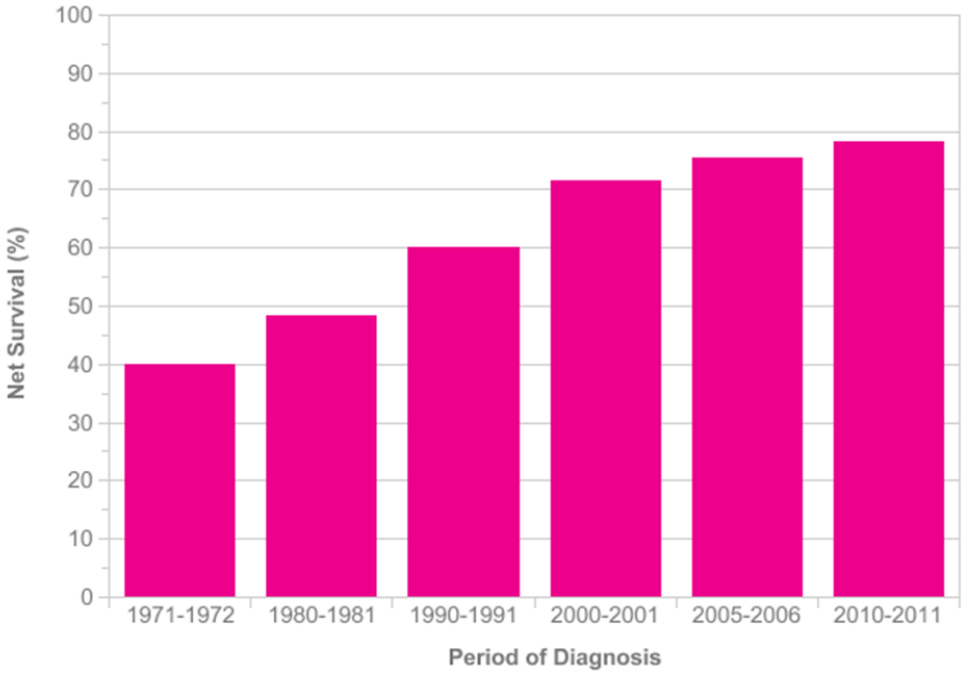

Figure 1:2 Breast cancer in women: 10-year net survival in England and Wales 1971-2011 (Cancer Research UK, 2018)

By contrast, male breast cancer is much less common; fewer than 1% of breast cancer diagnoses occur in men (Brinton *et al.*, 2008). In the UK, there is an incidence of about 350 new cases per year (Speirs and Shaaban, 2009) and the lifetime risk for men is about 1 in 870 (Cancer Research UK, 2018). Male breast cancer incidence rates have risen slightly in the USA; from 1.0 per 100,000 in the late 70's to 1.2 per 100,00 by early 2000s. The age standardised incidence rate is also rising, although to a lesser extent in the UK (Speirs and Shaaban, 2009). There has been far less research focused on male breast cancer and there is less clear evidence about the role of lifestyle factors in its aetiology. Much of the risk seems to be on non-modifiable factors such as age, radiation exposure and genetic factors (Brinton *et al.*, 2008). As breast cancer in males is rare and with a more uncertain aetiology, it was decided to focus this research study on women who have had a diagnosis of breast cancer.

In the UK, there were about 1.2 million cancer survivors in 1992, and that number rose to around 2 million by 2008. The population of cancer survivors has grown by about 3% per year so it is estimated that the prevalence will rise to about 4 million by 2030 (Cancer Research UK, 2018). It has been estimated that 1 in 8 of those over 65 are cancer survivors (Maddams *et al.*, 2009) and so this represents a significant proportion of UK older adults. One of the largest groups of cancer survivors

in the UK are women who have had breast cancer (Maddams *et al.*, 2009; Maher, 2013). The development of breast cancer, its treatments and the possible implications for health and wellbeing will be explored in the next section.

1.2 Breast cancer biology and aetiology overview

The structure of the breast is composed of stroma, adipose and glandular tissue arranged in lobes and ducts (**Figure 1:3**). The lobes and ducts are lined by an epithelial layer that includes stem cells with hormone receptors. These cells undergo mitosis and maturation in response to endocrine stimulation by hormones including oestrogen and progesterone, and growth factors including insulin-like growth factor-1 (IGF-1) (Howell *et al.*, 2005). Oestrogen, mainly in the form of 17 beta-oestradiol (E2), and progesterone are largely produced by the ovaries after the menarche during menstrual cycles and lactation, and by the placenta during pregnancy. Oestrogen stimulates cell division, growth and development of breast tissue. These cycles of hormone production and concomitant development of the breast epithelium continue until hormone levels fall around the menopause, resulting in involution of the lobules, deposition of adipose tissue and breast regression (Howell *et al.*, 2005; Institute of Medicine, 2012; Osborne and Boolbol, 2014). After the menopause, ovarian production of oestrogen largely ceases; though lower levels of E2 and oestrone continue to be made by peripheral adipose tissue, vascular endothelium, and osteoblasts by aromatisation of the androgen androstenedione (Ali and Coombes, 2002). Therefore, increased adiposity can increase aromatisation and levels of circulating oestrogen after the menopause which can lead to increased stimulation of ductal epithelial cells.

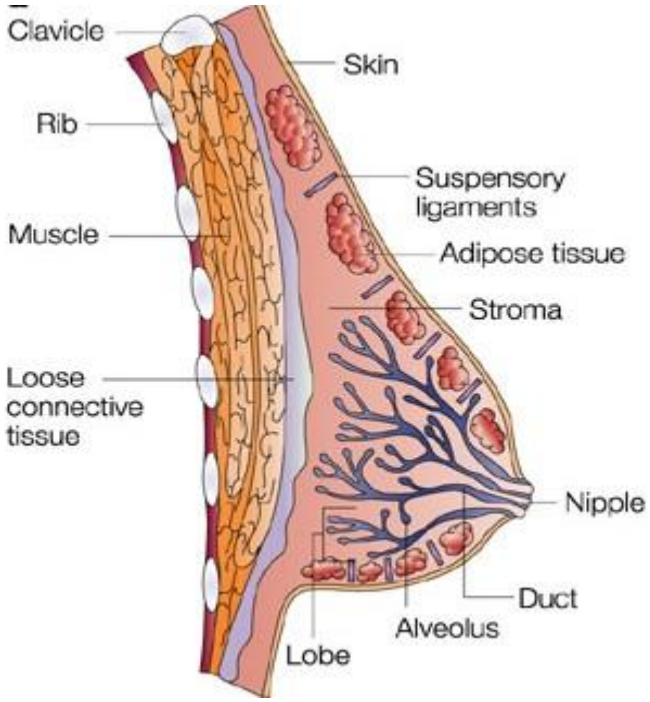

Figure 1:3 The structure of the breast

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Carcinogenesis is a complex multi-step process in which healthy cells are progressively altered and a tumour may result from the growth of one original cancer cell (Weinberg, 2014). Most breast cancers are carcinomas that develop in ductal epithelium (World Cancer Research Fund/American Institute for Cancer Research, 2017). Carcinogenesis includes a series of gene changes that cause epithelial cells to pass through pre-cancerous stages such as ductal carcinoma *in situ*, eventually becoming invasive. These DNA changes occur over a long period of time and therefore cancer incidence rises with age; breast cancer risk doubles every decade until the menopause when the rate of increase reduces (McPherson, Steel and Dixon, 2000). **Figure 1:4** below shows how risk rises with age and that most diagnoses occur during the post-menopausal period.

Breast cancer usually develops due to acquired genetic changes, although in a minority of cases it may occur due to inheritance of mutations within Breast Cancer genes 1 and 2 (BRCA1 and BRCA2) (Institute of Medicine, 2012). In healthy epithelium, cell division is regulated, and DNA integrity maintained by the activity of a variety of genes known as oncogenes and Tumour Suppressor Genes

(TSG). During oncogenesis, changes to these genes accumulate; those alterations that result in increased cell survival or proliferation are more likely to be passed onto progeny cells (Tabchy *et al.*, 2009). Sporadic gene alterations may be due to DNA mutation and/or epigenetic modification of oncogenes and TSG resulting in a disruption of the control of cell division (Institute of Medicine, 2012). Once oncogene and TSG function are affected, the rate of further genetic change increases as processes of DNA checking and repair break down (Tabchy *et al.*, 2009). BRCA1 and BRCA2 are TSG involved in DNA repair; inheriting a mutated BRCA1 increases breast cancer risk by 45-85% (Teegarden *et al.*, 2012) as further genetic change becomes more likely. BRCA1 and BRCA2 are also often hypermethylated and silenced in sporadic breast cancer (Teegarden *et al.*, 2012; Weinberg, 2014). Tumour cells usually have several activated oncogenes and TSG suppressed by mutation or hypermethylation (Weinberg, 2014) that result in a number of phenotypic hallmarks of cancer such as genome instability, resistance to apoptosis, replicative immortality and chronic inflammation (World Cancer Research Fund/American Institute for Cancer Research, 2018). Diet may impact on breast cancer risk as nutrient sufficiency may affect epigenetic gene modification of oncogenes and tumour suppressor genes (Teegarden *et al.*, 2012).

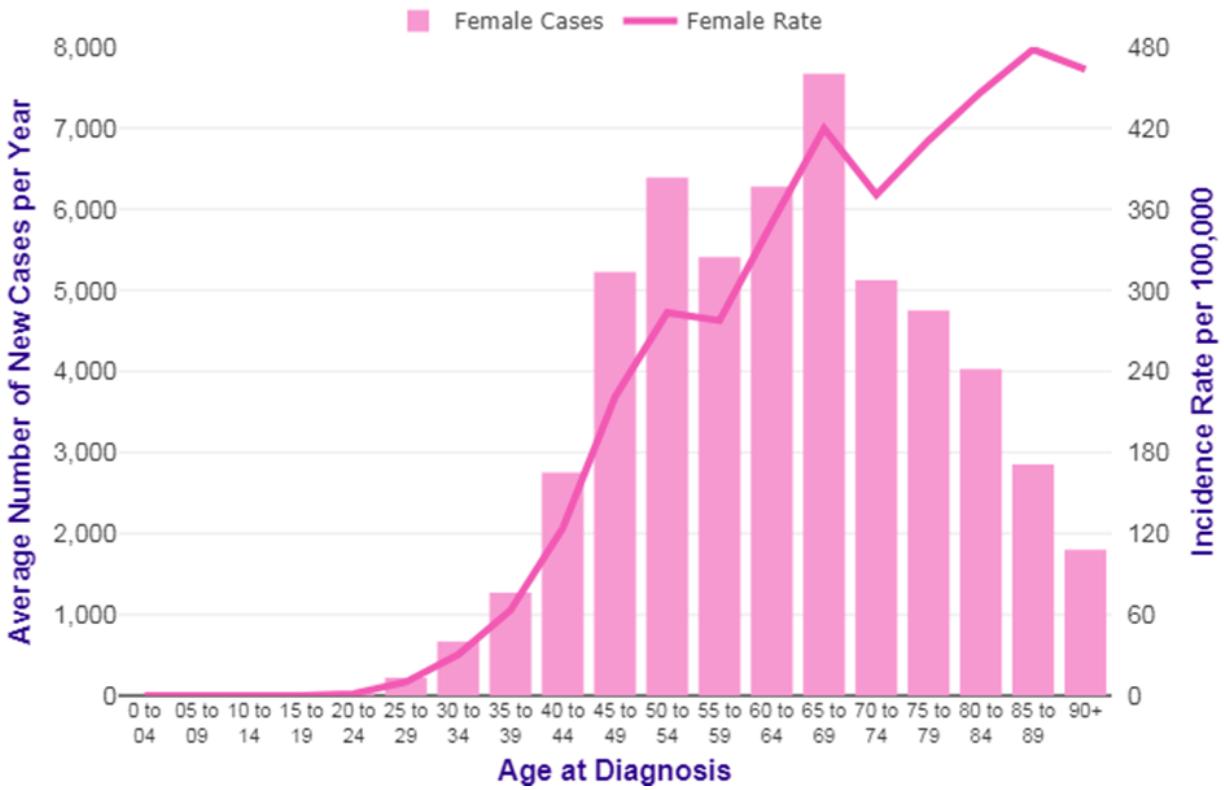

Figure 1:4 Average number of new breast cancer cases per year and age specific incidence per 100,000 population, females UK 2013-2015 *(Cancer Research UK, 2018)*

Carcinogenesis in breast epithelium is most likely to occur when cells divide rapidly with insufficient time for DNA repair. This risk is increased when breast epithelium is exposed to higher levels of oestrogen that stimulate hyperproliferation. Therefore many life events and choices that increase lifetime exposure to oestrogen may increase breast cancer risk **(Box 1)** (Howell *et al.*, 2005). Food intake can impact on this as high energy and protein diets are associated with decreased age of puberty and menarche and later menopause which increases the duration of oestrogen exposure and may increase breast cancer risk (Institute of Medicine, 2012).

BOX 1 Factors affecting lifetime oestrogen exposure and Breast Cancer risk (World Cancer Research Fund/American Institute for Cancer Research, 2017)

- Early puberty and menarche before 12
- Late menopause after 55
- Nulliparity
- Having first child after 30
- Breast feeding
- Use of hormone replacement therapy (HRT)
- Use of oral contraceptives

The risk of developing breast cancer is multifactorial (**Figure 1:5**) and includes a variety of other factors. As discussed in **Section 1.1** above, the incidence and prevalence of breast cancer is heterogenous across different parts of the world; however, incidence tends to track economic development. Migrants tend to assume the risk of their host country within 1-2 generations which suggests that much of this variation in risk is due to environmental rather than genetic differences (World Cancer Research Fund/ American Institute for Cancer Research, 2017; World Cancer Research Fund/American Institute for Cancer Research, 2018). Most environmental risk factors are related to nutrition and lifestyle including obesity, inflammation, alcohol, birth weight (Teegarden *et al.*, 2012), often via an influence on oestrogen exposure. The links between diet and breast cancer risk will be discussed in the next section.

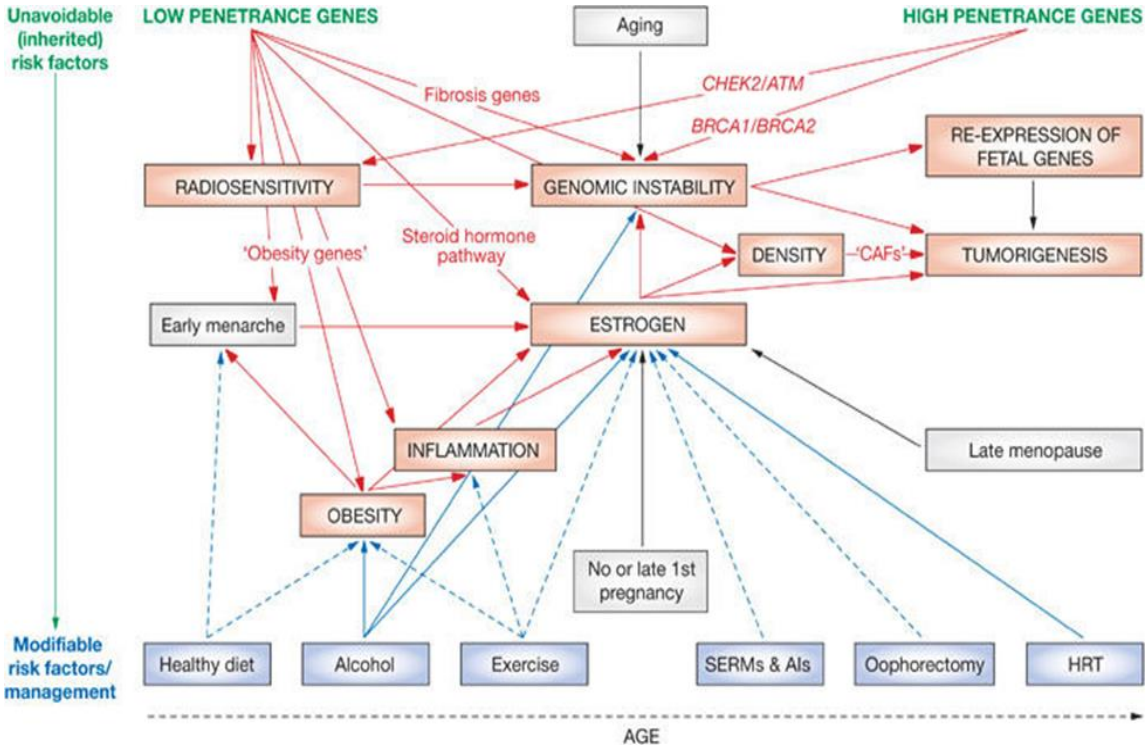

Figure 1:5 The many complex risk factors affecting breast cancer *The diagram summarizes the unavoidable (inherited) and modifiable risk factors that can ultimately lead to tumorigenesis. Genes/pathways/risk factors are shown in red; inherited or unmodifiable factors are shown in green; modifiable variables are shown in blue; life events are represented by grey boxes; increased/positive effects are denoted by solid arrows; and reduced/negative effects are denoted by dashed arrows. AIs, aromatase inhibitors; ATM, ataxia telangiectasia mutated; BRCA, breast cancer early onset; CAFs, cancer associated fibroblasts; CHEK2, CHK2 checkpoint homolog; HRT, hormone replacement therapy; SERMs, selective oestrogen receptor modulators.*

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1.3 Diet and breast cancer risk

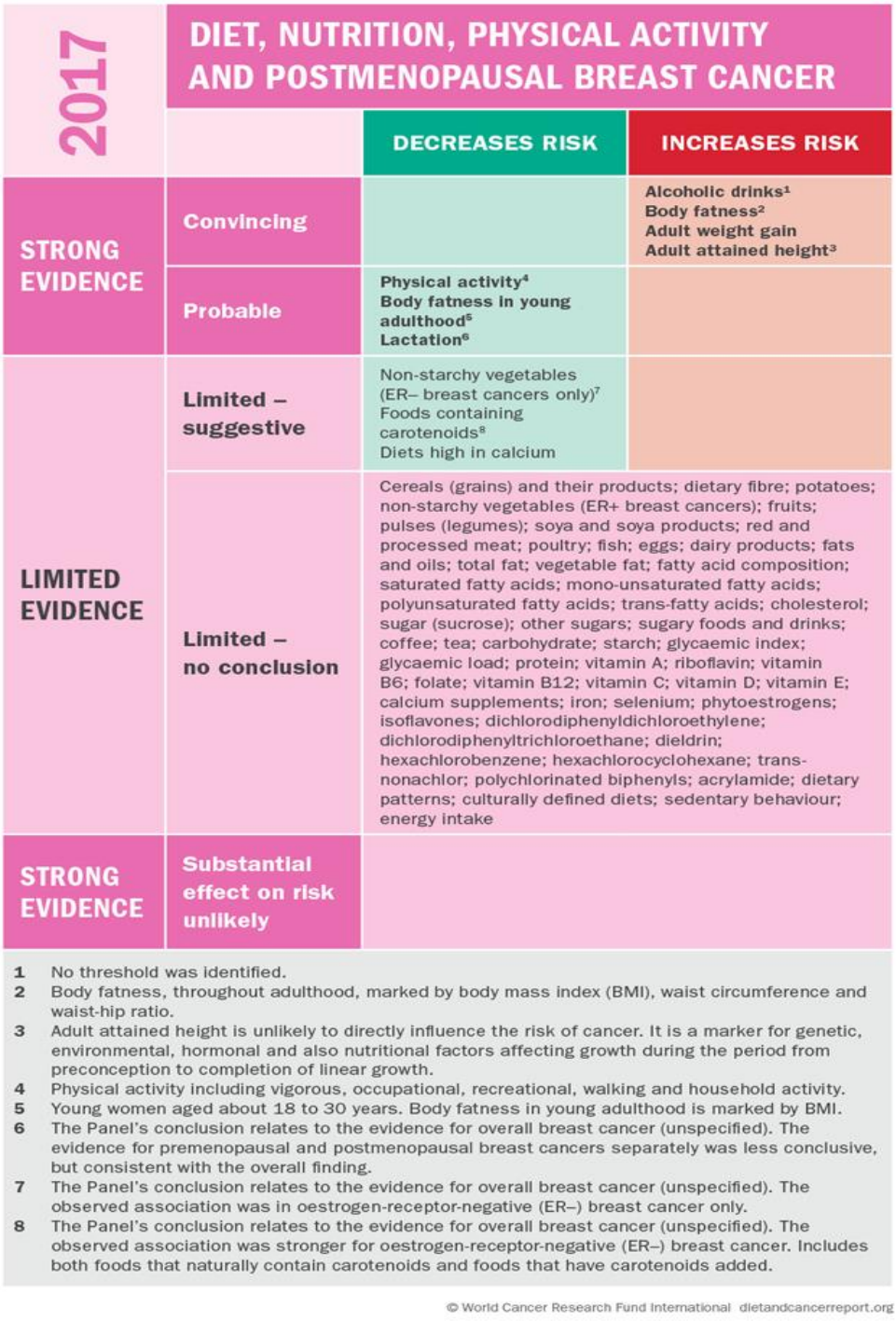
As discussed in **Section 1.2** above, there are many risk factors for breast cancer. Some of these such as family history, birthweight, age, menstrual and reproductive history and adult attained height, are unmodifiable in adulthood while lifestyle factors can be modified by individuals or populations. Brennan *et al.* (2010) estimate that about a third of breast cancer cases could be prevented by dietary modification. This suggests that behaviour change at the level of the individual or population could reduce cancer risk and incidence (Brennan *et al.*, 2010). Any behaviour change intervention,

such as the one in the current study must be based on robust evidence and therefore the evidence for the links between diet and breast cancer risk are considered in this section.

In 1997, the World Cancer Research Fund (WCRF) and the American Institute for Cancer research (AICR) published a first expert report of evidence based recommendations to reduce individual and population cancer risks (World Cancer Research Fund /American Institute of Cancer Research, 1997). This was followed in 2007 by a second expert report on food, nutrition, physical activity and the prevention of cancer (World Cancer Research Fund/ American Institute of Cancer Research, 2007). These reports were the result of international systematic reviews and summarised the available evidence on causal associations between lifestyle factors and risk of many different cancer types. Subsequently, the evidence for post-menopausal and pre-menopausal breast cancer risk was updated in 2017 (World Cancer Research Fund/American Institute for Cancer Research, 2017). **Figure 1:6** and **Figure 1:7** summarise the findings of this report (World Cancer Research Fund/American Institute for Cancer Research, 2017) which showed that there was good evidence that alcoholic drinks increased breast cancer risk, while physical activity decreased risks. Body fatness was considered to increase risks of post-menopausal breast cancer, while reducing risks of premenopausal breast cancer though there is some more recent evidence that central obesity may increase risks of triple negative breast cancer which is more common in younger premenopausal women (Agurs-Collins, Ross and Dunn, 2019). There was no probable or convincing evidence of any specific foods that affected breast cancer risk (World Cancer Research Fund/American Institute for Cancer Research, 2017). An updated third expert report was published recently (World Cancer Research Fund /American Institute for Cancer Research, 2018b) and upheld these key findings.

Causal associations are ideally investigated by experimental studies such as randomised controlled trials (RCT). It is problematic to obtain RCT evidence on the effect of nutrient intake on breast cancer mortality and morbidity due to the difficulties of manipulating dietary components while controlling confounding variables over long periods of time (World Cancer Research Fund/American Institute for Cancer Research, 2018). Therefore, few RCT have been carried out; instead, most of the evidence for **Figure 1:6** and **Figure 1:7** (and **Figure 1:9** in **Section 1.4** below) comes from observational studies which are more limited in their ability to establish causality. In most cases these were epidemiological studies using a prospective cohort or nested case-study design in which lifestyle including nutritional intake was measured longitudinally and subsequent comparisons were made

between those who developed breast cancer and a comparative group who did not (World Cancer Research Fund/American Institute for Cancer Research, 2018). There are few factors where the evidence was found to be convincing or probable which may be in part due to these difficulties in carrying out robust research.



2017

DIET, NUTRITION, PHYSICAL ACTIVITY AND POSTMENOPAUSAL BREAST CANCER

		DECREASES RISK	INCREASES RISK
STRONG EVIDENCE	Convincing		Alcoholic drinks[1] Body fatness[2] Adult weight gain Adult attained height[3]
	Probable	Physical activity[4] Body fatness in young adulthood[5] Lactation[6]	
LIMITED EVIDENCE	Limited – suggestive	Non-starchy vegetables (ER– breast cancers only)[7] Foods containing carotenoids[8] Diets high in calcium	
	Limited – no conclusion	Cereals (grains) and their products; dietary fibre; potatoes; non-starchy vegetables (ER+ breast cancers); fruits; pulses (legumes); soya and soya products; red and processed meat; poultry; fish; eggs; dairy products; fats and oils; total fat; vegetable fat; fatty acid composition; saturated fatty acids; mono-unsaturated fatty acids; polyunsaturated fatty acids; trans-fatty acids; cholesterol; sugar (sucrose); other sugars; sugary foods and drinks; coffee; tea; carbohydrate; starch; glycaemic index; glycaemic load; protein; vitamin A; riboflavin; vitamin B6; folate; vitamin B12; vitamin C; vitamin D; vitamin E; calcium supplements; iron; selenium; phytoestrogens; isoflavones; dichlorodiphenyldichloroethylene; dichlorodiphenyltrichloroethane; dieldrin; hexachlorobenzene; hexachlorocyclohexane; trans-nonachlor; polychlorinated biphenyls; acrylamide; dietary patterns; culturally defined diets; sedentary behaviour; energy intake	
STRONG EVIDENCE	Substantial effect on risk unlikely		

1 No threshold was identified.
2 Body fatness, throughout adulthood, marked by body mass index (BMI), waist circumference and waist-hip ratio.
3 Adult attained height is unlikely to directly influence the risk of cancer. It is a marker for genetic, environmental, hormonal and also nutritional factors affecting growth during the period from preconception to completion of linear growth.
4 Physical activity including vigorous, occupational, recreational, walking and household activity.
5 Young women aged about 18 to 30 years. Body fatness in young adulthood is marked by BMI.
6 The Panel's conclusion relates to the evidence for overall breast cancer (unspecified). The evidence for premenopausal and postmenopausal breast cancers separately was less conclusive, but consistent with the overall finding.
7 The Panel's conclusion relates to the evidence for overall breast cancer (unspecified). The observed association was in oestrogen-receptor-negative (ER–) breast cancer only.
8 The Panel's conclusion relates to the evidence for overall breast cancer (unspecified). The observed association was stronger for oestrogen-receptor-negative (ER–) breast cancer. Includes both foods that naturally contain carotenoids and foods that have carotenoids added.

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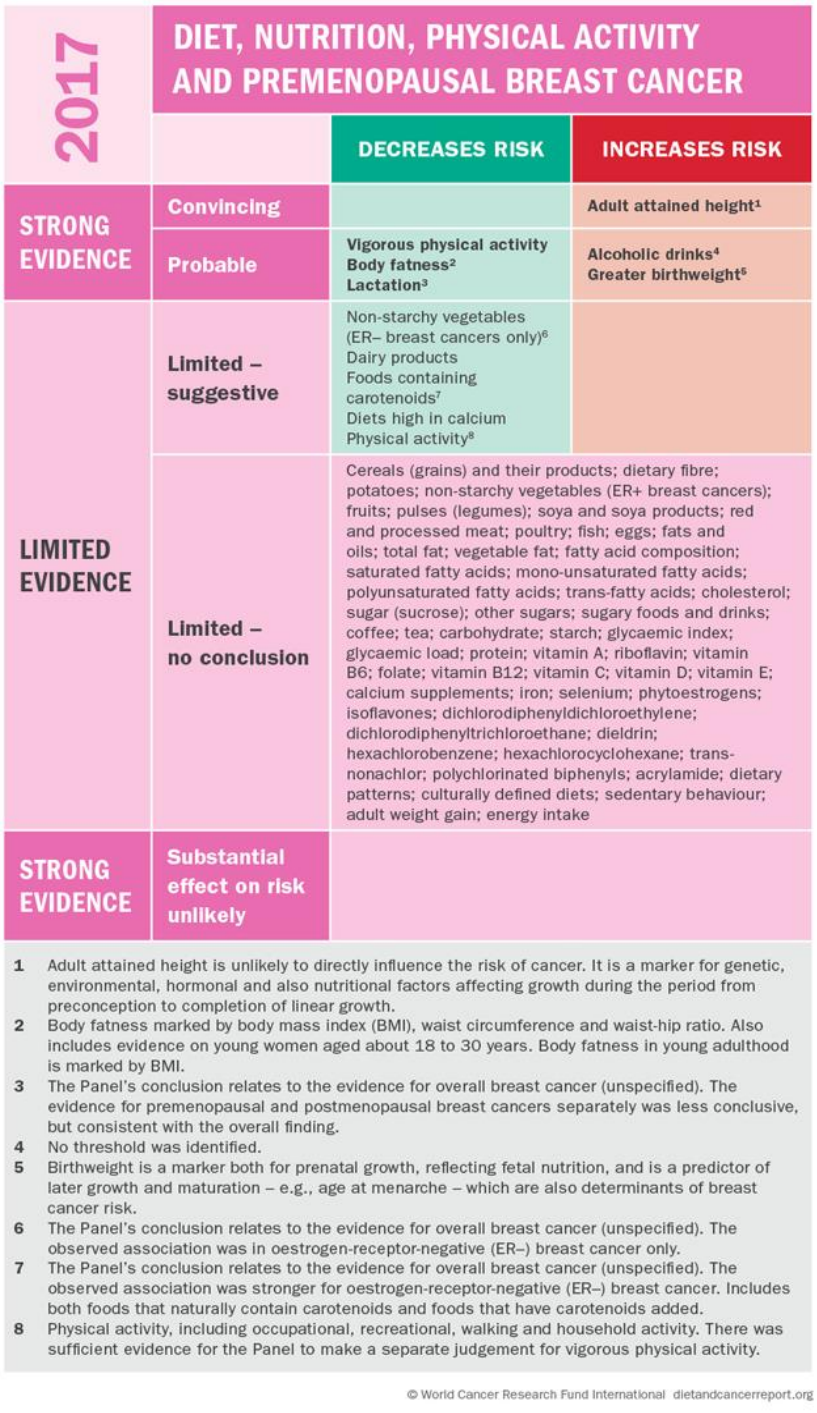
Figure 1:6 Summary of the evidence of effects of different factors on post-menopausal breast cancer risk. This material has been reproduced from the World Cancer Research Fund/American Institute for Cancer Research. Diet, Nutrition, Physical Activity and Cancer: a Global Perspective. Continuous Update Project Expert Report 2018. Available at dietandcancerreport.org.



2017	DIET, NUTRITION, PHYSICAL ACTIVITY AND PREMENOPAUSAL BREAST CANCER		
		DECREASES RISK	INCREASES RISK
STRONG EVIDENCE	Convincing		Adult attained height[1]
	Probable	Vigorous physical activity Body fatness[2] Lactation[3]	Alcoholic drinks[4] Greater birthweight[5]
LIMITED EVIDENCE	Limited – suggestive	Non-starchy vegetables (ER– breast cancers only)[6] Dairy products Foods containing carotenoids[7] Diets high in calcium Physical activity[8]	
	Limited – no conclusion	Cereals (grains) and their products; dietary fibre; potatoes; non-starchy vegetables (ER+ breast cancers); fruits; pulses (legumes); soya and soya products; red and processed meat; poultry; fish; eggs; fats and oils; total fat; vegetable fat; fatty acid composition; saturated fatty acids; mono-unsaturated fatty acids; polyunsaturated fatty acids; trans-fatty acids; cholesterol; sugar (sucrose); other sugars; sugary foods and drinks; coffee; tea; carbohydrate; starch; glycaemic index; glycaemic load; protein; vitamin A; riboflavin; vitamin B6; folate; vitamin B12; vitamin C; vitamin D; vitamin E; calcium supplements; iron; selenium; phytoestrogens; isoflavones; dichlorodiphenyldichloroethylene; dichlorodiphenyltrichloroethane; dieldrin; hexachlorobenzene; hexachlorocyclohexane; trans-nonachlor; polychlorinated biphenyls; acrylamide; dietary patterns; culturally defined diets; sedentary behaviour; adult weight gain; energy intake	
STRONG EVIDENCE	Substantial effect on risk unlikely		

1 Adult attained height is unlikely to directly influence the risk of cancer. It is a marker for genetic, environmental, hormonal and also nutritional factors affecting growth during the period from preconception to completion of linear growth.
2 Body fatness marked by body mass index (BMI), waist circumference and waist-hip ratio. Also includes evidence on young women aged about 18 to 30 years. Body fatness in young adulthood is marked by BMI.
3 The Panel's conclusion relates to the evidence for overall breast cancer (unspecified). The evidence for premenopausal and postmenopausal breast cancers separately was less conclusive, but consistent with the overall finding.
4 No threshold was identified.
5 Birthweight is a marker both for prenatal growth, reflecting fetal nutrition, and is a predictor of later growth and maturation – e.g., age at menarche – which are also determinants of breast cancer risk.
6 The Panel's conclusion relates to the evidence for overall breast cancer (unspecified). The observed association was in oestrogen-receptor-negative (ER–) breast cancer only.
7 The Panel's conclusion relates to the evidence for overall breast cancer (unspecified). The observed association was stronger for oestrogen-receptor-negative (ER–) breast cancer. Includes both foods that naturally contain carotenoids and foods that have carotenoids added.
8 Physical activity, including occupational, recreational, walking and household activity. There was sufficient evidence for the Panel to make a separate judgement for vigorous physical activity.

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Figure 1:7 Summary of the evidence of effects of different factors on pre-menopausal breast cancer risk. This material has been reproduced from the World Cancer Research Fund/American Institute for Cancer Research. Diet, Nutrition, Physical Activity and Cancer: a Global Perspective. Continuous Update Project Expert Report 2018. Available at dietandcancerreport.org.

All methods of assessing nutrient intake are limited (**Chapter 4.2.5**); most of the studies reviewed in the World Cancer Research Fund/ American Institute for Cancer Research (2017) report assessed dietary intake using Food Frequency Questionnaire (FFQ) methods. This allows a ranking of nutrient intakes rather that providing reliable intake data and this method might also be considered a limitation (Brennan *et al.*, 2010). FFQ are a self-report method of assessing dietary intake which may be affected by recall bias and could mask dietary effects. However, prospective study designs were preferred and case control studies generally excluded to reduce the effects of recall bias (World Cancer Research Fund/American Institute for Cancer Research, 2017). As most of the research studies gathered dietary information prospectively, not retrospectively, this was not able to account for dietary intake during adolescence which may affect breast development and subsequent breast cancer risk (Michels *et al.*, 2007) and may also be a limitation. Most of the research reviewed in the recent breast cancer report (World Cancer Research Fund/ American Institute for Cancer Research, 2017) focused on the effects of individual nutrients or foods on breast cancer risk. Other research studies have suggested that it is the pattern of dietary intake that might affect cancer risk, rather than the intake of specific nutrients (Supic, Jagodic and Magic, 2013). Nutrients act together in metabolic pathways and may have synergistic effects, so considering patterns of intake may be more meaningful (Karimi *et al.*, 2013). Dietary patterns were not considered in the second expert report (World Cancer Research Fund/American Institute for Cancer Research, 2007) though the third expert report (World Cancer Research Fund /American Institute for Cancer Research, 2018b) included an increased focus on patterns of diet and physical activity which may affect overall nutrition quality and resilience to genetic and epigenetic challenges and therefore may influence breast cancer risk. The current study aimed to investigate intervention impacts on overall dietary habits and nutrition quality for these reasons.

Table 1:1 A comparison of cancer prevention recommendations from 2007 and 2018

	WCRF/AICR (2007) Cancer prevention recommendations	**WCRF/AICR (2018) Cancer prevention recommendations**
1	Body Fatness: Be as lean as possible within the normal range of body weight	Be a healthy weight. Keep your weight within the healthy range and avoid weight gain in later life.
2	Physical activity: Be physically active as part of everyday life	Move more. Be physically active as part of everyday life-walk more and sit less.
3	Food and drinks that promote weight gain: Limit consumption of energy dense foods and avoid sugary drinks	Avoid high calorie foods. Limit consumption of fast foods and other processed foods high in fat and sugar
4	Plant foods: Eat mostly foods of plant origin	Enjoy more grains, veg, fruit and beans. Eat a wide variety of wholegrains, vegetables, fruit and pulses such as beans
5	Animal foods: Limit intake of red meat and avoid processed meat	Limit consumption of red and processed meat. Eat no more than 3 portions of red meat a week and eat little if any processed meat.
6	Alcoholic drinks: Limit alcoholic drinks	For cancer prevention, don't drink alcohol. If you do, limit alcoholic drinks and follow national guidelines
7	Preservation, processing, preparation: Limit consumption of salt and avoid mouldy grains or pulses	Limit consumption of sugar sweetened drinks. Drink mostly water and unsweetened drinks.
8	Dietary supplements: Aim to meet nutritional needs through diet	Don't rely on supplements. Eat a healthy diet rather than relying on supplements to protect against cancer.
9	Breastfeeding: Mothers to breastfeed. Children to be breast fed	Breastfeed your baby. If you can, breastfeed your baby for 6 months before adding liquids or other foods.
10	Cancer survivors: follow the recommendations for cancer prevention	Cancer survivors. After a cancer diagnosis, follow our recommendations if you can

The second expert report lifestyle included recommendations to reduce overall cancer risk (World Cancer Research Fund/American Institute for Cancer Research, 2007). Although absolute evidence of causality has not been established, Gonzales *et al.* (2014) recommend using the best evidence available to make recommendations even when the evidence is not convincing. In the second and third expert reports the evidence was judged by an expert panel and recommendations were made where evidence of a causal association was convincing or probable (World Cancer Research Fund/American Institute for Cancer Research, 2018; World Cancer Research Fund/American Institute for Cancer Research, 2007). A summary of the recommendations from both reports is presented in **Table 1:1**. Both sets of recommendations are very similar, and this consistency can be seen to increase confidence in the evidence on which the recommendations are based. The key differences include strengthened advice to avoid alcohol, rather than limit it, due to the more convincing recent evidence of this as a risk factor. The 2018 recommendations also include clearer guidance on reducing intake of red meat and avoiding fast foods. The recommendations in the second expert report were used in designing the lifestyle intervention in this study; the third expert report was published after completion of the interventions, but its recommendations were in line with the content of the programme.

There is growing evidence that following the World Cancer Research Fund/ American Institute of Cancer Research (2007) recommendations can reduce cancer risk. Following the recommendations, especially those for body fatness, intake of plant food and alcohol was associated with a significantly reduced risk of invasive breast cancer in post-menopausal women (Hastert *et al.*, 2013). Catsburg, Miller and Rohan, (2014) report that following six or seven of the WCRF/AICR guidelines reduced breast cancer risk by 31%; meeting each guideline was associated with a 4-6% risk reduction. This is also supported by Romaguera *et al.* (2012) who found that following the recommendations resulted in a reduced risk of cancer overall and of breast cancer in particular. Following a healthy diet pattern was found to reduce breast cancer risk compared to those who do not (Karimi *et al.*, 2013) and in a large prospective 10.9 year cohort study of post-menopausal women an overall healthy lifestyle index was associated with reduced breast cancer risk (McKenzie *et al.*, 2015). A recent systematic review provided strong evidence that adherence to these guidelines can reduce cancer risk and breast cancer risk (Kohler *et al.*, 2016). In a case controlled study carried out in Spain, there was good evidence that complying with the recommendations might reduce breast cancer incidence

especially in post-menopausal women and especially in some hormone receptor subtypes (oestrogen receptor positive (ER+), progesterone receptor positive (PR+), human epidermal growth factor 2 receptor negative (HER2-) and positive (HER+) tumour subtypes) (Castelló *et al.*, 2015). A 'prudent' dietary pattern was associated with decreased breast cancer risk, while a 'drinker' dietary pattern was associated with increased risk (Brennan *et al.*, 2010). By contrast, in a Mexican case control study, adherence to WCRF/AICR (2007) recommendations was not associated with breast cancer risk, though there was a negative association after excluding body mass index (BMI) in overall and post-menopausal populations. However, as this was a case control study it may be subject to reporting bias, and interpretation of BMI in response to breast cancer risk in a Mexican population is unclear (Fanidi *et al.*, 2015). There is also some evidence of an inverse relationship between adherence to a Mediterranean diet in Greece and postmenopausal breast cancer risk (Trichopoulou *et al.*, 2010). It was also found in a healthy, ethnically diverse group of pre-menopausal women that adherence to WCRF guidelines and having a healthy BMI were both correlated to lower levels of biomarkers of oxidative stress and inflammation which might lower future disease risk (Morimoto *et al.*, 2015). These studies provide further evidence that following the lifestyle recommendations in **Table 1:1** can reduce cancer risk which also suggests that the associations identified in the systematic reviews are causal.

Evidence of a causal association between a dietary component and breast cancer risk is strengthened if there is evidence of a mechanism for its action. The third expert report (World Cancer Research Fund/American Institute for Cancer Research, 2018) used 18 systematic reviews of epidemiological evidence, supported by experimental evidence from human*, in vitro* and animal studies to give evidence of mechanisms. Nutrition can impact on breast cancer risk via several mechanisms in addition to the effect on oestrogen exposure discussed in **Section 1.2** above.

The process of oncogenesis may include epigenetic changes to regulatory genes (**Section 1.2**). Epigenetic processes switch genes on and off by the addition or removal of methyl groups to cytosine residues in DNA and lysine residues in histones (methylation) (Teegarden *et al.*, 2012). Silencing of regulatory TSG by hypermethylation is common in cancer cells, while hypomethylation allows gene transcription to resume. Accurate methylation relies on the supply of key nutrients such as folate and gene regulation may be affected by folate status: a diet insufficient in key nutrients may therefore impact on cancer initiation and progression via inappropriate methylation

(Teegarden *et al.*, 2012). Many other dietary components, such as phytonutrients from a plant-based diet may also interact to promote DNA demethylation and may be able to reactivate silenced TSG, reducing cancer risk (Supic, Jagodic and Magic, 2013). There is some *in vitro* evidence that soy can reverse hypermethylated silencing of BRCA1 in breast cancer cells (Romagnolo and Selmin, 2012) and some authors recommend increasing soy intake to reduce risk of breast cancer and breast cancer recurrence (Gonzales *et al.*, 2014). Plant based diets were associated with lower cancer risk and this may be due to increased intake of phytonutrients with multiple possible effects on cancer initiation and progression; however, these diets also tend to reduce adiposity (Gonzales *et al.*, 2014).

There is strong evidence that alcohol intake increases breast cancer risk (**Figure 1:6** and **Figure 1:7**) and it is now recommended that drinking alcohol is avoided to reduce overall cancer risk (**Table 1:1**). Pooled results of cohort studies show a 9% increase in post-menopausal breast cancer risk and a 5% increase in pre-menopausal breast cancer risk per 10g ethanol intake/day (World Cancer Research Fund/ American Institute for Cancer Research, 2017). The mechanism of action for this increased risk is uncertain, though it has been proposed that ethanol is metabolised to form acetaldehyde and reactive oxygen species (ROS) that can damage DNA. It is also hypothesised that alcohol can increase circulating oestrogen levels, and that a high alcohol intake is associated with a low plasma folate level that can affect epigenetic mechanisms and may make breast tissue more susceptible to oncogenesis (World Cancer Research Fund/American Institute for Cancer Research, 2018).

Observational studies suggest that increased adiposity increases breast cancer risk in post-menopausal women. The increased risk due to obesity also shows a dose-response relationship; each 5 kg/m^2 excess weight increases post-menopausal breast cancer risk by around 12% (Parkin and Boyd, 2011). This dose-response relationship also suggests that this association is causal, and this is also supported by proposed mechanisms. As discussed in **Section 1.2**, increased adiposity may increase the production of oestradiol and oestrone by aromatisation (Institute of Medicine, 2012) resulting in a higher level of circulating oestrogen and concomitant increased breast cancer risk (World Cancer Research Fund /American Institute for Cancer Research, 2018b). In addition, increased adiposity is associated with lower levels of adiponectin, and increased levels of leptin, insulin and insulin-like growth factor-1 (IGF-1) which affect cell proliferation, apoptosis, inflammation and angiogenesis which impact on breast cancer risk, and these effects may be reversed by weight loss (Harvie and Howell, 2012). Abdominal adiposity may increase breast cancer

risk more than subcutaneous adipose tissue in post-menopausal women (Howell *et al.*, 2005; Teegarden *et al.*, 2012). Surprisingly, obesity is associated with reduced breast cancer risk in pre-menopausal women, which may be due to an association with anovulation and reduced levels of sex hormones (World Cancer Research Fund /American Institute for Cancer Research, 2018b).

The lifestyle recommendations presented in **Table 1:1** are aimed at the public to prevent cancer occurrence; however, they were also recommended for cancer survivors and therefore were used to develop the lifestyle intervention for the current study. The evidence discussed in this section suggests that there are associations between dietary habits and breast cancer risk. It may be beneficial to develop public health strategies to engage all women in long-term healthy diet and lifestyle habits to reduce their breast cancer risk and to reduce the populational incidence (McKenzie *et al.*, 2015).Changes in eating behaviour are not easy for people to implement (Atkins and Michie, 2013) and for those without a cancer diagnosis there may be less motivation to follow these guidelines. There may be more incentive for people to improve their lifestyle following breast cancer diagnosis and treatment and this group are considered in the next section.

1.4 Breast cancer survivors

A breast cancer survivor can be defined as someone who has had a breast cancer diagnosis. This includes women at any subsequent stage; during and after primary treatment, those deemed to be cured and those with a cancer recurrence (Maddams *et al.*, 2009; World Cancer Research Fund International, 2014; World Cancer Research Fund /American Institute for Cancer Research, 2018b). However, it does not include those with a benign or pre-malignant diagnosis (World Cancer Research Fund International, 2014). Breast cancer includes more than 20 different neoplastic diseases (Tabchy *et al.*, 2009; World Cancer Research Fund International, 2014); sub-types are often classified according to key features including age at diagnosis and hormone receptor status (**Box 2**). Each type of breast cancer also has a different treatment regime and prognosis (World Cancer Research Fund International, 2014). Breast cancer survivors are therefore a very diverse group in terms of diagnosis, type and stage of treatment and prognosis.

Breast cancer treatment usually involves surgery to remove the lump and/or breast and lymph nodes. Most patients also have localised radiotherapy; some will also have systemic chemotherapy and may also have reconstructive surgery (World Cancer Research Fund International, 2014).

Hormone treatments may be given where the tumour is hormone receptor positive. Oestrogen receptor antagonists may be given to block oestrogen action, or aromatase enzyme inhibitors may be used to inhibit the post-menopausal production of oestrogen in adipose tissue (Ali and Coombes, 2002). Acute treatment is usually completed within 12 months, while hormone treatment may continue for 5 to 10 years to reduce the risk of cancer recurrence or a second primary diagnosis (Runowicz *et al.*, 2016).

Box 2 Ways of categorising different types of breast cancer

- Age at diagnosis (pre and post-menopausal)
- Location of the primary tumour (ductal or lobule)
- Whether the tumour is invasive or non-invasive (in-situ); *in-situ tumours remain within the basement membrane, while invasive tumours spread through this layer to the surrounding tissues* (Sainsbury, Anderson and Morgan 2000)
    - Invasive tumours are staged according to the degree of invasion, tumour size and the extent of tumour spread, usually via the lymphatic system (localised, regional, distant) (Sainsbury, Anderson and Morgan 2000)
- The presence or absence of hormone receptors
    - Oestrogen receptor-α (ER+/-),
    - Progesterone receptor (PR+/-)
    - Human epidermal growth factor 2 receptor (HER2+/-)
    - Or those without any of the above type of receptor are known as triple negative breast cancer (TNBC)

There are a wide range of possible effects of a cancer diagnosis and treatment on health and wellbeing (**Figure 1:8**) (Khan *et al.*, 2011; Richards, Corner and Maher, 2011; Murphy and Girot, 2013). Many breast cancer patients demonstrate a reduced quality of life after treatment (Vacek *et al.*, 2003). Treatment effects may be immediate or appear years or decades later and increasingly cancer survivors live long enough to develop treatment related conditions (Maher, 2013). Treatment effects may include fatigue, pain, breathing difficulty, nausea, appetite loss, unintended weight loss, cognition problems, hot flushes, sexuality concerns and decreased quality of life (QoL) (Partridge and Nekhlyudov, 2014). Breast cancer treatments can also increase risks of future secondary conditions (Pekmezi and Demark-Wahnefried, 2011) including cardiovascular disease

(Maher, 2013), hypothyroidism and osteoporosis (Khan *et al.*, 2011). Those with stage II and III disease at diagnosis can have more intense treatment which can increase treatment impacts (Runowicz *et al.*, 2016). Treatment can also have psychological impacts on body image (Runowicz *et al.*, 2016), cognition, depression, anxiety and fear of recurrence (Cheng, Sit and So, 2016). Breast cancer survivors are at higher risk of developing a second primary breast cancer or a recurrence at the same site (Sainsbury, Anderson and Morgan, 2000). Patients aged less than 35 are more likely to develop local recurrence than older patients (Sainsbury, Anderson and Morgan, 2000). Many cancer patients (47.3%) express a fear of their cancer recurring (Macmillan Cancer Support, 2013). Non-cancer mortality is also higher for survivors than that of the general population; survivorship care has therefore been recommended (Post and Flanagan, 2016) as some of the long-term health and psychological sequelae of treatment could be mitigated by nutrition and physical activity interventions (Robien, Demark-Wahnefried and Rock, 2011; World Cancer Research Fund/American Institute for Cancer Research, 2018).

Two influential early trials investigated the effects of diet on survival following breast cancer. The Women's Intervention Nutrition Study (WINS) found that a low-fat diet could increase recurrence free survival following breast cancer treatment (Blackburn and Wang, 2007). Research on diet and breast cancer survival has often focused on single nutrients or foods rather than overall diet (Kim, Willett *et al.*, 2011), however the Women's Healthy Eating and Living study (WHEL) was a large trial looking at the effect of a diet pattern high in vegetables, fruit and fibre and low in fat. It did not find any change in survival or recurrence over a 7.3 year period (Pierce *et al.*, 2007).

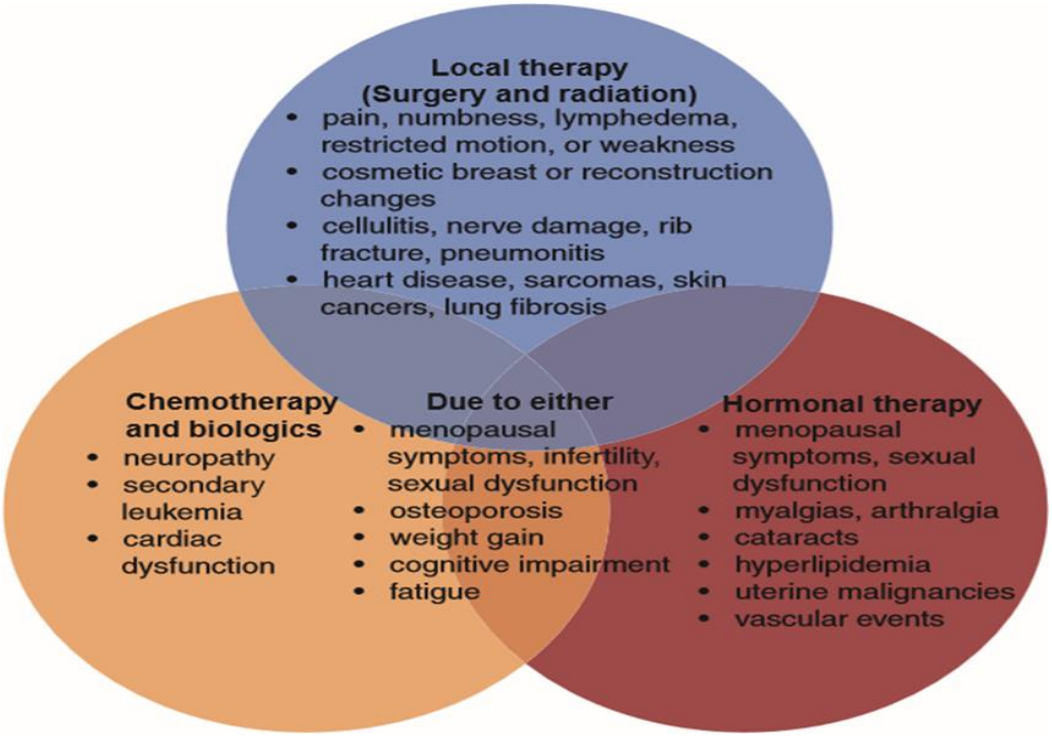

Figure 1:8 Long term and late physical effects in breast cancer (Partridge and Nekhlyudov, 2014). Reprinted by permission from Wolters Kluwer Health, Inc. Diseases of the Breast 5th Ed., Harris J.R *et al.* (2014)

A systematic review of the evidence that diet, nutrition and physical activity can have a causal impact on mortality following breast cancer diagnosis was carried out in 2014 and updated in 2018 (**Figure 1:9**) (World Cancer Research Fund International, 2014; World Cancer Research Fund /American Institute for Cancer Research, 2018b). Few RCT have been carried out with breast cancer survivors and so evidence in this systematic review was largely based on observational prospective studies on single foods or nutrients. Findings were limited by the heterogeneity of cancer survivor populations and possible reverse causation as breast cancer and its treatment may also affect lifestyle (World Cancer Research Fund /American Institute for Cancer Research, 2018b). Therefore, the evidence of the causal effects of specific foods or nutrients on mortality was limited in all cases (**Figure 1:9**). The current study looked more broadly at impacts of the lifestyle intervention on the diet quality and a range of health and wellbeing outcomes.

Figure 1:9 shows that there was limited evidence suggesting that foods containing soy and foods containing fibre might decrease all-cause mortality 12 months or more after diagnosis. The evidence also suggested that increased body fatness after diagnosis might lead to a poorer prognosis from cancer and non-cancer causes, while increased physical activity might decrease risks. Although increased adiposity has been found to decrease risks of developing pre-menopausal breast cancer (**Section 1.3**), being overweight or obese do not appear to have a similar protective effect in premenopausal breast cancer survivors (Chan *et al.*, 2014). Weight is a risk factor in general for cancer recurrence (Richards, Corner and Maher, 2011) and weight gain after breast cancer diagnosis has been associated with a higher mortality from cancer and non-cancer causes (Robien, Demark-Wahnefried and Rock, 2011). Weight gain is common during treatment especially chemotherapy and is usually associated with a loss of lean tissue perhaps due to reduced activity (Rock and Demark-Wahnefried, 2002; Chan *et al.*, 2014; James-Martin *et al.*, 2014). It is unclear why overweight and obese breast cancer survivors have increased mortality risks, and there is some suggestion that this may be due to a tendency to under-dose chemotherapy agents which are prescribed per kilogram body weight (World Cancer Research Fund /American Institute for Cancer Research, 2018b). Interpreting the effects of weight loss can also be complex as unintentional weight loss can be associated with a poorer prognosis where it is due to sarcopenia and cachexia (World Cancer Research Fund /American Institute for Cancer Research, 2018b). **Figure 1:9** shows that the evidence suggests that body fatness increases risks of mortality from breast cancer and other causes and therefore supports the guidelines for breast cancer survivors to maintain a healthy body weight, for obese women to lose weight after treatment and for overweight women to avoid weight gain during treatment (Chan *et al.*, 2014). Therefore, in the current study the effects of the intervention on adiposity was assessed as one of the outcome measures.

Cancer survivors might benefit from input on nutrition and lifestyle to support recovery and reintegration back into normal life, to improve QoL and possibly to also improve survival (Stull, Snyder and Demark-Wahnefried, 2007; Murphy and Girot, 2013). Therefore, it is recommended that breast cancer survivors should receive lifestyle advice and access to appropriate lifestyle programmes (Macmillan Cancer Support, 2013) and this will be discussed in the next section.

Figure 1:9 Summary of the evidence linking lifestyle and mortality in breast cancer survivors This material has been reproduced from the World Cancer Research Fund/American Institute for Cancer Research. Diet, Nutrition, Physical Activity and Cancer: a Global Perspective. Continuous Update Project Expert Report 2018. Available at dietandcancerreport.org.

1.5 Breast cancer survivors and behaviour change

Many women who have breast cancer are interested in learning more about lifestyle change and are interested in having a more active role in managing their own health (Rock and Demark-Wahnefried, 2002; Davies, Batehup and Thomas, 2011). This interest may reflect a desire to have agency post-diagnosis (Beeken *et al.*, 2016). Cancer diagnosis is a traumatic event that can have a wide impact on people's lives; behaviour change can help people to regain control (Connerty and Knott, 2013). Loss of self-confidence is common for cancer survivors especially in the period following primary cancer treatment and support may be needed to re-build this (Richards, Corner and Maher, 2011). Despite their interest in lifestyle change, few cancer survivors make behaviour changes (Corbett *et al.*, 2018) or follow the recommendations in **Figure 1:9** above and on average their lifestyle is equivalent to that of the general population (Stull, Snyder and Demark-Wahnefried, 2007; Robien, Demark-Wahnefried and Rock, 2011; Ceccatto *et al.*, 2012). Cancer survivors may be motivated to improve their lifestyle to increase wellbeing, maintain health and prevent recurrence. A cancer diagnosis might provide a 'teachable moment' or opportunity to promote behaviour change (Murphy and Girot, 2013). Therefore, targeted lifestyle interventions may be able to support this group to convert interest into action (Robien, Demark-Wahnefried and Rock, 2011).

Nutrition knowledge and access to healthy food is not enough to improve healthy eating in most cases (Corbett *et al.*, 2018). Social cognition theory (SCT) recognises that self-regulation and self-efficacy may also play a vital role in enabling healthier food choices, especially in challenging situations. Self-regulation is the ability to set goals, plan and monitor (self-regulate) the diet and long-term behaviour change is unlikely unless the skills necessary to do this are developed. Perceived self-efficacy is the perceived ability to exercise control over health habits (Bandura, 2005; Green *et al.*, 2014). Self-regulation skills can be learned and practiced and lead to an improvement in perceived self-efficacy which is associated with a healthier pattern of eating (Johnson, Pratt and Wardle, 2012). Therefore, in addition to developing nutrition knowledge, lifestyle interventions are more effective if they aim to develop self-efficacy and self-regulatory behaviours (Anderson, Winett and Wojcik, 2007). Those participants who are able to develop higher levels of self-efficacy are more likely to translate lifestyle improvement plans into action and are more likely to maintain behaviour changes and recover after lapses (Maes and Karoly, 2005; Janssen *et al.*, 2013; Mann, de Ridder and Fujita, 2013; Ochsner, Scholz and Hornung, 2013). Lifestyle interventions using self-regulation to

promote goal directed mechanisms to maintain healthy behaviours have been shown to be effective in cardiac rehabilitation patients (Janssen *et al.*, 2013) and in long term weight control (Teixeira *et al.*, 2015). Therefore, the design of the programme in this doctoral study was intended to promote behaviour change in this way.

The breast cancer treatment period is demanding and may itself affect dietary intake and food preferences (Coa *et al.*, 2015) so lifestyle interventions may be more effective if they are timed to occur after this. However, patients may be motivated to make behaviour changes soon after diagnosis (Stull, Snyder and Demark-Wahnefried, 2007) and this motivation may decline over the lengthy treatment period. Patients may also be keen to make behaviour changes during the treatment period to avoid or mitigate the associated weight gain (James-Martin *et al.*, 2014), treatment effects and to improve long term outcomes (Harvie, 2017). Patients are often interested in face to face interventions although travel and attendance may be problematic and other modes of delivery may be preferable (Robien, Demark-Wahnefried and Rock, 2011). Intervention design should therefore consider timing and mode of delivery to ensure good recruitment and retention (Stull, Snyder and Demark-Wahnefried, 2007). Further research is needed to investigate different modes of lifestyle education (Murphy and Girot, 2013) and is considered as part of the current study.

The lifestyle intervention in the current doctoral study intended to encourage women to improve their lifestyle by improving physical activity as well as improving nutritional intake in line with the recommendations in **Table 1:1**. There is evidence that increased physical activity is also associated with decreased breast cancer risk. For example, in pooled cohort study data, a comparison of the least and most physically active showed a decreased risk of 13% in post-menopausal breast cancer (World Cancer Research Fund/American Institute for Cancer Research, 2017). Increased physical activity after diagnosis can also have positive impacts on metabolism, muscle mass, physical fitness and psychological outcomes (Travier *et al.*, 2014) and was therefore included in this intervention. However, the focus of this doctoral research study is on the impact of nutritional change.

There are many research studies aiming to assess the effectiveness of nutrition and physical activity interventions; most of these assess the effects of interventions on mortality, morbidity or physiological biomarkers (Campbell *et al.*, 2012). There is little evidence of the effect of interventions on health behaviour and wellbeing (Demark-Wahnefried and Jones, 2008). It has been recommended that lifestyle change interventions for cancer survivors should be trialled (Maher,

2013) and that research studies should address the most effective models of intervention delivery in terms of wider health outcomes (Richards, Corner and Maher, 2011). The present study was intended to address these concerns particularly with respect to nutrition; the aim and objectives are presented below.

1.6 The aim and objectives of the study

Breast cancer diagnosis and treatment and their consequent physical and psychological challenges may affect people's perception of their own health risks and this may provide an opportunity for behaviour change. This study aimed to provide an original contribution to the debate about the most appropriate ways to provide nutritional care to those following initial breast cancer treatment and the methodological challenges of assessing this type of complex intervention. In this doctoral study, a healthy eating and physical activity intervention was developed following a narrative review of the research context as presented in this chapter. An integrative review of primary research studies was carried out to find what is already known about the design of effective lifestyle interventions for women who have had breast cancer and the findings are presented in **Chapter 2** and also informed the design of this intervention.

This research study was designed to systematically collect data to assess the overall impact of the lifestyle intervention. The research was carried out in two stages;

- A **feasibility study** was carried out and the findings are presented and discussed in **Chapter 5**. The findings from this study informed the design of the main research study.
- The **main research study** involved the collection of data before, during and after participants attended the lifestyle intervention.

The aim of the study was to explore the impact of the group lifestyle intervention for women who have had treatment for breast cancer.

The research objectives were:

1. To explore the use of a quasi-experimental evaluation design in which each person acts as their own control, to investigate the impact of the lifestyle intervention.
2. To identify contexts and mechanisms for change as part of a realist evaluation of the intervention,

3. To explore the changes in dietary habits, self-efficacy and health of participants over time,
4. To investigate the concerns of participants about their lifestyle and health, and how these changed over time during and after participation in the lifestyle programme,

The main study design included a unique combination of the Medical Research Council (MRC) framework for the evaluation of complex evaluations and realist evaluation. It used a within-subject quasi-experimental design using a mixed methods approach. The methodological approach is discussed in **Chapter 3**, while the methods employed are discussed in **Chapter 4**.

The main study investigated whether the intervention was causally associated with changes in health and wellbeing parameters, an elaboration of the mechanisms of action and a consideration of the contextual effects on the outcomes. Data were collected 2-3 months before and approximately 12 months after participation in the lifestyle programme. The quantitative results are presented in **Chapter 6**, while the qualitative findings are presented in **Chapter 7**. The quantitative and qualitative results are synthesised and discussed in **Chapter 8** and a critical reflection of the research process is included in **Chapter 9**. The study is concluded in **Chapter 10**. This study intended to facilitate future development of the intervention to make it more effective and targeted to the most appropriate groups of breast cancer survivors. It is anticipated that this will inform the design of future lifestyle interventions for breast cancer survivors, to maximise the chances of promoting long term behaviour change and health improvements.

Chapter two: Literature review

2 Literature review

2.1 Introduction

In **Chapter 1** the effects of dietary behaviour on breast cancer risk and recovery were outlined. In the light of this evidence, it has been recommended that nutritional support for breast cancer survivors should be provided (World Cancer Research Fund /American Institute for Cancer Research, 2017) though it is still unclear how this could best be achieved. Hershman *et al* (2013) recommend that future research should determine the most efficient and effective way of delivering survivorship care and therefore a literature review was carried out to determine what is already known about this. This literature review was carried out using the principles of integrative review (Whittemore and Knalfl, 2005) so that the findings from a range of study designs such as trials, observational and qualitative studies could all be included. This aimed to review evidence of the ways in which intervention designs influenced dietary behaviour change, wellbeing and quality of life in female breast cancer survivors. It aimed to find what worked, for whom, in which contexts and how this might have occurred. The results of this literature review informed the design of the intervention used in the current study (**Chapter 5.5**).

This literature review was carried out systematically to reduce bias. Online searches were carried out using the electronic databases Cumulative Index for Nursing and Allied Health (CINAHL), Academic Search Complete and Medline using the search terms in **Box 3** below.

Box 3 Search terms

(cancer survivor* AND breast)

AND (Food OR nutrition OR diet OR obesity OR BMI OR “lifestyle” OR “life style” or “healthy eating)

AND (intervention OR trial OR program*)

Searches were carried out separately with each search engine using the same search terms; in each case additional narrowing criteria were applied (**Box 4**). Searches were carried out for research published from 2007 onwards, as this is when the second expert report was published including the recommendations that were used in designing the current study (World Cancer Research Fund/American Institute for Cancer Research, 2007).

Box 4 Narrowing criteria used with each search engine

CINAHL: from 2007; English language; female. Major headings: breast neoplasms, survivors, cancer survivors, obesity, Quality of life, diet, weight loss, lifestyle, BMI, Body weight, food, lifestyle changes, habits, sedentary lifestyle = 31 articles

Academic Search Complete: scholarly (peer reviewed), 2007, English, academic journals, Subject: breast cancer patients= 79 articles

Medline: 2007, English language, human, female. Subjects: survivors, breast neoplasms= 163 articles.

Additional articles were identified by other means including manual searching of bibliographies and other articles previously identified and used in the development of the research proposal. All identified articles were saved in one file and duplicates were removed. Screening of abstracts and titles was carried out in line with the guidance of the PRISMA group (Moher *et al.*, 2009) using the inclusion and exclusion criteria in **Table 2:1**.

Full texts of each article were then obtained and used for more detailed checking of articles against the inclusion and exclusion criteria. **Figure 2:1** shows a flow chart showing the numbers of articles identified, screening, eligibility and the selection of the final sample. The searches were carried out during 2018 and were repeated in April 2019 to check for recent publications and so is complete up to that date.

A summary of the 26 studies selected for inclusion are reported in **Table 2:2**. Data was extracted from each of the studies individually using a data extraction form. This was a systematic process and ensured that consistent information was extracted from each study. A quality assessment of each article was also carried out using the Mixed Methods Appraisal Tool (MMAT) (Hong *et al.*, 2018) as this tool is designed to be used with qualitative, quantitative and mixed methods study designs and could therefore be used to appraise the range of studies identified. As recommended in the MMAT guidance (Hong *et al.*, 2018) the studies were appraised qualitatively using the tool as a prompt and this was used as a guide to judge the strength of evidence provided in each case. Studies were not excluded on this basis; rather less weight was given to poorer quality studies. Initially a small sample of 3 studies was appraised using the tool and this was discussed with the supervisory team; it is advised to have a least 2 reviewers to review studies independently (Hong *et al.*, 2018). However, the rest of the studies were reviewed by the researcher alone. A MMAT appraisal tool form was

completed for each study using the published guidance; screening questions were completed in each case followed by questions relevant to the study design in each case. The key findings from the data extraction and quality review are also reported in **Table 2:2**.

Table 2:1 Inclusion criteria used to select articles for inclusion in the literature review

Inclusion criteria	**Exclusion criteria**
Breast cancer survivors' data included and accessible separately	Mainly survivors of other cancers; data not disaggregated for breast cancer
Women	Men
Primary empirical study of lifestyle intervention, trial or pilot	Observational study or systematic review
Considers the influence of intervention design and/or behaviour change/adherence in a real-world setting	Intervention design not considered or only considered superficially. Main aim to investigate biological mechanisms of lifestyle change.
Study aim includes effect on healthy eating, dietary improvement, healthy weight.	Intervention focus on other aspects such as physical activity, or on single nutrients, meal replacements, supplements or single foods.
Reports key findings before and after intervention, and comparative data if appropriate	Only base line data reported
Published 2007 or later	Published before 2007
Outcome measures include wellbeing, QoL, self-efficacy, behaviour change, dietary intake,	Outcome measures mainly mortality or morbidity data, biomarkers, BMI and calorie intake.
Quantitative, qualitative study or intervention evaluation.	Reports of study design, recruitment protocol.

2.2 Overview of the included studies

The 26 included studies were heterogenous in design, participant population, intervention and outcome measures and therefore the extracted study data did not meet the assumption of homogeneity (Boland, Cherry and Dickson, 2017). It was not appropriate for the extracted data to be combined in meta-analysis. Instead a narrative synthesis of key themes arising from across the

included articles was carried out using the guidance of Aveyard, Payne and Preston (2016) and guidance on carrying out integrative reviews (Whittemore and Knalfl, 2005).

Most of the included research studies were conducted in the USA and/or Canada (19), although others were carried out in Australia (3), Brazil (1), Spain (1), and South Korea (2); none were set in the United Kingdom. The studies included a variety of study types including qualitative studies, evaluations, single arm studies, quasi-experimental studies and RCT, including triple arm studies. The included studies addressed a wide variety of research aims; many were testing weight loss interventions, while others were focusing on healthy lifestyles or survivorship interventions.

2.2.1 Quantitative studies

Several of the included studies (n=9) were either evaluations, single arm pre-post trials or small non-randomised trials (**Table 2:2**). These studies often had small numbers of participants, several had fewer than 30 and so were likely to be underpowered. Therefore, many of the reported outcomes did not reach statistical significance which may have been because the intervention did not lead to change or might have been due to a type II error. These smaller studies therefore provided weak evidence of outcomes.

One of the included studies was an evaluation; however, data was only collected after the intervention; (Muraca *et al.*, 2011) without baseline data the results were impossible to interpret. This study was also considered to be very weak as the outcome data collected were incomplete and data collection tools appeared not to have face validity. Some of the non-randomised trials were single arm studies in which measures before and after the intervention were compared. Without control or comparative data in many cases it was not possible to tell if the intervention had led to any observed changes; it is also possible that changes over time after diagnosis and treatment would occur in any case. Campbell *et al.* (2012) found an improvement in QoL by the end of the intervention (24 weeks) and at follow up (36 weeks). The participants in Campbell's study were about 2 years post-treatment and these improvements might have been part of an ongoing recovery process. In one study comparative data was included, but the control and intervention groups were not randomised and were unlikely to have been equivalent at baseline (Schiavon *et al.*, 2015) so the significant differences in outcome are difficult to interpret and provide weaker evidence of intervention effects. Some of these non-randomised studies (Stolley *et al.*, 2009; Travier *et al.*, 2014)

were preliminary to further intended large RCTs. The data from these preliminary studies can identify possible changes in outcomes and can be used as a basis for further robust research but do not in themselves provide strong evidence of intervention effects.

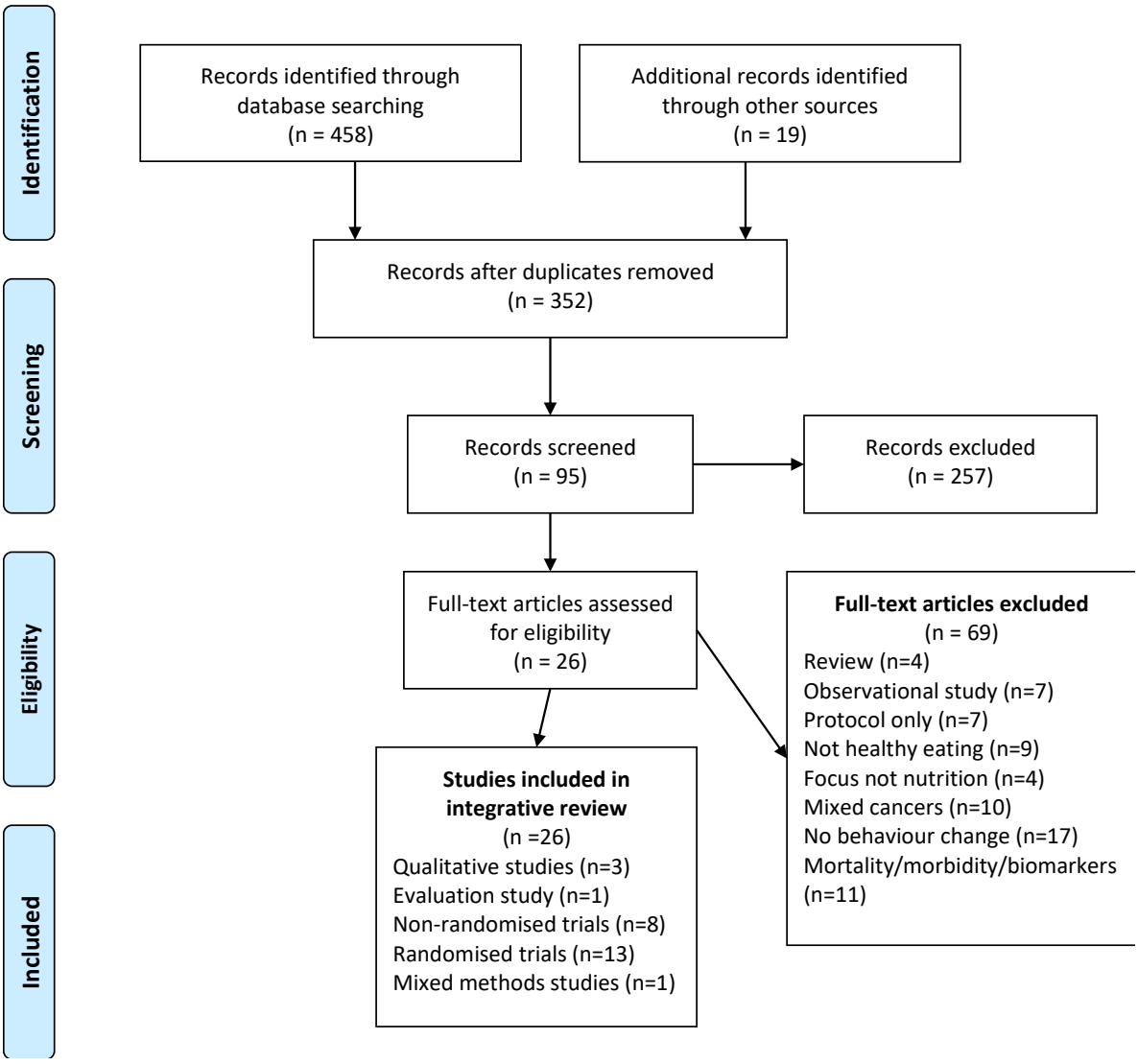

Figure 2:1 Flow chart summary of the selection of articles for the literature review *(using flow chart from* Moher *et al.* (2009)

Several of the included studies (n=13) were trials including randomisation to parallel intervention and control groups (**Table 2:2**). Randomisation should ensure that the control group (CG) and intervention group (IG) are equivalent at baseline and a comparison of outcome data should provide

stronger evidence of causal associations between the intervention and observed effects. However, there was a lot of variation in what happened to the CG across the studies. The CG sometimes received "usual care" which was not defined. In other cases, the CG were provided with lifestyle information which may have affected behaviour. In the study reported by Stolley *et al.* (2017) lifestyle information was provided to the CG as this was a required outcome following ethical review. Participants consenting to a study and then assigned to the CG often make behaviour changes anyway (Travier *et al.*, 2014) which may be more likely to occur if lifestyle information is provided. Several of the studies did find that CG participants had changes in outcome measures which made comparisons between the CG and IG problematic. Differences in outcomes between the CG and IG in some cases were not statistically significant. For example, in the lifestyle intervention reported by Kim, Shin *et al.* (2011) there were no statistically significant improvements in diet or physical activity, though the CG had also made lifestyle improvements. It is possible that some of the effects of lifestyle interventions appear to be non-significant and this may be, at least in part, because the results are being compared to those who have been provided with lifestyle materials and may be motivated to make changes as they have agreed to join a behaviour change trial and are therefore not acting as "controls", though they do at least provide a comparison between two different modes of promoting behaviour change. The strongest evidence of intervention effects was provided by larger trials with clarity about both the intervention and control treatments (Conlon *et al.*, 2015; Demark-Wahnefried *et al.*, 2015; Stolley *et al.*, 2017). The quantitative studies discussed above were able to investigate whether interventions had changed outcomes; although the strength of the evidence that they provide may be limited by the study design.

2.2.2 Qualitative and mixed methods studies

Qualitative research studies are able to explore the ways in which interventions might or might not work within their settings. Three of the reviewed studies (Balneaves *et al.*, 2014; Fazzino, Sporn and Befort, 2016; Terranova *et al.*, 2017) reported focus group or interview research carried out after an intervention. A fourth article (Sheppard *et al.*, 2016) reported a mixed methods study in which an RCT was carried out followed by a qualitative process evaluation to investigate mechanisms of action. These qualitative studies were able to explore the perspectives of participants. The goals of participants may not be the same as those of researchers and their criteria for success of the study may not be the same. In quantitative studies investigating weight loss trials, simple weight loss or

indicators of adiposity were often the primary outcome measure and were the key criteria by which the "success" of the research was measured. Participants may initially join an intervention to lose weight, though in retrospect may regard other aspects such as improved physical fitness as a success, even without weight loss (Balneaves *et al.*, 2014).

Qualitative studies aim for depth rather than breadth and so the number of participants is not necessarily an indicator of the strength of the evidence provided. Fazzino, Sporn and Befort (2016) carried out a very large study with 186 qualitative interviews. However, the interview data was only captured using notes, with no recording or transcription so it is not possible to check that the findings are derived from the data and therefore provided weak evidence.

2.3 Intervention timing

The studies were very varied in many aspects of intervention design, making it difficult to compare results. One difference was in the timing of the intervention within the patient journey. Some studies recognised the benefit of capitalising on the 'teachable moment' soon after diagnosis which might enhance motivation for lifestyle improvement but recognised the practical constraints that ongoing treatment might present in terms of participant attendance and engagement. Schiavon *et al.* (2015) uniquely carried out a small pilot nutrition education intervention while women were still undergoing treatment. On average, the IG group did not gain significant weight during treatment while the CG did. This is an interesting though preliminary result suggesting that offering an intervention during the treatment period might avoid weight gain which could have ongoing health benefits and avoid the need to lose weight after treatment. Balneaves *et al.* (2014) reported that participants recommended that interventions should be offered to all breast cancer patients as the next stage of normal care at the end of primary treatment, to enhance intervention attendance and recruitment. Travier *et al.* (2014) recruited participants within 6 months of completing treatment; however, in future trials plan to invite participation before treatment finishes so that the intervention is viewed as a continuation of treatment. Hershman *et al.* (2013) recruited participants within 6 weeks of completion of treatment although in this case the intervention only involved a 1-hour attendance and so may have been feasible. Reeves *et al.* (2017) recruited participants who were 9-18 months post-diagnosis, aiming to see if early recruitment was feasible. Most of the participants said that the timing was suitable and about a third would have preferred it sooner. Reeves *et al.* (2017) therefore recommended recruiting close to treatment end, or during treatment.

Most interventions were offered after the end of primary treatment (except endocrine therapy). Park *et al.* (2016) intended to recruit people within 3 months of completing treatment, but had difficulty in recruiting a sufficient number of participants which led to broadening of inclusion criteria to within 18 months of diagnosis. Lawler *et al.* (2017) recruited participants on average 14 months post diagnosis and most (66%) said the timing was about right, though a minority 24% would have liked to attend the programme earlier. Stolley *et al.* (2017) recruited those who were at least 6 months post-treatment while Sheppard *et al.* (2016) applied an upper limit and recruited women 6 months to 5 years post treatment. Some studies did not exclude those for whom diagnosis was further in the past. Griffith *et al.* (2012) recruited participants with a mean time since diagnosis of 7.2 years; one had been 19 years since diagnosis, and it is unclear how this might affect the capacity for behaviour change.

2.4 Intervention recruitment

In many of the reported studies it is unclear whether the findings would have external validity as the inclusion and exclusion criteria made many breast cancer patients ineligible. For example, Harrigan *et al.* (2016) screened 825 people and recruited 100. Demark-Wahnefried, *et al.*, (2015) screened 5027 potential participants and enrolled 697 of these for randomisation; many participants were excluded for diagnoses of other medical conditions. This excludes many possible confounding factors and leads to enrolment of a more homogenous sample to increase the internal validity of the study. However, this may also reduce the external validity of any findings as in any group of breast cancer survivors most are older adults and many have second diagnoses. Demark-Wahnefried *et al.* (2014) had an additional requirement for participants to have an appropriate and willing biological daughter and was a barrier to recruitment that the research team recognised. Lee *et al.* (2014) excluded a high proportion of potential participants for medical reasons, or lack of access to the internet or mobile phone as this was requirement for the intervention. They recognised that this resulted in a participant group that was not representative of the breast cancer survivor population and their participants tended to be younger and more highly educated. Lynch *et al.* (2016) recruited participants to a commercial weight loss programme. The participants had to pay a monthly fee and join a gym or buy fitness equipment. Therefore, the study recruited participants from a higher socioeconomic group that may not be representative of the wider younger breast cancer group that was targeted. In many studies those with healthy lifestyles or with

healthy weight profiles were excluded from participation, however Park *et al.* (2016) included those who already had healthy behaviours which may have resulted in a ceiling effect in terms of outcome measures.

In many of the included studies most of the participants were white, well-educated and middle class; for example, Harrigan *et al.*, (2016); Lynch *et al.* (2016); Park *et al.* (2016). Several studies attempted to redress this balance by targeting underrepresented sections of society or recruiting from health facilities in areas with a more diverse population. Some studies were aimed at African American breast cancer survivors as this population have poorer outcomes and are underrepresented in survivorship research (Stolley *et al.*, 2009, 2017). Sheppard *et al.* (2016) and Knobf, Erdos and Jeon (2018) explicitly recruited black women with breast cancer and had programmes targeted for their group and culture. Greenlee *et al.* (2015) targeted the Hispanic breast cancer survivor population which also has a higher risk of recurrence and mortality and is also underrepresented in research. Their intervention was targeted in terms of recipes and cultural values and was conducted in Spanish. Lawler *et al.* (2017) recruited participants from a clinic in a disadvantaged and ethnically diverse population and was therefore able to recruit a sample more representative of the wider patient population. Schiavon *et al.* (2015) seemed to have recruited all patients who attended a breast clinic within the study period. Those patients who were not recruited to attend the intervention had their data reported as the control. This resulted in the recruitment of a broader range of participants with lower average levels of education; most had a maximum of eight years of schooling, so fewer than in other studies and the team ensured that appropriate language levels were used. The review showed that intervention studies may need to ensure that the sample recruited to intervention research is representative of the breast cancer survivor population. This should ensure that findings are applicable to the local context and can be generalised to a wider patient population if appropriate.

2.5 Intervention length and intensity

The included studies were very variable in terms of intervention length (**Table 2:2**); ranging from a single 1-hour meeting (Hershman *et al.*, 2013) to a 1-year intervention (Harris *et al.*, 2013; Demark-Wahnefried *et al.*, 2015) with the majority lasting for 12 or 24 weeks. Kim, Shin *et al.* (2011) trialled a 12-week intervention of weekly personalised calls, but it did not result in improvements in diet quality and they suggest that intervention might not have been long enough to see behaviour

change. Park *et al.* (2016) involved a 4-month intervention and although some dietary improvements occurred, these were not sustained 3 months later. They suggest that this was too short a period with too few interactions to maintain change, without further support during the follow up phase (Park *et al.*, 2016). Amongst the studies reviewed in this study there was no consensus over the ideal length of an intervention to develop new and sustainable lifestyle habits, though 12 weeks might be a minimum.

The reviewed interventions were also varied in terms of their intensity. Harrigan *et al.* (2016) reported a low intensity intervention with 5.5 hours of telephone counselling over a 6-month period. Some of the longer interventions were even less intense; Demark-Wahnefried *et al.* (2014) report a 1-year trial that only involved participants receiving a workbook and 6 mailings. Harris *et al.* (2013) had a more intensive intervention with 16-24 hours of group sessions over 6 months followed by phone calls each month for 6 months. Fazzino *et al.* (2016) also included about 24 hours of group phone calls over 6 months; though some participants felt these became inconvenient and too lengthy. Greenlee *et al.* (2015) also included about 24 hours of group sessions over a shorter period (12 weeks). Some programmes were more intensive; Stolley *et al.* (2009) involved 46 classes over a 6-month period, while Campbell *et al.* (2012) included 68 hours of attendance in 6 months; some participants found that it was difficult to attend this frequently (Balneaves *et al.*, 2014). By contrast, Travier *et al.* (2014) reported a 12-week trial which required clinic attendance 3 times per week and despite this achieved very high attendance and statistically significant weight loss and improvements in health and wellbeing. There was no consensus over the ideal intensity of interventions to facilitate behaviour change. Intensive contact or attendance might be practically problematic, especially for face-to-face sessions.

2.6 Intervention mode of delivery

Face to face delivery might be the gold standard for intervention delivery; Harrigan *et al.* (2016) suggests this is the case for weight loss interventions. Where interventions were delivered in person, they were often designed to facilitate attendance, especially for those with employment or caring responsibilities. Greenlee *et al.* (2015) held sessions on Saturday mornings, though they report that attendance was still a barrier and recommend having fewer sessions or using online materials. In another case, sessions were held in the evenings although overall attendance was only 55% (Stolley *et al.*, 2017), although in contrast Travier *et al.* (2014) offered morning and evening group sessions

and had good attendance and good levels of weight loss and health improvement. Campbell *et al.* (2012) recommend that time of day and travelling distance need to be considered in face-to-face interventions. However, attendance may be more practicable where other modes of delivery are used, and this will be considered in the next section.

Alternative methods of delivering interventions were trialled in several of the included studies. Lee *et al.* (2014) piloted an online intervention to avoid problems of travel and to increase accessibility and found the intervention had high levels of participation and adherence. Lynch *et al.* (2016) trialled the use of an online weight loss programme for younger breast cancer patients and found that weight loss occurred, but that retention was low (43.3% at 12 months) which might suggest that engagement was low. Harris *et al.* (2013) compared weight loss in two group interventions; via phone calls or in-person attendance. They found that weight loss was equivalent in the two groups at the end of the intervention, though drop out was higher in the phone group and again might suggest lower levels of engagement with remote attendance. Interventions delivered by phone and/or mail can be effective though; Schiavon *et al.* (2015) report an effective phone and mail intervention as after 6 months participants reported increased fruit and vegetable consumption and avoidance of in-treatment weight gain. Harrigan *et al.* (2016) found that in person counselling and telephone counselling both led to significant weight loss over 6 months but that despite the reduced convenience, attendance was better in person (61% attended all sessions) than in the telephone counselling group. Drop out was also much higher in the telephone group; only 44% retention compared to 67% in person and 58% in the control group, again suggesting reduced engagement with remote attendance.

Some interventions with remote attendance also involved personalisation which may have enhanced their effectiveness. Reeves *et al.* (2017) report an individual intervention delivered over 6 months via 16 personal phone calls with significant weight loss and high satisfaction. Lawler *et al.* (2017) delivered a phone based personalised lifestyle coaching intervention, which resulted in weight loss over 6 months. Individual phone counselling might also provide emotional support and enhanced self- efficacy (Kim, Shin *et al.*, 2011) which might account for higher engagement in these cases.

Face to face sessions were often able to include practical activities which allows participants to rehearse intended behaviours in a supportive environment. Some programmes included developing

practical skills to encourage healthy eating such as cooking skills, weighing food portions, reading food labels and choosing foods on shopping trips (Griffith *et al.*, 2012; Greenlee *et al.*, 2015). Shared activities and shared meals also encouraged group cohesion (Stolley *et al.*, 2009). Some face to face interventions were also able to include a variety of physical activities in a supportive and safe environment (Stolley *et al.*, 2009); in remote interventions participants were encouraged to be more physically active but opportunities to do this were not provided. Therefore, face to face sessions were able to provide more practical activities which may develop skills and confidence and encourage self-efficacy and adherence which may be key mechanisms to support behaviour change.

This review has found that face to face interventions may be practically difficult to attend and therefore alternative modes of attendance have been trialled. Remote interventions may have reduced engagement, although this can be enhanced by personalisation. However, remote interventions are not able to offer practical activities and may therefore offer fewer opportunities to develop skills to enhance behaviour change. The mode of delivery utilised may also impact on the support that is offered to participants and this is considered in the next section.

2.7 Support for participants

This review seems to suggest that remote methods of delivery can be effective, but others might result in lower levels of engagement or completion. The observed differences may have been partly due to variations in support provided by group attendance compared to individual interventions. Balneaves *et al.* (2014) reported that participants valued being part of a face-to-face group where members were able to support each other to move beyond cancer, return to normality, and not be treated like “heroes”. Some remote interventions were also able to promote group support; Fazzino, Sporn and Befort (2016) reported that a phone intervention used conference calls and this supported behaviour change as participants felt that they were accountable to the other group members as well as to themselves. However it was reported that not all participants contributed in the calls and that skilled facilitation was required to ensure that the group interacted effectively. Sheppard *et al.* (2016) had bi-weekly group meetings over 12 weeks but focus group data suggested that more opportunities for the group to interact would have been useful, again suggesting that skilled facilitation and time might be central to engender peer support. Travier *et al.* (2014) suggest that the high intensity of their group intervention may have promoted peer support and group cohesion with a positive impact on outcomes.

Participants in some studies identified that a lack of outside support from family and friends could be a barrier to behaviour change (Stolley *et al.*, 2009; Terranova *et al.*, 2017). A mailed intervention was designed to promote family support for participants. Demark-Wahnefried *et al.* (2014) recruited mothers who had had breast cancer with their overweight daughters and anticipated that they would support each other to increase weight loss but it did not have the expected effect. They suggest that allowing people to nominate a support person might be better than recruiting biological daughters who were then active participants in the trial rather than supporting their mothers. The authors recommend more research in how best to use a support person and whether that person is best chosen by participants (Demark-Wahnefried *et al.*, 2014). Balneaves *et al.* (2014) found that participants suggested that family and friends be included in interventions to provide support at home and could be given specific supportive tasks. Some participants identified a ripple effect in which interventions also benefitted family and friends who had also adopted healthier lifestyles and lost weight. Terranova *et al.* (2017) also recommend formal involvement of a support person at least at an initial session or to be provided with written materials to improve understanding and support. In a recent group intervention, participants were encouraged to bring a support person of their choice to group sessions and about a third of the group did so (Knobf, Erdos and Jeon, 2018). This suggests that they found this helpful, though this was a small feasibility study, so it was not possible to tell if support partners enhanced outcomes.

This review suggests that participant support from peers, family or friends might be a significant factor to encourage behaviour change and can be promoted in different intervention modes of delivery but requires skilled facilitation to be achieved. There seems a consensus that the formal involvement of a support person might be beneficial in future interventions.

2.8 Intervention content and aims

2.8.1 Intervention specificity

The included studies were all aimed at breast cancer survivors, though the intervention content was not always specific to that group. The content of some was specific for breast cancer survivors, while the content of others focused on cancer survivors in general, or a general population. None of the interventions appeared to have followed reporting guidelines for behaviour change interventions such as (Borek *et al.*, 2015) or for complex interventions (Craig *et al.*, 2008). In some cases, very little detail of intervention content was included (Hershman *et al.*, 2013; Harrigan *et al.*, 2016) so it was

difficult to judge the impact of the intervention focus. Park *et al.* (2016) compared a group provided with generalised lifestyle information to one provided with more breast cancer specific materials to promote behaviour change, but this did not result in improved outcomes suggesting that both were equally useful. Lawler *et al.* (2017) reported outcomes following a generalised healthy lifestyle programme that was not specific to cancer survivors or to breast cancer. The intervention was successful as it did result in weight loss and increased physical activity, though there was a high dropout suggesting that it did not meet the needs of all. Some participants suggested that the programme should be more specific to the physical abilities of breast cancer survivors. Some interventions were based on American Cancer Society guidelines (ACS) and so were aimed at cancer survivors in general (Greenlee *et al.*, 2015; Lynch *et al.*, 2016; Sheppard *et al.*, 2016). Focus group data suggested that some participants would have liked more application of the programme to a breast cancer context (Sheppard *et al.*, 2016). Another intervention was based on the Diabetes Prevention Programme (DPP) but with adaptation for AICR/WCRF guidelines to make it breast cancer specific (Harrigan *et al.*, 2016). Campbell *et al.* (2012) also adapted the DPP programme to include aspects specifically relevant to breast cancer such as soy, alcohol, bone health, hormone treatments and weight gain. These studies suggest that programmes with a focus on breast cancer patients might be preferred.

2.8.2 Intervention aims; weight loss or healthy eating.

Many of the included studies were weight loss trials. Many participants had gained weight after their diagnosis; in one study participants had gained on average 3.3±5.8 Kg (Reeves *et al.*, 2017). Weight gain during treatment was reported to be demotivating and resulted in a loss of confidence that weight loss was possible (Terranova *et al.*, 2017). In their study, many participants were motivated by wanting support to lose weight (Terranova *et al.*, 2017). In many of the included trials, participants lost weight in the short term at least, though most did not achieve the target weight loss set by the research team, for example Stolley *et al.* (2009). In some cases, weight was regained following the intervention, for example, Stolley *et al.* (2017). Balneaves *et al.* (2014) reported that other outcomes than weight loss were viewed positively by participants; such as a change in perspective from being on a diet to adopting a long-term healthy lifestyle. In another intervention, participants felt there was too much emphasis on weight loss (Lawler *et al.*, 2017). Weight loss is likely to be more difficult for breast cancer patients due to treatment-related effects such as fatigue,

joint pain and hot flushes (Terranova *et al.*, 2017). This suggests that a broader focus on health outcomes might be more reflective of the experience of participants attending interventions.

Some of the included studies aimed to promote healthy eating rather than weight loss and this might also address participant motivations. Terranova *et al.* (2017) report that some participants wanted to return to their pre-treatment healthier lifestyle. One small underpowered trial focused on health but still resulted in some non-significant weight loss (Greenlee *et al.*, 2015). A second trial aimed to improve diet quality and found that this was also associated with improved weight related outcomes (Tometich *et al.*, 2017). These studies suggest that interventions that focus on healthy eating might still achieve some weight loss as a result; a focus on diet quality might be most appropriate for breast cancer survivors.

2.8.3 Social cognition theories

In addition to the focus on healthy eating or weight loss, many of the reported interventions were designed on the principles of social-cognition theory (SCT) including aspects such as mindful eating (Harrigan *et al.*, 2016), motivational interviewing (MI) and principles of behaviour change (Harris *et al.*, 2013), self -monitoring and feedback (Fazzino *et al.*, 2016), Transtheoretical Model (TTM) stages of change and self-efficacy and self-regulation (Greenlee *et al.*, 2015). Some of the interventions included a consideration of goals, barriers and strategies to overcome them, for example (Griffith *et al.*, 2012; Lee *et al.*, 2014; Lynch *et al.*, 2017) and it was found that this approach could enhance self-efficacy. Mosher *et al.* (2013) found that improved self-efficacy was associated with increased dietary improvement; however self-efficacy was assessed using a single item question rather than a multi question scale and may therefore have been less reliable. Action planning was found to enhance self-regulatory behaviours and may provide a way in which these can be maintained after the end of programmes. By contrast, Park *et al.*, (2016) found in a large 3-arm mailed RCT that materials designed to develop skills of awareness and self-reflection did not improved outcomes. In another study self-monitoring was promoted and was found to be valuable but also a burden and did not always provide the anticipated motivation to maintain changes (Terranova *et al.*, 2017). Many of the included studies suggest that promotion of self-efficacy might enhance behaviour change, though Schiavon *et al.* (2015) suggest that SCT approaches mainly benefit those with higher educational levels and so may not be appropriate in all contexts.

2.8.4 Public involvement in research design

In several studies, there was public involvement in intervention design. Greenlee *et al.* (2015) reported the use of community focus groups and interviews in tailoring materials to Hispanic populations; this process was used to identify mediators and barriers to behaviour change that were then addressed in the programme. In a similar way, focus group research was used to inform intervention content (Stolley *et al.*, 2009; Griffith *et al.*, 2012). Another intervention successfully included trained survivor coaches who delivered individual motivational interviewing (MI) phone calls with participants (Sheppard *et al.*, 2016). It seems that community involvement in the design and delivery of interventions for breast cancer survivors might be beneficial to tailor interventions to the requirements of the population.

2.9 Intervention outcomes

2.9.1 Blinding

Many of the trials used self-reported outcome data such as measures of dietary intake and quality of life. This data might be open to participant bias as participants would have been aware of the study aims and were usually aware of their allocation to IG or CG. In their study, Hershman *et al.* (2013) and Lee *et al.*, (2014) did not inform participants of their allocation to reduce this potential bias, though participants may have been informally aware of it. Park *et al.* (2016) reported that members of the CG knew their allocation, but IG members did not know which of two intervention groups they were in, perhaps meaning that CG data may have been more biased than IG data. Blinding of participants might reduce bias but may raise questions about whether participants were fully informed about the study prior to consent. In many cases other objective measures were also used, such as weight and biomarkers. In many cases the outcome assessors were blinded to the intervention group allocated (Demark-Wahnefried *et al.*, 2014; Harrigan *et al.*, 2016) while in other cases it was not clear whether this was so (Kim, Shin *et al.*, 2011; Mosher *et al.*, 2013). Blinding of participants was not possible in many of the included trials; reporting bias was countered as objective measures were also used to triangulate participant reported data to increase the reliability of findings.

2.9.2 Measures of adiposity

Most of the studies reported measures of adiposity whether they were weight loss or healthy eating trials. In several studies higher attendance or intervention participation was associated with increased weight loss. Campbell *et al.* (2012) reported the outcomes of an intensive 24-week intervention and found that higher attendance was associated with higher weight loss. This was a single arm trial so it was not clear whether this was a causal association, or the direction of any causality. Harrigan *et al.* (2016) also found in a 3-arm RCT that weight loss was better for those who attended all sessions, though the direction of the association was again unclear. Several studies suggested that change in waist circumference was a more sensitive measure of adiposity than change in weight, BMI or percent fat mass (Demark-Wahnefried *et al.*, 2014; Tometich *et al.*, 2017). In some of the studies objective biomarkers were also reported. Harrigan *et al.* (2016) in a 3-arm RCT found that both intervention groups had weight loss, but also a reduction of C-reactive protein (CRP), insulin, leptin and interleukin-6 (IL-6), suggesting than inflammation was reduced and that the weight loss achieved was physiologically relevant.

Most of the studies reported weight loss over the intervention period which appeared to be associated with attendance; though it was unclear which aspects of the intervention had resulted in this.

2.9.3 Dietary intake

Even in trials where weight loss had occurred, it was not always clear whether the behaviour changes had also resulted in improved nutritional quality. Several studies collected 3-day food intake data (Kim, Willett *et al.*, 2011; Griffith *et al.*, 2012; Lee *et al.*, 2014). Campbell *et al.* (2012) collected 3-day food diary records but many of these were incomplete which made it difficult to determine dietary intake; the authors recommend that food diary records are reviewed at the time of collection. Lee *et al.* (2014) reported that dietary recall data were used to derive a diet quality index which suggested that nutritional improvement had occurred. Kim, Willett *et al.* (2011) also derived diet quality indices which showed a significant reduction in diet quality in the intervention group. The authors suggest that this may have occurred as the participants had high diet quality before the intervention so may have been a ceiling effect. They suggest altering the inclusion criteria to target those who have poorer diets and are less physically active in future interventions. Participants found the completion of food diaries onerous (Sheppard *et al.*, 2016); in some studies

less onerous alternative methods were used such as questionnaires to assess fruit and vegetable intake (Park *et al.*, 2016) or diet history questionnaires (Mosher *et al.*, 2013) or multiple recall methods (Kim, Shin *et al.*, 2011).

2.9.4 Attendance and retention

Several of the included studies aimed to investigate the feasibility of the interventions they were trialling and reported on attendance and retention as proxy measures of engagement or satisfaction. Several studies report high levels of engagement and/or completion of the programme which suggests that lifestyle interventions are generally feasible and acceptable to the breast cancer population (Mosher *et al.*, 2013; Lee *et al.*, 2014; Travier *et al.*, 2014; Park *et al.*, 2016; Reeves *et al.*, 2017). In most cases it is unclear what factors affected the attendance and completion rates. In face to face programmes younger participants might have found find it harder to attend due to work and family commitments (Campbell *et al.*, 2012). It may be that retention provides a better indicator of overall motivation and engagement while a lower attendance might reflect the practical realities of participants' lives. Stolley *et al.*, (2017) reported a very high retention (over 80% at 12 months) which suggested high motivation and engagement, however mean attendance was low (55%) which may have been due to the practical difficulties of attending group sessions twice each week for 6 months. Where a programme was less intense participation may be more possible; Griffith *et al.*, (2012) reported 100% participation in a 1 year intervention, and though this was a very small pilot (n=8) it suggested that the culturally adapted programme was acceptable to the target population.

As discussed in **Section 2.6** above, retention was sometimes lower in programmes without in-person attendance which may reflect lower levels of engagement rather than practical issues. For example, Lynch *et al.* (2016) and Lawler *et al.* (2017) both report lower levels of completion. Where attendance was remote, personalisation may have increased commitment and motivation in some cases. Kim, Shin *et al.* (2011) also found high levels of completion (91%) and 100% participation in intervention phone calls; 95% found the intervention helpful suggesting that the intervention was feasible and acceptable. Less intense interventions may also have a higher retention; Demark-Wahnefried *et al.* (2014) report high (90%) retention over 12 months in their mailed intervention. The review suggests that lifestyle interventions are generally well received; engagement is promoted by face-to-face attendance and personalisation, while attendance is more problematic with longer and more intensive interventions especially amongst younger women.

2.9.5 Quality of life

Participants on lifestyle programmes might experience a number of psychological benefits from participation. Balneaves *et al.* (2014) report in a qualitative study that many participants were motivated to join their intervention by a fear of cancer recurrence; they also report a loss of self-confidence and self-esteem, plus memory problems and fatigue following breast cancer diagnosis and treatment. Participants reported that the programme enabled them to regain lost inner strength and to make the transition from patient back into wider society. These findings suggest that development of confidence and self-efficacy might be important factors in the promotion of behaviour change in lifestyle interventions for this population.

Several studies reported the effects of interventions on quality of life (QoL) using quantitative instruments. Some studies found a measurable increase in QoL over the intervention period for example Campbell *et al.* (2012) and Kim, Shin *et al.*, (2011). By contrast, Stolley *et al.* (2009) reported that participants reported that they felt empowered to make lifestyle changes after the intervention but QoL measures did not increase, perhaps due to ceiling effects. Demark-Wahnefried *et al.* (2015) found that although QoL improved over the first 6 months of their trial, this subsequently declined and was not significantly different after 12 months when intervention ended. Unexpectedly, in this weight loss study, depressive symptoms increased over time and were statistically greater than control at 24 months. This was an unexpected result. The authors suggest it might be that those on a weight loss diet feel more socially isolated and decreasing support from the intervention may have resulted in increased depressive symptoms; however this is speculation as no data was collected on reasons for this (Demark-Wahnefried *et al.*, 2015). Although participants lost weight initially, there was some recidivism in the longer term which may also have increased depressive symptoms. This was a very large RCT and therefore provides strong evidence that this might be the case. Almost 20% of the participants at baseline had scores indicating that they might be at risk of depression. The authors argue that those with depression are less likely to lose weight and more likely to relapse after weight loss and these factors might contribute to this result.

These studies show that although in some cases interventions improve QoL, this was not always the case and improvements may not be maintained. The studies provide good evidence from a large trial that a long and intensive weight loss trial might improve QoL in the short term only but might increase depressive symptoms in the long term. Weight loss and maintenance might be even more

problematic for breast cancer patients than for a general population and a failure to do so could further reduce confidence and self-efficacy. It might be that interventions focusing on weight loss may expose participants to a risk of failure to achieve intended lifestyle goals. These studies show the importance of long term follow up and this is considered in the next section.

2.9.6 Long term effects

Many of the included studies reported that changes had been achieved over the intervention period. However, longer term follow up data was also provided in some cases and show whether the changes had been maintained. Long term maintenance may be more difficult to achieve than the initial change due to a loss of vigilance and intervention support (Terranova *et al.*, 2017). Mosher *et al.*, (2013) suggest that self-efficacy may be important to increase the durability of dietary improvement and they recommend that dietary interventions are designed to increase self-efficacy for healthy eating. In some studies weight loss was achieved and maintained, for example Harrigan *et al.* (2016) which suggests that participants had developed skills in order for this to occur. In another study, significant weight loss was achieved during the intervention; participants were provided with protein shakes and pre-prepared meals which were easy and convenient (Fazzino, Sporn and Befort, 2016). This may have facilitated weight loss but is unlikely to be sustainable in the long term as it did not develop the necessary skills for continuation of behaviour change. Interventions may also need to be long enough to allow healthy habits to develop which are sustainable; Travier *et al.* (2014) suggest 20 weeks might be appropriate.

Terranova *et al.* (2017) suggested that long term support might be needed after interventions to encourage maintenance. In one study, intervention participants showed anthropometric improvements which reduced after the end of the intervention, while the self-guided control group lost weight more gradually but this continued in the long term (Stolley *et al.*, 2017). This suggested that the intervention group might have needed support to maintain the changes while control group members were able to maintain lifestyle improvements without support. It might be that control groups members had developed sustainable self-motivation and self-efficacy. Fazzino, Sporn and Befort (2016) report that participants own internal motivation was crucial for behaviour change. Members of the phone group were found to have better maintenance than members of a face to face group even though both had some ongoing phone support (Harris *et al.*, 2013). The authors suggest that the group in-person sessions may have provided more peer support, although the

phone sessions were more personalised. They suggest that the difference at 12-month follow up may have been because the phone group had continued to have infrequent but familiar support while the in-person group had lost their peer group and had to adapt to a phone support. This may have resulted in the observed differences (Harris *et al.*, 2013). This suggests that ongoing support should be a continuation of that provided during the intervention.

2.10 Summary

The aim of this literature review was to find out what was already known about lifestyle intervention design and behaviour change in breast cancer patients. None of the reviewed studies were carried out in the UK context, and findings may not be generalisable to the UK healthcare regime and culture. Many of the studies were small underpowered, pilot or feasibility studies and so the findings from these were treated with caution. More account was taken of larger trials, several of which were focused on weight loss rather than health improvement. Quantitative trials can address questions of whether an intervention led to statistically significant change, though results were challenging to interpret due to the multiplicity of differences between the intervention and comparison groups. However, trials do not provide understanding of how and why changes did or did not occur or how future improvements can be made. The review provided some qualitative data which gave some insights on mechanisms to support change from the participants' perspective.

This literature review suggests that interventions may be best carried out towards the end of, or soon after, treatment ends. External validity may be maximised by inclusive recruitment criteria. The review suggests that interventions of at least 12 weeks long may allow for habitual behaviour to develop but may become too onerous if they are too much longer or too intensive. Face to face group interventions with facilitation to encourage group support may increase engagement. However, they should be arranged to maximise attendance, and might be more suited to participants without conflicting employment or caring commitments. Participants might need ongoing support for maintenance following an intervention. Remote interventions including personalisation might encourage engagement and may also develop skills to encourage long term maintenance by developing self-motivation. Programmes with content specific to the breast cancer survivor context may improve behaviour change. Interventions with a focus on healthy eating rather than weight loss might still lead to weight loss but could avoid negative consequences, including risk of depression and a sense of failure, where weight is not lost or is re-gained. Interventions that aim

to develop skills of self-efficacy and self-motivation may be more likely to lead to long term change. Face to face interventions that include practical activities may enhance skills and peer support. Outcomes may be improved where participants are encouraged to attend with a friend or family member as a support person. The findings of this review were used in the development of the intervention used in this doctoral study, and this is discussed in **Chapter 5.** The research approach used to investigate the impact of the intervention is considered in the next chapter.

Table 2:2 Characteristics of studies included in the review

Qualitative Studies								
Author, year	**Setting, sample**	**Aims**	**Study type**	**Intervention type**		**Duration**	**Key Findings**	**Quality Review**
Balneaves 2014	Canada n=9,	To explore experiences and perspectives of participants	Focus groups & telephone interviews 8 weeks after intervention.	Weight loss, group pilot	Reduced calorie plus 150 mins PA. Based on DPP	24 weeks: 3 times a week	Peer support, safe environment, transition from treatment, healthy eating, effects on family and friends. Improved energy, self-esteem and confidence	Planned as focus group study
Fazzino 2016	USA n=186	To identify mechanisms contributing to weight loss	Qualitative; phone interviews on completion of intervention	Group phone-based weight loss	Weight loss plus 225 mins PA per week. 5 a day plus 2 protein shakes, entrees.	6 months; 1-hour weekly group conference call	Accountability to group and self. Importance of the group, convenience of diet, PA and self-monitoring hard to maintain. Internal motivation.	Weak: data captured using notes; no audio recording and transcription
Terranova 2017	Australia n=14	to explore experience of weight loss intervention.	Semi-structured phone interviews 7.5±0.5 months after intervention	Pilot weight loss phone intervention trial with controls.	Weight loss PA 210 mins per week, reduce energy intake, behavioural therapy	12 months; 16 phone calls and tailored text messages.	*Facilitators*: family; the coach; self-monitoring, self-motivation and new habits. *Challenges*; poor family support, family problems, treatment effects; comfort eating; conflicting advice; weight maintenance.	Transparent reporting throughout.
Evaluation studies								
Muraca 2011	Canada n=42	Evaluation of lifestyle programme for BC to achieve/ maintain a healthy weight	Evaluative questionnaire after programme plus data collected on stage of change for diet and exercise	***Taking charge programme***; small group face to face weight loss programme	Healthy eating and physical activity using TTM and motivational interviewing	10-12 weeks 5 X 2hr sessions based on TTM theory	High attendance 85.7% to 97.6% (across 5 groups) Weight loss 1.8– 2.26 kg (across 5 groups); satisfaction reported as high; data not valid. Most participants' report action or maintenance stage	Weak; Very limited reporting and analysis of results. No comparative data, just after intervention

Non-randomised trials								
Author, year	**Setting, sample**	**Aims**	**Study type**	**Intervention type**		**Duration**	**Key Findings**	**Quality Review**
Campbell 2012	Canada n=14	To test feasibility & efficacy of weight loss programme	Single arm, pre-post pilot study	Small group face to face weight loss programme	Reduced energy low fat diet plus 150 mins PA Based on DPP	24 weeks :16 x 2hr diet sessions plus 2x 45 mins exercise	Mean weight loss 3.8±5.0 Kg, reduced BMI, % fat, waist to hip ratio. No change in energy intake. QoL score improved. Rated useful, 67% attendance	No control group and underpowered
Griffith 2012	USA n=8	Feasibility of a culturally adapted (WINS-c) for African Americans	Single arm pre- post pilot study.	***Women's Intervention Nutrition Study (WINS)*** Small group	Healthy eating: Reduce fat intake, increase F/V. Based on SCT	1 year 8 x individual sessions, 5 group sessions and phone calls	Mean dietary intake of fat decreased. % calories from fat reduced. Significant decrease in Calcium intake and non-sig decrease in vitamin D. F/V increased.	Small pilot study so underpowered. No control
Knopf 2018	USA n=30 plus 10 partners	Feasibility of a culturally grounded lifestyle programme	Single arm trial Feasibility study for participants; partners also invited. Age < 65.	***Healthy Sisters*** Interactive group	Healthy eating and physical activity; education and empowerment	6 weeks x 2 hours Group sessions	Improved healthy lifestyle behaviour, physical activity, nutrition, stress management, emotional wellbeing, 85.7% retention.	Long term data not presented. Open questions included. No control. underpowered
Lawler 2017	Australia n=53	To see if Get Healthy Service (GHS) is suitable for BCS	Single arm pre-post pilot study	***Get Healthy after Breast Cancer*** individual telephone	GHS: weight loss, healthy eating and PA; not cancer specific	6 months; 10x calls of 10-20 mins plus health coach.	62% completed programme, 92% of completers had high satisfaction. Self-reported sig. increased PA, weight loss, improved QoL.	Included some open questions. No control
Lynch 2016	USA n=30 < 50 years old	To test feasibility, of a lifestyle intervention	Single arm pre-post pilot study. Included BC and testicular cancer	Web based weight loss programme. SCT	Commercially available online weight loss programme	1 year: weight loss, and weight maintenance	Retention and adherence rates of BC low. Lost 3.2% weight at 6 months and 4.9% at 12 months.	Convenience sample. Fees reimbursed for adherence. No control.

Non-randomised trials (continued)								
Author, year	**Setting, sample**	**Aims**	**Study type**	**Intervention type**		**Duration**	**Key findings**	**Quality Review**
Schiavon 2015	Brazil n=18, control= 75	Effects on nutrition and oxidative stress	Non-randomised 2 arm trial. Control received guidelines	Nutrition education intervention by telephone and mail	To increase F/V and reduce red and processed meat. Based on SCT	1 year. Bi-weekly phone calls plus monthly bulletins	Intervention group significantly increased F/V compared to control. Control group significantly gained weight, intervention group did not.	Two groups not equivalent.
Stolley 2009	USA n=23	To test feasibility and impact for AA BCS	Single arm pre-post evaluation study.	***Moving Forward*** weight loss trial	Using SCT and health belief model	6 months: 2 x group sessions per week.	High satisfaction. Valued social support, food labels, portions, empowerment to change lifestyle. Structured PA. mean weight loss of 3%	Convenience sample. Also included an evaluation questionnaire. No control.
Travier 2014	Spain n=42	To assess participation and adherence to intervention	Pre-post test pilot study	Group face to face weight loss intervention.	Healthy eating, menu planning, preparing and cooking food. Goal setting.	12 weeks; 24 x 75 mins PA sessions & 12 x 60 min diet sessions	Weight loss occurred, also increased QoL, reduced energy intake, increased physical fitness and reduced intake of fat and carbs. 88% completion	No control group, but good compliance.
Randomised controlled trials (RCT)								
Demark-Wahnefried 2014	Puerto Rico, Guam and USA 68 mother-daughter pairs; n=136	Feasibility of a mother-daughter weight loss intervention, and effect of individual or team approach	Parallel group RCT 3 armed and single blinded. Control group, team tailored and individual tailored groups. Based on ACS guidelines.	***DAMES trial*** (Daughters and Mothers against Breast Cancer). Mailed weight loss intervention	Focus on portion control, reduced energy intake and at least 150 mins per week of aerobic exercise and x2 strength training	12 months 1 workbook and 6 newsletters mailed over the period.	90% retention. Mothers in individualised group lost weight and reduced BMI & waist more than controls or team, but not sig. Sig. reduction of waist in both intervention groups compared to control. Healthy eating index improved more in team	Well-designed but under-powered. Low rate of recruitment

Randomised controlled trials (RCT) *(continued)*								
Author, year	**Setting, sample**	**Aims**	**Study type**	**Intervention type**		**Duration**	**Key findings**	**Quality Review**
Demark-Wahnefried, 2015	USA n=692	To see if significant weight loss can be achieved and maintained	2 arm RCT; weight loss group and attention control **Control** had ACS guidelines.	***ENERGY trial*** Intensive group intervention	Weight loss and QoL trial	1-year; 26 x1-hour group sessions plus 26x phone/ email	Intervention group had sig. more weight loss at 12 and 24 months. Borderline increases in vitality and physical function at 6 months declined over time. Depressive symptoms increased to significance at 24 months.	Strong evidence. A very large intervention. Not clear if assessors were blinded.
Greenlee, 2015	USA n=70 Hispanic	To see effect of a culturally based approach to increase F/V and decrease fat intake	RCT; 2 arm trial Based on ACS/AICR nutrition guidance. **Control** had written dietary recommendations for BC survivors.	***Cocinar para su salud***! Conducted in Spanish.	Healthy eating trial Covers healthy eating, nutrition, practical cooking and food shopping trips.	12 weeks; 9 group sessions (24 hours) Data collected at baseline, 3, 6 and 12 months	At 3 and 6 months ate more F/V than controls. Sig. decreases in % calories from fat, and % calories overall and waist. 87% retention at 6 months both arms. > 60% attended all sessions; 18% none.	Well conducted, though not clear if outcome assessors blinded.
Harrigan 2016	USA n=100	To compare 6-month changes in body weight, in 3 groups	3 arm RCT; in person counselling, telephone counselling and control (usual care) **Control**: lifestyle brochures and referral.	***LEAN study*** (Lifestyle Exercise and Nutrition) Adapted for BC from DPP/ WCRF/AICR	Individualized sessions to reduce calories and fat intake, increase physical activity and behavioural therapy	6 month, 11x 30 min sessions; follow up after 12 months	All groups lost weight at 6 and 12 months. Both intervention groups had significantly better results than control. Intervention groups had a significant decrease in CRP compared to controls. Weight loss maintained at 12 months.	Good, though self- assessment of body weight 12-month weight data.

Randomised controlled trials (RCT) (*continued*)								
Author, year	**Setting, sample**	**Aims**	**Study type**	**Intervention type**		**Duration**	**Key findings**	**Quality Review**
Harris 2013	USA n=52	To find acceptability, feasibility and effectiveness on weight loss	Pilot study. 2 arm trial; in-person or phone calls. **Comparison group** rather than control	***CASTLE study*** (Cancer Survival Through Lifestyle Change)	Weight loss by group sessions or individual phone calls. Aimed to increase PA and reduce calorie intake. SCT/MI	**1 year:** 16x 1.5 hr group or 24x 15 min phone calls over 6 months, then monthly calls	Both groups had sig. weight loss over 6 months with no sig. diff between groups. Between 6-12 months phone group maintained weight loss, while in-person group gained weight.	Weak. Planned as RCT but not randomised. Outliers excluded from data.
Hershman 2013	USA n=126	To evaluate the effect of an in-person survivorship intervention	2 arm RCT: control and intervention **Controls**: had NCI survivorship information	Survivorship intervention. Individual face to face session	Based on ACSO guidelines	Had a 1 hour meet for tailored lifestyle advice.	No significant improvements in intervention group over control. Though intervention associated with decreased health worry at 3 months, but not at 6 months.	Intervention was only a 1 hour discussion.
Kim 2011	South Korea, n=45	To test feasibility and effects of an exercise and diet (SSED) intervention	RCT; 2 arm pilot Control and individual phone and workbook intervention group.	Healthy lifestyle stage matched to TTM stages	Aimed to improve QoL (fatigue, anxiety, depression) and stage of readiness for PA and diet improvement	12-week; weekly phone calls. exercise 30 mins x5 per week and balanced diet (7+ F/V per day)	91% completion. Intervention group had sig. better readiness for diet and exercise. QoL better in intervention group but not stat sig. but diet quality index lower due to elevated protein intake. Intervention highly rated.	Pilot study so underpowered. Most data were self-assessed.
Lee 2014	South Korea n= 59	To see if intervention for BC is feasible and effective.	RCT pilot; control group had an information booklet.	Web based self-management and dietary intervention (**WSEDI)** programme	TTM based programme; stage of change, process of change, self-efficacy. Stage matched to TTM	**12-week.** WSEDI x2 per week; assessment, education, planning, feedback.	Self-efficacy for F/V improved, proportion who exercised 150mins a week, ate 5-a day, diet quality, and QoL all improved sig more in intervention group. 89% consistently participated.	Pilot study so small sample. Outcome data self-reported. Participants were blinded to group

Randomised controlled trials (RCT) *(continued)*								
Author, year	**Setting, sample**	**Aims**	**Study type**	**Intervention type**		**Duration**	**Key findings**	**Quality Review**
Lee 2014	South Korea n= 59	To see if intervention for BC is feasible and effective.	RCT pilot; control group had an information booklet.	Web based self-management and dietary intervention (**WSEDI)** programme	TTM based programme; stage of change, process of change, self-efficacy. Stage matched to TTM	**12-week.** WSEDI x2 per week; assessment, education, planning, feedback.	Self-efficacy for F/V improved, proportion who exercised 150mins a week, ate 5-a day, diet quality, and QoL all improved sig more in intervention group. 89% consistently participated.	Pilot study so small sample. Outcome data self-reported. Participants were blinded to group
Mosher 2013	USA and Canada n= 306 BC patients	A trial to see if changes in self-efficacy explain effects diet at 2 years	RCT study of prostate and BC patients: 2 arm mailed intervention Controls received NCI information	***FRESH START*** mailed trial materials tailored based on SCT	Increase F/V, decrease fat, increase PA	10-month trial. Workbook and 7 tailored mailings	*ONLY results specific to BC included*. Self-efficacy may influence long term practices in BC survivors. Especially increased F/V consumption and a reduction in % energy as fat	Self-report data collected via computer assisted phone calls. Not clear if any blinding
Park 2016	USA n=173	To test TTMI, standard lifestyle managemen t (SLM) with control	3 arm RCT Controls received materials after study. Intervention groups blinded	***Targeting the teachable moment*** (TTMI) mailed intervention	Increase F/V, reduce fat intake and increase PA. Based on **Fresh Start** and SCT	4-months. 8 mailings Payment received after assessments	F/V increased to similar degree in both intervention groups but decreased after intervention. Adherence quite high. High satisfaction; preference for mailed intervention	self-reported data. Intervention groups blinded.
Reeves 2017	Australia n=90	To test feasibility, and efficacy of intervention following treatment.	Pilot RCT; 2 armed. Weight loss trial versus control (usual care; received information after trial).	***Living well after breast cancer*** Telephone behavioural weight loss trial.	Increased PA, reduced energy intake based on SCT.	6 months 16 phone calls from lifestyle coaches Tailored with feedback.	Mean weight loss, reduction in fat mass and waist circumference sig. greater in intervention. No other stat sig. effects. High satisfaction with intervention and its timing.	Study underpowered. No follow up

Randomised controlled trials (RCT) *(continued)*								
Author, year	**Setting, sample**	**Aims**	**Study type**	**Intervention type**		**Duration**	**Key findings**	**Quality Review**
Stolley 2017	USA n= 246 Controls received written materials	Effects of a weight loss programme for AA BCS.	RCT 2 arms: self-guided versus interventionist guided	***Moving Forward;*** based on ACS guidance and SCT.	Weight loss Reduced energy, increased F/V and increased PA	6 months; x2 nutrition and PA groups per week plus texts support	All lost weight, but IG lost sig. more. Body composition changes and behavioural changes greater in IG. Some weight gained in IG after intervention. Retention high, >50% attendance	Comparison group rather than control group
Tometich 2014	USA n= 68 mother-daughter pairs	To test associations between diet, exercise and weight related outcomes.	Secondary analysis of data from previous 3 arm RCT; mailed weight loss intervention; Individually tailored/team / attention control	***DAMES trial*** (Daughters and Mothers against Breast Cancer)	Mailed diet and exercise weight loss trial based on SCT	12 months 1 workbook and 6 newsletters mailed over the period	Mothers had better diet quality than daughters. Improved diet quality associated with reduced waist circumference but not BMI or weight. Changes in calorie intake or PA not associated with weight	Small group sizes Self-reported data. Adherence unclear
Mixed methods study								
Sheppard 2016	USA n=31 Controls received NCI materials	To assess efficacy of culturally targeted lifestyle intervention for black BC survivors. Mi	Pilot 2 arm RCT: weight loss versus usual care. Weight loss, increase PA, improve dietary intake	***Stepping STONE*** study (Survivors taking on nutrition and exercise) based on SCT and ACS guidance.	Group intervention. Nutrition information, exercise groups and survivor led MI phone sessions.	12 weeks; 6x 90-minute group sessions plus 6 MI call with survivor coach	High adherence (70%) and satisfaction (86%). Intervention group were more active, lost some weight, reduced BMI, increased PA, reduced energy intake, and decreased % energy from fat. Participants reported moving to next TTM stage.	Pilot study so underpowered. Rationale for mixed methods not explicitly made. No follow up. IG had lower bodyweight.

Abbreviations: ***AA*** *African Americans;* ***ACS*** *American Cancer Society;* ***AICR*** *American Institute of Cancer Research;* ***ASCO*** *American Society of Clinical Oncology;* ***BC*** *breast cancer;* ***BCS*** *breast cancer survivor;* ***BMI*** *body mass index;* ***CG*** *control/comparison group;* ***CRF*** *cardiorespiratory fitness;* ***DPP*** *diabetes prevention programme;* ***F/V*** *fruit and vegetable intake;* ***IG*** *intervention group;* ***MI*** *motivational interviewing;* ***NCI*** *National Cancer Institute;* ***PA*** *physical activity;* ***QoL*** *quality of life;* ***SCT*** *social cognition theory;* ***TTM*** *transtheoretical model;* ***Sig****. statistically significant.*

Chapter three: Methodology

3 Methodology

3.1 Background to the research study

Since 2012, the University of Worcester (UW) has offered a 12-week group lifestyle intervention that aimed to promote physical activity and healthy eating for groups of women who had completed primary treatment for breast cancer. The content of the lifestyle intervention was based on a narrative review of research evidence supporting dietary and physical activity recommendations for reducing the risk of breast cancer, and recommendations to promote the health of cancer survivors. This recommends that cancer survivors maintain a healthy body weight, be physically active, and eat a nutritious diet to reduce future health risks (World Cancer Research Fund/American Institute for Cancer Research, 2007; World Cancer Research Fund International, 2014). This evidence was discussed and critically evaluated in **Sections 1.3** and **1.4**.

The UW lifestyle intervention involved group activities such as keeping a food diary, sharing recipes, eating healthy foods together in shared meals, trying new foods, using food labels to make healthy eating choices and weighing foods to discuss portion size. In the physical activity sessions, participants were encouraged to try different activities such as using gym equipment, Tai Chi, Pilates and walking for health. The programme also included the setting of realistic personal behaviour change goals and discussions of ways to pursue and maintain them. Patients who were interested in joining the intervention were referred by local clinical staff.

The UW lifestyle intervention was offered annually for three years and during this period some informal review was carried out. Evaluation suggested that improvements in the health and lifestyle of attendees may have occurred; some appeared to have had improvements in anthropometric measures, dietary intake and self-reported wellbeing. Participants also reported valuing the intervention. However, this data was collected under non-standardised conditions for review with group members and staff and was therefore treated with caution; longer-term follow up data were not collected. Prior to designing and carrying out the main research study, a feasibility study of the lifestyle intervention was carried out (**Section 1.6**) and the design of this will be discussed in the next section.

3.2 Design and aims of the feasibility study

The MRC guidance on the evaluation of complex interventions advise carrying out an initial feasibility and piloting phase (**Section 3.4.1**) prior to carrying out a main research study (Craig *et al.*, 2008). The current study design was guided by the MRC framework (**Section 1.6**) and therefore an initial study was carried out.

Feeley and Cossette (2015) recommend carrying out a pilot study to assess the feasibility and acceptability of the study design by getting feedback from participants so that the intervention and the research design can both be optimised before carrying out the main study. Lancaster, Dodd and Williamson (2004) also suggest that pilot studies may lead to a change in study design and can be used to test data collection tools and intervention acceptability as part of an iterative process of intervention and study design (Thabane *et al.*, 2010). The MRC framework use the terms 'feasibility study' and 'pilot' without a clear distinction (Craig *et al.*, 2008) and these terms are sometimes used synonymously (Thabane *et al.*, 2010; Giangregorio and Thebane, 2015).

In the current doctoral research study an initial feasibility study was carried out in line with the guidance of Arain *et al.* (2010) as it was a small study carried out before the main study to inform study and intervention design. It aimed to investigate the feasibility of processes involved in intervention delivery and the ability of the collection tools to capture relevant changes that might result. It also aimed to evaluate the experience of participants; to find out whether the intervention addressed their concerns and invited feedback on ways in which the intervention could be improved. This allowed participants to have a voice in the design of the intervention and the main research study (**Section 2.8.4**)**.** Arain *et al.* (2010) advise that a feasibility study might be conducted with a more flexible methodology and may focus on fewer components than the main study. In this study, the feasibility study had a single arm study design with no collection of comparative or follow up data. The research methods used in the feasibility study are discussed in **Chapter 4.1**, while the findings and their implications are discussed in **Chapter 5.** The methodological approach used in the main study is considered in the rest of this chapter.

3.3 Research paradigms and main study design

Researchers working within a particular discipline often form communities of specialists who share a framework of ideas about the world and ways of investigating it (Morgan, 2007). This framework is known as a paradigm and is a shared system of beliefs, values, assumptions and practices (Braun and Clarke, 2013). An adopted paradigm influences views about the most appropriate ways to gain useful knowledge in a subject area. The implications of the shared paradigm are often axiomatic and research questions or hypotheses are generated and research studies are designed and implemented within these implicit frameworks (Bowling, 2014).

The concept of a research paradigm was first described by Thomas Kuhn in 1962 (Morgan, 2007; Chalmers, 2013). The research paradigm may encompass the philosophical stance on the nature of reality (ontology), the nature of knowledge (epistemology) as well as views about axiology, methodology and research design (Johnson, Onwuegbuzie and Turner, 2007; Swift and Tischler, 2010; Cresswell, 2014). Researchers working within a paradigm are said to be working in a period of *normal science* in which the paradigm assumptions may be generally accepted within the research community and often are not discussed or challenged. Existing paradigms are often highly resistant to change, even in the light of contrary evidence (Gray, 2014). A period of *revolutionary science* occurs when these assumptions are strongly and persistently challenged. A paradigm shift might eventually occur and some members of the research community may switch to working within a new paradigm with a different set of assumptions (Morgan, 2007). While this paradigm shift occurs, underlying metaphysical assumptions are often more openly discussed and contested (Morgan, 2007).

Health research is a multi-disciplinary field and draws on many academic subject areas including social sciences, psychology, medicine, nutrition and public health. A quantitative positivist paradigm was dominant across most of these subjects until the mid to late twentieth century (Draper, 2007; Denscombe, 2008). Since then, this dominant paradigm has been challenged in some areas and paradigm shift has occurred towards an alternative constructivist paradigm, particularly within social sciences (Morgan, 2007). However, in nutrition and health research, a quantitative positivist paradigm remains dominant (Swift and Tischler, 2010). In nutrition intervention research this has often led to a focus on hypothesis testing to determine whether interventions 'work' by looking for

statistically significant changes in mortality or morbidity rather than a broader consideration of how interventions might work, for whom and in which contexts and how they might be improved. Nutrition researchers may not be very open to alternative research approaches (Green and Thorogood, 2009); qualitative research is still not fully accepted and may be seen as unscientific (Fade, 2003; Swift and Tischler, 2010; Braun and Clarke, 2013). From the 1990s, a third pragmatic paradigm also developed (Cresswell, 2014) and has become more widely used especially in evaluating health interventions (Evans, Coon and Ume, 2011; Curry *et al.*, 2013) and is the paradigm underpinning this research study.

Table 3:1 Key paradigms underpinning health research

	Positivist/post-positivist paradigm	**Pragmatist paradigm**	**Constructivist paradigm**
Approach	Quantitative approach	Mixed methods approach	Qualitative approach
Ontology	Realist ontology	Critical realist ontology	Relativist ontology
Epistemology	Positivist/post-positivist epistemology empiricism	Contextualist epistemology	Interpretivist epistemology
Methodology	Hypothesis testing, using statistical analysis, objective data collection. Falsification. Reductionist. Experimental design or observational cohort or cross-sectional survey design Hierarchies of evidence to determine causal associations hypothetico-deductive methods.	Using a study design that addresses the research question. May include experimental or quasi-experimental design combined with experiential qualitative data collection. Abductive, intersubjective and transferable research.	Naturalistic design. May be experiential or critical. Exploratory and qualitative study design. Focus on complexity. May generate theory inductively Embraces subjectivity Data co-constructed by researched and researcher; participatory.

As discussed above, there are currently three contrasting paradigms (**Table 3:1**) in operation in different health research communities. Much scientific and medical quantitative research (including nutrition research) operates within a period of *normal science* in which the dominant positivist paradigm is implicitly accepted, is largely uncontested and rarely considered in research outputs. In

contrast much qualitative health research operates within a constructivist paradigm which challenges the positivist *status quo* and stimulates philosophical and methodological debate (Johnson, Onwuegbuzie and Turner, 2007) and controversy between different research communities. The pragmatist paradigm has emerged and become more widely used and advocates that research methodology be driven by the research questions that it seeks to answer, rather than being driven by an underpinning philosophical stance. The three contrasting paradigms of positivism, constructivism and pragmatism will be considered in the following sections together with their relationship to the design of this doctoral study.

3.3.1 Positivist and post-positivist quantitative paradigms

A traditional view of science is that it aims to uncover positive facts about the natural world derived from objective observation (Chalmers, 2013; Cresswell, 2014). This positivist approach is linked to an empirical epistemology, in which knowledge is thought to be gained by objective measurement to reveal the underlying real truth (Braun and Clarke, 2013). This is a realist ontological position in which one stable reality is thought to exist separately from human understanding and can be uncovered by careful investigation (Green and Thorogood, 2009; Swift and Tischler, 2010). The researcher makes objective quantitative observations and develops theoretical knowledge from these. Hypotheses aiming to establish causal relationships between factors are deduced from the theory and experiments are designed to rigorously test them. Chalmers (2013; p36) explains this by saying that;

> "*It is the sense in which experimental outcomes are determined by the workings of the world rather than by theoretical views about the world that provides the possibility of testing theories against the world.*"

This approach is known as the hypothetico-deductive method, or scientific method and is still dominant in the natural sciences (Bowling, 2014) and in health and nutrition (Swift and Tischler, 2010). In nutrition research this approach is widely used to test the efficacy of specific supplements, nutrients, foods, diets or interventions on health outcomes to see if they 'work'.

Most processes in the real world, rather than in an experimental situation, are complex and multi-factorial. To understand the contribution of each separate factor they are often investigated one at a time in scientific investigations. An experimental factor is varied while confounding factors are minimised so that causal relationships can be investigated (Chalmers, 2013). Experiments are

designed to attempt to falsify hypotheses; and if they resist falsification then they are assumed to probably be true (Chalmers, 2013; Bowling, 2014) and findings are generalised from the study sample to the wider population (Tariq and Woodman, 2010). Progress in understanding occurs as subsequent studies gain a better understanding of the 'true' picture of reality (Green and Thorogood, 2009). Data collection is usually undertaken using a systematic and transparent approach using accurate, validated and reliable tools to avoid bias (Bowling, 2014; Cresswell, 2014). Nutrition research is complex as it includes the nutritional complexity of the diet interacting with individual people with different genomics, metabolic requirements, body compositions and varied lifestyles. Much experimental nutritional research is carried out by attempting to alter one dietary or nutritional factor and then to look for changes in outcome measures. However, making one dietary change can often lead to other consequent nutritional alterations which may make the interpretation of results difficult. All of this makes nutrition research challenging.

Experimental research undertaken within a positivist paradigm assumes that this is an objective process and that findings are not affected by the characteristics of individual researchers (Braun and Clarke, 2013). Research in this paradigm is assumed to be value free (Green and Thorogood, 2009) and the research process is assumed to be unaffected by the researcher's views, beliefs or expectations based on prior theoretical knowledge (Swift and Tischler, 2010). Critics of positivism, however, have argued that all research is value laden and is influenced by the culture and social context of the researcher and by their assumptions (Bowling, 2014). Even perception is not entirely objective and can be influenced by background, culture and expectations (Chalmers, 2013).

Scientific enquiry is carried out by people and is therefore influenced by social contexts such as health policies, funding priorities, previous research findings and the views of peers. Some might consider that all research should be part of society in that it should be designed to have impact and so should not be value free and therefore cannot be entirely objective (Green and Thorogood, 2009) as posited by some positivists. In more recent years these arguments have resulted in a paradigm shift amongst some quantitative researchers towards an alternative post-positivist paradigm in which findings are probably true if they are supported by inferential statistics based on the probability that observed findings are correct and generalisable (Gray, 2014). Post-positivists may still use the scientific method to collect data accurately and objectively to avoid bias and to ensure validity and reliability and to search for truth (Cresswell, 2014). The post-positivist paradigm

is often linked to a critical realist ontology and a contextual epistemology (**Table 3:1**) in which there may be one stable reality but that this can only be partially explained in research as researchers are influenced by theory and context which introduces some subjectivity (Braun and Clarke, 2013); therefore findings can only at best represent an approximate or probable truth.

The author of this doctoral study originally trained in biology and worked in immunology and genetics and later taught human physiology and nutrition to health professionals and practitioners. The author adopts a post-positivist stance when considering research in the natural sciences including the complex physiological effects of nutrients on physical health. However, this study aimed to investigate the broader impacts of a lifestyle intervention on human participants and there has been much debate about the appropriateness of scientific method to this type of research study (Tariq and Woodman, 2010; Curry *et al.*, 2013). By searching for simple cause and effect relationships both positivist and post-positivist research can be seen as reductionist and may be considered less appropriate for research into human phenomena as these are usually complex and multi-factorial (Tariq and Woodman, 2010). In many areas of human behaviour research, the alternative constructivist paradigm has emerged, and this will be considered in the next section.

3.3.2 Constructivist qualitative paradigm

Positivism has been a dominant paradigm in many areas of health research; however, a more holistic approach may be more appropriate to investigate the nuances of human behaviour. Food behaviour is complex and cannot be explained simply in terms of a series of biological mechanisms but is also dependant on psychological processes, social contexts and culture (Draper, 2007). People think about and reflect on their health behaviour (Green and Thorogood, 2009) so there is a multiplicity of internal and external factors interacting and affecting it.

Research aiming to explore human behaviour and why people behave as they do, often involves exploratory research questions which would not be addressed by taking a positivist stance. Instead, research may be planned within a constructivist paradigm in which the positivist paradigm is rejected. A constructivist paradigm is underpinned by a relativist ontology (**Table 3:1**) in which reality is seen to be multiple and socially constructed. It also may include an interpretivist epistemological position that embraces subjectivity in research and uses inductive research methodologies aimed at the development of theories from data (Swift and Tischler, 2010) and may

therefore be considered to be diametrically opposed to a positivist epistemology. Other groups of researchers might adopt the mid-ground between a positivist and a constructivist view; a contextual epistemological position is essentially constructivist but still aims to find the truth (or a truth) and is therefore often linked to a critical realist ontology (Braun and Clarke, 2013).

Constructivist health research usually collects qualitative data to explore meanings in context with a focus on complexity (Cresswell, 2014). Many constructivist researchers would consider research to be a participatory and cooperative activity in which participants become co-investigators. The research data are therefore affected by the culture, assumptions and experience of researchers and participants. A participatory approach is considered useful for evaluating programmes (Green and Thorogood, 2009) such as the lifestyle programme being investigated in this study. Research designs within this paradigm are usually based on naturalistic rather than experimental study designs as health behaviour is influenced by context (Green and Thorogood, 2009). Data analysis generates a description of phenomena that is thick (as it includes contexts) and rich (as it includes complexity and contradiction). In this paradigm it is accepted that qualitative data analysis is partial and subjective and aims to find *a* truth rather than *the* truth as relativist ontology accepts that there are multiple realities that can be dependent on research and social contexts. Qualitative data analysis is evidenced from the data which gives voice to the participants, and identifies patterns and associations; it may also lead to inductive theory development (Braun and Clarke, 2013). Constructivist research can be *critical* or *experiential*. In critical qualitative research the research data are further analysed and interrogated to investigate further meanings and social structures and in this case the investigators' interpretations are more important than the words of the participants (Braun and Clarke, 2013). By contrast, experiential qualitative research is still open and exploratory, but focuses on the participants' perspectives, and not just the factors that the researchers anticipated to be of relevance. The data collected are taken at face value and are of prime importance to the analysis (Braun and Clarke, 2013). In this doctoral study, experiential qualitative data were collected and analysed as outlined above to explore the experiences of participants and their interpretations of the intervention.

Qualitative research has been criticised as it may be seen to be biased and affected by the researchers' subjective views and assumptions (Denzin and Lincoln, 2008). Constructivist researchers bring their own subjectivity to research process although this can be seen as a strength.

This subjectivity is often accounted for in the analysis by critical reflection on the role of the researcher in the light of their culture, experience and epistemological position (Braun and Clarke, 2013). Qualitative research has also been criticised for a lack of generalisability as it relies on small samples and focuses on context, although generalisability in qualitative research is more related to theoretical or conceptual generalisability and whether findings might be transferable to other contexts (Swift and Tischler, 2010). In this research study, an experiential approach to qualitative data collection is taken, set within a contextual epistemology and a critical realist ontology as the research questions are concerned with participants' experiences of the lifestyle intervention and behaviour change and the meanings that these have for them.

Quantitative and qualitative research produce different kinds of knowledge that can be complementary in researching patterns of nutrition behaviour and in designing interventions (Draper, 2007). Positivism and constructivism are often seen as opposites; each based on different ontological and epistemological assumptions and with different methodologies and methods. Both approaches have strengths and limitations; and both are useful to health research; therefore, a third pragmatist paradigm that combines the advantages of each using a mixed methods approach has been used more recently in health intervention research and is discussed in the next section.

3.3.3 Pragmatic mixed methods paradigm

Health research often crosses disciplinary boundaries so a flexible choice of research design is useful (Swift and Tischler, 2010). Studies such as the one discussed here, that aim to evaluate health interventions may include a qualitative aspect to access the patient perspective in addition to an experimental or quasi-experimental design to collect quantitative data (Curry *et al.*, 2013).

There has been a rapidly increased use of mixed methods health research operating within a discrete pragmatic paradigm (Denscombe, 2008) over the last 20 years (Tariq and Woodman, 2010). A mixed methods approach is one in which both quantitative methods with statistical analysis and qualitative methods with thematic analysis are integral to the research design. The mixed methods design often includes a synthesis of both types of data to garner a more complete and all round understanding of the research questions (Tariq and Woodman, 2010; Evans, Coon and Ume, 2011; Cresswell, 2014). All methods have limitations and in mixed methods research one approach can overcome the weaknesses of the other (Cresswell, 2014) and induction (theory generation) is as

important as deduction (theory testing) (Borglin, 2015). The current study was conducted using mixed methods within this pragmatic paradigm. The two approaches can be used to triangulate findings and together have complementary strengths to address broad and complex questions including the evaluation of health interventions (Evans, Coon and Ume, 2011; Curry *et al.*, 2013) and were therefore used to address the research aim of this doctoral study.

Researchers are often trained in one paradigm and may question the validity of research conducted within another. Some researchers have claimed that mixed methods research includes incompatible inconsistencies in epistemology and ontology between the quantitative and qualitative elements of the study design as they are underpinned by opposing positivist and constructivist world views (Blackwood, O'Halloran and Porter, 2010). Blackwood, O'Halloran and Porter (2010) claim that there is an ontological contradiction in using a mixed methods approach as the constructivist assumptions underlying qualitative data collection challenge the reductionist positivist and realist positions that underpin the quantitative (Blackwood, O'Halloran and Porter, 2010). This is not the view taken in this doctoral study. There is often blurring and overlap between positivist and constructivist paradigms in research projects (Denscombe, 2008; Evans, Coon and Ume, 2011). Quantitative studies are not always positioned entirely within a positivist or post-positivist paradigm and qualitative studies may not always be positioned within a constructivist paradigm. For example, some quantitative questionnaires collect qualitative data using open questions which may be analysed using a semi-quantitative content analysis of qualitative data (Hennink, Hutter and Bailey, 2011) suggesting that the qualitative data are being analysed within a positivist or post-positivist paradigm. Braun and Clark distinguish between "large Q" qualitative research positioned within a constructivist paradigm, and "small q" qualitative research that is not; they claim that qualitative research conducted as part of a mixed method study is rarely positioned within a qualitative constructivist paradigm (Braun and Clarke, 2013; p. 4-5). The current study adopts a flexible and pragmatist paradigm to underpin the mixed methods approach adopted.

Morgan (2007) argues that different researchers use the term 'paradigm' in different ways and that this difference has confused arguments about whether there are inherent philosophical contradictions in mixed methods research. The terminology used to discuss ontology and epistemology is not consistently used by different writers (Gray, 2014), which does not add clarity to the debate. Social researchers tend to define paradigms as epistemological stances and have

emphasised the metaphysical considerations of ontology and epistemology. This meaning of 'paradigm' has been important in a period of paradigm shift as it has allowed researchers to challenge the dominance of positivism (Morgan, 2007). However, paradigms can also be considered as systems of knowledge acquisition that can be described as research communities (Morgan, 2007). Denscombe also argues for an alternative use of the term paradigm that he claims is more in line with the original proposition of Kuhn in regarding a paradigm as a community of practice (Denscombe, 2008). This broader definition of paradigm is less rigid and can include a variety of ways in which a research question can be investigated and can accommodate changes in research practice over time. Morgan argues for a definition of a paradigm as the shared views of researchers in a specialist field about what are worthwhile research questions and appropriate ways of addressing them (Morgan, 2007). Using these looser definitions of paradigm, researchers can move between different perspectives within research practice (Denzin and Lincoln, 2008). Morgan argues for a further shift towards a pragmatic paradigm in which an integrated methodology is central and connects up to epistemology and down to methods rather than epistemology being central and leading to the other two (Morgan, 2007). He argues that research is never entirely inductive or deductive but rather in reality moves between the two; he calls this *abductive* reasoning. He also argues that research is never purely objective or subjective and argues for an *intersubjective* approach, and that research findings are not either generalisable or purely context dependant and instead argues for an alternative concept of *transferability*. In summary Morgan argues that qualitative research may tend to be inductive, subjective and contextual, while quantitative research tends to be deductive, objective and generalisable while mixed methods research can be abductive, intersubjective and transferable underpinned by an integrated pragmatic methodology (Morgan, 2007). A flexible pragmatic research approach can investigate both the subjective and physical aspects of health, bringing together the philosophical assumptions of both (Swift and Tischler, 2010) and is therefore appropriate to the current study.

In this mixed methods research study, a pragmatic view is taken so that the research question is central and that the most appropriate methods have been selected to address this. The research design is therefore driven by the problem that it seeks to investigate rather than underlying theory (Denscombe, 2008; Tariq and Woodman, 2010) and the researcher is not committed to one system of philosophy or reality although the whole study is underpinned by a critical realist ontology

(Blackwood, O'Halloran and Porter, 2010). Within this approach it is assumed that there is an external world that exists outside of human awareness but also one that is constructed in the human mind (Cresswell, 2014).The researcher of the current study has been able to critically appraise different strategies and choose what is judged to be the most appropriate for the current research question.

3.3.4 The paradigm and approach adopted in the current study

This research study aimed to explore the impact of a lifestyle intervention for women who have completed breast cancer treatment. To address the research objectives (**Chapter 1.6**) a pragmatic paradigm was adopted in which the design of the research was driven by the research aim and the objectives. Some of the research objectives, for example investigating the concerns of participants about their lifestyle and health, and identifying contexts and mechanisms for change, are exploratory and were investigated using a qualitative approach. Other research objectives concerned changes in dietary habits, self-efficacy and physical health and were investigated using quantitative measurement. Therefore, a mixed methods approach was used within a pragmatic paradigm underpinned by a critical realist ontology, and a contextual epistemology and the mixed methods approach was used triangulate and strengthen the findings by looking at the impact from different perspectives.

Mixed methods research is an emergent paradigm, and there is relatively little published guidance on how it should most effectively be implemented (Evans, Coon and Ume, 2011; Curry *et al.*, 2013). There is also little guidance on integration of the quantitative and qualitative data, validation of the data collection methods or standards against which to appraise the quality of mixed methods research (Johnson, Onwuegbuzie and Turner, 2007). In the next section the frameworks used to guide the design of this research study will be considered.

3.4 Evaluation frameworks

3.4.1 Evaluating interventions

In evidence-based practice there is a need for health care interventions, such as the one discussed in this study, to be critically reviewed to investigate their merit or value as a pre-requisite to wider implementation. This research study aimed to assess the overall impact of the lifestyle intervention. The impact of the intervention is likely to be multi-faceted; however one aspect is to establish whether or not there was a causal link between the intervention and the outcomes as this is a

concern of all health intervention studies (Sidani, 2015). However, the study also aimed to investigate the ways in which the intervention might work and how it could be used effectively in different contexts.

Randomised controlled trials (RCTs) are widely recognised as the most reliable research design for assessing the efficacy of simple health interventions such as drug treatments (Campbell *et al.*, 2000). They are the most valid way of minimising the effects of confounding variables and therefore increasing the internal validity of a study and estimating its effects (Jamal *et al.*, 2015; Sidani, 2015; Tarquinio *et al.*, 2015). RCTs are usually quantitative studies conducted within well-established positivist or post-positivist paradigms to establish whether a drug 'works'. This is addressed by comparing outcome data of those receiving the drug to a parallel placebo group and using inferential statistical testing to establish whether a statistically significant difference is obtained. RCTs aim to establish a causal relationship between the treatment and outcomes by minimising bias and the effects of confounding factors. Participants are usually randomly allocated to be part of the intervention or control group to ensure their equivalence in terms of confounding factors. Ideally RCTs are double-blinded to avoid bias; both the participants and the researchers are unaware to which group each participant belongs (Sidani, 2015).

Drug trials are relatively simple interventions in which parallel groups of participants either receive a standard dose of a standard drug or do not and the outcomes of each group can be compared using an RCT design. It is increasingly recognised that other types of healthcare intervention should also be rigorously tested using equivalent procedures (Campbell *et al.*, 2000). However most other types of health interventions are composed of several different interacting ingredients making them more complex and more difficult to evaluate. In complex interventions, some of the elements act independently, while others act synergistically (Campbell *et al.*, 2007) which a reductionist method of scientific enquiry would not reveal. This can only be explored by using a more holistic approach. The complexity of the evaluation of a health intervention may also relate to the research aim being addressed; a simple question may investigate whether or not an intervention works while a question concerning how an intervention works and in which context is likely to be reflective of a complex approach (Richards, 2015). The lifestyle intervention that is being investigated in this doctoral study is a complex intervention and required a study design that would reflect this.

It is challenging to evaluate complex interventions as they are made up of component parts that may be difficult to define and specify and replicate by other research groups (Campbell *et al.*, 2000; Hawe, Shiell and Riley, 2004). In order to improve the quality of research studies seeking to evaluate complex health interventions and to avoid research waste (Hallberg, 2015; Richards, 2015), the Medical Research Council in 2000 (Campbell *et al.*, 2000; Medical Research Council, 2000) published a framework to guide their design. This framework recommended an iterative process that was initially based on the stages of drug development and the use of RCTs. This framework was revised in 2008 (Campbell *et al.*, 2007; Craig *et al*., 2008; Craig and Petticrew, 2013) and this revised framework was used to guide the design of the current study. Table x shows the phases of this study mapped to the stages in the MRC revised framework (Craig *et al*., 2008).

Table 3:2 Stages in the development of the current doctoral study mapped to the revised MRC framework for the evaluation of complex evaluations (Craig *et al*., 2008)

Stages recommended in revised MRC framework	**Corresponding stages of the current study**
Developing the intervention and its theoretical basis	• Context and background to the study (**Chapter 1**) • Integrative literature review (**Chapter 2**)
Piloting and feasibility to assess recruitment, retention, variability and effect size	• Feasibility study to inform intervention design and delivery and main study design (**Chapters 3.2, 4.1, 5)**
Evaluating using an RCT or alternative study design using mixed methods	• Main research study using a novel quasi-experimental design and mixed methods (**Chapters 4.2, 6,7**)
Reporting on systematic review**,** details of intervention, outcomes	• Integrative literature review (**Chapter 2**) • Quantitative results (**Chapter 6**) • Qualitative findings (**Chapter 7**) • Discussion (**Chapter 8**) • Conclusions and recommendations (**Chapter 10)**
Implementing	• Recommendations (**Chapter 10)**.

The revised MRC framework (Craig *et al.*, 2008) also emphasises the importance of context when developing and evaluating an intervention. It recognises the limitations of a simple RCT study design

to investigate a complex intervention as results will only indicate whether the intervention has worked. If results are negative, they will not indicate which aspect of the intervention caused the lack of effect or whether the whole intervention was not effective (Hawe, Shiell and Riley, 2004; Campbell *et al.*, 2007; Craig *et al.*, 2008). Traditionally, RCTs do not investigate *how* an intervention might work as they do not consider process theory or mechanisms of action or contextual factors and therefore don't address external validity (Jamal *et al.*, 2015; Hanley, Chambers and Haslam, 2016). MRC guidance recommends that researchers also carry out a process evaluation alongside an outcome evaluation to focus on the intervention mechanisms so that any positive results might be applied in a different context (Campbell *et al.*, 2007). The MRC framework recommends the use of qualitative research for process evaluation and to explore barriers to behaviour change (Campbell *et al.*, 2000). The revised framework is therefore recommending a mixed methods approach to intervention evaluation and was used to guide the design of this study. Mixed methods research studies to investigate the impact of health interventions are more likely to yield deeper and richer findings than a simple quantitative trial design alone (Hallberg, 2015; Minary *et al.*, 2019; O'Cathain *et al.*, 2019). Although the current study did not use a separate process evaluation, it utilised instead a qualitative element integral to the mixed methods research design, which was underpinned by the ideas of realist evaluation and the rationale for this is explored in the next section.

3.4.2 Realist evaluation

Evaluation studies often aim to investigate whether outcomes have been *caused* by an intervention. Causality cannot be directly observed but may be inferred from observation (Marchal *et al.*, 2013); in 1965 Austin Bradford-Hill outlined criteria to establish causality (Richards, 2015). The approach used to achieve this can be underpinned by different theories of causation. Experimental or RCT studies depend on establishing successionist causality; while realist evaluation is underpinned by generative causality based on ideas of scientific realism (Greenhalgh *et al.*, 2009).

Successionist causation is based on the concept of constant conjunction first described by David Hume (Marchal *et al.*, 2013). It underpins the traditional experimental and quasi-experimental approach to evaluation involving a repetition of studies in which outcomes repeatedly follow the intervention in the experimental group but not the equivalent control group. Therefore, it is concluded that the intervention *caused* the outcomes. This research design does not investigate *how* the intervention led to the outcomes and so this has often been described as the 'black box'

approach as the intervention is investigated as if it were a single independent variable, and there is no analysis of the role of different elements within it (Pawson and Tilley, 1997).This type of experimental study design has high internal validity as confounding variables are reduced and the intervention standardised. However, it may have a low external validity as it is unclear which features of the programme are essential for its success when it is implemented elsewhere (Tarquinio *et al.*, 2015). Consequently, when an intervention is repeated in other contexts the findings are often mixed and inconclusive and the intervention may be seen as ineffective as it does not seem to work consistently (Bonell *et al.*, 2012; Grant *et al.*, 2013). When evaluating complex interventions such as the one in this doctoral study, it is not the programme as a unit that works, but a mix of the elements that generate change together with its contiguous context (Pawson, 2002). Therefore in order to address the research objective to identify contexts and mechanisms for change (Chapter 1.6), an alternative research design is required to identify the active ingredients required for wider implementation.

Realist evaluation investigates theories about how an intervention might work. It aims to open the 'black box' of an intervention to explore the mechanisms of change that are triggered in different contexts and to understand in which contexts this is most likely to occur (Pawson and Tilley, 1997). It investigates the mechanisms and processes which link interventions and outcomes to explain the link between cause and effect (Pawson and Tilley, 1997) and this mechanistic explanation underpins generative causality. This approach is more holistic and focuses on *how* the intervention might work (or not) as well as whether or not it does (Gill and Turbin, 1999). Realist evaluations require researchers to have a good theoretical understanding of possible mechanisms and context effects before data collection occurs so that they can be identified; these were considered in the current study in **Chapters 1.5** and **2**. Realist evaluation aims to test and explore the relationships between context, mechanism and outcomes (CMO configurations) to determine how contexts might trigger the mechanisms that lead to outcomes (Linsley, Howard and Owen, 2015). In realist evaluation, contexts and mechanisms are the factors that might affect the success or failure of different aspects of an intervention. The definitions of contexts and mechanisms are contested (Lacouture *et al.*, 2015), may be interpreted differently by different researchers and may change longitudinally (Herens *et al.*, 2017). However, in this study the contexts are defined as the locations and capabilities of key players which may enable or constrain outcome effects (Lacouture *et al.*, 2015)

especially those affecting socio-cultural relationships (Jolly and Jolly, 2014). The intervention mechanisms represent the reasoning and reactions of participants in response to the intervention and the participant choices and capacity to change (Lacouture *et al.*, 2015). Data collection can also provide insights into reasons why an intervention may not result in the desired outcomes (Gill and Turbin, 1999) which can lead to improvement and is far more useful than just finding out that it does not work. This approach recognises that intervention research operates within natural contexts which are open, complex and dynamic systems which might reduce internal validity, making it more difficult to establish causality (Hallberg, 2015). However, a realist evaluation may identify the elements of an intervention that increase the likelihood of triggering the mechanisms leading to the desired outcomes and can therefore increase the external validity as it provides evidence of how to optimise an intervention and who it is most likely to benefit. In many interventions the outcomes are due to the reasoned responses of participants to the intervention resources; and these together constitute the mechanisms which may work on a continuum, rather than as a switch to switch on or off the outcomes; they may have a mediating or moderating effect (Dalkin *et al.*, 2015). These aspects can be investigated using a pragmatic research design and multiple data collection methods as outcomes are likely to have a multiple causality (Craig *et al.,* 2008; Sidani, 2015).

Realist evaluation is usually carried out in research underpinned by a interpretivist epistemology in which outcome data may be analysed and reported according to the worldviews of researchers and so may represent one of many possible outcomes (Pawson and Tilley, 2004). A constructivist account of the impact of an intervention may be seen by some researchers to lack objectivity and produce findings that are not generalisable. Contexts and mechanisms are not viewed as confounders to be minimised but as an essential part of an explanation of the outcomes (Linsley, Howard and Owen, 2015). Realist evaluation studies are often observational studies carried out without control or comparative data and this may be seen as a weakness as observational evidence alone cannot establish that causal associations have occurred (Greenhalgh *et al.*, 2009; Bonell *et al.*, 2012; Dalkin *et al.*, 2015). Evaluation studies may need to combine the best of experimental and constructivist approaches in a study design that is pluralist and theory driven (Pawson and Tilley, 1997; Blackwood, O'Halloran and Porter, 2010), and is a part of the rationale for the mixed methods approach adopted in the current study.

As mentioned in **Section 3.4.1** above, the MRC revised framework recommends the use of a qualitative or a mixed method process evaluation to investigate intervention contexts and mechanisms. In many ways the aims of a process evaluation are aligned to those of realist evaluation. In this study the qualitative data collection was part of the overall mixed methods study design and drew on the ideas of realist evaluation and of process evaluation. In addition to the collection of process evaluation data, the revised MRC framework recommends the collection of quantitative outcome measures from RCTs or alternative types of trial. Several more recent studies have integrated these two approaches to develop realist RCT designs (Lewin, Glenton and Oxman, 2009). In this doctoral study, realist RCT and alternative RCT designs are considered in the next section in relation to the design of the current study.

3.4.3 Realist RCT

Realist RCTs are research designs that integrate features of realist evaluation and RCT design in order to keep the strengths of the RCT while addressing the weaknesses through a consideration of how the intervention works to improve the external validity (Jamal *et al.*, 2015). Realist RCTs investigate both the effectiveness of an intervention and also include an integral process evaluation that uses empirical evidence to develop theory about causal mechanisms, processes and mechanisms of action to investigate how it might apply in other contexts (Jamal *et al.*, 2015). Realist RCT studies can develop theories of change and how these might be increased and diminished when the intervention is applied in different contexts (Jamal *et al.*, 2015).

Realist evaluation is usually underpinned by a critical realist ontology (**Table 3:1**) and researchers using this approach are likely to be taking a constructivist epistemology and would reject the assumed positivist epistemology of an RCT (Dalkin *et al.*, 2015). Other researchers argue that the positivist philosophy underpinning the RCT makes it difficult to align with realist evaluation based on critical realism (Marchal *et al.*, 2013; Van Belle *et al.*, 2016) and instead they recommend the use of theory informed RCT designs which consider context and mechanism and theory but are based on positivist principles. However, an RCT design offers the least biased approach to measuring outcome effects and increase internal validity while studies without comparative data are less able to do this (Jamal *et al.*, 2015). Instead, the realist RCT adopts a more pragmatic epistemology (**Section 3.3.3);** realist RCTs are not necessarily positivist and research methods do not necessarily determine epistemology. Realist RCT allow the development of generalisable intervention theory

and the effectiveness of an intervention using an RCT or modified trial design (Bonell *et al.*, 2012; Jamal *et al.*, 2015). The alternative RCT trial designs that were considered in the current study are discussed in the next section.

3.4.4 RCTs and alternative trial designs.

The MRC framework for the evaluation of complex interventions recommends the use of an RCT or an alternative trial design to evaluate interventions. For several reasons, an RCT was not used in the current study. The use of a parallel group design would have meant that participants in the control arm of the study would not have been able to attend the intervention, and it was felt that this was unethical. Potential participants volunteer for the study as they are interested in attending it; if some had been randomly allocated to a non-intervention arm then retention and compliance may have been compromised.

In the current study, the facilities can only accommodate a maximum of 15 participants at a time and so it was intended to run a series of 3 intervention groups, whose results would be amalgamated in the final data analysis. An alternative stepped-wedge study design was considered as it would have allowed all participants to eventually attend the intervention (Brown and Lilford, 2006). In a stepped-wedge study design, participants are randomised to different attendance groups who participate one group at a time, while those waiting to attend provide comparative data. This was the intended study design prior to running the feasibility study (**Chapter 5**). However, the challenges of recruiting participants during the feasibility study led to a change of design as it became apparent that many potential participants found it difficult to attend at pre-set times as would occur if attendance groups were decided by random allocation. Therefore, the study design was changed to one in which all potential participants were able to attend the intervention and were able to choose which group to join.

Quasi-experimental study designs can investigate causality but usually lack a key element of an RCT such as randomisation or parallel groups (Tarquinio *et al.*, 2015; Woodside *et al.*, 2015) and this was the approach taken in this doctoral study. Instead of having a separate control group, data was collected over an 11-week period before the intervention started and this was compared to data collected before and after the intervention. In this way, participants acted as their own controls. This comparative data was used to investigate causality as changes observed before and after the intervention may be due to other confounding factors, such as the passage of time since completion

of treatment or regression to the mean (Stephenson and Imrie, 1998). Many study designs and especially RCTs are designed to include single or double blinding to avoid bias. Double blinding is often used in parallel group RCTs when both the participants and researcher are unaware to which group the participant belongs. This was not possible in this study as all participants attended the intervention and acted as their own controls. Neither was single blinding possible in this case as this was a doctoral research study with a lone researcher to collect and analyse the data. This limitation is acknowledged, and standardised protocols for data collection were used to reduce any bias (**Chapter 4.2).** Due to the practical resource limitations, this study was only able to accommodate a maximum of 45 participants and would therefore not be a fully-powered trial in terms of determination of causality. However, the main study was also used to explore the use of a novel alternative study design in evaluation research, and also aimed to determine contexts and mechanisms to inform future intervention design. These aspects were addressed by the inclusion of qualitative data analysis within the mixed methods design.

3.5 Mixed methods research designs

As discussed in **Section 3.3.4** above, the main research study was carried out using a mixed methods study informed by the revised MRC framework (Craig *et al.*, 2008) and the principles of realist evaluation (Pawson and Tilley, 2004). It was also designed with reference to a published classifications of mixed methods study designs (Cresswell and Plano Clark, 2011). There are many different mixed methods study designs used in health intervention research to address both explanatory and exploratory research questions (Teddlie and Tashakkori, 2009; Borglin, 2015) and these have been classified into many different research design typologies that can be used as a framework or guide (Cresswell and Plano Clark, 2011). This study used a fixed rather than emergent mixed methods design as it was planned as a mixed methods study from the development stages (Cresswell and Plano Clark, 2011). Mixed methods study designs also vary in the level of interaction between the quantitative and qualitative strands, their relative priority, their timing and the process for integrating the findings (Borglin, 2015). The current study used a c*onvergent parallel design* in which the data from the quantitative and qualitative strands of the study was used to triangulate and gain a more complete understanding of the research objectives (Teddlie and Tashakkori, 2009; Curry *et al.*, 2013; Borglin, 2015). In this study design both strands of data collection occurred within the same phases of the study and each carried equal weighting. The two strands of data were

analysed separately using methods appropriate to each (**Chapter 4.2**). The two strands of data were subsequently mixed during the interpretation and discussion phase when the complementary data were used to triangulate findings on the same topic (**Chapter 8**).

This research study included the collection of quantitative data from food diaries, anthropometric measures and patient reported outcome measures (PROMs) and the collection of qualitative data from individual interviews, evaluation forms and PROMs. The quantitative and qualitative strands had equal priority and collection of both was concurrent (rather than sequential) as both were collected in each phase of the study. Data analysis was carried out in parallel as the analysis of data from each strand was carried out separately and findings integrated during the interpretation phase (Borglin, 2015). The data from each strand were mixed during the interpretation phase following analysis. For most of the data collection an *identical sample* study design (Borglin, 2015) was used in which the same research participants were used, where possible, for quantitative and qualitative data collection. The final qualitative data collection was carried out using a *nested sample* which was purposively selected for individual interviewing 12 months after the intervention (**Chapter 4.2.7.2**).

3.6 Summary of the paradigm, framework and design adopted in the main study

This study was carried out to establish the impact of the lifestyle intervention on participants and to explore the ways in which this had been achieved. The main research study used a novel convergent parallel mixed methods design using both qualitative and quantitative data collection. The research design was informed by realist evaluation (Pawson and Tilley, 2004; Fletcher *et al.*, 2016) and was applied across all phases of the MRC revised framework for the evaluation of complex interventions (Craig *et al.*, 2008) using a within-subject quasi-experimental design (Sidani, 2015). Using these together it was intended to explore whether the intervention was associated with changes in the outcome measures and to investigate some of the contexts and mechanisms that facilitated or inhibited change. The data was also used to explore the use of the novel quasi-experimental evaluation design in which each person acted as their own control, to investigate the impact of the lifestyle intervention. The methods used to carry out both the feasibility study and the main study are considered in the next chapter.

Chapter four: Research methods

4 Research methods

4.1 Phase 1: feasibility study methods

4.1.1 Feasibility study recruitment

The aims and design of the initial feasibility have been previously discussed **(Chapter 3.2).** Ethical approval for this initial study was granted by the UW Institute of Health and Society Ethics committee (**REC RICHARDSON 2014/2015 221**).

A small group of participants were recruited to the feasibility study and they attended the 12-week lifestyle intervention. Recruitment leaflets (**Appendix 1.1**) for the were distributed via local clinical staff and were also distributed within the University and local retail outlets. Those who expressed an interest in the study were contacted with further information (**Appendix 1.2**). All participants were informed about the intervention and research study and were provided with a participant information sheet during the first week. The following week they were invited to participate in the feasibility study, and all consented to do so (**Appendix 1.3**). Details of the feasibility study intervention are presented in **Table 4:1** below.

This initial study was a single-arm study and most data were collected during the first and last week of the intervention to assess the ability of the tools to capture change over the intervention period, to evaluate the participant experience and to determine intervention and research feasibility as discussed previously (**Chapter 3.2**). The following tools were used:

- Patient Reported Outcome Measure (PROM); Measure Your Concerns and Wellbeing (MYCaW) (Paterson *et al.*, 2007),
- Anthropometric and physical health measures including a calculation of Body Mass Index (BMI), calculation of a waist to hip ratio, and measurement of blood pressure (BP),
- 4-day estimated food diary,
- Evaluation forms completed in the middle and at the end of the intervention.

The data collection tools used in the feasibility study are presented in **Appendix 1,** the methods are presented below**,** while the results are presented and discussed in **Chapter 5**.

Table 4:1 Outline of the sessions in the feasibility study intervention

Week No.	Physical activity	Healthy eating	Snack with tea
1	**Icebreaker**. **Baseline testing**:	***Activity****: complete a food diary*	Biscuits
2	**Fitness Suite Session 1**: Using CV equipment. Pedometers. Goal setting	**Overview for the programme**; Diet review: Goal setting. Eatwell plate	Cubed fruit
3	**Pilates**	**Fruit and Vegetables**. 5-a day and portion size	Cubed veg, salad, hummus.
4	**Gym Session 2**	**Food labels**	Healthier biscuits
5	**Walking** for health and local groups	**Drinks**	Herbal teas and dark chocolate
6	**Gym session 3:** Using resistance machines and light weights	**Whole grains and fibre**	Tea and nuts and seed
7	Activity Review: Short **Gym session 4**	**Protein and fats**	Drinks made with milk alternatives
8	**Tai Chi**	**Breakfast and snacks**	Healthier cereal bars, oat cakes, nut butters
9	**Gym Session 5** and Review	**Healthy lunches**	Soups
10	**Negotiated Practical 3:** Tai Chi, Pilates, walk etc.	**Evening meals**	Healthy version of a cake
11	**Gym Session 6**: Pedometer Review	**Shared buffet meal**	Variety of healthy drinks
12	**Repeat measures** and r**eview:** evaluation sheet		Healthier cake

4.1.2 Feasibility study: concerns and wellbeing

4.1.2.1 Introduction to assessment of wellbeing

The main study aimed to determine the impact of the lifestyle intervention on the concerns of participants about lifestyle and health. Outcome measures were used to assess the impact on these aspects and the feasibility of their use was explored in the initial feasibility study (**Chapter 3.2**). The outcome measures selected for use in research depends on a conceptualisation of health which is contested (Bowling, 2005). Health research has often depended on a narrow view of health as an absence of disease; this is difficult to measure and many objective measures of health in fact measure disease and lack of physical function (Bowling, 2005). This narrow view of health is not in line with the research aim and objectives of this doctoral study and so although objective measures of health were used (**Section 4.1.3**) the patients' perceptions of the impact of the intervention in terms of their concerns and wellbeing were also sought.

A more holistic concept of health as a positive and multifaceted concept has led to an increased interest in the measurement of quality of life and wellbeing. One type of instrument that can be used to measure change brought about by interventions such as the lifestyle intervention in the current study asks participants to rate Health Related Quality of Life (HRQoL). Any association between the intervention and a change in HRQoL can then be investigated. Quality of life (QoL) can depend on a wide range of aspects of life including financial, employment and housing, many of which are unlikely to be affected by health interventions. Therefore, in health research the focus is usually narrowed to factors relating specifically to health (Bowling, 2005). HRQoL is also a wide-ranging concept though and is affected by a multiplicity of interacting factors; however, these are often grouped into a functional domain and a wellbeing domain. These facets of quality of life can only be measured by asking people about them and this has led to the development of many Patient Reported Outcome Measures (PROMs). Many PROMs that assess HRQoL focus on objective ratings of the functional domain and therefore focus on functional limitations which again can seem to be rather negative and not appropriate for the current study. There are many general HRQoL tools, and many cancer-specific and even breast cancer specific tools (Davies *et al.*, 2009). However, as these focus on asking participants to grade functional deficits they were deemed to be inappropriate to the aim of the programme in which a more holistic and positive view of recovery and rehabilitation was to be fostered.

Wellbeing is a broad and subjective contested concept that is also difficult to measure; it encompasses aspects such as happiness, life satisfaction, self-esteem and self-efficacy (Knight and McNaught, 2011). Wellbeing can be seen as the extent to which happiness and satisfaction with life has been obtained and may be based on a perception of the overall balance of negative and positive aspects of life. These various dimensions of wellbeing are all subjective and so rely on subjective self-ratings (Bowling, 2005). There are limitations to the use of subjective PROMs to measure wellbeing; for example, the standards against which people may measure their perceptions might change over time. They are also limited by floor and ceiling effects; if the lowest rating is selected there is no option for selecting a lower score if further deterioration occurs, and likewise further improvement are not captured once the highest rating has been selected. However, despite limitations, they are still widely considered to be a vital part of intervention evaluation (Bowling, 2005).

4.1.2.2 Different types of PROM

In the current study, it was important to capture the patient perspective to meet the study objectives. Therefore, the use of a short patient generated PROM that was responsive and appropriate to the participant group was included. An increase in the use of PROMs in health research is congruent with an increased importance of investigating impact of treatments or interventions from the patient perspective, rather than that of a clinician or researcher (Jolliffe *et al.*, 2015). Warrington, Absolom and Velikova (2015) consider that the use of PROMs is useful to support patients with the long-term effects of cancer and cancer therapy to address the complex needs of cancer survivors and encouraging self-management.

PROMs may be generic for overall HRQoL or wellbeing, or can be specific for different health conditions (Guyatt, Feeny and Patrick, 1993). Many of the generic and disease specific questionnaires are also very lengthy; Warrington, Absolom and Velikova (2015) report that it is important not to overburden participants with onerous questionnaires which can also reduce completion rates, and therefore in this study a very short PROM was used. Many disease-specific PROMs ask participants to score themselves against standardised questionnaire items, many of which may not be relevant. Several authors report that most cancer specific and breast cancer specific tools are designed for acute use for those who are newly diagnosed or still in treatment.

They would lose face validity if used for the current study which is for those who have completed primary treatment and may not capture the longer term important sequelae (Avis, Ip and Foley, 2006; Pearce, Sanson-Fisher and Campbell, 2008; Davies *et al.*, 2009). There are few tools aimed at cancer survivors (Davies *et al.*, 2009) and short-term cancer survivors are underrepresented (Pearce, Sanson-Fisher and Campbell, 2008). Those aimed at long-term survivors do not address issues that might be of relevance in the current study such as fear of recurrence which may be more significant in the shorter-term post diagnosis. The Quality of Life Cancer Survivors tool (QoL-CS) was considered unsuitable for use in a group setting as in the current study as it asks participants to rate distress at diagnosis and treatment (Avis, Ip and Foley, 2006). Like other specific tools it asks participants to rate many pre-determined areas some of which would not be relevant as they are unlikely to be impacted by a lifestyle intervention, for example sexual function and their use could therefore reduce responsiveness. Responsiveness is the ability of an instrument to detect change over time (Guyatt, Feeny and Patrick, 1993) and is therefore an important consideration in the current study. Both generic and disease specific PROMs are useful though their effect sizes may only be small to moderate which may limit their power to identify statistically significant change. For these reasons, none of these specific or general instruments in which participants are asked to rate themselves against pre-set criteria were used in the current study.

Patient generated quality of life instruments require participants to select and rate aspects of life that are of most importance to their personal quality of life and wellbeing. Patient generated PROMs are usually reliable and very responsive (Martin *et al.*, 2007) so are suitable to use to investigate the effect of an intervention such as the one in the present study. In this study it was decided to use a patient generated PROM to focus on issues of most concern to participants and of relevance to the lifestyle programme. MYCaW, the PROM selected for use is discussed below.

4.1.2.3 Development of MYMOP and MYCaW

The Measure Your Medical Outcome Profile (MYMOP) is a patient generated PROM that was initially developed to monitor symptoms before and after treatment and has been widely used (Paterson *et al.*, 2000). It requires patients to identify and rate symptoms of concern. It has been found to have high completion rates compared to other widely used general HRQoL measures such as EuroQoL (EQ-5D) and Medical Outcomes 6-item survey (MOS-6Q) (Paterson *et al.*, 2000). MYMOP was also more responsive compared to the Short Form (SF-36) health profile in a primary care practice

(Paterson, 1996) with higher response and completion rates. It was also found to be more patient focused than other general tools (Paterson, 2012).

MYMOP was used to assess outcomes following the use of complementary therapies in cancer care (Peace and Manasse, 2002), though the scale had to be modified to ask about "concerns" rather than "symptoms" to maintain validity. Following this, Paterson *et al.* (2007) developed the Measure Your Concerns and Wellbeing (MYCaW) tool from MYMOP to evaluate cancer support services. MYCaW allows participants to identify and rate two concerns and wellbeing rather than rating symptoms (Jolliffe *et al.*, 2015). MYCaW was developed and trialled over a 6-year period; it was piloted at two cancer support centres was also found to be highly responsive, acceptable to patients and with good content and face validity (Polley *et al.*, 2007). MYCaW has been validated against a general HRQoL scale which is well validated and often used with people with cancer (Functional Assessment of Chronic Illness Therapy with spirituality extension (FACIT-SpEx)) (Jolliffe *et al.*, 2015). Since its development, MYCaW has been used in a wide variety of clinical contexts to evaluate the effectiveness of complementary therapies in cancer care (for example Vaghela *et al.*, 2007; Seers *et al.*, 2009; Frenkel *et al.*, 2010; Harrington, Baker and Hoffman, 2012; Ostenfeld-Rosenthal and Johannessen, 2014; Polley *et al.*, 2016). The validity of a tool continues to be evidenced as more studies use it (Guyatt, Feeny and Patrick, 1993) and so the wide use of MYCaW can contribute to this. MYCaW has also been used in other contexts such as in evaluating complementary therapies for patients with motor neurone disease (Hughes *et al.*, 2012) and in a hospital based palliative care service (Briscoe and Browne, 2014) in a trial to investigate the effectiveness of an holistic needs assessment tool (Ahmed *et al.*, 2015) and in a trial evaluating the effectiveness of reflexology in managing lymphoedema secondary to breast cancer treatment (Whatley *et al.*, 2016).

Some studies suggest that quantitative questionnaire data may present a more positive picture of patient experiences than qualitative interview findings which may be more cautious and nuanced (Pollock *et al.*, 2011). Many patient-generated PROMs collect some qualitative data which can contribute to identifying the full range of impacts that individuals have experienced (Polley *et al.*, 2007). The MYCaW tool was used in the current study as it is a very short and simple patient generated tool which is valid and responsive, collects both quantitative and qualitative data and has been widely used in similar research contexts. Therefore, the MYCaW tool was used in the feasibility

study to determine whether it was able to capture changes that might represent intervention impacts and to evaluate the experience of participants **(Chapter 3.2**).

4.1.2.4 Feasibility study: MYCaW data collection

In order to explore the concerns of participants and whether these were addressed by the feasibility study intervention, participants were invited to individually complete the Measure Your Concerns and Wellbeing (MYCaW) tool (Paterson *et al.*, 2007) (**Appendix 1.4**) on the first and last days of the programme. In the first week of the intervention, participants were invited to identify two main areas of concern that they anticipated the programme might address. The tool invited participants to rate each of these concerns on a 7-point Likert scale from 0 (*not bothering me at all*) to 6 (*bothers me greatly*). Participants were also invited to rate their general feeling of wellbeing on a scale of 0 (*as good as it could be*) to 6 (*as bad as it could be*). The MYCaW profile was a mean of these 3 scores. The second data collection was completed by participants without being able to see their original MYCaW ratings. The follow up MYCaW tool also invited participants to provide some qualitative comments on other things that have affected their health and what has been most important to them personally in the feasibility study intervention (**Appendix 1.4)**. The MYCaW results are reported in **Chapter 5.2.2** and discussed in **Chapter 5.3.**

4.1.2.5 Framework analysis of MYCaW qualitative data.

The MYCaW qualitative data was analysed using a framework method. Framework analysis is a method of qualitative analysis that was originally developed for use in social policy research and allows for systematic and auditable analyses (Ritchie and Spencer, 1994). It is a flexible method suited for many research approaches and has more recently been widely used in health practice research (Gale *et al.*, 2013). It is an approach that is appropriate for analysis of data to address specific research questions (Srivastava and Thomson, 2009) as in the current study and has been suggested for analysing qualitative data for process evaluations of complex interventions (Atkins *et al.*, 2015). It includes a thematic analysis in which findings are presented in a table of themes and cases, retaining the integrity of data from individuals and allowing for between-case and inter-case analysis (Green and Thorogood, 2009). Framework analysis usually follows key stages of; familiarisation, framework development, indexing, charting and interpretation (Ritchie and Spencer, 1994). Some themes are usually identified *a priori* to address research questions, while others can be developed in response to themes emerging from the data (Rabiee, 2004), however, in the current

study a pre-existing framework (Polley *et al.*, 2007) was used to analyse the MYCaW data. This framework was considered appropriate as it was developed using qualitative data gathered using the MYCaW tool in several integrative cancer centres and so in a context relevant to the current study. Polley *et al.* (2007) carried out a content analysis of data collected from many participants (n=782). The data were thematically categorised, and this was used to develop the framework. The framework has been externally validated using participant focus groups and was demonstrated to have good inter-rater reliability (Polley *et al.*, 2007). The qualitative framework was updated found to be generalisable across different integrated oncology settings and was found to capture a wider range of concerns compared to other cancer related PROMs (Jolliffe *et al.*, 2015). This framework has been used by most studies using MYCaW (for example Vaghela *et al.*, 2007; Seers *et al.*, 2009; Frenkel *et al.*, 2010; Harrington, Baker and Hoffman, 2012; Polley *et al.*, 2016). This framework was therefore used in the current study and allowed comparison of data to that obtained in other studies.

MYCaW data in the present study was handwritten by participants in response to questions on the MYCaW tools; answers were usually brief, from a few words to a sentence or two. The handwritten responses were read in the familiarisation stage and were then typed verbatim. The two concerns identified by participants on the first MYCaW form were analysed together. Most of the data were indexed according to the Polley frameworks (Polley *et al.*, 2007; Jolliffe *et al.*, 2015). However, the responses to the final question on important aspects of the intervention did not fit the Polley framework and so a unique framework was developed and used for responses to this question only. Data were charted manually in MS Excel 2016.

4.1.2.6 Feasibility study MYCaW quantitative data analysis

There has long been a controversy around the methods used to analyse and report data generated using Likert-type scales (Norman, 2010) such as the MYCaW tool used in this study. The controversy centres on whether data generated is ordinal or interval, with concomitant implications for the appropriate reporting and analysis.

It is generally agreed that items on a Likert scale generate ordinal, rather than interval, data. An ordinal variable is one in which categories are mutually exclusive and ordered (Knapp, 1990) but in which the distances between the categories cannot be assumed to be equal (Jamieson, 2004) as it

would be in an interval scale. In a typical Likert scale, all of the categories are named and so it cannot be assumed that the strength of feeling that leads someone to choose between "agree" and "strongly agree" is equal to the choice between other named pairs of categories (Jamieson, 2004). The MYCaW tool (Paterson *et al.*, 2007) (**Appendix 1.4**) invites participants to identify and rate two concerns on a 7-point Likert-type scale from 0 (*not bothering me at all*) to 6 (*bothers me greatly*). Participants are also invited to rate their general feeling of wellbeing on a scale of 0 (*as good as it could be*) to 6 (*as bad as it could be*). Therefore, in the MYCaW scale, only the categories at the limits of the scale are described in words. Participants select the best rating for themselves between these two described extremes. In this case, it might be argued that the categories are more likely to be equally spaced within the minds of the participants as each category has not been externally defined. However, in this study it is assumed that the data collected from individual MYCaW items was at the ordinal level of measurement.

Knapp (1990) and Jamieson (2004) both argue that when describing ordinal data generated using Likert-type scales, it is inappropriate to calculate means and standard deviations; they recommend the use of mode or median when the numbers of the scale represent verbal statements (Jamieson, 2004). In contrast to the concerns of Knapp, (1990) and Jamieson (2004), Carifio and Perla (2008) assert that although individual Likert-type items generate ordinal data, collections of Likert items (Likert scales) produce interval data, especially if they are composed of 8 or more items. They recommend that Likert scales generate interval data if analysing more than one Likert item (Carifio and Perla, 2008; Norman, 2010). On this basis they agree that ratings from Likert scales can be summarised using means and standard deviations (Carifio and Perla, 2008). The MYCaW tool consists of 3 items which are summarised as a MYCaW profile which can therefore be considered to be interval data and analysed on that basis. Many published studies also state that MYCaW data is considered to be ordinal and yet most report the dispersion of the data as mean and standard deviation (for example Seers *et al.*, 2009; Harrington, Baker and Hoffman, 2012). In line with the recommendations of Carifio and Perla (2008) and in line with the methods used in other published studies, the MYCaW data in this study was summarised using means and standard deviations. This allows the results from this study to be compared with those of other published studies. However, although this is likely to be appropriate when reporting the MYCaW profile, results of individual MYCaW items are ordinal and means calculated were treated with caution and were compared to

median values. The mean MYCaW scores and MYCaW profile scores before and after the intervention were calculated. The change in MYCaW score for each participant was also calculated.

4.1.3 Feasibility study: physical health measures

Physical health data were collected in the feasibility study to see whether the parameters measured were able to capture changes that might represent intervention impacts. Data were collected on the first and last day of the intervention.

4.1.3.1 Feasibility study: anthropometric measures

Introduction

Weight gain is common during breast cancer treatment due to both a loss of muscle mass and an increase in adiposity (Norat *et al.*, 2014; Simmonds, Mitrou and Wiseman, 2014) especially during chemotherapy treatment (Chan *et al.*, 2014). Lifestyle recommendations to reduce cancer risk advise that adults should keep body weight as low as possible within the healthy range (World Cancer Research Fund/American Institute for Cancer Research, 2007). Breast cancer recommendations also advise overweight women to avoid weight gain during treatment and obese women to lose weight following treatment to reduce risks and improve outcomes (Chan *et al.*, 2014).

Body fatness can be directly measured using techniques such as dual-energy x-ray absorptiometry (DXA) (Murgatroyd, Bluck and Watson, 2015) or Magnetic Resonance Imaging (MRI) however the necessary equipment was not available for this study. Therefore, a direct method of measurement of adiposity was not possible. However, body fatness is also linked to body weight which was an outcome measure reported in this study. Body weight also depends on height and therefore Body Mass Index (BMI) (Kg/m^2) and was used in this study as an indirect indicator of body fatness. It is well known that body weight and BMI both depend on the mass of both adipose and non-adipose tissue and that in very muscular individuals a high BMI may occur with a low adiposity. In this study population, however, BMI is likely to be a reliable indicator of body fatness as breast cancer survivors are reported to be relatively inactive (Campbell *et al.*, 2012). Any change in weight or BMI measured over time is also more likely to be indicative of a change in adiposity than a change in lean tissue as this is the most variable determinant of overall body weight (World Cancer Research Fund/American Institute for Cancer Research, 2017). Therefore, indirect measures of body fatness were made to assess the impact of the intervention on this aspect of physical health.

Weight and BMI were used as proxy measures of body fatness but do not take account of the location of adipose tissue. Body fat may accumulate in sub-cutaneous tissue, or intra-abdominally around and within body organs. Central obesity can have a greater negative impact on health than peripheral fat (Swanton, 2008). Abdominal adipose tissue is more metabolically active and may be an important site of oestrogen metabolism, particularly after the menopause (**Chapter 1.3**). An increased waist circumference and increased waist to hip ratio is also associated with an increased post-menopausal cancer risk (World Cancer Research Fund/American Institute for Cancer Research, 2017). There is no standardised method of measuring abdominal fatness (World Cancer Research Fund/American Institute for Cancer Research, 2007) though many research studies use waist circumference and waist to hip ratio (Institute of Medicine, 2012). In this study, indicators of possible central adiposity were waist circumference, hip circumference, and waist to hip ratio.

Data collection

The weight and height of participants was measured to determine whether the intervention was associated with weight change. Participants had their weight and height measured following removal of shoes and using published protocols (Swanton, 2008; Boodhna *et al.*, 2014). Participant height was measured using a SECA 217 stadiometer and weight was measured using a set of weighing scales (OMRON Karada BF511). In some circumstances where a reading of height was missing, due to lack of availability of a stadiometer offsite, a Last Observation Carry Forward (LOCF) method was used, as height would not be expected to change significantly. Waist and hip circumference were measured following published protocols (Swanton, 2008; Boodhna *et al.*, 2014) using a SECA 29 ergonomic measuring tape. Participants removed outer or bulky clothing and positioned the tape measure at their own waist or hip.

Data analysis

Body mass index (BMI) was calculated in Kg/m^2. The mean and standard deviation of the weight, height, BMI, waist circumference, hip circumference and waist to hip ratio at each data collection point were calculated. In the UK, the NHS advice is that a healthy weight is one within a BMI range of 18.5-24.9 Kg/m^2 (National Health Service, 2018) and this reference range was used in the current study. In women, health risks increase where there is a waist circumference measurement of 80 cm or more and increase substantially above 88cm, and are also increased with a waist to hip ratio of 0.85 or more (Swanton, 2008) and these were the cut off values used in this study.

4.1.3.2 Feasibility study: blood pressure and heart rate

Introduction

Cardiovascular disease is a major cause of non-breast cancer mortality and morbidity and risk may be elevated following breast cancer treatment compared to the general population (**Chapter 1.4**). Blood pressure within normal range may benefit survival in breast cancer patients (Emaus *et al.*, 2010). Resting heart rate and blood pressure are indicators of cardiovascular health (Cooney *et al.*, 2010) and were measured to determine their ability to capture any cardiovascular changes during the feasibility study.

Data Collection

Blood pressure and heart rate were measured using an electronic sphygmomanometer (OMRON Healthcare M6 Comfort). This was carried out using published protocols (British and Irish Hypertension Society, 2017) usually on the arm that had been unaffected by surgical treatment. In most cases the measurement was only taken once; it was only repeated if the participant or researcher felt that the value obtained was in error, in which case the reading was repeated, and the last set of values were used. Participants were reminded that readings were being taken for research purposes and not diagnostic reasons. Where participants or researchers were concerned about their heart rate or blood pressure, they were advised to consult their General Practitioner (GP) or other health care provider for checking and advice.

Data analysis

The mean and standard deviation of resting heart rate, systolic and diastolic pressure were calculated. The change in each of these parameters was also calculated. A high blood pressure was considered to be 140/90 mmHg or above (Boodhna *et al.*, 2014).

4.1.4 Feasibility study: dietary intake

Introduction

There are no ideal methods of measuring dietary intake and it is particularly difficult to accurately record nutritional composition of composite foods (Michels *et al.*, 2007) and to account for the wide variation in diets from day to day and between different people (NHS National Institute for Health Research / Medical Research Council, 2015). Dietary intake data were collected in the feasibility study to see whether the food diaries were able to capture changes that might represent differences in dietary habits over the intervention period.

Nutritional assessment measures can be objective or subjective. Objective methods of dietary assessment attempt to reduce error and bias by directly observing or measuring intake by direct observation, preparation and analysis of duplicate meals, or by analysis of biomarkers of nutritional intake (NHS National Institute for Health Research / Medical Research Council, 2015). However, these methods are all resource intensive and beyond the scope of this doctoral study. Therefore, a subjective measure of dietary intake was used instead which relied on self-reporting by participants.

Many large-scale nutrition surveys use a Food Frequency Questionnaire (FFQ) method to gather data on dietary intake as it is less resource intensive than other methods. Completion of FFQs is relatively quick and easy for participants making it more accessible to a wider population (Crozier *et al.*, 2008). The FFQ is a subjective retrospective method and requires participants to recall consumption over a preceding period. Kristal *et al.* posit that accurate dietary recall is limited to a few days (Kristal, Peters and Potter, 2005) which may call into question the reliability of the data produced by FFQ. FFQs usually focus on commonly eaten foods and therefore may not capture the range of foods eaten with a concomitant effect on estimates of nutritional intake. In addition, many authors (for example Kristal, Peters and Potter, 2005; Slimani *et al.*, 2015) have questioned the sensitivity of the FFQ for use even at large scale population level and therefore it may not be responsive or sensitive enough to detect any changes in dietary habits that occurred over the study period, although this lack of sensitivity is challenged by others such as Willett and Hu (2007). FFQs are intended to measure dietary habits over a long period of time (Crozier *et al.*, 2008) and were therefore not considered to be appropriate to capture changes in dietary behaviour in a small group over the 12-week intervention period in this study. For the above reasons, it was decided not to use FFQ as the data collection tool in this study.

Data collection

This study collected dietary data using a subjective 4-day estimated prospective food diary in which participants were asked to self-report all items of food and drink as they were consumed. This reduced the risk of forgotten or misremembered foods although, in error, some items may have been completed retrospectively (Slimani *et al.*, 2015). The diary was also open-ended and therefore flexible to use with different diets in and out of the home. Food diaries were also used as part of the intervention in the current study as recording food and drink can help participants to self-monitor and can promote behaviour change (Slimani *et al.*, 2015).

The collection of dietary data over several days can take account of within participant variation and infrequently eaten foods (NHS National Institute for Health Research / Medical Research Council, 2015). The National Diet and Nutrition Survey (NDNS) is a large cross-sectional survey of the UK population and was originally set up using a 7-day weighed food diary method (Whitton *et al.*, 2011) which was reputed to be the gold standard method of recording dietary intake due to the accuracy of recording portion size. This method has a high participant burden which can result in study fatigue with the number of items recorded in food diaries declining over the 7 days (Slimani *et al.*, 2015). It is also associated with a reduced response rate recruiting mainly well-motivated and able potential participants (Crozier *et al.*, 2008). More recently the NDNS changed to using a 4-day estimated food diary to reduce participant burden. In line with the NDNS this was the approach used in the current study; the template included both weekend days as intakes on both have been shown to be different (Whitton *et al.*, 2011).

Concerns have been expressed about the accuracy of portion sizes recorded in estimated diaries (Whitton *et al.*, 2011). The food data collected may be less accurate in terms of portion size, but the diary is likely to be more complete. One study at least found no significant differences in intakes between weighed and estimated food diaries (Whitton *et al.*, 2011). Many sources suggest that the accuracy of food diary data is improved if diaries are reviewed after completion and participants probed for any missing data (NHS National Institute for Health Research / Medical Research Council, 2015; Slimani *et al.*, 2015), while other studies have suggested that this is not necessary (Kolar *et al.*, 2005; Kristal, Peters and Potter, 2005). Kolar compared nutritional analysis from 3-day food diaries with and without review and the data from both were comparable (Kolar *et al.*, 2005). In the feasibility study, food diaries were not reviewed. As portion size was estimated in the current study and it was recognised that this may not be accurate; however, the data was analysed to look for a change in intake, rather than an absolute value.

Participants completed a 4-day food diary (**Appendix 1.5**) after attending the first day of the intervention and a second food diary was completed during the final week.

Data analysis

Food diaries were completed by hand and returned to the researcher for nutritional intake analysis using Weighed Intake Software Package (NetWISP version 4.0) (Tinuviel Software) to find mean daily intake for selected nutrients. The mean daily intake of energy and key nutrients at the start and end of the intervention, and the mean change in daily intake were calculated and are reported in **Chapter 5.2.4.**

4.1.5 Feasibility study: evaluation questionnaires

Introduction

In line with the aims of the feasibility study (**Chapter 3.2**), the evaluation questionnaires were intended to evaluate the experience of participants; to find out whether the intervention addressed their concerns and invited feedback on ways in which the intervention could be improved. This allowed participants to have a voice in the design of the intervention and the main research study. The mid intervention evaluation form provided an opportunity for any unmet participant needs to be addressed during the remainder of the programme.

Data collection

Participants were invited to provide written evaluative feedback midway through the intervention and during the final week. The mid-intervention review questionnaire asked 5 open questions about the participants' experience of the programme up to that point and the end of programme evaluation form asked 6 open retrospective questions. Both forms asked about;

- Aspects liked or found useful
- Aspects less useful or that could be improved
- Other areas that could be included
- Any other comments or feedback

The mid-programme form also asked about the relevance of the programme, while the end of programme form asked what had been gained from it and whether the programme timing was suitable (**Appendix 1.6**).

The evaluation sheets were provided to participants in hard copy and were completed by hand during an informal break within the group sessions. The evaluation forms were completed anonymously, and it was therefore not possible to ascribe feedback to individual participant

identification numbers. To reduce the risk of social desirability bias, participants were briefed to answer honestly so that the research team could learn from their experiences.

Data analysis

The completed evaluation forms were read carefully as part of the process of familiarisation. The data were then electronically transcribed, and the forms were analysed together using a framework approach as discussed previously (**Section 4.1.2.5**). There were only a small number of completed evaluation forms and so a very simple framework for analysis was used focusing on positive and negative aspects.

4.2 Phase 2: main study methods

4.2.1 Introduction to the main study

This section will consider the methods used in carrying out the main study that was designed to evaluate the impact of the main study intervention in line with the study aim (**Chapter 1.6**). It will also test the use of a within-subject quasi-experimental design in which each participant acted as their own control and will investigate the contexts and mechanisms that may have impacted on outcomes in line with the research objectives (**Chapter 1.6**).

4.2.1.1 Main study approvals

The main study involved the recruitment of participants largely from an NHS Trust and therefore NHS ethical approval and research approval was required before the study could commence. An application for ethical approval was made to the NHS Research Ethics Committee (REC) (REC reference 15/WM/0332) via the Integrated Research Application System (IRAS) (IRAS project ID 181365). The student and Director of Studies attended a meeting of the REC on 16th September 2015. Amendments were made following feedback from the Committee and a favourable ethical opinion was obtained on 2nd November 2015. An application was then made to the local NHS Trust Research and Development (R&D) (reference WAT131115) and, following minor amendments to the Participant Information Sheet (PIS), agreement was granted for the Trust to act as a Participant Identification Centre (PIC) in this research study on 25th February 2016. The amended PIS was resubmitted to the NHS REC who agreed on 3rd February 2016 that this was not a substantial amendment and did not require further ethical review. The main research trial was also registered in the publicly accessible database Research Registry (Researchregistry765). This project was also

approved by the University of Worcester Institute of Health and Society Ethics committee on 19th January 2016 (approval code FRJR190116).

Following these approval processes, the NHS Trust requested that a video about the research project be made available to be shown on screens in the waiting area. A video was made by the research team and was submitted to the REC as a substantial amendment. This was approved on 4th May 2016 (REC reference 15/WM/0332- amendment 1). The approval documents are presented in **Appendix 2.1.**

4.2.1.2 Main study: recruitment

It was intended to recruit 45 participants for the main study in 3 groups of 15. This sample size was based on the feasibility study findings (**Chapter 5.3.1**), other previously published studies and practical considerations. It is estimated that the Trust follow-up about 5,000 breast cancer patients each year (Goonewardene and Thrush, 2014) and most participants were drawn from this restricted local population. The University facilities also limited each intervention group to a maximum size of about 15 and feasibility study data suggested that participants might find large groups more daunting. The feasibility study also had a drop out of 25%, which might be expected to also occur in the main study. Therefore, if 45 participants were recruited and 75% retention were achieved, this may result in a final group size of 34. It was not possible within practical constraints to recruit further participants which limited the potential to determine if the intervention caused statistically significant effects. However, the study was also able to investigate the novel quasi-experimental design to investigate intervention impacts and was able to use qualitative data alongside quantitative data to explore possible contexts and mechanisms in line with the study objectives (**Chapter 1.6).**

Several similar lifestyle intervention studies have been published using comparable numbers of participants. Schiavon *et al.* (2015) carried out a non-randomised controlled trial of a nutrition intervention for women with breast cancer with an intervention group of 18. Campbell *et al.* (2012) carried out a single arm trial of a weight loss intervention with a group of 14 cancer survivors, while Muraca *et al.* (2011) carried out a single arm diet and physical activity intervention for breast cancer survivors with 51 participants. In another parallel group lifestyle intervention, there were 50 women in the intervention group and 50 in the comparison group (Saxton *et al.*, 2006). Therefore, the

proposed group size of 45 was consistent with other studies while also practical within resource limitations and the local potential population size.

Patients were recruited to participate in the research study using a purposive sampling strategy with the NHS Trust acting as a Participant Identification Centre (PIC). The inclusion criteria were that participants were to be women who had completed their initial breast cancer treatment (surgery, chemotherapy, radiotherapy), who could speak and understand English and wished to engage in the lifestyle programme. The participant group were therefore self-selecting and included a majority who had no evidence of current breast cancer as well as those having long term treatment for secondary metastatic disease.

Recruitment of participants began in March 2016 and continued until April 2017. Throughout this period, leaflets (**Appendix 2.2.1**) inviting participation in the study were available in the NHS Trust and a recruitment video was shown on screens in the waiting area. The researcher spoke about the study at patients' information evenings and at a support group run by clinical staff. NHS staff handed out leaflets and mentioned the study to patients who attended for follow up appointments. Interested patients contacted the researcher directly and were then provided with a participant information sheet (**Appendix 2.2.2**) and had the opportunity to ask questions. Those who wished to join the study were invited to an individual meeting with the researcher as soon as practically possible; it was anticipated that this would be about 11 weeks before the intervention began. These meetings were carried out at the University or at participants' own homes, in which case lone working guidelines were followed (University of Worcester, 2018b).

In the initial meeting with potential participants, the participant information sheet. was discussed, and informed consent was requested in writing (**Appendix 2.2.3**). The researcher verbally emphasised confidentiality, the right of participants to decline to participate, their right to withdraw from the study at any time, and the right to withdraw data, in line with UW Ethics policy (University of Worcester, 2014) and in line with the approvals discussed in **Section 4.2.1.1** above. If informed consent was given, participants were allocated a unique Participant Information Number (PIN).

4.2.1.3 Main study: Pattern of data collection

Initial data collection occurred at the individual baseline meeting with each participant (**Table 4:2**). Potential participants who were still being treated for primary breast cancer, were not able to join the research study until treatment was completed when consent was again requested. Once recruited to the research study, qualitative data from all participants was used in the qualitative data analysis (**Chapter 7**), while those who withdrew or who were still in treatment at baseline were excluded from the quantitative analysis, as in both cases these participants had several items of missing data. This data was considered to be *missing at random* (MAR) and was therefore excluded in line with ethical approvals (**Section 4.2.1.1)** and in line with the guidance of Dancey, Reidy and Rowe (2012).

The different groups providing quantitative data are summarised below;

- **Overall group**: all participants
- **Quantitative analysis group**: participants who had completed treatment at baseline and did not withdraw during the intervention.
- **Follow up group**: participants in the quantitative analysis group who also provided data at 12-month follow up

The study included data collection at various time points before, during and after the intervention (**Table 4:2**).

A year after completing the intervention, participants were invited to a follow up meeting. In line with ethical approvals (**Section 4.2.1.1**) participants were only contacted following verbal confirmation from NHS staff that this was clinically appropriate. Data collection occurred (T4) at the follow up meeting. Some participants in the quantitative subgroup did not attend the 12-month follow up (T4) and so their data was excluded from long term analyses as appropriate. At this meeting, participants were also asked if they would be willing to be interviewed about their experiences. Before the interviews were carried out, participants were given a copy of the participant information sheet as a reminder and the details of the interview were discussed. If participants were willing to proceed, they completed an additional copy of the consent form to indicate that this was the case before the interviews began.

Table 4:2 Data collection protocol

Data collection	**Time 1 (T1)** **Baseline** (From 11 weeks before intervention)	**Time 2 (T2)** **Intervention week 1**	***Mid-intervention***	**Time 3 (T3)** **Intervention week 12**	**Time 4 (T4)** **Follow up** (About 12 months after the intervention)
Demographic data	✓				
Anthropometric data	✓	✓		✓	✓
Dietary intake (food diary)	✓	✓		✓	✓
Self-efficacy rating	✓	✓		✓	✓
Patient Reported Outcome Measure (PROM)	✓	✓		✓	✓
Evaluation forms			✓	✓	
Individual Interviews					✓

4.2.1.4 Main study: data analysis

The quantitative element of the research was carried out using a quasi-experimental design (**Chapter 3.6**) in which participants acted as their own controls. The data collected at T1 and T2 were used as control data and were compared to intervention data collected at T2 and T3 (**Box 5**) to determine whether the intervention had led to statistically significant change. The study also aimed to investigate long term effects following the intervention by comparing T3 and T4 data and T2 and T4 data.

BOX 5 Calculation of comparative and intervention quantitative data

Comparative change= T2-T1

Intervention change = T3-T2

Long term change after intervention= T4-T3

Long term change from start of intervention= T4-T2.

Data from the quantitative subgroup were entered in Microsoft (MS) Excel 2016 for initial descriptive analysis and then exported to IBM SPSS Version 24 for more detailed and inferential analyses. The data files were screened for errors by checking for any data that was out of range (Pallant, 2013) and any errors were identified and corrected from the raw data. Normality testing was carried out to determine whether inferential analysis should be carried out using parametric or non-parametric methods (Field, 2012; Pallant, 2013). Parametric tests are more powerful than non-parametric tests and are therefore considered to be the better choice for inferential analysis where appropriate (Carifio and Perla, 2008). Parametric tests are appropriate where assumptions are met about the parameters of the population distribution from which the sample has been drawn (Pallant, 2013) and were used where testing showed that the data were normally distributed. Results from inferential analysis were interpreted using a significance level of 0.05 in each case.

4.2.2 Main study: demographic data

An initial questionnaire was used to collect demographic data from participants at recruitment (**Appendix 2.3.1**) to identify the characteristics of the research sample, for example in terms of age, ethnic group and educational background and types of treatment. These data were also used to check eligibility for the study in line with inclusion criteria (**Section 4.2.1.2**). Where participants were still in primary treatment at baseline, they were initially ineligible to join the research study. For those participants, demographic data was collected again after their treatment was completed. Data were collected about the participants' household and cooking arrangements as part of an exploration of contextual factors. Brief details of medical history were collected, and any food allergies were noted to ensure safety during food tasting. Quantitative data were analysed using those with a full set of data at T1, T2 and T3 (quantitative analysis group) and a smaller subset of those who also had data at T4 (follow up group). A 2-tailed t-test comparison was made of those in each group and those excluded in each case to check for any demographic differences.

4.2.3 Main study: self-efficacy ratings

Introduction

Nutrition knowledge and access to healthy food may not be sufficient to improve healthy eating behaviour (Stadler, Oettingen and Gollwitzer, 2010). According to Social Cognition Theory (SCT), self-regulation and self-efficacy may also play a pivotal role in enabling adults to make healthier

food choices, especially in real-world situations (Mosher *et al.*, 2013). If people who have had breast cancer aim to eat a healthy diet, their likelihood of doing so may be determined, at least in part, by their capability to regulate their eating behaviour through planning and monitoring. Self-efficacy is a measure of perceived confidence in the abilities to choose and prepare healthier foods even in adverse circumstances and has been associated with healthier eating choices (Bandura, 2005; Anderson, Winett and Wojcik, 2007)(**Chapter 1.5**).

One of the research objectives of this study (**Chapter 1.6**) was to determine the impact of the lifestyle programme on self-efficacy and therefore the potential for continued behaviour change. To address this objective, a self-efficacy data collection tool was used. The strength of perceived self-efficacy is associated with the amount of effort that is made to follow a particular behaviour or habit (Maes and Karoly, 2005) in this case to follow a healthier diet. If the intervention can enhance the strength of the perceived self-efficacy of participants to choose a healthier diet, then this may increase the chances that participants are able to develop long term healthy eating habits in line with the study objective. Therefore, the strength of perceived self-efficacy was determined at each data collection time point in the study.

Self-efficacy is not a generalised ability, but rather is context dependent and therefore data collection tools are tailored to the behaviour of interest (Bandura, 2006). There are a variety of styles of tools used in the literature to collect self-efficacy data; they often use a variety of "can do" statements and participants rate their confidence in their ability to achieve them regularly using a variety of rating scales (for example Stadler, Oettingen and Gollwitzer, 2010; Kim, Chae and Yoo, 2012; Mosher *et al.*, 2013; Champion *et al.*, 2013). The self-efficacy scale used in the current study was adapted from the "*Self-efficacy to regulate eating habits*" scale published by Bandura (Bandura, 2006; p322). The original tool was designed to be used by those following a low-fat weight loss diet and therefore some of the items were not appropriate and were reworded or removed. The number of items in the tool was therefore reduced from 30 in the original tool to 15 items in the current study; this is within the range of the number of items in self-efficacy tools for other contexts in Bandura (2006). The wording of eight of the items was amended where it was felt to make the item more appropriate for a UK audience; for example, the item "*During vacations*" was reworded as "*When you are away on holiday*". The title of the tool was also amended from "*Self-efficacy to regulate eating habits*" in Bandura, (2006) to "*Self-efficacy to improve eating habits*". The

introduction and instructions at the beginning of the tool were also based on the wording on the Bandura tool with some slight amendments. The original Bandura tool and the one used in the current study are both presented in **Appendix 2.3.2** for comparison.

The scales used to collect self-efficacy data are usually based on at least a 5-point scale; for example Champion *et al.*, (2013) use a 5 point scale; Ochsner, Scholz and Hornung (2013) use a 6 point scale and Kim, Chae and Yoo (2012) use a 10-point scale. The scale used in the current study was the same as that used by Bandura (2006); for each statement participants were asked to rate their confidence on a scale from 0=cannot do at all, through 10-unit intervals to 100=highly certain can do. Preliminary verbal instructions were given by the researcher and participants were advised to rate their current capabilities. Bandura (2006) suggests using a practice item prior to data collection, but this was not done to reduce participant burden. The amended tool was not piloted prior to use in the current study; however, 7 of the items are identical to those used on the original tool while the 8 items were based on it. Cronbach alpha was calculated to check internal consistency of the tool and was calculated in SPSS using the method reported in Pallant (2013) and Field (2012). The Cronbach alpha coefficient in this study was 0.95 (**Appendix 2.5.1**). A Cronbach alpha above 0.7 is considered to be acceptable, while a value above 0.8 indicates good internal consistency (Pallant, 2013) so this result suggests that the internal reliability of this scale was very high. However, a full validation of this revised tool was beyond the scope of the study and was not carried out. Therefore the results were treated with caution.

Data collection

Self-efficacy data were collected from participants as outlined in **Table 4:2**. At the individual baseline meeting, the researcher explained the instructions verbally and participants then completed the tool unaided. At subsequent data collection points, participants completed the tool individually, usually while in the intervention group and following a brief verbal reminder from the researcher.

Data analysis

A self-efficacy profile score (mean of the 15 separate ratings) was calculated for each participant at each time point. The group overall mean self-efficacy rating and standard deviation at each data collection occasion was also calculated. Lorig and Holman (2003) and Kim, Chae and Yoo (2012) suggest that in a self-efficacy tool of this type, a mean score of 7 or greater on a 10-point scale

indicates a good chance that planned actions might be achieved while a rating of below 7 indicates that the planned behaviour is less likely to be actioned. As the current study used a 100-point scale, a rating of 70 or above was used as a cut off and therefore, the number (and percentage) of participants scoring a mean profile score of 70 or above on each occasion was also reported.

Normality testing of the self-efficacy profile scores was carried and showed that the data were normally distributed at each time point (**Appendix 2.5.1).** Self-efficacy profile scores are a combination of 15 separate ratings and can be treated as interval level data (Carifio and Perla, 2008) and appear to be normally distributed. Therefore, parametric methods of analysis were used. A one-way repeated measures ANOVA was conducted to compare self-efficacy profile scores at T1 Baseline (before the intervention), T2 (start of the intervention) and T3 (end of the intervention) using data from the quantitative subgroup. The analysis was carried out using SPSS according to the methods outlined in Pallant (2013). A second one-way repeated measures ANOVA was performed to see whether the self-efficacy scores changed over the subsequent 12-month period; this was carried out using the self-efficacy profile data of participants who provided self-efficacy data at all 4 time points.

4.2.4 Main study: physical health measures

An aim of the study was to determine any changes in health and to what extent these might be associated with the intervention. Therefore, physical health measures from the quantitative analysis group were recorded as indicated in **Table 4:2**.

4.2.4.1 Main study anthropometric measures

Anthropometric data collection and data analysis was carried out using methods outlined in **Section 4.1.3.1** at time points indicated in **Table 4:2**. The weight, height and BMI of participants were measured to determine whether the intervention was associated with weight change. The proportion of participants whose weight was within the healthy BMI range at each time point was determined. In addition, the number and percentage of participants with a waist circumference and waist to hip ratio within healthy ranges were also calculated. Normality testing showed that most, but not all, of the anthropometric data were normally distributed (**Appendix 2.6.1**). However, Field (2012) suggests that with larger samples, even where data appeared not to be normally distributed, parametric tests could still be used. Norman (2010) also asserts that parametric tests are based on

an assumption of normality of the distribution of the means, rather than the distribution of the data itself. The Central Limit Theorem shows that for sample sizes of more than 5 or 10 per group, the means are approximately normally distributed regardless of the original distribution. Therefore parametric testing of these data sets was carried out using one-way repeated measures analysis of variance (ANOVA).

4.2.4.2 Main study: blood pressure and heart rate

Blood pressure and heart rate were measured as outlined in **Section 4.1.3.2** above. A test of normality was used to determine whether parametric or non-parametric methods of significance testing should be used with this data set as discussed previously (**Section 4.2.1.4**). The Kolmogorov-Smirnov statistic was more than 0.05, indicating non-significance and normality of distribution, for systolic blood pressure, diastolic blood pressure and heart rate for the quantitative analysis group at T1, T2 and T3 and for the follow up group at each time point (T1, T2, T3 and T4), with one exception. The data for diastolic blood pressure after the intervention (T3) in both groups had a significance value of less than 0.05 which was a significant result and indicated that this set of data was not normally distributed (Field, 2012; Pallant, 2013). However, parametric testing was used as the sample size was large as discussed previously **(Section 4.2.4.1**). The mean and standard deviation of systolic blood pressure, diastolic blood pressure and heart rate were calculated at each time point and compared using one-way repeated measures ANOVA. The data was used to determine whether the intervention was associated with a decrease in mean blood pressure or heart rate. A blood pressure of more than 140/90 mmHg may be indicative of hypertension and increased cardiovascular risk (Boodhna *et al.*, 2014) and the proportion of participants with a healthy blood pressure was also determined at each time point.

4.2.5 Main study: dietary intake

Introduction

One of the research objectives of this study was to determine whether the intervention was associated with changes in dietary habits and therefore nutritional quality of participants (**Chapter 1.6**). Nutritional quality can be defined in terms of nutrient density per calorie (Christifano *et al.*, 2016) or the quality and variety of the overall diet (Wirt and Collins, 2009). Nutritional quality is an important consideration as the overall pattern of nutrient intake may influence epigenetic processes

and therefore breast cancer risk (Karimi *et al.*, 2013; Supic, Jagodic and Magic, 2013). Diet quality can be assessed quantitatively using pre-defined indices to assess alignment with national guidelines (Wirt and Collins, 2009), although the development of such indices is complex and can lack objectivity and predictive value (Waijers, Feskens and Ocké, 2007) and scoring of intakes may be rather arbitrary (Kim, Shin *et al.*, 2011). However, diet indices have been used in several recent studies of lifestyle or weight loss interventions for breast cancer survivors. For example, Christifano *et al.* (2016) assessed diet quality using 24-hour recall data and a Healthy Eating Index to score alignment with US national healthy eating guidelines and found an association between increased diet quality determined in this way and weight loss in breast cancer survivors. Anderson *et al.* (2016) used FFQ and healthy eating index to assess diet quality in a weight loss trial in breast cancer survivors and found increased fruit and vegetable consumption and decreased percent energy from fat, while George *et al.* (2011) used FFQ followed by healthy eating index to assess diet quality in a large observational study of post diagnosis diet quality and prognosis following breast cancer. Some studies have developed indices to show compliance to the WCRF guidance (Hastert *et al.*, 2013; Karimi *et al.*, 2013; Catsburg, Miller and Rohan, 2014). In this study nutritional quality was determined in terms of the extent to which dietary changes indicated a change in the healthiness of the diet in line with World Cancer Research Fund/American Institute for Cancer Research (2018) nutritional recommendations (**Chapter 1.3**) that were discussed with participants during the intervention (**Chapter 5.5)** and these are summarised in **Box 6** below.

Box 6 Indicators of the healthiness of the diet

1. **Energy** (*Recommendation*: Be a healthy weight)
2. **Carbohydrate, starch, sugars, free sugar, sucrose and Glycaemic Load (GL)** (*Recommendations*: Limit consumption of fast foods and other processed foods high in sugar. Limit consumption of sugar sweetened drinks)
3. **Fibre and vitamin C** (*Recommendation*: Eat more grains, vegetables, fruit and beans)
4. **Sodium** (*Recommendations*: Limit consumption of fast foods and processed meat)
5. **Total fat, saturated fat and cholesterol** (*Recommendations*: Limit consumption of fast foods and other processed foods high in fat. Limit consumption of red and processed meat.)

Data collection

Dietary intake data was collected using an estimated food diary method at each data collection point **(Table 4:2**).The food diary template was trialled during the feasibility study (**Chapter 5.3.2.3**) and was then modified to encourage participants to include more detail about portion size and to allow the researcher to record food codes and portion sizes estimated during nutritional analysis (**Appendix 2.3.3**). An additional initial questionnaire was also added to the front page of the food diary to gather details about core foods that were frequently missed out in the feasibility study, as recommended in the literature (NHS National Institute for Health Research / Medical Research Council, 2015). Participants were verbally briefed individually on diary completion during the T1 data collection session and the groups were reminded during the T2, T3 and T4 sessions. Food diaries were returned to the researcher during intervention sessions, or by post or email. A stamped addressed envelope was provided to encourage food diary return, and one reminder was sent by email, however participants were aware that each aspect of data collection was voluntary.

Data analysis

Completed food diaries were analysed using Nutritics Research Edition software (Version 5.094) as the NetWISP software used previously in the feasibility study was no longer available. Portion size was estimated in the current study and it was recognised that this may not be accurate; however, the data were analysed for change in intake, rather than absolute values. As participants were acting as their own controls it was anticipated that inaccuracies would be broadly consistent across each data collection period despite the subjectivity of the method. Diaries were analysed using a standardised protocol in which food codes and portion size used for analysis were recorded systematically and checked. Participant estimated or weighed portion sizes were used where available. If not available, portion sizes for branded foods were checked online. For other foods demographic average or medium portions, as suggested by the software, were used. Where food details were missing, consistent coding was utilised; for example milk was always assumed to be semi-skimmed unless specified otherwise as recommended by Whitton *et al.* (2011). Foods that were not specified in the food diary but may have been eaten (such as butter or spread with toast, or milk in coffee) were not included in the analysis, although milk was included on breakfast cereal in all cases whether listed or not. At each data collection time point, foods were inputted into the software meal by meal across all available diaries to enhance consistency.

The dietary analysis data were exported into MS Excel 2016 and were screened for errors by checking for data out of range as discussed in **Section 4.2.1.2**. The data were analysed to look for changes in mean intake of key nutrients that might indicate a change in the healthiness of the diet in line with World Cancer Research Fund/American Institute for Cancer Research (2018) nutritional recommendations. Therefore, mean intake per day and standard deviation were calculated at each time point for the nutrients indicated in Box 6. There was only one item of missing data; one participant had completed 3 days of the diary (rather than 4) at the end of the intervention (T3)**.** In this one case, the mean daily nutrient intake at T3 was therefore taken over 3 days rather than 4.

The data were exported into SPSS (version 24) and normality testing was carried out for each nutrient at each time point (**Appendix 9.1**) as discussed previously **(Section 4.2.1.2**). In the quantitative analysis group (n=22) at T1, T2 and T3, and the follow up group (n=10) at T1, T2, T3 and T4, the Kolmogorov-Smirnov statistic was more than 0.05 in most cases, indicating a normal distribution of scores. The nutrient intake data were interval level data, and the majority were

normally distributed. Therefore, it was decided to use the parametric one-way repeated measures ANOVA test to see if there were significant differences in nutrient intake over the different time points. If the data for any of the nutrients that were not normally distributed showed a significant change over time, then the result was also checked using the non-parametric Friedman test.

The mean contributions of key macronutrients to overall mean energy intake was also calculated so that comparison could be made to UK nutritional recommendations (British Nutrition Foundation, 2019) and to ascertain if the intervention had an impact on these. Normality testing was carried out (**Appendix 2.8.1**) and showed that in most cases the data were normally distributed. One-way repeated measures ANOVA tests were carried out to ascertain if any of the differences were significant.

4.2.6 Main study: Concerns and wellbeing

MYCaW data collection

MYCaW data were collected from participants as previously outlined in **Section 4.1.2.4** at each time point **(Table 4:2)**. At baseline, the MYCaW first form (**Appendix 1.4.1**) was completed by participants during their individual meeting with the researcher. The process was explained to the participant who was invited to identify two concerns that they hoped would be addressed by attending the lifestyle programme. The participants were invited to write these themselves in their own words on the form. Where participants preferred, the researcher wrote the concerns verbatim on the participants' behalf and read them back for checking and confirmation. Participants then rated their concerns by indicating on the Likert scale themselves.

On subsequent occasions (T2, T3 and T4) most of the participants completed the MYCaW forms midway through an intervention session. They were each handed a photocopy of their previously identified concerns (but not their baseline rating of them). They then rated the concerns individually; participants who were not in attendance were invited to complete them in a subsequent meeting with the researcher. At the start of the intervention (T2) the MYCaW first form (**Appendix 1.4.1**) was again used for data collection. After the intervention (T3) and at 12-month follow up (T4) the MYCaW follow up form (**Appendix 1.4.2**) was used to collect the rating of the original concerns and in addition asked open questions about participants' current health and about important aspects of the intervention.

Qualitative data analysis

The qualitative data collected on the MYCaW forms were analysed using a framework approach (**Section 4.1.2.5**). The handwritten responses to questions on the MYCaW tools were usually brief, from a few words to a sentence or two. The handwritten responses were read in the familiarisation stage and were then typed verbatim. The data were then indexed and charted manually in MS Excel 2016.

At baseline (T1) qualitative data about participant concerns were collected using the MYCaW first form. The two concerns identified by participants were analysed together. After the intervention (T3) and at 12-month follow up (T4) data were also collected via an open-ended question on the follow up MYCaW form about other factors that might have affected participants' health. The data in both of these cases were categorised using the frameworks developed by Polley *et al.* (2007) and Jolliffe *et al.* (2015). The follow up MYCaW form used at T3 and T4 also asked participants to identify other important aspects of the intervention. The responses to this question did not fit the published framework, instead a novel framework was developed to analyse evaluation data (**Section 4.2.7.1**) and was also used to analyse responses to this final question which invited evaluative responses. This novel evaluative framework included some similar aspects to those in the published framework (Polley *et al.*, 2007; Jolliffe *et al.*, 2015) such as support and group work, however other themes were different as these were responses to a lifestyle, rather than therapeutic, intervention. Using this evaluation framework, responses were reported in the key themes of; knowledge and understanding; motivation and confidence to change; group sessions and practical activities. Analysis across the themes and cases was carried out to address the study aim and the objectives.

Quantitative data analysis

The Likert-scale ratings of concerns and wellbeing collected on the MYCaW forms were analysed quantitatively. Data were entered and screened as discussed in **Section 4.2.1.2**. In two instances, a single item of data was missing and in these two cases only, a previous or subsequent rating was carried forward or back as appropriate using a Last Observation Carry Forward (LOCF) technique as outlined by Dancey, Reidy and Rowe (2012) and in line with NHS REC Ethical approval (**Appendix 2.1)** and as used by Harrington, Baker and Hoffman (2012). One participant did not identify or rate

a Concern 2 at any time point, and therefore this participant was excluded from analyses involving Concern 2.

Mean scores and standard deviations were calculated at each time point. Differences in the mean MYCaW scores were compared using inferential statistics. It is usually considered that parametric tests can only be used to analyse normally distributed interval level data **(Section 4.2.1.2).** Jamieson (2004) asserts that data from Likert scales is often not normally distributed, and so even if the data is considered to be interval data, parametric methods should not be used. Norman (2010) concludes that parametric methods are robust and can be used with Likert data. However, in most published studies the MYCaW data was analysed non-parametrically (Vaghela *et al.*, 2007; Seers *et al.*, 2009; Harrington, Baker and Hoffman, 2012; Polley *et al.*, 2016; Whatley *et al.*, 2016) while (Frenkel *et al.* (2010) used both parametric and non-parametric tests although the rationale was not specified and it was not clear which test was used for which analysis. A test of normality was carried out which showed that most of the MYCaW raw data was not normally distributed as, in most cases, the Kolmogorov-Smirnov test statistic indicated a significant result ($p<0.05$))(**Appendix 2.4.1**). Likert data collected for Concern 1, Concern 2 and Wellbeing are ordinal level data, while only the MYCaW Profile data are interval level data. Therefore, the data did not meet the assumptions for parametric testing and so it was analysed further using non-parametric methods: this was also in line with methods used in most published studies.

The MYCaW data was analysed with the non-parametric Friedman Test using methods outlined in Pallant (2013) and Field (2012). This test was used to determine whether there were significant differences in the data over time (T1, T2, T3 and T4). Separate analyses were carried out for each of the four parameters; Concern1, Concern 2, Wellbeing and MYCaW profile. Subsequently, *post-hoc* testing was carried out using four separate Wilcoxon Signed Rank tests to identify between which time points any difference had occurred and to assess statistical significance in each case. As four *post-hoc* tests were carried out, a Bonferroni adjusted alpha value (Pallant, 2013) of 0.0125 (0.05/4) was used to assess significance, to reduce the risk of type I error. Where differences were found to be statistically significant, the Wilcoxon Signed Rank test Z scores were used to manually calculate effect size (Pallant, 2013) and the calculated values were evaluated using the guidance of Cohen (1988). The calculation was carried out using the formula:

Effect size(r)= $Z/\sqrt{N}$

N= number of observations over both time points

Changes in participants' rating of their wellbeing and concerns between T1 and T2 (comparative data) were calculated and compared to changes in ratings between T2 and T3 (intervention data). A further Wilcoxon Signed Rank test was carried out to determine whether any difference in the changes of ratings were statistically significant. This comparison was used to assess whether the intervention might have been causally associated with any significant change in concerns or wellbeing.

As well as analysing the mean change in MYCaW scores, it is useful to consider whether identified changes are likely to represent meaningful change to participants. Guyatt *et al.* (1998) suggest that using a 7-item scale with descriptions of each item, a change of greater than 0.5 for each item is likely to represent the minimum change that might represent a clinically significant change for the patient. Paterson *et al.* (2007) agreed with Guyatt *et al.* (1998) and considered a change of 0.5 is a minimally important change, a moderate change is a change of 1.0, and that a change of 1.5 can be considered large. Seers *et al.*, (2009) considered a change of between 0.7 and 1.0 for each item to represent a significant change while a change of 1.0 represented a moderate difference and a difference of greater than 1.5 was large. The scale in this doctoral study is a 7-point scale but only includes written descriptions of the highest and lowest ratings and so the data was interpreted more cautiously according to the guidance of Seers *et al.* (2009). Therefore, in this study, a change of 0.7 or greater in the MYCaW profile score of an individual was considered to represent a meaningful change to the life of the participant. Changes of MYCaW profile scores between 0.69 and -0.69 were categorised as "no change", a reduction of 0.7 or more was categorised as representing reduced concerns and/or improved wellbeing and an increase of 0.7 or more was categorised as representing increased concerns/reduced wellbeing. Guyatt *et al.* (1998) and Seers *et al.*(2009) reported comparisons of the percentage of participants who had a significant improvement in MYCaW ratings over the intervention period compared to those with no change or with a deterioration. In this study the number and percentage of participants who reported no change, reduced concerns/improved wellbeing or increased concerns/reduced wellbeing are reported for the comparative and intervention data. A Wilcoxon Signed Rank test was used to determine whether there was a significant difference between these two sets of data. Polley *et al.* (2016) also reported

the percentage of participants with clinically relevant changes (at least 1 point) at 12 months. Similarly, in this study, the number and percentage of participants reporting meaningful changes in concerns/wellbeing in the long term were reported using data from those who attended the 12-month follow up.

4.2.7 Main study: qualitative data

Introduction

In this study the qualitative data were used to identify the context and mediators for change as part of a realist evaluation of the intervention and in line with the study aim and its objectives (**Chapter 1.6).** Qualitative data were collected using evaluation forms and semi-structured interviews.

4.2.7.1 Main study: intervention evaluation

Data collection

Participants were invited to provide written evaluative feedback on their experience of attending the lifestyle programme midway through the programme and during the final week as described previously (**Section 4.1.5**). The forms were identified by PIN only and were returned anonymously. One participant had not completed treatment before the mid-intervention evaluation and so data from this participant at that time point was excluded in line with approvals (**Section 4.2.1.1**).

Data analysis

The completed evaluation forms were read carefully as part of the process of familiarisation. The data were then electronically transcribed and both forms from each participant were analysed together using a framework approach as discussed previously (**Section 4.1.2.5**). An initial framework was developed in MS Excel 2016 based on the research objectives (**Chapter 1.6**) and the findings of the literature review (**Chapter 2)**. This draft framework was tested by the researcher and the Director of Studies together by analysing a subset of forms from 7 participants which resulted in refinement of the framework through an iterative process. The final framework included key themes of; knowledge and understanding; motivation and confidence to change; group sessions and practical activities. The transcribed data was used to populate the framework on a case-by-case basis. The data were then reported thematically across the cases.

4.2.7.2 Main study: semi-structured interviews

Introduction

As discussed in **Chapter 3.6,** this study was not carried out to investigate whether the intervention worked, but rather was intended to be a more exploratory study in which an interpretative approach was used involving the collaboration of the researcher and the researched. Qualitative interviews were conducted to explore the lived experiences of a sample of individual participants in response to the intervention. A focus group approach was discounted as the aim of qualitative data collection was to explore personal rather than overall or collective experiences (Mason, 2018). Interviews were deemed to be the most appropriate method to explore this personal story of participants to gain their insider perspective (Hennink, Hutter and Bailey, 2011). It was anticipated that the interview data would contribute to the interpretation and analysis of other qualitative and quantitative findings by suggesting contexts and mechanisms underpinning the observed outcomes, as recommended by MRC guidance for the evaluation of complex interactions (Craig *et al.*, 2008) and principles of realist evaluation (Pawson and Tilley, 2004). This was used to address the study objectives to identify the contexts and mechanisms for behaviour change and to identify changes in dietary habits, concerns or health over time (**Chapter 1.6**). In-depth interviews were carried out around a year after the end of the intervention to allow interviewees to retrospectively reflect on the short and long-term impacts of the intervention. Recall bias (Green and Thorogood, 2009) may also have influenced responses as the interviews were carried out up to 18 months after initial recruitment and more than 12 months after the intervention ended. The interviews were carried out either in participants' own homes, or at the University, according to participant preference. The University was already familiar to the interviewees through their attendance at the intervention, and therefore it was anticipated that participants would feel at ease in either location. This is important as participants are more likely to provide real and personal experiences if they feel comfortable in the interview (Green and Thorogood, 2009; Braun and Clarke, 2013). Further reflections on the interview process are included in **Chapter 9.5**.

Data collection

Participants attending the 12-month follow up meetings were invited to indicate their willingness to be considered for the interview phase. Those who volunteered to be interviewed might have been those who were more engaged with the programme, though in fact most of those who attended the follow up did volunteer (22 or 91.7%). Interviewees were purposively selected from this group based on the types of breast cancer treatment they had received, and time since diagnosis and completion of treatment to capture a diversity of contexts and experience. There are no agreed criteria to establish sample size in qualitative research studies. Many different types of qualitative studies claim to determine sample size in terms of achieving '*data saturation'*; though this was originally intended for use in grounded theory research (Malterud, Siersma and Guassora, 2016). In this study, analysis of data occurred after data collection was completed and so it would not have been possible to determine when '*data saturation*' had been achieved. An intended sample size of 6-8 was determined through discussion with the Director of Studies based on her previous experience and practical constraints. The size of the intended sample size was informed by the guidance of Malterud, Siersma and Guassora (2016). In this study the interviewees had high study specificity as they had all participated in the intervention, the researcher was able to purposively select participants with a diversity of experience, and rapport had already been established with participants so detailed and relevant dialogue was anticipated, suggesting that a smaller sample size might be appropriate. However, the limited experience of the researcher in qualitative interviewing is acknowledged.

In framework analysis, data analysis can be carried out concurrently during or after data collection (Srivastava and Thomson, 2009); in this study however, interview data were analysed after all the interviews were completed. Therefore, it was not possible to check on the quality of data provided to address the research questions or to adjust the sample size accordingly as the research progressed. It has been said that '*data saturation'* is achieved when further sampling and analysis would not reveal any new insights; though it is doubtful whether this could often practically be achieved (Green and Thorogood, 2009; Hennink, Hutter and Bailey, 2011). It is also questionable whether this aim of achieving '*data saturation'* aligns with a constructivist approach to research which recognises that all knowledge is partial (Malterud, Siersma and Guassora, 2016). Therefore it

was considered to be more appropriate to use an adequate sample to allow some new insights about the research question to be gained, as suggested by Pilnick and Swift (2011).

Interview data was collected using a semi-structured interview method using a flexible open-question interview guide (**Appendix 2.3.5**). The interviews were carried out according to the published guidance on questioning and probing, layout of the room and audio-recording (Braun and Clarke, 2006; Green and Thorogood, 2009; Hennink, Hutter and Bailey, 2011; Mason, 2018) and in line with reporting guidelines (Tong, Sainsbury and Craig, 2007; O'Brien *et al.*, 2014). The participant information sheet (**Appendix 2.2.2**) was reviewed with participants just before the interviews and a verbal reminder that the interview could be paused at any time and that answering each question was voluntary. The interviews were audio-recorded using an Olympus WS-750M digital voice recorder. As a novice interviewer, the researcher aimed to use the interview guide flexibly to explore unanticipated themes and aimed to develop listening and probing skills through the interview process. The researcher kept some notes to keep track of additional questions to ask and attempted to use silences to allow the participant to reflect and construct the narrative as recommended by Mason (2018).

Data analysis

Ideally at least two researchers would code the first few interviews independently and then develop codes through discussion (Gale *et al.*, 2013) while in this study the analysis was carried out by the doctoral candidate. Pilot interviews were not used; instead, the first two interviews were carried out, transcribed and reflected on by the doctoral candidate and the Director of Studies before the second phase of interviews began. The audio-recordings and transcripts of the initial interviews were checked for researcher interruption, use of prompts and questioning as recommended by Green and Thorogood (2009) and this was used to refine interviewer skills. The interview guide was also reviewed and refined to include an additional introductory question on how participants had heard about the programme to put the interviewee at ease. Extra prompts were added to be used as appropriate to gain more depth **(Appendix 2.3.5**). The first two interviews were carried out on the same day; after reflecting on this it was decided to carry out each subsequent interview on separate days to allow enough time for the researcher to prepare and reflect on the process and to write summary notes. This is in line with the guidance of Braun and Clarke (2013).

The interview data were analysed using a framework approach as discussed previously (**Section 4.1.2.5**). This method is often used to analyse semi-structured interview data though it requires some homogeneity amongst the interviews (Gale *et al.*, 2013). In this case, the interviews concerned the shared experience of the intervention and were likely to include some homogeneity of themes. This was a suitable method to use in this mixed method study as it is not aligned to any philosophical approach (Gale *et al.*, 2013) and is suitable for use in both deductive and inductive studies. In this case an inductive approach was taken with an open-ended approach to coding rather than using a pre-existing framework as in **Section 4.1.2.5** above. The interview recordings were transcribed verbatim using a professional transcription service but were then reviewed as part of the familiarisation process. Transcription involved literal coding of what was said (Fade and Swift, 2011) and non-verbal data were not collected or analysed; this was an experiential qualitative study in which participants words were taken at face value to gain the perspective of the participants (**Chapter 3.3.2**). Member checking of transcripts and their analysis was not used in this study for pragmatic reasons such as time constraints.

A novel framework was developed (**Appendix 2.9**) as part of the method of analysis and interpretation. The framework was used to organise and manage the data (Gale *et al.*, 2013). Analysis was carried out systematically using the following stages, based on (Ritchie and Spencer, 1994):

1. **Familiarisation:** the audio-recordings of each interview were listened to several times and the transcripts were checked and edited for accuracy and anonymisation. The summary notes taken at the time of each interview were read again for context and used to aid interpretation of the recordings. This enabled an overview of each interview to be gained before analysis began.
2. **Identifying a thematic framework:** Following the familiarisation phase, a framework of themes and codes was developed. This was initially adapted from the framework previously used in this study to analyse the evaluation data (**Section 4.2.7.1)**. The framework was refined by an iterative process. Initially it was reviewed and adjusted to include themes identified in the literature review (**Chapter 2**) and to address the study aim and objectives as recommended by Rabiee (2004)**.** This tentative framework was refined as each interview

was analysed through several iterations to ensure that it captured any unanticipated themes. The themes and codes were then numbered hierarchically (**Appendix 2.9).**

3. **Indexing:** There was a systematic application of codes from the finalised framework across the entire data set. The interview transcripts were re-read and sections of text that applied to each code were identified and numbered in the margin.
4. **Charting:** Data reduction occurred in this stage as text identified by indexing was summarised or quoted and placed in the appropriate cell of the matrix in MS Excel 2016. The summarised data were entered in the matrix by codes organised in columns and cases in rows.
5. **Mapping and interpretation:** The final stage involved identifying the relationships between and within cases on the matrix. The interpretation was carried by focusing on the following criteria using the guidance of Rabiee (2004): within case frequency; intensity of feeling expressed, specificity of personal experience, extensiveness between cases and overall concepts.

4.3 Summary of research methods

The feasibility study was carried out using a single arm design and collected both quantitative and qualitative data to address the aims (**Chapter 3.2**). The results and discussion of the feasibility study data and the ways in which this informed the main study are reported in **Chapter 5** below. The main study was then carried out using a quasi-experimental design and a convergent mixed methods approach (**Chapter 3.5** and **3.6**) and this chapter has discussed the parallel and separate collection and analysis of quantitative and qualitative data. The quantitative results from the main study are presented in **Chapter 6** and the main study MyCaW and qualitative findings are presented in **Chapter 7**. The findings of the two strands were then brought together and synthesised to discuss findings in relation to the research objectives in **Chapter 8**.

Chapter five: Feasibility study results and discussion

5 Feasibility study results and discussion

5.1 Introduction

The design and aim of the feasibility study have been previously reported in **Chapter 3.2,** and the methods used were discussed in **Chapter 4.1.** The results and discussion and implications for the main study are presented below, followed by a summary of the main study intervention.

5.2 Feasibility study results

5.2.1 Feasibility study recruitment

Twenty-six potential participants expressed an interest in the programme. Several people who were interested were unable to attend, mainly for practical reasons. The intervention was planned to be held on a weekday afternoon and some were unable to attend as the sessions clashed with school collection times, the rush hour or due to employment and a reluctance to take more time off work. Eight people (31%) joined the intervention.

The intervention retention was 75%; two participants withdrew from the study. One withdrew after the first week and the other about halfway through the programme. Mean attendance at intervention sessions for the whole group (n=8) was lower than anticipated (58%). The average attendance of the participants who completed the intervention was 69%. Participants had to miss sessions due to pre-planned holidays as well as for unexpected employment demands, ill health, and family commitments. The remaining six participants completed the programme, and their data are reported below.

5.2.2 Feasibility study: Concerns and wellbeing

All participants completed the MYCaW data collection tool on day 1 (n=8), but 2 participants withdrew and therefore had their data excluded. Therefore only n=6 participants provided the MYCaW data analysed below.

5.2.2.1 MYCaW qualitative data

Before the programme began, participants identified a variety of concerns and rated these concerns as very significant issues for them personally (**Section 5.2.2.2**). The concerns were categorised using framework analysis (**Chapter 4.1.2.5**) into four key themes adapted from Polley *et al.* (2007) and

Jolliffe *et al.* (2015); psychological and emotional concerns, physical concerns, hospital cancer treatment concerns and concerns about wellbeing.

Some participants identified negative psychological and emotional concerns such as feeling weepy and emotional or feeling depressed. In other cases, participants identified more positive concerns including a need to move forward after completing treatment.

"Trying to find 'new' normal - moving on from where I am" (4)

Several participants had physical concerns. The most commonly expressed concerns in this area were about weight gain; for some they reported needing to lose weight before they would be offered reconstructive surgery. Some also identified physical concerns such as tiredness or joint problems. Some of the joint issues identified were unrelated to cancer treatment.

***"**BMI needs to be lower for reconstructive surgery" (5)*

Only one participant reported a treatment concern; she reported concerns about joint pain as a side effect of her medication.

Several participants had wellbeing concerns. Several participants wanted to improve their levels of physical activity and/or improve their diet. Some were interested in improving levels of food knowledge to make healthy choices, while others expressed concerns about finding the motivation to make lifestyle changes.

"Improve activity-motivation" (1)

At the end of the programme, the MYCaW follow-up tool (**Appendix 1.4.2)** invited participants to identify factors, other than the programme, that might have affected their health. Four of the six participants (67%) who finished the programme completed this section of the tool. Their data was categorised into four key themes adapted from Polley *et al.* (2007) and Jolliffe *et al.*, (2015); awareness of wellbeing, social support, work situation and health issues using a framework analysis approach (**Chapter 4.1.2.5**) .

One participant found that it was difficult to maintain the lifestyle changes as she had returned to full time work. In another case, a participant's health had been negatively affected by family

problems. In most cases, ongoing cancer treatment had negatively impacted on health either due to medication affecting weight or causing hot flushes, or sickness. In two cases further cancer surgery or metastasis had also impacted on health. One participant also commented that other family members had also lost weight, suggesting that the intervention had impacted more widely in the household.

A final question on the MYCaW follow-up form asked about the most important aspects of the intervention. All six participants responded to this question and the responses were categorised using framework analysis (**Chapter 4.1.2.5**). The responses to this question did not fit with the published framework (Polley *et al.,* 2007; Jolliffe *et al.*, 2015) and were instead categorised into 5 themes; nutrition sessions, exercise sessions, being with group members, self-development and other aspects.

The nutrition sessions were commented on by 4 of the participants and all of the comments were positive. This feedback suggested that the nutrition sessions were useful and the focus on healthy eating was valued. Participants were able to understand the science behind the advice and use the information to assess their own diet and identify changes that they might need to make;

> *" Discuss food in a healthy way. Assess the food you eat. Understand the science behind it " (4)*

Four participants commented on the exercise sessions and they valued the opportunity to think about moving more, and safely try and discuss different types of exercise. In one case, a participant felt that the exercise might have been too soon after her surgery.

Three participants commented on the value of sharing with others who had had similar experiences as they had been able to gain ideas, support and comradeship.

Two participants commented that they had gained control over their health choices as they were more able to make informed choices;

> *"Realising that I still have an element of control over my health and wellbeing and that its worth the investment" (8*)

One participant commented that both she and another family member had lost weight.

5.2.2.2 MYCaW quantitative data.

The mean MYCaW ratings and standard deviation (SD) for Concern 1, Concern 2, Wellbeing and the overall MYCaW Profile before and after the intervention are presented in **Table 5:1**.

Concern scores: These data show that before the intervention the participants had high levels of concern. The mean rating of Concern 1 was 5.2 showing that on average this was close to being "as bad as it could be" and therefore presumably it was on this basis that participants selected this as their primary concern. The range of the ratings for Concern 1 shows that all participants rated this at 4 or higher, showing that for all participants this was rated as a real issue. There was still a high rating of Concern 2 (mean = 5.0), though this was less than for Concern 1. The data showed lower mean ratings of concerns by the end of the intervention.

Wellbeing scores: The participants' mean rating of their wellbeing was better as indicated by a lower value (mean = 3.5). The range of ratings of wellbeing among the group was wide with some rating it close to "as good as it could be". The data showed lower mean ratings of wellbeing (improved wellbeing) at the end of the intervention.

Profile Scores: The profile scores showed a decrease between the start and end of the intervention.

Table 5:1 Mean (SD) MYCaW ratings of concerns and wellbeing before and after the feasibility study intervention (n=6).

Mean MYCaW rating (SD)	Concern 1	Concern 2	Wellbeing	MYCaW Profile
Before	5.2 (0.8)	5.0 (0.6)	3.5 (1.8)	4.6 (0.9)
After	3.2 (2.5)	3.2 (1.6)	2.0 (1.8)	2.8 (1.4)

MYCaW ratings are scored between 0-6; a higher MYCaW rating indicates a higher level of concern or lower level of wellbeing. MYCaW profile is the mean of ratings of Concern 1, Concern 2 and Wellbeing.

Table 5:2 shows the change in concerns and wellbeing for each participant. This shows that in most cases there was a decrease in MYCaW ratings, indicating a decrease in concerns or improved wellbeing, or no change in rating indicating no change in wellbeing or level of concern. In one case there was an increase in MYCaW scores (participant 3; concern 1) and this represented an increase in concerns. However, the data show that in each case there was a decrease in the MYCaW profile,

indicating an overall decrease in concerns and/or improved wellbeing. There was a very wide variation in the changes in scores, so although there was an improvement in the mean MYCaW Profile score (-1.8) there was also a large standard deviation.

Table 5:2 Changes in MYCaW score during the feasibility study intervention (rating after – rating before).

Participant number	Change in concern 1	Change in concern 2	Change in wellbeing	Change in MYCAW profile
1	0	0	-1	-0.3
3	1	-2	-1	-0.7
4	-4	-2	-2	-2.7
5	-4	-1	-1	-2.0
7	0	-2	-1	-1.0
8	-5	-4	-3	-4.0
Total	-12	-11	-9	-10.7
Mean	-2.0	-1.8	-1.5	-1.8
Standard deviation (SD)	2.6	1.3	0.8	1.4

Negative values indicate a decrease in MYCaW ratings that indicate a decrease in concern or improvement in wellbeing.

5.2.3 Feasibility study: physical health measures

Physical health data were collected at the start and end of the intervention as discussed in **Chapter 4.1.3** and are presented in **Table 5:3** below. Numbers of participants from whom data were collected for each parameter are included as in some cases data were missing in error, or in one case as a participant declined to have data collected.

Table 5:3 Physical health parameters before and after the intervention

	Before the intervention Mean (SD)	**After the intervention** Mean (SD)	**Change** Mean (%)
Heart rate (beats per minute) (n=2)	90 (1.4)	89 (2.8)	-1.0 (-1.1%)
Systolic BP (mmHg) (n=5)	139.0 (24.9)	124.6 (19.1)	-14.4 (-10.4%)
Diastolic BP (mmHg) (n=5)	87.0 (8.3)	77.2 (9.3)	-9.8 (-11.3%)
Waist circumference (cm) (n=6)	94.3 (13.7)	92.9 (14.7)	-1.4 (-1.48%)
Hip circumference (cm) (n=6)	115.2 (12.0)	113.2 (9.6)	-2.0 (-1.74%)
Waist to hip ratio (n=6)	0.8 (0.1)	0.8 (0.1)	0.0
Height (cm) (n=6)	165.5 (7.9)	165.4 (8.3)	-0.1 (-0.06%)
Weight (Kg) (n=6)	84 (14.7)	81.9 (12.6)	-2.1 (-2.5%)
Body Mass Index (BMI) (Kg/M^2) (n=6)	30.9 (6.1)	30.2 (5.4)	-0.7 (-2.3%)

All of the physical health parameters (other than waist to hip ratio) showed a mean decrease between the start and end of the intervention. There was no change in the mean waist to hip ratio.

5.2.4 Feasibility study: dietary intake

Participants completed a 4-day food diary (**Appendix 1.5**) after attending the first day of the intervention and a second food diary was completed during the final week (**Chapter 4.1.4**). Two of the six participants (33%) who completed the programme did not return their second food diaries and were therefore excluded from the food diary analysis.

The findings for reported mean macronutrient intake are presented below in **Table 5:4**. The data appear to show a decrease (-6.5%) in mean energy intake and a decrease in intake of most macronutrients except saturated fat which showed a slight (2.8%) increase, and there was no change in the mean fibre intake. There also appeared to be a reduction in reported mean alcohol intake, and in fact no alcohol intake was reported at all at the end of the intervention. The greatest

apparent mean decreases in intake were in non-milk extrinsic sugar (-28.8%), polyunsaturated fat (-27.1%) and starch (-23.5%).

Table 5:4 Mean macronutrient intake before and after the intervention (n=4)

Nutrient	Mean intake before the intervention	Mean intake after the intervention	Change in mean intake (% change)
Energy Kcal/d	1867.8	1559.3	-308.5 (-6.5%)
Protein g/d	75.1	66.3	-8.8 (-11.7%)
Carbohydrate g/d	216.5	175.6	-41.0 (-18.9%)
Sugar g/d	99.5	84.3	-15.2 (-15.3%)
NMES g/d	46.0	32.7	-13.3 (-28.8%)
Starch g/d	114.8	87.9	-26.9 (-23.5%)
Total fat g/d	79.0	71.1	-7.8 (-9.9%)
Saturated fat g/d	29.2	30.1	0.8 (2.8%)
Monounsaturated fat g/d	25.7	22.3	-3.4 (-13.2%)
Polyunsaturated fat g/d	13.3	9.7	-3.6 (-27.1%)
Fibre (AOAC) g/d	20.2	20.2	0.0
Alcohol g/d	6.9	0.0	-6.90 (-100%)

*NMES- non-milk extrinsic sugar, **AOAC Association of Analytical Chemists method of fibre analysis

The mean intakes of micronutrients are reported below in **Table 5:5**. The data appear to show that the reported mean intake of micronutrients had decreased by the end of the intervention, although by contrast the mean intake of vitamin C had increased (43.3%). The largest reductions in reported mean intake of micronutrients were of sodium (-31.5%) and carotene (-29.1%).

Table 5:5 Mean intake of selected micronutrients before and after the intervention (n=4)

Nutrient	Mean intake before the intervention	Mean intake after the intervention	Change in mean intake (% change)
Sodium mg/d	2686.5	1839.8	-846.7 (-31.5%)
Potassium mg/d	3306.3	2752.3	-554.0 (-16.8%)
Iron mg/d	13.4	10.0	-3.4 (-25.4%)
Vitamin D µg/d	3.8	3.2	-0.6 (-15.8%)
Vitamin C mg/d	121.8	174.5	52.7 (43.3%)
Carotene µg/d	4930.8	3497.8	-1433.0 (-29.1%)
Vitamin E µg/d	8.5	6.2	-2.3 (-27.1%)

5.2.5 Feasibility study: evaluation questionnaires

Evaluation forms were completed by participants as reported in **Chapter 4.1.5** above. Four participants (67%) completed the mid-programme evaluation while five participants (83%) completed the end-of-programme evaluation form. The qualitative data from both questionnaires were analysed together using a framework analysis approach **(Chapter 4.1.2.5)** using themes of positive aspects of the programme and suggestions for improvement.

Participants found many aspects of the programme useful including meeting people with similar experiences, gaining lifestyle information, the exercise sessions and thinking about healthy eating rather than dieting.

"A better 'relationship' with food."

Some valued the pedometer and realising that small changes can be effective. Some commented that the programme provided a useful transition from being a patient.

"A bridge between 'medical treatment' and the scary return to 'real life'"

Participants also commented that they had gained self-confidence, knowledge and that it had reduced their concerns.

"The feeling of 'dread' has lessened."

Participants found that the programme had been enjoyable, relevant, supportive and motivational; it had helped them to focus on how to improve their lifestyle and that the small group size prevented it from being too daunting.

Suggestions for improvement included changing the timing of sessions to avoid the rush hour and school collection time. There was also a suggestion that a medical history should be taken and that the exercise session should be after the nutrition session, so participants could stay for longer in the gym if they wished. There was also a suggestion that there could be a greater focus on diet and weight loss with an additional weigh in.

5.3 Feasibility study discussion

This section considers the ways in which the feasibility study results have addressed the previously reported study aims (**Chapter 3.2**) and the implications for the main study.

5.3.1 The feasibility of processes involved in intervention delivery and study design

The feasibility study results (**Section 5.2.1**) indicated that there were difficulties in recruitment as only 26 potential participants expressed an interest in joining the study. Therefore, further recruitment methods were also introduced to use in the main study and are discussed in **Chapter 4.2.1.2**. Of those expressing an interest in the study only 31% were recruited, mainly due to practical issues of attendance in person. In the light of these findings, during the main research study the lifestyle intervention was scheduled in the mornings or evenings to avoid the rush hour and the school run. For this reason, participants in the main study were not randomised to different attendance groups as originally planned, and this is discussed further in **Chapter 4.2.1.2**. Instead, participants were able to choose between the 3 groups, and it was anticipated that this would allow those who were working, or who had caring or other responsibilities to choose the most convenient group to attend.

Due to the relatively low attendance in the feasibility study (69%), in the main study participants were given at least three months' notice of session dates and times to allow regular attendance as

far as possible. The intervention groups were also scheduled to avoid school holidays. Retention on the intervention was 75%, the 25% drop out might also be expected to occur in the main study. Participants who dropped out were invited to provide feedback but did not provide reasons for their withdrawal.

The feasibility study group was very small, and some evaluation feedback (**Chapter 5.2.5**) suggested that a larger group may have been daunting. This was considered when designing group size for the main study. Suggestions to change intervention session timings for the greater convenience of participants were also incorporated in the plans for the main study.

The qualitative MYCaW data (**Section 5.2.2**) and evaluation questionnaire data (**Section 5.2.5**) suggested that the intervention appeared to be useful to participants. All of the participants answered an additional question on the MYCaW follow up form about important aspects of the intervention (**Section 5.2.2.1**). These data suggested that the nutrition sessions were useful and valued supporting the continuation of the approach previously used in intervention delivery. The comments were mainly positive, though the intervention timing may not have been ideal for one person and therefore this was identified as an area to be explored in the main study. Peer support was valued and useful and so it was intended to continue to foster this in the main study. Two commented that they had gained more control over their lifestyle to promote health, which suggested an improved self-efficacy. Therefore, the intervention appeared to be feasible and relevant to the needs of participants and so many key aspects of the intervention were retained during the main research study (**Section 5.4**)**.**

5.3.2 The ability of the collection tools to capture relevant changes that might result.

5.3.2.1 MYCAW tool

Changes in mean ratings of concerns and wellbeing collected by the MYCaW tool were reported in **Section 5.2.2.2**. Previous studies (Paterson *et al.*, 2007) have suggested that with a 7 point Likert scale such as that used in the MYCaW tool, a change in rating of 0.5 is the minimal change that is likely to reflect a small, noticeable difference for the participant, while a change of 1.0 is likely to reflect a moderate difference and a change of 1.5 indicates a large difference. Using this rating suggests that the mean changes in concern 1, concern 2, wellbeing and MYCaW profile reflect large differences in those concerns. Therefore, despite the very small sample the feasibility study

provided some evidence that there was a reduction in some concerns and some improvement in wellbeing, and these results indicated that this tool was able to capture intervention impacts and it was therefore retained for use in the main study.

The MYCaW data suggested that the lifestyle intervention may be associated with reduced concerns and improved wellbeing. This may be because the programme itself had contributed to allayed concerns and improved wellbeing for participants; however, without comparative data it is unclear whether this is the case or whether the improvement may have been due to other confounding factors including the passage of time. These findings informed the development of the main research study which was designed to include the collection of comparative data in order that causal relationships may be investigated. It also involved the collection of additional qualitative interview data to investigate the mechanisms by which this may have occurred. The research design of the main study is discussed in **Chapter 3.6.**

The MYCaW follow up tool completed at the end of the intervention (**Section 5.2.2.1**) collected qualitative data about changes and impacts. It was emphasised that all aspects of data collection were voluntary, and only 4 (67%) of those completing the tool chose to answer the additional question about other things affecting health (**Section 4.1.2.5**). This suggests that some participants had no additional factors affecting their health which they wished to share with the research team. The factors affecting health identified by participants were mainly factors that were likely to have had negative impacts on health, wellbeing or the ability to make behaviour changes. The MYCaW ratings at the end of the intervention may have been affected by these issues that had impacted on participants alongside the intervention. These answers provided additional context to the MYCaW ratings which showed a large improvement in spite of many of these other issues and supported the ability of this tool to collect useful data on intervention impacts.

5.3.2.2 Physical health measures

The physical health data collected at the beginning of the programme suggested that many of the participants were at increased health risks and would potentially benefit from an improved diet and increased physical activity to meet the recommendations for cancer survivors (World Cancer Research Fund / American Institute of Cancer Research, 2007; World Cancer Research Fund/American Institute for Cancer Research, 2018a). This suggested that the intervention might

be appropriate for the participant group. The initial mean body mass index (BMI) was 30.9 and the range was 24.4-39.7 suggesting that most participants were in the overweight or obese category (National Health Service, 2018). The mean blood pressure (BP) was also 139.0 / 87.0 mmHg which is close to the cut off value for hypertension of 140/90 mmHg (Boodhna *et al.*, 2014). The mean waist circumference was 94.3cm which is within the "substantially increased risk" category as it is over 88cm; most participants had a waist circumference above 80 cm suggesting increased health risk (Swanton, 2008). A waist to hip ratio (WHR) or more than 0.85 indicates increased health risk in women (Swanton, 2008). The initial mean waist to hip ratio (WHR) was below this (0.8), though 50% of participants were in the increased health risk category. All of the parameters, other than waist to hip ratio, showed a mean reduction over the intervention period suggesting that beneficial changes may have occurred and were captured by the physical health measures that were recorded. These data suggest that there may have been a reduction in adiposity; however, weight change is a long-term process and significant change may not be seen during the relatively short time period of the intervention. Therefore in the main study, long term follow up was included to capture any changes that might take longer than 12 weeks, and to see if any changes made were sustainable. Any observed changes in physical health may have been due to other factors, and the quasi-experimental approach was used in the main study to address this. To minimise the occurrence of missing data in the main research study, data were collected using standardised protocols and data collection tools **(Chapter 4.2).**

5.3.2.3 Dietary intake

Only 67% of the final food diaries were retuned, and this may have been because their completion was found to be too onerous. In addition, some commonly consumed foods, such as milk, bread and spread, were not always recorded on each consumption occasion. The food diary form used in this feasibility study **(Appendix 1.5)** was therefore amended for use in the main study (**Appendix 2.3.3**) to include an initial questionnaire in which participants could easily record these regularly eaten foods. It was anticipated that this might make the form simpler to complete and therefore less onerous and may reduce missing data in the main research study. The feasibility study food diary form did not have a separate space for participants to record portion sizes, or a space for the researcher to record food codes and quantities during analysis; the main study food diary was therefore revised to address these shortcomings.

The data collected from the food diaries appeared to show a reduction in the reported mean intake of most nutrients at the end of the intervention. However, the feasibility study nutrient intake data set was very limited as it was based on the food diaries of only four participants. As the sample size was so small it was not possible to judge whether changes in nutrient intake had occurred. However, steps were taken to reduce missing data in the main study and intervention impacts on nutrient intake was investigated further. It was not possible to determine whether improved nutritional intake had occurred in line with recommendations to reduce cancer risks and for cancer survivors that were the basis of the nutritional aspect of this intervention (World Cancer Research Fund/American Institute for Cancer Research, 2007; World Cancer Research Fund /American Institute for Cancer Research, 2018a) **(Chapter 1.3).** Therefore, it was decided in the main study to focus on intakes of key nutrients that might indicate changes in line with these recommendations **(Chapter 4.2.5)**.

5.3.2.4 Evaluation questionnaires

The evaluation questionnaires were completed by most, but not all participants (as each aspect of data collection was voluntary). The data were analysed using a simple framework with two themes; positive aspects of the intervention and suggestions for improvement (**Chapter 4.1.5**). It was anticipated that this would address the feasibility study aims to give voice to participants in the design of the main study intervention.

The evaluation data (**Chapter 4.1.5)** supported the assertion that the intervention was useful, and reduced fears and improved confidence, and this was in line with reduced concerns and improved wellbeing suggested by the MYCaW data (**Chapter 5.2.2**) and supported the intention to retain the key intervention features. In spite of the intention to focus sessions on healthy eating, one participant wanted a greater emphasis on weightloss and suggested interim weighing could occur. In the main study this was addressed by making scales available to participants for personal use before, during or after the sessions. There was also an intention for an increased focus in sessions on personal goal setting, which may be for weight loss in some cases.

The evaluation questionnaires provided useful feedback on participant experience and were therefore retained in main study. This suggests that the programme did address the concerns of participants and these positive aspects were all incorporated into the programme in the main

research study. These suggestions were considered in the design of the intervention for the main research programme. It was recognised that in the main study a more robust analysis framework would need to be developed based on the research objectives of the main study and from the data collected. In addition, to capture more a detailed account of possible contexts and mechanisms, qualitative interviews were included in the main study.

5.3.3 An evaluation of the experience of participants

The aim of this feasibility study was to find out whether the intervention addressed the concerns of participants. It also aimed to ascertain how the participants suggested that the programme could be improved. This study data did suggest that participants found the programme to be relevant and useful and may have made some positive lifestyle changes over the 12 weeks of the programme.

The MYCaW qualitative data (**Section 5.2.2.1**) showed that participants had a variety of concerns in areas that were addressed by the nutrition, exercise and/or group support aspects of the intervention. This suggested that the programme was likely to be relevant to the concerns of participants and this was confirmed by the reduction in concerns reported in **Section 5.2.2.2** above. Participants identified ways in which the programme had supported and motivated them to make changes. There also appeared to be an associated improvement in wellbeing. This was supported by some of the evaluation feedback indicating reduced fears and concerns.

MYCaW follow up qualitative data (**Section 5.2.2.1)** suggested that some participants reported that they had gained more control over their lifestyle. A key purpose of the intervention was to develop the skills of self-regulation and self-efficacy to lead to long term behaviour changes based on the recommendations outlined in **Chapter 1.3**. Following positive feedback from the feasibility study and outcomes of the literature review, the main study intervention had an increased focus on developing these skills of self-regulation and self-efficacy by developing knowledge and skills, group support and motivation and self-confidence in making behaviour changes (**Chapters 1.5** and **2.8.3),** and an additional self-efficacy rating tool was used in the main study to measure the impact of this.

5.4 Summary and implications for main study

The feasibility study findings supported a continuation of the key features of the intervention in the main study. The main study intervention intended to promote increased knowledge about lifestyle and breast cancer survivors using discussion and practical activities. Within the sessions, generic

lifestyle information was applied to the breast cancer survivor context so that it would be personally applicable to participants. Rather than a didactic approach, the focus in sessions was a relaxed and informal discussion of the application lifestyle recommendations to the real lives of participants. This was supported by the provision of evidence-based publications on lifestyle and cancer for use as prompts for discussion during the sessions and for participants to review and reflect on later or with family and friends.

The focus of the intervention was on a positive approach to healthy lifestyles rather than on dieting and weight loss. The aim was to develop the self-confidence of participants by achievement and progress. Participants were encouraged to set and review personal goals. There was a focus on developing group interaction through an ice breaker activity, name cards in each session, discussion within the sessions and during informal breaks, sharing food and drink each week, and collaborating in practical activities. A week-by-week summary of sessions is presented in **Table 5:7**.

The main research study was intended to investigate whether any of these intervention features were 'active ingredients', as described by Borek *et al.* (2015: p8) that might contribute to an understanding of how the intervention might work. These processes have also been described as 'contexts and mechanisms' as part of a realist approach to intervention evaluation (Pawson and Tilley, 1997). The main research study was intended to investigate these varied elements and the research methods used are discussed in **Chapter 4.2**.

The feasibility study findings were used to streamline the design of the main research study and feedback from the participants contributed to this process . It also allowed trialling of recruitment processes and of running the intervention, and the use of some of the data collection tools**.**

The main changes made in response to the feasibility study are outlined below;

1. **Recruitment processes**

   Where possible participants were given at least 3 months' notice of session dates and times to improve attendance. Group interventions were scheduled in the mornings and evenings to avoid rush hour and the end of the school day, and participants were able to choose between different times to improve recruitment and attendance. For this reason, participants were not randomised to different attendance groups.

2. **Practical aspects of running the intervention**

   As suggested in the feedback, intervention sessions included nutrition first followed by the exercise session so that participants could stay in the gym after the end if they wished to continue exercising.

3. **Data collection tools**

   Protocols and tools for collection of physical health data were modified and standardised to reduce the amount of missing data and to improve the validity and reliability of data collected. Food diary forms were modified to encourage participants to include more detail about portion sizes, to reduce participant burden and to allow the researcher to record food codes and portion sizes during nutritional analysis. An initial section was added so that participants could record details of commonly eaten foods. Participant numbers were included on all data collection tools, including evaluation questionnaires. Demographic data including medical history was collected to ensure the safety of participants and to allow this information to be used during data analysis. A new framework was developed to analyse the evaluation data in the main study. Further data collection was included in the main research study to investigate behaviour change, contexts and mechanisms. Long term data collection was also added to determine whether changes were sustained after the intervention. A novel quasi-experimental research design was used in which participants acted as their own controls, to enable further investigation of causality over the intervention period.

4. **Participant target sample size**

   This feasibility study contributed to determining the optimal group size for the main research study. For practical reasons it was decided to run 3 intervention groups. The Wellbeing Centre where the intervention was run can safely accommodate a maximum of about 15 participants. Feedback from participants also suggested that a large group size might be more daunting. Therefore, for these reasons a sample size of 45 was envisaged.

The feasibility study findings, together with the results of the literature review (**Chapter 2**) were used to refine the intervention for use in the main research study and this is discussed in the next section.

5.5 Design of the main study intervention

The characteristics of the main study intervention are summarised in **Table 5:6** using the checklist and guidance from Borek *et al.* (2015). Details of the week-by-week sessions are summarised in **Table 5:7** below.

Table 5:6 Characteristics of the intervention delivered in the main research study using criteria of Borek et al. (2015)

Intervention design	
1. Intervention source or development methods	*The University developed the intervention in 2012 (**Chapter 3.1**) following an informal review of the literature and collaboration of academic staff in psychology, health, sports science and staff from the University Wellbeing Centre together with local clinical staff. A feasibility study and an integrative literature review (**Chapter 2)** informed the refinement of the intervention for use in this doctoral study.*
2. General setting	*City centre University campus with attached Wellbeing Centre used by students, local community, and various rehabilitation groups.*
3. Venue characteristics	*Intervention was run in a seminar room and adjacent physical activity/ gym facility. Nutrition sessions were held in the seminar room. Tables and chairs were arranged in small groups of 4 for the first session to facilitate icebreaker activities, and for subsequent sessions were arranged in one large rectangle to facilitate discussion between participants. The facilitator sat with participants. Physical activity sessions were introduced in the seminar room but were held in the gym area which was usually closed to other users during the sessions.*
4. Total number of group sessions	*12*
5. Length of group sessions	*2 hours; 1-hour physical activity and 1-hour healthy eating (with a break between the 2 sessions)*
6. Frequency of group sessions	*Weekly; on Wednesday mornings (10.30-12.45) (groups 1 and 2) or Thursday evenings (18.00-20.15) (group 3)*
7. Duration of the intervention	*12 consecutive weekly sessions; September to December (group 1) or April to July (groups 2 and 3; which ran concurrently).*

Intervention content	
8. Change mechanisms or theories of change	*Social cognition theory – aim to develop self-regulation skills and self-efficacy to promote long term behaviour change in line with WCRF recommendations for cancer survivors (**Chapter 1.5)***
9. Change techniques	*Self-efficacy: goal setting and review, enhance knowledge and understanding, learn from peers, develop skills, try new foods. Focus on moving forward and enhancing health, rather than weight loss to avoid possible negative consequences **(Chapter 2.9.5)**. Focus on adding in foods rather than avoiding foods; making small changes.* *Develop peer support: name badges, icebreaker activities, shared eating and drinking each week, shared meal, discussion time during breaks and within sessions, informal and responsive atmosphere, use of activities and prompts to stimulate discussion.*
10. Session content	*For outline of sessions see* **Table 5:7** *below. Each session had a standard session plan that was used with each group. Sessions were focused on application of content to a breast cancer survivor context.*
11. Sequencing of sessions	*There was a progression of session content. Sessions started with introduction and icebreaker, then covered: diet review: fruit and vegetables: food labels; drinks; wholegrains and fibre; proteins and fats; breakfast and snacks; lunches; evening meals; shared buffet meal; seasonal food and review.*
12. Participants' materials	*Handouts provided from World Cancer Research fund as available from www.wcrf-uk.org, such as "Eatwell during Cancer", "Healthy living after cancer", "Making sense of food and drink labelling", "Solely fish cookbook" and "Reducing your risk of breast cancer", also WCRF posters on red and processed meat and portion sizes.* *Also materials from NHS on Eatwell guide and 5-a-day, and British Nutrition Foundation resources on food labels, Healthy eating on a budget, Healthy eating out of the home and also diagrams of behaviour change cycle.*

13. Activities during the sessions	*Trying different physical activities; Pilates, Tai chi, cardiovascular gym equipment, using resistance apparatus/light weights, power walking, monitoring steps per day using a pedometer, goal setting and review.* *Healthy eating sessions; trying new healthy foods, bringing in photos of a meals eaten, reading food labels, weighing portions of fruit and vegetables, weighing out sugar in drinks, goal setting and review, reading food labels from home, sharing recipes, sharing a buffet meal (foods brought in by participants to share with group).*
14. Methods for checking fidelity of delivery	*The sessions were run by the same staff in the same facilities using the same programme and session plans. The doctoral candidate was present throughout most sessions to check informally for fidelity of delivery and met with other staff to review planning and delivery*
Participants	
15. Group composition	*The overall composition of the groups is reported in* ***Chapter 6.1.***
16. Methods for group allocation	*Participants were able to choose which of the 3 groups to join.*
17. Continuity of participants' group membership	*Members of group 1 mainly stayed in the same group, though one member swopped to group 2. Groups 2 and 3 ran concurrently; most group members only attended one group. A small number attended which ever session they were able to, especially where they returned to work and then swopped from daytime to evening sessions.*
18. Group size.	*The aim was to have 3 groups of maximum size of 15 due to restrictions of room size. The mean number in each group was 14.3; the evening group was smaller than each of the daytime groups (****Section 6.1****).*
Facilitators	
19. Number of facilitators	*The doctoral candidate ran most of the healthy eating sessions. An academic colleague who had previously been involved in delivering the original intervention ran some sessions when the doctoral researcher was not available.*

	The physical activity sessions were run by one member of the Wellbeing Centre staff assisted by part time staff members. Specialist facilitators were used to run some of the physical activity sessions such as Pilates and Tai chi.
20. Continuity of facilitators' group assignment	*The main facilitators ran each of the 3 groups.*
21. Facilitators professional background	*The doctoral candidate is an experienced University lecturer in nutrition, as is the academic colleague who ran some of the nutrition sessions. The physical activity sessions were run by the Operations Manager of the Wellbeing Centre who is a REPS (Register of Exercise Professional) qualified.*
22. Facilitators' personal characteristics	*The facilitators were of a similar age to the participants. The nutrition facilitators were both female, while the PA facilitator was male.*
23. Facilitators' training in intervention delivery	*Physical activity sessions- REPS qualified to run physical activity sessions.* *Nutrition sessions: Experienced HE lecturer with a teaching qualification and a Fellow of the HEA (Higher Education Academy)*
24. Facilitators training in group facilitation	*As above*
25. Facilitators' materials	*There were session plans for each week outlining topics, activities and resources.*
26. Intended facilitation style.	*Relaxed, informal and supportive style to encourage group interaction and peer support.*

Table 5:7 Main research study intervention session plan

Week No.	Physical activity	Healthy eating	Break with drink and snack to try
1	**Icebreaker**. Introduction to the programme and programme information sheet. In tables of 4. Name cards. Overview of research project. Reminder about info sheet and consent form. **Baseline testing**: Briefing on completion of food diaries. ***Activity over the next week****: complete a food diary*		Tea, digestive biscuits
2	**Fitness Suite Session 1:** Introduction and basic practical session. Using CV equipment. Pedometer review and goal setting	Collect in food diaries. Sit around large table in one group. **Review of current diet**: How do you feel about your diet? Who cooks and shops at home? What do you want to get out of the programme? Goal setting. Behaviour change cycle. Cancer prevention guidelines. Eatwell guide overview. ***Activity for next week:*** *Take a photograph of a plate of food you have eaten*	Tea and satsumas and grapes
3	**Negotiated Practical 1:** Pilates	Discuss food photographs and review Eatwell guide. **Fruit and Vegetables**. 5-a day leaflet. Review fruit & vegetable (F&V) intake yesterday. Pulses. Portion size and weighing activity. Ways to increase F&V intake. WCRF poster on F&V portions. Phytonutrients. Grapefruit and drugs. Soya and breast cancer. ***Activity over the next week:*** *collect labels from foods you have eaten to bring next week.*	Tea and oatcakes and hummus with salads, rainbow colours.
4	**Gym Session 2** Benefits of physical activity. What is Physical Activity? Setting Exercise Intensity. How much do we do? Individual Pedometer data? What can we do?	**Food labels**: Review of food labels to look for salt, sugar, fat, fibre, protein. Do you use labels to make food choices? How are you getting on? Salt guidelines. Review of goals. British Nutrition Foundation (BNF) labels handout. Scientific Advisory Committee on Nutrition (SACN) guidance on free sugars. ***Activity for next time: Collect*** *labels from drinks or drinks containers to bring next week.*	Tea and packets of healthier biscuits Apples and apple cutter

5	**Walking for health** and local walking groups. Walking Practical	**Drinks**: Sugar in drinks; hot drinks, fruit juices, fizzy drinks. Activity: weighing out sugars in different drinks. Caffeine. Fluid intake, alcohol guidelines and alcohol and calorie content of different drinks. Healthier drink suggestions. Alcohol and WCRF guidance. Artificial sweeteners ***Activity for next time***: Collect *wrappers from bread or pasta or cereal to bring in next time.*	Herbal teas, dark chocolate, walnuts, cashew nuts
6	**Gym session 3:** Using Resistance machines/light weights	**Whole grains and fibre**: benefits of fibre, whole grain foods such as pasta, rice, bread, flour, breakfast cereals, oats, nuts and seeds. Ways to increase fibre. SACN new fibre guidelines. Fibre and cholesterol. Plant stanols. Energy density. **Mid-intervention evaluation sheets**. Review of goals.	Tea and nuts and seeds. Falafel.
7	**Activity Review: How are we doing so far?** Motivation, barriers etc. Stages of behaviour change Short Gym session 4	**Protein and fats**: red and processed meat; benefits of fish, non-animal sources of protein, healthy cooking oils. WCRF poster on red meat. Dietary cholesterol and blood cholesterol. Calcium and vitamin D and bones. Fat soluble vitamins. WCRF guidance on cooking oils. Different types of milk; soya, rice, oat, almond milk tasting session. Low fat products. Portion size, Eatwell guide review. **Activity for next week:** Bring in breakfast recipe idea and/or cereal label.	Varied non-diary and soya yogurts and milks to try Nut butters, oak cakes bananas.
8	**Negotiated Practical** 2: Tai Chi	**Breakfast and snacks**: discussion of menu planning and menu suggestions; porridge, eggs, nut butters, healthy cereals and muesli comparison. Healthy breakfast ideas. Healthy snacks. Portion sizes poster WCRF. Hormone treatments and weight gain. Healthy weight loss. Fortified cereals: calcium and vitamin D **Activity**: bring in healthy lunch suggestions/ recipes	Tea and healthier cereal bars, seeds. 70%, 80% and 90% cocoa chocolate.
9	**Gym Session 5** and	**Lunches:** Discussion of recipes and menu suggestions. Soups; bought and	Tea and soups /salads to try.

	Review	homemade. Healthy packed lunches. Healthy sandwiches and healthy eating in cafes. Toppings for jacket potatoes. Hormone treatments and weight WCRF guidelines to reduce breast cancer risk. **Activity**: bring in healthy dinner suggestions.	
10	**Negotiated Practical** 3: Tai Chi, Pilates, walk etc	**Evening meals**: Discussion of recipes and menu suggestions. Healthy choices in restaurants and when entertaining. Healthy versions of family meals and ready meals. Satiety. Timing of meals and speed of eating. **Activity:** bring in healthy food for a shared lunch. Review of goals.	Tea and healthier carrot cake, berries and plain soya yogurt.
11	**Gym Session 6** Pedometer Review.	**Shared buffet meal**: Bring in healthy food and explain why you chose it. WCRF healthy living after cancer, health eating on a budget, healthy eating outside the home. ***Activity****: complete a food diary*	Frittata, mixed salad, healthy biscuits.
12	**Gym session**	Seasonal food advice from WCRF/ BNF. Goal review. Evaluation sheet. Repeat measures. Arrangements for 12-month follow up meeting. Summary of guidance from WCRF 2007 and WCRFI 2014. Goal review and goal maintenance.	Cup of tea and healthy cake

Chapter six: Quantitative analysis of main study data

6 Quantitative analysis of main study data

In this chapter, the data collected using the quantitative data collection tools (**Chapter 4.2)** are analysed and presented. This includes data on recruitment, demographic factors, self-efficacy ratings, anthropometric measures, blood pressure and heart rate, and dietary intake respectively. The quantitative and qualitative MYCaW data are presented together in **Chapter 7** below.

6.1 Main study: recruitment

Participants were recruited as discussed in **Chapter 4.2.1.2** above. 54 requests for further information were received from potential participants; of these, 80% (n=43) subsequently consented to join the study. There were 11 people who expressed interest in participating but did not proceed to join the study for a variety of reasons, including being unable to attend due to work and other commitments (n=3), already had a healthy lifestyle so may not benefit (n=3), programme too long (n=1), or no longer interested/no response (n=4). The recruitment of 43 in the current study was close to the target for recruitment of 45 (**Chapter 4.2.1.2**).

Amongst the 43 women who consented to join the study, a number (n=7) were still in the final stages of primary treatment and so did not initially meet the inclusion criteria at baseline testing. These participants still wished to participate in the lifestyle intervention and so they were included in it, although initially were not included in the research study. After each of these participants completed their treatment, consent for inclusion in the research study was requested again. Each of these participants gave their consent and their outcome data were only used from that point onwards, in line with ethical approvals (**Chapter 4.2.1.1**). A small number of participants withdrew from the programme (n=5, 11.6%) and therefore data was not obtained from them at T3 or T4. Those who withdrew from the study or were still in treatment at baseline were excluded from the quantitative analysis.

A year after the end of the intervention, all participants (n=43) were invited to follow up meetings; in total, 24 (55.8%) responded and attended the 12-month meeting in which long term data (T4) were collected. Those who did not attend the final meeting had data missing at T4 and were therefore excluded from quantitative analysis of follow up data. The treatment of missing data is further discussed in **Chapter 4.2.1.2**.

Demographic data were collected at recruitment and are reported in **Table** 6:1 The demographic **and social characteristics of the study participants**

below. The table summarises the demographic data for three groups of participants;

- **Overall group** (n=43): all participants
- **Quantitative analysis group** (n=31): participants who had completed treatment at baseline and did not withdraw during the intervention.
- **Follow up group** (n=20): participants in the quantitative analysis group who also provided data at follow up (T4)

Recruitment to the quantitative and qualitative arms of the study are summarised in **Figure 6:1** below.

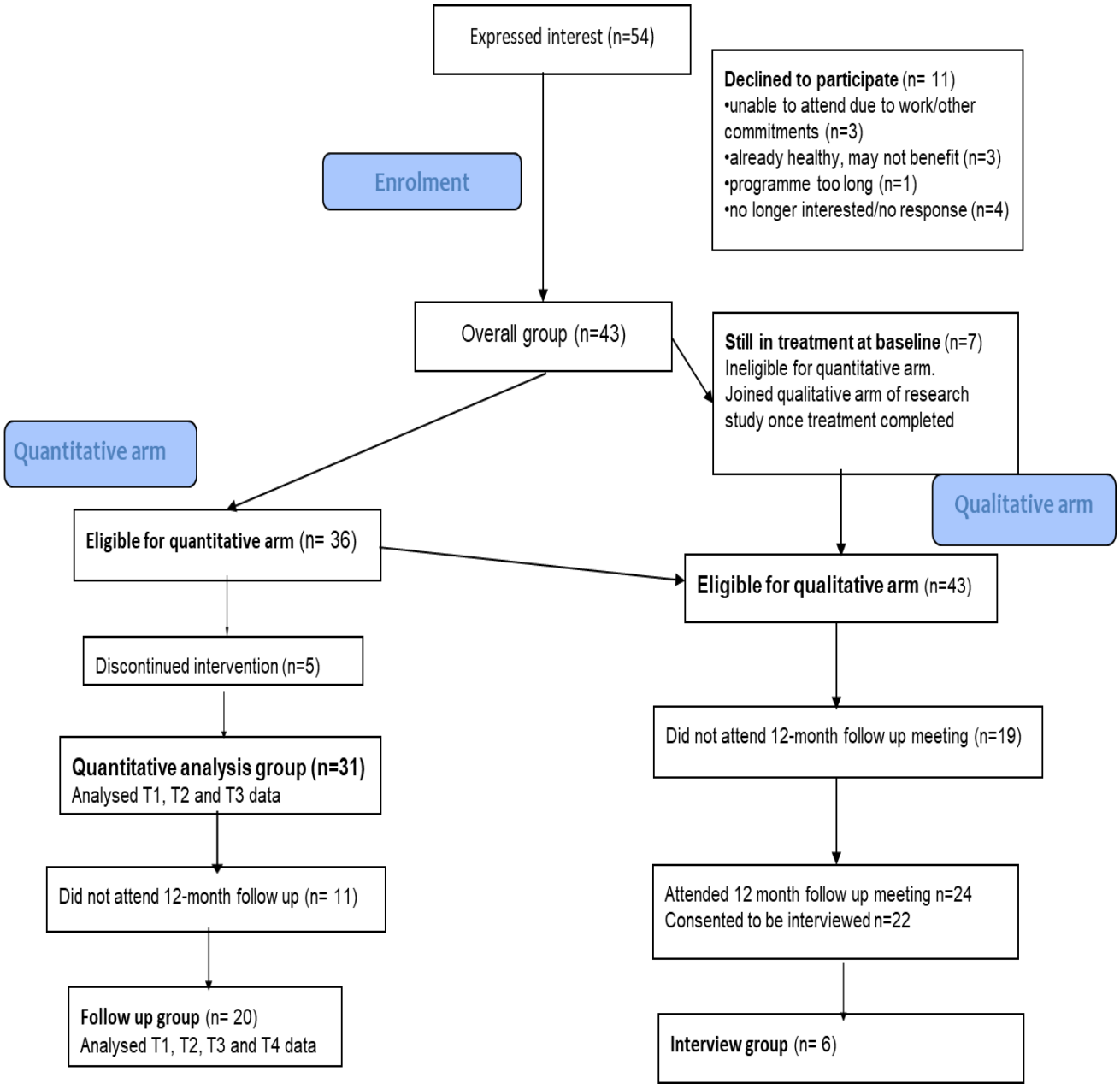

Figure 6:1 Flow chart of recruitment to qualitative and quantitative arms of the study

6.2 Main study: demographic data

A 2-tailed t-test comparison of baseline demographic data for those included in the quantitative analysis group (n=31) and the 12 participants who were excluded from it, either as they were still in treatment at baseline (n=7) or because they discontinued the intervention (n=5) (**Figure 6:1**). The t-test showed that there were no significant differences in the data, except for the time since

completion of treatment. This was not surprising as those still in treatment (n=7) were excluded on that basis. A second t-test was carried out to compare the demographic data for those included in the follow up group (n=20) with those in the quantitative analysis group who were excluded from it as they did not attend the 12-month follow up meeting (n=11) **(Figure 6:1)**. There were no significant differences in variables between those included and those who were excluded, which suggested that the data from those included might be generalisable to the wider patient population and that the missing data were missing at random.

The participants had a broad range of ages (from 25-69 years) and a majority were over 50 (**Table 6:1**). Members of the quantitative analysis group and the follow up group had very similar characteristics to the overall group. The overall group was not very diverse; most of the participants were ethnically white (overall 95.3%) and in general had a high level of education. Most of the participants did not live alone; most lived with one other person (44.2%). This might have affected the ability of participants to make dietary changes as meals may need to meet the needs of the entire household. However, most of the participants prepared the household meals (62.8%) and only 11.6% reported that meals were prepared by another household member suggesting that most participants would be able to influence their own food choices.

The participants in the overall group were very varied in the time that had elapsed since breast cancer diagnosis; the year of first diagnosis ranged from 2004 to 2016 (**Table 6:1**). In the overall group, the largest proportion (32.6%) had been diagnosed in 2016; recruitment for the programme occurred between March 2016 and April 2017 so these participants had been recently diagnosed. The quantitative group included a smaller proportion of people diagnosed in 2016 (22.6%) as several with recent diagnoses were still in treatment and therefore had been excluded from the quantitative analysis group. A few participants (14%) had been diagnosed more than 4 years previously. A few in this group had had a second more recent breast cancer diagnosis but had also completed primary treatment, although those receiving subsequent maintenance treatment were not excluded. Data was also collected on the time that had elapsed since primary treatment (excluding hormone treatment) was completed.

Table 6:1 The demographic and social characteristics of the study participants

		Overall group (n=43)	**Quantitative group** (n=31)	**Follow up group** (n=20)
Age: mean years (SD)		54.7 (9.95)	55.7 (9.68)	57.4 (9.68)
Range (years)		25-69	26-69	26-69
Ethnic group:	White	41 (95.3%)	30 (96.8%)	19 ((95%)
number (%)	Other	2 (4.7%)	1 (3.2%)	1 (5%)
Education:	No qualifications	3 (7.0%)	3 (9.7%)	2 (10%)
number (%)	GCSE level	8 (18.6%)	5 (16.1%)	4 (20%)
	A level	13 (30.2%)	11 (35.5%)	7 (35%)
	Degree	11 (25.6%)	7 (22.6%)	5 (25%)
	Postgraduate	8 (18.6%)	5 (16.1%)	2 (10%)
Other people in the household:	0	3 (7.0%)	3 (9.7%)	2 (10%)
	1	19 (44.2%)	14 (45.2%)	10 (50%)
number (%)	2	10 (23.3%)	8 (25.8%)	3 (15%)
	3	7 (16.3%)	4 (12.9%)	3 (15%)
	4	3 (7.0%)	2 (6.5%)	2 (10%)
	5	1 (2.3%)	0 (0.0%)	0 (10%)
Meal preparation:	Self	27 (62.8%)	21 (67.7%)	14 (70%)
	Other	5 (11.6%)	4 (12.9%)	2 (10%)
number (%)	Shared	11 (25.6%)	6 (19.4%)	4 (20%)
Year of diagnosis:	*Range*	2016-2004	2016-2004	2016-2007
	2016	14 (32.6%)	7 (22.6%)	5 (25%)
number (%)	2015	10 (23.3%)	9 (29.0%)	5 (25%)
	2014	8 (18.6%)	8 (25.8%)	5 (25%)
	2013	4 (9.3%)	2 (6.5%)	1 (5%)
	Before 2013	6 (14.0%)	5 (16.1%)	4 (20%)
	No answer	1 (2.3%)	0 (0.0%)	0 (0.0%)
Time since completion of treatment:	Ongoing	7 (16.3%)	0 (0.0%)	0 (0.0%)
	0-6 months	15 (34.9%)	13 (41.9%)	9 (45%)
	6-12 months	4 (9.3%)	4 (12.9%)	4 (20%)
number (%)	1-2 years	8 (18.6%)	7 (22.6%)	3 (15%)
	2-4 year	5 (11.6%)	4 (12.9%)	2 (10%)
	>4 years	4 (9.3%)	3 (9.7%)	2 (10%)
Primary treatment:	Radiotherapy	39 (90.7%)	27 (87.0%)	18 (90%)
	Chemotherapy	32 (74.4%)	22 (71.0%)	13 (65%)
number (%)	Surgery	42 (97.7%)	30 (96.8%)	19 (95%)
	Hormone	36 (83.7%)	26 (83.9%)	17 (85%)
Other medication:	**Total**	33(76.7%)	25 (80.6%)	15 (75%)
	BP medication	5 (11.6%)	4 (12.9%)	3 (15%)
number (%)	Glycaemic control	4 (9.3%)	3 (9.7%)	3 (15%)
	Cholesterol control	4 (9.3%)	4 (12.9%)	4 (20%)
	Bone health	4 (9.3%)	2 (6.5%)	2 (10%)
	Anti-depressants	8 (18.6%)	7 (22.6%)	3 (15%)
Other health factors:	**Total**	19 (44.2%)	13 (41.9%)	8 (40%)
	Diabetes Type I/II	5 (11.6%)	4 (12.9%)	4 (20%)
number (%)	Hypertension	3 (7.0%)	3 (9.7%)	3 (15%)
	Musculoskeletal	11 (25.6%)	9 (29.0%)	5 (25%)
	Tired/fatigue/anaemia	3 (7.0%)	3 (9.7%)	2 (10%)

The largest group had completed treatment within the previous 6 months (34.9%) and a small minority had completed treatment more than 4 years previously (9.3%). This intervention was intended for women who had completed primary treatment, so it was unexpected that at baseline testing 16.3% of potential participants were still in treatment but were keen to attend the intervention. There was interest in attending the lifestyle programme in those with a wide variety of timeframes since completion of primary treatment.

As part of their breast cancer treatment, most participants in the overall group had had surgery (97.7%) and radiotherapy (90.7%) while most had also had chemotherapy (74.4%) and hormone treatment (83.7%) (**Table 6:1**). Participants were also asked about other medication that they were taking, and other medical conditions that might affect their ability to make lifestyle changes; these data are unlikely to include all other medical diagnoses and are likely to be underestimates. However, 76.7% of the whole group reported taking other types of medication. Around a fifth of the participants were taking antidepressants (18.6%), while some were taking medication for bone health, or control of blood pressure, cholesterol, or glycaemia. 44.2% of the participants declared other health conditions. Amongst the medical conditions reported, a number had diabetes type I or II (11.6%) and about a quarter also had musculoskeletal problems that might impact on their ability to engage in physical activities (25.6%). Some participants appeared to have several different medical diagnoses in addition to breast cancer. These other diagnoses and medications may impact on the ability of participants to make lifestyle changes.

Retention of participants on the lifestyle intervention was good; of the 43 participants who joined the intervention, 88.4% (n=38) completed it and had data collected afterwards (T3) (**Table 6:2**) which suggests that it was regarded as beneficial by most. Only 5 participants (11.6%) withdrew from the programme; the reasons for their withdrawal are not known. There was also a high participation rate with a mean attendance of all 43 participants of 8.6/12 sessions (71.5%) again suggesting that the programme was of value. Attendance of those in the quantitative analysis group was higher than the overall group. There was a significant difference ($p<0.001$) between attendance of those in the quantitative analysis group and those who were excluded from it; this may have been as the overall group included those who withdrew part way through. Attendance was higher again in the follow up group (**Table 6:2**), but there was no significant difference in attendance between those in the follow up group and those who were excluded from it, suggesting that they were

comparable. Retention in the quantitative analysis group and follow up group was 100% and therefore higher than in the overall group, but this was to be expected as those who withdrew from the programme were excluded.

Table 6:2 Attendance and retention on the lifestyle intervention

	Overall group (n=43)	**Quantitative group** (n=31)	**Follow up group** (n=20)
Mean (SD) number of sessions attended°	8.6 (2.62)	9.5 (1.77)*	9.9 (1.52)
Mean (SD) attendance (%)	71.5 (22.44)	79.1 (14.75)*	82.5 (12.66)
Retention: number (%)	38 (88.4%)	31 (100%)	20 (100%)

*°Out of 12 intervention sessions, *indicates a significant difference compared to those excluded {p≤0.001)*

The protocol for data collection was discussed in **Chapter 4.2.1.3** above; intervention data collection occurred on the first and last days of the 12-week lifestyle intervention (T2 and T3) and so for the majority who attended these two sessions these data collection points were 11 weeks (77 days) apart. Where individual participants were unable to attend the final data collection session, this was arranged at a subsequent convenient date and resulted in a longer period between these data collection sessions. Therefore, the mean time period between T2 and T3 was around 12 weeks (**Table 6:3**).

Table 6:3 Mean time period (number of days) over which intervention and comparative data were collected

	Comparative data collection period (Days T2-T1)) Mean (SD)	**Intervention data collection period** (Days T3-T2) Mean (SD)
Overall group (n=43)	60.5 (27.68)	84.6 (20.29)*
Quantitative analysis group (n=31)	62.5 (27.10)	83.1 (18.44)*
Follow up group (n=20)	58.2 (29.34)	82.7 (19.54)*

**indicates a statistically significance between intervention and comparative data (p≤0.05) (T-test)*

Comparative data collection occurred at baseline (T1) and the first day on the intervention (T2). T1 data collection occurred during the baseline testing meeting and it was intended that it should be about 11 weeks (77 days) before the T2 data collection so that it would be comparable to the period between T2 and T3. The baseline testing was carried out during individual appointments once

potential participants had expressed an interest in joining the study. Recruitment continued until just before the intervention to maximise recruitment and so the timing of baseline data collection varied. However, t-test analysis showed that, in each case, the mean number of days between T1 and T2 was a significantly shorter period than between T2 and T3 (**Table 6:3**). As the comparative data was collected over a shorter mean period than the intervention data there was less time for outcome data to change. Therefore, the two sets of data may not have been entirely comparable, and this is a limitation of the study. There were no significant differences in the mean length of the data collection periods between the follow up group and those who were excluded from it suggesting that the follow up group was drawn from the same population as the quantitative analysis group.

6.3 Main study: self-efficacy ratings

Self-efficacy data from the quantitative analysis group were screened and corrected as outlined in **Chapter 4.2.1.4.** Self-efficacy profile scores were calculated for each participant at each time point as discussed in **Chapter 4.2.3**. One item of data was missing; one participant had left a single question unanswered (question 14 at T3) and the profile score in this case was the mean of the 14 remaining items**.**

The mean self-efficacy profile ratings of the quantitative analysis group before and during the intervention (T1, T2 and T3) are presented in **Table 6:4**. The data show that participants had a very wide range of scores at baseline; at T1 from 92.7 to 28.7 indicating a wide range of initial perceived self-efficacy for healthy eating. This range was wide at all time points suggesting a wide variation within the participant group. The mean profile scores show a small decrease in self-efficacy during the comparative period (T2-T1) before the intervention but show a larger increase in self-efficacy over the trial period (T3-T2), suggesting that perceived self-efficacy improved during the intervention.

As outlined in **Chapter 4.2.3,** a self-efficacy profile rating of 70 or above for individual participants may indicate that planned changes are more likely to be actioned. The number (and percentage) of participants at each time point meeting this cut-off are also reported in **Table 6:4**. The results show that the percentage of participants rating their overall self-efficacy as greater than 70 was 29% at baseline (T1) and this figure fell slightly to 23% at the start of the intervention (T2) but rose to 39%

at the end of the intervention. The results suggest that the intervention was associated with an increase in the proportion of participants whose perceived self-efficacy was likely to result in healthy eating action.

Table 6:4 Self-efficacy profile ratings before and during the intervention for the quantitative analysis group (n=30)

	Baseline (T1)	**Intervention start (T2)**	**Intervention end (T3)**
Range of self-efficacy profile scores	92.7-28.7	87.3-33.3	96.0-36.0
Mean (SD) self-efficacy profile score	57.4 (17.6)	56.9 (15.7)	67.3 (15.8)*
No. (%) participants with self-efficacy profile ≥ 70	9 (29%)	7 (23%)	12 (39%)
No. (%) participants with self-efficacy profile < 70	22 (71%)	24 (77%)	19 (61%)

(T1= Baseline before the intervention, T2= week 1 of intervention, T3= week 12 of intervention, SD= standard deviation.)

**indicates a statistically significance between mean self-efficacy profile at T3 and T2; and between T3 and T1 (p≤0.01)*

Inferential analysis was carried out to see if the apparent differences in the perceived self-efficacy profile scores over time were statistically significant. A one-way repeated measure ANOVA was conducted to investigate the apparent differences in self-efficacy profiles at T1, T2 and T3. The findings showed a statistically significant difference ($p < 0.01$) in the mean self-efficacy profile scores (Wilks' Lambda (λ) = 0.7, p=0.004). The effects size (partial eta squared (η^2)) was 0.32 indicating a large effect using the guidelines proposed by Cohen (1988). *Post-hoc* analysis indicated that there was a significant difference in mean self-efficacy profile ratings between the start (T2) and end (T3) of the intervention (p=0.003), and between baseline (T1) and the end of the intervention (T3) (p=0.008). Other differences were not significant (p>0.05). This identified that the significant change in self-efficacy occurred over the course of the intervention, while there were no significant changes during the comparative period (T2-T1). The comparison of comparative and intervention results in this quasi-experimental trial suggest that the improvement in perceived self-efficacy may have been due to intervention effects rather than other confounding factors.

The data presented above suggest that the intervention led to an improvement in self-efficacy over the period of the intervention. The data from the follow up group (n=20) were also analysed to see if the perceived self-efficacy profile changed following the intervention. The data for the follow up group at all 4 time points are reported in **Table 6:5** and **Figure 6:2**.

Table 6:5 Self-efficacy profile ratings over time for the follow-up group (n=20)

Self-efficacy profile scores	Baseline (T1)	Intervention start (T2)	Intervention end (T3)	Follow up (T4)
Mean (SD)	54.0 (18.7)	56.6 (15.7)	67.2 (14.4)*°	65.5 (16.7)
Number≥ 70 (%)	5 (25%)	5 (25%)	8 (40%)	11 (55%)
Number< 70 (%)	15 (75%)	15 (75%)	12 (60%)	9 (45%)

(T1= Baseline before the intervention, T2= week 1 of intervention, T3= week 12 of intervention, T4= 12 months post-intervention. SD= standard deviation.)

**indicates a statistically significant difference between self-efficacy profile at T3 and T2 (p≤0.05)*

° indicates a statistically significant difference between self-efficacy profile at T3 and T1 (p≤0.01)

The proportion of participants in the follow-up group rating their self-efficacy at 70 or above increased from 40% to 55% between the end of the intervention (T3) and the 12-month data collection (T4) suggesting that, for some at least, self-efficacy continued to improve after the end of the intervention. The data also showed that the mean self-efficacy slightly decreased in the 12-month period after the intervention. Inferential analysis was carried out to see if the apparent changes in mean self-efficacy profiles were statistically significant **(Appendix 2.5**).

A one-way repeated measures ANOVA was carried out (**Chapter 4.2.3**) to see if the apparent changes in mean self-efficacy profiles over time were statistically significant. This second analysis also showed a significant difference over time (Wilks' Lambda (λ)= 0.569, p=0.02) and a large effect size (partial eta squared (η^2) = 0.431) which were similar to the initial analysis of data for the larger quantitative analysis group as described above. *Post-hoc* analyses of this smaller follow up group also showed some similar findings; there was a significant difference in self-efficacy profile ratings over the intervention period (T3-T2) and between baseline and the end of the intervention (T3-T1). There were no other significant differences. There were no significant differences over the comparative period (T2-T1) suggesting that improved mean self-efficacy may have been maintained over the 12 months following the intervention end (T4-T3). However, there were also no significant

differences between baseline (T1) and the 12-month follow up (T4), or between the intervention start (T2) and the 12 month follow up (T4) so the overall impacts were unclear.

Figure 6:2 Changes in self-efficacy rating over time for the follow up group (n=20)

T1= Baseline before the intervention, T2= week 1 of intervention, T3= week 12 of intervention, T4= 12 months post-intervention

**indicates a statistically significant difference between self-efficacy profile at T3 and T2 (p≤0.05)*

° indicates a statistically significant difference between self-efficacy profile at T3 and T1 (p≤0.01)

The quantitative data discussed in this section indicated that the intervention may have led to an increase in mean perceived self-efficacy, which may have been maintained over the following 12-month period. The data also suggest that the proportion of participants with a perceived self-efficacy that is likely to be associated with behaviour change increased during the intervention and continued to increase over the follow up period.

6.4 Main study: physical health measures

6.4.1 Main study anthropometric data

Anthropometric data from the quantitative analysis group were screened and corrected as outlined in **Chapter 4.2.1.4.** The data were analysed as discussed in **Chapter 4.2.4.1.**

The mean and standard deviation for weight, height, BMI, waist circumference, hip circumference and waist to hip ratio at baseline, and at the start and end of the intervention (T1, T2 and T3) in the larger quantitative analysis group are presented in **Table 6:6**. At baseline, most participants were overweight or obese (77%); just under a third (29%) were in the obese category, with fewer (22.6%) having a BMI within the healthy range. The data show that mean weight and BMI were very similar at baseline (T1) and the intervention start (T2); that was a small decrease in mean weight over the comparative period of 0.3% (0.2 Kg) but there appears to be a larger decrease in mean weight of about 1.4% (1.1Kg) between the start and end of the intervention (T2 and T3). There also appeared to be small improvements in the proportion of people with a healthy BMI at the end of the intervention (T3). The percentage of those with a BMI in the healthy range was maintained over the comparative period but increased from 22.1% to 25.8% over the intervention period supporting the view that some weight loss had occurred.

A one-way repeated measures ANOVA was conducted to compare mean participant weight before and during the intervention (T1, T2 and T3) in the quantitative analysis group (**Table 6:6** and **Appendix 2.6**). This showed that there was a significant effect for time (Wilks' Lambda (λ) = 0.657, p=0.02). The partial eta squared (η^2) was 0.343 indicating a large effect (Cohen, 1988). P*ost-hoc* analysis showed that the significant difference was between the start and end of the intervention (T3-T2) and between baseline and the end of the intervention (T3-T1), with no significant difference over the comparative period (T2-T1). Therefore, the observed decrease in mean weight was likely to be due to the impact of the intervention.

Table 6:6 Anthropometric measures before and during the intervention for the quantitative analysis group (n=31).

	Baseline (T1)	Intervention start (T2)	Intervention end (T3)
Mean Weight (Kg) (SD)	76.5 (13.7)	76.3 (13.4)	75.2 (13.7)*°
Mean Height (m) (SD)	1.635 (0.07)	1.639 (0.07)	1.636 (0.07)
Mean BMI (SD)	28.7 (5.2)	28.4 (5.0)	28.1 (4.9)°[a]
Number (%): *Healthy weight*	7 (22.6%)	7 (22.1%)	8 (25.8%)
Overweight	15 (48.4%)	15 (48.4%)	13 (41.9%)
Obese	9 (29.0%)	9 (29.1%)	10 (32.3%)
Mean waist circumference (cm) (SD)	90.6 (9.2)	90.6 (9.9)	89.8 (10.0)
Mean hip circumference (cm) (SD)	108.4 (10.2)	108.4 (10.0)	106.8 (11.7)
Mean waist to hip ratio (WHR) (SD)	0.84 (0.06)	0.84 (0.06)	0.84 (0.05)
Number (%) with; *Waist < 80cm*	5 (16.1%)	5 (16.1%)	6 (19.4%)
Waist 80-88cm	3 (9.7%)	8 (25.8%)	5 (16.1%)
Waist> 88cm	23 (74.2%)	18 (58.1%)	20 (64.5%)
WHR≤ 0.85	17 (54.8%)	17 (54.8%)	15 (48.4%)

T1= Baseline before the intervention, T2= week 1 of intervention, T3= week 12 of intervention, T4= 12 months post-intervention. SD= standard deviation, BMI= Body Mass Index.

°*indicates a statistically significant difference between T3 and T1 (p≤0.01)*

**indicates a statistically significant difference between T3 and T2 (p≤0.01)*

[a]*indicates a statistically significant difference between T3 and T2 (p≤0.05)*

Anthropometric data for the smaller follow up group (n=20) are presented in **Table 6:7**. The data showed a 2% weight loss over the intervention period compared to a 0.4% weight gain over the comparative period, again suggesting that the intervention was associated with weight loss. A further one-way repeated measures ANOVA was carried out to compare mean weight across all four time points to investigate longer term effects. This again showed a significant difference over time (Wilks' Lambda (λ) = 0.423, p = 0.002) and the partial eta squared (η^2) suggested a large effect (0.577). *Post-hoc* analysis again showed a statistically significant difference between the start and end of the intervention (T2 and T3) (p=0.002), with no significant difference over the comparative period (T1 and T2) or over the 12-month period following the intervention (T3 and T4) suggesting that weight loss was maintained. However, as there were also no statistically significant differences between mean weight at baseline and follow up (T1 and T4) or between intervention start and follow up (T2 and T4) this was more difficult to interpret. However, the data also show an increase

from 25% to 35% in the percentage of participants with a BMI within the healthy weight range between the end of the intervention and follow up, supporting the view that weight loss continued after the end of the intervention.

Table 6:7 Anthropometric measures over time for the follow up group (n=20)

	Baseline (T1)	Intervention start (T2)	Intervention end (T3)	Follow up (T4)
Mean Weight (Kg) (SD)	75.1 (13.9)	75.4 (14.0)	73.9 (13.9)*	73.6 (13.4)
Mean Height (M) (SD)	1.6295 (0.08)	1.6322 (0.07)	1.6275 (0.07)	1.6272 (0.07)
Mean BMI (SD)	28.3 (4.6)	28.3 (4.7)	27.9 (4.5) [a]	27.8 (4.8)
Number (%); *Healthy weight*	5 (25.0%)	5 (25.0%)	5 (25.0%)	7 (35.0%)
Overweight	10 (50.0%)	9 (45.0%)	9 (45.0%)	7 (35.0%)
Obese	5 (25.0%)	6 (30.0%)	6 (30.0%)	6 (30.0%)
Mean waist circumference (cm) (SD)	91.0 (10.4)	91.5 (11.1)	90.4 (1.7)	90.2 (12.3)
Mean hip circumference (cm) (SD)	107.6 (9.4)	107.7 (9.7)	106.2 (11.5)	106.3 (10.6)
Mean waist to hip ratio (WHR) (SD)	0.84 (0.06)	0.85 (0.07)	0.85 (0.05)	0.85 (0.07)
Number (%) with: *Waist < 80cm*	3 (15.0%)	3 (15.0%)	4 (20.0%)	4 (20.0%)
Waist 80-88cm	3 (15.0%)	5 (25.0%)	4 (20.0%)	7 (35.0%)
Waist> 88cm	14 (70.0%)	12 (60.0%)	12 (60.0%)	9 (45.0%)
WHR< 0.85	10 (50.0%)	9 (45.0%)	9 (45.0%)	12 (60.0%)

SD Standard Deviation, BMI body mass index (T1= Baseline before the intervention, T2= week 1 of intervention, T3= week 12 of intervention, T4= 12 months post-intervention. SD= standard deviation.)

**indicates a statistically significant difference between T3 and T2 (p≤0.01)*

[a]indicates a statistically significant difference between T3 and T2 (p≤0.05)

A one-way repeated measures ANOVA was conducted to compare mean BMI across the comparative and intervention periods using data from the quantitative analysis group (T1, T2 and T3) (**Table 6:6**). This showed that there was a significant effect for time (Wilks' Lambda (λ) =0.706, p=0.006) with a large effect size (partial eta squared (η^2) = 0.294). *Post-hoc* analyses showed that the difference in mean BMI was between the start and end of the intervention (T3-T2) and between baseline and the intervention end (T3-T1), while there was no significant difference over the comparative period (T2-T1). Therefore, the observed decrease in mean BMI was likely to be due to the impact of the intervention.

The long-term impacts of the intervention on mean BMI were also investigated by conducting a one-way repeated measures ANOVA over all 4-time points using data from the follow up group (n=20) (**Table 6:7**). This again showed a significant difference (Wilks' Lambda (λ)=0.631, p=0.045) with a

large effect size (partial eta squared (η^2) = 0.369). *Post-hoc* analysis confirmed that there was a statistically significant difference between the start and end of the intervention (T3-T2) (p=0.05) and no significant difference over the comparative period (T2-T1). The data seem to show that the reduction in mean bodyweight was maintained over the follow up period (T4-T3), and this was also suggested as there were no significant differences in the data over this period. However, there were also no significant differences in mean BMI between baseline and follow up (T4-T1) or between intervention start and follow up (T4-T2) making this more difficult to interpret. The comparative and trial data for the quantitative analysis group provide some evidence that the intervention was associated with a reduction in mean weight and BMI and follow up data suggest that this may have been maintained over 12 months.

The mean waist circumference at all time points was above the target of 88 cm (**Chapter 4.2.4.1**). At baseline, within the quantitative analysis group, a minority of participants (16.1%) had a healthy waist circumference (< 80 cm), while the majority had a waist circumference over 88cm (74.2%). Mean waist circumference did not appear to change over the comparative period (T1-T2) while there was a small apparent decrease over the intervention period (T2-T3). This pattern was also apparent with the follow up group which also appeared to show that the decrease in mean waist circumference was maintained over the follow up period. However, none of these differences were statistically significant (**Appendix 2.6).** There was a small increase in the proportion of participants with a healthy waist circumference at the end of the intervention (T3), although the proportion with a waist circumference over 88 cm also decreased over the comparative period and increased again over the intervention period so this did not appear to be an intervention effect. There was also a small decrease in mean hip circumference over the intervention period compared to the comparative period which appeared to be maintained over the follow up period (**Table 6:7**) although again these were not found to be significant (**Appendix 2.6**)**.**

In this study, a healthy waist to hip ratio (WHR) was taken to be less than 0.85 (**Chapter 4.2.4.1**). By this criterion, at baseline just over half of the participants had a healthy WHR and this was unchanged at T2 in the quantitative analysis group (**Table 6:6**). There were no statistically significant differences in WHR at T1, T2 and T3 in the quantitative group or at T1, T2, T3 and T4 in the follow up group (**Appendix 2.6**) although there was a small increase in the number and percentage of

participants with a healthy WHR in the follow up period (T4-T3). This study does not provide evidence of any effects of the intervention on waist or hip circumference or WHR.

6.4.2 Main study: blood pressure and heart rate

In the quantitative analysis group, the mean systolic blood pressure (SBP) appeared to show a significant decrease over the intervention period: however, it also showed a significant increase over the comparative period and no significant difference between baseline and intervention end**.** In the follow up group, there was no significant difference in mean SBP over the intervention or comparative periods, though there was a significant difference in mean SBP between the start of the intervention and the 12-month follow up (**Appendix 2.7).** Therefore the data on SBP were difficult to interpret.

The data provided no evidence of any change in mean DBP in the quantitative analysis group over the intervention period. In the follow up group, there was a significant decrease in mean diastolic blood pressure during the intervention, and between the start of the intervention and the follow up and following the intervention. There was no significant difference in mean DBP during the comparative period. This contrasted with the results in the quantitative analysis group discussed above. The data on mean DBP were therefore difficult to interpret. The results also showed no significant differences in the mean heart rate (HR) over time in the quantitative analysis group or the follow up group (**Appendix 2.7)**.

The results discussed above were all based on mean values obtained from the groups. Any changes in cardiovascular parameters were also considered in terms of effects on individual participants. Therefore, the data were also analysed to determine the number and percentage of participants with DBP and SBP below 90/140 mmHg at each time point. The findings for the quantitative analysis group show that most participants (87%) had an SBP below 140 mmHg at baseline and this was maintained after the intervention. In the follow up group there appeared to be an increase in those with a SBP below 140 mmHg from 80% to 90% across the intervention and this was maintained at follow up. In the quantitative analysis group, a lower proportion of participants had a healthy DBP at baseline (67%). These data suggest that the proportion of people with a healthy DBP appeared to rise over the course of the programme (to 80%). This trend is also seen in the data for the follow-

up group; the proportion of participants with a healthy DBP appeared to rise over the intervention period and be maintained over the subsequent 12 months **(Appendix 2.7)**.

6.5 Main study: dietary intake

Food intake data were collected at the different time points as discussed in **Chapter 4.2.1.3**. In all cases, the raw data were screened and corrected, and normality testing was carried out as outlined in **Chapter 4.2.1.4.**

A total of 22 members of the quantitative analysis group provided food diary data at baseline (T1), intervention start (T2) and end (T3) and their data were used to investigate short term change in mean daily nutrient intake during the intervention compared to the control period before the intervention. The results are presented in **Table 6:8**.

The data for mean daily nutrient intake appear to show a reduced mean daily intake of energy (227.4 Kcal or 12.9% decrease) and several nutrients across the trial period (T3-T2) compared to the comparative period (T2-T1). There appeared to be a decrease in mean daily intake of most nutrients across the intervention period, except for vitamin C, fibre and cholesterol which appeared to show a modest increase. These apparent differences between the 3 time points were investigated further by inferential analysis using a one-way repeated measure ANOVA (**Chapter 4.2.5**) and the findings are also reported in **Table 6:8** and in **Appendix 2.8**.

The results show that there was a significant effect for time in mean daily intake of energy, carbohydrate, starch, GL and sodium. In each case the partial eta squared (η^2) was greater than 0.14 indicating a large effect size (Cohen, 1988). *Post-hoc* analyses of these data showed that in each case there was a statistically significant difference in the data between the start and end of the intervention (T3-T2) while there was no significant difference over the comparison period (T2-T1) (**Appendix 2.8**). This suggests that there was a reduction in mean daily intake of these nutrients associated with the intervention, although there was no significant change overall in each case between baseline and the end of the intervention (T3-T1), making this harder to interpret. However, normality testing showed that the data for mean starch intake at the intervention start (T2) and mean intake of sodium at baseline (T1) were not normally distributed and therefore the data for these nutrients may not have met the assumptions for parametric testing (Pallant, 2013). Therefore,

inferential analyses of the data for mean daily intake of starch and sodium were repeated using the non-parametric Friedman test as discussed in **Chapter 4.2.5**.

Table 6:8 Mean (SD) daily intake of key nutrients before and during the intervention for the quantitative analysis group (n=22)

Mean (SD) daily intake of key nutrients	Baseline (T1)	Intervention start (T2)	Intervention end (T3)
Energy (Kcal/d)	1593.3 (448.5)	1655.1 (383.4)	1430.1 (360.5)*
Carbohydrate (g/d)	172.2 (64.7)	184.0 (53.3)	155.6 (45.5)**
Starch (g/d)	92.9 (31.3)	100.9 (29.4)	84.8 (26.9)®
Sugars (g/d)	76.7 (38.4)	80.7 (36.9)	69.4 (26.8)
Free sugar (g/d)	25.3 (17.5)	27.7 (21.0)	18.6 (13.7)
Sucrose (g/d)	20.5 (12.7)	21.5 (15.2)	16.4 (10.1)
Glycaemic load (GL)	84.3 (36.2)	88.6 (29.7)	71.4 (24.5)**
Protein (g/d)	73.9 (17.1)	74.1 (16.1)	70.2 (13.4)
Total fat (g/d)	63.1 (19.5)	63.3 (18.2)	54.5 (21.7)
Saturated fat (g/d)	22.1 (9.2)	23.3 (9.4)	18.5 (9.0)
Cholesterol (mg/d)	257.0 (98.8)	256.8 (89.3)	259.7 (132.5)
Fibre (g/d) [a]	20.1 (6.4)	19.9 (4.9)	20.2 (6.5)
Vitamin C (mg/d)	96.5 (45.5)	92.0 (32.0)	106.0 (49.5)
Sodium (mg/d)	1748.8 (642.8)	1872.1 (588.6)	1524.1 (497.2)®
Alcohol (g/d)	5.9 (7.3)	7.6 (10.2)	5.2 (8.0)

T1= Baseline before the intervention, T2= week 1 of intervention, T3= week 12 of intervention. SD= standard deviation. [a] Determined by Association of Analytical Chemists (AOAC) method

**indicates a statistically significant difference between T3 and T2 (p≤0.05) (ANOVA)*

***indicates a statistically significant difference between T3 and T2 (p≤0.01) (ANOVA)*

®Indicates a statistically significant difference between T3 and T2 (p≤0.05) by parametric, but not by non-parametric, testing

The Friedman test results indicated that the data did not quite show a significant difference in mean daily intake of starch (p=0.057) or of sodium (p=0.094) over time, although as the data approached significance this may indicate a tendency towards a reduced intake. In contrast to the results from parametric analysis, these results do not confirm that a change in mean daily sodium or starch intake

occurred over the course of the intervention, suggesting that the only significant changes in mean daily intake over the intervention period were decreases in energy, carbohydrate and GL.

Table 6:9 Mean (SD) daily intake of key nutrients over time for the follow up group (n=10)

Mean (SD) daily intake of key nutrients	Baseline (T1)	Intervention start (T2)	Intervention end (T3)	Follow up (T4)
Energy (Kcal/d)	1764.4 (427.3)	1763.9 (422.2)	1536.5 (387.7)	1447.4 (377.0)*
Carbohydrate (g/d)	201.3 (67.5)	198.0 (65.6)	160.2 (47.8)®°	163.9 (53.6)*
Starch (g/d)	105.1 (32.5)	100.4 (25.9)	83.2 (24.4)°	88.4 (27.8)
Sugars (g/d)	93.1 (39.0)	94.5 (44.5)	75.3 (29.4)	74.5 (32.1)
Free sugar (g/d)	30.5 (18.0)	37.7 (25.7)	19.2 (16.5)	19.7 (9.6)
Sucrose (g/d)	26.4 (15.1)	27.9 (19.2)	19.5 (12.1)	19.9 (13.0)
Glycaemic load (GL)	98.9 (37.9)	101.2 (33.2)	76.8 (27.0)®	77.0 (28.8)*
Protein (g/d)	76.5 (13.2)	78.3 (12.7)	74.5 (16.9)	65.6 (15.1)
Total fat (g/d)	68.0 (19.2)	66.4 (20.8)	64.3 (25.4)	56.7 (18.1)
Saturated fat (g/d)	24.6 (7.8)	26.1 (11.1)	23.4 (10.1)	19.7 (7.3)
Cholesterol (mg/d)	242.6 (56.4)	261.2 (60.4)	289.5 (150.4)	207.0 (107.9)
Fibre (g/d) [a]	22.0 (6.7)	20.3 (5.6)	21.2 (6.6)	21.5 (7.8)
Vitamin C (mg/d)	96.0 (34.4)	90.2 (36.6)	117.3 (45.4)	97.7 (39.2)
Sodium Na (mg/d)	1702.2 (523.2)	1897.3 (512.7)	1628.6 (431.0)	1459.7 (451.5)
Alcohol (g/d)	5.9 (7.0)	8.8 (12.3)	2.8 (3.0)	2.8 (4.9)

T1= Baseline before the intervention, T2= week 1 of intervention, T3= week 12 of intervention, T4= 12 months post-intervention. SD= standard deviation. [a] Determined by Association of Analytical Chemists (AOAC) method.

**indicates a statistically significant difference between T4 and T2 (p≤0.05)*

® indicates a statistically significant difference between T3 and T2 (p≤0.05)

° indicates a statistically significant difference between T3 and T1 (p≤0.05)

All members of the follow up group (n=20) were invited to complete food diaries after 12 months (T4). However, only 10 of these participants provided a complete set of food diaries at all four time points for analysis of longer-term nutritional change (**Chapter 4.2.5**). The mean daily intake and

standard deviation of key nutrients at each time point for these members of the follow up group are presented in **Table 6:9**.

Table 6:9 shows that changes in mean intake were greater during the intervention than the comparative period in all cases. In most cases there was a decrease in intake, except for vitamin C, fibre and cholesterol which showed an increase as was seen in the quantitative analysis group. However, the observed differences over time were not statistically significant in any cases except for energy, carbohydrate, starch and glycaemic load. The data sets for these nutrients were normally distributed at all time points for the follow up group (**Appendix 2.8)** and so parametric testing was deemed appropriate (**Chapter 4.2.5**). The data were analysed using a one-way repeated measure ANOVA (**Chapter 4.2.5**) For each of these nutrients , the partial eta squared (η^2) statistic was greater than 0.014 indicating a large effect size (Cohen, 1988). *Post-hoc* analyses were carried out for those nutrients where there was a statistically significant difference in mean intake over time to determine at which time points these differences had occurred. These findings are also reported in **Table 6:9** and in **Appendix 2.8**. The *post-hoc* tests indicated that there were no significant differences in mean intake between baseline (T1) and the start of the intervention (T2) for any of these nutrients indicating that there were no significant changes in mean daily intake during the comparative period. Neither were there any significant differences in mean daily intake between the end of the intervention (T3) and the 12-month follow up (T4) suggesting that there was no evidence of change in mean dietary intake during the post-intervention period.

The data from the follow up group suggested a significant change in daily mean carbohydrate intake between the start and end of the intervention (T3-T2). Comparing this to carbohydrate intake over the comparative period (T2-T1) suggests that reported intake of carbohydrate had reduced in response to the intervention; this is in line with findings for the larger quantitative group reported above in **Table 6:8**. Also, in line with the findings with the larger quantitative group, there was a significant decrease in mean daily GL between the start and end of the intervention. In addition, the data show a significant decrease in mean daily GL between the start of the intervention (T2) and the 12-month follow up (T4) suggesting that the change in GL was sustained. Interestingly, for two other parameters (energy and carbohydrate) a significant difference in mean daily intake was also seen between the start of the intervention (T2) and the long- term follow-up (T4). For energy this

significant difference was found after 12 months, even though it was not seen between the start and end of the intervention and so only occurred over the longer follow up period.

A significant difference in mean intake of starch in the follow up group occurred (**Table 6:9**). *Post-hoc* analysis showed that this occurred between baseline (T1) and the end of the intervention (T3). Without comparative data it is unclear whether this change in mean starch intake was in response to the intervention. The change also did not appear to be maintained as there was no significant difference in starch intake between any other time points. This result contrasts with the findings from the larger quantitative analysis group discussed above, which found that there were no significant differences in mean daily starch intake when the data was analysed using non-parametric methods as one data set was not normally distributed.

Table 6:10 The contribution of carbohydrate, free sugars, total fat and saturated fat to mean daily energy intake over time for the quantitative subgroup (n=22)

Macronutrient intake as % of mean daily energy intake	**Baseline (T1)**	**Intervention start (T2)**	**Intervention end (T3)**	**DRVs as % of energy intake**
Carbohydrate (%)	39.9	41.4	40.8	**50%***
Carbohydrate and fibre (%)	42.5	43.9	43.7	
Free sugars (%)	5.5	5.9	4.7	**≤ 5%**
Total fat (%)	35.7	34.5	33.6	**≤35%**
Saturated fat (%)	12.3	12.5	11.3	**≤11%**

T1= Baseline before the intervention, T2= week 1 of intervention, T3= week 12 of intervention

DRV- Dietary Reference Values (British Nutrition Foundation, 2019)

** recommended intake of carbohydrate including all starch, sugars and dietary fibre.*

The contributions of selected macronutrients to the mean energy intake at each time point were calculated for the quantitative group (n=22) and the follow up group (n=10) and are presented in comparison with recommended levels of intake (British Nutrition Foundation, 2019) in **Table 6:10** and **Table 6:11** respectively. There were no significant differences between the mean contribution of these macronutrients to energy intake over time. The mean daily carbohydrate and fibre intake was below recommendations at all time points. The mean daily intake of free sugars only met the recommendation at intervention end (T3), though at baseline 54.5% (n=12) already reported a

personal mean daily intake of free sugar below 5%, which rose to 63.6% (n=14) at the end of the intervention. The mean daily intakes of saturated fat were above the recommendations at all time points. The mean daily intake of total fat did not meet the recommendations at baseline in the quantitative group, or at intervention end or after 12-months in the follow up group. These data suggest that further nutritional improvement might be beneficial to participants.

Table 6:11 The contribution of carbohydrate, free sugars, total fat and saturated fat to mean daily energy intake over time for the follow up group (n=10)

Macronutrient intake as % of mean daily energy intake	Baseline (T1)	Intervention start (T2)	Intervention end (T3)	Follow up (T4)	DRVs as % of energy intake
Carbohydrate (%)	42.1	41.5	39.3	40.1	**50%***
Carbohydrate and fibre (%)	44.6	43.8	42.1	43.1	
Free sugars (%)	6.2	7.4	4.4	4.8	**≤ 5%**
Total fat (%)	34.8	34.0	36.7	33.2	**≤35%**
Saturated fat (%)	12.6	13.2	13.2	11.5	**≤11%**

T1= Baseline before the intervention, T2= week 1 of intervention, T3= week 12 of intervention, T4=12 months after the intervention end.

DRV- Dietary Reference Values (British Nutrition Foundation, 2019)

** recommended intake of carbohydrate including all starch, sugars and dietary fibre.*

The food diary data suggest that the intervention was associated with nutritional change, in particular a reduced intake of energy, carbohydrate and a reduced glycaemic load. These reductions were also apparent 12 months after the intervention and therefore seem to have been maintained in the long term. These reductions suggest that the intervention may have had some impact on the nutritional intake of participants. However, the data on macronutrient contributions to energy intake of the group, suggest that further changes would be required for the group to meet nutritional recommendations.

6.6 Summary

The intervention had good recruitment, attendance and retention which suggested that it addressed some needs amongst participants. It was associated with a statistically significant

improvement in mean perceived self-efficacy for healthy eating and small significant mean reductions in body weight and BMI, and a reduction in mean daily intake of energy, carbohydrate and a reduced glycaemic load.

There was no evidence of changes in mean ratings of perceived self-efficacy or in weight, BMI or in intake of energy, carbohydrate or GL over the 12-month period after the intervention. This may suggest that improvements were maintained over this longer-term period, or at least it does not provide evidence of relapse. Surprisingly, the proportion of participants with a high self-efficacy for healthy eating increased over the subsequent 12-months in the follow up group.

Quantitative data collection provided evidence that the intervention had an impact on some aspects of health and wellbeing of participants. It was not able to provide evidence to suggest which aspects of the intervention enhanced or inhibited the outcome effects. Changes in outcomes occurred for some participants but not others and it is not clear which groups of participants might have benefitted more. This was explored by the qualitative arm of the study and the findings of this are reported in the next chapter.

Chapter seven: Analysis of main study MYCaW and qualitative data

7 Analysis of main study MYCaW and qualitative data

7.1 Concerns and wellbeing

7.1.1 Initial concerns and problems

At baseline (T1), participants completed an initial MYCaW form on which they identified one or two current concerns or problems in their own words (**Chapter 4.2.6**). The qualitative data from these forms were analysed using the analysis guideline for MYCaW (Polley *et al.*, 2007; Jolliffe *et al.*, 2015) as discussed in **Chapter 4.1.2.5**. Data from seven participants were not included as they were still in treatment at baseline and their data was therefore excluded in line with ethical approvals (**Chapter 4.2.1.1**). Data are reported below from the remaining 36 (84%) participants; this includes five participants who did not complete the programme. Most participants identified two concerns, although two participants identified just one. One of these subsequently identified a second concern at the start of the programme (T2) and this concern was therefore also included in the analysis. The qualitative data from both concerns from each participant were analysed together and the numbers of comments in each category are presented in **Table 7:1**.

The problems and concerns were identified by participants individually at baseline and are likely to represent their main reasons for joining the lifestyle programme. The participants had previously received the Participant Information Sheet (**Appendix 2.2.2**) and had had an opportunity to ask questions before consenting to join the study. They were therefore aware of the aim of the programme before completing the MYCaW form. As in the feasibility study (**Chapter 5.2.2.1**) the concerns raised fell into four key themes; psychological and emotional concerns; physical concerns; hospital cancer treatment concerns and concerns about wellbeing. The Framework also included an additional category of 'Practical concerns', but none of the participants raised concerns relevant to this and so this theme was not included in this study. The concerns raised under these headings will be discussed below.

Table 7:1 Summary of categories of concerns and problems identified at baseline

MYCaW Concerns and Problems: Super-categories°	% (number) of participants with concerns in each super-category* (n=36)	MYCaW: Breakdown of super-categories°	Number of concerns identified in each sub-category**
S1 Psychological and emotional concerns	41.7 % (15)	S1.b Body image concerns	2
		S1.e Emotional problems	2
		S1.g Fear and anxiety	2
		S1.k Stress and tension	1
		S1.l Support	11
S2 Physical concerns	61.1% (22)	S2.a Hot flushes and night sweats	1
		S2.c Pains/aches	2
		S2.d Physical problems not related to cancer	3
		S2.e Poor energy levels	1
		S2.f Cancer recurrence	8
		S2.h Weight change	13
S3 Hospital cancer treatment concerns	16.7% (6)	S3.c Side effects of hormonal treatment	2
		S3.d Side effects of surgery	4
S4 Concerns about Wellbeing	88.9% (32)	S4.a Exercise	25
		S4.g General wellbeing	6
		S4.e Nutrition	22

**Participants each identified 2 concerns. **individual concerns may be included in more than 1 super-category or subcategory. Other subcategories are not included as no relevant concerns were identified. °Using framework produced by Polley et al. (2007) and* Jolliffe *et al.* (2015).

7.1.1.1 Psychological and emotional concerns

Psychological or emotional concerns were identified by 41.7% of participants (**Table 7:1**). A small number of participants had specific concerns such as wanting to have a more positive outlook or

wanting to reduce stress and anxieties. Other participants identified specific worries about cancer recurrence or body image and wanting to get back into clothes worn before diagnosis.

Most of the comments identified in this super-category were about support needs. Some wanted to meet other people and be part of a group, several anticipated that this might provide the information, motivation, confidence or encouragement that they needed to eat more healthily, exercise more or lose weight.

> *"I am hoping it will motivate me to lose weight and exercise more" (9)*

One participant wanted to contribute to the current research project to help to support others.

7.1.1.2 Physical concerns

A majority of the participants (61.1%) identified physical concerns or problems at baseline; these were mainly related to body weight and/or cancer recurrence. Some were interested in lifestyle improvement to strengthen physical health to reduce risks of cancer recurrence or spread;

> *"To live and eat a healthy diet to give my body the best chance it can to stop it returning" (1)*

Many participants identified physical concerns relating to body weight. Some were concerned that they had gained weight, especially if this was abdominal weight gain; others were finding it difficult to maintain or lose weight. Some people specifically wished to lose weight as they were aware of the associations between adiposity and cancer recurrence risks; this awareness may be due to taking anti-oestrogen medication and knowing its mode of action;

> *"Weight loss generally, specifically middle age spread due to concerns over oestrogen production in fat" (6)*

In other cases, participants just wanted to lose weight, tone up and improve general levels of fitness and energy. In some cases, this was to reduce or avoid the need for medication for other long-term conditions such as type II diabetes.

Some people had specific concerns that were likely to have affected their motivation and confidence to make behavioural changes without support. One person wanted to improve hip mobility while another wanted to reduce pains under the arm that occurred with exercise; it was unclear whether this was a result of breast surgery. In both cases the ability to be physically active was likely to be

reduced. Another person had problems with mouth pains, again it was unclear if this related to cancer treatment but was likely to affect food choices.

7.1.1.3 Hospital cancer treatment concerns

A minority of participants (16.7%) identified health concerns that had occurred because of cancer treatment. Some were concerned that long term hormone medication had resulted in difficulties in weight control; this may have reduced their confidence and motivation in making lifestyle changes. Another participant was concerned that hormone treatment led to hot flushes in stressful situations and wanted to compare experiences of this with others.

Other participants expressed concerns about decreasing shoulder or arm strength and mobility following breast surgery. This was found to have affected range of movements or lifting abilities. Again, these concerns may have affected baseline levels of physical activity in participants.

7.1.1.4 Concerns about wellbeing

Most participants (88.9%) had concerns about wellbeing which were largely related to diet and exercise. Many participants expressed the desire to return to a healthier lifestyle and regain health and fitness. This implied that, for some, their lifestyle had become less healthy since diagnosis and that following treatment now wished to improve it as part of their physical recovery.

Many participants expressed an interest in improving their aerobic and cardiovascular fitness or physical strength. Several people wanted to maintain their levels of physical activity, or to be more active and to start taking more exercise; but some needed support to develop their confidence to do so. Some wanted to know what to do to improve fitness, while others wanted to try different types of exercise and to find the most suitable type;

> *"I like the sound of doing exercise and learning what I need to do. Being confident about it" (21)*

Many participants also identified that they wanted to improve their diet, again some suggested that this had changed during breast cancer treatment:

> *"Poor diet since diagnosis" (29)*

Some were interested to know more about healthy eating generally, for themselves and their family. Some people felt that they ate quite healthily but had quite repetitive dietary habits and were

interested in new ideas of foods to add in for health. As discussed in **Section 7.1.1.2** above, some of these concerns were to improve healthy eating for weight management.

Some participants had concerns about healthy eating with a cancer diagnosis and wanted more details about what to eat and what to avoid. There is a great deal of information about this in the public domain and some wanted clarification on foods that might increase cancer risks.

The concerns identified in the MYCaW initial forms at baseline identify a wide variety of issues as might be expected from a very heterogenous group. As the participants were aware of the programme details before completion of these forms, it is not surprising that many of the concerns raised related to healthy eating and physical activity. The data highlighted common concerns about body weight, cancer recurrence and sequelae of cancer diagnosis and treatment that had had a negative impact on lifestyle. Another key message from participants was the requirement for support to address these issues. Participants ratings of these concerns over time are explored in the next section.

7.1.2 Ratings of concerns and wellbeing

Data about the participants' reported levels of concern and wellbeing were collected at four time points; T1, T2, T3 and T4 as discussed in **Chapter 4.2.1.3** above. Data were collected using the MYCaW tool and analysed as discussed in **Chapter 4.2.6.** This section includes a report and analyses of MYCaW scores from the quantitative analysis group and follow up groups (**Section 6.1**).

Quantitative MYCaW data were screened and corrected as outlined in **Chapter 4.2.1.4.** Mean participant rated concerns and wellbeing in the quantitative analysis group before and during the intervention (T1, T2 and T3) are reported in **Table 7:2**. The table shows that the highest level of worry was about Concern 1 at baseline (mean 4.8). This was expected as participants were asked to identify their main concern. There was a slightly lower level of worry about Concern 2 at baseline and again this was as expected as participants were asked to identify their next most pressing concern as Concern 2. One of the participants did not identify a second concern; therefore, there was one item of missing data for Concern 2 at each data collection point. At baseline, the mean Wellbeing score was lower (2.6) indicating a higher rating of wellbeing, while the mean summary MYCaW profile score was 3.8.

Table 7:2 Self-rated mean concern and wellbeing (MYCaW) before and during the intervention for the quantitative analysis group (n=31)

	Baseline (T1)	**Intervention start** (T2)	**Intervention end** (T3)
Mean (SD) rating of Concern 1	4.8(1.00)	4.7(1.29)	2.4(1.73)
Mean (SD) rating of Concern 2*	4.1(1.33)	4.5(1.22)	2.6(1.57)
Mean (SD) rating of Wellbeing	2.6(1.34)	2.7(0.98)	1.8(1.32)
Mean (SD) MYCaW profile	3.8(0.85)	4.0(0.89)	2.3(1.22)

T1= Baseline before the intervention, T2= week 1 of intervention, T3= week 12 of intervention, SD= standard deviation. MYCaW ratings are scored between 0-6; a higher MYCaW rating indicates a higher level of concern or lower rating of wellbeing. MYCaW profile is the mean of ratings of Concern1, Concern 2 and Wellbeing.

**One participant did not identify and rate concern 2, so n=30 for concern 2 at T1, T2 and T3.*

The mean scores appeared to stay about the same during the comparative period between baseline (T1) and the first week of the intervention (T2), suggesting that minimal change in concerns occurred over time before the intervention start (mean period 62.5 days; see **Table 6:3**). By contrast, all the mean MYCaW scores reduced over the intervention period (between T2 and T3) indicating a reduction in concerns and improved wellbeing. Data from the follow up group over all 4 time points were also analysed and showed apparent reductions over the intervention period (**Table 7:3**). These reductions in concerns and improvement in wellbeing appeared to be maintained in the long term as mean ratings at 12 months after the intervention (T4) were comparable to those at the intervention end (T3). Inferential analysis was carried out to determine whether these apparent changes were statistically significant.

Table 7:3 Self-rated mean concerns and wellbeing (MYCaW) over time for the follow up group (n=20)

	Baseline (T1)	**Intervention start** (T2)	**Intervention end** (T3)	**Follow up** (T4)
Concern 1	4.5 (0.94)	4.5 (1.28)	2.5 (1.82)*	1.8(1.36)*
Concern 2	4.2 (1.20)	4.5 (1.19)	2.7 (1.72)*	1.9(1.17)*
Wellbeing	2.4 (1.14)	2.8 (0.91)	2.0 (1.43)*	1.8(1.59)*
MYCaW profile	3.7 (0.66)	3.9 (0.83)	2.4 (1.36)*	1.8(1.06)*

*T1= Baseline before the intervention, T2= week 1 of intervention, T3= week 12 of intervention, T4= 12 months post-intervention. SD= standard deviation. MYCaW ratings are scored between 0-6; a higher MYCaW rating indicates a higher level of concern. MYCaW profile is the mean of ratings of Concern1, Concern 2 and Wellbeing. *statistically significant result compared to T2 ($p<0.0125$; Bonferroni adjusted alpha value)*

The data set was analysed to see if there were significant differences in the MYCaW ratings of the follow up group over the four time points (T1, T2, T3 and T4)**.** Friedman test results indicated that there was a statistically significant difference in Concern 1, Concern 2, Wellbeing and MYCaW profile over the four time points (T1, T2, T3, T4). Inspection of median values supported the trends in the mean values presented above; no change in levels of concern between T1 and T2, a decrease between T2 and T3 and a maintenance or decrease in concerns between T3 and T4 **(Appendix 2.4**). This suggested that the significant differences in the data identified by the Friedman tests in all cases occurred during the intervention (between T2 and T3). This was further investigated by *post-hoc* testing of the data.

The *post-hoc* Wilcoxon Signed Rank test results showed that there were no statistically significant differences in concerns/wellbeing over the comparative period before the intervention (T1-T2); however, there were statistically significant reductions in concerns and improvements in wellbeing over the course of the intervention (T3-T2) and these differences were still apparent between the intervention start (T2) and the 12-month follow up (T4). There were no statistically significant differences in concerns or wellbeing in the year following the intervention (T3-T4) suggesting that positive changes occurred during the intervention and were maintained for a year afterwards (**Table 7:3**). The *post-hoc* analysis confirmed that the statistically significant difference in concerns and wellbeing occurred between the start and end of the intervention (T2-T3) in each case. Effects sizes were calculated (**Chapter 4.2.6**) and showed that the intervention had a large effect on Concern 1 (effect size= 0.55), Concern 2 (effect size= 0.51) and MYCaW Profile (effect size= 0.57), while it had a medium effect on Wellbeing (effect size= 0.40).

This doctoral study was carried out using a quasi-experimental design (**Chapter 3.4**) in which participants acted as their own controls. Comparative data collected in the period before the start of the intervention were compared to trial data collected over the course of the intervention. This comparative and trial data for the quantitative analysis group were compared, to identify possible intervention effects. Therefore, analysis was carried out to compare the changes in participant rated concerns and wellbeing during these two periods. The findings are presented in **Table 7:4** below. The table shows that there was very little change in MYCaW ratings over the comparative period between baseline and the start of the intervention suggesting that the concerns identified at baseline remained at the start of the intervention (2.6% increase in MYCaW profile), while there

were reductions in concern and improvements in wellbeing in the trial period between the start and end of the intervention (42.5% decrease in mean MYCaW profile). Differences in the comparative and trial data were again found to be significantly different using a Wilcoxon Signed Rank test suggesting that this was an intervention effect.

Table 7:4 Mean (SD) change in self-rated participant concerns (MYCaW) during the comparative and trial periods for the quantitative analysis group (n=31)

	Mean change (SD) in MYCaW ratings during comparative period (T2-T1)	**Mean change (SD) in MYCaW ratings during the trial period** (T3-T2)
Concern 1	-0.1 (1.14)	-2.3 (1.87)**
Concern 2	0.3[a] (1.03)	-1.9[a] (1.85)**
Wellbeing	0.1 (1.22)	-0.8 (1.24)*
MYCaW profile	0.1 (0.67)	-1.7 (1.22)**

MYCaW ratings are scored between 0-6. The figures represent the change in MYCaW ratings. A negative number indicates a reduced level of concern and/or improvement in wellbeing; a positive number indicates an increased level of concern or decrease in wellbeing.

**indicates a statistical significance between the test and comparative data (p≤0.05), ** indicates significance (p≤0.001)*

[a] n=30 for Concern 2 as one participant did not identify and rate Concern 2.

The data analysis has shown that statistically significant changes in mean ratings of concerns and wellbeing occurred over the course of the lifestyle intervention; a comparison of the intervention and comparative data have suggested that this may be due to the intervention itself, and not due to the passage of time or other confounding variables. However, a statistically significant change may not necessarily represent a noticeable improvement in the life of individual participants. Therefore, the data were also analysed to investigate the proportion of participants for whom the changes in MYCaW ratings were likely to represent a meaningful change in health or wellbeing (**Chapter 4.2.6**). This was defined as a change in the overall MYCaW profile score of 0.7 or more for individual participants, rather than mean changes across the group. **Table 7:5** presents the number and percentage of participants in the quantitative analysis group (n=31) for whom changes in their MYCaW profile met this criterion. The table shows that during the trial period most participants (74.2%) were likely to have experienced a meaningful reduction in concerns or improvement in wellbeing and this compares with only a small percentage (6.5%) who did so during the comparative period (without the effect of the intervention).

Table 7:5 The number of participants (%) with meaningful changes in MYCaW profile scores in the quantitative analysis group (n=31)

Number of participants (%)	**Comparative period** (T2-T1)	**Intervention period** (T3-T2)
Reduced concern *Score change <-0.7*	2 (6.5%)	23 (74.2%)
No change *Score change from -0.69 to 0.69*	27 (87.1%)	8 (25.8%)
Increased concern *Score change >0.7*	2 (6.5%)	0 (0.0%)
Total	31 (100%)	31 (100%

These data show that the intervention was not equally useful to all participants and around a quarter (25.8%) had no meaningful change in their MYCaW ratings. However, this compared favourably with the comparative period when most participants (87.1%) appeared to have no change in their concerns or wellbeing. These data suggest that for most participants the observed decrease in concerns and improvement in wellbeing were likely to reflect real improvements in quality of life during the intervention period and this is likely to be due to the intervention effects, as no equivalent improvement occurred during the comparative period.

Table 7:6 The number of participants (%) with meaningful changes in MYCaW profile scores in the short and long term for the follow up group (n=20)

	Intervention effects		**Long term effects**	
Number of participants (%)	**Comparative period** (T2-T1)	**Intervention period** (T3-T2)	**After the intervention** (T4-T3)	**Intervention start to follow up** (T4-T2)
Reduced concern *Score change <-0.7*	0 (0%)	14 (70%)	8 (40.0%)	19 (95.0%)
No change *Score change from -0.69 to 0.69*	18 (90%)	6 (30%)	9 (45.0%)	1 (5.0%)
Increased concern *Score change >0.7*	2 (10%)	0 (0.0%)	3 (15.0%)	0 (0.0%)
Total	20 (100%)	20 (100%)	20(100%)	20 (100%)

The data were also analysed to investigate whether the short-term changes experienced during the intervention persisted in the longer term. Therefore, data from the follow up group were also analysed to see if meaningful changes in MYCaW ratings changed after the intervention (**Table 7:6**). Over the 12-month period after the intervention, a small minority of participants had increased concerns or reduced wellbeing (15%) while the majority had either maintained their concerns/wellbeing (45%) or had experienced further meaningful improvements (40%). This

suggested that, for the majority, the changes experienced in the intervention are likely to be maintained. An analysis of overall data (T4-T2) showed that almost all participants (95%) were likely to have a meaningful improvement in wellbeing and reduction in concerns a year after the intervention, compared to their wellbeing/concerns at the start of the intervention. This suggested that the intervention might have promoted meaningful and long-term positive changes in concerns and wellbeing for most participants. Ratings of concerns and wellbeing might also be impacted by things other than the intervention, and this is explored in the next section.

7.1.3 Other things affecting health

At the end of the intervention (T3) and at the 12-month meeting (T4), participants were asked an additional open question on the follow up MYCaW form about other things that had been affecting health. These other variables might have had an influence on participants' quantitative rating of their concerns or wellbeing at these time points. The reported comments were again coded using the analysis guideline for MYCaW (Polley *et al.*, 2007; Jolliffe *et al.*, 2015). The framework categorises both positive and negative impacts on health and these are indicated in the sub-categories listed in **Table 7:7** below. The question responses were reported in the key themes of; awareness of wellbeing; major life events; social support; work situation; health issues; other categories were not relevant to the responses and so were not included.

Table 7:7 Summary of "Other things affecting health" reported on MYCaW form after the intervention

MYCaW Other things affecting health: Super-categories°	**T3 Intervention end** **Breakdown of Super-categories°** (n=23)			**T4 12 month Follow up** **Breakdown of Super-categories°** (n=19)		
	% (number) participants with comments in each super-category*	Number of comments identified in each sub-category**		% (number) participants with comments in each super-category*	Number of comments identified in each sub-category**	
OT1 Awareness of wellbeing	70.0% (16)	OT1a Taking exercise (+)	4	89.5% (17)	OT1a Taking exercise (+)	12
		OT1b Improved nutrition (+)	4		OT1b Improved nutrition (+)	7
		OT1c Improved awareness of own wellbeing (+)	5		OT1c Improved awareness of own wellbeing (+)	4
		OT1d Difficulties in maintaining change (-)	7		OT1d Difficulties in maintaining change (-)	2
OT3 Major life events	4.3% (1)	OT3c Bereavement (-)	1	5.3% (1)	OT3c Bereavement (-)	1
OT4 Social support	4.3% (1)	OT4b Family problems (-)	1	15.8% (3)	OT4b Family problems (-)	3
OT5 Work situation	26.0% (6)	OT5a Improved work set-up or financial situation (+)	1	15.8% (3)	OT5a Improved work set-up or financial situation (+)	3
		OT5b Work or financial problems (-)	5		OT5b Work or financial problems (-)	0
OT6 Health issues	46.2% (12)	OT6a Cancer related (+) issues	0	42.1% (8)	OT6a Cancer related and positive issues	2
		OT6b Cancer related (-)	5		OT6b Cancer related and negative issues	3
		OT6c Non-cancer related (-)	8		OT6c Non-cancer related (-)	4

**% of those providing a response at each time point; **individual concerns may be included in more than 1 subcategory, °Using framework produced by Polley et al. (2007).*

(-) indicates a negative impact on health, (+) indicates a positive impact on health.

7.1.3.1 Other things affecting health at the end of the intervention (T3)

MYCaW data were collected from all the participants who completed the lifestyle programme (n=38) and of these, 23 (60.5%) provided an answer to the additional open question about other things affecting health. The responses are presented in **Table 7:7**. The responses showed that by the last week of the intervention some participants had started to make lifestyle changes and to notice improvements in wellbeing. Some reported increased levels of physical activity, while others reported satisfaction with making dietary improvements such as eating smaller portions, eating a lower sugar diet, starting to eat breakfast or eating more mindfully. As a result, a few reported positive changes with long term conditions with one person having improved blood sugar and cholesterol levels and another was no longer taking anti-depressants. Several people reported improvements in wellbeing; with some feeling more positive or that they were moving forward or being motivated to prioritise and continue with the changes made.

Other people were having more difficulties in starting or maintaining behaviour change. In some cases, their ability to make changes had been impacted by family problems or family commitments. In a few cases bereavement or having friends receive terminal diagnoses had adversely affected wellbeing. Returning to work after sick leave was associated with difficulties in finding the time to sustain changes, and increased stress that some participants linked with a reduction in wellbeing. Some recognised that making time for health improvement might be important and one had given up work to do so.

> *"I have given up work to concentrate on my health and recovery. This has greatly improved my wellbeing. I now do Pilates, acupuncture, and aromatherapy massage regularly" (39)*

One participant reported knowing what to do but needed further support to do it. Being too busy and being stressed was linked by some to other minor health problems and common infections. In some cases, further surgery such as reconstruction had interrupted their lifestyle improvement, in two cases medication was thought to be making changes difficult to sustain.

These data suggest that participants had started to make healthy behavioural changes during the intervention though many were experiencing difficulties in maintaining changes.

7.1.3.2 Other things affecting health at the 12-month follow up (T4)

MYCaW data were collected from the 24 participants who attended the 12-month follow up (T4) session, and 19 (79%) provided an answer to the additional open question about other things affecting health.

Some participants had overcome issues that had previously prevented them from being more physically active. **Table 7:7** shows that there were many more positive comments about taking exercise at T4 compared to T3. The increased levels of physical activity had been achieved by a variety of strategies such as buying a dog, joining a gym, joining an exercise group or joining a sponsored cycle ride. It seemed that many had prioritised being more physically active and had made it an integral part of their lives. Some reported improved health and wellbeing as a result.

> *"Lots of exercise- part of my lifestyle and routine now"(18)*

Some also reported dietary changes that in some cases seemed to have become part of their regular habits and had sometimes led to changes in the diet of the wider family as well. This suggests that people had remembered lifestyle recommendations and had implemented some of them;

> *"Eating salad most working days for lunch-regularly having 5-10 fruit/veg a day" (40)*

Some people reported being more aware of their own wellbeing and that they were now taking steps to manage this. Participants reported being more mindful, learning to relax, staying positive or addressing stressful issues, although one participant (who attended the follow up in December) reported a low mood in winter. Others reported family issues such bereavement and care of elderly parents which had created additional stress and pressure. There was a recognition by one participant that stress can negatively impact on healthy eating choices.

> *"I am more aware of my wellbeing and concentrating on what's right for me. Trying to use my time wisely and spending time with positive people the best I can" (28)*

Over the 12-month period some had returned to work, while others had reduced work commitments or retired or changed careers to allow a greater focus on health and wellbeing.

Changes in health had also impacted on the ability to change behaviour. One had had reconstructive surgery and was subsequently unsure what exercises would be appropriate, another had been involved in a car accident. Other health changes were more positive. Several participants appeared

to be concerned about taking medication and reported positive changes; one reported switching to an improved cancer medication, while others had been able to stop taking anti-depressants or had been able to reduce a requirement for diabetes medication. One participant was concerned about the side effects of hormone medication;

> *"It is always a nagging concern regarding bone density and the ongoing medication which I have to take. Sometimes feels like being on a hamster wheel"(24)*

Overall these data seem to suggest that 12 months after the end of the intervention participants were still engaging with behaviour change and had embedded more changes into their daily lives than before. Participants seemed keen to use lifestyle to improve wellbeing and where possible to reduce the need for medication. This may reflect meaningful milestones in their progress towards recovery.

7.1.4 Important aspects of the intervention

At the end of the intervention (T3) and at the 12-month meeting (T4), participants were invited to answer an open evaluative question about important aspects of the intervention on the follow up MYCaW form (**Chapter 4.2.6**). At T3, MYCaW data were collected from all participants who completed the lifestyle programme (n=38) and 26 (68.4%) of these provided an answer to this additional question. At T4 MYCaW data were collected from the 24 participants who attended the 12-month follow up (T4) session, and 22 (91.7%) provided an answer. As discussed previously, the responses did not fit the framework in the analysis guideline for MYCaW (Polley et al., 2007; Jolliffe et al., 2015). Instead, the data were analysed using the evaluation framework developed as part of this study (**Chapter 4.2.7.1**) and a summary of the numbers of responses obtained in each framework category at T3 and T4 are presented in **Table 7:8**. The findings are reported below in **Section 7.2** together with data from the evaluation forms.

Table 7:8 Summary of "Important aspects of the intervention" at the end and after 12 months.

Evaluation framework	**T3 Intervention end** %* (number) of participants with comments in each category (n=26)	**T4 12-month follow up** %* (number) of participants with comments in each category (n=22)
Knowledge and understanding	61.5% (16)	54.5% (12)
Motivation and confidence	61.5% (16)	72.7% (16)
Group sessions	42.3% (11)	45.5% (10)
Practical activities	38.5% (10)	4.5% (1)

**% of those providing a response at each time point*

7.2 Intervention evaluation

Evaluation forms were used to collect feedback data from participants at the middle and end of the 12-week lifestyle programme. The methods for collecting and analysing the evaluation form data were described in **Chapter 4.2.7.1.** At least one evaluation form was completed by 84% (36/43) of participants; 32 (74.4%) of participants completed both forms. Mid-intervention evaluation reviews were received from 33 participants; however, one of these participants was still in treatment at the mid-point so her data was excluded in line with approvals (**Chapter 4.2.1.1**) and analysis of data from the other 32 participants (76.7% of those who joined the intervention) was carried out. Post-intervention evaluation data was analysed from 35 (81.3%) participants at the end of the programme; all participants had completed treatment by this point, so no data was excluded.

The evaluation form data provides feedback from most of the participants including some of those who were still in treatment at baseline. None of the five participants who withdrew from the programme completed evaluation forms and so their perspectives could not be included. A summary of the numbers of responses obtained for each framework theme is reported in **Table 7:9** below and a summary of the combined findings from the evaluation forms and the MYCaW open question on "Important aspects of the Intervention" (**Section 7.1.4)** are discussed by theme in the rest of this section.

Table 7:9 Summary of evaluation form responses

Evaluation framework Super-categories	Mid-intervention			Intervention end (T3)		
	%* (number) participants with comments in each category n=32	Number of comments identified in each sub-category**		%* (number) of participants with comments in each category n=35	Number of comments identified in each sub-category**	
1. Knowledge and understanding	96.9% (31)	1.1 Relevance and use	31	97.1% (34)	1.1 Relevance and use	30
		1.2 Detail and depth	15		1.2 Detail and depth	16
2. Motivation and confidence	50% (16)	2.1 Awareness and aims	8	80.0% (28)	2.1 Awareness and aims	12
		2.2 Support for change	10		2.2 Support for change	17
		2.3 Changes made	4		2.3 Changes made	14
3. Group sessions	65.6% (21)	3.1 Session format	14	100% (35)	3.1 Session format	35
		3.2 Group atmosphere	8		3.2 Group atmosphere	23
		3.3 Shared experience	12		3.3 Shared experience	24
		3.4 Shared learning	10		3.4 Shared learning	14
4. Practical activities	84.4% (27)	4.1 Physical activities	20	74.3% (26)	4.1 Physical activities	23
		4.2 Nutrition activities	16		4.2 Nutrition activities	9

**% of those providing a response at each time point **individual concerns may be included in more than 1 subcategory*

7.2.1 Knowledge and understanding

7.2.1.1 Relevance and use

The data suggest that almost all participants found the programme content personally relevant. Most specifically responded to that effect and many elaborated that it was informative and useful; one participant commented that she had also found it therapeutic. Most did not identify any areas for improvement which suggested that they were satisfied with the programme as it was; a few specifically stated this. However, two participants commented mid-programme that the nutrition content was too simple (**Section 7.2.1.2).**

Most participants seemed to view the programme content as useful. Several felt knowing more about the effects of diet, the nutritional content of foods and food labelling would help them to make healthy eating choices. Some commented that the programme included useful tips and ideas of changes that would be easy to make. One person commented that they liked the programme being specific to breast cancer and a couple of people commented that the programme would be useful to others with breast cancer indicating that they felt it to be of value;

"*I think the programme should be made available to as many patients as possible!"* (14)

At the end of the intervention, participants felt more informed and had a greater understanding of the effects of healthy food choices and exercise. They also valued having had time to apply this to their own lifestyles.

"Obtaining information which can be used in little steps over the coming months" (24)

At the 12-month follow up, participants appreciated that they had received advice and ideas of foods, recipes and exercises which had enabled progress towards goals, suggesting that behaviour changes had been implemented and maintained.

"Receiving information. Clear messages. The latter two have stuck and my diet is dramatically different now" (26)

7.2.1.2. Detail and depth

Many participants commented that they found the nutrition content clear and informative. In some cases, participants found that the content reminded them about, or confirmed for them, information previously known and so provided reassurance about their lifestyle. Other participants learned new or more detailed information that was surprising or enlightening. Some participants found that they learned more about familiar topics suggesting that knowledge was extended and enhanced.

"..explained in detail information I didn't know regarding nutrition" (16)

Some participants would have liked more detail in the nutrition advice discussed. A few liked the explanations of links between lifestyle and cancer while others would have liked to cover more of the latest research findings.

"Would like much more in-depth and scientific knowledge to be shared" (20)

At the mid-intervention point, individual participants identified specific topics that they would like covered including;

- the effects of breast cancer medication on appetite and fitness,
- mental health following breast cancer diagnosis and treatment,
- dairy and breast cancer,
- supplements for breast cancer,
- interactions of drugs such as Tamoxifen with foods,
- sugar and cancer,
- Soy and oestrogen receptor positive (ER+) breast cancer,
- Nutritional and medicinal uses of herbs and spices.

At the end of the intervention there were still suggestions to include more scientific detail and to consider the dietary supplements although some of the other aspects were not mentioned so may have been addressed in the second part of the programme. One or two commented that many patients carry out their own online research about lifestyle following diagnosis and would have liked the group to have considered myths and misinformation in the media as these can engender guilt.

A couple of participants commented that the written information provided during the programme was informative and a useful reference; though one or two again found the content too basic and may have benefitted from signposting to further information.

> *"It is useful to have all the handouts to reflect and continue to absorb over the coming months"* (24)

Some participants had been very physically active prior to their diagnosis and now wanted to return to previous levels of fitness. They felt there was an assumption that participants were inactive, and a couple commented that they felt patronised by discussions of the benefits of physical activity to health.

The data indicated that the participants formed a very diverse group in terms of their prior knowledge and information needs which was complex to address within a group setting. The intervention aimed to develop the knowledge and skills of participants (**Chapter 5.5**) to provide

motivation and confidence in changing behaviour and their feedback on this aspect will be discussed in the next section.

7.2.2 Motivation and confidence to change

7.2.2.1 Awareness and aims

During the intervention, participants reflected that the programme had led to an increased awareness of healthy eating and physical activity. In some cases, this had resulted in a changed attitude towards their own lifestyle and increased intentions to make healthy changes.

> *"Making me re-evaluate and re-think" (27)*

By the end of the intervention, some felt empowered and confident to continue with changes already made. Some participants identified an intention to take ownership of their own health and to achieve new lifestyle goals. This suggests that, for some, the new knowledge and understanding gained from the programme had become internalised and had contributed to preparation, activation or maintenance of personalised behaviour change goals.

> *"A more determined, and informed, desire to control my health" (3)*

A year on, participants reported that the programme had provided a catalyst and support for change. Some reported thinking about and prioritising health and wellbeing more following the programme. They reported that they had been able to make small changes as they had more confidence, determination and a positive attitude to wellbeing, suggesting that for some their self-efficacy had increased.

> *"Now feel totally in 'control' of eating- when I eat badly it's my choice-also don't worry about it and get back to eating well. Not being unkind to myself! (18)*

7.2.2.2 Support for change

Most participants found the programme supported them to make lifestyle changes. They felt that they had become better informed which helped them to make healthy choices. The handouts helped this process as they could be subsequently read and reflected on to determine future actions.

> *"I feel much stronger and empowered by this knowledge" (14)*

Many participants commented that the programme had motivated them to make changes; it had provided a stimulus. One participant felt that they had been challenged to try new things and to change routines, and it may be that this could lead to the development of new habits. They also liked being provided with practical suggestions of changes that would be easy to make. Others commented that staff and other group members were supportive and that the programme helped them to be positive about long term change. One participant also appreciated that she did not feel pressured to make changes. This may have allowed participants to take ownership of any personal progress.

Some participants felt that they were encouraged and gained confidence, for example to become more physically active. Others commented that it was useful to be encouraged to make changes through a series of small steps and to be encouraged that taking any amount of exercise was beneficial. This approach was intended to develop self-efficacy. Paradoxically, one participant commented that her confidence in making healthy choices may have decreased initially through increased awareness of the unhealthy choices that she might make. Some felt that the weekly meetings supported maintenance of changes even when participants found this difficult to do, suggesting that the programme length might be important to embed change.

> *"More confidence and a reason to 'keep on going on' with exercise and diet change" (39)*

> *"My whole outlook has improved; I feel very positive and my anxiety levels have reduced considerably. I have also stopped taking sleeping tablets. Feeling supported" (23)*

7.2.2.3 Changes made

By the middle of the intervention, only a few participants reported making changes to their meals, though one commented that she had started to plan the weekly menu in advance. Another participant felt that it would take time to make changes.

> *"… but I think that it will take me a while to make changes. I hope I can do so before the end of the programme… " (27)*

By the final week, more participants reported having implemented small changes in line with programme recommendations to set small manageable goals. Some had been prompted to add in new foods such as beans and pulses, seeds or couscous. In other cases, foods or ingredients had been reduced; one had reduced the salt in family meals while another was avoiding processed

foods. One participant was enjoying cooking more frequently. Some participants thought that they already had a good diet before the programme but reported that they were now eating more healthily. A few commented that they now felt healthier and two had lost weight.

Several participants had gained confidence and the impetus to return to exercise and were now more active. One participant reported that she was now active for more than 45 minutes every day while others now walked more often or attended new exercise classes or groups. One reported that her increase in physical activity had helped her to manage other health conditions.

Some participants reported having more confidence to stimulate change and reasons to keep going with it; one commented that she was now able to maintain changes even when she was not feeling well, suggesting improved self-efficacy. After 12 months, many participants reported being more in control of their lifestyle and were continuing with changes to meet personal goals.

> *"Changed many aspects of everyday eating eg. sugar intake, wholemeal foods-made me think ahead. Conscious of regular exercise." (12)*

7.2.3 Group sessions

7.2.3.1 Session format

A couple of participants commented that the programme was well organised, and they liked learning about different aspects each week; although one felt that is was less structured than she had expected. In groups 1 and 2 the nutrition session was followed by the exercise session. A few participants questioned whether it would be better to have the exercise session first. One felt that they would have had more energy if that had been the case. Others felt that it may have resulted in better attendance at the exercise sessions, as some people left after the nutrition part.

The aim was to have a maximum group size of 15. Although the mean group size was 10.2, at times there were up to 18 in some morning sessions. One person commented that she would not have wanted the group to be any larger, while another felt that it was too large. The participants were very varied in the time since diagnosis and one suggested that it might have been useful to recruit people straight after treatment as she felt that the need was greater at that time.

> *"I feel a smaller class size would be more personal and give individuals a better chance to discuss any issue raised" (22)*

"Maybe all attendees could be at around the same time post-treatment? As this is a time when you can feel a little lost!" (10)

Groups 1 and 2 were run at different times of year on a Wednesday morning, group 3 ran on a Thursday evening in parallel to group 2. Most of the participants felt that the day and time of the sessions was suitable for them. This was not unexpected as the participants had been able to choose which group to join. A few participants did find it difficult to attend; one found it difficult due to working full-time, while others had been able to arrange work around the sessions. One person suggested running the sessions fortnightly as it was sometimes difficult to attend every week. Some in groups 2 or 3 appreciated that they could swap between the day and evening sessions to fit in with other commitments. One commented that the programme length was enough to allow for behaviour change, suggesting that a shorter programme may not have allowed time for sustained improvements.

"I definitely agree that the 12-week program is necessary to produce any real change" (27)

Some people felt that the 2-hour sessions could have been longer as the physical activity sessions were rather rushed and often over ran. One felt that sessions were a little too long.

As this was a group face to face programme participants were required to travel to the University for each meeting. One commented that the location was far from her home; another commented on the difficulties of congestion and parking; the timing of the programme had been planned to avoid the rush hour as far as possible.

7.2.3.2 Group atmosphere

Most of the participants found the group sessions enjoyable, which may have been an important factor in participants continuing to attend and engaging with the sessions. Many liked the atmosphere which they found to be relaxed and informal; one commented that they found the group to be;

"Very positive and uplifting" (26)

Many participants also found the group to be very friendly with good camaraderie; some commented that they have made new friends. This is likely to have encouraged participants to share concerns and experiences and to support each other in making changes together, and this is considered in the next section.

"It is a supportive, informal environment which is useful and relaxed with others… in a non-threatening way" (24)

7.2.3.3 Shared experiences

Most of the participants valued the social aspect of the group and several commented on the companionship and friendships that they had made. One participant felt that it was beneficial for the group to meet on a regular basis. It may be that this regular meeting over 12 weeks allowed time for group cohesion to develop so that people felt comfortable with each other and therefore able to share personal experiences. Some commented that they were a lovely group of people of like-minded people, suggesting that cohesion had occurred.

Most participants valued the opportunity to spend time with people in a similar situation; for some this was not something they had done before.

"Many people don't get a chance to speak to others in this situation in their normal daily life" (16)

Many participants particularly valued being able to speak informally to others who had had breast cancer to swap ideas and exchange information and concerns. Some commented that this made them feel less isolated. It may that participants felt alone during treatment and therefore found it positive to be part of a group where their experience was shared.

"Not feeling so 'alone'-lots of people have been on this journey" (30)

"..especially meeting ladies in similar situations-made me feel more 'normal'" (35)

In each weekly session there was a break where participants were able to make hot drinks and share healthy snacks and this was an opportunity to socialise. A few participants would have liked more time for this informal discussion, suggesting that it was a valued part of the programme. This contrasts with a view of a few that sessions were too long (**Section 7.2.3.1**) though it may be that the sessions were too long and the break too short. This suggests a need to balance the division of time for group discussions and informal interactions. In the nutrition sessions, there was usually some new information used as a prompt for group discussion around the weekly topic. Some participants commented that on occasions this discussion went off at a tangent. More informal discussion time might have helped the nutrition discussion to have retained focus. Several

participants felt that the group had supported and encouraged each other, and it may be that this peer support helped group members to initiate and maintain change.

"… enjoyed the group of lovely inspiring women" (40)

A year later, several participants reiterated that the group discussions and friendships remained an important element of the programme. For some it seemed that they had maintained peer support from members of the group on an on-going basis even after the end of the intervention and that this was really valued.

7.2.3.4 Shared learning

The informational element of the programme was intended to be delivered mainly through group discussion stimulated by prompts. Generally, many participants enjoyed learning together with others in a similar position. One commented that the group discussions were thoughtful and useful; they liked sharing information, tips and ideas. They enjoyed discussing nutritional topics such as food labelling and liked to hear about foods that each other were trying. They found it encouraging to learn from each other. A few commented that they would have liked more time to discuss topics together; as mentioned in **Section 7.2.3.3,** sometimes the discussion went off topic which some found frustrating**.** By contrast, one participant appeared not to like the discussion approach as she commented as a negative feature that sessions were;

"*Conversational rather than instructional" (34),*

which suggested that this would not have been her preferred style.

Many participants liked to exchange ideas and views about healthy eating with each other. This may have referred to discussions that the groups had had about some contentious issues such as dairy and soy and breast cancer where a variety of perspectives were expressed. The informal group discussions are likely to have been important for participants to share experiences of making lifestyle changes. One indicated that she valued;

"Hearing how everyone else struggles to maintain the 'Healthy element'" (41)

Participants also seemed to like learning together when trying out gym equipment and trying new types of exercise. This suggested that the group element was of importance to participants in all

aspects and they seemed to prefer activities that incorporated a group element. Practical activities within sessions will be discussed in the next section.

7.2.3.5 Practical activities

7.2.3.5.1 Physical activities

Many participants enjoyed experiencing a range of new types of exercise that they had not tried before in a relaxed group. Some would have liked more physical activity sessions.

> *"..opportunity to experience different exercise types in a safe environment."(36)*

One had found the pedometer provided during the intervention useful to increase her levels of physical activity, while another had experienced health benefits to her left arm which was presumably affected by surgery.

> *"Getting the pedometer has helped. Have gone from 7000 steps per week to over 60,000 per week" (23)*
>
> *"In the gym-using my left arm more has really helped" (1)*

One was already physically active and so did not find this part of the programme so useful, though another commented that they liked the opportunity to add different exercises into their current regime. Some found it useful to learn new skills such as warm up routines and ways to estimate exercise intensity, and perhaps these skills would be useful to participants when exercising outside the group.

Several people seemed to enjoy group sessions such as Pilates, yoga and Tai Chi, rather than using the gym equipment. Some people suggested offering a wider range of activities instead of some of the gym sessions. These exercise sessions were all carried out as a group and are therefore more sociable which may have been important compared to exercising individually in the gym. They sometimes also included an element of mindfulness or relaxation. One commented that a different location might have been preferable for Tai Chi and Pilates sessions as the ambience would be improved without the noise of gym equipment and with more relaxing music suggesting that this aspect was important. One participant would have liked the programme to include relaxation sessions to deal with the stress and anxiety that can result from having breast cancer, and perhaps the mindful aspect of the group sessions was helpful with this aspect.

Some participants would have liked to know more about the benefits of each type of exercise and wanted a brief introduction; some felt that on occasions the introduction was too long leaving insufficient time to try the exercises. Some liked the chance to do gentle exercise; others felt that some classes were too energetic for the group. One was concerned about some of the upper body exercises being too intense. A couple of people felt that they wanted advice about different levels of intensity that they could choose between, including more advanced options. Including more opportunities for setting personal goals for physical activity might have been a useful addition.

> *"The exercise is very general-it is difficult to find a level that suits. The instinct is to follow the group." (32)*

Several people liked Pilates and would have liked more of these sessions, another would have liked more power walking sessions, again, a sociable group activity. Although many seemed to like to exercise in a group, a few would also have liked some follow up about their personal progress.

One person liked having an introduction to the various types of gym equipment and one particularly liked that they were learning to use the equipment as a group. However, several would have preferred fewer gym sessions. One commented that these sessions were less useful as she would never join a gym.

At the end of the intervention, one participant suggested providing information about classes that could be continued after the group finished, suggesting that she was thinking about continuing outside the programme. A couple of participants commented that they would carry on with some types of exercises.

7.2.3.5.2 Nutrition activities

Nutrition activities were used to learn skills and change attitudes to heathy eating. Many participants enjoyed trying the healthy snacks and drinks that were provided each week. People commented that this prompted them to sample things that they would never have bought or tried. Some commented that it had been useful to try alternatives; this may have referred to trying dark chocolate of different cocoa content or tasting alternatives to milk.

> *"I've tried some foods I wouldn't have thought of trying" (41)*

Others liked learning to read nutrition labels; participants were encouraged to bring labels from packets and bottles from home to interpret and share ideas of foods they have tried. They also liked learning about new recipes; though some would have liked more of this as presumably this would help to implement healthy changes. They also shared photos of meals that they had eaten which one participant found useful.

> *"It's been great bringing in photos/articles/packets etc. to discuss visually and to discuss particular products has been useful" (29)*

Food diaries were completed as part of the quantitative data collection **(Chapter 6.5),** a few participants commented that they would have liked to see the outcomes from these with pointers for nutritional improvement, suggesting that for some a more personalised nutrition advice might have been beneficial. Participants were encouraged to seek individual nutrition appointments in the University student-led nutrition clinic after the intervention. A couple of people suggested that this could be made available during the programme.

The nutrition programme focused on healthy eating rather than weight loss *per se*. However, a couple of participants would have liked the programme to have included more focus on weight loss and another participant would have liked a mid-programme weigh-in. Presumably these participants had personal weight loss goals.

7.3 Individual interviews

A sample of 6 participants was purposively selected from those who had volunteered at the 12-month follow up meeting (**Chapter 4.2.7.2**). Interviewees were selected to be heterogenous and to include at least one participant from each of the 3 intervention groups. Participants were also selected to include a range of ages (44-68 years), different treatment regimes (4 had had chemotherapy and 2 had not), varied year of diagnosis (2011-2016) and time since completion of treatment (from more than 4 years to still in treatment at baseline). It was anticipated that these participants might have had a range of experiences of, and responses to, the intervention due to the diversity of contexts.

The interviews were carried out 12-14 months after the end of the intervention, and around 18 months since their recruitment into the study. It was anticipated that participants would therefore be able to retrospectively reflect on their personal experience of attending the intervention and any

consequences or effects. The issues raised, and consequences reported are likely to be of personal significance as they had been retained over a long period of time.

The lengths of the interviews varied from 20 to 44 (mean 36.3) minutes. The data were analysed using a framework approach as discussed in **Chapter 4.2.7.2** and are reported below thematically. There were 3 key themes identified;

- Preparing for lifestyle change,
- Initiation of lifestyle change,
- Maintaining lifestyle change.

7.3.1 Preparing for lifestyle change

Participants reflected on their interest in joining the lifestyle intervention. Three sub-themes were identified; motivation for lifestyle change, the timing of the intervention within their personal patient journey and support after the end of breast cancer treatment. These themes are explored in this section.

7.3.1.1 Motivation for lifestyle change

Several of the interviewees reported concerns around cancer recurrence, and this appeared to be ongoing both for those who had only recently completed treatment and for those who completed it some years previously. There was an implication that concerns might reduce to some extent over time; one participant reported being more able to manage tension around recurrence after a period of years. Another reported being halfway through the 10-year period in which recurrence is more likely, suggesting that her concerns were long term.

> *"..because I'm now five, maybe six years out, I think….So yeah, I'm halfway through the 10-yer period where you think, is it coming back or will it come back?" (33)*

Ongoing concerns might be increased in response to life events. One participant reported having a scare following a follow-up mammogram. Another reported that she did not attend any support groups for many years in part as she was concerned how she would cope if a group member passed away and therefore avoided a situation in which fears might be raised.

Concerns around cancer recurrence were an important motivator for lifestyle improvement for some participants. Participants reported an interest in cancer specific diet and lifestyle advice such as foods to be cautious about eating following diagnosis to reduce risks of recurrence.

> *"Because, you know, you know roughly what eating healthily is, I think everybody does, and then you choose whether to do it or not. But if it's something to do with a medical condition that could actually affect you in a good or bad way, totally different." (17)*

In addition to concerns about specific foods or nutrients, some were concerned about weight gained prior to diagnosis or during treatment and were keen to address this.

> *" And it did spur me on because I had put on some weight in the previous couple of years leading up to the cancer. I'd been having a very stressful time at work. And then the culmination of being diagnosed with cancer and I just thought this is it, I've got to pull myself back together again because this is not right" (3)*

Fears of recurrence might form an important context to the impacts of the lifestyle intervention. Some were concerned about the effects of body weight on recurrence risks. One was concerned about oestrogen production from adipose tissue following completion of a course of oestrogen blocking medication and this may have been a motivator for behaviour change. Concerns about recurrence may also inhibit behaviour change; one participant avoided exercise as the breathlessness and pain she experienced increased fears that these were signs of recurrence.

> *"Or, I'd think oh, what is that? It's one sided. And you do start to have that in the back of your mind…..what's the difference between, I suppose muscle soreness and an ongoing pain" (30)*

Rather than a focus on recurrence, some were keen to promote long term recovery following treatment through lifestyle improvement. For some, this involved a desire for dietary improvement or loss of weight gained before diagnosis or during treatment. Participants reported on the varied effects of the different phases of their treatment on their diet and weight. For some, steroid treatments had increased appetite and food intake while chemotherapy had reduced the sense of taste and pleasure of eating. One participant had been aware of infection risks and had avoided uncooked foods such as salads during chemotherapy and had then experienced acidity and sickness during radiotherapy. These changes had sometimes reduced eating to a functional activity and are likely to have disrupted previous eating habits. Therefore, some wished to return to healthy eating. This suggested that the intervention might have benefitted those who had previously had a healthy

diet as it was unlikely to be maintained through treatment as well as benefitting those aiming for dietary improvement.

> *“Because of the cancer, to try and eat more healthily to help myself recover quicker, if you like rather than eating, just eating because I like what I was cooking. So actually, trying to put positive things back in*" (39)

Participants were also keen to regain physical fitness lost during the treatment period and to become more active and feel better. Participants reported a loss of upper body strength following surgery especially on the mastectomy side and a loss of muscle mass and fitness over the treatment period due to lack of activity. One participant had an extended period of extreme fatigue during and after treatment and wanted to recover from that. Another participant had been physically fit prior to diagnosis but reported that she had stopped all exercise during treatment and had lost confidence to re-engage with it. This suggests that a physical activity programme was beneficial not only to those who had previously been inactive but also for some who had previously been physically fit.

> *"I wanted to try and get back to some kind of <u>normality</u> because I was just at that point totally unfit" (39)*

Several participants had other long-term health conditions such as high cholesterol, diabetes or joint pain that they reported might benefit from lifestyle improvements. The lifestyle programme was seen by some as a way of regaining control over their health and improving overall quality of life.

> *"And anything that would help us to live better and quality of life is obviously going to be beneficial to all of us" (33)*

7.3.1.2 Timing of the intervention within personal patient journey

Participants described how the timing of the intervention had impacted on their readiness to make behavioural changes. The main sub-themes were the effects of diagnosis, treatment and readiness to move forward and these are discussed in this section.

Participants talked about the shock of diagnosis and a suggestion that this might persist through the treatment period. There was a suggestion that for some the shock might reduce over time, although the diagnosis was not something that people got used to. This shock initially motivated some

participants to want to find out more; though this might be focused on the reasons for the diagnosis and its causes.

> *"… and if I in any way could have been responsible for my breast cancer" (37)*

There was a suggestion that in time this shock may also motivate some participants to want to regain control of their health by making lifestyle improvements. However, acceptance of the diagnosis and readiness for behaviour change, for some, took years following the end of treatments.

> *"I think when you've finished your treatment and straightaway you're then trying to find answers sometimes as to why it was you…but I don't think I would have been in the right frame of mind to really properly analyse what I should be doing…and I think I was too mixed up then. After a few years I think I was just a bit more ready to analyse it differently, or take the information differently…" (17)*

There were a variety of views reported about the ideal time to join the intervention in relation to treatment. However, there was a consensus that lifestyle changes would not be possible or appropriate during chemotherapy as it was too demanding, nor before radiography as its timing and effects would be uncertain. For some participants it was appropriate to join the intervention group towards the end of radiotherapy treatment. One participant was ready to move forward at this early stage and was keen to join the intervention for peer support through radiography and to start to prepare for the end of treatment. Other participants who joined the intervention after their treatment was finished, reported that they would not have attended an intervention during radiotherapy treatment as it had caused them to become lethargic. Treatment was found to be a long and demanding phase during which life was put on hold, though this might vary depending on the intensity of treatment. Some participants would not have coped with attending the programme during treatment and would not have been able to focus on it. One did not feel that her mind or body were ready, at that stage.

> *"I couldn't have done it while I was having treatment because I didn't know what day of the week it was" (37)*

The stage at which people felt ready to attend the lifestyle intervention was variable; some were ready towards the end of radiotherapy, others shortly after finishing treatment while others did not feel ready until a year or more later. Participants reported a need to have mentally adjusted before preparing for behaviour change, and this happened at different times for different people. The

programme offered support for people to move on to the next stage of their recovery when they were ready to do so, rather than the intervention being suitable for participants to join at a pre-defined point in their patient journey.

Some of the participants reported being ready for change before joining the programme. Some had already started to take some exercise but wanted to join the programme to become even more physically active. Others wanted to exercise with a breast cancer specific group, while others wanted to make behavioural changes but were looking for support to do so. Some participants wanted to take back control of their health following treatment. Some reported wanted to get out and do something, or to re-engage with others following the treatment period.

> *"..it was almost like new beginnings. ...But because I'd finished, I've done, I'm not that anymore. I'm not that patient anymore. Now we're going to do something about it." (39)*

The programme may have supported some to gain agency in their transition from patient back into society. The support needs of participants following the end of treatment are considered next.

7.3.1.3 Support after breast cancer treatment

Many participants found out about the lifestyle intervention through support that they were accessing after treatment. Some were still attending 12-monthly hospital follow-up appointments and heard about the programme from there. One commented that there was insufficient support available after the end of treatment and no nutrition advice, so she was interested in joining the programme. This suggested that the intervention filled a gap in NHS provision for this participant.

> " *You're basically just left to fend for yourself*" (17)

Some participants were attending support groups run by breast care nurses and had received information about the programme in these meetings. One suggested that she was keen to attend as the information was provided by the nurses who she held in very high regard. Others found out about the programme from an online breast cancer forum or had spoken informally to previous participants. Some had chosen not to attend any face-to-face support groups previously. This may have been as this intervention group was seen to be focusing on moving forward, rather than looking back at diagnosis and treatment which some wished to avoid.

Participants reported a variety of types of support that they wanted from the intervention. Some wanted support and reassurance about their lifestyle, others wanted support from others in the same situation.

> *" I think for me it was to go out and do something. I felt I'd isolated myself quite a lot through treatment…I wrapped myself in cotton wool almost and then didn't want to unwrap myself. And it is, you know, yeah I've been…and other people are back at work fulltime or they are doing so much more" (30)*

In one case a participant particularly wanted support from people who had recent experience of treatment. Others wanted breast cancer specific physical activity support to ensure that any exercises were tailored to those who had had surgery and other treatments and to ensure that exercise did not lead to further damage.

Some wanted to gain information about nutrition either to facilitate dietary changes or to find out about why their cancer had occurred and whether it was linked to other long-term conditions. In general participants often had an interest in food and they already knew about general healthy eating. People were interested in knowing more about the latest ideas on diet and breast cancer. They were often confused by contradictory dietary advice that they obtained from the media and wanted breast cancer specific information that was backed up by scientific research.

> *" As I said the main thing for that was I just wanted as much knowledge as I could and I wanted it to start as soon as possible*"(3)

The information provided in the intervention was found to be interesting and enjoyable. In retrospect several said that their views on lifestyle had not changed as their diet had been quite healthy anyway. There was a suggestion that it was preferable to focus on healthy foods to be added to the diet, rather than foods to avoid, and that explanations about why foods might have health effects were found to be useful.

> *"And that was what was the positive thing about that and made it easier to actually follow because you could see the reasoning behind it*" (17)

Participants were receiving support following treatment from a variety of forums, but still perceived a need for additional breast cancer specific diet and exercise support.

7.3.2 Initiation of lifestyle change

Participants experiences of attending the lifestyle sessions are explored in this section. Five sub-themes were identified; format of the group sessions; group discussions; written resources; group activities and household and friends.

7.3.2.1 Format of the sessions

The group sessions were perceived as being positive and enjoyable. The groups were very mixed in terms of ages and stages and all were found to have had different things to contribute without dominating the group, which was seen as a positive. The atmosphere was found to be comfortable.

> *" I think everyone was quite open and not cynical about the programme" (30)*

The length of the intervention was seen to be about right. It was perceived as being not too long to maintain interest; it was suggested that attendance may have reduced if it had been longer. One person commented that if it had been shorter, then those missing a session would have missed too much. Evening sessions helped participants to attend.

7.3.2.2 Group discussions

The sessions included group discussions on healthy eating topics and informal discussion time in the break. The opportunities to share experiences and develop friendships were appreciated. Some were inspired by other group members, especially by those who were still in treatment. Participants felt supported by being able to share experiences of breast cancer and were able to talk about aspects that they felt would not be understood by others who had not had it. Talking to others was felt to help some to move on from treatment and gain confidence to change behaviour.

> *"No I think even, because I think especially with women that have had it, you're more likely to say things that you might not say to a friend or even your husband, or you might have a little niggle, ooh is it normal to..." (37)*

Participants also found that they enjoyed learning from discussions with their peers, for example the effects of fruit juice on insulin were clearly remembered. Participants recognised that it is difficult to change behaviour and so found it helpful to discuss positive and negative experiences within the group. Learning from others was found to be useful and interesting.

> *"Well we share our experiences. You really do. And I mean it's yeah and women need other women, they actually do…So yes friendship and learning from one another"(33)*

The group discussions helped some to feel more positive about themselves and gain confidence and to start to make the changes that they wanted to make.

> *"…but I feel much more positive about myself now than I did, or my image, my self-image now than I had done for a little while. And I think that the course did help me to, just pull myself together to do it" (3)*
>
> *"it put me in a more positive frame of mind about coping with it"(17)*

7.3.2.3 Written resources

The group sessions included the use of booklets and leaflets as prompts and to be referred to outside the sessions by participants. These were often found to be useful and interesting; some had shared them with family members or used them for recipe ideas after the intervention. They were also useful when participants had missed a session. One participant had given some of the booklets away to another support group, suggesting that some were not useful or relevant to her personally, though she had kept some and had referred to them.

Most of the written resources were produced for the general public by the World Cancer Research Fund. One of these leaflets was on lifestyle and breast cancer and included their recommendations to reduce cancer risk, which are also recommended for cancer survivors **(Chapter 1.4**). This was used as a discussion prompt in all groups and stirred strong feelings on one occasion. Two participants in one group reported how one of their peers was upset as she had followed the recommendations prior to diagnosis but had still got breast cancer. This issue was not raised by participants who attended the other two groups. Another participant also reported feeling cross about the Eatwell Guide (NHS, 2019) resource that was discussed in another session as she felt that it implied blame for her diagnosis.

> *"I remember you gave out a chart, I think it may have been a plate that was divided up. And I got quite cross….because it was implying that we were to blame….because you do feel, because when you've had breast cancer or I should think any cancer, you must think well I did, well why me? Why did I get it, what have I done? Is it what I've had to eat, what I've, maybe in my youth I drank too much…" (37)*

This may suggest that further discussion of risk and probability might be required where lifestyle risk factors are discussed. The participants also felt that as they had already had breast cancer it was too late to review lifestyle advice, such as advice on alcohol consumption, to reduce breast cancer risks.

> *"Well it's too late once you got it isn't it? Yeah. If you've already had cancer there's no point saying well this could, if you drink this this could cause cancer. Well I've already got it so it's too late" (39)*

This suggests that it may be beneficial to only use resources aimed explicitly at cancer survivors to avoid causing upset, especially where people are still looking for the causes of their breast cancer.

7.3.2.4 Group activities

Participants valued the practical activities included in the sessions that they were able to engage in as part of a group. Participants found it useful to try different types of exercise to identify their own preferences. Some had continued to practice new types of exercise to which they had been introduced. Others valued breast cancer specific support to develop confidence in exercising safely following surgery and other treatments, and to understand that any increase in physical activity was beneficial. Some had subsequently had the confidence to continue to exercise independently or had joined local exercise groups.

Participants also found it useful to taste different foods and to explore personal preferences. One commented that she would not have tried the foods otherwise. Some had subsequently incorporated some of the foods into their diet. This suggests that talking about foods to encourage healthy eating, without tasting them, may not have led to behaviour change.

> "*The tasting the little bits as well, that was nice.....with the milks you brought in which was interesting, because I wouldn't have particularly bought those milks. But it was quite nice tasting them and seeing the difference in them. Some of them I quite like. We do have almond milk now as well." (39*)

Participants liked sharing foods and found it encouraging to see how others had modified recipes to make them more nutritious. Some valued sharing photos of meals prepared by others in the group to support this discussion. However, one was not confident in using digital photography to do this, while another was discouraged by seeing what she perceived as the more interesting contributions of others.

7.3.2.5 Household and friends

Most participants had discussed the programme with their households or with friends; and had had encouragement from them to make lifestyle changes. In other cases, participants had received little

support. One participant did not receive support as household members were unaware of the intervention and did not discuss it or the breast cancer.

> *"...they don't talk much about the cancer or even, yeah, reference it really at all. So I probably for that reason didn't actually say why I needed to make changes...." (17)*

In another case, a partner who prepared the meals was unwilling to make any changes to their own dietary habits which made behaviour change more challenging.

> *"Yeah I said to him about the seeds and the, I have quinoa and…..he doesn't, he just says not eating that rubbish" (37)*

The wider family were not always helpful; an unsupportive relative was reported to have implied that the diet of one participant might have caused her breast cancer diagnosis, which had caused upset.

Some participants prepared most of the meals for the rest of the family. In these cases, dietary changes were shared, and the diet of other family members also improved consequently. Sometimes, other family members also had their own dietary requirements due to medical conditions or preferences and these sometimes superseded the preferences of the participant. Sometimes, family members liked to eat unhealthy snacks and so these were available in the house, making change more difficult for the participant.

> *" I mean the biggest difficulty is that my [family member] has never put on weight and he can virtually eat what he likes. And... he loves chocolate and biscuits and things....and he does quite like to have company when he's having them. So, it's a question of just saying no..."(3)*

Some participants had discussed healthy eating with others; particularly sugars in foods and reading food labels.

The data suggested that most participants were supported by family and friends to make lifestyle changes during and after the intervention. However, in some cases relatives were unaware of the intervention or made unsupportive comments or were unwilling to make dietary changes themselves; these factors made changes more difficult for participants to make. The ability of any changes initiated to be sustained in the long term are discussed in the next section.

7.3.3 Maintaining lifestyle change

The ability of participants to maintain changes after the intervention had ended are discussed in this section. Four sub-themes were identified and are considered; making easy changes; embedding changes; relapses and ongoing support.

7.3.3.1 Making easy changes

Participants reported having maintained a variety of lifestyle changes after the intervention. There had often been a focus on informed choices to make small, achievable and autonomous changes. After the intervention, some reported a raised awareness and greater focus on making healthy lifestyle choices and had more confidence to do so.

> *"You were told that just a bit can help, that was positive and made it more achievable"(17)*

During the intervention, some participants had found a form of exercise that they liked and continued with it afterwards. These choices included running, Pilates, Tai Chi, yoga or joining a gym. Some had built up their physical activity gradually and were now exercising more than once a week.

Participants had also made small changes to their diet; some had added in foods tried during the intervention. Some had reduced portion sizes, while for other the intervention had provided ideas about a wider range of foods to incorporate into meals, such as more fish, pulses, nuts and seeds. Some had also reduced their snacking and reported eating fewer cakes and desserts. Some read food labels more, improved their meal planning or had changed their food shopping list.

> *"So it just made me think a bit more about is that worth eating really? Is that going to be good for me rather than I'm just eating.."(30)*

> *" I probably think more about what I am eating. I don't go in for these fads…. in the paper"(37)*

Some participants recognised that their household arrangements made changing shared meals difficult. Therefore, they had focused on making personal dietary changes which would not impact others. Some had changed their lunches or snacks or reduced their intake of fruit juice. Some made successful small changes to the main meal by introducing a wider variety of vegetables which could

be offered to family members according to preferences, or by having fish when others were having meat.

7.3.3.2 Embed changes

In some cases, it appeared that lifestyle changes had become embedded into routine behaviour. Some had made time to attend exercise classes several times a week, or others were now regular dog walkers. The programme had given participants ideas of additional foods to include in their meals and had become a regular part of the diet. Some felt that they had achieved their goals as they had returned to, or exceeded, previous levels of fitness and healthy eating.

> *"I'm probably better, fitter now than I was before I had cancer"(39)*

7.3.3.3 Relapses

Some participants reflected on their experiences of relapses from healthy eating. One found that completion of the food diaries for the research study had helped her to focus on healthy eating and avoid relapses.

> *"And it is quite a motivator if you have to write things down…So that was a big motivator having the food diary actually" (30)*

Some participants reflected that the behaviour change cycle had helped them to recover following episodes of unhealthy eating, often at social occasions. The cycle helped them to avoid negative responses to a relapse and they were therefore able to restart eating healthily subsequently. There was a recognition that the intervention in this study aimed to promote long-term healthy eating in contrast to a short-term weight loss diet.

> *"It's like when you do an ordinary diet and if you put weight back on you don't go back to that diet normally do you? But this isn't, this is a life change food programme I suppose isn't it?" (17)*

7.3.3.4 Ongoing support

Several people identified ongoing support that they felt would be useful after the end of the 12-week intervention. Some had ongoing weight concerns, some had ongoing information needs and some suggested ways that any support could be provided.

Several participants still wanted to lose weight. One knew what to do but just needed to make a start, while another planned to follow a published diet regime. One was unsure what other changes she could make to reduce her BMI to within the healthy range, suggesting that she needed further

support. Participants were interested in receiving additional information after the end of the intervention. Some suggested receiving a summary of the latest research or having a forum to ask questions about diet and exercise on an ongoing basis. A telephone support line, an online forum or a newsletter were suggested. One would have liked to have ongoing personalised dietary support via food diary analysis and feedback.

Some participants maintained their current exercise regime by being part of a group that provided motivation and support. Some had continued to meet some fellow participants on a regular basis and so had developed their own informal support group.

> *" I've belonged to gyms before, but I think I'm better with the group because it doesn't take much for me to give up" (37)*

7.4 Summary

Qualitative data were collected from participants at different time points during the research process using various data collection tools. The initial concerns of participants were collected at baseline using the MYCaW tool, and these concerns and wellbeing were rated before, during and after the intervention. The MYCaW tool was also used to collect qualitative data on other things affecting health and the most important aspects of the intervention during the final week of the intervention and after 12 months. The experiences of being part of the intervention groups were collected in the middle and end using feedback forms. Reflections on the entire process were collected by semi-structured interviews at least a year after the intervention ended. These methods collected data with several commonalities and with similar themes emerging during analysis.

The qualitative data suggested that the intervention might be of benefit to a wide variety of participants and that this was not dependent on previous lifestyle as treatment had often disrupted previous health habits. The data identified several contextual factors that might have impacted on intervention outcomes for individual participants. These included readiness for behaviour change, social support, stress, employment demands and treatment intensity. The data also suggested several mechanisms which may have impacted on outcomes, including peer support, shared experiences and group discussions. In **Chapter 8** these qualitative findings will be considered together with the quantitative results in order to address each of the research objectives.

Chapter eight: Discussion of findings

8 Discussion of findings

8.1 Introduction

The aim of this study was to investigate the impact of the group lifestyle intervention (**Chapter 1.6**). Many studies of lifestyle interventions for breast cancer survivors are investigated using a parallel group RCT design (for example Blackburn and Wang, 2007; Pierce, 2009; Swisher *et al.*, 2015) in which the intervention is investigated as though it were a single entity and data is collected to test the hypothesis that the intervention caused the intended outcomes. The current doctoral study took a different approach; instead of hypothesis testing, the research study formed part of an iterative process to develop an intervention that might meet the needs of the local breast cancer patient population **(Chapter 3.4.1**). It was recognised that the lifestyle intervention was a complex one in which outcomes would be affected by contexts interacting with other interventional features (Tarquinio *et al.*, 2015). Therefore, in this study, these multiple factors were investigated to tease out some of the key contexts and mechanisms to facilitate further refinement of intervention design. This was approached by separately collecting both quantitative and qualitative data in order to investigate whether there was evidence that change had occurred and to explore how this might have been facilitated or inhibited (**Chapter 3.5**). The quantitative arm of this study collected data using a quasi-experimental research design and the results were reported in **Chapter 6**, while the findings from an analysis of qualitative and MYCaW data were presented in **Chapter 7.** In this chapter the findings from these two arms of the study will be integrated and analysed. The chapter includes a sequential discussion of research outcomes relevant to each research objective. The chapter ends with a consideration of the study limitations and an overall summary.

8.2 To explore the use of a quasi-experimental evaluation design in which each person acts as their own control, to investigate the impact of the lifestyle intervention (Research objective 1)

8.2.1 Recruitment and external validity

The current study had a quasi-experimental design (**Chapter 3.6)** and as a consequence had inclusive recruitment criteria. Participants acted as their own controls and therefore were not excluded on the basis of confounding variables. Instead the study aimed to select a participant sample that was broadly representative of the local patient population that might access any future interventions.

Therefore any findings were likely to be transferable to this wider patient group increasing external validity.

Participants were largely self-selecting; 79.6% of those who made contact for more information about the study were recruited. This is a much higher proportion that in many other lifestyle interventions; for example Winger *et al.* (2014) recruited only 29.7% of older long-term cancer survivors who expressed an interest in joining their diet and exercise intervention; this was only 3.2% of those who were initially invited. In traditional RCT studies, stringent inclusion and exclusion criteria aimed at reducing effects of confounding factors can result in a sample population that is not representative of the general patient population. Other RCTs tend to recruit a younger participant group who are more homogenous and who lack co-morbidities (Tarquinio *et al.*, 2015). This may mean that results are skewed with low external validity as it is unclear to whom the findings may apply (Blackwood, O'Halloran and Porter, 2010).

The demographic data collected in this study (**Table 6:1**) suggested that the inclusive recruitment methods had resulted in a study sample that was heterogenous in terms of age and treatment history. The participant group included a wide range of ages from 25-69, with a mean age 54.7 years. **Figure 1:4** showed that the mode age of patients at diagnosis in the UK was 65-69, so the participants in this study were a younger group than this would suggest, although most (79%) were over 50. Other large lifestyle intervention studies reported a similar mean participant age; the Women's Intervention Nutrition (WINS) trial recruited post-menopausal women aged 48-79 years with a breast cancer diagnosis; the mean age of those recruited was 58 years (Pierce, 2009). This is a higher mean age than the current study although as pre-menopausal women were excluded this is likely to account for the difference. The Women's Healthy Eating and Living (WHEL) trial (Pierce *et al.*, 2002) enrolled women aged 18-70 years at diagnosis and had an average age at study entry of 53 years; a little less than in the current study. The participant group recruited in this doctoral study and other published trials, may not be representative of older breast cancer patients.

In the current study, 76.7% of participants reported that they were taking other medication and 44.2% reported having another health condition that might affect their ability to exercise or alter their diet (**Table 6:1**); other health conditions might have been unreported. These data suggest that a high proportion of participants had other co-morbidities. It is challenging to compare these data

to the local population to ascertain if it were likely to be representative. The 2011 census return for the county shows that 17.9% of the population report having a long term health condition that limits daily activities (County Public Health Intelligence Team, 2013). This suggests that about 80% of the local population report being in good health, although the proportion of older adults with good health is not reported. However, the data confirmed that the study included participants with a wide range of other co-morbidities.

The sample recruited in the current study was not ethnically diverse: the vast majority reported being white (95.3%). However, this proportion is comparable to the local county population which is 92.4% white; both being higher than the population average for England (79.8%) (County Public Health Intelligence Team, 2013). In other studies, there was often a high proportion of white participants recruited even in more ethnically diverse areas. The WINS and WHEL trials both report approximately 85% of their sample were ethnically white (Pierce, 2009). In order to recruit a more ethnically diverse sample, some studies developed and trialled culturally adapted interventions. Several US studies targeted African American (for example Griffith *et al.*, 2012; Demark-Wahnefried *et al.*, 2014; Stolley *et al.*, 2017) or Hispanic American (Greenlee *et al.*, 2015) populations to ensure that research was representative of local breast cancer patient populations.

The sample population in the current study were also well educated; 25.6% had a degree and 18.6% had a postgraduate qualification, so a total of 44% of the sample were educated to degree level or above. This is much higher than the proportion of 26.3% graduate or above reported for women aged 50-64 in England and Wales in 2011 and may have been affected by the University setting (**Section 8.3.1.5**). The proportion of this study sample having no qualifications (7%) was also much lower than the population figure those aged 50-64 in England and Wales (25.1%)(Office for National Statistics, 2014). This suggests that the sample was skewed towards those with a higher level of educational qualification and this may not be representative of the local patient population. Other intervention studies have also reported recruitment of well-educated participant groups; for example Demark-Wahnefried *et al.* (2012) recruited a large sample of older cancer survivors, and found that over 60% had had a College education and the WINS and WHEL trials both report around 50% of participants were College graduates (Pierce, 2009). By contrast Greenlee *et al.* (2015) recruited a sample in which around a third of participants were educated to less than high school level.

The participants recruited in the current study were largely self-selecting and the group largely consisted of younger, white and well-educated participants, with a range of co-morbidities. This might have resulted in self-selection bias if the characteristics of participants choosing to participate were also characteristics that might influence outcomes (Tarquinio *et al.*, 2015); in this case, the volunteer characteristics might not match those of the wider patient group.

Though recruitment was good, unexpectedly several participants (n=7) were still in treatment at baseline and as discussed previously were only able to join the study once treatment was completed (**Chapter 4.2.1.2**). They were therefore excluded from the quantitative arm of the study so the quantitative groups were reduced in size (**Figure 6:1**) and were fewer than would be required for a fully powered RCT study. However, in a quasi-experimental study design in which participants act as their own controls a smaller sample size might be sufficient as the potential effects of different personal, health or clinical confounding variables is minimised (Sidani, 2015).

8.2.2 Randomisation and retention

The current study had a quasi-experimental design (**Chapter 3.6)** which did not include randomisation. In traditional RCT studies of lifestyle interventions for cancer survivors , such as the WINS and WHEL trials (Pierce, 2009), participants are recruited and subsequently randomised to intervention or control groups. Adamson *et al.* (2006) suggest that participants randomised to control groups may demonstrate 'resentful demoralisation' leading to lower engagement and higher drop out. In the current quasi-experimental study, participants acted as their own controls and so there was no randomisation. All participants were therefore able to attend the intervention thereby removing the risk of 'resentful demoralisation'. In this study, 11.6% of participants dropped out of the study during the lifestyle intervention. This is equivalent to the 11.9% drop out reported in a single arm body weight loss trial (Travier *et al.*, 2014) and is in line with an expected drop out of up to 10% for lifestyle interventions for breast cancer survivors reported by Saxton *et al.* (2006). Drop out was much higher in a diet and physical activity intervention for a mixed group of cancer survivors reported by James *et al.* (2015). In this study, dropout following randomisation and before baseline testing for the control arm (31.8%) was about twice that of the intervention arm (15.7%) (James *et al.*, 2015). This discrepancy occurred even though this was a waiting list control group and participants randomised to it would still be able to access the intervention after the 8-week control

data collection period. This supports the assertion that those allocated to a control group might become disengaged.

As there was no randomisation in this doctoral study, participants were able to choose which of the three intervention groups to join, which it was anticipated would maximise engagement and attendance. In a telephone counselling diet and physical activity intervention for mixed cancer survivors, Winger *et al.* (2014) found that better attendance was associated with improved diet and exercise behaviours. They recognise that the identified association between attendance and outcomes might not be causal, but they still recommended the adoption of flexible strategies to improve attendance. This was attempted in the current study as two intervention groups ran during the daytime, while one ran in the evenings and was selected by those with daytime commitments. The groups were run during the autumn or the spring and again participants were able to choose which they wished to attend depending on their other commitments such as holidays or planned medical procedures. In the spring, the day and evening groups ran in parallel and some participants swapped between the groups where necessary to avoid missing sessions. This flexibility may have contributed to good attendance, with an overall attendance of 71.5% and mean session attendance of 8.6 sessions out of 12. The good attendance and retention also suggested that the intervention was well-received.

8.2.3 Comparative data

In this doctoral study, the use of a quasi-experimental study design in the quantitative arm of the study allowed for collection of comparative data without the need for recruitment of parallel control groups. This allowed a comparison of change over the intervention period to change over a similar period of time before the intervention (**Chapters 4.2.1.3** and **4.2.1.4**). This comparison strengthened the assertion that the intervention might have caused the observed changes, rather than change having occurred simply due to other confounding factors, especially the passage of time since diagnosis and treatment (**Chapter 3.4.4**). As participants acted as their own controls, the influence of other confounding factors was likely to have been reduced. Therefore, this study can provide some evidence of causality while recognising that any findings are to be treated with caution as RCT evidence was not obtained. However, this study design did not allow the collection of comparative data over the 12-month follow up period and so this phase of the research was effectively a single

arm trial. Therefore the follow up findings were less conclusive and could have been due to the passage of time or other confounding variables rather than the impact of the intervention.

This quasi-experimental study did not include the use of separate control groups and therefore avoided the ethical challenge of depriving control group participants access to an intervention that may have been beneficial to them (**Chapter 3.4.4**). Other RCT studies have varied in the treatment offered to control groups. It can be difficult to determine the use of an appropriate control treatment while working ethically in the design of lifestyle interventions following breast cancer treatment. In some cases, control treatments can inadvertently impact on outcomes as discussed in C**hapter 2.2.1** and this was avoided by the design of the current study.

8.3 To identify contexts and mechanisms for change as part of a realist evaluation of the intervention (Research objective 2).

8.3.1 Contexts that may impact on research outcomes

In this study, key intervention contexts were identified (**Table 8:1**) following a review of the literature **(Chapter 2)**, analysis of qualitative data (**Chapter 7**) and experience of running past intervention groups. The participants attending the intervention were individuals with personal social, psychological and health contexts (**Chapter 3.4.2**) that might have impacted on responses to the intervention and therefore the observed outcomes. The consideration of the participant contexts was intended to identify groups within the local breast cancer population who might benefit most from this type of intervention. This could be used to focus future recruitment criteria to maximise impact. The setting and delivery of the intervention were also key context factors which were considered to inform future interventional developments.

Table 8:1 Contextual factors that may have affected outcomes

Context C1	Experience of breast cancer diagnosis and treatment
Context C2	Previous lifestyle and health
Context C3	Intervention timing
Context C4	Support from family and friends
Context C5	Intervention setting and delivery

8.3.1.1 Experience of breast cancer diagnosis and treatment (Context C1)

A key contextual factor (Context C1) in this study was the participants' experiences of breast cancer diagnosis and treatment. It has been recognised that cancer diagnosis is a traumatic event and without an endpoint or cure, patients are confronted by their own mortality which can result in ongoing fear (Connerty and Knott, 2013). In this study, a fear of cancer recurrence was reported as a key motivator for behaviour change (**Chapter 7.3.1**) as participants wanted to improve their lifestyle to reduce risks. Fear of recurrence is very common, affecting almost half of cancer survivors (Macmillan Cancer Support, 2013). Risk perception is recognised as a determinant of behaviour change (Maes and Karoly, 2005). Cancer diagnosis has been described as a 'teachable moment' (Murphy and Girot, 2013) where motivation to change lifestyle may be high.

In the current study, some were ready to make lifestyle changes, while others might not have been ready to do so. The shock of diagnosis can continue for a long period of time and may have counter-productive effects in which some participants might initially be more concerned with finding a cause for their diagnosis than in making lifestyle changes and might not be ready to engage in the lifestyle programme (**Chapter 7.3.1.2**). Using the Transtheoretical Model (TTM) of behaviour change (Prochaska *et al.*, 1994; Green *et al.*, 2014) these participants might be in the pre-contemplative stage. In this study, a few participants in one session became upset (**Chapter 7.3.2.3**) when reading resources about lifestyle and breast cancer risk. This may be more likely to occur where participants were still searching for explanations for their diagnosis. It might be that participants who have accepted their diagnosis and are ready to move forward might benefit more from participating in a lifestyle intervention and are more able to process nuanced discussions around risk **(Section 7.3.1.2**). In this study, participants appeared to reach this stage at different times following diagnosis. It might improve intervention efficacy if participants were able to join the intervention when personally ready to engage in lifestyle change.

Participant experiences of diagnosis and treatment in this study were very heterogenous in terms of age of diagnosis, location, grade and stage of the tumour, hormone receptor status, intensity of treatment and time since treatment end. It has previously been reported that breast cancer treatment can lead to fatigue, pain, breathing difficulties, nausea or appetite loss and psychological effects such as depression (Partridge and Nekhlyudov, 2014; Cheng, Sit and So, 2016; Runowicz *et al.*, 2016) **(Chapter 1.4)**. In this study, participants reported a multiplicity of effects on health that

affected their ability to engage in behaviour change and their motivation to do so. Corbett *et al.* (2018) found that although motivation was high, many cancer survivors do not change behaviour for a wide variety of reasons including the physical and emotional sequelae of diagnosis and treatment. The breast cancer treatment regime is long and demanding (Connerty and Knott, 2013) and, in this study, by the end of treatment, some participants reported that they had changed eating habits or become socially isolated or physically inactive (**Chapter 7.3.1**). Habits are repeated behaviours which occur automatically in a stable environment (Verplanken, 2006) and the treatment period is likely to represent a lengthy change in environment which may have led to changes in eating and exercise habits. It has been reported elsewhere that cancer treatment often results in changes in the ability to smell and taste food, changes in food preferences and aversions, and in appetite and the enjoyment of eating (Coa *et al.*, 2015) which can result in altered nutritional intake. In this study, some participants reported weight gain, which is common post-diagnosis in cancer (Sedjo *et al.*, 2014) especially breast cancer (Coa *et al.*, 2015) and is also associated with a loss of muscle mass and strength and a loss of physical fitness. Weight gain can also result in a loss of self-confidence and self-esteem and increased depressive symptoms (**Section 8.4.3.1**).

In the current study, there was often a lack of confidence in becoming more physically active due to a fear of damaging the body, especially on the surgery side (**Chapter 7.3.1).** Loss of self-confidence is common in cancer survivors after the end of primary treatment (Richards, Corner and Maher, 2011) and may be a barrier to behaviour change. In some cases, participants were motivated (**Chapter 7.3.1**) to regain control of their health following treatment, to improve their quality of life and to facilitate their transition back from being a patient to daily life. Beeken *et al.* (2016) found that cancer survivors were interested in improving their diet to improve wellbeing and to gain agency. The focus on health improvement in this study might have meant that most participants, despite their varied experiences of treatment, were able to engage with and benefit from the intervention.

8.3.1.2 Previous lifestyle and health (Context C2)

The data in this study suggested that the intervention was beneficial both to those who were sedentary before diagnosis, as well as those who were physically active. As discussed in **Section 8.3.1.1**, treatment can result in a loss of fitness and of confidence to exercise and participants benefitted from support to exercise safely whether or not they had previously been active (**Chapter**

7.2.3.5.1). Some previously active participants needed support to build up and return to previous activity levels (**Chapter 7.3.1.1**). The varied experiences of physical activity meant there was a need to accommodate both those who were previously physically active and those who were new to exercise or had limited mobility (**Chapter 7.3.2.4**). In some other studies participants with co-morbidities were excluded as exercise was carried out remotely without supervision and participants who were physically active were also excluded (for example Snyder *et al.* (2008). In this study, all exercise sessions were supervised in a dedicated exercise facility and both physically active participants and those with other health conditions, were able to be included and to benefit from it. In the current study, some participants were motivated to reduce the effects of other health conditions or to reduce their requirement for medication and so their inclusion in the intervention has additional potential benefits (**Chapters 7.1.1** and **7.3.1.1).**

The intervention was also of benefit to those with, or without, a healthy diet before diagnosis. The data suggested that eating patterns were disrupted during treatment (**Chapter 7.1.1**) and that the intervention encouraged improved nutritional intake and the development of healthier patterns of eating (**Section 8.4.1.7**). Over-eating may also occur in response to the stresses of diagnosis and treatment (Balneaves *et al.*, 2014), and could be exacerbated by stress (Terranova *et al.*, 2017). The intervention was potentially impactful, whether participants were of a healthy body weight or not, through a focus on healthy eating and increased physical activity. Some participants wanted to return to health, body weight or fitness that they had had prior to diagnosis (**Chapters 7.1.1** and **7.3.1**). Many published lifestyle interventions for breast cancer survivors were aimed at weight loss and excluded those who were not over-weight or obese (for example Snyder *et al.* (2008) while in other cases participants were excluded on the basis of diet. Greenlee *et al.* (2015), for example, excluded those who consumed 5 or more portions of fruit and vegetables per day. Castelló *et al.* (2015) found that following WCRF cancer guidance could reduce cancer risk, even for those who already had quite a healthy lifestyle, supporting the view that the intervention could be beneficial to those who had previously eaten a healthy diet and been physically active.

In this study, the previous lifestyle and health of participants prior to diagnosis was very varied (**Table 6:1** and **7.1.1**). Some had previously been very physically active, while others had not, some had previously had a healthy diet and had been of a healthy body weight, while others had been over-weight or obese prior to diagnosis. Some had previously been healthy while others had a

variety of long- term conditions. The data supports the inclusion of these categories of participant in any future interventions.

8.3.1.3 Intervention timing (Context C3)

The participants in this study varied in the point during their patient journey when they felt ready to engage in lifestyle change (**Chapter 7.3.1.2**). It was intended that those recruited in the current study would have completed their primary treatment, and this was stated in the participant information sheet sent out to those who expressed interest in joining the study **(Appendix 2.2.2).** However, at baseline testing, several potential participants (n=7) were still in treatment. This might suggest that there is a demand for a lifestyle programme amongst those who are nearing the end of treatment; although this level of interest may simply have been due to their receipt of information at ongoing clinic appointments or support groups (**Chapter 4.2.1.2**). By contrast, some of the participants in the current study had completed treatment several years previously (**Table 6:1**) which also suggested that the need for a lifestyle programme persisted. In this study some reported not feeling ready to engage in the intervention until years after diagnosis (**Chapter 7.3.1.2**).

There are different views expressed in the literature about the most appropriate time to offer a lifestyle intervention. Other studies recruited participants soon after completion of treatment (Reeves *et al.*, 2017) or some months or years after intervention end (Griffith *et al.*, 2012). Some suggest that intervening soon after diagnosis could capitalise on the 'teachable moment' (**Chapter 1.5**) (Stull, Snyder and Demark-Wahnefried, 2007) and could mitigate against treatment effects including body weight gain (James-Martin *et al.*, 2014; Schiavon *et al.*, 2015; Harvie, 2017). Weight gain after diagnosis has been associated with a worse prognosis (Richards, Corner and Maher, 2011; Robien, Demark-Wahnefried and Rock, 2011) and early weight loss may be able to reduce the higher recurrence in the years following diagnosis (Chlebowski and Reeves, 2016). It has also been suggested that lifestyle programmes could become the next stage after medical treatment (Balneaves *et al.*, 2014; Travier *et al.*, 2014) to maximise recruitment and engagement and to smooth the transition from patient to survivor (Milliron, Vitolins and Tooze, 2014).

The data from this study suggested that joining an intervention towards the end of treatment might be appropriate for some, but not all, participants. The appropriate timing for individuals might depend on the intensity of treatment received which is dependent on the stage and grade of the cancer at diagnosis (Sainsbury, Anderson and Morgan, 2000; Runowicz *et al.*, 2016). Some

participants in this study may have been too shocked and distressed initially to engage in behaviour change (**Section 8.3.1.1**) while others found it easier to attend and engage at an early stage while they were still on sickness absence (**Chapter 7.3.1.2**). It appeared that participants were ready to engage in a behaviour change intervention at different time points depending on their individual context.

8.3.1.4 Support from family and friends (Context C4)

In the current study there was a view that the end of treatment and professional support was rather abrupt (**Chapter 7.3.1.3**). Subsequently, some accessed informal face to face or online support groups, while others had avoided these and felt unsupported. Some who had avoided other support groups accessed this intervention as it focused on moving forward towards recovery. In this context, support from family and friends might be beneficial.

In this study, participants varied in the level of support that they gained from family and friends in making behaviour changes (**Chapter 7.3.2.5**). Some were very well supported and dietary improvements also benefitted others in the household. In other cases, family members were reluctant to change family meals or made unsupportive comments. Occasionally, families were not aware of the intervention and so were unable to help. Support from family and friends can be a facilitator for behaviour change, but can also be a barrier where insufficient support was available or where family problems occurred (Terranova *et al.*, 2017).

Balneaves *et al.* (2014) suggest that a support person should also be involved in interventions. Several other interventions included the use of supporters either informally by being invited to attend sessions (Stolley *et al.*, 2009) or by more formal recruitment as suggested by Travier *et al.* (2014). In some cases biological daughters (Demark-Wahnefried *et al.*, 2014; Tometich *et al.*, 2017) or family or friends were recruited but also participated in the intervention rather than providing support (Spector *et al.*, 2012; Conlon *et al.*, 2015). However, the recruitment of participating partners did not seem to affect participant outcomes (Knobf, Erdos and Jeon, 2018).

Support from family and friends was an important context affecting behaviour change. Some other studies recommend that family or friends are included in interventions as supporters to ensure that awareness and understanding of recommendations occurs (Stolley *et al.*, 2009; Terranova *et al.*, 2017). In some other studies the formal involvement of a support person was included but this was

not part of the current intervention. In future interventions it might be beneficial to involve a family member or support person to attend at least one session or briefing and receive written information about ways to support a participant to make lifestyle changes.

8.3.1.5 Intervention setting and delivery (Context C5)

In this study, this face-to-face group intervention was delivered in a University Wellbeing Centre, rather than in a clinical setting, which may have helped participants in the transition from patient back to the wider world. The sessions were set in a gym and adjacent seminar room. The gym was well-equipped in terms of specialist staff and resources to allow for the practical activities to occur. In this study, some participants found it too noisy for more mindful activities such as Tai Chi (**Chapter 7.2.3.5.1**). The University setting and staffing may have discouraged the attendance of those with less positive educational experiences and may have contributed to recruitment of a group with high academic achievement **(Section 8.2.1)**. It might be that a community setting might encourage more representative participation; in other studies that were run in community settings a broader range of participants was recruited (Stolley *et al.*, 2017).

The intervention was held in a city centre setting to ease the use of public transport from the surrounding areas. Unfortunately, the setting did not have on-site parking facilities, and a few participants found travelling problematic due to distances from home, traffic congestion and parking issues (**Chapter 7.2.3.1**). Attendance has been reported to be more problematic for younger participants in other studies, due to work and family commitments, compared to older and retired participants and that timing and location are important considerations in face to face interventions (Campbell *et al.*, 2012). In this study, the choice of session to attend was appreciated by participants (**Chapter 7.2.3.1**). Greenlee *et al.*, (2015) recommend including fewer sessions supplemented by online materials to facilitate attendance. However, it is also recognised that time is needed for new behavioural habits to become established (Verplanken, 2006) and therefore a behaviour change intervention might need to be long enough to allow this to occur. This intervention was for 2 hours each week for 12 weeks, and participants felt that this length was appropriate (**Chapter 7.2.3.1**). This contrasted to views of some others in the literature; Kim, Shin *et al.* (2011) suggested that 12 weeks might not be long enough for behaviour change, while Park *et al.* (2016) suggested that a 4 month intervention may be too short. Some participants in this study felt that a longer or more

intense intervention might make attendance more problematic and could result in higher drop out (**Chapter 7.3.2.1**).

The University setting and in person attendance may have been problematic for some participants. Befort *et al.* (2016) suggest the use of telephone intervention to surmount barriers to attendance. Alternate modes of attendance may be more convenient, although remote interventions may provide less group support which may result in lower attendance and engagement (Harrigan *et al.*, 2016).

8.3.2 Intervention mechanisms for change

The intervention developed in this study was designed to encourage behaviour change (**Chapter 5.5**) and in this section the mechanisms (**Chapter 3.4.2)** that may have affected the outcomes are explored**.** In the literature there is no agreed framework of mechanisms to promote behaviour change (Carey *et al.*, 2018). Therefore, in this study, key mechanisms were identified following a review of the literature **(Chapter 2**), analysis of qualitative data (**Chapter 7)** and experience of leading intervention groups. Any intervention is likely to lead to outcomes due to an interplay of contexts (**Section 8.3.1**) and a multiplicity of mechanisms interacting. This section considers key intervention mechanisms **(Table 8:2**) to be considered as part of an iterative process of intervention development.

Table 8:2 Mechanisms to promote behaviour change

Mechanism M1	Increase knowledge and understanding of healthy eating and physical activity guidelines for breast cancer survivors
Mechanism M2	Improve confidence and motivation to take control of lifestyle and wellbeing
Mechanism M3	Develop and rehearse skills to make and sustain healthy lifestyle choices
Mechanism M4	Increase peer support

8.3.2.1 Increased knowledge and understanding (Mechanism M1)

Increased knowledge and understanding can contribute to the initiation and maintenance of behaviour change (**Chapter 1.5**). In this study, qualitative data suggested that most participants found the intervention to be informative, useful, interesting and enjoyable (**Chapters 7.2.2** and **7.3.2**). Participants felt more informed and felt the content could be applied to lifestyle

improvement over time. Participants reported that increased understanding made recommendations easier to follow. A few participants wanted more scientific detail about nutrition as has been reported in other studies such as Balneaves *et al.* (2014) where written information was perceived as too simple. There may have been expectations of a higher level of coverage in this study due to the University setting (**Section 8.3.1.5**) and as many participants had high levels of education (**Table 6:1**). Motivation and engagement may have been affected for those who felt that the level of coverage was not appropriate.

Participants valued that the intervention in the current study was specifically designed for women with a diagnosis of breast cancer (**Chapter 7.3.1**); several studies in the literature were also specific to breast cancer (**Chapter 2.8.1**) (for example Muraca *et al.* (2011) and Reeves *et al.* (2016) while in others generic lifestyle interventions were amended to include breast cancer content (for example Campbell *et al.*, 2012; Harrigan *et al.*, 2016) suggesting that this was an important aspect. Interview data (**Chapter 7.3)** suggested that participants were interested to know the latest evidence about health and diet as there was confusion about contradictory advice in the media (**Section 8.4.1.5**). Some participants in this study found the WCRF booklets provided were a useful resource, although a few found that the consideration of nutrition and breast cancer risk was counter-productive (**Section 8.3.1.1** and **Chapter 7.3.2**) for example in the context of alcoholic drinks (**Section 8.4.1.6**). In future interventions, it may be more effective to focus on behaviour change for wellbeing and recovery following breast cancer, rather than on lifestyle and breast cancer risk.

8.3.2.2 Confidence and motivation (Mechanism M2)

A breast cancer diagnosis can provide motivation for lifestyle improvement, although treatment can result in a loss of self-confidence (**Chapter 1.5**) which the intervention was intended to address (**Chapter 5.5**). Knowledge and understanding gained during the intervention (**Section 8.3.2.1**) changed participants' attitudes to lifestyle and increased motivation and confidence for behaviour change (**Chapters 7.2.1** and **7.3.1**) and was therefore a key mechanism that may have impacted on outcomes.

Participants reported that they had gained confidence by making small achievable changes (**Chapter 7.3.3)** and from peer support; learning from, and being inspired by, others in the group (**Chapters 7.2.3** and **7.3.2**). Participants also gained confidence in their own capabilities by experiencing different physical activities in a safe and supportive environment (**Chapter 7.2.3.5.1**). The focus of

the intervention was on healthy eating, rather than weight loss to avoid negative sequelae which could reduce confidence and motivation where weight loss did not occur (**Chapter 2.8.2**). Some participants wanted a greater emphasis on health behaviours to increase for health, rather than things to avoid or limit (**Section 8.4.3.1)** which could also impact on motivation**.**

During the intervention, participants may have been externally motivated by the sessions and peer support. After the intervention, internal motivation may be more important in the long-term maintenance of changes (**Chapter 2.9.6**). Participants gained confidence and motivation from the positive group atmosphere and appreciated that there was no pressure to make changes so that they were able take control of their own health (**Chapter 7.3**). The intervention intended to develop the agency of participants through personal goal setting and review (**Chapter 7.2.2**).

8.3.2.3 Develop and rehearse skills (Mechanism M3)

The intervention intended to develop skills so that participants were able to make informed lifestyle choices for long-term behaviour change (**Chapter 1.6)**. Skills were developed through the use of practical activities (**Chapter 7.2.3.5**) which were possible due to the face-to-face context and the setting in a well-resourced University environment (**Section 8.3.1.5; context C5**). The intervention sessions included practical sessions on trying different physical activities, reading nutrition labels, sharing foods and exploring taste preferences, and modifying recipes and meals for health (**Chapter 5.5**). Skill development was intended to increase knowledge and understanding (**Section 8.3.2.1**) and for participants to apply this to their personal context. This was also intended to increase self-confidence of participants in making behavioural changes (**Section 8.3.2.2**).

In most other reported studies, recommended foods were discussed but not sampled, though some also included practical activities such as cooking, shopping and shared eating (Greenlee *et al.*, 2015; Knobf, Erdos and Jeon, 2018); in this study, different foods were sampled each week. In the current study the opportunity to try different physical activities in a safe and supportive environment was appreciated and allowed participants to find preferred activities to continue with long term. In some other studies, increased home-based physical activity was encouraged but supervised exercise was not included (Mosher *et al.*, 2008; Harrigan *et al.*, 2016; Tometich *et al.*, 2017) which may be less supportive of behaviour change.

Intervention sessions were intended to develop skills of self-efficacy and self-regulation, so that motivation to make lifestyle changes could be translated into action, even in adverse situations (**Chapter 1.5**). These skills were intended to promote behaviour change resulting in healthier eating (Johnson, Pratt and Wardle, 2012). The key role of these skills in promoting behaviour change has been widely recognised in the literature (**Chapter 2.8.3**) and outcome data in this study in relation to development of self-efficacy skills are considered in more detail below (**Section 8.4.2)**. During sessions, participants set and reviewed personal health goals and used the TTM behaviour change cycle (Prochaska *et al.*, 1994) to monitor progress and to aid recovery from relapse. In qualitative interviews this was recognised as being useful **(Chapter 7.3.3).** Participants need confidence, motivation and support in order to recover from relapses in order to achieve long term change. Participants in this study reported having difficulties making changes (**Chapter 7.3.3**) and gained support from sharing these experiences with the group (**Chapter 7.3.2.2** and 7.3.3.4).

8.3.2.4 Increased peer support (Mechanism M4)

Support from family and friends for participants to make behavioural changes was recognised as a key contextual factor in this study (**Section 8.3.1.4; C4)**. Participants are likely to need support to make behavioural changes (**Chapter 2.7**) although not all participants had outside support and therefore support from peers within the study was a key mechanism to impact on intervention outcomes. This was a face-to-face intervention and was designed to enhance group cohesion with opportunities for socialising and shared eating (**Chapter 5.5**). Participants reported that they had enjoyed being part of a group and for many this was a key aspect of the intervention; opportunities for informal discussion were valued by participants **(Chapters 7.2.3** and **7.3.2.2)**. The group sessions were found to be relaxed, supportive, positive and enjoyable, which may have contributed to the good attendance and retention (**Section 8.2.2**). The social aspect of the intervention and the resultant friendships and peer support were highly valued (**Chapters 7.2.3** and **7.3.2.2**) and are likely to have positively affected outcomes. The group setting enabled sharing of experiences and shared learning to occur which were also valued (**Chapters 7.2.3** and **7.3.2.2)** and may have contributed to peer support.

In this study, peer support was possible as it was a face-to-face intervention that met weekly over 12 weeks which allowed time for a group rapport to develop (**Chapters 7.2.3** and **7.3.2.2**). Participants valued learning from their peers and were also encouraged and inspired by their peers.

The meetings provided a forum to share successes and challenges of making behavioural changes which might have helped to develop confidence and motivation and therefore self-efficacy and self-regulation skills. For some participants, peer support continued beyond the end of the intervention as they had continued to meet and support each other.

Peer support was common in other reports of group interventions (for example Balneaves *et al.*, 2014; Travier *et al.*, 2014) although it was more formalised by Conlon *et al.* (2015) where a peer buddy system was used in group sessions. Mechanisms for establishing peer support within remote intervention groups were used in other studies. In an online intervention Lynch *et al.* (2016) included online peer discussion boards for social support, while a telephone intervention (Fazzino, Sporn and Befort, 2016) included group facilitation using conference calls. Formal peer support was also included in one study in which 'survivor coaches' were trained and led individual telephone coaching sessions with participants (Sheppard *et al.*, 2016) which may be a useful approach to ensure peer support is provided for all. There seemed to be a wide recognition in the literature that the facilitation of peer support enabled behaviour change and should therefore be considered in the design of future interventions.

8.4 To explore the changes in dietary habits, self-efficacy and health of participants over time (Research objective 3).

8.4.1 Dietary habits

In this study, over half of the participants initially expressed concerns about nutrition **(Table 7:1**). These concerns were very varied and included concerns about treatment effects on diet or body weight, or desires to promote recovery and wellbeing, or to reduce recurrence risks. As discussed above **(Section 8.3.1.1)** a diagnosis of breast cancer might provide a stimulus for behaviour change, however other studies have found that the diets of those with a breast cancer diagnosis are no different from those of the general population (Stull, Snyder and Demark-Wahnefried, 2007; Robien, Demark-Wahnefried and Rock, 2011; Ceccatto *et al.*, 2012) and most do not meet national nutritional guidelines (Milliron, Vitolins and Tooze, 2014) as discussed in **Chapter 1.5**. Despite interest in lifestyle, few cancer survivors make behaviour changes (Corbett *et al.*, 2018). One of the research objectives of this study was to provide support to improve the dietary habits of participants in line with World Cancer Research Fund recommendations for cancer survivors (**Table 1:1**) to promote health and wellbeing. Therefore, the intake of key nutrients was reported (**Chapter 6.5**) as

discussed in **Chapter 4.2.5** and the impact of the intervention on intake of these key nutrients are discussed below.

8.4.1.1 Energy

One of the WCRF recommendations is to maintain a healthy body weight for cancer prevention (**Table 1:1**) and in this study energy intake was reported, to indicate whether the intervention had made an impact in meeting this recommendation **(Chapter 4.2.5)**. This recommendation is also considered in the context of anthropometric measures in **Section 8.4.3.1**.

Data from the quantitative analysis group (n=22) showed a significant reduction in mean daily energy intake in the short term during the intervention period compared to the comparative period, suggesting that this was a response to the intervention (**Table 6:8**). The follow up group (n=10) also showed a significant reduction in mean daily energy intake, but in this case between the start of the intervention and the 12-month follow up (**Table 6:9**). There was decrease of 12.9% over the intervention period compared to 0.5% over the comparative period although this difference was not statistically significant, perhaps due to the smaller sample size. However, the reported mean daily energy intake decreased further after the intervention and reached significance at the 12-month follow up, showing the need to have longer term data collection so that the impact could be seen. These data suggest that the intervention was associated with a decrease in mean intake of energy over the intervention period and this reduction may have continued over the subsequent 12 months.

A decrease in energy intake may have helped some participants to achieve the WCRF guidelines to maintain a healthy body weight **(Table 1:1**). At baseline, most participants were overweight (48%) or obese (29%) (**Table 6:6**) and so might have benefitted from this reduction in mean daily energy intake to promote achievement of this recommendation. In this study, the subjective food diary data was self-reported and might be subject to reporting bias especially in estimation of portion size (Whitton *et al.*, 2011). It is well known that energy intake is often under-reported (Scientific Advisory Committee on Nutrition, 2015) and this is more common in older women who are obese or those trying to lose weight (Briefel, Alaimo and Chia-ying, 1997; Christifano *et al.*, 2016) and therefore may have been a bias in this study in which participants were aware of the recommendation to maintain a healthy body weight. However, these results are supported by the anthropometric data (**Section 8.4.3.1)** which found a significant body weight loss and reduction of BMI occurred over the

intervention period and the proportion of participants with a healthy body weight also increased (**Table 6:6** and **Table 6:7**). These results are also supported by evaluation (**Chapter 7.2.2.3**) and interview data (**Chapter 7.3.3**) in which participants reported making dietary changes such as reducing portion sizes and reduced snacking which may be the reasons for the observed decreased energy intake.

In this study, the reported mean daily energy intakes for both groups at all time points were well below the recommended Estimated Average Requirements (EAR) for women , which decreases from 2175 Kcal/d to 1912 Kcal/d between age 19 to 74 respectively (British Nutrition Foundation, 2019) and which includes the ages of all participants in this study **Table 6:1.** However, the mean daily energy intakes at baseline are consistent with national findings for women aged 19-64 (1553Kcal/d) (Whitton *et al.*, 2011). A daily energy intake of 1200-1500 Kcal/d for body weight loss in overweight and obese breast cancer patients has been suggested (Travier *et al.*, 2014) and the mean energy intake in the current study was within this range at the end of the intervention in the quantitative group, and by 12 months afterwards in the follow up group (Table 6:8 and Table 6:9) suggesting that intake following the intervention was at an appropriate level to promote body weight loss.
These data suggest that a reduction in energy intake occurred during the intervention and in the longer term after it had ended. This is likely to represent an improved achievement of WCRF recommendations for some of the participants and may also represent an improvement in nutrition quality which will be explored in the subsequent sections.

8.4.1.2 Carbohydrate, starch, sugar, free sugar, sucrose and Glycaemic Load (GL)

The WCRF recommendations advise a reduced consumption of fast foods, processed foods and drinks high in sugar (**Table 1:1**). In this study the intake of carbohydrates, starch, sugar, free sugar, sucrose and Glycaemic Load (GL) were reported to indicate whether the intervention had made an impact on meeting these recommendations **(Chapter 4.2.5).**

Data from the quantitative analysis group (n=22) showed that there was a 15.4% decrease in mean daily intake of total carbohydrate over the course of the intervention which was statistically different to intakes over the comparative period (Table 6:8). Therefore, the reduction in the mean carbohydrate intake was likely to be due to the intervention effects. Data from the follow up group (n=10) were analysed to see whether this change was maintained after the intervention end. The results again show a significant decrease in mean daily intake of carbohydrate between intervention

start and end and between intervention start and the 12-month follow up, suggesting that the mean decrease in carbohydrate intake was maintained (Table 6:9). The percentage contribution of carbohydrate to mean energy intake was below the recommendation of 50% (British Nutrition Foundation, 2019) at all time points in both groups (**Table 6:10** and **Table 6:11**). The total carbohydrate data used in this study included starch and all sugars, but did not include fibre (Nutritics, 2019) while this is included in the recommended figure (British Nutrition Foundation, 2018) and so they are not directly comparable. Fibre contributes 2 Kcal per gram (British Nutrition Foundation, 2018) and the combined % contribution of carbohydrate and fibre to energy intake in both groups at all time points was also below the 50% recommendation. This suggests that dietary intake of carbohydrate was under reported throughout the study, or that further nutritional improvement was required even after the intervention end.

As the data showed a decrease in mean daily intake of total carbohydrate, it was therefore surprising that it showed no significant differences in mean daily intake of starch, sugars, free sugars or sucrose over the intervention period. The intervention sessions (**Chapter 5.5**) included a discussion of the WCRF guidelines to reduce sugar intake (**Table 1:1**) together with guidance on intake of free sugars (Scientific Advisory Committee on Nutrition, 2015). Activities in sessions including weighing out sugars contained in soft drinks and a discussion of starch and sugars on food labels. In interviews, participants recalled discussions on the effects of fruit juice and insulin and reported sharing information about sugars in foods with family and friends (**Chapter 7.3.2.5**). As the interviews were carried out 12 months after the intervention end, this suggested that the information had been internalised and retained. However, there was no evidence from the quantitative data of a change in consumption of starch, free sugars, sucrose or sugars over the course of the intervention.

The reported mean daily intake of free sugars in this study was well below the national findings of 50g per day (g/d) recently reported for women aged 19-64 (Public Health England, 2018). The % contribution of free sugars to the mean daily energy intake was above the recommended maximum of 5% in both groups at baseline and intervention start (**Table 6:10** and **Table 6:11**) suggesting that further nutritional improvement was required. However, it was again well below the national mean % contribution of energy intake which was 11.2% for women aged 19-64 (Public Health England, 2018). In the quantitative group at baseline, 54.5% of participants reported mean daily free sugar intakes below 5% (**Chapter 6.5),** suggesting that the group already had a low intake: nationally only

13% of women aged 19-64 met the 5% maximum figure (Public Health England, 2018). These data support the suggestion that the reported free sugar intake for the study sample was lower than the general population at baseline and only required some participants to reduce their intake for the group mean intake to meet this guideline. In both groups the mean intake of free sugars appeared to decrease after the intervention although this change was not statistically significant. The mean daily intake of starch in the quantitative analysis group decreased across the intervention and this approached significance which may be indicative of a trend towards reduction. In both cases the lack of significance might be a type II error (Pallant, 2013) due to the small sample size (n=22) which was reduced due to missing data, which is a limitation in this study (**Section 8.4.1.10**). In the smaller follow up group there was a significant reduction in mean starch intake between baseline and intervention end, which suggests that a reduced intake may have occurred, although without comparative data it is difficult to attribute this directly to the intervention. A small non-significant decrease in mean starch intake also occurred over the comparative period, and it may be that some participants began to change their diet in anticipation of starting the intervention. Travier *et al.* (2014) reported that participants allocated to control groups can change their diet and a similar process may have occurred here.

Glycaemic load (GL) is a measure of the blood glucose response to foods eaten and is dependent on carbohydrate quantity and quality (Scientific Advisory Committee on Nutrition, 2015). In this study the daily GL was calculated from the glycaemic index (GI) using Nutritics Research Edition software (Version 5.094). There was a significant decrease in the mean daily GL over the intervention period in the larger quantitative analysis group (Table 6:8)**.** In the smaller follow up group, there was also a significant difference in mean daily GL over the intervention period and between the intervention start and 12- month follow up (Table 6:9) suggesting that the reduced daily GL was maintained for a year following the intervention end. A daily GL of less than 80 is considered to be low, a daily GL between 80 and 120 is medium, and more than 120 is high (Nutritics, 2019). The data suggest that, on average, the participants had a medium daily GL at baseline and at intervention start but this was low by the end of the intervention and after 12 months. This reduction in mean daily GL is likely to reflect an improvement in diet quality with possible health benefits. Lower GL diets are associated an increased body weight loss in overweight and obesity (Thomas, Elliot and Baur, 2009) and with reduced cardiovascular and diabetes health risks (Scientific Advisory Committee on Nutrition, 2015).

The food diary data indicate that the intervention was associated with decreases in mean total carbohydrate intake and reductions in daily glycaemic load. These findings are supported by evaluation (**Chapter 7.2.2.3**) and interview data (**Chapter 7.3.3**) in which participants reported making dietary changes such as avoiding cakes and desserts and reducing sugar intake which are likely to have contributed to the decreased carbohydrate intake and reduced daily GL outcomes.

8.4.1.3 Fibre and Vitamin C

A key aspect of the intervention was to encourage increased fruit and vegetable intake in line with WCRF recommendations to eat more vegetables, wholegrains, fruit and beans (**Table 1:1**). During intervention sessions the WCRF recommendations, the Eatwell guide and 5-a day recommendations for fruit and vegetable intake were discussed (**Chapter 5.5**). Participants were also provided with different fruits, vegetables, nuts and seeds to sample to promote increased intake. It was anticipated that mean daily intake of fibre and vitamin C might increase if dietary improvement in line with these recommendations occurred.

There were small increases in mean daily intake of vitamin C over the course of the intervention, compared to the changes over the comparative period (**Table 6:8** and **Table 6:9**) and although these differences were in the anticipated direction, they were not statistically significant. As discussed previously for starch and sugar intake, this may be a type II error (**Section 8.4.1.2**) or could indicate that there was no change in vitamin C intake. The mean intakes of vitamin C at all time points in both groups were well above the Reference Nutrient Intake (RNI) for adult women of 40 mg/day (British Nutrition Foundation, 2019) and this suggests that participants had sufficient intake of vitamin C before the intervention. This may be a ceiling effect and may indicate that the participant groups were eating enough fruit and vegetables to meet vitamin C guidelines before the intervention.

The mean daily intake of fibre did not appear to change at any time point in either group (**Table 6:8** and Table 6:9) suggesting that the intervention did not impact on it. In contrast to the findings for vitamin C, the intake of fibre for both groups at each time point was well below the current guideline of at least 30g of fibre per day (Scientific Advisory Committee on Nutrition, 2015) although this was not unexpected as nationally only 4% of women aged 19-64 do meet this recommendation for fibre (Public Health England, 2018). However, the mean daily intake for both groups, at all-time points was above the mean daily intake of 17.2 g per day recently reported for the wider population of

women (British Nutrition Foundation, 2018) suggesting that the intake of this group was above the population average before the intervention start. These data suggest that an increase in fibre intake might be beneficial to participant health but did not appear to have occurred in response to this intervention. There is some limited evidence that increased fibre intake may decrease mortality at 12 months following a breast cancer diagnosis (World Cancer Research Fund International, 2014). Increased fruit and vegetable consumption can also lead to increased intake of other nutrients such as folate which may protect against mutation or epigenetic change (Thomson *et al.*, 2007; Institute of Medicine, 2012; Teegarden *et al.*, 2012), although it is unclear whether or not increased fruit and vegetable intake has an influence on recurrence risk (Pierce *et al.*, 2007).

These data do not provide evidence of any effects of the intervention on vitamin C or fibre intake, which may suggest that fruit and vegetable intake was not increased and therefore the WCRF recommendations were not followed. The qualitative evaluation (**Chapter 7.2.2.3**) and interview findings (**Chapter 7.2.2.3**) suggested that some participants had reported increased fruit and vegetable consumption, although this may not have been a sufficient change to impact group mean values significantly. A limitation of the study is that the quantity of fruit and vegetables consumed per day were not directly measured (**Chapter 4.2.5**) for example by using a fruit and vegetable FFQ or questionnaire as in Park *et al.* (2016). Alternatively, objective measurement of biomarkers such as plasma carotenoid levels could have been used, and have been used in other studies such as Zick *et al.* (2017) and Pierce *et al.* (2007), Using this method Pierce *et al.* (2007) were able to show a sustained increase in fruit and vegetable over several years, and may have been a more sensitive measure to use in this study; however this was beyond the resources available in this small scale doctoral study.

8.4.1.4 Sodium

Cancer survivors are at increased risk of cardiovascular disease (Stull, Snyder and Demark-Wahnefried, 2007; Maher, 2013) which can contribute to reduced quality of life and non-cancer mortality. A higher intake of dietary sodium (as salt) is associated with increased risk of hypertension which is a risk factor for cardiovascular disease (Department of Health, 2014). Therefore, in the intervention, salt reduction and the WCRF recommendations **(Table 1:1)** of reducing intake of salt, fast foods and processed meat were discussed **(Chapter 5.5**). It was anticipated that any dietary

changes made in response to this recommendation might be reflected in a reduced mean daily sodium intake.

In the quantitative analysis group, there was an apparent decrease in mean daily sodium intake over the course of the intervention, but this was found not to be a statistically significant **(Chapter 6.5**). In the smaller follow up group, the results appeared to indicate an apparent reduction over time, but again this was non-significant (**Chapter 6.5**). As discussed previously, although non-significant the observed changes were in the anticipated direction for nutritional improvement and might be a type II error due to small group size (Pallant, 2013) (**Section 8.4.1.10).** The mean sodium intake at baseline and intervention start for both groups was above the Reference Nutrient Intake (RNI) for women of 1600 mg/d (British Nutrition Foundation, 2019); although it was below the RNI at the end of the intervention in the quantitative subgroup and after 12 months in the follow up group. However, as discussed above, the data do not provide evidence that a statistically significant reduction in mean daily sodium intake occurred, although in interviews some participants reported a decrease in salt intake. The mean daily sodium intakes for both groups at all time points were below the maximum recommended intake of 6g of salt per day, which is equivalent to 2400mg sodium per day (Department of Health, 2014). The sodium intake data reported in this study were determined from the food diary data as discussed in **Chapter 4.2.5**. which may provide an underestimation of intake (Scientific Advisory Committee on Nutrition, 2003). The most accurate measure of salt intake in by 24-hour urine collection (Department of Health, 2014) which was beyond the resources of this small scale study. A recent survey determined 24-hour urinary sodium excretion of adult and found a mean estimated daily intake for women aged 19-64 6.8g/d of salt, which is equivalent to 2720 mg/day of sodium and is above recommendations (Department of Health, 2014). The mean sodium intake data in the current data was lower at all time points than that reported in the Department of Health (2014) study and lower than the recommended maximum, which may be because the participants in this study had a lower intake than the wider population of women, or it may be lower due to the use of the food diary method. The reported data were above the RNI before the intervention start however, suggesting that a reduction of intake might be beneficial to the ongoing health of participants.

8.4.1.5 Total fat, saturated fat and cholesterol

The influential Women's Intervention Nutrition Study (WINS) was a large RCT trial which found that a low fat diet could reduce recurrence risks in breast cancer survivors (Blackburn and Wang, 2007) and this led to a number of interventions aiming to reduce fat intake (*for example* Saquib *et al.*, 2008; Sedlacek *et al.*, 2011; Griffith *et al.*, 2012; Thompson *et al.*, 2012). However, the Women's Healthy Eating and Living (WHEL) study did not find any association between recurrence and survival and a low fat diet with high consumption of fruit and vegetables (Pierce *et al.*, 2007) and the influence of a low fat diet on survivorship is unclear. A more recent study (Scientific Advisory Committee on Nutrition, 2019) found no evidence that reduced mean daily intake of saturated fat affects breast cancer risks. However, breast cancer survivors can also be at increased risk of cardiovascular disease (Maher, 2013) (**Chapter 1.4**) and this may be modulated by alterations in dietary fat intake (British Nutrition Foundation, 2019). The WCRF recommendations (**Table 1:1**) to limit the consumption of fast foods, processed foods high in fat, red meat and processed meat were discussed during the intervention (**Chapter 5.5)** and it was anticipated that adherence to these recommendations might be reflected in a reduction in mean daily intake of total fat, saturated fat and cholesterol. Cardiovascular health is discussed further in **Section 8.4.3.2** below.

In the larger quantitative analysis group, the mean daily intake of total fat and saturated fat appeared to reduce over the intervention compared to the comparative period, but although this was in the anticipated direction to indicate reduced intake, these were not significant differences (**Table 6:8).** There was no reduction in mean daily cholesterol intake. The smaller follow up group showed reduced mean daily intake of total fat, saturated fat and cholesterol after 12 months, although again these differences were not significant, perhaps due to the small group size (n=10) (**Section 8.4.1.10**). However, qualitative MYCaW data suggested that one participant at least had a reduced serum cholesterol by the end of the intervention (**Chapter 7.1.3.1).**

The UK national dietary recommendations are that mean saturated fat intake should contribute no more than 10% of total energy due to association of high saturated fat intake with elevated blood cholesterol and increased cardiovascular risk (British Nutrition Foundation, 2019). The % contribution of saturated fat to mean energy intake was above recommendations in both groups at all time points (**Table 6:10** and **Table 6:11**) suggesting that there was room for further nutritional improvement even at the end of the intervention. A reduction of saturated fat to meet the guideline,

and replacement by unsaturated fats, could reduce serum total cholesterol, low density lipoprotein (LDL), high density lipoprotein (HDL) and improve glycaemic control with concomitant reduced cardiovascular risks (Scientific Advisory Committee on Nutrition, 2019). By contrast, a recent study suggested that it might instead result in increased HDL and increased reverse cholesterol transport (Morton *et al.*, 2019); these studies demonstrate the controversy about health effects of fat intake (**Section 8.3.2.1**). In the current study, the saturated fat % contribution to energy intakes were higher than those reported for the general UK population. Between 2014 and 2016, saturated fat intake for the 19-64 age group was 11.9% and appeared to be higher amongst older adults aged 65-74 (12.5%) (Scientific Advisory Committee on Nutrition, 2019). Most participants in the current study were over 50 **(Chapter 6.1**), this may in part account for their higher mean intake.

In the quantitative analysis group, the % contribution of total fat to mean daily energy intake was above the 35% maximum recommendation (British Nutrition Foundation, 2019) at baseline. It appeared to meet guidelines by the end of the intervention, although this difference was not statistically significant (**Table 6:10**). In the smaller follow up group, the % contribution of total fat to mean daily energy intake did not demonstrate any significant change in this study (**Table 6:11**). Therefore, this study did not find that the intervention had an impact on % contribution of fat to total energy intake. This contrasts with findings in some other studies in the literature; for example, in a 6-month intervention, significant decreases in the % contribution to energy of total fat , which reduced from 32.2% to 28.0% and saturated fat, from 10.3% to 8.1% were achieved (Anderson *et al.*, 2016). However, in the Anderson *et a*l. (2016) study, nutrient intake was determined using FFQ rather than food diary data which may be a limitation (Kristal, Peters and Potter, 2005) and was also a body weight loss intervention without any follow up so this reduced fat intake may not have been maintained in the longer term.

8.4.1.6 Alcohol

Alcohol and its link to breast cancer risk and ways to reduce intake were addressed during the intervention **(Chapter 5.5**) in line with WCRF recommendations to avoid or limit alcohol to within national guidelines **(Table 1:1**). Between the publication of the Second Expert Report (World Cancer Research Fund/American Institute for Cancer Research, 2007) and publication of the Third Expert Report, evidence of links between alcohol and breast cancer have strengthened, putative mechanisms have been clarified and the advice has changed from limit alcoholic drinks, to don't drink alcohol for cancer prevention (World Cancer Research Fund /American Institute for Cancer

Research, 2018a) and these guidelines are also advised for cancer survivors. There is a current consensus that drinking alcohol increases risks of getting several cancers including breast cancer (Committee on Carcinogenicity (COC), 2015).

In the current study, the quantitative analysis group data did not show any trends in alcohol intake and there were no statistically significant differences. In the smaller follow up group, there was a trend in the anticipated direction at the end of the intervention and at follow up, although again these differences were not statistically significant, which may be due to the small sample size (n=10) (**Section 8.4.1.10**). However, the mean daily alcohol intake for both groups at all time points was well below the UK guidelines which recommend a maximum intake of 2 units or 16g per day (Department of Health, 2016) while Wood *et al.* (2018) recommend a lower intake of no more than 100g alcohol per week, (or 14g/day) for least effect on cardiovascular mortality. In this study, the highest reported mean daily alcohol intake for the group was well below these recommendations and the lowest group mean was only 2.8g/d or about 20% of the lower value. This indicates that the participant group, on average, had alcohol intakes well below national guidelines even at baseline and so were already conforming to the WCRF guidance to limit intake, although it is recognised that self-reported alcohol consumption data is prone to bias and under reporting (Wood *et al.*, 2018). In addition, several participants in this study did not report drinking any alcohol at baseline and this may have been a floor effect as the intake level was not able to reduce for these people. However, low levels of alcohol consumption still increase mortality risks compared to those who do not drink at all so further decreases could still have been beneficial; there is a dose-response relationship between alcohol intake and mortality with no lower threshold (Committee on Carcinogenicity (COC), 2015).

The convincing evidence of a link between alcohol consumption and breast cancer risk (**Chapter 1.3**) was discussed as part of the intervention (**Chapter 5.5**) to improve the knowledge and understanding of participants in order to promote behaviour change **(Section 8.3.2.1: Mechanism 1)**. However**,** qualitative interview data (**Chapter 7.3.2.3**) suggested that at least one participant did not find these discussions useful as participants had already had a breast cancer diagnosis and health risks of drinking alcohol were felt to be well known. A recommendation from this study is to focus on health benefits of alcohol reduction for breast cancer survivors rather than a discussion of breast cancer risk (**Section 8.3.2.1**). However, participants have a right to accurate information and

clear advice about alcohol in order to make informed choices (Department of Health, 2016) and to set their own lifestyle goals.

8.4.1.7 Nutrition quality

In this study, a research objective was to consider the impact of the intervention on overall nutrition quality, rather than an impact on specific nutrients (**Chapter 1.6**). In this study, nutritional quality was considered as the extent to which dietary changes might have led to improvements towards meeting the WCRF guidelines **(Chapter 1.3**). This was determined by looking at changes in intake of selected nutrients rather than the use of a pre-defined diet quality index (**Chapter 4.2.5**).

The contribution of mean intake of saturated fat to calorie intake remained higher than the recommended maximum of 11%, as although there was a decrease in mean saturated fat intake (g) there was also a decrease in mean calorie intake so the contribution of saturated fat to this remained above 11%. The intake of free sugar as % contribution to energy intake decreased and at follow up met the recent reduced target of 5% (Scientific Advisory Committee on Nutrition, 2015). The mean daily glycaemic load also decreased to a significant extent between the start of the intervention and the 12-month follow up **Table 6:11.** As discussed above, in this study there was evidence of a reduction in mean daily energy intake, mean daily carbohydrate intake and in daily GL. These changes were likely to indicate nutritional improvement. Observed changes in mean daily intake of other nutrients such as vitamin C, fibre, salt and saturated fat were in the anticipated direction but did not achieve statistical significance, perhaps due to missing data; this limitation is considered below in **Section 8.4.1.10.** These data are likely to represent improved achievement of the WCRF recommendations by the participant groups overall.

This assertion that the intervention had a positive impact on nutrition quality is supported by the qualitative data (**Chapter 7.2.2.3)** in which some participants reported making nutritional changes that had affected health by the end of the intervention. These changes included making changes such as adding new foods, more mindful eating, planning weekly meals, cooking more and avoiding processed foods. These reported changes also suggest that improvements in nutritional quality may have occurred. However, some of these changes may not be reflected in the quantitative data as each participant set different goals and made different changes.

8.4.1.8 Long-term change

As discussed in the previous section, improved nutritional quality might reduce further genetic or epigenetic damage (World Cancer Research Fund /American Institute for Cancer Research, 2018a) and therefore improve long term cancer outcomes. Non-cancer mortality is also higher in cancer survivors (Post and Flanagan, 2016) and nutritional change can also modify metabolic processes to reduce risks of other conditions such as cardiovascular disease. Long-term behaviour change might be required to allow enough time for these impacts to occur. This was addressed by collecting data 12 months following completion of the intervention.

Data from the smaller follow up group showed that there were no significant differences in mean nutrient intake between the end of the intervention and the follow up suggesting that intake was maintained after the intervention (**Table 6:9**). The mean daily intake of carbohydrate and daily GL both reduced significantly over the intervention period and this reduction was maintained at 12 months. Intake at follow up was also significantly lower than intake at intervention start which provides further evidence that nutritional changes were maintained. The intervention was also associated with reduction in mean daily intake of energy between the start of the intervention and the 12-month follow up (but not between the start and end of the intervention). The mean daily energy intake appeared to decrease further after the intervention and so the reduction became significant at 12 months. Again, this supports the hypothesis that dietary improvement was maintained and may even have increased, over the longer term.

Qualitative MYCaW data provided evidence of continuing nutritional improvement after the end of the intervention (**Chapter 7.1.3.2).** There was an increase in the number of participants reporting nutrition changes that had positively impacted on health between the end of the intervention and the 12-month follow up **(Chapter 7.1.4)**. At follow up, fewer participants reported having difficulties in maintaining changes, and for some the changes that they had made appeared to have become part of daily life. After 12 months participants appeared reported to be more in control of their lifestyle (**Chapter 7.2.2.3**). Interviews after 12 months (**Chapter 7.3.3**) provided further evidence of maintenance with greater dietary focus and integration of small, easy changes into daily life, with some reporting strategies to recover from relapse and ways in which ongoing support had been achieved. Different people made different changes as the diet was not specified and so changes may not have been reflected in the quantitative data.

A goal of this intervention was for changed behaviour to become habitual so that it occurred automatically without conscious effort and became the new default behaviour (Verplanken, 2006) and was therefore likely to be sustained in the long term. As discussed in **Section 8.3.1.5** participants need time to set goals, change attitudes and make changes that become routine. Frequent repetition is required for this to occur; a 12-week intervention period may be too short a period for this process to be completed. Rather this intervention aimed to provide a stimulus for changes which could then become self-sustaining over time. One strategy to achieve this is to design longer interventions to allow time for further repetition and support. However, even in very long interventions, outcome effects can reverse after trial completion, perhaps due to a loss of motivation or support. Relapse is common in lifestyle obesity interventions in general (Teixeira *et al.*, 2015) and maintenance after an intervention is reported to be more difficult to achieve than the original outcomes (Terranova *et al.*, 2017). In weight loss trials, long term weight regain is commonly seen both in cancer and non-cancer groups (Chlebowski and Reeves, 2016). Internal motivation, self-efficacy and self-regulation may be important predictors of long-term body weight outcomes (Teixeira *et al.*, 2015) (**Section 8.3.2.3: mechanism M3**). In order to maintain changes after an intervention, participants may need to have developed their own internal motivation (Fazzino, Sporn and Befort, 2016) and in this intervention, participants were encouraged to set their own goals and monitor their progress towards achievement (**Section 8.3.2.2; mechanism M2**). This was intended to encourage personalisation, personal motivation and confidence in order that participants would take ownership of their own changes and continue with them after intervention end. The data seem to suggest that this was achieved to some extent.

Ongoing support might be important to avoid relapse after intervention end. Long interventions may be needed for slow gradual body weight loss with long follow up to maintain changes (Milliron, Vitolins and Tooze, 2014). In a weight loss trial, weight regain was less in a group receiving bi-weekly telephone based group counselling (Befort *et al.*, 2016). However, in the current study ongoing support was not provided. At 12 months, some participants had accessed peer support through continuing to meet informally with fellow participants (**Section 8.3.2.4: mechanism M4**) or by joining exercise groups. Support from family and other household members might also be able to facilitate long term change; the support of family and friends is likely to be an important contextual factor (**Section 8.3.1.4; context C4)** and formalising this within future interventions is a recommendation for practice.

8.4.1.9 Impact of the intervention on family and friends

During the feasibility study some participants reported that their families had made dietary changes (**Chapter 5.2.2.1).** Balneaves *et al.* (2014) report a "ripple effect" of health improvement on the social contacts of participants in their study. Therefore, it was anticipated that family and friends in this study might be motivated to follow intervention dietary recommendations to support participants in maintaining their personal changes (**Section 8.3.1.4: context C4**). The WCRF recommendations are aimed at the general public (**Table 1:1**) and if adopted by family and friends could reduce their own risks of cancer and other long-term conditions and have positive impacts on health and wellbeing.

In the current study, most participants lived with other people; only 3 people (7%) lived alone; about half (44.2%) lived with one other person, while 48.8% lived with more than one other person (**Table 6:1**). This suggested that most ate with other household members who might also have been impacted by the intervention. In most cases, the household were aware of the intervention and of the changes that the participant was trying to make. However, occasionally, family and friends were unaware and so were not impacted (**Chapters 7.3.2.5**). Most of the participants (88.4%) in this study were involved in producing meals (**Table 6:1**) and therefore influencing the dietary habits of the household. Dietary changes made by participants might be expected to impact on the diet of the wider household especially where the participants were central to the food choices made and some reported that family diet had improved, sometimes by default. Some family members were reported to have consciously improved their lunches and snacks in addition to family meals **(Chapter 7.3.2.5**). Sometimes, where the participant did not make the household food choices, the family cook had not agreed to alter or adapted family meals, or change their own snacking habits, suggesting that changes did not occur. Some reported that they had shared written resources from the intervention with family and friends and encouraged them to read food labels and reduce sugar intake which may also have impacted on their dietary intake **(Chapter 7.3.2.5**).

In the current study, there was some limited evidence of household engagement in the lifestyle intervention although this was variable within the participant group.

8.4.1.10 Limitations of missing food diary data

Food diaries are a subjective method of measuring dietary intake, and it is recognised that this data collection method is open to bias. In this study, participants may have wished to show themselves to have improved their diet following participation. Awareness of healthy eating has been shown to alter reporting of certain foods (Whitton et al., 2011) and may have been the case in the current study where healthy eating was a focus of the intervention. Even with a 4-day estimated food diary the participant burden is high, and it is possible that the food eaten is altered to make completion of the diary easier. For several nutrients discussed above, a change in mean intake appeared to have occurred in the anticipated direction, but inferential analysis showed that the result was non-significant, suggesting that dietary change had not occurred (**Table 6:8** and **Table 6:9**). In most cases the eta squared statistic suggested that the effect size was large or medium sized and therefore the non-significant results might also have been due to a type II error due to the study being underpowered with small sample sizes (Pallant, 2013). The food diary sample size was smaller than anticipated due to non-responses; participants were required to complete food diaries over four days while at home and then to return the diaries by email or post. In the quantitative analysis group, only 71% (n=22) returned all food diaries completed before and during the intervention (T1, T2 and T3), while only 50% (n=10) of the follow up group completed and returned food diaries at each data collection point (T1, T2, T3 and T4). This resulted in missing data. It is recognised that those who returned completed food diaries might not have been representative of the wider participant group who did not.

This level of completion of food diaries in this study suggested that participant burden of completing food diaries was too high for some. Food diaries are known to place a high burden on participants (Slimani *et al.*, 2015) and this may explain the missing data in this study. Some authors have promoted the use of other methods of data collection to assess dietary intakes such as FFQ (Willett and Hu, 2006) or 24-hour recall and Diet Quality Indices (DQI) (Christifano *et al.*, 2016) as these reduce participant burden. The rationale for the use of food diaries in this study was discussed in **Chapter 4.2.5**. In hindsight an alternative method might have reduced the amount of missing data and therefore improved the quality of data collected. Chlebowski and Reeves (2016) suggest the use of technology driven strategies such as smart phones in trials of body weight loss interventions for breast cancer survivors. An alternative method of data collection in this study might have been to

use a smart phone diet application such as Libro (Nutritics, 2019); though this was not available when the research proposal was developed. It is possible that some participants would not be comfortable to use a smart phone app. In this study some participants were not familiar with email and in interview one participant reported that she was not familiar with mobile phone technology and was not able to take and share photos **(Chapter 7.3.2.4).**

8.4.2 Self-efficacy

As discussed previously (**Chapters 1.5**), knowledge about healthy eating alone is often not sufficient to lead to behaviour change, even for those with a breast cancer diagnosis (Stadler, Oettingen and Gollwitzer, 2010; Corbett *et al.*, 2018). The development of self-efficacy skills can increase the chances of initiating and maintaining a healthier lifestyle (Johnson, Pratt and Wardle, 2012; Janssen *et al.*, 2013). Therefore, this intervention was intended to develop these skills in participants (**Section 8.3.2.3: mechanism M3**) to support their achievement of long-term lifestyle goals (**Chapter 5.5).** Perceived self-efficacy for healthy eating was measured using a revised 15-item tool as described in **Chapter 4.2.3** and the mean of these items was determined for each participant at each time point to find a self-efficacy profile score (out of 100). A full validation study of the revised self-efficacy tool was beyond the scope of this study and therefore the findings were treated with caution.

At baseline, the mean perceived self-efficacy of participants in the larger quantitative analysis group was found to be quite low at 57.4 (**Table 6:4**) suggesting that the group were not confident in their abilities to eat healthily in a range of situations. There was a wide range of profile scores (from 92.7-28.7) indicating that some participants at baseline already had very high levels of self-efficacy, which might result in a ceiling effect as there was little or no potential for these ratings to rise further in response to the intervention. Others had a very low self-efficacy profile score suggesting very low confidence in their abilities to make changes. This may reflect a loss of confidence which can occur during the cancer treatment period (**Section 8.3.1.1; context C1**) (Richards, Corner and Maher, 2011). The wide range of self-efficacy profile scores at baseline may also have reflected the diversity of the participant group and their very varied contextual experiences of treatment (**Table 6:1**) and previous health and lifestyles (**Section 8.3.1.2: context C2)**). As discussed previously, self-efficacy profile scores of 70 or more may indicate an increased chance of behaviour change **(Chapter 4.2.3**). At baseline, only 29% had self-efficacy profile scores above this level, supporting the view

that that self-efficacy was low for most participants. These findings are also supported by MYCaW qualitative data which showed that, at baseline, some participants were looking for additional support to provide motivation, confidence and encouragement to make behaviour changes (**Chapter 7.1.1).** This suggested that some participants initially felt unable to achieve their lifestyle goals and may account for the low perceived self-efficacy in those cases. Some participants had experienced difficulties in body weight control, which may have reduced their confidence in achieving behaviour change goals (**Chapter 7.1.1**).

Over the comparative period (T2-T1), there was a small non-significant decrease in the mean self-efficacy profile score and in the % of participants scoring above 70 (**Table 6:4**) suggesting that the passage of time did not change perceived self-efficacy. By contrast, over the intervention period (T3-T2) there was a statistically significant increase in mean perceived self-efficacy profile scores with a large effect size compared to baseline ratings and ratings at the intervention start. Over the intervention period, the mean self-efficacy profile increased by more than 10 points to 67.3, and there was also a corresponding increase in the proportion of participants with a profile score over 70 (from 23% to 39%) (**Table 6:4**). A comparison of the findings over the intervention and comparative periods in this quasi-experimental trial therefore suggest that the intervention was associated with an improvement in the mean perceived self-efficacy of participants. Though this finding was made using an unvalidated questionnaire, it is supported by evaluation and interview data (**Chapters 7.2.1** and **7.3)** in which participants reported that they gained confidence during the intervention to take ownership of their health and to pursue new health and lifestyle goals. One participant reported that her confidence in making healthy choices may have decreased through the programme through increased awareness of the unhealthy choices that she might make (**Chapter 7.2.2**). This may have represented her transition from unconscious incompetence to conscious incompetence and may have been a necessary first step in raising awareness before she was able to progress to conscious competence (Luft and Ingham, 1955) as part of changing behaviour. However, even at the intervention end most participants still had self-efficacy profile score below 70 and therefore at a level indicating that planned behaviour changes were less likely to be actioned. This may be as the intervention period of 12 weeks was not long enough for the self-efficacy of those with a very low baseline profile to achieve improvement to support behaviour change. MYCaW qualitative data **(Chapter 7.1.3)** supported this view, as at the end of the

intervention several people reported that they were having difficulties in making changes and some needed more support. At the end of the intervention participants might have been aware of personal behaviour change goals but may not have embedded new habits into daily routines.

In the smaller follow up group, the results were in line with those discussed above **(Table 6:5)**; there was a statistically significant difference in the group mean self-efficacy profile between intervention start and intervention end, but not over the comparative period. This suggests that self-efficacy in this smaller group was in line with that of the larger quantitative group and therefore that findings from the two groups were comparable. During the follow up period (T4-T3) there was a small but non-significant decrease in the group mean self-efficacy profile, suggesting that levels of perceived mean self-efficacy for healthy eating stayed about the same during the 12-months after the intervention, though the self-efficacy of some individuals may have decreased. The mean self-efficacy profile at 12 months was also not significantly different to the mean ratings at baseline or the intervention start; although this may be due to the smaller size of this follow up group and may be a type II error (Pallant, 2013). By contrast the % of participants with a self-efficacy profile above 70 continued to increase between the intervention end and the 12-month follow up, increasing from 40% to 55%. This supports the view that the improvements in perceived mean self-efficacy due to the intervention were retained over the following 12 months and may have increased further for some participants resulting in a majority having a perceived self-efficacy profile which was more likely to result in meeting healthy eating goals a year after the intervention had ended. Qualitative data suggested that this was the case; after a year some reported having a more confident and determined attitude to wellbeing. Some felt empowered and more in charge, suggesting greater self-efficacy **(Chapter 7.2.2**) or reported having more confidence to make and maintain changes (**Chapter 7.3**).

The quantitative data above suggested that the intervention may have increased perceived self-efficacy which may have also continued to improve over the subsequent year, which is likely to have improved the potential for continued behaviour change in some of the participants. This improved self-efficacy may in part account for the reported improvements in nutritional quality (**Chapter 6.5**), and the improvements in anthropometric measures (**Chapter 6.4.1)** and reduced levels of concern (**Chapter 7.1.2).** Mosher *et al.* (2013) found that improved self-efficacy (assessed using a single item) was associated with increased dietary improvement, while Park *et al.* (2016) found that

strategies to improve awareness and self-reflection did not improve outcomes. The variations in the responses of individuals to the interventions are likely to have been affected by the individual participant contexts (**Section 8.3.1)**. Cancer survivors are often interested in gaining agency post-diagnosis (Beeken *et al.*, 2016) by regaining control of their own health (Rock and Demark-Wahnefried, 2002; Davies, Batehup and Thomas, 2011; Connerty and Knott, 2013). The impact of the intervention on self-efficacy may also depend on previous educational experience; Schiavon *et al.* (2015) suggested that intervention approaches based on social cognition theories **(Chapter 1.5**) such as the current study might most benefit those with higher educational levels.

As outlined in **Section 8.3.2** several intervention mechanisms might, in part, account for the impact of the intervention on the self-efficacy of participants. Following the intervention, participants felt more informed **(Section 8.3.2.1: mechanism M1)**, and therefore may have gained confidence about making healthy choices (**Chapter 7.3).** Self-efficacy might also have increased as participants gained confidence and motivation to improve their lifestyle **(Section 8.3.2.2: mechanism M2).** Participants reported feeling more in control (**Chapter 7.3**) which may have contributed to developing skills to make and maintain healthy choices **(Section 8.3.2.3: mechanism M3).** The role of peer support also appeared to be central to improved self-efficacy (**Section 8.3.2.4: mechanism M4).**

8.4.3 Health of participants

8.4.3.1 Anthropometric data

At baseline, most participants in this study were over-weight or obese (77.4%) (**Table 6:6**) suggesting that weight loss would be beneficial to health. This is a higher proportion than expected as it has been reported that generally 50% of women with breast cancer in the West are overweight or obese (Reeves *et al.*, 2014); some women joined this study due to weight concerns **(Section 8.5**). The data from this study suggested that the intervention was associated with a statistically significant decrease in mean body weight and mean BMI (**Chapter 6.4.1**) which supports the finding that it was also linked to a reduced mean energy intake reported above (**Section 8.4.1.1**). The mean weight loss over the intervention period (T3-T2) was statistically significant, but modest; it was 1.4% in the quantitative analysis group and 2.0% in the follow up group which is far less than the Wing and Hill (2001) definition of weight loss as intentional loss of 10% of initial body weight. A systematic review suggested that most, but not all, behaviourally based weight loss interventions for breast cancer survivors achieved at least a 5% weight loss (Reeves *et al.*, 2014) and therefore most achieved a

greater weight loss than in the current study. The current study included 22.4% participants who were a healthy weight at baseline (**Chapter 6.4.1**) which may partly explain the lower decrease. Although, it is not clear whether the lower weight loss achieved in this study would impact on participant health and quality of life.

The current lifestyle intervention was mindful of the Health at Every Size (HAES) approach (Bacon and Aphramor, 2011) and therefore focused on dietary changes and increased physical activity for health and to meet the personal goals of participants, rather than a specific focus on weight loss *per se*. However, the WCRF lifestyle recommendations (World Cancer Research Fund/American Institute for Cancer Research, 2007) were also discussed with participants as part of programme sessions which included their recommendation to maintain a healthy weight. Despite the focus on health, significant mean weight loss was achieved in the current study. By contrast, the WHEL trial of a low fat and high fruit and vegetable diet in breast cancer survivors resulted in dietary change, but not significant weight loss over 6 years (Pierce, 2009). Many other interventions were weight loss trials and achieved greater losses over the trial period, perhaps in part as they only recruited obese or overweight breast cancer patients. Reeves *et al.* (2017) achieved a 3.7% mean weight loss although this was over a 6-month period and so the rate of weight loss was similar to the current study. Travier *et al.* (2014) achieved a higher mean weight loss (7.8%) over the same time 12-week period as the current study. However, neither of these studies achieved 10% mean weight loss as defined by Wing and Hill (2001). Some studies achieved weight losses of greater than 10% by using structured interventions including provided calorie controlled shakes and pre-prepared meals. Christifano *et al.* (2016) and Befort *et al.* (2012) both achieved a mean weight loss of over 13% in this way with positive physiological impacts on some biomarkers indicating that health improvement had occurred. However, these interventions may have been more akin to short term weight loss diets than long term behaviour change programmes. Some of the participants in the Christifano *et al.* (2016) study reported that the pre-prepared foods made the diet convenient and easy to follow although it became repetitive (Fazzino, Sporn and Befort, 2016). Weight loss interventions using provided shakes and meals may lead to significant levels of short-term body weight loss but are unlikely to build skills and knowledge for maintenance (**Section 8.3.2.3).** These studies (Befort *et al.*, 2012; Christifano *et al.*, 2016) did not collect follow up data, so it is not clear if the weight losses were sustained.

Weight losses in this study were anticipated to be mainly from adipose tissue as participants were encouraged to increase levels of physical activity to maintain muscle mass (**Chapter 1.5**). The statistically significant reductions in mean body weight and BMI suggest that losses did occur, although this does not indicate the location of these losses. At baseline, in this study most participants (72.4%) had waist circumferences above 88 cm (**Table 6:6**) which is indicative of abdominal adiposity and increased health risks (Swanton, 2008). As discussed previously (**Chapter 1.3**), abdominal adiposity has a greater influence than sub-cutaneous tissue on plasma levels of leptin, insulin, IGF-1 and adiponectin levels. The mean waist circumference at all time points was also 88cm or above suggesting that a reduction of visceral adipose tissue would be beneficial. Ross and Rissanen (1994) used magnetic resonance imaging (MRI) to show that energy restriction and exercise in obese women resulted in reductions of adipose tissue preferentially from visceral rather than subcutaneous areas, and therefore it was anticipated that a similar pattern of relative losses might have occurred in the current study. However, there were only non-significant decreases in mean waist or hip circumference over the intervention period and no significant changes in waist to hip ratio (WHR) so no change in abdominal adiposity was detected in this study. In their study, Ross and Rissanen (1994) found significant reductions in mean waist and hip circumference, but not in WHR suggesting that it may not be a sensitive measure of altered abdominal adiposity. It has been suggested that waist circumference is the most sensitive anthropometric measure of abdominal adiposity (Tometich *et al.*, 2017) although in the current study, there was no evidence that the intervention had an impact on it. Travier *et al.* (2014) achieved a significant reduction in mean waist and hip circumference in a small single armed 12-week weight loss trial and their results did suggest that a reduction in abdominal adiposity had occurred, unlike the current study.

Reeves *et al.* (2014) found that most weight loss trials for women with breast cancer did not collect long term data over 12 months (Reeves *et al.*, 2014) in line with definitions of weight loss maintenance (Wing and Hill, 2001). In the follow up group in this study, the mean body weight and mean BMI at intervention end and after 12 months were not significantly different which suggested that weight loss achieved during the intervention was maintained over the subsequent year and therefore that long-term change may have occurred. In the follow up group there was also an increase in the proportion of participants with a healthy BMI at follow up period (**Table 6:7**) supporting the view that weight loss was maintained or extended. In another large weight loss trial

for older colorectal, breast and prostate cancer survivors, weight losses were sustained over the subsequent 12 months (Demark-Wahnefried *et al.*, 2012). The mean weight loss of 2.8% was greater than the current study, but was achieved over 1-year period, rather than 12-weeks and so represented more gradual loss. Their study also found that weight loss was maintained, as it appeared to be in the current study, although their data were self-reported and might have been subject to bias. Their study also included data from men and those with other cancer diagnoses so may not be directly transferable to a breast cancer population.

Weight loss is difficult to maintain even in a general non-cancer populations (Teixeira *et al.*, 2015); Wing and Hill (2001) suggest that more than 20% of overweight or obese people are able to achieve and maintain weight loss of at least 10% for at least 12-months. However, this suggests that up to 80% of general populations would be unsuccessful in sustaining weight loss. They suggest that the chances of maintaining weight loss rises over time and is much better after 2-5 years. Weight maintenance may be even more problematic in a breast cancer context (**Section 8.3.1.1; context C1**) as experiences of breast cancer treatment are likely to have a negative impact on behaviour change (Terranova *et al.*, 2017). Treatment effects of relevance might include weight gain, loss of muscle mass, fatigue, body image issues, depression and anti-oestrogen medication, and therefore additional support might be required. Chlebowski and Reeves (2016) in a systematic review suggested that longer interventions of more than 2 years might be required for female cancer survivors to support weight loss maintenance. However, intervention length may not be the only issue; the WINS trial was very long and although weight losses were maintained over about 5 years (Pierce, 2009), outcomes still reduced after the intervention end (Chlebowski and Reeves, 2016). A systematic review has suggested that mediators associated with successful long-term weight control in general populations included autonomous motivation, self-efficacy and self-regulation skills (Teixeira *et al.*, 2015). Therefore, weight loss interventions for breast cancer survivors might also need to incorporate mechanisms to support participants to become more informed about healthy eating **(Section 8.3.2.1: mechanism M1**), develop confidence and motivation (**Section 8.3.2.2: mechanism M2**), self-efficacy and self-regulation skills (**Section 8.3.2.3: mechanism M3**) and peer support (**Section 8.3.2.4: mechanism M4)** if behaviour changes including weight loss are to be maintained, whatever the intervention length.

Interventions may have short-term positive psychological impacts; in this study a participant reported being well enough to discontinue anti-depressant medication by the end of the intervention (**Chapter 7.1.3)** suggesting an improvement in mental health had occurred. Befort *et al.*(2012) found that their 6-month weight loss intervention was associated with improvements in depressive symptoms and body image in the short term, although the long-term effects were not measured. Bacon and Aphramor (2011) argue that weight loss interventions do not have long-term successes, so their potential health benefits are not realised and may have unintended negative impacts. Long-term consequences can include weight regain, body image problems, low self-esteem, depression scores and guilt (Ulian *et al.*, 2018). Following one large 12-month weight loss intervention reviewed in **Chapter 2.9.5,** QoL and body image ratings declined and depressive symptoms became significantly worse than controls after 2 years (Demark-Wahnefried *et al.*, 2015). The authors suggest that participants with depression are less likely to lose weight and more likely to relapse after weight loss. In their study, 20% of participants had depressive symptoms at baseline; depressive symptoms are more common after breast cancer treatment (Cheng, Sit and So, 2016). In the current study, 22.6% of the quantitative analysis group reported to be taking anti-depressant medication at baseline (**Table 6:1**) so that weight loss might have been particularly difficult for this group of participants to achieve. Depression might be an important contextual factor in reducing likelihood of behaviour change (**Section 8.3.1.1: context C1**) and might in part account for the modest mean weight loss achieved. Two participants in the current study identified body image concerns at baseline (**Table 7:1**). Breast cancer treatment is likely to have a negative impact on body image due to breast surgery and reconstruction, hair loss, skin changes and weight gain (Runowicz *et al.*, 2016). Poor body image has also been associated with less successful body weight loss (Teixeira *et al.*, 2015) and therefore this might be another significant contextual factor in the current study (**Section 8.3.1.1: context C1**). In an older large survey of a general (non-cancer) obese population, women rated depression, stress and low self-esteem as key reasons for a vicious circle in which weight gain and relapse occurred (Cachelin, Striegel-Moore and Brownell, 1998) and supports the importance of psychological health to weight loss success.

Weight control was a concern for participants in the current study and was raised both at baseline (**Chapter 7.1.1**) and in follow up interviews (**Chapter 7.3**). Weight gain is common during and following breast cancer treatment (Reeves *et al.*, 2014), especially in those who have had

chemotherapy (Vance *et al.*, 2011). In the current study, over 70% of those in the quantitative analysis group reported that they had had chemotherapy (**Table 6:1**) and were therefore more at risk of post-diagnosis weight gain. Sedjo *et al.*(2014) found that a mean weight gain of 4.5% had occurred in a large group of breast cancer patients between diagnosis and enrolment on their weight loss study. Weight gain following diagnosis is often accompanied by a loss of lean tissue caused by the adoption of a more sedentary lifestyle due to fatigue, depression and loss of muscular strength and mobility following surgery (Davies, Batehup and Thomas, 2011) and is likely to be an important contextual factor to interventional weight loss success (**Section 8.3.1.1: context C1).** Weight gain in treatment can result in a loss of confidence that weight loss is possible and so additional support may be needed to facilitate change (Terranova *et al.*, 2017) through development of self-efficacy (**Section 8.3.2.3**). Some in this study had previously tried to lose body weight but felt that this was hampered by the effects of long-term hormone medication (**Chapter 7.1.1**). In this study, 83.7% of participants reported taking hormone therapy (**Table 6:1**) which may have affected their confidence in their ability to control their weight and may also be an important contextual factor (**Section 8.3.1.1**). There is no evidence of an association between Tamoxifen and weight gain while aromatase inhibitors have been found to lower the risk of gaining more than 5% body weight (Vance *et al.*, 2011; Sedjo *et al.*, 2014), although participant beliefs may have reduced self-efficacy for weight control.

The current intervention was developed to focus on promoting health, rather than weight loss, as outlined in **Chapter 5.5.** This approach was taken in response to the literature review findings **(Chapter 2.8.2)** and the recommendations of Bacon and Aphramor (2011) to focus on health improvement with, or without, weight loss. Some participants in this study recognised that this approach was beneficial to long term lifestyle improvement, and recovery from relapse and was distinctly different to a short-term weight loss diet **(Chapter 7.3.3).** In another study participants who were eating healthily and exercising regularly but not losing weight would have liked less focus on weight loss (Lawler *et al.*, 2017). While, in another weight loss study the initial primary motivation of participants was to lose weight, eventually some would have preferred a greater focus on sustainable dietary improvements rather than weight loss (Balneaves *et al.*, 2014). However, in this doctoral study, some participants would have preferred a greater focus on weight loss (**Chapter 7.2.3.5.2)** which supports the assertion that participants should set their own goals to allow

personalisation of the intervention. Participants in this study were concerned about body weight due to personal weight gain and an awareness of post-menopausal impacts of adipose tissue on circulating oestrogen and breast cancer risks (**Chapters 7.3.1 and 1.3**). They may also have been aware of the possible impacts of weight gain on outcomes following breast cancer treatment (Richards, Corner and Maher, 2011; Robien, Demark-Wahnefried and Rock, 2011). Although the intended focus of the intervention was on health the WCRF recommendations **(Table 1:1**) to be a healthy weight were discussed in sessions **(Chapter 5.5)** and anthropometric measures were taken as part of the data collection process as it was an easily measurable outcome to show change which inevitably raised issues of weight control within the context of health improvement.

8.4.3.2 Blood pressure and heart rate

As discussed in **Chapter 1.4** treatment effects can lead to cancer survivors having a long-term increased risk of secondary conditions (Maher, 2013). This elevated non-cancer mortality risk for cancer survivors is largely due to increased cardiovascular risks (Robien, Demark-Wahnefried and Rock, 2011). Emaus *et al.* (2010) assert that normal range blood pressure may be beneficial to breast cancer survival. The feasibility study (**Chapter 5.2.3**) found that there was a reduction in SBP, but not DBP, and so an intention of the main study was to investigate if the intervention had an impact on this aspect of health, in line with study objectives **(Chapter 1.6).** It was anticipated that if participants made lifestyle improvements such as reduced intake of sodium and saturated fat and increased physical activity in response to the intervention, this might be reflected by changes in blood pressure and heart rate as indicators of improved cardiovascular health.

Systolic (SBP) and diastolic (DBP) blood pressures and heart rate were determined as outlined in **Chapter 4.2.4.2.** A limitation was that only a single reading of blood pressure and heart rate was taken from each participant at each time point. Single readings have been used in another similar study (Thomson *et al.*, 2010) while in other studies the number of readings and detail of the protocol followed was unclear (Stolley *et al.*, 2015; Sheppard *et al.*, 2016). Some other studies used a mean value of two readings (Courneya, 2012; Rock *et al.*, 2015). In the current study, these readings were taken in a group situation where it was not practically possible to take more than one reading and this is recognised as a limitation of the study. The cardiovascular data were not normally distributed and therefore have been treated with caution. In this study any changes in mean blood pressure or

heart rate were also difficult to interpret as some participants had diagnosed pre-existing cardiovascular disease and/or were taking anti-hypertensive medication.

In the larger quantitative analysis group, there was an unexpected significant increase in mean SBP over the comparative period (T2-T1) (**Chapter 6.4.2**) which might suggest that cardiovascular health had declined over time. A similar finding was reported by Sturgeon *et al.* (2017) following a 12-month intervention to improve heart health in breast cancer patients with BRCA genes. They found that cardiovascular health declined in the control group, while it was maintained but did not improve in the intervention group. In this doctoral study, the comparative period was much shorter than that reported by Sturgeon *et al.* (2017) and may have been too short a period for change in SBP to occur. An alternative explanation is that the apparent increase in mean SBP over the comparative period might have been due to another confounding factor or measurement or equipment error. If this were the case, the subsequent borderline significant decrease ($p \leq 0.05$) in mean SBP (**Appendix 2.7**) over intervention period is difficult to interpret and may not provide evidence of changed cardiovascular health. There was also no significant difference in mean SBP between baseline and intervention end, supporting the conclusion that there was no evidence that the intervention had an impact on mean SBP over this period. In the smaller follow up group, the intervention period was not associated with a reduction in mean systolic blood pressure. There appeared to be a significant reduction in mean SBP between intervention start and the 12-month follow up **(Chapter 6.4.2**) which might suggest that reductions in mean SBP continued over the 12-month period following intervention end perhaps due to the maintenance of healthy behaviours after the end of the intervention.
However, given the possible unreliability of the data collected at intervention start this difference may be due to a measurement error and may not reflect an actual change in SBP.

There was no statistically significant change in mean DBP over time for the larger quantitative analysis group, while in the smaller follow up group there was a significant reduction in mean DBP over the intervention period (T3-T2), between intervention start and follow up (T4-T2) and between the intervention end and the follow up (T4-T3) (**Chapter 6.4.2**). Even though the data collected at intervention start might not be reliable (as discussed above for SBP) these data do suggest that further reduction in mean DBP occurred after the intervention end, again perhaps due to continued

lifestyle improvement in the 12 months following the intervention and might be indicative of improved cardiovascular health.

In both groups the mean SBP was just above 120 mmHg and was therefore within the healthy range, as might be expected as most participants had SBP below 140 mmHg (**Appendix 2.7**). The data showed that the percentage of participants with SBP below 140mmHg (over 85%) did not appear to change in response to the intervention. As there was a high proportion of participants with SBP below 140mmHg at baseline, this may have been a ceiling effect. In some cases, this may have been indicative of good cardiovascular health or having a diagnosed cardiovascular condition and taking anti-hypertensive medicine to control blood pressure. At baseline 11.6% of the total group reported taking anti-hypertensive medication, which rose to 12.9% in the quantitative analysis group and 15% in the follow up group(**Table 6:1**). The proportion of participants with a healthy DBP appeared to increase over the intervention period (T3-T2) in both groups and to be maintained over the 12 months in the follow up group which may indicate that the intervention led to an increased proportion of participants having a healthy DBP although this may also have been due to confounding factors. These confounding factors make these results difficult to interpret and they do not provide evidence that the intervention had an impact on blood pressure. Food diary data did not show any significant decrease in mean daily intake salt, total fat or saturated fat (**Section 8.4.1.4** and **8.4.1.5**) which may have contributed to the observation that mean blood pressure did not significantly improve.

There were no significant differences in resting heart rate (RHR) over time in either group, therefore there was no evidence that the intervention had any effect on heart rate. The intervention was intended to increase the physical activity of the group, though this was not a main focus of the research study and data on the level of physical activity were not collected. It may be that the intervention did not have positive effects on physical fitness and therefore resting mean heart rate was unchanged; there may have been insufficient time for changes in physical health to occur, or this may have been a type II error due to the small sample size (Pallant, 2013). The mean resting heart rate (RHR) in both groups at each time point were below 80 beats per minute (bpm) which was well below 100 bpm maximum (British Heart Foundation, 2018). However, a RHR of greater than 90 bpm has been associated with an increased risk of CVD, CHD and mortality (Cooney *et al.*,

2010), while Hsia *et al.* (2009) found that RHR of above 76 bpm in post-menopausal women was associated with increased risk of coronary events. Therefore, a reduction of mean RHR might have been beneficial even though the baseline mean RHR was within normal range. RHR could have been affected by stress and anxiety of participants. At baseline stress, anxiety, fears and concerns were identified by participants as motivations for joining the intervention and their ratings of these concerns was high **(Chapter 7.1.2).** Levels of concern appeared to reduce over the intervention period and beyond but did not seem to impact significantly on mean RHR.

8.5 To explore the concerns of participants about their lifestyle and health, and how these changed over time during and after participation in the lifestyle programme (Research objective 4).

In the feasibility study (**Chapt**er **5.2.2.2**) there was some evidence that the intervention led to significant reductions in some concerns and improvement in wellbeing, and qualitative data suggested that the concerns of participants were addressed by the intervention. A study objective was to investigate this in more detail. Evidence about the impacts of the intervention on participant concerns and wellbeing were obtained from the evaluation forms and the interviews **(Chapter 4.2.7**) and quantitative and qualitative responses to the MYCaW forms **(Chapter 4.2.6)**. In the quantitative analysis group at baseline, MYCaW mean ratings (on a scale of 0 to 6) showed high levels of concern (4.8 Concern 1; 4.1 Concern 2) (**Table 7:2**). These ratings were a little lower than those reported for another large cohort of breast cancer survivors (5.09 Concern 1; 4.69 Concern 2) (Harrington, Baker and Hoffman, 2012), and a little higher than those reported in other studies of cancer patients generally (Jolliffe et al., 2015; Polley et al., 2016); suggesting that levels of concern in these studies were comparable. Wellbeing is a multi-faceted construct as discussed in **Chapter 4.1.2.1**; the mean ratings of wellbeing identified at baseline (**Table 7:2**) in the quantitative group were much lower (2.6) than the ratings of concerns, suggesting that participant wellbeing was rated much more positively as was also found in other studies (Harrington, Baker and Hoffman, 2012; Jolliffe et al., 2015; Polley et al., 2016.).

Breast cancer treatments can have a wide range of impacts on health and wellbeing **(Chapter 1.4)** and the experience of treatment and diagnosis was a key contextual factor in this study **(Section 8.3.1.1; context C1)**. Following breast cancer treatment, patients can experience distress, anxiety,

depression, fatigue, fear, sleep disturbance and cognitive dysfunction which can reduce QoL (Meneses and Walker, 2014; Cheng, Sit and So, 2016; Post and Flanagan, 2016)**.** Within the current participant group, treatment intensity was variable **(Chapter 1.4)**; over 70% had received chemotherapy (**Table 6:1**) suggesting a more intense treatment regime which might have had greater impacts. Those who have had chemotherapy report a lower QoL while those who have had a mastectomy report increased body image concerns (Vacek *et al.*, 2003) which may be reflected in levels of concern and wellbeing. Qualitative MYCaW data collected in this study at baseline identified the main concerns of participants (**Chapter 7.1.1**). Many participants expressed concerns relating to the shock of diagnosis, recurrence fears, stress or anxiety (**Chapters 7.1.1** and **7.3.1**). These are likely to be key contextual factors that may have affected outcomes for different individuals (**Section 8.3.1.1: context C1**). There were many concerns regarding body weight due to previous lifestyle **(Section 8.3.1.2 context C2),** weight gain during treatment (**Section 8.3.1.1: context C1**) or difficulties in achieving a healthy weight (**Section 8.4.3.1**).

As discussed in **Section 8.3.1.3 (Context C3),** intervention timing is likely to have been another important contextual factor affecting intervention impacts. It might be expected that the concerns of participants would reduce over time, although research shows that the reduced quality of life following breast cancer treatment can persist (Vacek *et al.*, 2003; Meneses and Walker, 2014). In the quantitative group, 41.9% of participants were within 6 months of treatment completion, while for others (9.3%) more than 4 years had elapsed since the end of treatment (**Table 6:1**) suggesting that their concerns were long lasting. A fear of recurrence was reported in this study and was a concern both for those who had recently completed treatment and for those who completed it some time ago **(Chapter 7.3.1**); concerns about recurrence may persist as treatment does not result in cure (Connerty and Knott, 2013). In this study, MYCaW ratings showed that the concerns and wellbeing in the follow up group were consistent over time as they did not change significantly over the comparative period between baseline and intervention start (mean period of 62.5 days) (**Table 6:3**). By contrast there was a statistically significant reduction in mean MYCaW ratings between the intervention start and the intervention end (**Table 7:2** and **Table 7:3)** showing that the intervention was associated with a reduction in mean levels of concern and an improvement in mean ratings of wellbeing. These are likely to be causal associations as change occurred over the trial period (T3-T2) and not over the comparative period (T2-T1), although it is recognised that this was a quasi-

experimental trial that was not blinded or randomised and might therefore be subject to bias (**Chapter 3.6**) and limitations (**Section 8.2.3).** These data also showed that during the trial period, most participants (74.2%) experienced an improved MYCaW profile rating of at least 0.7 (**Chapter 4.2.6),** which was a much higher proportion than during the comparative period (6.5%). These improved ratings were likely to represent a personally significant improvement in quality of life (**Chapter 4.2.6)** in response to the intervention, as has been found is some other studies (Kim, Shin *et al.*, 2011; Campbell *et al.*, 2012).

Data from the follow up group (**Table 7:3)** showed that there were no significant changes in MYCaW ratings between the end of the intervention and the 12-month follow up. This suggests that improvements may have been maintained but had not significantly improved. This may be a type II error or a ceiling effect or might be as additional support may be needed after the intervention end if further improvement is to occur. Mean MYCaW ratings at follow up were also significantly lower than at the intervention start, showing that after 12 months mean ratings of concerns and wellbeing were still significantly better than they had been before the start of the intervention. These trends in the MYCaW data showed a long-lasting reduction in participant concerns and improvement in wellbeing had occurred, although there were no comparative data with which to compare this. **Table 7:6** shows that in the 12-month period following the intervention, the MYCaW rating in a minority of participants (15%) worsened, although these were maintained or showed further improvements (85%) for the majority. This suggested that concerns and wellbeing were maintained for most. Almost all participants (95%) had experienced an overall improvement in their MYCaW ratings that was likely to be reflected by a meaningful improvement in their quality of life between the intervention start and the follow up about 15 months later.

The significant improvements in mean MYCaW ratings over the intervention period are likely to have been due to its impacts, although these changes may have also been due to other factors. Quantitative data about other confounding variables were not collected, though participants acted as their own controls which may have minimised the effects of other factors and qualitative data was collected at T3 and T4 on other factors affecting health via the MYCaW form. Qualitative data showed that participants had experienced several negative confounders during the intervention period that may have influenced MYCaW ratings; these included bereavement and negative changes at work or within the family (**Chapter 7.1.3**). However, these negative changes were unlikely to

account for the observed positive changes in mean MYCaW ratings. Participants also reported positive changes affecting health, and most of these were likely to be intervention effects, such as taking more exercise, improved nutrition, improved awareness of wellbeing and suggest that the reduced concerns and improved wellbeing may have been due to participants having implemented lifestyle change. In other studies, Terranova *et al.* (2017) found that increased physical activity improved wellbeing and Balneaves *et al.* (2014) found that their intervention had psychological benefits due to improved fitness and improved confidence and self-esteem which reduced stress and anxiety about diagnosis. This could have an additive effect as increased motivation and self-esteem can also facilitate behaviour change (Terranova *et al.*, 2017). In this study some had developed their confidence and motivation (**Section 8.3.2.2: mechanism M2),** while others reported having difficulties in making changes often due to time constraints or stress which were inhibitory factors (**Section 8.3.2.3: mechanism M3**). Some participants were having further surgery or medication changes which had also made health improvement more difficult (**Section 8.3.1.1: context C1).** At the 12-month follow up, more participants reported making lifestyle improvements and fewer reported having difficulty in making changes suggesting that confidence and motivation had improved over time and was likely to have become embedded (**Section 8.3.2.2: mechanism M2).** This supports the assertion that changes were long term and may have improved wellbeing and reduced some concerns. Some gained confidence as they were able to take ownership of lifestyle changes (**Section 8.3.2.2: mechanism M2** and **Section 8.3.2.3: mechanism M3).** Connerty and Knott (2013) found that cancer survivors were able to gain personal control by becoming better informed to maintain a healthy lifestyle, while Stolley *et al.* (2009) report that after their intervention participants felt empowered to have healthier lives. Some participants had previously been confused by contradictory nutrition advice in the media and felt empowered by becoming better informed and having greater understanding of the rationale for lifestyle recommendations (**Section 8.3.2.1:mechanism M1).** This may have reduced concerns, although information that was deemed too simple or patronising could have been an inhibitory factor. Peer support was also an important mechanism to reduce concerns and improve wellbeing (**Section 8.3.2.4: mechanism M4**). In other studies, participants were inspired by other group members and sharing experiences normalised them (Balneaves *et al.*, 2014). The group provided peer support through sharing experiences and by learning together with good camaraderie and this social aspect may be a key reason for reduced concerns and improved wellbeing. Therefore, the face-to-face context of the

intervention might have been crucial to the achievement of the outcomes (**Section 8.3.1.5: context C5**).

The data therefore clearly suggest that the intervention was associated with a reduction in concerns and improved wellbeing which persisted over the following 12-month period. This suggests that long term improvements in quality of life had occurred.

8.6 Study limitations

In this study, the small sample size may have been a limitation (**Chapter 4.2.1.2)**, particularly in the quantitative arm where the study may have been underpowered resulting in type II errors. Missing data also reduced sample sizes for nutritional analysis as discussed previously (**Section 8.4.1.10**) and also occurred due to drop out and exclusion of data from participants in treatment (**Chapter 4.2.1.2**). The recruited sample was largely well-educated and white but were heterogenous in terms of their age, health and lifestyle and were likely be representative to the local breast cancer population. The follow up group might have been more engaged in behaviour change and therefore not representative of the entire sample. However, the findings are therefore likely to have good local external validity and be transferable to local and similar contexts.

The quantitative arm of the study had a quasi-experimental design without randomisation (**Section 8.2**) or blinding which increased the risks of bias. Participants acted as their own controls which may have removed the effects of some confounding variables and reduced the required sample size, although the comparative period was shorter than the intervention period (**Chapter 6.1**). Due to the study design, comparative data were not collected over the follow up period. Therefore, where associations were found these might not have been causal.

Much of the data collected was subjective, and may have been biased due to the 'Hawthorne effect' (Adamson *et al.*, 2006) where participants change their behaviour due to trial participation rather than intervention effects. Some objective data was collected, but the self-efficacy tool was not validated (**Section 8.4.2**) and blood pressure and heart rate were only measured once (**Section 8.4.3.2**) and therefore the findings from these measures must be treated with caution.

The doctoral candidate recruited the participants, led the intervention and collected and analysed the data which may also have resulted in unconscious bias**.** Although there was some triangulation

with objective data or with qualitative data, the findings must be interpreted with caution. In the next chapter (**Chapter 9**) the researcher has reflected on the research process.

8.7 Summary

This chapter has considered the use of a quasi-experimental study design to evaluate the lifestyle intervention. It has also discussed the mediation of outcomes by a complex interplay of mechanisms, the health and social contexts of participants and intervention setting. The impacts of the intervention over time on participant concerns and wellbeing, dietary habits, self-efficacy and health were also examined. The study conclusions are presented in the final chapter (**Chapter 10**).

Chapter nine: Critical reflection

9 Critical reflection

9.1 Introduction

I found my doctorate study very challenging and reflected on different issues as they arose so that I could decide how to proceed. I kept a research diary throughout the process and wrote reflective field notes immediately following intervention sessions and data collection meetings. I also kept notes from each supervisory meeting that included our deliberations on key issues and problems. I have referred to these field notes and supervision summaries in writing this reflection. In this chapter I have reflected on the dual role of researcher and practitioner, participant vulnerability, nutrition knowledge and exercise needs, and my own reflexive practice. In thinking about these particular aspects I used the ERA (Experience, Reflection, Action) cycle of reflection (Jasper, 2013) to guide my thinking, and in each case this is mirrored in the structure of my writing. I have finished the chapter by reflecting on my PhD journey.

9.2 Dual role of researcher and practitioner

Experience

In this project I was the intervention leader and ran the nutrition sessions but was also the researcher. In the group sessions I was often acting in both roles concurrently as I was both leading the group and gathering research data. This sometimes resulted in role conflict for me as I was unsure which role should take precedence where there was tension between the two. For example, I was conflicted when gathering interview data when participants talked about difficulties in their life. As a practitioner I wanted to coach and encourage, but as a researcher I wanted to gain unbiased data. I also experienced dual role conflict when potential participants wanted to join the intervention while they were still in treatment and I had to decide whether or not to exclude them from the study. As a researcher I was aware that these participants did not meet the inclusion criteria, and yet as a practitioner I wanted these participants to have the choice to attend.

Reflection

In both of these cases, I was initially unsure what to do. I did not feel that it was ethical either to leave interviewees without support or exclude people from the intervention. My own values as a practitioner meant that I was not comfortable in excluding people who were still in treatment as they might benefit from attendance. However these participants could not be recruited to my study

if my own inclusion criteria were to be adhered to. This situation had occurred when I was recruiting for groups 2 and 3 after the study had begun and it was too late at this stage to apply for an amendment to the inclusion criteria. I was not able to offer these participants a later intervention to attend after the research, as it was not clear if or when one would be available. A similar tension in the practitioner-researcher role was explored by Park, Usher and Foster (2014) in their RCT trial of a weight loss lifestyle intervention for people with mental health diagnoses. In their study, some of those allocated to the control group insisted on attending the intervention and were not prepared to wait for an later intervention group. Park, Usher and Foster (2014) reflected on this and in the light of their dual roles of nurse and researcher and decided that participant needs were paramount. The control participants were therefore not excluded from their intervention, with a concomitant impact on their study data and outcomes.

My own study is an example of applied research where the aim is to evaluate our intervention in order to improve it to better meet people's needs, and so to exclude people against their wishes seemed to me to be counter to my underpinning research philosophy. My study was designed with a participatory and cooperative view of research in which people were recruited as participants rather than research subjects and therefore I regarded their views and needs as important and this was consistent with my values as a practitioner, but also with my values as a researcher. My study design (**Chapter 3.6**) was influenced by my values as a practitioner and a researcher as well as from my fulltime job as a University Lecturer; I had opted for a quasi-experimental design in part to avoid recruiting participants who would be allocated to a control group (**Chapter 8.2.2**), thereby avoiding the issues encountered by Park, Usher and Foster (2014). Hay-Smith *et al.*, (2016) recognise that clinician-researchers can experience a conflict between patient needs and research priorities, but they suggest that both sets of obligations should be considered together. They suggest that clinician-researchers should prioritise patient wellbeing as well as the requirements for ethical research and this was the joint approach that I tried to take. The UW ethics policy (University of Worcester, 2018a) requires researchers to mitigate any risks of harm to participants which I saw as a requirement to support participants in research interviews and to support them to attend our intervention if that was their wish. Following my reflection on tensions in the dual role of researcher-practitioner, I decided that I would try to adhere to both sets of obligations where that were possible but if in doubt, that the needs of the participants were paramount.

Action

I decided that although the participants could not join the research study until treatment was completed in line with my ethical approval, they were still able to join the intervention if they wished, with a full understanding that they would not be able to provide quantitative data. Once they had completed their treatment, I invited them to join the research study on the basis that they would be able to contribute qualitative data from this point onwards (**Chapter 4.2.1.2**). In the interview situation, I separated out my time acting as a practitioner and a researcher. I was able to act as a researcher before and during the interview but reverted to a practitioner role once the research interview was over and the audio recorder was switched off. This allowed me to debrief with participants and to provide support, as necessary. These actions allowed me to follow my obligations both as a researcher and as a practitioner in both cases while remaining true to my own values.

9.3 Participant vulnerability

Experience

I wanted to provide written materials for participants in intervention sessions. I chose to use resources produced for the general public and written by reputable organisations, that were scientifically accurate and relevant to those who had a breast cancer diagnosis. I reviewed the material used and did not used any that I thought might cause worry. However, as discussed previously in Chapters **7.3.2.3, 8.3.2.1** and **8.4.1.6** some participants became angry and/or upset in an intervention session when written materials on lifestyle guidance to reduce cancer risk were reviewed. This upset was recalled by interview participants more than a year later showing that it had evoked strong feelings in the group.

Reflection

Due to my previous experience of running lifestyle interventions, I was aware that people joining my study might be considered to be a 'vulnerable' population. There are many different meanings of this term; for example, in the context of seeking consent for a research study, the UW ethics policy (University of Worcester, 2018) lists vulnerable groups as: children; persons lacking mental capacity; and persons whose first language is not English. The participants in my study were not

vulnerable in these terms. However, Maher and Fenlon (2010) suggest that cancer survivors in general are a vulnerable population in terms of having ongoing health problems, reduced QoL and increased psychological distress. By contrast, rather than it applying to particular groups, Martin, Tavaglione and Hurst (2014) suggest that all humans are vulnerable but the extent which this might be manifested will be different in different contexts. In my study the vulnerability of the participants might be more manifest during the intervention and it was my role to be aware of this and to mitigate this risk. During my first meetings with participants, some people identified that they were still coming to terms with their diagnosis and felt anger or fear, while other participants also had to face ongoing or further treatment such as reconstructive surgery. Ferrell *et al.* (1997) and Tiedtke *et al.* (2012) identified that people may experience strong emotions due to the trauma of diagnosis, fears of recurrence, experience of family distress, and awareness of their own mortality. This can lead to an increased risk of depression, sleep disturbance, sadness, reduced quality of life and cognitive dysfunction (Cheng, Sit and So, 2016). I was aware that participants emotions might be stirred during sessions and I attempted to plan the intervention with that at the forefront of my mind, as I did not want to cause additional distress. My main concern was that in discussing ways for people to improve their lifestyle, this might provoke negative emotions about their previous lifestyle, especially where people might be looking for a reason for their diagnosis or might raise fears that their lifestyle might increase future recurrence risks. Despite my awareness of this, some people did become upset when reviewing publications about lifestyle recommendations. These guidelines were discussed as they are also recommended for cancer survivors. Some participants were angry as they had had a healthy lifestyle and yet still had breast cancer, while others felt that the booklet implied that they were to blame for their own diagnosis, or that it was too late to reduce risks as they had already had their diagnosis (**Chapters 7.3.2.3** and **8.4.1.6**). In my application to the NHS REC (**Chapter 4.2.1.1**) I recognised that participants' medical history may result in their becoming distressed during intervention or data collection sessions and I had made plans to mitigate this risk in line with UW ethics policy (University of Worcester, 2018) by identifying referral points and having a second staff member available to provide emotional support during sessions if required. However I really wanted to avoid causing distress in any future sessions.

Action

This upset had only occurred with one group, and I reflected on the issues before I repeated the session with the next group. I avoided referring to publications that estimated numbers of cancer cases that could be avoided by making lifestyle changes and focussed on resources for cancer survivors rather than those about reducing risk . I made sure that I emphasised that the intervention was about moving forward and improving health and wellbeing following treatment, not about looking back for reasons which could not be known. I emphasised that people should set their own goals and enjoy their food. We discussed the same booklet with the next group and I think that I introduced it more sensitively, with no further upsets. Following my reflections, I recommended that future interventions focus on wellbeing and recovery rather than risk and that interventions might be more beneficial for those who are ready to make behaviour changes, rather than for those looking for reasons for their diagnosis (**Chapter 10.3).**

9.4 Nutrition knowledge and exercise needs

Experience

The intervention group members were very diverse in terms of their nutrition knowledge and exercise needs and I found it challenging to accommodate this within the group sessions that I led.

Reflection

Some participants were already very knowledgeable about nutrition and had already read widely about links with breast cancer risks, while nutrition was a new area for others. However, as this was not a teaching situation, I planned the sessions to be focussed on group discussions and practical activities so that participants could learn from each other. In this programme I did not specify the changes that participants should make, but rather I aimed to encourage people to set their own goals to personalise the behaviour changes that they wanted to make. I planned to lead discussions so that participants could share their successes and challenges in making lifestyle changes to meet their personal goals and I hoped that this would get around the issue of participants having different previous levels of knowledge. I am an experienced University lecturer, and I had had experience of running previous intervention groups, so I planned to use my facilitation skills to encourage discussion and participation. However this did sometimes result in discussion going off topic

(**Chapter 7.2.3.4**) and I sometimes found it challenging to allow people to have their say while keeping sessions relevant to all.

The nutrition sessions included a lot of open discussions which allowed participants to raise a range questions; some of which were very challenging for me to respond to. Some questions about scientific details were difficult for me to answer in a way that was appropriate for those with less previous knowledge or interest. Greenlee *et al.* (2015) modified their intervention to meet the needs of a wider participant group with less educational experience and I aimed to do this, but it was not easy for me to achieve where I was less in control of what was discussed, and participants were able to raise issues of concern to them personally. Participants often wanted me to tell them the 'facts' as they had come across a lot of contradictory information in the media about foods that might affect recurrence risk which provoked worry. These concerns were difficult for me to address simply as of course research results are often complex and nuanced. For example**,** around the time of the intervention there was a widely reported controversy about the effects of dietary saturated fat on coronary heart health which caused public confusion (British Nutrition Foundation, 2017) and was raised in one of the groups as part of discussions around eating dairy products. This is a complex area of research as results from low saturated fat trials can depend on which macronutrient replaces saturated fat, which is often not reported (British Nutrition Foundation, 2017). Therefore, people had seen media reports of these research findings which appeared to be contradictory. I felt that this type of uncertainty may have reduced peoples' confidence in nutrition recommendations. I found that answering these questions often involved discussions about risk, and I was aware that I wanted to answer truthfully without raising fears or giving false reassurance, especially as some participants were facing fears of their own mortality. It is difficult to explain risk with a general population group, and I considered alternative way of explaining it such as looking at the effects of different health behaviours on 'effective age' compared to chronological age (Spiegelhalter, 2016) and although this may have helped to communicate risk I also felt that it might raise fears in this vulnerable group.

Some of the participants in the group had been very physically active prior to diagnosis and wanted to engage in vigorous exercise, while others had been sedentary and wanted gentle exercise. This made it difficult for the team to plan and supervise sessions that addressed this range of previous experience and need. Some people found the sessions too vigorous.

Action

Where the group asked detailed scientific questions I decided to answer briefly at the time, and later provided more detailed written materials that people could take if they were interested. However some participants wanted more detailed scientific knowledge (**Chapter 8.3.2.1)** so this did not appear to meet the needs of all. I continued to run the sessions with a clear plan to keep on track but mainly through discussion. The sessions were not didactic, but rather focussed on health improvement and the application of lifestyle recommendations to peoples own lives through discussion and practical activities, so that the content might be relevant to all. which did seem to address the differences in previous knowledge. Most people seemed to like this approach though some would have liked more structured sessions (**Chapter 7.2.3.4**). Goal setting was used to personalise the intervention for individuals to achieve their own personal healthy eating and exercise goals and was a recommendation for future practice to increase the use of goal setting and review (**Chapter 10.3**).

I worked with the wellbeing centre staff to organise the exercise sessions. The exercise sessions were run by staff in the wellbeing centre who were qualified and experienced to supervise these exercise sessions safely. I found it useful that staff emphasised that any increase in physical activity was beneficial. The team also used individual goal setting so each person was working at own level and we provided pedometers that people could use to record their own steps each day to encourage them to increase their own level of physical activity.

9.5 Reflexivity

As a lone researcher, I recognise that my own personal opinions, values, and beliefs will have influenced my study design, data collection and data analysis and therefore my study outcomes. Therefore I have tried to be reflexive so that my study findings can be judged against this, as recommended widely in the literature (*for example*, Mays and Pope, 2000; Lacey and Luff, 2007; Draper and Swift, 2011; Fade and Swift, 2011). In carrying out this study I adopted contextual epistemology and critical realist ontology within a pragmatic paradigm (**Chapter 3.3.4**). I took the view that there is one stable reality that this research study aimed to partially explain using both mixed methods.

My background is in biological sciences and nutrition practice and though I am confident that there is evidence that nutrition and physical activity can have a positive effect on breast cancer recovery, I adopted a neutral stance when collecting and analysing quantitative data on the impacts of this specific intervention in these contexts and how these might come about. In collecting qualitative data I adopted a reflexive approach rather than a neutral stance as this arm of my study was exploratory and I recognised that the interview data was co-constructed between the interviewees and me, and I acknowledge my active role in this. My interviews could have been affected by many things. I already knew the participants through the lifestyle intervention, perhaps making this a form of 'acquaintance interviewing'. Braun and Clarke (2013) posit that this involves the researcher entering into a dual relationship with participants; although in this case the participants only knew me in a research capacity which included previous data collection and delivery of the lifestyle intervention sessions. However, I ensured that this pre-existing research relationship did not make people feel pressure to participate in the interviews or to disclose more than they wished to in the interview by following the guidance of Braun and Clarke (2013). Power relationships can affect the willingness of participants to be open or critical (Pilnick and Swift, 2010). The participants knew that I was a lecturer in nutrition, and I may have been perceived as an expert and therefore I was more powerful in terms of the research situation. This may have influenced the responses that participants gave. However, I carried out the interviews in a relaxed manner to negate this effect and our pre-existing relationship helped to foster an empathetic and relaxed rapport which had been previously established during the intervention sessions. I was also a similar age to most of the interviewees and the same sex and so I hoped that this would reduce the 'distance' (Mays and Pope, 2000) between us making the discussions open and relaxed.

I had refined and implemented the lifestyle intervention that was the subject of this study. I recognised that participants might exhibit social desirability bias (Green and Thorogood, 2009) in their responses to my interview questions, rather than give a real reflection of their position and may have felt pressure to focus only on positive impacts of the lifestyle programme as I had been involved in delivering it. However I focussed the interviews on the personal experiences and feelings of participants about their lifestyle and were not an evaluation of the intervention, to counteract this effect.

9.6 My PhD journey

Before starting my thesis, I primarily saw myself as a scientist as I had a background in biology, human physiology, and nutrition. I had previously carried out both qualitative and qualitative research, though when I began my thesis, I was most familiar with RCT trials as the gold standard method of finding out whether or not an intervention worked. I had originally intended to carry out some kind of quantitative trial to see whether our lifestyle intervention was impactful. When I began my doctorate, I was a full-time senior lecturer, and I joined an informal support group of health colleagues who were at various stages of their own doctoral study. As I attended this group and doctoral research training sessions, I became more aware of the powerful impact that listening to participants might have in my study. I shifted my position from being a post-positivist to a pragmatic paradigm view of the research that I wanted to carry out. I discussed research designs with my original Director of Studies, and she suggested that I read about the evaluation of complex intervention and this seemed to fit in with my evolving world view.

During my first year of study, Dr Erol took over as my Director of Studies and in further discussion she introduced me to the ideas of realist evaluation which also aligned with my developing ideas. I read widely about evaluation of complex intervention and realist evaluation and originally planned to carry out a stepped wedge trial. However, during my feasibility study I found that this would be difficult to carry out and would require randomisation which I was not comfortable doing. I became very interested in research design and read more about the value of alternative trial designs and once I came across quasi-experimental trials, I realised that this would address my concerns and I designed my main study on this basis. After carrying out my feasibility study I applied for and gained NHS ethical approval. I found this to be a very rigorous and time-consuming process but in thinking through my application it really helped to clarify my ideas. However, having NHS ethical approval also meant that I was not able to make changes to my study as it progressed without applying for minor or major amendments and I also felt that this reduced my room for manoeuvre. When I was first planning my study, without really knowing what would be required for a doctorate, I think that I made my study too complex and probably planned to collect too much data, but once I had started it was too late to change.

In retrospect I increasingly saw the value of the qualitative data in giving voice to participants to determine better ways of designing and delivering interventions, and if I were doing this study again, I would have included more longitudinal qualitative data collection and would have used fewer quantitative tools preferably with input from participants at the design stage. Carrying out this study has confirmed my views that all interventions are complex and should probably be studied as such using mixed methods. I really grew to appreciate the wisdom of the realist approach to evaluation and the benefits of the quasi-experimental design that I used. As a part-time doctoral student my study was able to extend over several years which allowed me more time to collect follow up data which would not have been possible in a 3-year doctoral study, and I do think that long term follow up after interventions is vital as the maintenance of behaviour change is such an important area to explore. However, as a part-time doctoral student I found the challenges of juggling part time research with the rest of my life very difficult. I have also learned that research is best done as a collaborative activity and if I were to carry out a similar study in the future, I would want to do it as part of a research team.

Chapter ten: Conclusions

10 Conclusions

10.1 Introduction

A lifestyle programme to increase physical activity and improve the nutritional intake of breast cancer survivors had previously been developed at the University by the doctoral candidate and colleagues. This current research study was initiated in response to the experience of leading the nutrition aspect of this intervention. It aimed to find out whether the intervention had beneficial impacts and to explore the ways in which mechanisms and contexts might have affected outcomes. As discussed previously in **Chapter 1**, both the incidence of breast cancer and survival of it have increased in recent years with a resultant large population of women who have a history of breast cancer. Breast cancer treatment can have both short-term and long-term consequences for mental and physical health. It can result in survivors having a lower quality of life and a higher risk of cancer and non-cancer mortality than the general population. Lifestyle improvement can improve recovery and mitigate these consequences and for this reason it has been recommended that lifestyle support be provided. The focus of this study was to provide some evidence about how this lifestyle support might best be achieved.

Lifestyle programmes such as the one in this study have multiple components and are therefore complex interventions. The design of this study was guided by the MRC framework for the evaluation of complex interventions together with the principles of realist evaluation (**Chapter 3**). A process of iterative intervention development was carried out; the pre-existing intervention was refined following literature review (**Chapter 2**), a feasibility study was carried out and it was further refined (**Chapter 5**) and subsequently trialled to investigate its impact. The study also aimed to explore the use of the quasi-experimental study design which was carried out within a pragmatic paradigm using a convergent parallel mixed methods approach (**Chapter 3**)**.**

10.2 Conclusions

The quasi-experimental trial design used in this study had many positive impacts (**Chapter 8.2**). It allowed for inclusive recruitment as participants were not screened for confounding variables, which may have increased the external validity of the findings. A smaller sample size was required than in an RCT as participants acted as their own controls **(Chapter 8.2.1**). As there were no separate control groups, participants were not randomised. Therefore, all participants were able to

attend the intervention when they wished, which might have improved engagement (**Chapter 8.2.2**) and avoided the need for an appropriate and ethical control treatment (**Chapter 8.2.3**). In this study, the use of a quasi-experimental trial was able to provide some evidence of causality, though this was less robust evidence than that which would be provided by an RCT. Using this study design, it was not possible to collect comparative data over the follow up period, which is a disadvantage compared to an RCT design.

The study found that many context factors affected participant responses to the intervention including experiences of diagnosis and treatment, previous lifestyle and health, timing of the intervention and social support (**Chapter 8.3.1.1**). The study found that the intervention was appropriate for a diverse range of participants irrespective of their experience of diagnosis and treatment or previous lifestyle. However, it may have been more beneficial to those who were already at the contemplative stage of the behaviour change cycle. The study found that key mechanisms for the initiation and maintenance of behaviour change were the development of knowledge and understanding, motivation, confidence, and skills (**Chapter 8.3.2**). Informal discussions and group activities provided peer support and were particularly valued (**Chapter 8.3.2.4**). However, a few participants found group discussion of the effects of lifestyle on breast cancer risk to be distressing as they already had a breast cancer diagnosis **(Chapter 8.3.2.1)**. Within the diverse participant group, some found that aspects of the intervention did not address their individual needs, particularly in the context of scientific information, facilitation of weight loss and intensity of physical activity (**Chapters 8.3.2.1, 8.4.3.1** and **7.2.3.5.1**).

This study found that participants had a good diet at baseline compared to the general UK population **(Chapter 8.4.1)** although the majority were overweight or obese **(Chapter 8.4.3.1**). The mean alcohol intake was below national guidelines, and this implied compliance at baseline with WCRF recommendations to avoid or limit alcohol (**Table 1:1**). Mean intakes of some nutrients such as vitamin C and sodium were also in line with UK guidance. However, for several nutrients such as saturated fat and fibre, mean intakes did not meet national recommendations at baseline (**Table 6:8**) and therefore there was a need for nutritional improvement**.** The group lifestyle intervention was found to have some impact on nutritional quality (**Chapter 1.6**). The intervention led to reduced mean intakes of some key dietary components such as carbohydrate and GL (**Chapter 8.4.1.2).** The study focus was on healthy eating, though it also resulted in a reduction in energy intake and a

corresponding reduction in body weight and BMI (**Chapter 8.4.3.1**). These changes appeared to be maintained for a year after the intervention ended and therefore may represent a sustained improvement in nutritional quality. These changes were likely to represent increased achievement of WCRF recommendations (**Table 1:1**) to maintain a healthy weight and limit foods high in sugar. However, the continued low mean intake of fibre and high intake of saturated fat indicated that there was no evidence that the WCRF recommendations to eat more grains, vegetables, fruit and to limit consumption of foods high in fat, were achieved (**Chapter 8.4.1**). There was also little evidence for an impact of the intervention on the healthiness of family meals and for some there was a lack of household support for participants in their endeavours for dietary improvement (**Chapter 8.3.1.4**) was found to be a barrier to behaviour change (**Section 10.5.3**). There was no evidence of an impact of the intervention on cardiovascular health (**Chapter 8.4.3.2)**. This study found that the group lifestyle intervention promoted behaviour change (**Chapter 1.6**) as it provided motivation and support (**Chapter 8.3.2.2**) and led to an increase in mean perceived self-efficacy for healthy eating. It increased the proportion of participants with self-efficacy ratings indicative of likely behaviour change action and this increase continued after the intervention finished (**Chapter 8.4.2**). However, many participants continued to rate their self-efficacy for healthy eating at a relatively low level which indicated a requirement for further ongoing support (**Section 10.5.4**).

Participants had high levels of concern at baseline and the intervention led to a large decrease in these concerns that appeared to be maintained over the following year. Participants identified a very wide range of concerns that the intervention addressed. The intervention also led to increased ratings of wellbeing that may also have been maintained after the end of the intervention (**Chapter 8.5**).

10.3 Practice recommendations

This doctoral study found that the intervention setting, and format were acceptable to participants as evidenced by good levels of recruitment, attendance, and retention (**Chapter 6.1**) and positive feedback which suggested that it was useful, beneficial, and enjoyable (**Chapter 7.2.3).** Therefore, it is recommended that the main features of the intervention design (**Chapter 5.5**) are retained. It is recommended that participants are not excluded on the basis of their previous diet or level of physical activity but are advised to join an intervention group when they are ready to engage in behaviour change, whether this is towards the end of treatment or several years afterwards, with

no upper time limit. It is recommended that future interventions should focus on recovery and improved wellbeing following the end of treatment, rather than a focus on reducing breast cancer risk. It is recommended that there is an increased focus on informal discussion and group activities to provide peer support and a greater emphasis on goal setting and review to increase the personalisation of the intervention.

10.4 Contribution to knowledge

This research study has contributed to knowledge about effective ways of providing lifestyle interventions for breast cancer survivors. As far as the doctoral candidate is aware, this study used a unique approach to this investigation. No other similar study based on the MRC framework for the evaluation of complex interventions and the principles of realist evaluation (**Chapter 3**) was identified. The literature review (**Chapter 2)** was carried out systematically but did not identify any similar UK empirical studies of lifestyle interventions and breast cancer with a focus on behaviour change theory and intervention mechanisms. No other studies were identified that used a quasi-experimental design, few focused on healthy eating rather than weight loss and few included a long follow up. This study has contributed to an ongoing process of intervention development and evaluation to better meet the needs of breast cancer patients.

Some of the data collection methods were unique to this study. The MYCaW tool has been widely used to evaluate health interventions but has not previously been used to compare intervention and control data. This provided stronger evidence that the intervention was causally associated with the outcomes and that the observed changes were not due to the passage of time or other confounding variables. The self-efficacy tool was modified to collect data on healthy eating which contributed to an understanding of how intervention effects might enhance the propensity for nutritional improvement.

The inclusion of the qualitative arm in this study gave voice to the research participants at several stages as key stakeholders. The participant input at the feasibility study stage (**Chapter 5**) helped to inform refinement of the intervention before the trial stage. Participant input during the trial stage (**Chapter 7**) was used to identify key contexts and mechanisms. This input had direct links to the recommendations for practice (**Section 10.3**) and for future research (**Section 10.5**). Input from participants was rarely reported in other studies (**Chapter 2.8.4**).

The study contributed to knowledge about ways to promote recovery after breast cancer. It provided evidence that the intervention was associated with long-term reductions in concerns and improvements in wellbeing and self-efficacy. The study has contributed to an understanding of how a lifestyle intervention might exert its effects due to an explicit consideration of key behaviour change mechanisms. It has identified benefits of a focus on healthy eating and found that this approach led to both dietary improvement and weight loss. It identified some advantages of a focus on recovery and health improvement rather than a focus on the effects of lifestyle on breast cancer risk, as participants already had a breast cancer diagnosis.

The study has contributed to a consideration of the mode of intervention delivery. It found that face to face intervention provided opportunities for informal discussion, peer support and skill rehearsal in groups that were likely to have impacted on outcomes. It has also found that the most appropriate time for participants to join an intervention might depend on their personal readiness for behaviour change.

In line with the principles of realist evaluation, claims of the generalisability of the findings are not made, as it is recognised that outcomes are dependent on contexts. This study sample had good external validity and therefore the findings may be transferable to similar contexts. More research is needed to investigate the outcomes in other situations (**Section 10.5**).

10.5 Future research agenda

The lifestyle intervention trialled in this study continues to be offered at the University (March 2020) and would benefit from further research as part of a dynamic iterative process of development. O'Cathain *et al.* (2019) have recently published additional guidance on developing complex interventions and have advocated stakeholder involvement in all stages of this process. A collaboration between researchers and the researched might provide the most productive approach to further intervention development to ensure that the needs of the wider patient populations are addressed. In response to this study, the following potential research areas have been identified:

10.5.1 Participant diversity and intervention contexts

As noted in **Chapter 4.2.1.2,** participants in this study were recruited from one local area and attended the intervention in one setting. Future interventions could be targeted to improve diversity of recruitment to ensure that it was representative of the wider national or international

breast cancer population. Future research might investigate intervention impacts in other settings and geographical areas. An exploration of the effects of these different contexts on intervention mechanisms and outcomes could contribute to tailoring the intervention to meet the needs of a wider recruitment group.

10.5.2 Collection of food diary data using mobile phone applications

In this study, the completion of food diaries was found to be a burden for participants and resulted in missing data (**Chapter 8.4.1.10**). A further research approach would be to investigate the use of smart phone applications (apps) to collect dietary intake data to determine whether this reduced missing data and increased the data reliability. It would also be useful to determine whether an app could increase personalisation by providing dietary feedback, as suggested by some participants in this study **(Chapter 7.2.3.5.2**). Some apps, such as Libro (Nutritics, 2019) allow voice activated input with photos to aid participant estimation of portion sizes which may facilitate inclusion of those participants who have less confidence with literacy or language skills and therefore might be more inclusive**.**

10.5.3 Attendance of a support person in the intervention

In this study it was found that some participants did not have support from family or friends and that this was a barrier to behaviour change (**Chapter 8.3.1.4**). In addition, this study did not find any evidence of a "ripple effect" (Balneaves *et al.*, 2014) of health improvement for the wider family (**Chapter 8.4.1.9**). Other studies have included a family member or friend in interventions (**Chapter 2.7**) to provide social support. A future research approach would be to explore the effect of participants inviting a family member or friend to some intervention sessions. The more formal inclusion of a support person may increase their understanding and engagement with the intervention and therefore increase the social support they were able to provide. A study could explore how best to do this, how it might work and whether it impacted on outcomes, including family meals.

10.5.4 Post-intervention support

In this study, many participants did not rate their self-efficacy for healthy eating very highly at the end of the intervention which might indicate that further support was required. Some participants suggested support that they would have found useful after the intervention had finished (**Chapter**

7.3.3). Relapse after interventions is common and maintenance of change may be more difficult to sustain than lifestyle improvement (**Chapter 8.4.1.8**). An area for further research would be to look at the most appropriate way to provide ongoing support after an intervention and the impact that this might have on long-term outcomes.

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