UNIVERSITY OF SOUTHAMPTON

FACULTY OF MEDICINE, HEALTH AND LIFE SCIENCES

School of Medicine

Reshaping breast care services – A role for dietitians?

Uptake and response to dietary intervention in postmenopausal women newly diagnosed with breast cancer

by

Jillian Milne

Thesis for the degree of Doctor of Philosophy

May 2009

Correction Sheet

UNIVERSITY OF SOUTHAMPTON

ABTRACT

Breast cancer survival rates have risen dramatically over recent years with many women expected to survive their diagnosis and live long and fruitful lives. As a result 'cancer survivorship' has become of interest to health care providers who state that future services must be developed that better meet the long term health needs and expectations of this group.

To this end, the role of health behaviour change in the secondary prevention of breast cancer is a popular area of research. To date, however, there are no published investigations into what the likely uptake in health promotion activities would be; an important consideration when developing health services.

Over a period of six months between April 2007 and September 2007, all eligible newly diagnosed postmenopausal women with breast cancer from the participating NHS trust were invited to participate in a clinical trial to assess uptake and response in a group healthy eating programme.

The primary outcome measures were to assess the proportion of women who enrolled on the healthy eating programme and to identify health behaviours that predicted enrolment. Secondary outcome measures were to assess the change in diet quality; change in weight and to identify health behaviours that predicted attendance at classes.

Twenty one percent (21%) of women invited agreed to attend the healthy eating programme and were subsequently randomly assigned to either the healthy eating programme (n=5) or the usual care group (n=6).

The results suggest that women newly diagnosed with breast cancer were not interested in attending healthy eating classes at the time of their diagnosis. However, screening rates fell significantly short of the target and therefore these results cannot be generalised to all newly diagnosed postmenopausal women with breast cancer. Further, due to poor recruitment, secondary outcomes could not be assessed.

In summary, the study was unable to provide information regarding the likely interest and response to a group health eating programme for newly diagnosed postmenopausal women with breast cancer. The reasons the study was unable to meet its aims was objectives were twofold; firstly the study failed to engage both NHS trusts for which approval was granted and secondly, screening procedures were not carried out as planned in the single remaining NHS trust.

FACULTY OF MEDICINE, HEALTH AND LIFE SCIENCES
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Doctor of Philosophy

UPTAKE AND RESPONSE TO DIETARY INTERVENTION IN POSTMENOPAUSAL WOMEN NEWLY DIAGNOSED WITH BREAST CANCER

by Jillian Margaret Milne

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DECLARATION OF AUTHORSHIP

I, **Jillian Margaret Milne** declare that the thesis entitled

Uptake and response to dietary intervention in postmenopausal women newly diagnosed with breast cancer

and the work presented in it are my own. I confirm that:

- this work was done wholly or mainly while in candidature for a research degree at this University;
- where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
- where I have consulted the published work of others, this is always clearly attributed;
- where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
- I have acknowledged all main sources of help;
- where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
- none of this work has been published before submission.

Signed: ……..

Date:……

Acknowledgements

I would like to thank the following people/organisations who have supported this project.

- Professor Barrie Margetts for his continued support and guidance
- NCRN nurses, Emma Widlake and Jenny Lowry for conducting the screening and recruitment of study participants
- Jenny Davies for always making herself available in times of need
- The NCCRCD for funding me to pursue a career in research
- The Macmillan Centre for allowing me to use their facilities
- The steering group members for their contribution to the study protocol
- Birmingham Clinical Trials Unit for randomising patients
- My husband Grahame Milne for his continued patience and understanding

List of abbreviations

ACRONYM	Meaning
ASWCS	Avon, Somerset and Wiltshire Cancer Services
BCDIP	Breast Cancer Dietary Intervention Project
BMI	Body Mass Index
COMA	Committee on Medical Aspects……
CONSORT	Consolidated Standards of Reporting Trials
CPPIH	Commission for Patient and Public Involvement in Health
DH	Department of Health
DNA	Deoxyribonucleic acid
DQI-R	Diet Quality Index – Revised
FACT-ES	Functional Assessment
FFQ	Food Frequency Questionnaire
GP	General Practitioner
HIP	Health in Partnership
ICAS	Independent Complaints Advocacy Service
ICH GCP	International Conference on Harmonisation Good Clinical Practice
ITT	Intention to treat
kg	Kilogram
LINks	Local Involvement Networks
m	Metre
MHLC	Multidimensional Health Locus of Control
NCI	National Cancer Institute
NCRN	National Cancer Research Network
NHS	National Health Service
NICE	National Institute for Clinical Excellence
OCS	Office for Cancer Survivorship
OSC	Overview and Scrutiny Committee
PALS	Patient Advocacy and Liaison Service
PCG	Primary Care Group
PCT	Primary Care Trust
PCTIF	Pharmaceutical Industry Competitiveness Task Force
PPI	Public and Patient Involvement
QUAL	Qualitative
QUAN	Quantitative
RCT	Randomised Controlled Trial

ACRONYM	Meaning
REC	Research Ethics Committee
SCS	Studies of Cancer Survivors
SD	Standard Deviation
SEER	Surveillance, Epidemiology and End Results
SPSS	Statistical Package for the Social Sciences
UK	United Kingdom
UKCRN	United Kingdom Clinical Research Network
WHEL	Womens Healthy Eating and Living
WHO/FAO	World Health Organisation/
WINS	Womens Intervention Nutrition Study
WINS UK	Womens Intervention Nutrition Study UK
mCTA	Model Clinical Trial Agreement

Chapter One

Introduction

1.0 Introduction

With a risk of more than one in three people receiving a cancer diagnosis during their lifetime, cancer is one of the most serious and widespread diseases in today's society.[1] Over the last 25 years, the number of new cases diagnosed has increased by 24%.[2] The incidence of cancer is set to continue its rise and by 2020 it is estimated that, globally, 15,000,000 new cases will be diagnosed each year.[3]

In contrast to these figures, cancer mortality rates fell by 11% over the last ten years.[4] Extensive resources and research efforts have gone into understanding the causes of cancer which have resulted in major improvements in cancer treatments. This, combined with better screening programmes leading to early detection of cancers, has contributed to improvements in survival for many cancer patients. Where cancer was once considered a death sentence, today it is, in some cases, curable and for many others has become a chronic disease.[2 3 5]

Breast cancer (the most common cancer accounting for 30% of all female cancers) has seen dramatic improvements in survival in recent times. Despite a continued rise in the incidence of breast cancer in the UK of 45% over the past 20 years, during the same period mortality rates have fallen by 31%.[4 6] This trend continues with survival rates for early breast cancer now around 90%.[3] The most recent estimate for breast cancer survivors in the UK is around 550,000 making this the largest group of all female cancer survivors.[7]

The progress made in terms of survival from breast cancer, whilst extremely welcome, has led to more and more women surviving their diagnosis and expecting to live long and fruitful lives. It has been argued that a struggle now exists between the "medical agenda" and the "personal agenda" as the medical model continues its treatment focus on removal of the cancer, whilst breast cancer patients deal with a broader agenda that may not be adequately met by the current medical model of care.[8] Understandably, breast cancer patients are asking health care providers what steps they can take to reduce their chance of a cancer recurrence and how they can improve their overall health and wellbeing.[5]

The scientific literature reports that many breast cancer patients have made changes to their lives after their diagnosis that often includes changes of a dietary nature, as these patients are believed to view nutrition as an important part of their cancer therapy.[9 10] Further, these patients are concerned with the lack of support offered by their health care providers to achieve this. As a consequence health providers are encouraged to assess whether the services they offer meet the changing needs and expectations of breast cancer survivors.[11]

This scientific evidence is supported anecdotally within my own clinical practice. Prior to commencing this PhD I worked as a research dietitian for the UK Women's Intervention Nutrition Study (WINS UK). The study was a feasibility study to determine if postmenopausal women with breast cancer could adopt a low fat diet and maintain this diet for two years. Once feasibility was established the study would support a larger efficacy study for a low fat dietary intervention and subsequent breast cancer outcomes. My role within the study was to conduct the nutrition education classes for both the control group who received healthy eating advice and the intervention group who received low fat dietary advice.

Over the 18 month period I worked in this role I was surprised by the positive feedback from both groups about how helpful the dietary advice was, with the majority of women stating they felt nutrition education should be offered as part of the standard care package after diagnosis.

In summary, both the scientific literature and anecdotal evidence supported the notion that women, newly diagnosed with breast cancer were interested in receiving nutrition counselling as part of their care package offered by health providers. At the time of this study breast cancer patients in the NHS had no routine access to nutrition advice and therefore a unique opportunity existed to develop services that better met the needs and expectations of cancer patients; a philosophy at the heart of NHS policy.[11]

However, patient desire for service development does not alone provide sufficient basis for the introduction of a new service and therefore scientific evidence demonstrating health benefits was considered.

When developing the rationale for this study, it was known at the time, that the scientific evidence for the proposed benefits (both physiological and/or psychological) following a change in dietary behaviour after a breast cancer diagnosis remained unclear. Two large randomised controlled trials were being conducted in the United States to investigate these relationships, the Women's Intervention Nutrition Study (WINS) and the Women's Healthy Eating and Living Study (WHEL). The breast cancer research community were hopeful that the results of these trials would provide the necessary evidence to support the expansion of routine services for this group of patients to include nutrition counselling. In the absence of this evidence, a change in dietary behaviour had been shown to improve general health and well-being and this outcome was considered sufficient to support the present study.

In either scenario outlined above, a gap in the evidence base for providing nutrition counselling after a breast cancer diagnosis still remained. Specifically, if such a service was offered by health providers, would it be well attended and therefore a viable option given the current economic climate? This gap in the evidence provided a unique opportunity to pilot a group "healthy eating" programme for newly diagnosed postmenopausal women with breast cancer. The purpose of the

study was to investigate the feasibility of nutrition counselling embedded within the current routine care services offered by the NHS.

The study offered a group “healthy eating” programme at the time of diagnosis, providing four x 120 minute classes over a six month period. As a pragmatic study, all newly diagnosed postmenopausal women with breast cancer were to be invited to join the programme. The study’s primary objective was to assess uptake in the group nutrition education classes.

It was hoped that the results of this study would make an important contribution by providing practical, real world information regarding the likely uptake and participation in health promotion activities aimed at newly diagnosed postmenopausal women with breast cancer and hence inform future cancer services planning.

1.1. Project summary

Overall Aims	1. To develop a group healthy eating programme for postmenopausal women newly diagnosed with breast cancer in partnership with breast cancer patients 2. To understand the factors that influenced **enrolment** and subsequent **participation** in a group "healthy eating" programme for newly diagnosed postmenopausal women with breast cancer. 3. To assess if a group "healthy eating" programme improved the diets of newly diagnosed postmenopausal women with breast cancer
Purpose	To inform cancer service development initiatives
Study design	Mixed methods – embedded experimental model **Study One**: Focus Groups QUALITATIVE (QUAL) **Study Two**: 1. Cross-sectional study (Qual + Quantitative (Quan)) 2. RCT (QUAN) 3. Cross-sectional study (Qual + Quan)

Table 1-1 Project Aims

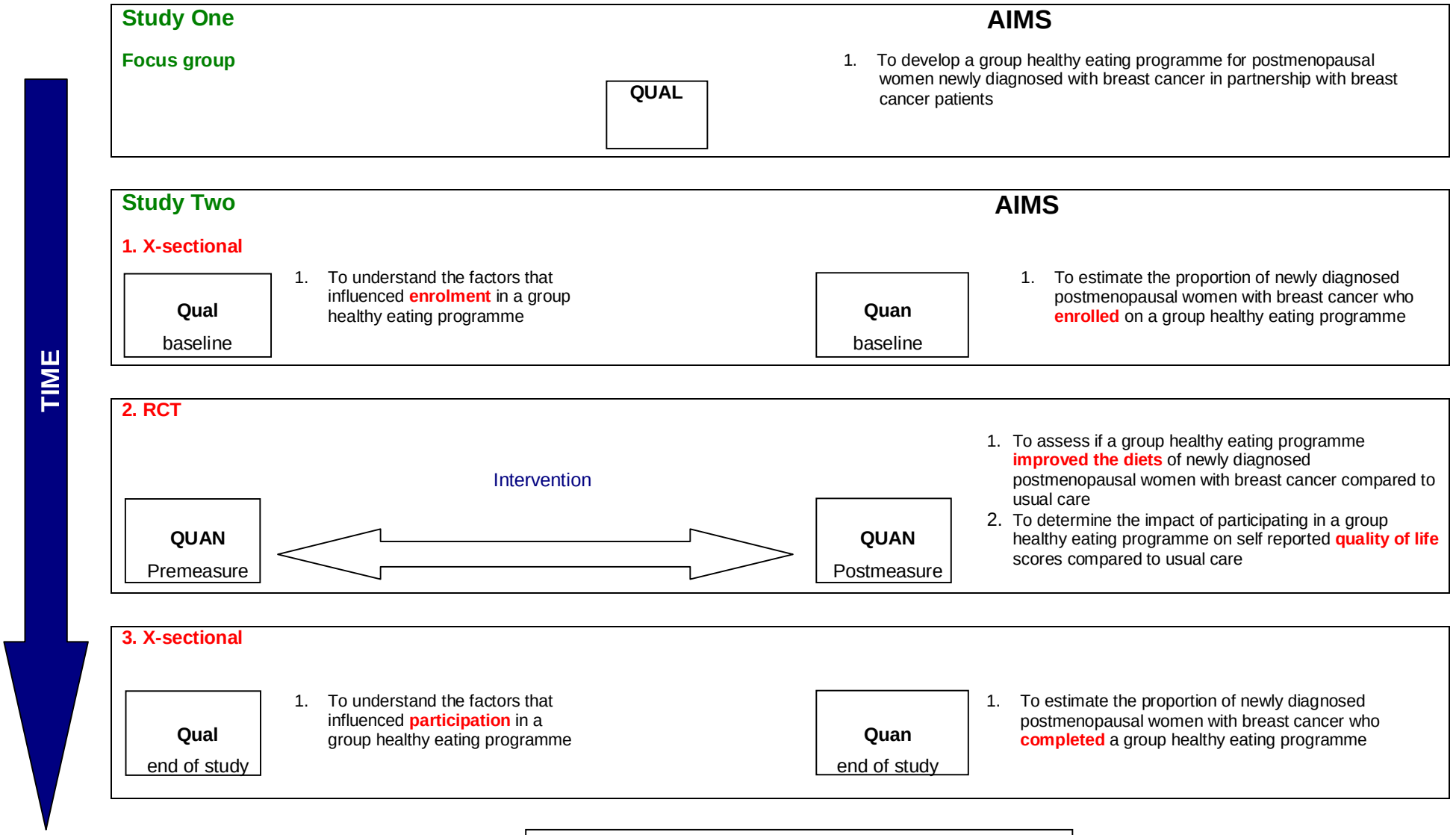


Figure 1-1 Proposed study design

1.2. Thesis summary

Chapter	Topic
One	Introduction and Project Summary
Two	Breast cancer
Three	Nutrition services in the NHS
Four	Methods
Five	Results
Six	Discussion
Seven	Conclusions
Eight	References
Nine	Appendices

Table 1-2 Thesis summary

Chapter Two

Breast Cancer

2.0 Breast Cancer

2.1. Chapter Introduction

The following chapter provides an overview of the latest breast cancer statistics. It goes on to discuss how breast cancer develops and the known causes of breast cancer. Finally, the chapter concludes with a section on breast cancer prevention, individually addressing primary, secondary and tertiary prevention. The main literature review is focussed on the role of diet in the secondary prevention of breast cancer as the present study offers postmenopausal women previously diagnosed with breast cancer a group healthy eating programme.

2.2. Prevalence of breast cancer in the UK

At the end of 2008 it was estimated that there were two million cancer survivors or approximately 3.3% of the UK population. Of those, breast cancer patients accounted for around 28% or 550,000 of all UK cancer survivors making them the largest group of all site specific breast cancers.[12]

With extensive resources and research efforts directed at understanding the causes of breast cancer, many advances have been made enabling major improvements in the treatment of breast cancer. This, in addition to more effective screening programmes has contributed to improved survival for many breast cancer patients. In 2001-2003, five year survival rates were 80% compared to 52% in 1971-1975 representing a change of around 30%.[13]

2.3. Incidence of breast cancer in the UK

Breast cancer accounts for around 30% of all female cancers making it the most common cancer in women. It is a major health burden within our society affecting one in eight UK women over a lifetime. The incidence of breast cancer has risen steadily over recent years with around 45,500 new cases diagnosed each year of which more than 80% occur in women over 50 years of age. [14]

2.4. How does breast cancer develop?

Hormones play a central role in the development of breast cancer as they modulate the structure and growth of breast tissue. Breast tissue develops under the influence of hormones such as oestrogen, progesterone, insulin and growth factors. The main periods of breast tissue development occur during puberty, pregnancy and lactation.[15]

During adulthood most cells, including breast cells, do not undergo cell division (outside periods of pregnancy and lactation) but rather enter an inactive period or become 'quiescent'. However, under the influence of certain growth signalling factors cells can be induced to leave their inactive state and re-enter the cell cycle leading to cell division and ultimately growth.[16]

Breast cancer is categorised as a hormone dependent cancer and as such must be initiated under the influence of a hormone. In the case of breast cancer, oestrogen is believed to play a central role in both the initiation and progression of breast cancer. Two predominant models for the mechanisms by which oestrogen exerts its effect have been proposed and it is likely that both mechanisms contribute to the development of both primary and secondary breast cancer.[15]

2.4.1. Oestrogen acting in the initiation of breast cancer

Oestrogen and its metabolites can act *directly* as genotoxic agents damaging DNA in turn initiating breast cancer development. This model explains the mechanisms in which breast cancer develops from exposure to chemicals, viruses and radiation.[15]

2.4.2. Oestrogen acting in the progression of breast cancer

Oestrogen can act *indirectly* through its action as a mitogen in breast tissue promoting cell proliferation. This higher cell division rate allows less time for DNA repair resulting in increasing mutations that can lead to carcinogenesis. This mechanism differs from the first model in that no specific initiator other than errors in replication is required for breast cancer development.[15]

2.4.3. Windows of opportunity for breast cancer development

Three windows of exposure for breast cancer development have been described by Russo et al (1990); pre puberty, post puberty/pre pregnancy and post pregnancy (see table 2-1). These windows of exposure are discussed below.

2.4.3.1. Pre puberty

The first occurs from hormonal exposure to pre-menopausal breast tissue *prior to differentiation* as seen in early menarche.[15]

2.4.3.2. Post puberty/pre pregnancy

In the second window of exposure, It is generally agreed that the longer the period of oestrogen exposure to Type 2 ducts, as would occur in women who have longer periods of nulliparity, the greater the risk of breast cancer development. The earlier the development of type 3 ducts due to full term pregnancy, the greater the risk reduction. This period is seen as one of the most important exposure periods in breast cancer development.[15]

2.4.3.3. Exposure to oestrogen post differentiation

The last period refers to prolonged or excessive exposure to hormones post-differentiation (when under normal conditions breast tissue becomes inactive), as seen in later onset menopause. Although this period is regarded as less significant, it is still classed as a measurable risk factor[15].

	Duct Type	Degree of proliferation	Degree of differentiation	Predominant period in lifetime
Window 1	Type 1	****		Before and after puberty
Window 2	Type 2	***	*	After puberty and nulliparous women
	Type 3	**	***	Develop in pregnancy
	Type 4	*	****	Requires completed pregnancy. Disappears after lactation
Window 3	Prolonged or excessive exposure post differentiation			

Table 2-1 Model of duct types in the female breast [15]

2.5. What causes breast cancer?

Extensive research has been conducted over the last three decades into the causes of breast cancer. Over that time, many risk factors have been identified. However few of these have become widely accepted as the causal link in the aetiology of breast cancer.

The following section discusses only those risks which are currently accepted within the scientific community as those known to cause breast cancer. The method to categorise breast cancer risks vary depending on the source of information. For the purposes of the following discussion, the sections are arbitrary and compiled by the author in a way that best represents the synthesis of the information reviewed.

2.5.1. Breast cancer risk factors

The following section describes risk factors associated with breast cancer. These are categorised as either demographic, environmental, genetic, medication, reproductive and menstrual and finally lifestyle factors.

2.5.1.1. Demographics

2.5.1.1.1. Age

The risk of developing breast cancer increases with age. Very few cases occur in young women in their teens or early 20's. However, breast cancer is the most commonly diagnosed cancer in women under 35 with an estimated 1,500 cases each year. Incidence rates continue to rise with age with more than 80% of cases occurring in women over 50 years, with the most diagnoses observed in the 50-69 age group.[17-19]

2.5.1.1.2. Sex

Breast cancer occurs in both men and women however for every 100 cases diagnosed in women, one man will receive a breast cancer diagnosis. Thus, female sex is considered a risk factor for breast cancer supporting the link between the female hormone oestrogen in the aetiology of the disease.[17 18]

2.5.1.1.3. Residence

Breast cancer rates vary considerably around the world, with the highest rates observed in developed countries and the lowest in less developed countries such as Africa and Asia.[17]

Interestingly, this variability cannot be adequately explained by genetic factors, as when people move from low to high incidence areas, their risk of developing breast cancer changes, reflecting that of the adopted country, providing strong evidence that breast cancer is largely an environmental disease. Much of the variation observed can be explained as women in high incidence countries have fewer children and breastfeed for shorter durations when compared to women in low incidence countries. [17-19]

2.5.1.2. Environmental exposures

2.5.1.2.1. Radiation

Exposure from ionising radiation such as x-rays, particularly during puberty, increases risk even at low levels. The mechanism is believed to due to direct DNA damage.[17-19]

2.5.1.3. Genetics

Despite popular belief, genetic causes of breast cancer are relatively low when compared to those attributable to sporadic causes. About 5-10% of all breast cancers are of an inherited nature, of

which 85% occur from the two most common high risk breast cancer susceptibility genes, the BRCA1 and BRCA2 genes. For those women who carry the BRCA1 or BRCA2 gene, there is an increased risk of ovarian cancer, secondary primary in the contralateral breast and a local recurrence after conservative treatment when compared to non carriers.[15 18 19] In the future it is likely more breast cancer cases will be attributed to genetic causes as more susceptibility genes are identified.

2.5.1.4. Medication

Oral contraceptives containing both oestrogen and progesterone cause a small, transient, increased risk of breast cancer; the increased risk disappears after cessation.[17-19]

Hormone replacement therapy is a cause of breast cancer. The effect is greater for oestrogen-progesterone combinations and risk increases with duration used. The increased risk appears to disappear a few years after cessation.[17-19]

2.5.1.5. Reproductive and menstrual history

As the risk of developing breast cancer is related to an individual's lifetime exposure to oestrogen, reproductive and menstrual factors that influence the duration of exposure to oestrogen have a significant impact on risk. These include age at menarche, parity, age at first pregnancy, breastfeeding and finally age at menopause.

As risk clearly increases with exposure, women who experience an early menarche, are nulliparous and experience late onset of menopause will be at the highest risk, whereas those women who had a late menarche, had children early, breastfed their children and experienced early menopause will be at the lower risk.[17-19]

2.5.1.6. Lifestyle

Undesirable lifestyle behaviours are believed to substantially increase the risk of developing breast cancer. A recent publication states that the population attributable risk[20] (PAR[1]) for these potentially modifiable risk factors including postmenopausal hormone use, alcohol consumption, adult weight gain and level of recreational activity is 40.7%. [21]

The review which follows is largely derived from the 2007 World Cancer Research Fund 2nd Expert Report Food, Nutrition, Physical Activity and the Prevention of Cancer.[19] This report is considered the most comprehensive report on the association between lifestyle and cancer risk. Due to the thoroughness of the scientific process involved in judging the evidence for the report, the panel's

[1] Population attributable risk is defined as the proportion of breast cancer incidence in the total population (both exposed and unexposed) that can be attributed to a specific exposure

decision has been taken as the view of the scientific community. As such, risks described in the following section that are reported by the WCRF panel are stated rather than discussed.

Breast cancer risk factors are presented separately for postmenopausal and premenopausal breast cancer.

POSTMENOPAUSAL BREAST CANCER		
Risk factor	**Judgement**	**Proposed mechanism**
Body fatness	There is abundant and consistent epidemiological evidence and a clear dose response, with robust evidence for mechanisms operating in humans. The evidence that greater body fatness is a cause of postmenopausal breast cancer is convincing.	Body fat directly affects levels of many circulating hormones, such as insulin, insulin-like growth factors, and oestrogens, creating an environment that encourages carcinogenesis and discourages apoptosis.
Abdominal fatness	There is a substantial amount of epidemiological evidence, but some inconsistency. There is robust evidence for mechanisms that operate in humans. Abdominal fatness is a probable cause of postmenopausal breast cancer.	Abdominal fatness is particularly associated with increased circulating oestrogens and decreased insulin sensitivity.
Adult weight gain	There is ample, consistent epidemiological evidence from both cohort and case-control studies. A dose response was apparent from case-control and cohort studies. Adult weight gain is a probable cause of postmenopausal breast cancer.	See body fatness

Table 2-2 Risk factors, panel judgement and proposed mechanisms for postmenopausal breast cancer [19]

POSTMENOPAUSAL BREAST CANCER		
Risk factor	**Judgement**	**Proposed mechanism**
Adult attained height	There is abundant prospective epidemiological evidence, which is generally consistent, with a clear dose response, and evidence for plausible mechanisms operating in humans. The evidence that factors that lead to greater adult attained height, or its consequences, are a cause of postmenopausal breast cancer is convincing. The causal factor is unlikely to be tallness itself, but factors that promote linear growth in childhood.	Adult attained height is an important nutritional marker for early life experiences. These early life exposures impact on several hormones that directly influence breast cancer risk.
Physical activity	There is ample evidence from prospective studies showing lower risk of postmenopausal breast cancer with higher levels of physical activity, with a dose-response relationship, although there is some heterogeneity. There is little evidence on frequency, duration or intensity of activity. There is robust evidence for mechanisms operating in humans. Physical activity probably protects against postmenopausal breast cancer.	Physical activity has a beneficial effect on body fat and is therefore protective against hormonal changes that occur with weight gain. In addition, physical activity may directly reduce levels of circulating oestrogens and androgens

Table 2.2 Cont

POSTMENOPAUSAL BREAST CANCER

Risk factor	Judgement	Proposed mechanism
Alcoholic drinks	There is ample, generally consistent evidence from case-control and cohort studies. A dose-response relationship is apparent. There is robust evidence for mechanisms operating in humans. The evidence that alcoholic drinks are a cause of premenopausal and postmenopausal breast cancer is convincing. No threshold was identified.	Alcohol interferes with oestrogen pathways in multiple ways to influence hormone levels and oestrogen receptors.

Table 2.2 Cont

PREMENOPAUSAL BREAST CANCER		
Risk factor	**Judgement**	**Proposed mechanism**
Body fatness	There is a substantial amount of consistent epidemiological evidence, with a dose response, but the mechanistic evidence is speculative. Greater body fatness probably protects against premenopausal breast cancer	See above as in postmenopausal breast cancer
Adult attained height	There are fewer data for premenopausal than for postmenopausal breast cancer. The epidemiological evidence is generally consistent with a dose response and evidence for plausible mechanisms. Greater adult attained height or factors that lead to it are probably a cause of premenopausal breast cancer. The causal factor is unlikely to be tallness itself, but factors that promote linear growth in children	See above as in postmenopausal breast cancer
Greater birth weight	There is general consistency amongst the relatively few epidemiological studies, with some evidence for a dose response.	The mechanistic evidence is speculative. Greater birth weight or factors that lead to greater birth weight are probably a cause of premenopausal breast cancer.
Alcohol	See postmenopausal breast cancer	See postmenopausal breast cancer

Table 2-3 Risk factors, panel judgement and proposed mechanisms for premenopausal breast cancer [19]

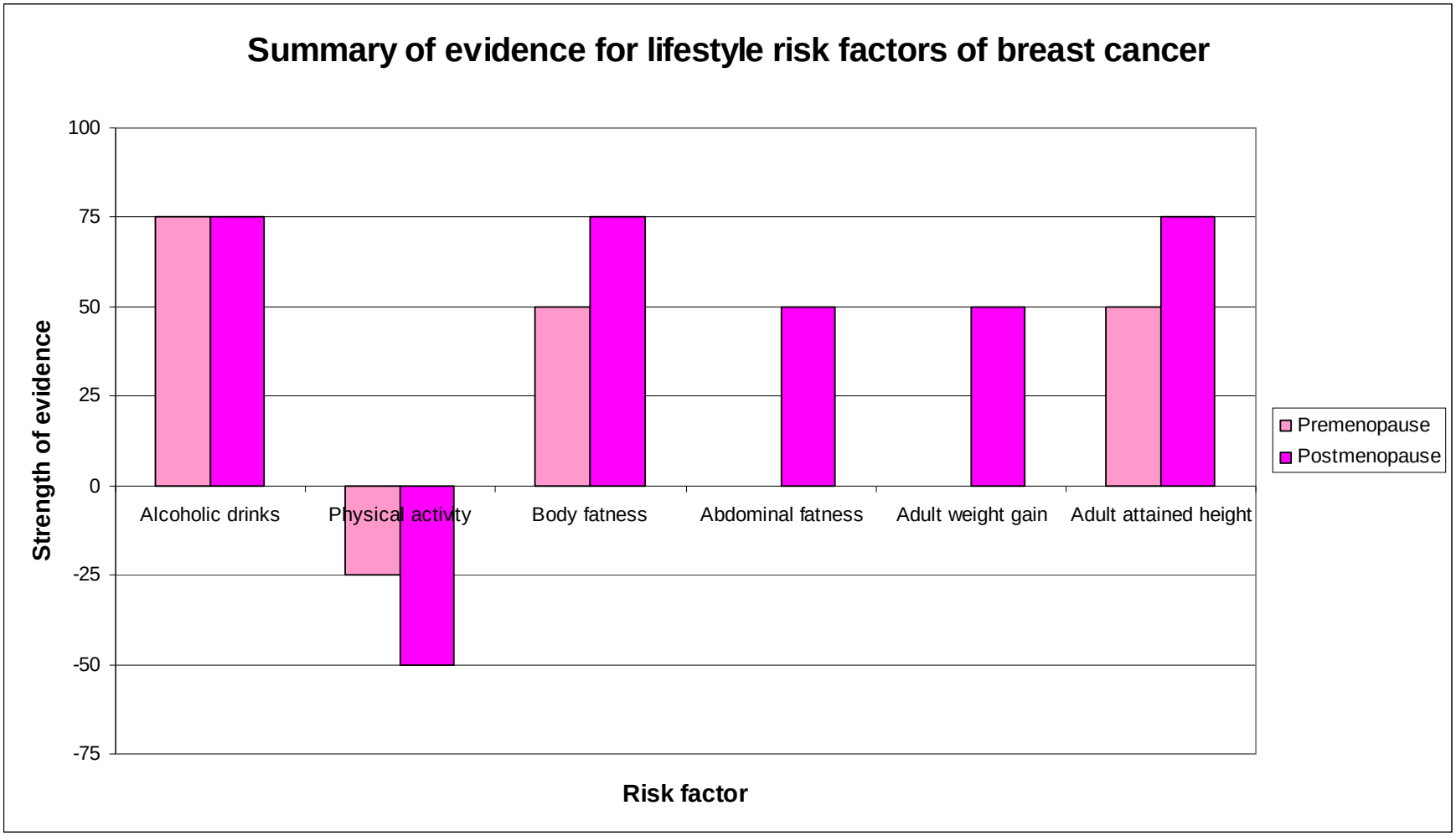


Figure 2-1 Summary of evidence for lifestyle risk factors for breast cancer [19]

2.6. Risk factor summary

Risk Factor category	Risk factor	Relative Risk[2]	Comparison group
Demographic	Age	4+	Increasing age (50+ vs <50)
		1.25 – 1.99	Increasing age (50-59 vs 40-49)
	Residence	1.25 – 1.99	Affluent country
Environmental exposures	Radiation	1.25 – 1.99	Especially < 20 yrs, high dose vs low dose
Genetic	Family history	4+	BRCA1, BRCA2 vs those without mutations
		2 – 3.99	Two or more first-degree relatives with breast cancer vs no family history
		1.25 – 1.99	One first degree relative or multiple second degree relatives with breast cancer vs no family history
Reproductive and menstrual history	Age at menarche	<0.8	Age at first period >14 vs <12 yrs
	Age at first pregnancy	1.25 – 1.99	First full term pregnancy >29 vs < 20
	Parity	1.25 – 1.99	Nullparity vs any childbirth
	Lactation	<0.8	Breastfeeding $\geq$ 12 months vs none
	Age at menopause	1.25 – 1.99	Age at menopause >50 vs <50 yrs

Table 2-4 Breast cancer risk factor summary [18]

[2] Relative risk is the ratio of the risk of developing breast cancer in exposed individuals compared to the risk in the unexposed [17]

Risk factor summary cont.

Risk Factor category	Risk factor	Relative Risk[3]	Comparison group
Lifestyle	Adult attained height	1.25 – 1.99	Height >174 vs <160cm
	BMI	1.25 – 1.99	BMI > 25 kg/m^2 (postmenopausal breast cancer)
		<0.8	BMI >30 vs <21 (premenopausal breast cancer)
	Alcohol	1.25 – 1.99	Daily intake of two alcoholic drinks or more vs never drinkers
	Levels of physical activity	<0.8	Increased physical activity vs no activity

Table 2.4 Cont

[3] Relative risk is the ratio of the risk of developing breast cancer in exposed individuals compared to the risk in the unexposed.

2.7. Breast Cancer Prevention

2.7.1. Primary Prevention[4]

As the causes of both pre and post menopausal breast cancer have been extensively researched and as such are well established within the scientific community, opportunities for breast cancer prevention are understandably based on reducing exposure to the known and identified risks.

Whilst many of these risks such as reproductive and menstrual factors are not amenable to modification, many are and cancer is considered largely a preventable disease. For many years, researchers and other agencies have tried to quantify estimates of preventability. The general consensus from these sources conclude that around two-thirds of all cancers could be prevented, one-third through the adoption of healthy diets and exercise patterns and a further one-third through the avoidance of smoking.[19]

Recently, new estimates for both overall cancer and specific cancer prevention have been published based on 2007 WCRF/AICR Diet and cancer report.[22] The latest figures suggest for the UK, around 42% of all breast cancers could be prevented through maintenance of appropriate food, nutrition, physical activity, and body fatness. The report goes on to state that these estimates are likely to underestimate the true level of preventability, clearly demonstrating that much can be done to prevent cancer, and in particular, breast cancer. Current public health goals for breast cancer prevention are as follows:

Recommendation
Be as lean as possible within the normal range of body weight.
Be physically active as part of everyday life
Limit consumption of energy-dense foods
Limit alcoholic drinks
Mothers to breastfeed; children to be breastfed

Table 2-5 Recommendations for the prevention of cancer [19]

[4] **Primary prevention** is defined as preventing the development of breast cancer.

2.7.2. Secondary prevention[5]

As the primary focus of this thesis was to assess the likely interest in a group nutrition education programme for newly diagnosed postmenopausal women with breast cancer, the following section discusses in detail the literature relating to issues around nutrition for breast cancer patients.

Whilst a large body of scientific evidence exists investigating the proposed benefits of nutrition on both physiological and/or psychological factors, the focus of this literature review is limited to the role of nutrition in the secondary prevention of breast cancer for several reasons.

Firstly, as a state registered dietitian, our professional body supports the concept that healthy eating patterns are best studied and benefits assessed using a whole diet approach as opposed to a specific nutrient approach. For this reason, the literature relating to individual food or nutrient components, such as phytoestrogens or dietary supplements has not been addressed in this review.

Secondly, although nutritional epidemiology has a long standing research history, enormous challenges still remain in accurately determining cause and effect relationships between food and health outcomes. For this reason a food versus a nutrient approach was adopted by the World Cancer Research Fund/American Institute for Cancer Research 2007 report on food, nutrition, physical activity and the prevention of cancer. [19] The expert panel justify this approach on the basis that identifying a true causal factor from a single nutrient carries unacceptable uncertainty and that any relationship found may reflect a marker for a particular food in which it is found, or for other dietary components found in that food.

2.7.2.1. Search strategy

A variety of sources were searched to identify all relevant articles. As the role for nutrition in breast cancer survivors was a relatively new area of study, broad search terms were used to ensure the search was inclusive.

Keywords: Breast cancer and Diet

[5] **Secondary prevention** is defined at preventing a recurrence of breast cancer

2.7.2.2. Electronic databases

2.7.2.2.1. AMED

1. Diet, Reducing/ or Diet, Macrobiotic/ or Diet, Atherogenic/ or Diet/ or Diabetic Diet/ or diet.mp. or Diet Surveys/ or Diet, Fat-Restricted/ or Diet, Carbohydrate-Restricted/ or Diet, Protein-Restricted/ or Diet, Sodium-Restricted/ or Diet Therapy/ or Diet, Vegetarian/ or Diet, Mediterranean/ or Diet, Cariogenic/ or Diet Records/ or Diet Fads/
2. limit 1 to humans
3. breast cancer.mp. or Breast Neoplasms/
4. limit 3 to humans
5. 2 and 4

2.7.2.2.2. BNI

1. Diet, Reducing/ or Diet, Macrobiotic/ or Diet, Atherogenic/ or "Diet"/ or Diabetic Diet/ or diet.mp. or Diet Surveys/ or Diet, Fat-Restricted/ or Diet, Carbohydrate-Restricted/ or Diet, Protein-Restricted/ or Diet, Sodium-Restricted/ or Diet Therapy/ or Diet, Vegetarian/ or Diet, Mediterranean/ or Diet, Cariogenic/ or Diet Records/ or Diet Fads/
2. limit 1 to humans
3. breast cancer.mp. or Breast Neoplasms/
4. limit 3 to humans
5. 2 and 4

2.7.2.2.3. CAB

1. Diet, Reducing/ or Diet, Macrobiotic/ or Diet, Atherogenic/ or "Diet"/ or Diabetic Diet/ or diet.mp. or Diet Surveys/ or Diet, Fat-Restricted/ or Diet, Carbohydrate-Restricted/ or Diet, Protein-Restricted/ or Diet, Sodium-Restricted/ or Diet Therapy/ or Diet, Vegetarian/ or Diet, Mediterranean/ or Diet, Cariogenic/ or Diet Records/ or Diet Fads/
2. limit 1 to humans
3. breast cancer.mp. or Breast Neoplasms/
4. limit 3 to humans
5. 2 and 4

2.7.2.2.4. CINAHL

1. Diet, Reducing/ or Diet, Macrobiotic/ or Diet, Atherogenic/ or "Diet"/ or Diabetic Diet/ or diet.mp. or Diet Surveys/ or Diet, Fat-Restricted/ or Diet, Carbohydrate-Restricted/ or Diet, Protein-Restricted/ or Diet, Sodium-Restricted/ or Diet Therapy/ or Diet, Vegetarian/ or Diet, Mediterranean/ or Diet, Cariogenic/ or Diet Records/ or Diet Fads/
2. limit 1 to humans
3. breast cancer.mp. or Breast Neoplasms/
4. limit 3 to humans
5. 2 and 4

2.7.2.2.5. EMBASE

1. Diet, Reducing/ or Diet, Macrobiotic/ or Diet, Atherogenic/ or "Diet"/ or Diabetic Diet/ or diet.mp. or Diet Surveys/ or Diet, Fat-Restricted/ or Diet, Carbohydrate-Restricted/ or Diet, Protein-Restricted/ or Diet, Sodium-Restricted/ or Diet Therapy/ or Diet, Vegetarian/ or Diet, Mediterranean/ or Diet, Cariogenic/ or Diet Records/ or Diet Fads/
2. limit 1 to humans
3. breast cancer.mp. or Breast Neoplasms/
4. limit 3 to humans
5. 2 and 4

2.7.2.2.6. HMIC

1. Diet, Reducing/ or Diet, Macrobiotic/ or Diet, Atherogenic/ or "Diet"/ or Diabetic Diet/ or diet.mp. or Diet Surveys/ or Diet, Fat-Restricted/ or Diet, Carbohydrate-Restricted/ or Diet, Protein-Restricted/ or Diet, Sodium-Restricted/ or Diet Therapy/ or Diet, Vegetarian/ or Diet, Mediterranean/ or Diet, Cariogenic/ or Diet Records/ or Diet Fads/
2. limit 1 to humans
3. breast cancer.mp. or Breast Neoplasms/
4. limit 3 to humans
5. 2 and 4

2.7.2.2.7. Medline

1. Diet, Reducing/ or Diet, Macrobiotic/ or Diet, Atherogenic/ or Diet/ or Diabetic Diet/ or diet.mp. or Diet Surveys/ or Diet, Fat-Restricted/ or Diet, Carbohydrate-Restricted/ or Diet, Protein-Restricted/ or Diet, Sodium-Restricted/ or Diet Therapy/ or Diet, Vegetarian/ or Diet, Mediterranean/ or Diet, Cariogenic/ or Diet Records/ or Diet Fads/
2. limit 1 to humans
3. breast cancer.mp. or Breast Neoplasms/
4. limit 3 to humans
5. 2 and 4

2.7.2.2.8. PsycINFO

1. Diet, Reducing/ or Diet, Macrobiotic/ or Diet, Atherogenic/ or "Diet"/ or Diabetic Diet/ or diet.mp. or Diet Surveys/ or Diet, Fat-Restricted/ or Diet, Carbohydrate-Restricted/ or Diet, Protein-Restricted/ or Diet, Sodium-Restricted/ or Diet Therapy/ or Diet, Vegetarian/ or Diet, Mediterranean/ or Diet, Cariogenic/ or Diet Records/ or Diet Fads/
2. limit 1 to humans
3. breast cancer.mp. or Breast Neoplasms/
4. limit 3 to humans
5. 2 and 4

2.7.2.2.9. Web of Science

1. Diet, Reducing/ or Diet, Macrobiotic/ or Diet, Atherogenic/ or "Diet"/ or Diabetic Diet/ or diet.mp. or Diet Surveys/ or Diet, Fat-Restricted/ or Diet, Carbohydrate-Restricted/ or Diet, Protein-Restricted/ or Diet, Sodium-Restricted/ or Diet Therapy/ or Diet, Vegetarian/ or Diet, Mediterranean/ or Diet, Cariogenic/ or Diet Records/ or Diet Fads/
2. limit 1 to humans
3. breast cancer.mp. or Breast Neoplasms/
4. limit 3 to humans
5. 2 and 4

2.7.2.3. Journal handsearching

Journal of Nutrition and Dietetics

2.7.2.4. Conference proceedings

American Association of Clinical Oncology; 2005; Atlanta
American Association of Clinical Oncology; 2006; Washington

2.7.2.5. Efforts to identify unpublished studies

National Research Register

2.7.2.6. Other sources

Additional articles were located through searching references of key articles

2.8. Nutrition in the secondary prevention of breast cancer

The following section provides a review of the literature in this area and is organised according to study design (see figure 2.2).

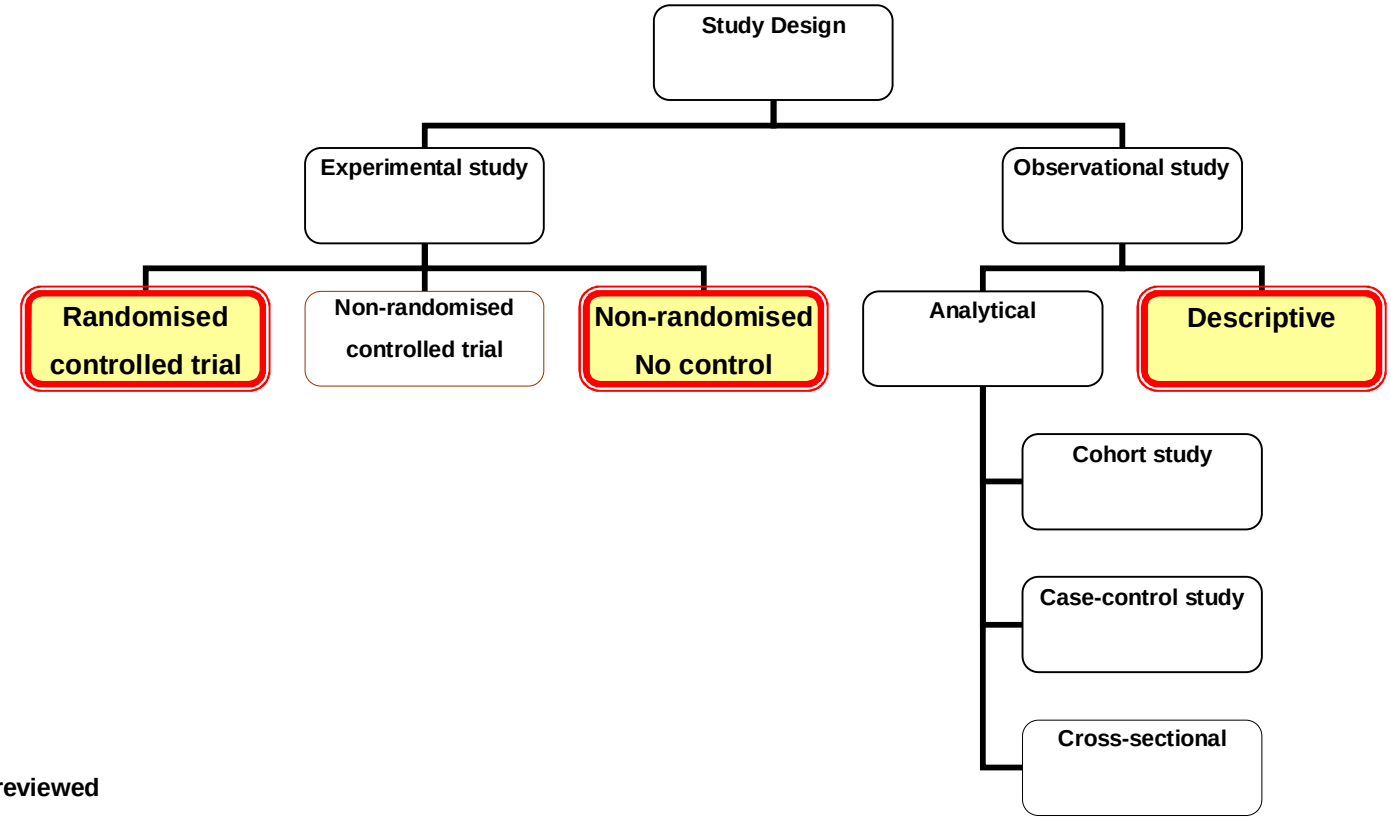
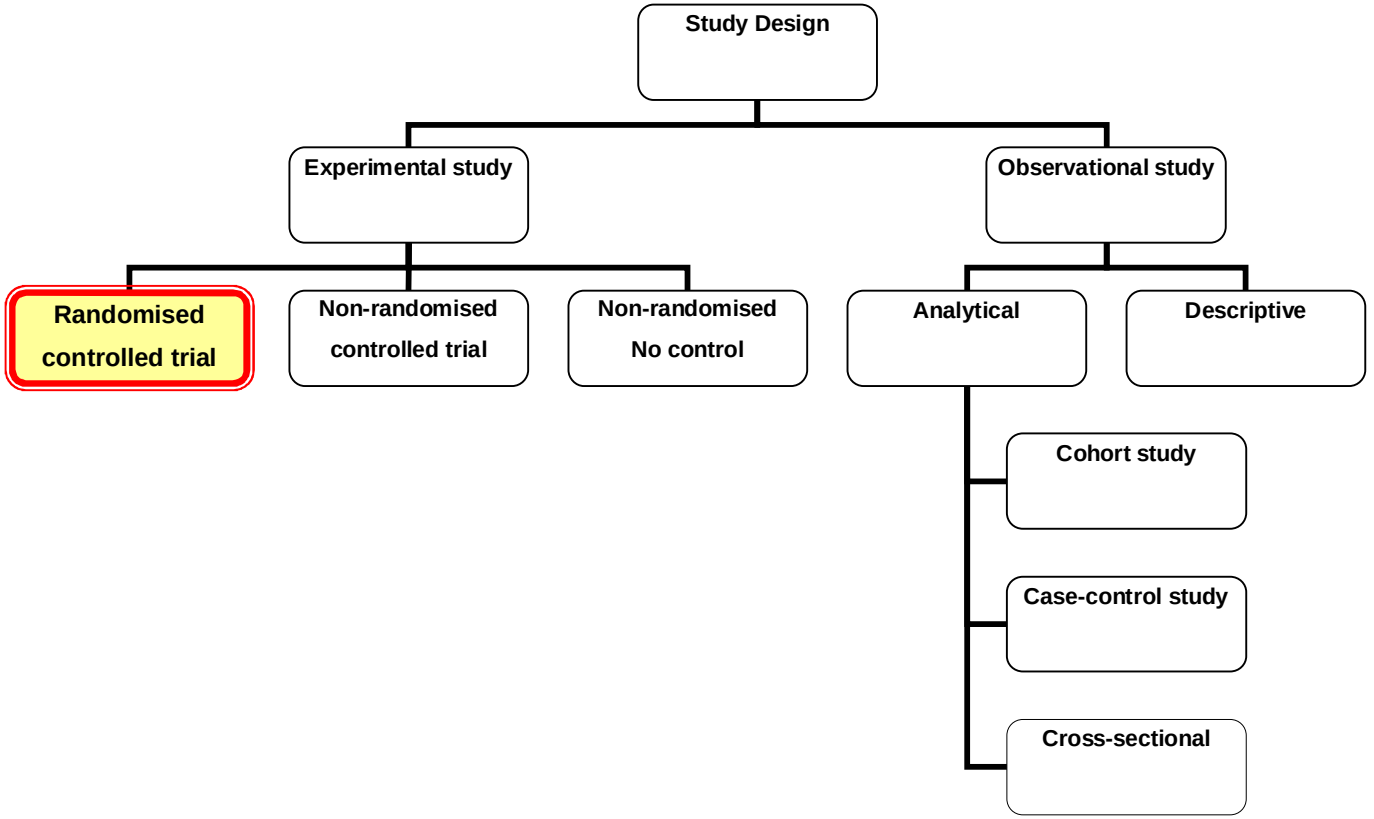


Figure 2-2 Study designs reviewed

2.8.1. Experimental studies

2.8.1.1. Randomised controlled trials



The following review is presented in accordance with the checklist from the CONSORT Statement for Parallel-Group Randomized Trials (2001).[23] Although many of the studies reviewed here were conducted before CONSORT, as it is now considered the "gold standard" for reporting RCT's and therefore interpreting the quality of the studies, these guidelines formed the basis for the critical appraisal.

This section begins with a summary of the publications reviewed and are listed by a trial code (which appear in table 2.6 in place of more lengthy trial descriptors). Further trial details are provided in tables 9.1 and 9.2 which can be found in appendix 9.1.

The review is then summarised in table 2.7 comparing each of the key elements outlined in the CONSORT statement (appendix 9.2) with the reviewed studies. The main narrative follows on from the summary tables.

Code	Trial/author	Author/s	Year	Title
1a	Nutrition Adjuvant Study	Greenwald et al[24]	1987	Feasibility studies of a low fat diet to prevent or retard breast cancer
		Chlebowski et al[25]	1987	A breast cancer nutrition adjuvant study (NAS): protocol design and initial patient adherence
		Chlebowski et al[26]	1990	Current status: Evaluation of dietary fat reduction as secondary breast cancer prevention
1b	WINS Feasibility	Chlebowski et al[27]	1993	Adherence to a dietary fat intake reduction program in postmenopausal women receiving therapy for early breast cancer
1c	WINS Stage III RCT	Chlebowski et al[28]	2007	Dietary fat reduction and breast cancer outcome: interim efficacy results from the Women's Intervention Nutrition study
2a	WHEL feasibility	Pierce et al[29]	1997	Feasibility of a randomized trial of a high-vegetable diet to prevent breast cancer recurrence
2b	WHEL RCT	Pierce et al[30]	2007	Influence of a diet high in vegetables, fruit, and fiber and low in fat on prognosis following treatment for breast cancer

Table 2-6 Trial codes and details

Code	Trial/author	Author/s	Year	Title
3	Djuric et al and Jen et al	Djuric et al[31]	2002	Combining weight-loss counselling with the weight watchers plan for obese breast cancer survivors
		Jen et al[32]	2004	Improvement of metabolism among obese breast cancer survivors in differing weight loss regimens
4	Holm et al and Nordevang et al	Holm et al[33]	1990	Dietary intervention as adjuvant therapy in breast cancer patients – a feasibility study
		Nordevang et al[34]	1990	Dietary intervention in breast cancer patients: effects on dietary habits and nutrient intake
		Nordevang et al[35]	1992	Dietary intervention in breast cancer patients: effects on food choice
5	BRIDGES	Hebert et al[36]	2001	Changes in women's diet and body mass following intensive intervention for early-stage breast cancer
6	De Waard et al	De Waard et al[37]	1993	A feasibility study on weight reduction in obese postmenopausal breast cancer patients
7	BCDIP	Kristal et al[38]	1997	Feasibility of using volunteer research staff to deliver and evaluate a low-fat dietary intervention: The American cancer society breast cancer dietary intervention project

Table 2.6 Trial codes and details (cont.)

Section and Topic	Descriptor	1a	1b	1c	2a	2b	3	4	5	6	7
Title and Abstract	How participants were randomly allocated to interventions	√	√	√	√	√	√	√	√	√	√
Introduction											
Background	Scientific background and explanation of rationale	√	√	√	√	√	√	√	√	√	√
Methods											
Participants	Eligibility criteria for participants and the settings and locations where the data were collected	X	X	X	√	√	√	√	√	√	√
Interventions	Precise details of the interventions intended for each group and how and when they were actually administered	√	X	√	X	√	√	√	√	X	√
Objectives	Specific objectives and hypotheses	X	X	√	√	√	√	√	X	√	√
Outcomes	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements	X	X	√	X	√	X	√	X	√	√
Sample Size	How sample size was determined and where applicable, explanation of any interim analyses and stopping rules	X	X	√	X	√	X	X	X	X	X

Table 2-7 Performance of reviewed studies compared to CONSORT checklist

Section and Topic	Descriptor	1a	1b	1c	2a	2b	3	4	5	6	7
Randomisation											
- Sequence generation	Method used to generated the random allocation sequence, including details of any restriction	X	X	√	X	√	√	X	X	X	X
- Allocation concealment	Method used to implement the random allocation sequence	X	X	X	X	√	X	X	X	X	X
- Implementation	Who generated the allocation sequence, who enrolled participants and who assigned participants to their groups	X	X	X	X		X	X	X	X	X
Blinding	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated	X	X	√	X	√	X	X	X	X	X
Statistical methods	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses	X	X	√	√	√	√	√	√	X	√

Table 2-7 Performance of reviewed studies compared to CONSORT checklist (cont.)

Section and Topic	Descriptor	1a	1b	1c	2a	2b	3	4	5	6	7
Results											
Participant flow	Flow of participants through each stage	√	√	√	√	√	√	√	√	√	√
Recruitment	Dates defining the periods of recruitment and follow-up	x	x	√	√	√	x	√	x	x	√
Baseline data	Baseline demographic and clinical characteristics of each group	√	√	√	√	√	√	√	√	x	x
Numbers analysed	Number of participants in each group included in each analysis and whether the analysis was by “intention-to-treat”. State the results in absolute numbers when feasible	√	√	√	√	√	√	√	√	√	√
Outcomes and estimation	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and aits precision	√	√	√	x	√	√	√	√	x	√
Ancillary analysis	Address multiplicity by reporting any other analyses performed, including subgroup analysis and adjusted analyses, indicating those prespecified and those exploratory	n/a	n/a	√	n/a	√	n/a	n/a	n/a	n/a	n/a
Adverse effects	All important adverse effects or side effects in each intervention group	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

Table 2-7 Performance of reviewed studies compared to CONSORT checklist (cont.)

Section and Topic	Descriptor	1a	1b	1c	2a	2b	3	4	5	6	7
Comment											
Interpretation	Interpretation of the results, taking into account study hypothesis, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes	X	X	√	√	√	√	√	√	X	√
Generalisability	Generalisability of the trial findings	X	X	?	?	√	X	X	X	X	X

Table 2-7 Performance of reviewed studies compared to CONSORT checklist (cont.)

2.8.1.2. Methods

2.8.1.2.1. Participants

Overall eligibility criteria were well documented however this was not the case for settings and locations, important considerations when assessing the relevance of the findings for the reader's own setting.[39]

2.8.1.2.2. Interventions

Overall, precise details of the interventions were poorly documented. For three of the trials reviewed, this information was not reported.[27 29 36]

For example trial 1b[27] reports "The dietary control group received minimal nutritional counselling".

Trial 3[29] provides the following description: Telephone counselling was provided across three phases of intensity and frequency of contact. A brief high-frequency contact phase of the intervention was aimed to encourage women to quickly achieve the study goals, with the counsellor monitoring performance. The second phase was less intense, and aimed to make changes so that the diet could be integrated into the women's way of life as well as to train the women in self monitoring of their diets. The third non-intensive phase was aimed at preventing relapse. Cooking classes were offered monthly throughout the study."

Trial 5[37] states "A balanced diet of 1,500 kcal was prescribed and discussed".

2.8.1.2.3. Objectives

The majority of the publications reviewed (7/10) reported the objectives of the study.

2.8.1.2.4. Outcomes

Despite good reporting of objectives, clearly defined primary and secondary outcomes were poorly described.

The importance of clearly stating outcomes cannot be overstated. Firstly a stated primary outcome is required to perform a power calculation and secondly without it the analysis cannot be considered transparent. It provides an opportunity for investigators to cherry pick results to find significant findings. Outcomes should be stated objectively.[40]

Of the papers reviewed only two publications objectively described their outcomes. The WINS study[28] stated an expected difference in relapse free survival of 7.5% between groups and the WHEL study[30] estimated a 19% difference in breast cancer events between groups.

2.8.1.2.5. Sample size

In order to estimate treatment effects a power calculation must be performed on the primary outcome. This should always be done a priori and stated in the protocol. The power calculation ensures that the study will have adequate power to detect the difference of interest in the two groups.[40]

Sample size calculations were only performed on two of the publications reviewed.[28 30] Most of the studies were feasibility studies and conducted many years ago which would explain the absence of such information. This does however have major influences on how the findings of these studies should be viewed.

2.8.1.2.6. Randomisation

Overall the randomisation process was poorly documented. Randomisation is the only way to ensure allocation to the comparison groups is unbiased and therefore the process should be reported clearly so that if the outcome differed between groups, the reader can be confident this difference occurred due to the treatment.

- **Random sequence generation**

Described in only two studies.[28 32]

- **Allocation concealment**

Only one study[30] reviewed reported how allocation concealment was achieved thus creating uncertainty regarding how unbiased the process was. Schultz et al [41] examined 250 randomised trials from 33 meta-analysis and found the treatment effect to be 30-41% higher in those trials without adequate allocation concealment.

- **Implementation**

Information on who generated the allocation sequence, who enrolled participants and who assigned participants to their groups was not reported in any of the studies reviewed.

2.8.1.2.7. Blinding

Blinding can occur at three points in a study; patients, treatment team and treatment evaluator/assessor. In a dietary intervention study it would not be possible to blind either the patient or the intervention team however blinded outcome assessment should be employed to ensure the outcome assessment is not biased. Outcome assessment blinding was reported in only two of the publications reviewed.[28 30]

2.8.1.2.8. Statistical methods

In general, a priori statistical analyses were well reported.

2.8.1.3. Results

2.8.1.3.1. Participant flow

Participant flow was poorly documented making it necessary to undertake a laborious task to determine numbers at each stage of the trial. Only three of the publications reviewed provided a clear description of participant flow.[28 30 37]

2.8.1.3.2. Recruitment

Five publications reviewed reported dates defining the periods of recruitment. The numbers of patients screened and invited is not always reported; an important consideration when assessing trials as the conversion rate from invitation to uptake indicates the interest in a dietary intervention. In the absence of this information, the length of time taken to recruit is the only proxy marker when considering this issue.

2.8.1.3.3. Baseline data

A summary of baseline comparisons were reported in six instances. Trial 7[38] provided baseline data but did do so separately for the control and interventions participants.

2.8.1.3.4. Numbers analysed

Further as table 2-8 highlights, the majority of studies had small numbers of participants, a feature that undermines the quality and interpretability of the findings.

Only two studies reviewed report an “intention to treat” (ITT) analysis.[28 30] The WINS Study[28] reported analysing data on all 975 participants from the intervention group and 1462 from the control. However, there is no explanation offered as to how the missing dietary data, outlined in the paper is calculated. Without this information it is difficult to assess whether the analysis is in fact ITT.

The other study to report an ITT analysis (the WHEL study) despite losing numbers through withdrawals and loss to follow-up, included data from all 3088 original participants in the final analysis. In the case of missing records, a conservative imputation model was utilised for follow-up data.

1. WINS								
Nutrition Adjuvant study	**BL[6]**	**3/12[7]**	**6/12[8]**	**12/12[9]**	**18/12[10]**	**24/12[11]**	**36/12[12]**	**48/12[13]**
Control	19	14						
Intervention	30	18						
TOTAL	**49**	**32**	**27**	**15**				
WINS stage II	**BL**	**3/12**	**6/12**	**12/12**	**18/12**	**24/12**	**36/12**	**48/12**
Control	147	111	100	72	55	36		
Intervention	143	108	96	83	55	35		
TOTAL	**290**	**219**	**196**	**155**	**110**	**71**		
Wins Stage III	**BL**	**3/12**	**6/12**	**12/12**	**18/12**	**24/12**	**36/12**	**60/12**
Control	1461			1328			1077	648
Intervention	975			840			654	380
TOTAL	**2436**			**2160**			**1731**	**1028**

Table 2-8 Numbers of participants with available data during each stage of study

[6] Baseline

[7] Three months

[8] Six months

[9] Twelve months

[10] Eighteen months

[11] Two years

[12] Three years

[13] Four years

2. WHEL								
WHEL Feasibility	**BL**	**3/12**	**6/12**	**12/12**	**18/12**	**24/12**	**36/12**	**48/12**
Control	**46**		**43**	**32**				
Intervention	**47**		**44**	**39**				
TOTAL	**93**		**87**	**71**				
WHEL RCT	**BL**							**72/12**
Control	1551							1488
Intervention	1537							1465
TOTAL	**3088**							**2953**
3. Djuric et al and Jen et al								
	BL	**3/12**	**6/12**	**12/12**	**18/12**	**24/12**	**36/12**	**48/12**
Control	**13**		**13**	**12**				
Weight Watchers	**10**		**9**	**8**				
Individualised	**13**		**9**	**9**				
Comprehensive	**11**		**10**	**10**				
TOTAL	**47**		**41**	**39**				
4.Holm et al and Nordevang								
	BL	**3/12**	**6/12**	**12/12**	**18/12**	**24/12**	**36/12**	**48/12**
Control	**119**					**106**		
Intervention	**121**					**63**		
TOTAL	**240**					**169**		

Table 2-8 Numbers of participants with available data during each stage of study (cont.)

5. BRIDGES								
	BL	**3/12**	**6/12**	**12/12**	**18/12**	**24/12**	**36/12**	**48/12**
Control	**56**			**49**				
NEP	**50**			**48**				
SRC	**51**			**46**				
TOTAL	**157**			**143**				
6. De Waard								
	BL	**3/12**	**6/12**	**12/12**	**18/12**	**24/12**	**36/12**	**48/12**
Control	**43**		**39**		**24**	**21**	**17**	**15**
Intervention	**59**		**55**		**27**	**25**	**23**	**18**
TOTAL	**102**		**94**		**51**	**46**	**40**	**33**
	BL	**3/12**	**6/12**	**12/12**	**18/12**	**24/12**	**36/12**	**48/12**
7. BCDIP								
	BL	**3/12**	**6/12**	**12/12**	**18/12**	**24/12**	**36/12**	**48/12**
Control	**71**	**59**	**53**	**53**				
Intervention	**73**	**63**	**62**	**57**				
TOTAL	**144**	**122**	**115**	**110**				

Table 2-8 Numbers of participants with available data during each stage of study (cont.)

2.8.1.4. Outcomes and estimation

Overall, summaries of outcome measures were reported.

2.8.1.4.1. Ancillary analysis

In the majority of cases, due to the relatively small numbers of participants involved there were no subgroup analyses conducted.

The WINS Stage III[28] study did however conduct several sub group analyses (not pre specified in the protocol) and several interim analyses were conducted. In these instances the Haybitle-Peto approach to α-spending was documented.

Similarly, the WHEL study also addressed issues of multiplicity in their design paper.[30]

2.8.1.4.2. Adverse effects

There are no known adverse effects in following both a low-fat or high fruit and vegetable, low fat diet.

2.8.1.5. Comment

2.8.1.5.1. Interpretation

Given the methodological issues presented in this discussion, the interpretation of the findings by the authors for all the studies reviewed was more positive that the results would indicate (table 2.9).

For example, it is the opinion of this reviewer that given the largely negative scores for the conduct of study 1b using CONSORT it is not appropriate for the authors to conclude *"Substantial and sustained dietary fat reduction with associated weight change can be achieved at relatively low cost within the context of conventional multimodality clinical management of postmenopausal women with localised breast cancer. Thus full-scale study of the potential influence of dietary fat intake reduction of breast cancer patient relapse and survival can now be considered".*

Trial	Conclusions
1a	Results suggest that a somewhat larger population of potential study participants will be required to successfully meet targeted accrual goals for studies involving alteration of dietary fat intake in the adjuvant cancer setting
1b	Substantial and sustained dietary fat reduction with associated weight change can be achieved at relatively low cost within the context of conventional multimodality clinical management of postmenopausal women with localised breast cancer. Thus full-scale study of the potential influence of dietary fat intake reduction of breast cancer patient relapse and survival can now be considered
1c	A way of life intervention reducing dietary fat intake, with modest influence on body weight, may improve relapse-free survival of breast cancer patients receiving conventional cancer management
2a	Results from the present study support the feasibility of conducting a large clinical trial to investigate the effect of this diet intervention on recurrence of breast cancer
2b	Among survivors of early stage breast cancer, adoption of a diet that was very high in vegetables, fruit, and fiber and low in fat did not reduce additional breast cancer events or mortality during a 7.3 year follow-up period
3	Despite the small size of the study, the differences in weight loss observed between intervention arms were large, with the combination of individualised counselling and the commercial weight watchers program proving to be more effective. This approach should be applicable to larger studies that test whether weight loss in breast cancer survivors can reduce their risk of disease recurrence
4	Dietary counselling resulted in a significant difference in intakes of dietary fat and carbohydrate between the intervention group and the control group after a two year period
5	Not clearly stated
6	With proper advice and guidance it is possible to achieve a weight reduction of 6kg or more in 50% of obese postmenopausal breast cancer patients
7	It is feasible to develop research protocols that include complex dietary interventions delivered by volunteer research staff

Table 2-9 Publication conclusions

The only study which provided an accurate interpretation giving due consideration to both strengths and limitations was the WHEL study.[30]

2.8.1.5.2. Generalisability

A number of issues bring the generalisability of these studies under question.

Firstly, it is unclear as to whether trial participants represented breast cancer patients in the wider context. Stringent specific inclusion and exclusion criteria were set out for the studies reviewed thus impacting of the external validity of the results.

Secondly, it is difficult to assess the proportion of women who were invited to enter the trial agreeing to participate, further limiting the strength of determining the generalisability of the findings. In those instances where conversion rates from screening to participation are reported, they highlight a relatively poor uptake.

Thirdly losses in the treatment arm are consistently higher than in the comparison group suggesting an inability to comply with the dietary intervention for many of the participants. Surprisingly this issue is not discussed in any of the reviewed publications.

Further, the sample sizes in the studies with the exception of trial WINS Stage III[28] and WHEL[30] were small making extrapolation to a larger population cautionary.

Lastly, the settings and locations were also poorly documented which could influence the generalisability of the findings.

Overall, these data cannot be assessed as generalisable. This is of some concern given that many of these trials were feasibility studies from which larger studies were based.

2.8.1.5.3. Summary of studies

With eight of the ten publications reviewed which can only be described as having plausible bias that seriously weakens confidence in the results, the quality of this body of work can only be summarised as poor. That said, a further discussion on the two large randomised controlled trials, the WINS[28] study and the WHEL[30] study is warranted.

The first to publish the results of their work was the Women's Intervention Nutrition Study (WINS). The study, a large randomised controlled trial investigated the effect of a low-fat diet on relapse free survival in postmenopausal women with breast cancer.

The study recruited 2437 postmenopausal women with breast cancer over the period of seven years, from February 1994 to January 2001. Women were assigned to either a low-fat diet (15% of

energy from fat) or an attention control group who received written information on general dietary guidelines.

The end points for the study were relapse events including local, regional and distal recurrences; ipsilateral recurrence following lumpectomy; and contralateral recurrence. Overall survival defined as death from any cause was a secondary endpoint.

The results showed that women in the intervention arm of the study had a 24% lower risk of relapse compared to the control group (HR = 0.76; 95% CI = 0.60 – 0.98). Further, the greatest effect, although not statistically significant, was observed in the oestrogen receptor negative group, a group for whom adjuvant treatment is limited.

The authors conclude that this interim efficacy analysis suggests a low fat diet may improve relapse free survival in postmenopausal women with breast cancer.

In contrast, the Women's Healthy Eating and Living Study (WHEL), another large, randomised controlled trial found no relationship between a diet, high in vegetables and fruit and fibre and low in fat and subsequent survival from breast cancer.

The WHEL study recruited 3088 women, both premenopausal and postmenopausal, from 1995 – 2000, a similar time period as in WINS. Women were assigned to the intervention (high vegetable – 5 serves and fruit – 3 serves and fibre – 30g, low fat – 15-20% of total energy intake) or the attention control group who received written materials on a healthy diet including five or more serves of vegetables and fruit, more than 20g of fibre and less than 30% total energy from fat.

Study endpoints were 1/ recurrence, which included local/regional or distal metastasis or new primary breast cancer and 2/ death from any cause.

Results showed that risk of recurrence or death was similar for both the intervention and control arm of the study. Therefore no survival benefit from consuming a diet high in vegetable, fruit and fibre, and low in fat was observed.

The discrepancy in the results of both of these studies is disappointing as it was hoped that these studies would provide strong evidence for the role of diet in the secondary prevention of cancer.

It is important to note at this stage the differences between the studies. Firstly, whilst both studies recruited large numbers of women, the WINS study was limited to postmenopausal women. Both dietary interventions prescribed low fat diets however levels in the WINS study were significantly lower with a target of 15% compared to 30% in WHEL. In addition the WHEL study targeted other dietary components, including vegetables, fruit and fibre.

Despite these differences in study design, a comparison between the WINS and the WHEL study results on the effect of dietary fat reduction on breast cancer outcomes is warranted and has been the subject of several publications since the original articles appeared in the scientific literature.[42 43 44 45]

The following explanations have been put forward which may help understand these differences. In total, four potential reasons have been identified; differences in baseline characteristics, differences in fat reduction, differences in weight loss and differences in time since diagnosis.

Firstly, both studies despite randomisation resulted in potentially important baseline differences between the intervention and control group. Specifically for WINS, there were higher numbers of women who had mastectomies (reported to have better outcomes than lumpectomy) in the intervention group and this in itself may have confounded the findings. The authors state that statistical adjustment was made and therefore any advantage in this group should have been eliminated.

The WHEL study too observed differences in baseline characteristics, again in treatment variables. The percentage of women in the intervention group who received adjuvant anti-oestrogen therapy and bilateral oophorectomy was slightly higher. Again the authors dealt with these differences through statistical analyses. The results yielded similar results for both adjusted and unadjusted models.

In both scenarios the baseline differences favoured the intervention group. In the case of the WHEL study, this suggests the null effect of the dietary intervention was even greater than reported. In the case of WINS, given a statistically significant finding was found, it may be possible that the observed difference was due to baseline differences favouring the intervention group. Thiebaut et al [44] state that post hoc covariate adjustment is not as inferentially as strong as analyses conducted on groups whose baseline characteristics are well matched and conclude by stating a degree of uncertainty must be taken into consideration when interpreting the overall findings of the WINS.

Secondly, change in fat intake after the intervention differed slightly between the two studies. The mean % fat intake at baseline for women in the intervention groups was 29.6% in the WINS study and 28.5% in WHEL and in the control groups 29.6% and 28.7% respectively. At one year fat intake had fallen to 20.3% in the WINS study compared to 22.7% in WHEL. Therefore at one year the reduction in fat in the WINS study was 2.4% greater compared to that achieved by participants in WHEL.

Whilst both studies followed participants for similar periods, five years in WINS and six in WHEL, no raw data was presented at the last follow up for the WINS study. Only mean % difference in fat

intake from baseline between the intervention and control groups was reported. Over the five years the mean % difference was -8.9 at one year, -9.0 at three years and -8.0 at five years. For the similar time intervals in WHEL (1,2 and 6 years), mean % difference in fat intake between groups was -5.7, -5.2 and -3.5 respectively. The mean % difference in fat intake does however expose an interesting point. Mean % fat intake for women in the intervention arm of the WHEL had not only returned to that levels observed at baseline but had slightly surpassed them (28.9%). The reason a 3.5% mean difference was observed was due to an even greater increase in % fat intake in the control group. Without the raw data from the WINS, it is difficult to assess if low intakes of fat were maintained as stated by the authors or whether the control group has increased their fat intake over the period thus artificially providing evidence for maintenance. This is further compounded by the degree of missing data in the WINS study which was approximately 30% at year three and 60% at year five.

This is an important observation as the latest endocrine therapy recommended for newly diagnosed breast cancer patients is aromatase inhibitors which essentially reduce up to 99% of oestrogen activity within the body.[15] If indeed the proposed mechanism by which a low fat diet works is by reducing circulating oestrogens, if this dietary pattern cannot be maintained after cessation of endocrine therapy (usually five years), any benefit from dietary modification is negated as women are protected via this medication.

Thirdly, weight loss observed in both studies differed. The mean weight at baseline for women in the intervention groups was 72.7 kg in the WINS study and 73.5 kg in WHEL and in the control groups 72.6 kg and 73.3 kg respectively. At one year weight had fallen to 70.6 kg in the WINS study compared to 73.0 kg in WHEL. Therefore at one year the reduction in weight in the WINS study was 1.6 kg greater compared to that achieved by participants in WHEL.

As seen in % fat intake no raw data was presented at the last follow up for the WINS study with results presented as mean difference in weight from baseline between the intervention and control groups. Over the five years the mean difference in weight was -2.3 kgs at one year, -1.8 at three years and -2.7 at five years.

For similar time intervals in WHEL (one, two and six years), mean difference in weight between groups was + 0.2 kgs, - 1.0 and + 0.4 respectively.

This observed difference in weight loss between the two studies may explain the findings of the WINS study and it has been suggested that weight loss and not a diet low in fat may be responsible for the survival benefit found by the WINS study group.[44]

Lastly WINS recruited women within one year of their breast cancer diagnosis whereas the average time since diagnosis in WHEL was four years. This may have resulted in an under

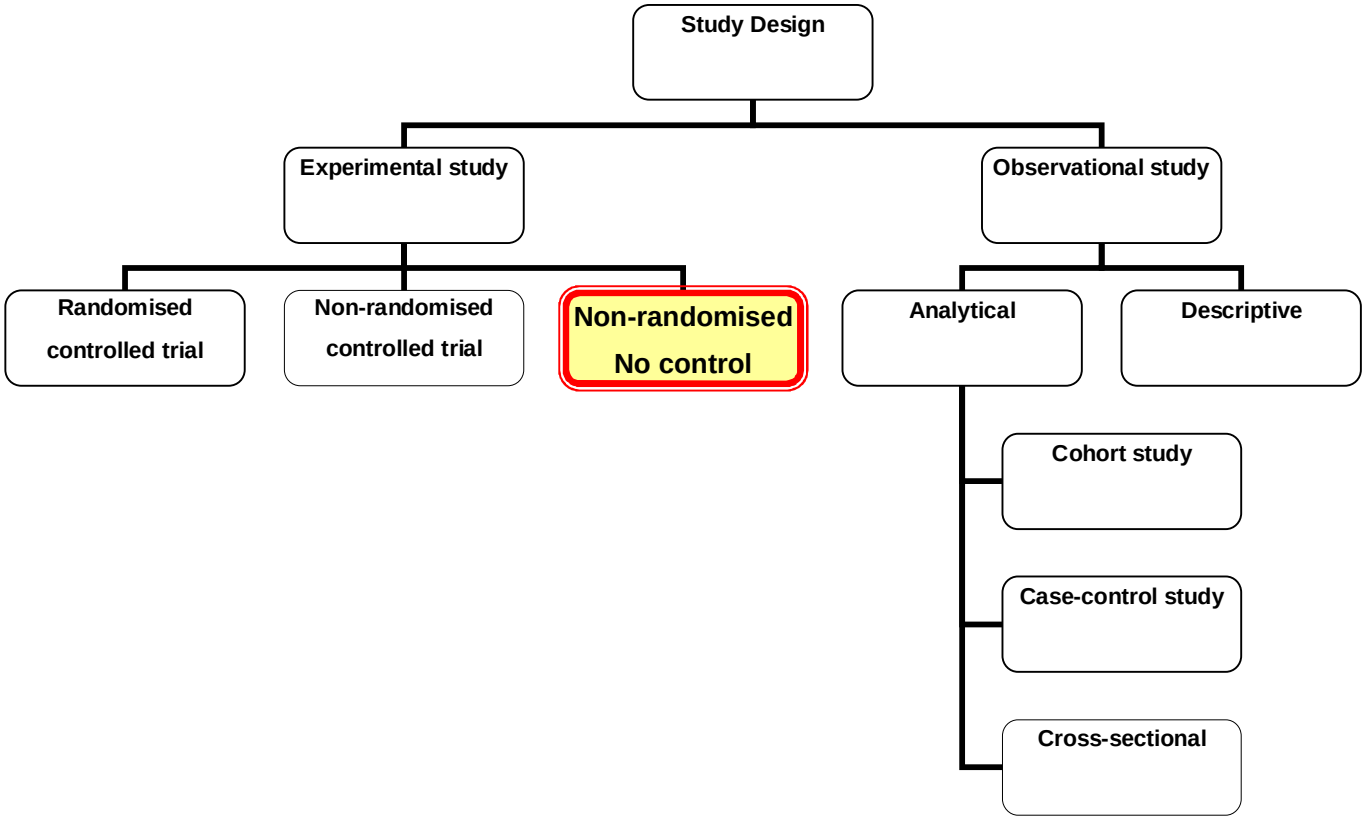
sampling of women most likely to experience a recurrence and therefore explained the findings that the WHEL eating pattern did not improve breast cancer outcomes.

Further, an unplanned sub group analysis in the WINS data found that women with oestrogen receptor negative tumours were conferred a greater survival benefit when compared to those with oestrogen receptor positive tumours. Whilst this finding is welcomed as currently this group has fewer adjuvant treatment options, it must be viewed cautiously. The finding may have occurred by chance or have arisen through confounding. Thiebaut et al[44] raise the possibility that the differences in mastectomy rates may have been more evident in the ER-ve group.

The WINS study has yet to report its final results. Once published, the findings may lay to rest many of the issues raised.

Taken in totality, despite two large, randomised controlled trials the question regarding the role of diet in the secondary prevention of cancer remains unclear.

2.8.1.6. Non-randomised non controlled trials



	Year	Author	Title
1	1998	Goodwin et al[46]	Multidisciplinary weight management in locoregional breast cancer: results of a phase II study
2	1998	McTiernan et al[47]	Anthropometric and hormone effects of an eight-week exercise-diet intervention in breast cancer patients: results of a pilot study
3	1988	Boyar et al[48]	Response to a diet low in total fat in women with postmenopausal breast cancer: A pilot study

Table 2-10 Publication details

	Aim	Invited	Started	Finished	Intervention details	Conclusions
1	To prevent weight gain and in those who were overweight to promote weight loss		61	39	Group (6-10) sessions 90 minute sessions weekly for ten weeks then monthly for ten months Education covered information on breast cancer and its treatment, nutrition, physical activity and psychological adaptation to breast cancer	The multidisciplinary team successfully prevented weight gain in women with newly diagnosed locoregional breast cancer and helped overweight women lose weight
2	To test the feasibility of recruiting, screening, enrolling and maintaining breast cancer patients in an intensive 8-week exercise and low-fat diet program	99		9	Dietary program consisted of a low fat diet(20% of total calories). After an initial visit where patients learned skills to change eating behaviours to adopt the dietary program and were provided with written information, they were contacted every 3 weeks by a nutritionist to assess adherence and provide further counselling. Participants were able to contact the nutritionist outside these arrangements	These pilot data indicate that breast cancer patients are highly motivated to join and adhere to an intense exercise-diet intervention and can experience significant measurable changes in anthropometric and fat mass measures
3	To determine whether postmenopausal breast cancer patients would adhere to a low fat diet		27	20	An individual initial consultation one month after baseline was provided to introduce the low fat eating plan after which group sessions (max 20) were held monthly for four months	Self selected patients can adhere to a low-fat diet

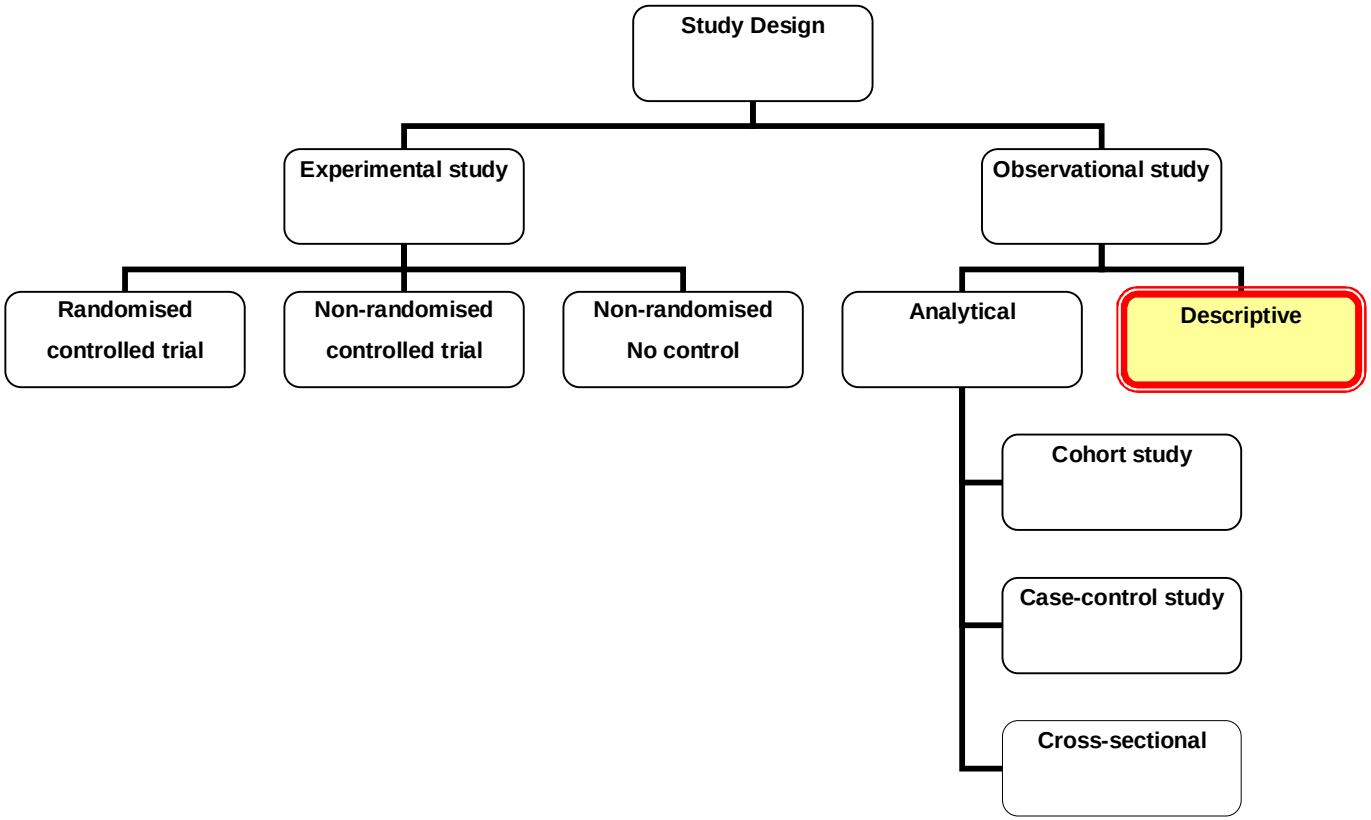
Table 2-11 Study details

The three studies reviewed here represent early works that were by and large feasibility studies focused on two of the prominent theories for the potential role of nutrition in the secondary prevention of cancer at the time; low-fat diets and weight reduction diets.

The studies do not provide solid evidence, due largely to the methodological weaknesses associated with non randomised, non controlled trials that either low fat diet or weight reduction diet interventions are either taken up and/or tolerated by breast cancer patients as suggested by some of the authors.

In contrast, participant flow would suggest the opposite with only half the original cohort left at the end of study one, only one-tenth of those invited agreeing to participate in study two, and only three- quarters of what was a small group to start with completing study three.

2.8.1.7. Observational studies



	Year	Author	Title
1	1999	Saxe et al[49]	Diet and risk for breast cancer recurrence and survival
2	2003	Goodwin et al[46]	Diet and breast cancer; evidence that extremes in diet are associated with poor survival
3	2005	Kroenke et al[50 51]	Dietary patterns and survival after breast cancer diagnosis
4	2006	Fink et al[52]	Fruits, vegetables, and micronutrient intake in relation
5	2006	McEligot et al[53]	Dietary fat, fiber, vegetable, and micronutrients are associated with overall survival in postmenopausal women diagnosed with breast cancer

Table 2-12 Publication details

In all, five studies were identified for review. Although all studies investigated the association between diet and breast cancer outcomes, the varying methodologies make it difficult to draw conclusions regarding this relationship.

Various **dietary measures** were used to assess the relationship. These included nutrient (1, 4, and 5) and micronutritient (3) analysis, dietary pattern analysis (2) and food group analysis (3, 5).

Various **endpoints** were investigated including recurrence (1), death from breast cancer (2), deaths from all causes excluding breast cancer (2, 5) and all cause mortality (1, 2, 3, 4).

Diet histories were taken at different points after a breast cancer diagnosis, from at the time of diagnosis (1, 3 and 5) and from 3 months after diagnosis (4) to a minimum of two years after diagnosis (2).

The **menopausal status** of participants varied between, with three of the studies (1, 3 and 4) including both pre and postmenopausal women for which the prognosis if significantly different, the fourth was limited to postmenopausal women only (5) and the last with premenopausal women (2).

Four of the studies used multivariate **analyses** to assess the relationship between dietary variables and breast cancer outcomes, adjusting for important known prognostic factors (1, 2, 4 and 5) whilst one did not (4).

Numbers of participants varied considerably between studies with the lowest at 149 (1) up to 2619 (2).

In addition to the methodological issues outlined above, the ability of Food Frequency Questionnaires (FFQ's) (which were used to measure diet in all of the studies reviewed) to accurately measure dietary nutrients is a source of great debate[54-57]. Whilst they may be useful in

determining an overall dietary pattern, it is doubtful whether they are useful/accurate at a nutrient level.

In addition, a further source of error exists in the dietary assessment as participants in all studies were asked to recall their usual diet in the twelve months before they received their breast cancer diagnosis; in effect introducing recall bias.

Reported results found a significant positive association between energy and recurrence (1), energy and all cause mortality using a linear model (1) and all cause mortality using a quadratic model (4), a western diet and mortality excluding breast cancer (2) and BMI adjusted for arm muscle circumference and all cause mortality (1). No other significant results were reported.

Overall, given the methodological issues outlined and the non divergence of reported results, no valid conclusions can be drawn from this body of literature on the relationship between diet and breast cancer outcomes.

2.8.2. Summary of secondary prevention studies

Several studies, including both experimental and observational studies investigating the role for diet in the secondary prevention of breast cancer over the last two decades were reviewed. The majority of the studies were feasibility studies investigating whether women could follow either a low fat or healthy diet, the results of which would inform future large scale randomised controlled trials.

To date, two large randomised controlled trials have been conducted investigating the role of diet in the secondary prevention of breast cancer. [28 30] The results of these two trials were published recently with the WINS study suggesting a lifestyle intervention aimed at reducing dietary fat intake may improve the relapse free survival of postmenopausal breast cancer patients in contrast to the WHEL study which found no such association. Several reasons have been identified to explain the conflicting findings including differences in study population; baseline characteristics; time since diagnosis and weight changes. The future publication of the final results from the WINS study may resolve some of these issues.

2.8.3. Tertiary prevention[14]

There is a paucity of evidence concerning the late effects of cancer treatments that could potentially be addressed by tertiary prevention activities. The evidence is largely derived from the paediatric literature therefore caution must be exercised when extrapolating long term health effects of cancer treatments to adult cancer survivors.

Breast cancer treatments do have associated complications however these are usually well tolerated with serious events confined in most instances to rare cases. Further, over the last five years there has been significant progress in treatments for breast cancer resulting in more effective, targeted and safe therapies.

At present it is not possible to reliably link specific treatment regimens to late or long term health effects and therefore no evidence exists for the role of dietary interventions in tertiary prevention activities.

2.9. Chapter summary

Breast cancer is the most common cancer in the UK accounting for 30% of all female cancers. Breast cancer will affect one in eight women in the UK over the course of a lifetime. The incidence of breast cancer has been rising steadily over recent years and this trend is expected to continue in the future. In contrast, survival rates from breast cancer have been steadily improving largely due to earlier detection and better treatments. The net result is an increasing number of women surviving a breast cancer diagnosis.

The hormone oestrogen plays a central role in the development of breast cancer and the risk associated with the disease are largely related to a women's lifetime exposure to oestrogen. Two predominant models for the role of oestrogen in both the initiation and progression of breast cancer have been proposed.

Known causes of breast cancer include, demographic, environmental, medication, and lifestyle factors along with reproductive and menstrual history. Whilst many risk factors are not amenable to change, especially in later life many are. The latest reports suggest that around 42% of all breast cancers could be prevented through appropriate food, nutrition, physical activity and body fatness.[22]

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[14] **Tertiary prevention** is defined at preventing late or long term effects of cancer treatment.

Despite almost twenty years of research into the role of nutrition in the secondary prevention of breast cancer, to date no evidence base guidelines exist specifically for this group other than to follow the recommendations for the primary prevention of breast cancer.

Further, there is a paucity of evidence on the late or long term effects of cancer treatment thus leaving a large evidence gap in the role for nutrition in tertiary prevention strategies.

At present we have limited knowledge regarding the health status of breast cancer survivors both at the time of diagnosis and beyond. The literature suggests that cancer survivors experience poorer health outcomes when compared to age matched individuals in the general population. Therefore, identifying appropriate interventions to improve health outcomes for this group is paramount.

Chapter Three

Breast cancer services in the NHS

3.0 Breast cancer services in the NHS

3.1. Chapter Introduction

With cancer classed as a chronic disease, the adoption and maintenance of healthy behaviours has become of paramount importance.[58] Cancer survivors face a diverse range of physical and emotional sequelae[59] and therefore health promotion could potentially play an integral role in the length and quality of survival.[60] [61] Demark-Wahnefried et al[62] stated that data clearly indicates cancer survivors are at greater risk for developing secondary cancers and other non-cancer diseases brought on by one or a combination of factors including treatment effects, genetic predisposition and common way of life factors providing us with a unique opportunity for health promotion.

The following chapter is presented under two main headings; the first outlines what services are currently provided by the NHS to women diagnosed with breast cancer and the second focuses on the types of services, based on the views of women which might better meet their needs and expectations. It should be noted that currently, on a National level, the views of breast cancer patients are not routinely assessed. In the absence of this information, the views of this patient group have been elicited from the scientific literature.

3.2. Current NHS services offered to breast cancer patients

3.2.1. Background

Current NHS breast cancer services have developed over the last 14 years as a result of several Department of Health initiatives beginning with the publication of the Calman Hine report.[63] The report was commissioned in response to the rising number of cancer diagnoses, variation in cancer outcomes and the resultant economic cost to the community. The work was undertaken by an expert advisory group on cancer whose task was to consider the direction in which cancer services should be developed.

The report was key is establishing a direction for cancer reform and its recommendations formed the basis of the 2000 NHS Cancer Plan [64], a document outlining a comprehensive strategy to tackle cancer.

Today, the types of services offered to breast care patients remained relatively unchanged. The extensive period of reform which has taken place over recent times has understandably focused on broader issues, such as reducing waiting times and providing high standard and quality care.

Substantial improvements have been made in this area with services now provided by specialist cancer units/centres under a local multidisciplinary team. However, the broader needs of cancer patients remain unmet. Without question further scope for developing services that better meet the needs and expectations of cancer patients still exist.

3.2.2. Short term care[15]

The current guidelines for the treatment of early breast cancer are as follows:[65]

Stages of treatment from the time of diagnosis until the end of curative therapies
Referral, diagnosis and preoperative treatment
Providing information and psychological support
Surgery
Postoperative assessment
Endocrine therapy
Chemotherapy
Radiotherapy
Primary systemic therapy
Complications of local treatment and menopausal symptoms

Table 3-1 Current guidelines for the treatment of breast cancer

Almost all patients will have first line surgery following a breast cancer diagnosis. This may sometimes be preceded with neoadjuvant chemotherapy to reduce the size of the tumour prior to surgery. Surgery is then followed with or without adjuvant treatments which may include chemotherapy, radiotherapy and endocrine therapy. The treatment regime is determined on an individual basis depending on the factors such as tumour size, grade and type, lymph node involvement and evidence of metastatic disease.[15]

3.2.3. Long term care[16]

The long term recommended follow-up for breast cancer patients are categorised as follow-up imaging and clinical follow up.[65] Clinical follow-up usually last for five years however there is a push for this to be reduced for three. Typically, follow up would occur on an annual basis or earlier if requested by the patient.

[15] Short term care is defined as care offered from the time of diagnosis to the end of primary surgery +/- chemotherapy, radiotherapy and the commencement of endocrine therapy

[16] Long term care is defined as care offered after the initial treatment for breast cancer and generally occurs at around one year post diagnosis if all primary treatments are involved.

3.3. Summary of NHS breast cancer services

By and large, services provided by the specialist multidisciplinary teams include, surgery, radiotherapy, chemotherapy and endocrine therapy. In the treatment pathway set out by NICE, it is clear that only one ancillary service i.e. the provision of psychological support is recommended in the short term treatment of breast cancer. There are no recommendations for ancillary services in the long term follow-up of breast cancer patients.

The multidisciplinary team responsible for service provision provides a variety of services which according to the Manual for cancer services[66] ***can*** include both core and ancillary services such as Dietetic representation, however in practice this does not occur. Historically, dietitians provide oncology services for patients who require enteral feeding due to compromised digestive systems, for example, head and neck cancer patients will often require nasogastric feeding due to surgery which renders the patient unable to feed under normal conditions. As a practising oncology Dietitian for many years, the only patients referred were those that required supplemental/alternative feeding.

As most breast cancer patients present as over nourished with more than half either overweight or obese, these patients are not referred to dietetic services. It has only been in recent years, that the evidence relating to overweight and obesity for this patient group and potentially negative outcomes have come to light. In an audit of all local hospitals (seven in total), none provided dietetic input to the MDT. Having locumed as an Oncology Dietitian in several UK hospitals, this situation was mirrored suggesting dietietic services do not contribute to either the short term or long terms care of breast cancer patients.

3.4. Developing breast cancer services: The NHS perspective

Public and patient involvement (PPI) has been a characteristic of the health service dating back to 1974 when Community Health Councils were established. Since that time, the structures have remained relatively unchanged until 2000 with the publication of the NHS Plan. These changes occurred largely as a result of the Kennedy Report [67] published after the Bristol Royal Infirmary Inquiry which investigated serious failures in the management of the care of children at Bristol Royal Infirmary who received complex heart surgery.

In making its recommendations the Kennedy report highlighted the need for great emphasis on the role of patient and public involvement in the health service. The report went on to recommend patients and the public should be entitled to participate in every aspect of healthcare.

As a direct consequence to this report, giving patients greater choice and greater say became a key area of reform for the new NHS. Today patient and public involvement are supported by both policy [68]; there are currently three key policy areas for patient and public involvement; policies that promote patient and carer participation in personal health care decisions, policies that promote better information and advice for patients and carers and lastly the focus of this chapter, *policies that promote patient and public involvement in NHS planning, delivery and standard setting,* and legislation through the "Health and Social Care Act 2001" and guidance [69].

Whilst acknowledging a constitutional duty to involve patients and the public in healthcare there are other potential benefits for PPI. Patient and public involvement in healthcare is described by the Government as key to the modernisation of the NHS being central to improving patients' experiences of health services.

The perceived benefits of patient and public involvement in healthcare include better health outcomes, better service delivery and planning, and greater patient experience with the health service.

3.4.1. Evidence of PPI in cancer services

As part of the "Health in Partnership" research programme, a study entitled "Developing and evaluating best practice for user involvement[17] in cancer services" was undertaken collaboratively with University of Warwick, University of West England, Macmillan Cancerlink, Bristol Cancer Help Centre and the Avon, Somerset and Wiltshire Cancer Services (ASWCS).

[17] User involvement is defined as activities involving users to evaluate and develop cancer services. It is noted by the authors that this definition excludes many activities regarded as involvement that related to opportunities for users to engage in decision making about their own care.

The project was set up to explore current mechanisms for user involvement, to establish if these mechanisms were effective and finally to develop a consensus statement on the suitable scope and role of users involvement in the assessment and development of cancer services.

The project was conducted in three stages. The first stage was a mapping exercise to document current ways in which users within ASWCS were involved in cancer services. The second stage was a consensus development exercise. Interviews were conducted with 37 users of cancer services and elicited views on their understanding, experience and satisfaction with user involvement. The final stage of the project was a questionnaire on users' attitudes toward user involvement. The questionnaire was developed from results from stage two. The overall outcome of the project was the development of a practical guide to help providers develop user involvement systems in cancer services. The twelve key findings from the study were as follows;

Key findings

1	There is general agreement on the importance of user involvement across the diverse professionals that provide and manage services for people with cancer
2	There is general consensus among stakeholders that users should be involved in decisions about their care and that the purpose of user involvement should be to improve cancer services
3	There is little agreement among stakeholders about other key issues, including the definition of users and the scope of user involvement. There is a need therefore to develop consensus around these areas
4	There is limited evidence of formal user involvement policies in cancer services within NHS organisations and there is little designated funding to promote such activities at all levels
5	There is evidence that user involvement is often elided or integrated with complaints procedures and/or clinical governance strategies. When this occurs it increases distrust and resistance among staff to undertaking user involvement activities

Table 3-2 Key findings

6	There is evidence that user involvement often takes the form of 'one off' activities. There is a need to develop systematic approaches that integrate a cycle of user involvement into basic service practice
7	The most effective forms of user involvement seem to be based on collaboration with the voluntary sector. There is evidence that resources currently provided do not meet the full costs of such participation
8	Professional responses are key to the success of user involvement and can also serve as a barrier to its development. There is evidence that categories of professionals perceive and approach user involvement in different ways. Policy and practice needs to be based on a recognition of professional experiences and standpoints
9	Professional education and support for user involvement in cancer services is an important prerequisite for the development of user involvement. Where professionals participate in user involvement activities, either voluntarily or because they are required to, there is often a demonstrable change in their orientation towards users. Professional education and support can also make a difference to the user experience, enhancing general satisfaction with care and with information and communication between professionals and users
10	**Some users may not want to be involved in the development of cancer services, although this may be influenced by the fact that the vast majority do not perceive themselves as being asked to be involved. A third of users surveyed who said that they would like to be involved also stated that they did not know how to get involved and were not given information about user involvement**
11	**Less than a quarter of users surveyed had actually experienced involvement: this experience primarily related to participation in drug trials, fundraising and questionnaires. There was limited evidence of 'direct' (i.e. decision making) as opposed to 'indirect' (i.e. providing information) involvement**
12	Among users with a positive orientation to involvement, a variety of methods were preferred including giving informal feedback to staff, participating in research and serving as a representative on a local NHS committee. Multiple methods are therefore needed to respond to the different aims of user involvement and respond to the preferences of users for getting involved

Table 3.5 Key findings cont

What is striking about these results is that there is little evidence that user involvement in cancer service development is taking place. Users are unsure of how to get involved. Further, in what little involvement there is, it is largely related to participating in cancer research projects, an activity that is unlikely to influence service planning or delivery.

3.5. Breast cancer services: the patients perspective

Despite little or no voice into the development of breast cancer services in the NHS, the views on the types of services breast cancer patients are interested in are widely reported in the scientific literature. The following section reviews the relevant literature from both observational and experimental studies.

3.5.1. Observational studies

Several observational studies have been conducted exclusively with breast cancer patients or as a subgroup within a larger study of cancer patients. Outcomes reported include the proportion of cancer patients reporting dietary change, the nature of these changes and lastly the reasons for these reported dietary changes. The details of these studies are summarised as follows:

Author	Cancer site	Eligible	Agreed	Recruited	Analysed	Outcome measure	Results
Maunsell et al[70]	Breast	282			250	1. Describe the nature and frequency of dietary change in the year after breast cancer diagnosis	- 41% reported making dietary changes - Reduction in Meat intake was most common dietary change
						2. Identify characteristics of women more likely to initiate such change	More likely to be younger
						3. Determine whether initiating such change is associated with psychological distress, an important component of quality of life	Higher initial psychological distress associated with initiation of dietary change
Maskarinec et al[71]	All	2452	439	143	143	1. Describe how cancer patients made long-term dietary changes after diagnosis	- 48% reported making dietary changes - Increase in vegetable was most common dietary change
					69	2. Compare commonly adopted nutritional strategies to the scientific evidence	Not reported in results
					69	3. Explore the rationale on which the decisions for dietary change were based	1. Increase well-being 2. Maintain health 3. Prevent recurrence 4. Avoid causes of cancer 5. Eat cancer-preventive foods 6. Take control 7. Follow advice
Salminen et al[72 73]	Breast prostate			303		Assess patient beliefs among Finnish women suffering from breast cancer or rheumatoid arthritis and to clarify the sources of information and dietary changes made by the patients during treatment and follow-up	- 30 % of breast cancer patients had changed their diet since diagnosis - reduction in animal fat and red meat most commonly change reported - reasons for dietary change were 1. desire for cure 2. alleviate symptoms of nausea 3. follow doctor's instruction

Table 3-3 Studies reporting proportions/reasons for dietary changes after a breast cancer diagnosis

Author	Cancer site	Eligible	Agreed	Recruited	Analysed	Outcome measure	Results
McBride et al[74] Demark-Wahnefried[10]	Breast Prostate	1667	988	920	920	To explore the relationship between psychological impact of cancer diagnosis and motivation for behaviour change	- 47% of breast patients reported consuming ≥ 5 serves of fruit and vegetables - 73% of breast patients reportedt fat intake <30% - 79% of overall patients were interested in health promotion programs -80% expressed a desire for intervention at within first 6 months after the cancer diagnosis
Tangney et al[75]	Breast	212		118	118	1. To describe dietary intake and overall diet quality 2. To describe symptomatology using Survey of feelings and attitudes 3. Describe potential interrelationships between dietary intake estimates and healthy eating index with symptom scores 4. Describe DEI, dietary estimates and symptomatoligies according to breast cancer stage, receptor status, or node status	-Mean energy intake 1230 -50% carbohydrate -18% protein -32% fat -67.2% “needs improvement category of healthy eating index
Patterson et al[76]	Breast Prostate Colorectal	509	504	356	356	1. Self reported changes in diet, physical activity, and dietary supplement use among cancer patients diagnosed up to 24 months in the past 2. Did patients feel any changes made improved their health and well-being	-40.4% respondents made dietary changes -Most common change an increase in fruit and vegetables -90% of respondents report the change improved their health and well-being

Table 3-3 cont. Studies reporting proportions/nature/reasons for dietary changes after a breast cancer diagnosis

Author	Cancer site	Eligible	Agreed	Recruited	Analysed	Outcome measure	Results
Blanchard et al[9]	Breast Prostate Colorectal Non-Hodgkins Lung	572		352	352	1. To examine whether or not adult cancer survivors changed their way of life behaviours since their cancer diagnosis 2. To examine whether or not a physician recommendation had a significant influence on adult cancer survivors changing their way of life behaviours 3. To conduct exploratory analyses examining the potential influence of various demographic variables on the way of life behaviour changes in adult cancer survivors	50.5% reduced fat intake 43.5% increased fibre 42.9% reduced red meat
Caan et al (LACE study[77])		5656	2614	2321		To examine modifiable way of life predictors of recurrence, survival and quality of life	Mean energy 1393kcal 47.9% carbohydrate 16.8% protein 34.7% fat Fruit 1.95 serves Vegetables 2.2 serves
Thomson et al[78]	Breast	7572 screened		3109	3084	To describe self reported dietary intake patterns before and after a breast cancer diagnosis	<u>Self reported</u> Decrease in red meat (61%) Increase in vegetables (60%) Increase in fruit (58%) <u>Actual changes</u> Fruit 2.3 serves for non-changers for changers Vegetables 2.8 for non-changers 3.0 for changers Total energy - non changers 1727 kcal - changers 1721 kcal % fat - non-changers 29.5% - changers 28.5%

Table 3-3 cont. Studies reporting proportions/nature/reasons for dietary changes after a cancer diagnosis

Author	n =	Age	Cancer site	Method of Ax
Maunsell et al[70]	250	All ages	Breast	Interview
Maskarinec et al[71]	91		Breast	Interview
Salminen et al[72 73 79]	303		Breast Prostate	Self-admin questionnaire
McBride et al[74] Demark-Wahnefried[10]	978	28-91	Breast Prostate	Mailed Questionnaire
Tangney et al[75]	117		Breast	Self-administered FFQ
Patterson et al[76]	356	20-79	Breast Prostate Colorectal	Telephone interview
Blanchard et al[9]	352	No range given	All sites	Self administered questionnaire
Caan et al[77]	2048	18-79	Breast	Self-administered FFQ
Thomson et al[78]	3084	18-70	Breast	Telephone dietary recalls

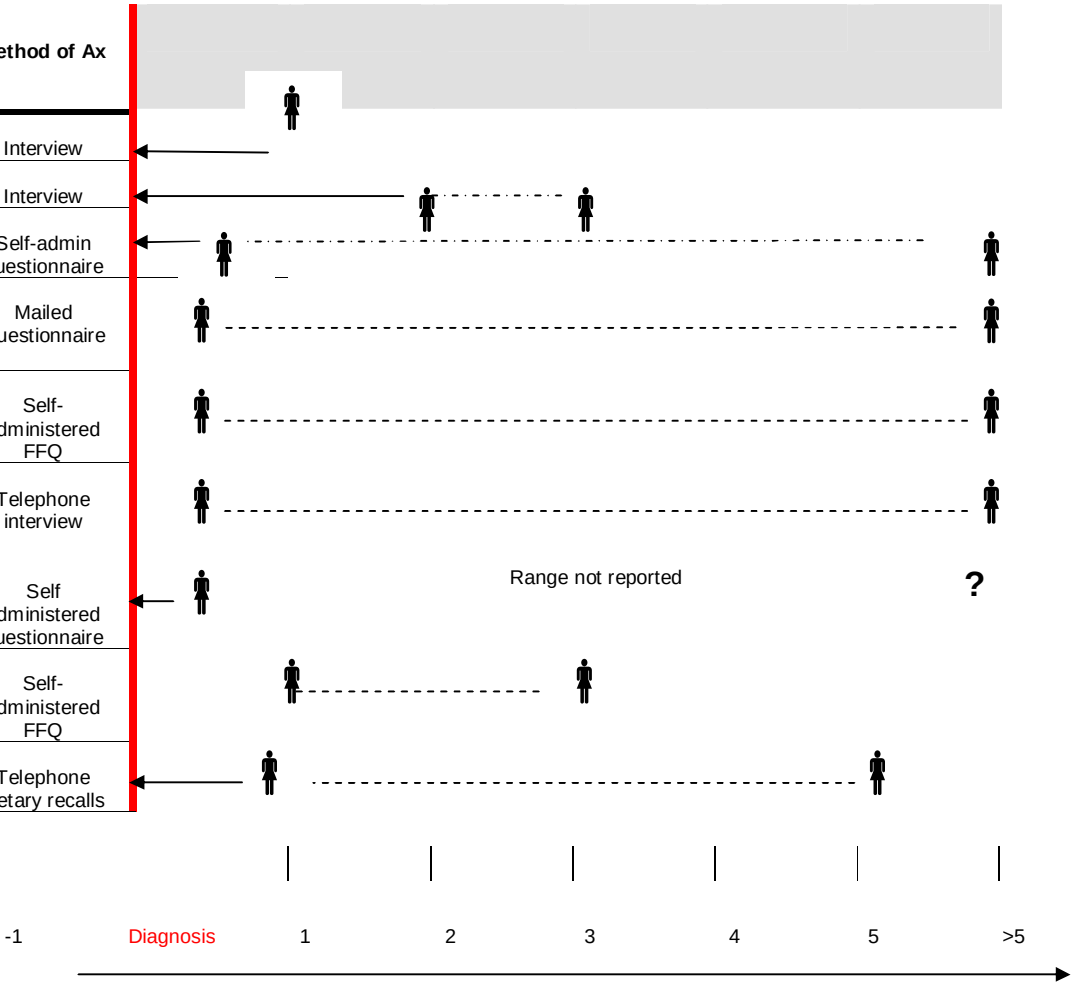

Figure 3-1 Studies reporting proportions/nature/reasons for dietary changes after a cancer diagnosis

These studies indicate that the proportion of women making changes to their diets after a breast cancer diagnosis range from 30-60%. These figures compare favourably with those found in the general cancer literature suggesting that significant numbers of cancer patients, irrespective of the cancer type, make changes to their diets after their diagnosis. Of interest is that the adoption of healthy eating behaviours occurs irrespective of the patient's belief in the diet-disease relationship. For example in a cross-sectional study of 378 breast cancer survivors only 15.5% of respondents believed diet was in some way responsible for their disease; however when asked about current health behaviours 94.6% reported consuming a healthy diet.[80] These results have been found elsewhere in the literature.[81]

The most common dietary changes reported were reduction in meat/animal fat and an increase in fruit and vegetable consumption which relate well to current nutritional guidelines. However there are reports of negative eating behaviours such as restrictive dieting practices with some women eliminating entire food groups.[82] Further dietary modifications are largely found in association with the widespread use of supplements which may or may not be of benefit.[83]

Overall these studies show that when put into the context of national nutritional recommendations for a healthy diet, changes are relatively small and therefore likely to be of little benefit and in some cases bear no resemblance to national guidelines. Whilst these results suggest that the majority of breast cancer patients are opportunistically making changes to their diets, caution is warranted as it could be argued that those patients who adopt healthier way of life behaviours are more likely to participate in such studies.

In the studies where the conversion rate from those approached to those who participate in the study is calculated, the response rates are of interest. These ranged from as low as 18% to as high as 100%.[9 10 70 71 73-76 78] In general however most of the studies had response rates of around 50%. In essence, this could potentially mean that with around half of those surveyed agreeing to participate in the study and of those around half report making dietary changes, the actual numbers of breast cancer patients making dietary changes in the general population could be as low as 25%.

Despite this cautionary note, the literature does suggest that dietary changes are both practiced and of interest to breast cancer patients. Further many of these studies[10 74 84 85] report that patients believe their health care teams should provide this information.

3.5.2. Experimental studies

Several experimental studies have been conducted with breast cancer patients whereby patients were invited to participate in dietary intervention studies. Whilst the purpose of these studies was not to assess interest in participating in a nutrition education programme, recruitment rates for these studies contribute to the overall understanding in this area.

Table 4.2 charts the conversation rates from invitation to participation in all randomised controlled trials conducted with breast cancer patients

The majority of reports did not document the number invited on the trial. As a proxy marker the time taken to recruit participants suggests that it took many years to recruit relatively few patients, indicating the uptake for these studies was poor.

For the one study that documented these figures[38] the conversion rate from eligibility to randomisation showed that 56% or around half of those invited agreed to participate, supporting the evidence found in observational studies.

	Trial	Active recruitment	Time since Dx	Screened	1st Eligibility	Invited	2nd Eligibility	Randomised	Completed trial	Completed follow-up
1	WINS Stage One -Nutrition Adjuvant Study[25]		<60days since surgery	Not reported	59	59				
2	WINS Stage Two - feasibility[27]		<190 days from surgery	Not reported	Not reported	Not reported		290	155	108
3	WINS Stage Three – RCT[28]		<190 days from surgery	Not available	Not available	Not available		2437	Not available	Not available
4	WHEL Feasibility[29]	May 93 Oct 94	<12 months to >55 months	Not reported	Not reported	Not reported		93	83	83
5	WHEL RCT[30]	1995 2000	Within 4 years of Tx	7572	4708	4708		3088	3023	3023
6	Djuric et al (2002)[31] Jen et al (2004)[32]		Within 4 years of Dx	Not reported	Not reported	Not reported		48	37	37
7	Holm (1990) and Nordevang et al (1990 and 1992)[33-35]	1983 1986	Between 4-6 months	Not reported	Not reported	Not reported		240	187	169
8	BRIDGES trial[36]		Not reported	Not reported	Not reported	Not reported		157	146	143
9	de Waard et al (1993)[37]	1987 - ?	Not reported	Not reported	107	Not reported		102	94	Not reported
10	BCDIP[86 87]	June 93 Mar 95	<6 months to >18 months	Not reported	521	521	293	144	110	110

Table 3-4 Randomised controlled trials

	Author	Screened	Eligible	Invited	Agreed to participate	Commenced trial	Completed trial
1.	Goodwin et al[46 88]	Not reported	Not reported	Not reported	61	61	39
2.	McTiernan et al[47]	Not reported	99		40	11	9
3.	Boyar et al[48]	Not reported	Not reported	Not reported	27	27	18

Table 3-5 Non-randomised trials

3.6. Opportunities for the development of health promotion activities in breast cancer services

Survival rates have improved for most cancers in both men and women in recent years and it is expected that they will continue to rise for most cancers in the future. With this upward trend in cancer survival set to continue the long term health issues facing cancer patients has fast emerged as a public health concern.[62] At present around one third of cancer patients survive their diagnosis and are considered completely cured. By 2010 this figure could rise to 50% and by 2020 80% of people diagnosed with cancer could expect to live a normal lifespan.[89]

Despite the recognition that future services need to be developed to meet the needs and expectations of the growing number of cancer survivors[59] very little is known about the long term issues that this group face. As such, understanding "Cancer survivorship" was labelled a national priority by the National Cancer Research Institute who in 1996 set up the Office of Cancer Survivorship (OCS) in the United States.

In order to address "cancer survivorship", information regarding the issues facing this group was required. Unfortunately these data did not exist. At the time there were four main sources of information on cancer survival.[90] These are described as

1. The first, the Surveillance, Epidemiology and End Results (SEER) registries provided demographic information on cancer survival but no information on health status was collected.
2. A second source of information came from the National Health Interview Survey which provided national data on the health of the US non-institutionalised civilian population.
3. The third source was the Childhood Cancer Survivorship study a collaborative, multi-institutional study of the long term health patients who survived five or more years after cancer treatment during childhood or adolescence.
4. In addition to these were descriptive reports from survivor cohorts from specific regional treatment centres or results from experimental studies.

By and large these sources did not provide adequate information in order to commence developing a clear strategy for tackling cancer survivorship. As a result the OCS set about to identify the poorly understood needs of cancer survivors and outlined six areas for research development (see table 5-1).

Number	Area
1	Descriptive, epidemiologic data on outcomes for cancer survivors who are more than one year post diagnosis
2	Intervention studies that develop and test strategies to prevent or diminish adverse outcomes or promote optimal health practices in survivors
3	Elucidation of the patterns of care recommended for and received by cancer survivors who are post treatment
4	Information on the experiences of survivors previously underrepresented in the literature
5	Instruments that accurately reflect the outcomes for and experiences of survivors across the post treatment trajectory
6	Research on the impact of cancer on the family

Table 3-6 Areas identified for research development

In addition to the work undertaken by the OCS a number of national reports on cancer survivorship have been developed through collaborative work with cancer survivors, health care providers, researchers and organisations that promote, plan and deliver programmes and services which aim to improve the lives of cancer survivors. The overall message from these reports highlights the need for a coordinated public health approach in addressing the needs of cancer survivors.[91 92]

In response to this call several initiatives have commenced aimed at addressing these gaps in evidence. The American Cancer Society's Behavioural Research Center has set up a series of three studies collectively know as the "Studies of Cancer Survivors" (SCS).[93]

The first study is a national prospective longitudinal study in both men and women which has enrolled over 6,000 cancer patients. The cohort will be followed for up to ten years and health data will be collected at one, two, five and ten years after diagnosis.

The second study is a national cross-sectional study of approximately 10,000 cancer patients in three cohorts of two, five and ten year survival categories. This study will provide data on short, medium and long term cancer survivors.

The third study involving over 16,000 cancer survivors and caregivers is comparing the quality of life and functioning of cancer survivors to their primary caregiver in the hope of gaining a deeper understanding of the issues faced by cancer caregivers.

To date, enrolment of all three studies is complete and it is hoped that the results of these studies will help to identify the physical, emotional and social issues faced by long term cancer survivors and their families.

Whilst the UK has been slower to engage with this new paradigm for cancer care[18], the Government has begun to address these issues and in 2004 the "Supportive and Palliative Care Guidelines" [94] were published detailing ways of improving cancer services in the UK. The guidance defines service models and details recommendations that ensure cancer patients, their families and carers receive support and care aimed at helping them cope with cancer and its treatment at all stages. One of the key recommendations of this guidance states that "Commissioners and providers working through Cancer Networks should institute mechanisms to ensure that patients' needs for rehabilitation are recognised and that comprehensive rehabilitation services ….are available to patients…..".[94]

3.7. Rationale for study

Despite government policy, procedures and legislation, clearly, patient involvement in the development of either general or specialist NHS services such as cancer services are, at present, alarmingly underperforming.

There is no question that cancer services have seen dramatic improvements since the publication of the NHS Cancer Plan in 2000. For example, cancer mortality rates are down, we have seen improved access and choice to cancer services; better screening and detection for cancer are in place, however, the vision of a patient-led NHS is far from a reality.

In acknowledging the expressed needs of breast cancer patients for health promotion activities, currently not offered within the NHS, the purpose of the present study was to assess interest in a

[18] In the period between submitting the thesis for examination and addressing reviewer's comments, the UK has launched the National Survivorship Initiative, a joint partnership between the Department of Health and Macmillan Cancer Support. The purpose of this joint venture is" to consider a range of approaches to survivorship care and how these can be best tailored to meet individual patients' needs".

group health eating programme in an attempt to provide evidence for health care providers which may lead to the expansion of services to include nutrition advice.

3.8. Chapter Summary

In summary, we have experienced a major shift in the focus of care for cancer patients from one in which interest has turned from acute care to managing long term health. We are now in a position where health care providers accept that we need to develop services that address the expressed long term health of cancer patients; currently these types of services are not generally part of the cancer trajectory.[95]

The challenge for the health service is to identify the types of services to develop and to understand the best ways in which to deliver these services that overcome barriers such as time, resources and expertise[96] that are faced in the NHS.

Chapter Four

Methods

4.0 Methods

4.1. Chapter Introduction

The following chapter describes the methods used to investigate the uptake and response to dietary intervention in postmenopausal women newly diagnosed with breast cancer. The methods were developed with representatives from patient, clinical and academic backgrounds. The specific roles they played are described in detail where appropriate throughout this chapter.

The chapter begins with an overview of the entire project which consisted of two studies, study one used focus groups to ascertain the views of patients in the development of study two (3 phases) which offered newly diagnosed postmenopausal women with breast cancer, a series of group healthy eating classes.

Both studies are presented separately and within each study the following subsections have been utilised; pre study planning followed by study protocol.

4.2. Project overview

Overall Aims	1. To develop a group healthy eating programme for postmenopausal women newly diagnosed with breast cancer in partnership with breast cancer patients 2. To understand the factors that influenced **enrolment** and subsequent **participation** in a "healthy eating" program for newly diagnosed postmenopausal women with breast cancer. 3. To assess if a group "healthy eating" program improved the diets of newly diagnosed postmenopausal women with breast cancer
Purpose	To inform cancer service development initiatives
Study design	Mixed methods – embedded experimental model **Study One**: Focus Groups (QUAL) **Study Two**: 1. Cross-sectional study (Qual + Quan) 2. RCT (QUAN) 3. Cross-sectional study (Qual + Quan)

Table 4-1 Project summary

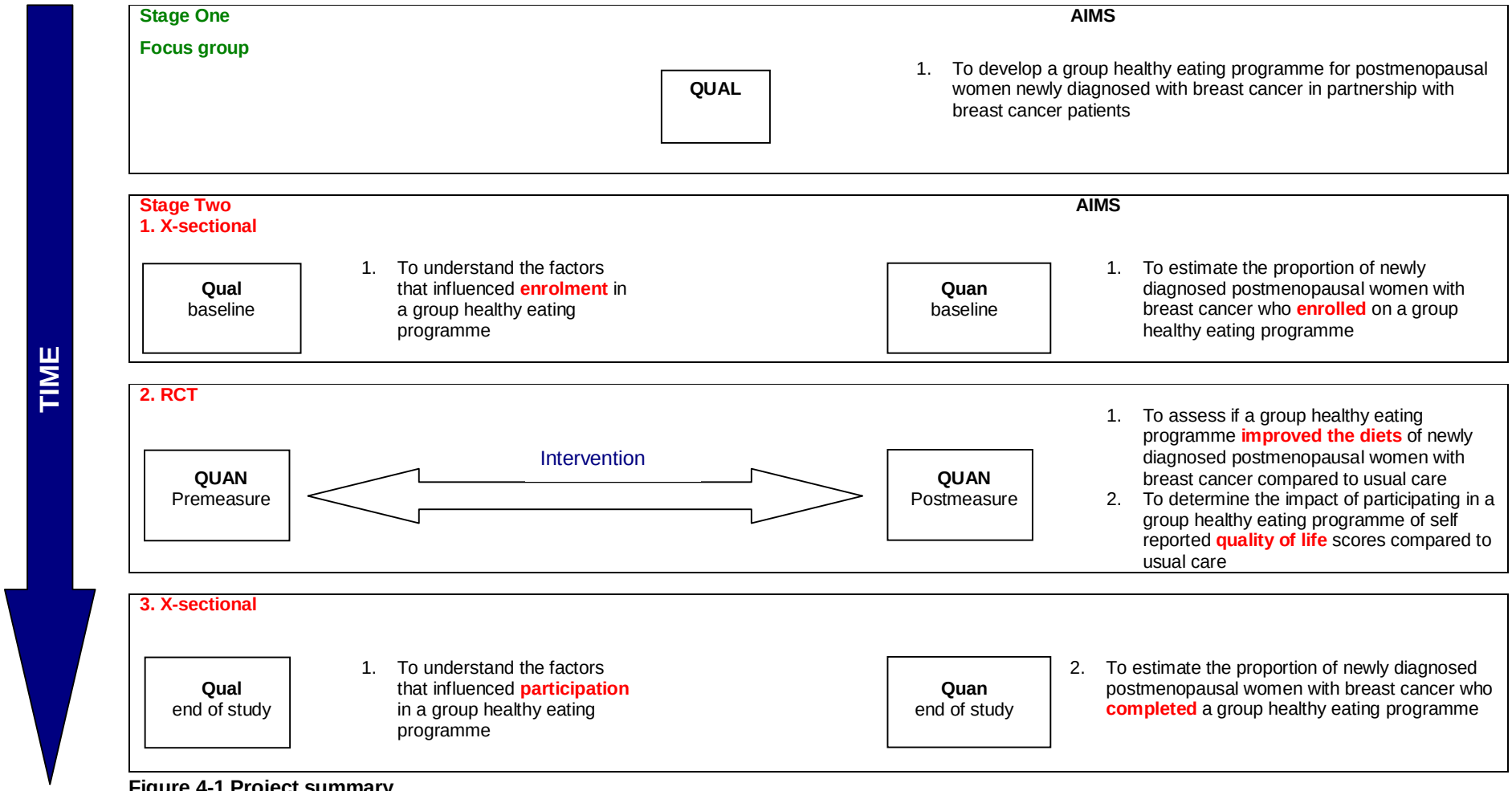

Figure 4-1 Project summary

4.3. Study One – Focus Groups

4.4. Pre study planning

4.4.1. Stakeholder involvement

4.4.1.1. NCRN consumer research panel

As a key component of good clinical practice, the views of patients in the development of the study were sought. A one hour presentation and subsequent discussion session was delivered by the Chief Investigator to the group. The presentation gave an overview of the proposed study to gauge interest in the project from a cancer patient's perspective.

4.4.2. Study approvals[19]

4.4.2.1. Ethical approval

Ethical approval was applied for as per standard National Ethics Approval procedures and policies.

4.4.2.2. R&D approval

Research and Development (R&D) approvals were applied for separately for each of the three participating NHS trusts, Basingstoke and North Hampshire NHS trust, Portsmouth NHS trust and Winchester and Eastleigh Healthcare trust as per standard trust procedures and policies.

4.4.2.3. NCRN adoption

An application was made to the National Cancer Research Network for adoption into the Networks Clinical Trials Portfolio as per standard procedures and policies.

4.4.2.4. Macmillan Cancer Centre

Portsmouth Hospitals Macmillan Cancer Centre was approached for approval to conduct the focus group at the centre.

[19] Dates for applications and approvals appear in the results

4.5. Study protocol

4.5.1. Aims

To engage cancer patients in the development of a group healthy eating programme for newly diagnosed postmenopausal women with breast cancer.

4.5.2. Objectives

To determine participants' consensus on the practical elements of the healthy eating programme to be offered to postmenopausal women newly diagnosed with breast cancer in study two. Specifically, to elicit views regarding the timing, number, duration, location and size of classes, in addition to preferred class topics and methods for class delivery.

4.5.3. Study design

Qualitative Study Design using Focus Groups. Focus Groups have been shown to be a useful research tool for the purpose of developing new programmes. They are unique in that they allow for group interaction whereby group members influence each other by responding to ideas and comments in the discussion. This results in a greater insight into the topic of interest.[97]

4.5.4. Study participants

4.5.4.1. Sampling frame

Postmenopausal women previously diagnosed with breast cancer at three local NHS trusts, Southampton Universities NHS hospitals trust, Portsmouth Hospitals NHS trust and Basingstoke and North Hampshire NHS trust.

4.5.4.2. Inclusion/exclusion criteria

Subjects for the focus groups were selected using purposeful sampling so that a diverse group of breast cancer patients were involved to ensure a broad range of views/experiences were captured.

Factors deemed important in describing the sampling matrix were as follows:

- Length of time since diagnosis
- Age
- Household size *
- Employment status *

* relevant when designing nutrition programmes

(see Appendix 9-3 for Sampling Matrix)

4.5.5. Screening

4.5.5.1. Basingstoke and North Hampshire NHS trust

Screening was conducted by both the chief investigator and the NCRN research nurse assigned to the study. Patients were randomly selected from a list of previously diagnosed breast cancer patients provided by the Breast Unit Data coordinator. Individual medical records were searched by hand until a woman representing each of the predetermined criteria in the sampling matrix was found.

4.5.5.2. Winchester and Eastleigh Healthcare trust

As above however screening was conducted solely by the chief investigator at this site.

4.5.5.3. Portsmouth NHS trust

As above however screening was conducted solely by the NCRN research nurse at this site.

4.5.6. Recruitment

Once potential participants were identified, these patients were contacted by letter asking them if they would like to take part in the focus group. The letter was signed by their Consultant. Correspondence (see appendices 9-4, 9-5) included:

- Covering letter from consultant
- Patient Information Sheet
- Consent form (consent obtained on the day of the focus group)
- GP letter

4.5.7. Study outcomes

The focus group was conducted in a non-threatening environment, off hospital premises. Expected group size was between 6-12 patients and the session was scheduled to run for approximately 1.5 hours. Light refreshments and travelling expenses were available.

The session was conducted by the chief investigator with the assistance of an oncology nurse practitioner and a representative from the National Cancer Research Network's consumer research panel, herself a breast cancer survivor. The session was conducted with a pre written topic guide (see table 4-2).

The information participants gave was anonymous and was used to develop the nutrition programme implemented in Study Two. Focus group participants were offered a copy of the results if they wished. Participation was voluntary and if patients could not come to the group, or decided not to attend, they were assured that their future care would not be affected in any way.

Type of Question	Question
Opening	1. After your diagnosis, did you make any changes to your diet?
Introductory	2. If so, did you seek dietary advice to help you make these changes?
Transition	3. What other sources did you use to find nutrition information? For example, a health professional, the internet, family/friends. 4. How helpful/unhelpful was the information you found?
Key Questions	*Thinking about your past experiences, if you had the chance to help design a nutrition education program for breast cancer patients…..* 5. What type of setting would you like to be offered these sessions? 6. Thinking about your cancer journey, when do you think the best time would be to schedule the sessions to fit in with your treatment and lifestyle? 7. What size group would be feel most comfortable in? 8. How much time would you be willing to give up to attend these sessions? 9. What are the key nutrition topics you would like to see covered? 10. How would you like the information to be delivered? For example, lecture, group discussion, guest speakers.
Ending	11. Suppose you had one minute to talk to the Minister for Health on the topic of dietary advice for breast cancer patients, what would you say? *(after a short oral summary by the facilitator)* 12. Is this an adequate summary? *(after a short overview of the purpose of the study)* 13. Have we missed anything?

Table 4-2 Topic guide for focus groups

4.5.8. Adverse Reactions and Their Management

Although there were no anticipated adverse reactions associated with taking part in focus groups, each patient's Clinical Nurse Specialist was advised of participation and was available to discuss any issues with the patients if they so chose.

4.5.9. Statistical analysis

Data were analysed manually using quantitative analyses.

4.5.10. Data Collection

Sessions were tape recorded as well as handwritten notes taken and transcribed at a later date.

4.6. Study Two – Stages one, two and three

4.7. Pre study planning

4.7.1. Stakeholder involvement

4.7.1.1. Steering Group

Prior to the writing of the following research protocol for Study Two, a steering group was set up. In total, sixteen senior clinical and academic staff was invited to attend the meeting where the background to the proposed study was presented by the chief investigator. At the end of the presentation, one hour was scheduled for discussion.

The purpose of creating a steering group was threefold. Firstly, it provided an opportunity for the chief investigator to gauge interest and receive feedback in the proposed study and secondly, it was hoped that by engaging senior clinical and academic staff in the design of study two, it would result in a research protocol that had been vigorously scrutinised by peers, thus potentially improving the likelihood of success of the study. Lastly, for more personal reasons, it was a networking exercise which could potentially benefit the chief investigator in future research projects.

4.7.1.2. Local stakeholder involvement

In order to gain local clinical support for the study, a request was made to present at the breast cancer multidisciplinary team meeting. By engaging breast unit staff early, it was anticipated that any issues/concerns regarding the study could be raised and dealt with prior to study commencement.

4.7.1.3. NCRN consumer research panel

As a key component of good clinical practice, the views of patients in the development of the study were sought. A one hour presentation and subsequent discussion session was delivered by the CI to the group. The presentation gave an overview of stage two of the study. Specifically, patients' views were elicited on both the appropriateness and perceived burden of the questionnaires proposed for use with the study.

4.7.2. Study approvals

4.7.2.1. Ethical approval

Ethical approval was applied for as per standard National Ethics Approval procedures and policies.

4.7.2.2. R&D approval

Research and Development (R&D) approvals were applied for separately for each of the two participating NHS trusts, Portsmouth NHS trust and Southampton Universities NHS Hospitals trust as per standard trust procedures and policies.

4.7.2.3. NCRN adoption

An application was made to the National Cancer Research Network for adoption into the Networks Clinical Trials Portfolio as per standard procedures and policies.

4.7.2.4. Randomisation service

An application was made to the Birmingham Clinical trials unit to conduct telephone randomisation for the randomised controlled trial.

4.7.2.5. Macmillan Cancer Centre

Two Macmillan Cancer Centres were approached, Portsmouth NHS trust and Southampton Universities Hospitals NHS trust for approval to conduct the group healthy eating classes at the respective centres.

4.8. Study protocol

4.8.1. Aims, Objectives and Hypotheses

Refer table 4-3

4.8.2. Study design

A mixed methods study design was employed (embedded experimental model). In total, the study was conducted in three phases, phase one at baseline and phases two and three at follow-up (see figure 4-1)

Study Two:

Stage 1. Cross-sectional study (Qual + Quan)
Stage 2. RCT (QUAN)
Stage 3. Cross-sectional study (Qual + Quan)

Stage	Aims	Objectives	Hypothesis
2.1	1. To estimate the proportion of newly diagnosed postmenopausal women with breast cancer who enrolled on a group "healthy eating" programme 2. To understand the factors that influenced **enrolment** in a "healthy eating" programme	1. To invite 400 newly diagnosed postmenopausal women with breast cancer to a group "healthy eating" programme during the recruitment period of six months 2. To describe the factors that determined whether or not newly diagnosed postmenopausal women with breast cancer enrolled on a "healthy eating" programme	1. 50% of newly diagnosed postmenopausal women with breast cancer will enrol in a "healthy eating" programme
2.2	1. To assess if a group "healthy eating" programme improved the diets of newly diagnosed postmenopausal women with breast cancer compared with usual care 2. To determine the impact of participating in a "healthy eating" programme on self reported quality of life scores compared with usual care	1. To compare change in overall diet quality scores in the "healthy eating" group with usual care 2. To compare difference in weight change in the "healthy eating" group with usual care 3. To compare self reported quality of life scores in the "healthy eating" group with usual care	1. Difference in change of overall diet quality scores would be 10 points higher for women in the "healthy eating" group compared to women in usual care. 2. Difference in weight change over the course of the intervention would be 3 kgs less in women enrolled in the "healthy eating" group compared to women in usual care.
2.3	1. To understand the factors that influenced **participation** in a "healthy eating" programme	1. To describe the factors that determined whether or not newly diagnosed postmenopausal women with breast cancer completed a "healthy eating" programme	

Table 4-3 Summary of aims, objectives and hypotheses

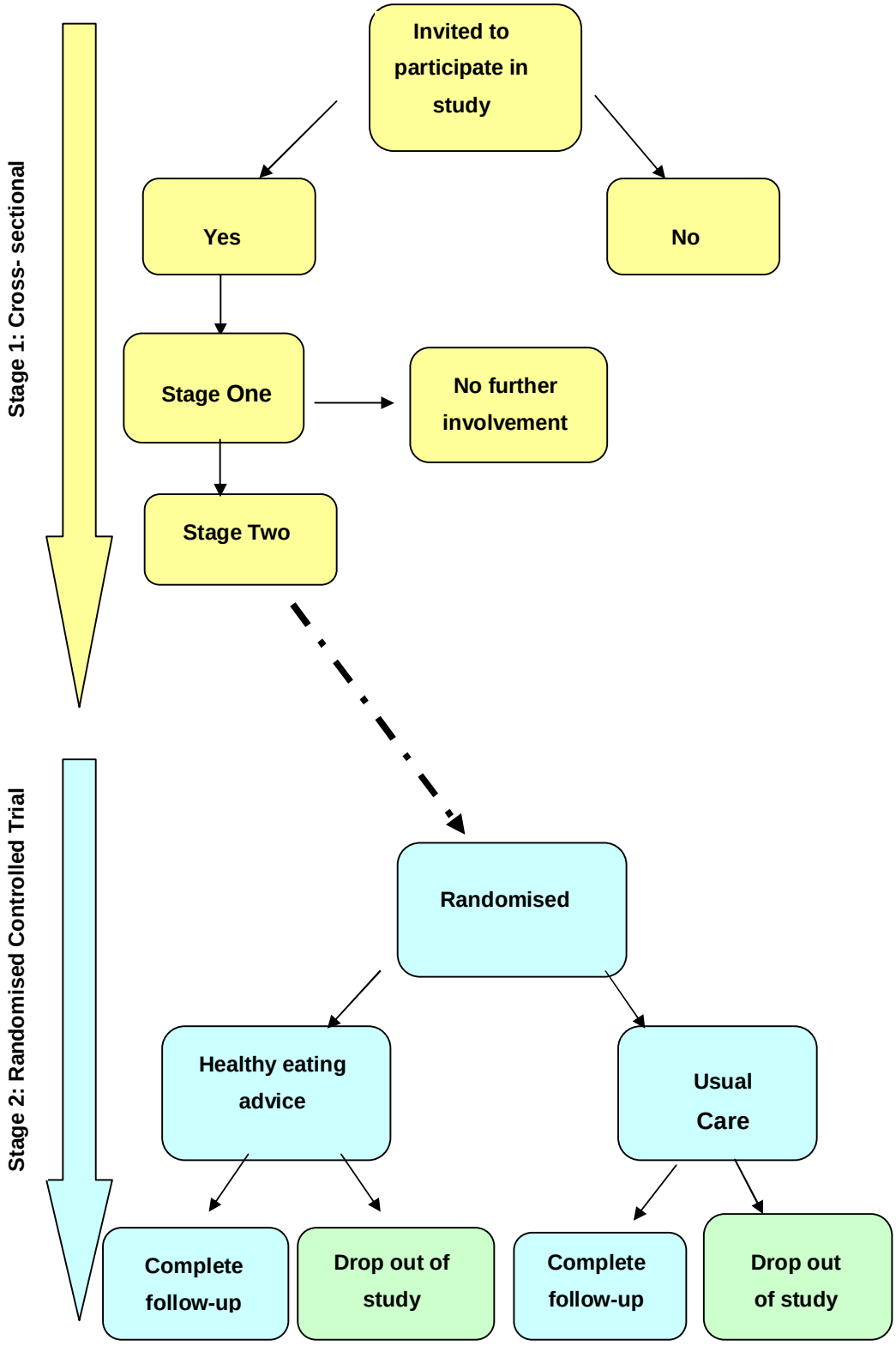

Figure 4-2 Participant flow

4.8.3. Study participants

4.8.3.1. Sampling frame

All postmenopausal women newly diagnosed with breast cancer at two local NHS trusts, Southampton Universities NHS hospitals trust and Portsmouth Hospitals NHS trust.

4.8.3.2. Inclusion/exclusion criteria

All post-menopausal women newly diagnosed with breast cancer were eligible to enter the trial. There were no exclusion criteria as this trial is a pragmatic trial intended to mimic a real life programme which could be feasibly implemented into the National Health Service.

As an inclusive trial, it was possible that a small number of women newly diagnosed with breast cancer would have metastatic disease. If this group of women wished to participate in the "healthy eating" programme, they were allowed to enrol as there are no contraindications to following a healthy diet. However, if the Dietitian delivering the "healthy eating" programme assessed the patient as at nutritional risk, they were immediately referred for individual dietary counselling by the Dietetic Department at the respective NHS trust.

4.8.4. Screening

Several methods for identifying patients at the time of a breast cancer diagnosis were employed, including review of the breast unit's cancer register, attending the breast teams' multidisciplinary meetings and liaising with the breast unit coordinator. As a member of the wider breast unit team, the precise method employed by the NCRN research nurse was left to their discretion.

4.8.5. Recruitment

Patients were sent a covering letter (appendix 9-13) signed by the lead Consultant surgeon at the participating NHS trust along with the patient information sheet (appendix 9-14) approximately one week after discharge from their primary surgery.

One week after receiving the letter a specialist research nurse from the Breast Unit telephoned the patient to see if they were considering entering the trial. If at that time patients expressed an interest in participating in either the "healthy eating" programme (study two phase two or the enrolment study (study two phase one), the nurse made arrangements to meet the patient during their next outpatient appointment where they were formally consented (appendix 9-15) to the trial. Once consented, patients GP's were notified of their involvement in writing (appendix 9-16).

Recruitment figures were scheduled to be emailed on a proforma document (provided by the CI) at the end of each month to the chief investigator over the course of the six-month intervention. The purpose of the monthly recruitment notifications was to monitor recruitment to the nutrition programme.

4.8.6. Outcomes Measures

4.8.6.1. Stage 1 - Cross-sectional study - Baseline

4.8.6.1.1. Primary outcome – Enrolment

The primary outcome measure was to estimate the proportion newly diagnosed postmenopausal women who enrolled on the group healthy eating programme.

4.8.6.1.2. Secondary outcome – Health determinants

The secondary outcome measure was to understand the factors that influenced enrolment in the group healthy eating programme.

Health determinants were assessed using the following questionnaires. All questionnaires are validated and are widely used to assess health related behaviours.

- *Rosenberg's self esteem scale*[98] (appendix 9-8)
    - A ten item Likert scale with answers to each item scored on a four point scale – from strongly agree to strongly disagree. Scores are summed for each item. The higher the score, the higher the self esteem

- *Multidimensional health locus of control (MHLC)*[99] (appendix 9-9)
    - The MHLC is a self administered questionnaire that takes about five minutes to complete. The questionnaire has a total of 18 items, and used a six point likert scale for responses. The 18 items are categorised into the three separate subscales, and provides a measure of three dimensions of health locus of control, internality, chance and powerful others. Separate scores for each subscale are derived by summing the scores on the six items in each subscale. The score on each item ranges from 1 = strongly agree to 6 = strongly disagree resulting in a scoring range for each subscale of 6-36.

- *Self rated overall health* (appendix 9-10)
    - A self rated 5 point likert scale – from poor to excellent

- *Food frequency questionnaire (FFQ)*[100] (appendix 9-11)
    - The Health Education Authority Health and Way of life Survey (HEA3), a validated 42 item FFQ which asks participants to describe their eating habits over the previous seven days will be used to collect dietary information. It is a simple self administered dietary assessment tool based on portion size and food frequency which takes about ten minutes to complete.
- *Socio-demographic variables*
    - Age

- Education
- Occupation
- Income
- Postcode

- *Anthropometric measures*
  - Height
  - Weight

4.8.6.2. Stage 2 – Randomised Controlled Trial

4.8.6.2.1. Primary outcome

Diet quality scores, weight and quality of life scores were measured at baseline and at six months.

4.8.6.2.2. Diet quality score

Diet quality was assessed based on the Diet Quality Index-Revised (DQI-R).[101] The DQI-R was chosen for its simplicity and ease of administration. The primary aim of this study was to understand factors that influenced enrolment on a "healthy eating" programme and therefore patient burden was a major consideration in selecting a dietary assessment tool. The DQI-R provided an estimate of diet quality relative to national dietary recommendations and is validated and used widely to measure eating patterns. Differences over time in scores derived from the DQI-R should reflect overall relative improvements in eating patterns. The index comprised ten components with scores derived from how closely the estimated intake met the target intake as indicated by prevailing dietary recommendations. Each of the ten components contributed a maximum of ten points to the overall DQI-R score with overall scores ranging between 0-100.

For the purposes of this study, a limited number of modifications to the original index were made. Six of the original categories were retained* (see table 4-4) to make five categories in the modified DQI-R (fruit and vegetables which are separate categories in the original index have been combined). Four new categories were assigned which reflect UK national dietary guidelines as outlined in the "Balance of Good Health" which formed the basis of the "healthy eating" programme.

	Dietary Component	Scoring Criteria	Score
1	Total fat ≤ 30% energy intake	≤ 30%	10
		30 - ≤ 40	5
		>40	0
2	Saturated fat ≤ 10% % energy intake	≤ 10%	10
		10 - ≤ 13	5
		> 13	0
3	5 servings of fruit and Vegetable per day+	≥ 100%	10
		50 – 99	5
		<50	0
4	5 servings of breads, cereals and potatoes	≥ 100%	10
		50 – 99	5
		<50	0
5	3 serves of meat, fish or alternatives	≥ 100%	10
		50 – 99	5
		<50	0
6	3 serves of dairy	≥ 100%	10
		50 – 99	5
		<50	0
7	Alcohol consumption ≤ 3 units per day	<3	10
		3	5
		>3	0
8	Sodium <2500mg per day	≤ 2500 mg	10
		2501 – 3000	5
		>3000	0
9	Dietary diversity score	≥ 6	10
		≥ 3 - <6	5
		<3	0
10	Dietary moderation score	≥ 7	10
		≥ 4 - <7	5
		<4	0
	Total Score		**100**

Table 4-4 Modified Diet Quality Index Score

The outcome measure for diet quality was the differences in change of diet quality scores.

4.8.6.2.3. Secondary Outcomes

4.8.6.2.4. Weight

Body weight was measured to the nearest 0.1kgs. The outcome measure for weight was the differences in change of weight.

4.8.6.2.5. Quality of life

The FACT-ES [102] (appendix 9-12) is a validated questionnaire designed to measure quality of life of women with breast cancer who are being treated with endocrine therapies. The FACT-ES measures five aspects of quality of life, physical, social/family emotional and additional concerns specific to breast cancer. Quality of life was measured at baseline and six months.

4.8.6.3. Stage 3 - Cross-sectional study – Follow up

4.8.6.3.1. Primary outcome – Health determinants

The primary outcome measure was to estimate the proportion of newly diagnosed postmenopausal women with breast cancer who completed a group healthy eating programme.

4.8.6.3.2. Secondary outcome – Health determinants

The secondary outcome measure was to understand the factors that influenced participation in a group healthy eating programme.

Health determinants were assessed using the following questionnaires. All questionnaires are validated and are widely used to assess health related behaviours.

- *Rosenberg's self esteem scale*[98] (appendix 9-8)
    - A ten item Likert scale with answers to each item scored on a four point scale – from strongly agree to strongly disagree. Scores are summed for each item. The higher the score, the higher the self esteem

- *Self rated overall health* (appendix 9-10)
    - A self rated 5 point likert scale – from poor to excellent

- *Food frequency questionnaire (FFQ)*[100] (appendix 9-11)
    - The Health Education Authority Health and Way of life Survey (HEA3), a validated 42 item FFQ which asks participants to describe their eating habits over the previous seven days will be used to collect dietary information. It is a simple self administered dietary assessment tool based on portion size and food frequency which takes about ten minutes to complete.
- *Socio-demographic variables*

- ❖ Age
- ❖ Education
- ❖ Occupation
- ❖ Income
- ❖ Postcode

- *Anthropometric measures*
  - ❖ Height
  - ❖ Weight

4.8.7. Sample size

4.8.7.1. Stage 1 – Cross sectional Study

4.8.7.1.1. Primary Outcome

4.8.7.1.2. Enrolment

With 400 participants and a proportion of women agreeing to enrol of 50%, the true proportion agreeing to enrol can be estimated within a width of +/- 5%, with 95% confidence

4.8.7.2. Stage 2 – Randomised Controlled Trial

4.8.7.2.1. Primary Outcome

4.8.7.2.2. Difference in diet quality scores

With a predicted enrolment rate of 50% and allowing for a 20% loss to follow-up, 160 women (80 per group) would remain at the end of the six month follow-up period. With 160 women the study would have more than 90% power to detect a mean difference of change in dietary scores of 10 points or more. A two sided 5% level of significance and standard deviation of 12kg was assumed[103]). A difference of 10 points in diet quality scores was considered clinically significant.

4.8.7.2.3. Secondary Outcome

4.8.7.2.4. Differences in weight change

Chlebowski et al (1993) reported a mean weight difference at six months of 3.26 $\pm$ 5.5 (mean and SD) between two groups of postmenopausal breast cancer patients enrolled in a dietary intervention study. With 160 women (80 per group) the study would have 80% power to detect a mean difference in change of weight of 3kg or more. A two-sided 1% level of significance and standard deviation of 5.5kg was assumed. A difference of 3 kgs was considered clinically significant.

4.8.7.3. Stage 3 – Cross-sectional study – Follow up

No sample size calculations were conducted for stage three.

4.8.8. Randomisation

Telephone randomisation was utilised in this trial. The Birmingham Clinical Trials unit provided the randomisation service. All baseline data was collected before group allocation occurred.

4.8.9. Blinding

As usual care for this group of patients is no routine dietetic contact; it was not possible to blind participants to their group allocation.

4.8.10. Data collection

All data was to be collected in person by the NCRN research nurse. This procedure was highlighted both verbally (at the training session) and in writing (within the training manual).

4.8.11. Intervention schedule

The intervention schedule was developed through focus group work with breast cancer patients conducted in study one.

Patients consenting to participate in the group "healthy eating" programme were required to attend 4 x 2 hour sessions. After the first class patients could choose when to attend the remaining three classes which did not have to be attended in order. This allowed some degree of flexibility for patients. Patients were asked to complete all four classes within six months of commencing the "healthy eating" programme.

With approximately 200 new diagnoses expected in each of the two proposed trusts over the course of the six month recruitment period and assuming a 50% enrolment rate, it was anticipated that numbers in the "healthy eating" classes would average around eight. Classes were held in the training rooms of the Macmillan Centres at each of the proposed sites.

The classes were delivered by the Chief Investigator, a State Registered Dietitian, registered with the Health Professionals Council. Classes were based on the "Balance of Good Health". The "Balance of Good Health" was produced by the Food Standards Agency, and is based on the Government's guidelines for a healthy diet.[104] The guide is comprised of five food groups and its key message is that both balance and variety are important for health. The aim of the programme was on improving general health and well-being of participants. In addition, nutrition during treatment and alternative diets and supplements were covered.

Lesson	Topics Covered	Learning Outcomes
1	Introduction Nutrition during cancer treatments Alternative diets/supplements	**Participants will be able to** -Understand common nutrition problems that occur during cancer treatments -Understand how to optimise nutrition during cancer treatments -Make informed choices about complementary and/or alternative therapies
2	The balance of good health[104]	**Participants will be able to** -Understand the 'balance of good health' -Identify the five food groups -Be familiar with and recall nutrients provided by the five good groups and their roles in the body -Calculate recommended portion sizes -Count portions -Be familiar with and recall safe levels of alcohol consumption
3	Cutting down on sugar, salt and fat Understanding food labels Eating out	**Participants will be able to** -Understand how to reduce salt, sugar and fats in the diet -Demonstrate the ability to read and understand food labels -Describe how to choose healthy options when eating out
4	Menu planning workshop	**Participants will be able to** -Plan a balanced weekly menu

Table 4-5 Details of nutrition education classes

4.8.12. Quality control measures

4.8.12.1. Screening and recruitment

Screening and recruitment was conducted by a specialist National Cancer Research Network Clinical Trials Nurse.

To provide a further level of quality control measures, a training session conducted by the chief investigator supported by a written training manual was undertaken with the relevant research staff. At this session, all aspects of the trials procedures were discussed in detail with the staff involved. At that point an opportunity to raise any issues/concerns that required clarification was presented.

4.8.12.2. Data

4.8.12.2.1. Diet quality

Each participant was to be given both verbal and written instructions on how to complete the food record by the NCRN research nurse consenting the patient to the trial at baseline and at six months follow-up. The questionnaires were to be checked for accuracy and completeness at that time.

4.8.12.2.2. Weight

Weights were measured on calibrated scales by a trained nurse.

4.8.12.2.3. Quality of Life

Each participant was to be given both verbal and written instructions on how to complete the FACT-ES by the NCRN research nurse consenting the patients to the trial at baseline and six months. The questionnaires were to be checked for accuracy and completeness at that time.

All data was to be collected in person by the NCRN research nurse. This procedure was highlighted both verbally (at the training session) and in writing (within the training manual). Further all data was set up to be electronically scanned independently by the School of Medicine's IT department who at study closure would provide a results spreadsheet.

4.8.12.2.4. Healthy eating classes

Lesson plans which clearly outlined the content and timing of how the class will be conducted were prepared prior to the commencement of the programme. This ensured uniformity in the delivery of the "healthy eating" programme throughout the intervention period.

4.8.13. Study period

Task	Date
Recruitment commenced	1 April 2007
Recruitment closed	30 September 2007
1st group commenced intervention	1 May 2007
Last group commenced intervention	1 October 2007
Last follow-up	31 March 2008
TOTAL TRIAL PERIOD	**April 2007 – March 2008**

Table 4-6 Trial dates

4.8.14. Data collection

	Stage 1	Stage 2 Baseline	Stage 2 6 months
Rosenberg's self esteem scale[98]	√ →		√
MHLC[99]	√ →		x
Self rated overall health	√ →		√
Food frequency record	√ →		√
Socio-demographic data	√ →		x
Height (m)	√ →		x
Weight (kg)	√ →		√
Fact-ES	x	√	√

Table 4-7 Data collection points

4.8.15. Data analysis

All data forms were to be delivered in a sealed envelope to the School of Medicine's IT department for electronic scanning. Once data collection was completed, a final results spreadsheet was to be given to the CI for analysis by the principal investigator.

4.8.15.1. Stage 1– Cross sectional study

4.8.15.1.1. Enrolment

The proportion of women who agreed to enrol on the "healthy eating" programme was reported with a 95% confidence interval.

4.8.15.1.2. Health behaviour determinants

Logistic regression was used to predict whether or not women chose to enrol in the “healthy eating” programme using questionnaire data and diet quality scores.

4.8.15.2. Stage 2 – Randomised controlled trial

4.8.15.2.1. Diet quality, weight and quality of life

Intention to treat (ITT) analysis was performed on the primary outcome on all subjects who were randomised. Per protocol analysis was also performed on the primary outcome. The primary outcome was the change in dietary score (at 6 months after enrolment compared to baseline). The outcomes of the two groups (usual care and “healthy eating” programme) were evaluated using ANCOVA (analysis of covariance), reporting the difference in scores with 95% confidence interval.

The secondary outcome of change in weight was also analysed using ANCOVA, but used a significance level of 1%. The change in quality of life scores was explored using ANCOVA.

All outcome variables were checked for the assumption of normality. If the assumption was not met, data transformations or equivalent non-parametric tests were conducted. SPSS for Windows (SPSS Inc., Chicago) and STATA for Windows (StataCorp) were the statistical packages of choice. The study was reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) statement and ICH Guidelines for Good clinical Practice.

4.8.15.3. Stage 3 – Cross sectional study

4.8.15.3.1. Health behaviour determinants

Logistic regression was used to predict whether or not a) women completed the “healthy eating” programme and b) whether women improved their diets using questionnaire data and diet quality scores. An exploratory logistic regression analysis was performed to assess whether the number of classes attended was a factor in women’s ability to complete and/or improve their diets.

Chapter Five

Results

5.0 Results

5.1. Chapter introduction

The following chapter presents the findings of this study. Each study is presented separately. Study one – Focus Groups is presented first followed by study two. As study two failed to achieve its aims and objectives, and therefore produced limited outcome data only stage one (uptake) results are presented in this chapter. Results from stages two and three can be found in appendix 9-18 for information purposes only.

5.2. Study One – Focus groups

5.3. Pre study planning

5.3.1. Stakeholder involvement

5.3.1.1. NCRN consumer research panel

A meeting was held with the local NCRN user group prior to commencement of the PhD in the pre funding planning stage. From there, panel members nominated themselves for further involvement. Three members provided expertise resulting in fine tuning of both the Patient Information Sheet (PIS) and the focus group question template.

5.3.2. Study approvals

5.3.2.1. Ethics

Stage of application	Date
Prepared	September 05 - November 05.
Submitted	The ethics application was lodged on 21 October, 2005
Reviewed	18 November, 2005
Provisional approval granted	2 December, 2005
Final approval granted	A favourable ethical opinion on 27 December, 2005 by the Southampton & South West Hampshire Research Ethics Committee B (REC Reference Number – 06/Q1704/144).

5.3.2.2. R&D

Stage of application	Date
Prepared	September 05 – November 05
Submitted	23 November, 2005
Approval granted	
NHHT	13 February 2006
WEHT	Not granted
Portsmouth	6 January 2006

5.3.2.3. NCRN adoption

Stage of application	Date
Prepared	September 2005
Submitted	October 2005
Outcome	Rejected. Advised to resubmit project as two separate applications for each study.
Study One submitted	9 December 2005
Approval granted	April 2006

5.3.2.4. Macmillan Cancer Centre

Stage of application	Date
Prepared	September 2005
Approval granted	October 2005

5.4. Study protocol

5.4.1. Aims and objectives

The aims and objectives of the focus group were met. The results are presented in 5.4.6.

5.4.2. Study design

As the focus groups aims and objectives were met, the study design was appropriate for the research questions.

5.4.3. Study participants

5.4.3.1. Sampling frame

The proposed sampling from three local NHS trusts was not achieved. The results are presented in table 5-1.

5.4.3.2. Inclusion/exclusion criteria

Due to a poor response from the initial mail out and subsequent changes to focus group participants, the proposed sampling matrix developed to ensure inclusion of diverse group of breast cancer patients was not achieved.

5.4.4. Screening

Despite recruitment problems, the initial screening procedures were conducted as planned. Participants were selected and subsequently invited to attend one of the three proposed focus groups, in accordance with the sampling matrix. In two sites however, two categories from the sampling matrix were not met as no patients could be identified as meeting the criteria. This resulted in sixteen rather than eighteen invitations being sent out for those two sites (see table 5-1).

5.4.5. Recruitment

Three NHS trust sites agreed to conduct one focus group respectively as per the sampling matrix. Reponses to invitations were as follows:

	Agreed	Declined	No Reply	Total invites
Trust One	4	2	10	*16
Trust Two	1	5	12	18
Trust Three	3	5	8	*16
TOTAL	**8**	**12**	**30**	**50**

Table 5-1 Response to focus group invitations

As a result of the poor response rate from initial mailing (refer table 5-1) the desired sampling frame was not achieved. Consequently an alternative recruitment approach was employed. At the recommendation of the breast care nurses, presentations were made to two of the three trusts' breast cancer support groups. For those women who were interested in taking part in the focus groups, contact details of the chief investigator were provided. This recruitment strategy resulted in the running of one focus group on May 23, 2006.

Of the seven women participating in the focus group, all but one were post menopausal (85.7%), three women received surgery alone (42.8%), two women had both surgery and radiotherapy (28.6%) and the remaining two had surgery alone (28.6%). Just over half of the women (57.1%) lived alone (Table 5-2).

	Diagnosis date	**Treatment Received**			**Employed**	**Post Menopausal**	**Living alone**
		Surgery	Surgery + Radiotherapy	Surgery + Chemotherapy + Radiotherapy			
1	Oct 05			√	√	√	√
2	May 01		√		√	√	√
3	Sept 01	√			√	√	√
4	Mar 05	√			√	√	x
5	Jan 05		√		√	√	√
6	May 01			√	√	x	Data not provided
7	Jun 02			√	x	√	√
	TOTALS	**2/7**	**2/7**	**3/7**	**6/7**	**6/7**	**5/6**

Table 5-2 Participant characteristics

5.4.6. Study outcomes

As stated in the protocol, unlike many focus groups where the aim is to explore patients' feelings and thoughts, the purpose of the focus groups in this study was a more qualitative exercise held to elicit patients' preferences on the practical aspects of the nutrition education classes. In total, six aspects of the nutrition education programme were discussed. Patients were offered a choice of several options in each aspect, with the view that where a clear majority was evident, these choices would be incorporated into the design of the "healthy eating" programme. The results were as follows:

5.4.6.1. Introductory questions

5.4.6.1.1. Question one

Of the seven women attending the focus group, four women reported changing their diet at the time of diagnosis. The remaining three reported changing their diet approximately six months after diagnosis.

5.4.6.1.2. Question two

All seven women sought nutrition advice to help them make changes to their diet.

5.4.6.1.3. Question three

When asked where they went for this information a variety of sources were reported.

Source	**Count**	**Rating**				
		Very unhelpful	Unhelpful	Neither helpful or unhelpful	Helpful	Very helpful
Books	6		1			5
Bristol Cancer Clinic	2					2
Internet	2					2
Newspapers/magazines	7					7
Lecture	2				1	1
Macmillan Centre	7					7
Hospital leaflets	1			1		
Other cancer patients	7					7
Breast Care Nurse	2		1	1		

Table 5-3 Sources of nutrition information

The most common sources of nutrition information for participants was the Macmillan Centre (n=7), newspapers and magazines (n=7), and other cancer patients (n=7). Interestingly, information was only sought from one health care professional (Breast Care Nurse) and the information was found to be unhelpful or neither helpful nor unhelpful.

5.4.6.2. Key questions

5.4.6.2.1. Question four

Participants were asked where they thought the classes should be held. They were given a choice between running the classes on hospital premises or, alternatively, classes could be held externally (such as a local library facility).

All participants agreed that attending the classes on hospital premises would be preferable. The venue should be chosen with the following factors in mind:

- Comfortable room
- Not in a clinical area
- Comfortable chairs
- Positive attitude of staff working in the area chosen
- Room should contain resources for cancer patients
- Tea/coffee making facilities should be available

5.4.6.2.2. Question five

Participants were asked by whom and when it would be best to approach patients to enrol on the study. All participants agreed that they would prefer to be approached by the breast care nurse on the ward whilst they were in hospital for their surgery.

5.4.6.2.3. Question six

The majority felt the best time to commence the classes would be no sooner than four to six weeks after their breast cancer diagnosis. This often corresponded to the time after surgery and before further treatment such as chemotherapy or radiotherapy.

5.4.6.2.4. Question seven

Participants were asked their preference regarding optimal class size. The group felt that a minimum of six and a maximum of ten would be ideal.

5.4.6.2.5. Question eight

Participants were initially asked to estimate the length of time, in their opinion it would take to teach a “healthy eating” programme. Opinion was divided with estimates ranging from one hour (n=1), three hours (n=1), 4-5 hours (n=4) and ten hours (n=1).

Participants were then asked over how many sessions the programme should be run. Again, opinion was divided with preferences of two sessions (n=1), four sessions (n=3) and six sessions (n=3) cited.

After being advised that the total time allocated to deliver the programme would be eight hours[20], they were then asked to decide between four x 2 hour sessions or eight x 1 hour sessions. All agreed that four x 2 hour sessions would be preferable, with around half dedicated to education and the latter half for discussion and questions.

5.4.6.2.6. Question nine

Participants were asked what key nutrition topics would they like covered in the classes in the context of a "healthy eating" programme. A range of topics were suggested and included;

- Vegetarianism
- Dairy free diets
- Alcohol
- Osteoporosis
- Smoking
- 5-a-day
- Organic
- Water – bottled or tap
- Fibre
- Food additives
- Food supplements

[20] Based on healthy eating programme in WINS UK

From this list, participants were then asked to individually prioritise no more than five areas and record their preferences on paper. Lists ranged from three to six suggestions.

Topic	Count	Percentage of participants choosing topic
Alternative diets (dairy free, vegetarianism)	7/7	100
Food supplements	5/7	71.4
Nutrition during treatment	4/7	57.1
Organic foods	3/7	42.9
Ideal body weight	3/7	42.9
Osteoporosis	2/7	28.6
Alcohol	2/7	28.6
Food additives	1/7	14.3
Water (bottled or tap)	1/7	14.3

Table 5-4 Number of times topics cited by individual participants

All participants (100%) cited interest in alternative diets, closely followed by food supplements (71.4%) , cited by five of the seven women, nutrition during treatment, cited four times (57.1%), ideal body weight, cited three times (57.2%), osteoporosis, cited twice (28.6%), alcohol, cited twice (28.6%), food additives, once (14.3%) and lastly water, once (14.3%) see table 5-4.

5.4.6.2.7. Question ten

Participants were asked to suggest different ways in which the class convenor could deliver the information. The following methods were suggested;

- Presentation
- Question/discussion time
- Videos
- Practical sessions such as taste testing healthy foods

5.4.7. Summary of focus group outcomes

In light of the discussions outlined, the design of the “healthy eating” programme incorporated the following practical components which were elicited from breast cancer patients taking part in the focus group.

Topic	Result
Timing of classes	To commence after surgery and before any further treatment begins
Number of classes	4
Duration of classes	2 hours
Location for classes	Macmillan Centres
Class size	6-12
Class topics	Healthy eating Alternative diets and supplements
Class delivery	Talks and practical sessions

Table 5-5 Focus group results summary

5.4.8. Adverse reactions and their management

No adverse reactions were observed.

5.5. Study Two

5.6. Pre study planning

5.6.1. Steering group

The steering group was set up with representatives from a wide range of backgrounds (see member list in appendix 9-17). The steering group were supportive of the project and through their involvement the research questions, hypotheses and methods were finalised and the project protocol was drawn up.

It was agreed at the time of this meeting, that further meetings would not take place; however individual member from the group agreed to be contacted if required. A data monitoring committee was discussed but unanimously rejected. The reason recorded from the minutes of the meeting stated that as there was no harm in the proposed intervention, no monitoring committee was required.

5.6.2. NCRN consumer research panel

Three members of the consumer research panel provided feedback on the patient information sheet (PIS). Comments were considered and where appropriate were incorporated into the final PIS.

5.6.3. Study approvals

5.6.3.1. Ethics

Stage of application	Date
Booked	9 August 2006
Submitted	24 August 2006
Reviewed	15 September 2006
Outcome	Rejected 28 September 2006
2nd submission prepared	September 2006
Booked	16 October 2006
Reviewed	29 November 2006
Outcome	A favourable ethical opinion on 27 December 2006 by the Southampton & South West Hampshire Research Ethics Committee B (REC Reference Number – 06/Q1704/144).

5.6.3.2. R&D

Stage of application	Date
Prepared	November – December 2006
Submitted	
SUHT	14 December 2006
Portsmouth	3 January 2007
Approval granted	
SUHT	19 March 2007
Portsmouth	Unable to obtain exact date[21]

5.6.3.3. NCRN adoption

Stage of application	Date
Prepared	July 2006
Submitted	July 2006
Approval granted	2 February 2007

5.6.3.4. Macmillan Cancer Centre

Stage of application	Date
Application made to use premises for group healthy eating classes	21 September 2006
Approval granted	
Portsmouth	September 2006
SUHT	11 April, 2007

[21] All trial documents were archived at the University of Southampton when I left the UK. Whilst I am able to reconstruct most of the dates I required through email and electronic documents, I was unable to locate an exact date for R&D approval at Portsmouth.

5.7. Enrolment and participation

5.7.1. Study period

During the period between April 2007 and September 2007, ninety seven newly diagnosed postmenopausal women with breast cancer were screened for eligibility at Southampton Universities NHS Hospital Trust. Figure 5-1 provides a diagram outlining participant flow.

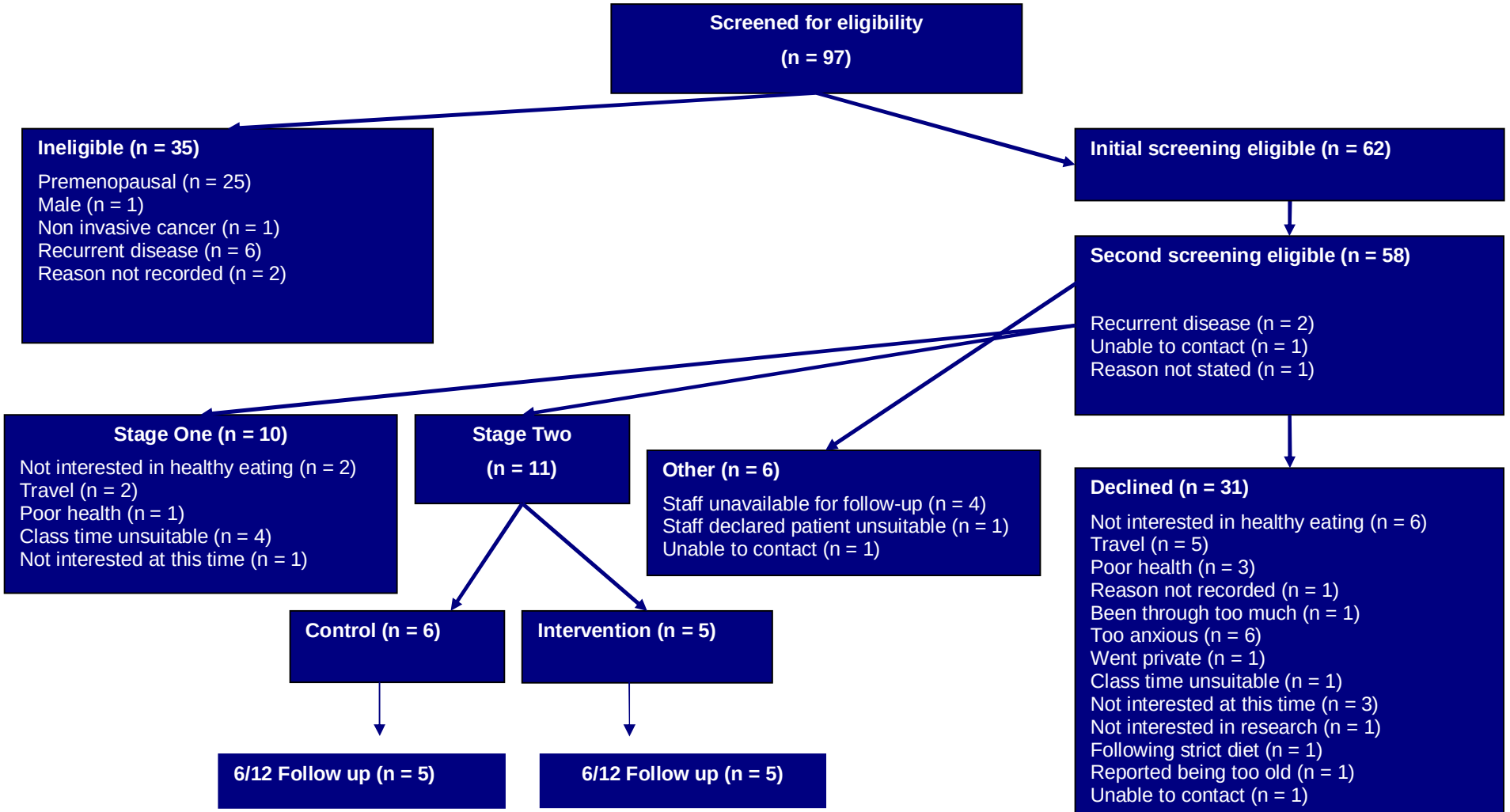

Figure 5-1 Participant flow

5.7.2. Study Two - Stage One – Enrolment

5.7.2.1. Baseline characteristics

Baseline characteristics of those women who agreed to participate and those women who declined were comparable (see table 5-6). The mean age of women who agreed was 66.6 ± 7.3 compared to slightly older group, 71.0 ± 9.8 who declined and in both groups approximately 75% of women were retired.

Characteristics	**Agreed enrolment**		**Declined enrolment**	
	Yes	**%**	**No**	**%**
	n = 11		**n = 41**	
Age	66.6 ± 7.3		71.0 ± 9.8	
Employment status				
• Full time	2	18.2	4	9.8
• Part time	1	9.1	0	0
• Unemployed	0	0	0	0
• Self employed	0	0	0	0
• Other (retired)	8	72.7	31	75.6
• Status not recorded	0	0	6	14.6

Figures reported as means and standard deviation

Table 5-6 Baseline characteristics of women invited to attend group healthy eating classes

5.7.2.2. Enrolment

During the recruitment period of six months (April 2007 – September 2007), 97 women newly diagnosed with breast cancer were identified by the research nurse of whom, 52 were subsequently invited to participate in the group health eating classes. In total eleven women (21%) enrolled on the healthy eating programme (see figure 5-2).

Response	Number	Percentage
Yes	11	21%
No	41	79%
Total Invited	**52**	**100%**

Table 5-7 Enrolment rates in healthy eating programme

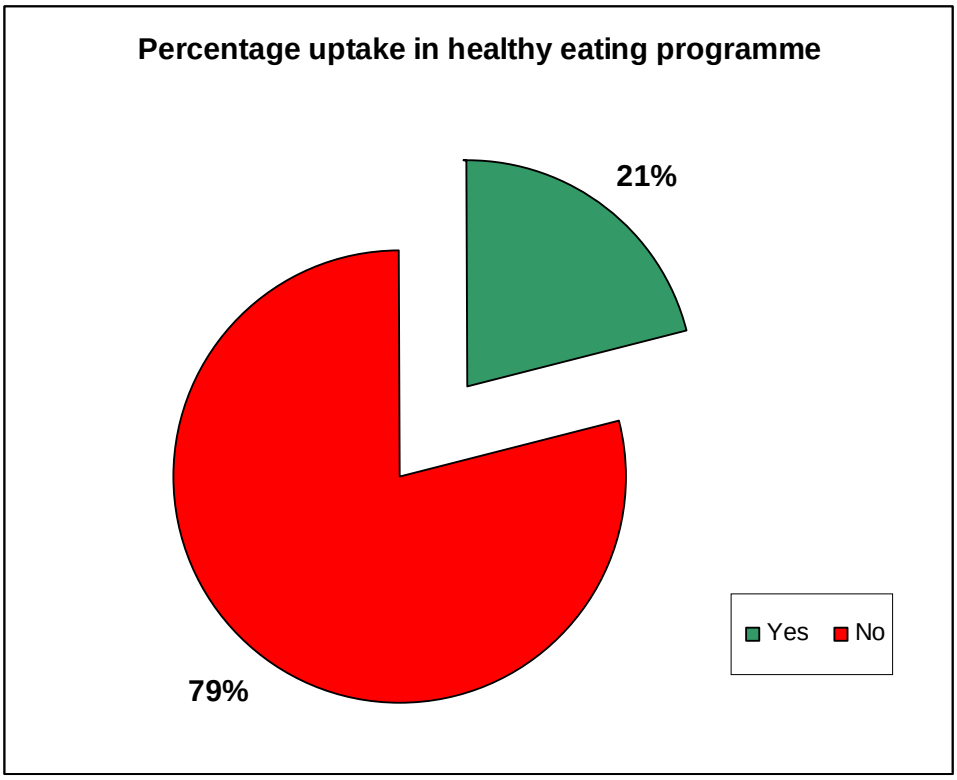

Figure 5-2 Percentage uptake in healthy eating programme

A wide range of reasons were cited for non-participation (see table 5-8). The most common reason given was not interested in health eating, which accounted for 19.5% or one-fifth of refusals. This was closely followed by travel (17.1%), too anxious (14.6%), class times unsuitable (12.2%), poor health (9.8%) and not interested at this time (9.8%).

Reason	**n = 41**
Not interested in healthy eating	8
Travel	7
Too anxious	6
Class time unsuitable	5
Poor health	4
Not interested at this time	4
Reason not recorded	1
Been through too much	1
Went private	1
Not interested in research	1
Following strict diet	1
Reported being too old	1
Unable to contact	1
Total	**41**

Table 5-8 Reasons for non-enrolment

5.7.2.3. Health Behaviour Determinants

Of the 41 women who declined participation, ten women agreed to complete baseline data in order to test whether health behaviour determinants predicted enrolment.

Binary logistic regression was used to analyse what effect the predictor variables had on whether or not women chose to enrol on the healthy eating programme[22]. As expected due to lack of power, no statistically significant differences were found between any predictor variables and whether or not women choose to enrol on the health eating programme. Summary statistics are presented in table 5-9.

That said a discussion of each of the four predictor variables (for which data was available) in terms of clinical significance follows.

Predictor	Agreed (n=11)	Declined (n=10)
Body mass index	31.3 ± 6.0	31.3 ± 8.6
Self rated diet	2.25 ± 0.5	2.57 ± 0.8
Self Esteem	24.3 ± 4.4	22.14 ± 4.8
Internal health locus of control	24.4 ± 4.6	23.9 ± 4.9
CHLC	16.1 ± 4.8	18.7 ± 2.6
Personal health locus of control	16.6 ± 5.2	18.4 ± 3.9

Table 5-9 Summary data for health determinants

[22] Diet quality could not be assessed due to missing/incomplete data sets

5.7.2.3.1. Body mass index

Body mass index was highly comparable between groups, with a mean score 31.3 in both those women who declined and those who agreed participation. Of all the women, only three who had data (15.8%) were considered normal weight with the remaining women (84.2%) categorised as overweight (42.1%), obese (31.6%) or morbidly obese (10.5%). These figures compare favourably to other estimates of obesity in women diagnosed with breast cancer.[105] [106]

Declined healthy eating programme		Accepted healthy eating programme	
Study number	**Score**	**Study number**	**Score**
205	**22.3**	201	25.3
208	27.8	204	**22.9**
212	31.8	210	**24.3**
231	Data missing	213	28.2
233	Data missing	217	40.6
238	49.5	221	28.9
240	27.0	223	36.0
241	27.4	228	36.2
253	26.8	230	34.2
257	37.4	235	29.8
		245	37.8
Mean and SD	**31.3 ± 8.6**	**Mean and SD**	**31.3 ± 6.0**
Median[23]	**27.6**		**29.8**

Note: Women with normal BMI scores appear in bold

Table 5-10 Body mass index scores

[23] Median scores are reported as a reference alternative summary statistic only. Results where appropriate are discussed as means and standard deviations.

5.7.2.3.2. Self rated diet

Study participants were asked to respond to the question "to what extent do you agree or disagree that you have a healthy diet overall?" using a five-point likert scale. Results were similar with the most common response in both groups agreeing with the statement.

Declined healthy eating programme		Accepted healthy eating programme	
Study number	**Score**	**Study number**	**Score**
205	3	201	2
208	2	204	2
212	Data missing	210	Data missing
231	4	213	2
233	Data missing	217	3
238	2	221	2
240	Data missing	223	2
241	2	228	2
253	3	230	Data missing
257	2	235	3
		245	Data missing

Table 5-11 Self rated diet scores

Frequencies were as follows:

Score	Response	Declined	Accepted
1	Strongly agree	0	0
2	Agree	4	6
3	Neither agree or disagree	2	2
4	Disagree	1	0
5	Strongly disagree	0	0
	Mode	**Agree**	**Agree**

Table 5-12 Self rated diet response frequencies

5.7.2.3.3. Self esteem

The results indicate that those women who enrolled on the programme had slightly higher self esteem with scores of 24.33 ± 4.6 compared to those women who declined participation scoring 22.14 ± 4.8.

As stated by the scales developers, there are no discrete cut-off points to define high or low self esteem. Of all the studies reviewed in chapter seven, only one utilised this scale; however the authors did not report observed scores.[36]

Declined healthy eating programme		**Accepted healthy eating programme**	
Study number	**Score**	**Study number**	**Score**
205	30	201	30
208	23	204	21
212	Data missing	210	Data missing
231	20	213	28
233	Data missing	217	28
238	15	221	19
240	Data missing	223	21
241	26	228	23
253	21	230	29
257	20	235	20
		245	Data missing
Mean and SD	**22.14 ± 4.8**	**Mean and SD**	**24.33 ± 4.6**
Median	**21**		**23**

Table 5-13 Self esteem scores (highest possible score = 30)

5.7.2.3.4. Locus of control

Small differences in scores were observed between groups. Those women who enrolled on the programme had slightly higher internal locus of control scores 24.4 ± 4.6 compared to those who declined enrolment 23.9 ± 4.9. This observation is supported in the literature where it has been reported that individuals with a high internal locus of control are more likely to engage in healthy behaviours.[107]

Again, very little comparison data could be found in the scientific literature. None of the studies reviewed in chapter seven utilised the MHLC. One diet intervention study where participants in a Polyp prevention trial completed the MHLC reported the following. In the intervention group, IHLC was 27.8 ± 4.9, CHLC 16.2 ± 6.1 and PHLC 22.5 ± 6.3. In the control group scores were IHLC 26.2 ± 5.2, CHLC 19.1 ± 5.7 and PHLC 24.5 ± 6.2. These scores vary from those observed in the current study.

When compared to healthy adult reference data provided by the authors of the scale, again the scores vary considerably. In healthy adults, IHLC was 25.55, CHLC 16.21 and 19.16.[99]

Dimension	Declined	Accepted
Internal health locus of control (IHLC)	23.9 ± 4.9	24.4 ± 4.6
Chance health locus of control (CHLC)	18.7 ± 2.6	16.1 ± 4.8
Powerful others locus of control (PHLC)	18.4 ± 3.9	16.6 ± 5.2

Table 5-14 Summary data for multidimensional health locus of control scales

Individual scores are described in table 5-15.

Declined healthy eating programme				Accepted healthy eating programme			
	Internal IHLC	**Chance CHLC**	**Powerful Others PHLC**		**Internal IHLC**	**Chance CHLC**	**Powerful others PHLC**
Study number				**Study number**			
205	18	20	21	201	26	25	18
208	28	21	20	204	24	14	11
231	23	16	16	210	26	17	17
233	Missing data	Missing data	Missing data	213	29	15	9
238	28	20	19	217	16	15	24
240	Missing data	Missing data	Missing data	221	21	23	16
241	29	20	12	223	29	12	17
253	17	14	17	228	29	13	24
257	24	20	24	230	20	11	13
				235	Missing data	Missing data	Missing data
				245	Missing data	Missing data	Missing data
Mean and SD	**23.9 ± 4.9**	**18.7 ± 2.6**	**18.4 ± 3.9**	**Mean and SD**	**24.4 ± 4.6**	**16.11 ± 4.8**	**16.6 ± 5.2**
Median	**23**	**20**	**19**		**26**	**15**	**17**

Table 5-15 Multidimensional health locus of control data

5.8. Chapter summary

Fifty-two postmenopausal women newly diagnosed with breast cancer were invited to attend a group healthy eating programme. Of those 11 (21%) agreed to participate. Reasons for declining participation varied, with “not interested in healthy eating” cited in approximately one-fifth of cases. At the end of the six month follow up, one woman from the usual care group withdrew from the study. No reason was provided.

The findings suggest that offering a group healthy eating programme for newly diagnosed postmenopausal women with breast cancer would not be feasible as the likely uptake would not justify such a service.

However the influence of inadequate screening resulting in low numbers of women invited to participate in the group healthy eating programme and further the degree of missing data for those women who did enrol must not be ignored when interpreting these data. These issues are explored in detail in the following chapter.

Chapter Six
Discussion

6.0 Chapter introduction

In 2007, the World Cancer Research Fund (WCRF) published the most comprehensive scientific report on “Food, Nutrition, Physical Activity and Cancer”, recommending all newly diagnosed cancer patients should receive nutritional advice.[19] Currently in the NHS, routine nutrition advice is not offered to cancer patients.

A relatively large body of qualitative evidence exists supporting the introduction of health promotion activities for newly diagnosed cancer patients.[9 19 70 71 73-76 78 79 94] However, to date, no data exists for policy makers to determine what the likely interest in these types of activities would be; an important consideration when planning and developing new services. Interest in such programmes could be extrapolated by reviewing enrolment data from the vast literature base of dietary intervention studies; however uptake in these interventions are generally poorly reported and very few have been conducted with breast cancer patients.

This project was set up to investigate uptake and response to dietary intervention in women newly diagnosed with breast cancer, in order to assist future cancer service development. Funding was provided by the Department of Health through their Research Capacity Development Award scheme. The project began recruitment in April 2007, concluding six months later in September 2007.

As the study did not achieve its goals and objectives, the following discussion does not focus on a review of the study as would normally occur. Instead the review is reflective of my experience of the study process, identifying where mistakes were made and suggesting ways in which to avoid such problems in future research programmes. The purpose of this reflective process was to demonstrate that the overall goal of both the Doctoral programme and the funding stream, that is the development of advanced research skills, has been achieved.

In view of the above, the discussion is set out in accordance with the health promotion planning and evaluation cycle described by Nutbeam (2006)[108] (see figure 6-1) which provides a structured framework with which to evaluate health promotion activities.

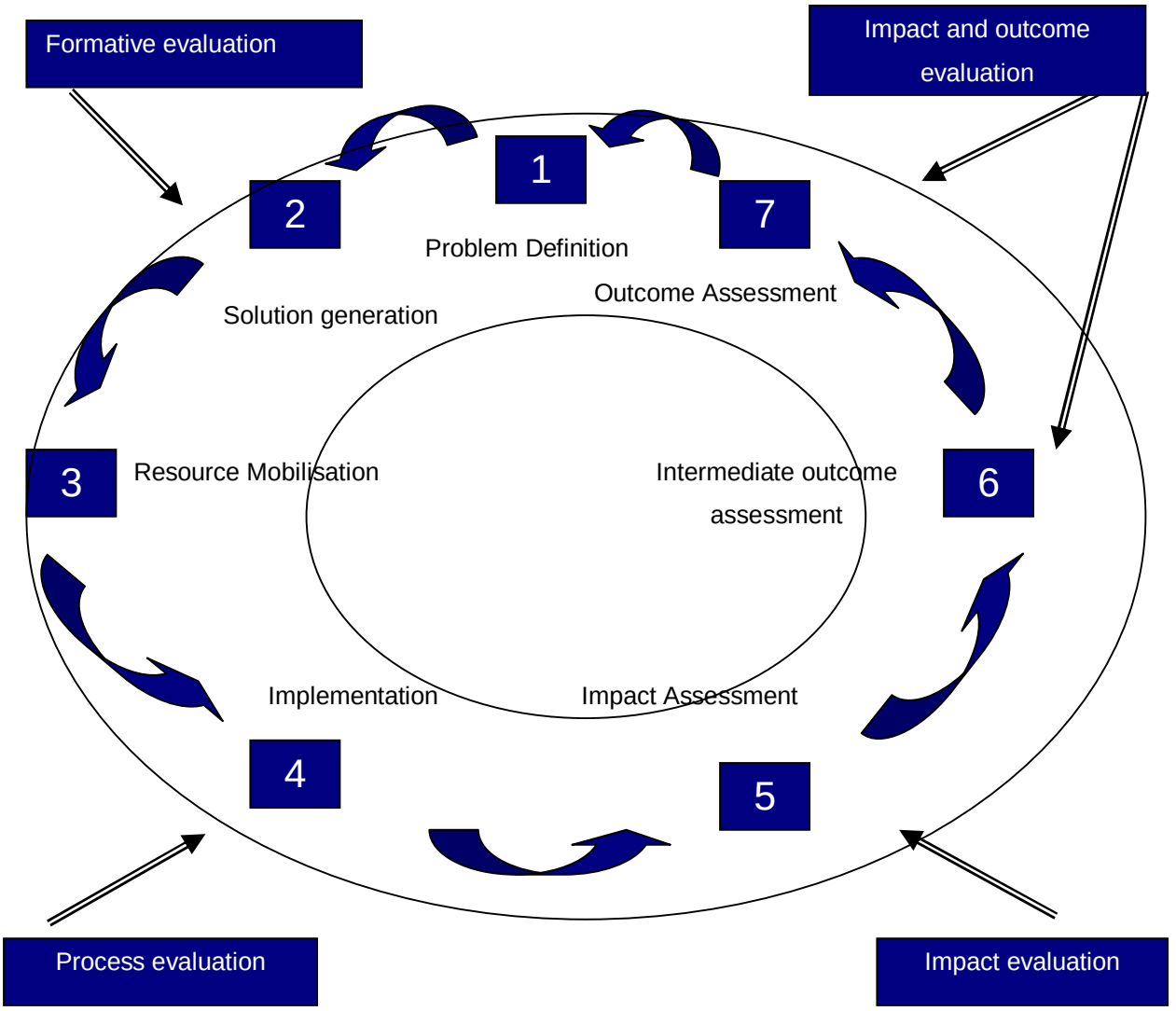

Figure 6-1 Health promotion planning and evaluation cycle

During the lifespan of the project, four levels of evaluation are proposed; formative, process, impact and outcome (the outer circle) (see figure 6.1).

The four types of assessment; formative, process and impact and outcome are discussed in their own right, with each section categorised further into subheadings describing 1) the purpose of the evaluation, 2) assessment of the current project, and 3) summary and 4) lessons learned.

6.1. Formative evaluation

6.1.1. Purpose of formative evaluation

Formative evaluation enables the development of an intervention that utilises the most relevant methods and materials, potentially resulting in an effective programme. It should be conducted in consultation with stakeholders and/or members of the target population.[108]

Several strategies were employed during the planning stage of this project and are discussed below. These included;

1. Focus groups with patients
2. Adoption of study into the local NCRN research portfolio
3. Macmillan Cancer Centre
4. Steering group
5. Involvement of independent and external Clinical Trials Unit for peer review and randomisation
6. Stakeholder engagement

6.1.2. Assessment

6.1.2.1. Focus groups

Whilst some of the parameters in which the intervention was to operate were predetermined (group education, during working hours, Dietetic led), in order to make the intervention feasible within the NHS setting, the views of cancer patients were sought when designing the practical components of the intervention. These included; number of sessions, length of sessions, preferred topics, location of sessions and lastly preferred size of group for sessions.

6.1.2.2. National Cancer Research Network

Both study one (focus groups) and study two (main study) projects were put forward and were successfully accepted to the local NCRN networks research portfolio. The benefits of being part of the NCRN research portfolio include training opportunities and assistance with conducting the research through network research nurses. Specifically the NCRN research nurses were tasked with carrying out the screening and recruiting for the focus groups and the screening, recruiting, and data collection for the intervention study.

In addition, the local NCRN network established a Consumer Research Panel which was set up to provide researchers with access to representatives from the target group i.e. cancer patients, in order to obtain feedback on all elements of proposed studies. Prior to applying for funding, the idea for the project was presented to this group. The feedback given after the presentation was very positive with a

number of members indicating their willingness to continue involvement in the project. This offer was accepted and at a later stage two members of the group were enlisted to review all patient documentation and a third member became part of the research team working on a paid basis to assist with the focus group work. In addition, this member went on to sit on the steering group.

Whilst ultimately, NCRN adoption was granted, it was not without its problems. After initially applying for NCRN adoption for the entire project, the application was declined. It was recommended that a separate application be made for each stage of the project. Despite, timely adoption for the focus group, approval for stage two was extremely drawn out. In total, submission to approval took seven months. This occurred as a result of the suspension of the application process for NCRN adoption which took place during the course of this study as a review of the procedure for adoption into the NCRN portfolio took place.

6.1.2.3. Macmillan Cancer Centre

As with other approval processes outlined previously, gaining permission to use the Macmillan premises at SUHT presented planning challenges. Despite making initial enquires as early as September 2006, approval was gained seven months later on 11 April, 2007. As with the NCRN, the Macmillan centre at SUHT was reviewing their guidelines for approving the use of Macmillan premises for research purposes.

After attempting to secure a slot at the board's meeting for several months (Macmillan postponed the meeting on three separate occasions), a meeting was finally held which resulted in approval to use the premises for the purposes of conducting the healthy eating classes.

Interestingly no such review was taking place at the Macmillan centre located at Portsmouth NHS trust, thus showing once again, a lack of consistency across organisations in policies and procedures.

Finally, both centres gave approval for their premises to be utilised for the group healthy eating programme.

6.1.2.4. Steering Group

Whilst the steering group was a success in terms of engaging with senior clinical and academic members and subsequent revisions to the protocol based on feedback, the steering group was not used to its full advantage. The terms of reference should have been more formalised with future meetings scheduled to assess the progress of the study. If such provisions had been in place, earlier remedial action could have been taken which may have improved the study outcomes.

6.1.2.5. Independent Peer review

The protocol was independently peer reviewed by the Birmingham Clinical Trials Unit. The summary review stated “the proposal is well-written and thought out (they have discussed the project with a variety of leading experts within the field), and asks an interesting question (with an easy to implement intervention) in an important disease area” (see appendix 9-18).

6.1.2.6. Stakeholder involvement (the local healthcare team)

When developing this project, the importance of local clinician support had been completely underestimated.

In order to gain hospital approval to conduct the study, a letter of approval was required from a lead clinician. At both sites, this approval letter was sought and gained from the respective lead surgeons. Despite similar approaches to obtaining this letter, the outcomes were quite different with one site eventually been withdrawn from the study.

In order to introduce the study to the clinical teams, a request to present at the multidisciplinary team meetings was made. At one of the two sites (the site which was withdrawn) no suitable date to present the study could be arranged. As a result, the principal investigator liaised only with the chief surgeon who went on to authorise the study at this site. The principal investigator had been involved with this clinician on an earlier, unrelated project and had therefore previously established a good rapport.

Further, from the principal investigators view, it was considered a benign intervention in terms that adopting a healthy diet is unlikely to cause any harm in this patient group. In the rare event where adopting a healthy diet was contraindicated for a particular participant, procedures were in place to identify and refer immediately to the dietetic department for nutrition support.

For both of these reasons, the principal investigator did not envisage any problems by not consulting with the wider clinical team. What became apparent at a later date however was that the dynamics of the clinical team differs from hospital to hospital and at this particular site it was suggested that it would have been more appropriate to discuss the study with clinical members within the different specialities; surgeons, oncologists, nursing and radiography.

Subsequently, a meeting was held where the principal investigator presented the study to a group of approximately twenty people including, oncologists, nursing staff and radiologists. In the opinion of the principal investigator, the meeting was quite hostile with comments suggesting the lead surgeon could not authorise a study independently. In the end however the group agreed to support the study. Again, only in the opinion of the principal investigator, this was due to the fact that recruitment rates at

each trust within a cancer research network are recorded and published as part of assessing networks against NCRN performance measures. With the high levels of predicted accrual numbers (this point was made during the meeting), this study had appeal on that basis only.

The study opened for recruitment on the proposed start date, however within one week of opening further problems were experienced. A senior nursing member of the team who was not present at the meeting did not support the study. Two main reasons were cited; firstly this member felt it inappropriate to invite women to eat healthily at the time of diagnosis and secondly, this person was uncomfortable with the fact that the research nurse who had been identified to screen and recruit for the study was male.

Attempts were made to reconcile the differences but in the end the decision was to withdraw the study from the site. The decision made was based on two grounds. Firstly, the original sample size of 400 was set based on the point estimate being within 5% either side of the true population value. For example if the point estimate was found to be 50%, then the true value or number of postmenopausal women newly diagnosed with breast cancer in the wider breast cancer population likely to enrol on a group healthy eating programme would be between 45% and 55%. By extending this range from $\pm$ 5% to $\pm$ 7.5% the target was recalculated given a revised sample size of 129 which was deemed achievable with only one remaining site taking part. Secondly, the time required to pursue a resolution was assessed as endangering the timely completion in the allocated three years for the Doctoral programme.

At the second site, no problems were encountered despite the same process being followed. Once again a request was made to present at the multidisciplinary team meeting and once again, this request could not be fulfilled. Subsequently, approval was gained from the lead surgeon after a presentation to his surgical team and only after experiencing the problems described above did the principal investigator arrange a meeting with the wider clinical team who raised no concerns and gave full support to the study.

The experience in gaining local support at these two sites provides a clear example of how local politics can undermine research studies from getting off the ground.

In addressing reviewers' comments in this revised thesis an important publication was identified. Following a consultation period, in March 2007 new mandatory measures, the "Cancer Research Network Measures"[109] were issued as part of the Manual for Cancer Services. Specifically, whilst acknowledging the National Cancer Research Network Co-ordinating Centre's procedures for cancer research, the Department of Health independently published their own quality performance measures

for Cancer Research Networks. Of note, measure 1C-152 states "The NSSG and the Clinical Lead of the Research Network should agree remedial actions for improving recruitment into approved trials and other well designed studies, with each of its MDT's following its meeting to discuss the MDT's recruitment". Compliance to this measure will be assessed through demonstrated remedial actions agreed by the NSSG Chair and the Research Clinical Lead.[109]

Further, measure 2 states that "the MDT must provide a written response annually to the NSSG's approved list of trials and other well designed studies which fulfils the following: for each clinical trial and other well designed study the MDT should agree to enter patients or state the reasons why it will not be able to; and the remedial action arising from the MDT's recruitment results, agree with the NSSG. Compliance with this measure will be assessed by demonstration of an appropriate written response to the aforementioned".

Interestingly, had these measures been in place at the time this study was underway, a more formal and hence satisfactory explanation may have been forthcoming as to why Portsmouth were unable to follow the approved protocol.

Secondly, the issue of unsatisfactory screening procedures by the NCRN research nurses could have been raised in an appropriate setting which may have lead to remedial action which could have potentially improved screening numbers.

6.1.3. Summary

Several strategies were employed during the planning stages of this project from as early as prior to the funding application, up to and including the design of the intervention. These strategies elicited the views from a wide range of stakeholders which included patient representatives, hospital representatives, a funding body representative, academic representatives, and charity representatives. In all these consultations, support for the project was high resulting in a project with clear research aims and objectives, hypotheses and outcomes.

Overall, the formative stage of the project was thorough; however two unforeseen problem areas were identified; lack of local support and the use of inaccurate screening methods, which ultimately undermined the success of the project.

6.1.4. Lessons learned

Neglecting to ensure adequate local support proved costly with one of the two sites not taking part in the study. Both the procedures for gaining hospital approval to conduct research and selection of NCRN adopted studies at individual NHS sites should be reviewed.

If, as in this example, the chief surgeon was deemed suitable to be the sole authorising person on the application by the hospital R&D department, how was it that other members of the clinical team were able to challenge the approval leading to the withdrawal of the site?

Further, the procedure used for selecting studies should be transparent. In the case of the site that was withdrawn, as stated previously, it is the opinion of the principal investigator that the main reason the current study was supported at the time of the meeting was for reasons of recruitment numbers and had very little (if anything) to do with the study itself.

With large numbers of protocols being received at each hospital site, if studies are chosen based on individual preferences, this system is undoubtedly unfair and requires immediate review. Indeed by its own admission in the 2004 review of the NCRN, local studies are not well supported and overall have contributed only a small proportion of total accrual into the NCRN research portfolio[110].

6.2. Process evaluation

6.2.1. Purpose of process evaluation

Process evaluation assesses how the intervention was implemented and was carried out during the delivery of the intervention. It concerns itself with the following questions;

1. Did the focus groups reach their target group?
2. Did the intervention reach its target group?
3. Was the intervention delivered as intended?
4. Were stakeholders/partners engaged in the process?

If done correctly, process evaluation will identify how a successful programme was conducted and conversely if the programme was unsuccessful, it will identify reasons for failure, so modifications can be made to improve the likelihood of future success [108].

6.2.2. Assessment

6.2.2.1. Focus groups target group

As stated in the study protocol, three focus groups were planned at three different NHS trust sites. However; no focus groups were conducted as planned. As the results indicated, interest shown in attending the focus groups when recruited as per protocol was limited. Overall, with 50 invitations sent, a positive response was received on only eight occasions.

It was recommended by members of the health care teams that potential participants might be recruited from the support groups which are established at each hospital site. Subsequently, the three relevant support groups were approached, of whom two expressed an interest in the project. Presentations were made to both groups and from one of these presentations sufficient women were recruited to hold one focus group.

6.2.2.2. Intervention target group

Over the six month recruitment period, the NCRN research nurse assigned to run the trial identified 97 women to be assessed for eligibility (including women with recurrent disease who were ineligible).

In contrast, figures provided by the Breast Unit Coordinator[24] stated that over the same period 146 new cases (not including recurrences) were registered. Using an estimate of ~20% cases occurring in premenopausal women, this left 118 women eligible women who should have been invited on the programme against the actual number of 58 (50%).

Based on these figures, clearly the study did not reach its target group which were all newly diagnosed postmenopausal women with breast cancer. To date, no reason for this disparity has been identified.

Further, a small number of women were excluded for reasons not specified by the protocol reducing the numbers of eligible women invited to participate in the programme.

6.2.2.3. Intervention delivery

6.2.2.3.1. Baseline data collection

As part of the remit of the NCRN research nurse, all baseline data were to be collected at the time of consent. What occurred, however, was that a number of data collection forms were posted to participants in direct violation of the specified protocol. When questioned, the research nurse stated

[24] A comparable figure was not available and was derived as described

that this transgression would be acceptable and was common practice in other clinical studies. The result of this error was twofold; firstly, a number of data collection forms were not returned and secondly the data on some of the returned forms were either missing or incomplete as these were not subsequently checked by the research nurse and followed up for data inaccuracies.

6.2.2.3.2. Resources

Allocated resources including, venue, electronic equipment, patient information resources, dietetic time were adequate to conduct the study as planned. No unforeseen expenditure occurred during the course of the programme.

6.2.2.3.3. Repeatability

All programme materials were pre-selected and the presentation pre-written to ensure the classes could be repeated.

6.2.2.3.4. Programme variability

Unfortunately as the programme did not run in two sites as originally planned and the programme leader delivered all the classes, there was no opportunity to assess variability between sites or between programme leaders.

6.2.2.3.5. Programme attendance

With so few participants an assessment of programme attendance would be inappropriate.

6.2.2.4. Stakeholder engagement

No measures were used to assess stakeholder engagement. With the problems experienced in the screening and recruitment processes, data regarding the strengths and weaknesses of the partnership would have been extremely useful.

6.2.3. Summary

Implementation problems were identified in both phases of the project.

In study one, the focus group work was not supported as planned. The predicted numbers were based on the qualitative literature that suggested half of all newly diagnosed breast cancer patients were interested in health promotion programmes specifically dietary services. From these data, numbers invited were twice those needed to successfully run a focus group. In retrospect, this may have been the first indication that in reality the interest in such a programme differed substantially from what the literature suggested.

In study two, several problems were experienced. Firstly, the screening process failed to identify all eligible patients and therefore reach its target group. This in turn resulted in fewer women being invited to participate in the programme and subsequently the observed recruitment rates could not be generalised beyond the cohort participating in the study. No provision was made a priori to deal with screening procedure failures. NCRN research staff are highly experienced in all aspects of trial management and therefore no concerns regarding the ability to accurately record each new breast cancer diagnosis could have been anticipated. This information is routinely collected by the Breast Unit as part of the minimum data sets required nationally by the Department of Health and should therefore have been freely accessible to the NCRN research nurse. For this reason, no piloting of the screening process was undertaken.

Secondly, the data collection procedures were not followed which led to missing and incomplete data. When coupled to substantially lower screening/recruitment rates than predicted, the study outcomes were severely compromised.

Lastly, on a positive note, the planning and development of all class materials prior to the start of the programme was well conceived and should ensure repeatability.

Overall the implementation phase of the project was poorly conducted.

6.2.4. Lessons learned

Whilst numbers recruited to the focus groups fell well short of those predicted, with only qualitative data available on the likely interest in health promotion activities, the best estimate was made with the available evidence. If similar studies were to be conducted in the future, alternative methods for estimating recruitment rates should be considered.

In phase two of the project, two potential measures could have been employed to improve the implementation stage of this project.

Firstly, had the procedure for screening been pre-tested/piloted these errors would be been highlighted and the procedure subsequently modified, in turn eliminating the problems that arose.

In the absence of the piloting phase, the problem could have been ameliorated had appropriate action been taken. During the course of the recruitment period a request was made to the research nurse

early in the six month recruitment period outlining concerns regarding poor screening/recruitment statistics. At that point the research nurse provided assurance that all potential patients were currently being screened and identified. This response was not checked with the breast unit data manager by the principal investigator. Had this occurred, the discrepancy would have been highlighted earlier and potentially may have been resolved.

Secondly and most importantly, the main problem was the lack of partnership between the principal investigator and the NCRN research nurse. The principal investigator wrongly used an autocratic approach to conduct the study.

In part, this was premeditated as it was felt at the time that in order to be scientifically credible, given the outcome was to assess the level of interest in a healthy eating programme in a "real life" situation, a conscious decision was made to distance the principal investigator from the practical aspects of the study so that no influence could be exerted on the uptake rate though coercion on either the research nurse or patients.

To this end, although not mandatory by the NCRN, a procedures manual (see appendix 9-19) was provided to the NCRN research nurse with a detailed description of all aspects involving screening and recruiting patients. It was assumed that if any problems arose they would be dealt with appropriately or alternatively the principal investigator would be contacted for guidance.

Further, having NCRN support was seen as an advantage as the staff would have already established a working relationship with their colleagues and this would potentially translate into a smoother working environment rather than if outside academic researchers came into a team with no prior working relationships. Whilst acknowledging these positive aspects of NCRN involvement, the process evaluation has highlighted some negative aspects of this arrangement.

Two potential areas for improvement have been highlighted. Firstly, a detailed agreement with regards to specific tasks between the two parties would have been advantageous, similar to the model clinical trial agreement (mCTA) published in 2003 and revised in 2006[111] for pharmaceutical research. The mCTA was the result of a joint Government and Industry initiative which reported on the performance of commercially sponsored clinical trials in the NHS. The report identified a number of problems in common with those experienced in the current study. These included poor recruitment and data quality.[112]

To date, there is no mandate to include Clinical Trials Agreements for non-pharmaceutical research however, in the NCRN 2004 review[110], the issue of data quality is raised. The review acknowledges

that the focus of performance to date as been largely on accrual rates to clinical trials. With those targets met and exceeded, the performance measures for future reviews needs to be expanded and crucially include measures of quality.[110] Whilst the UKCRN have extended their performance measures in 2007 the initial focus will concentrate on three key criteria; “balance of portfolio, accrual of study participants to pre-defined targets and speed of conduct to pre-defined timelines”. (personal communication, Morgan, C, UKCRN 9/07/08). To date, no performance measures for data quality have been established and therefore this area remains unaccountable.

At present a working group (currently in the early stages) has been formed to develop national competencies for research nurses. At the time of writing this revised thesis, draft competencies have been published and are currently open for consultation by invitation.

6.3. Outcome evaluation

6.3.1. Purpose of outcome evaluation

The purpose of outcome evaluation is to assess the extent of how the programme achieved its aims and objectives. It is often categorised into two separate measures, impact assessment, which focuses on short term/intermediate goals and outcome assessment focused on the long term outcomes of the study.

The structure for the following outcome evaluation is best described pictorially and is depicted below in figure 6-2.

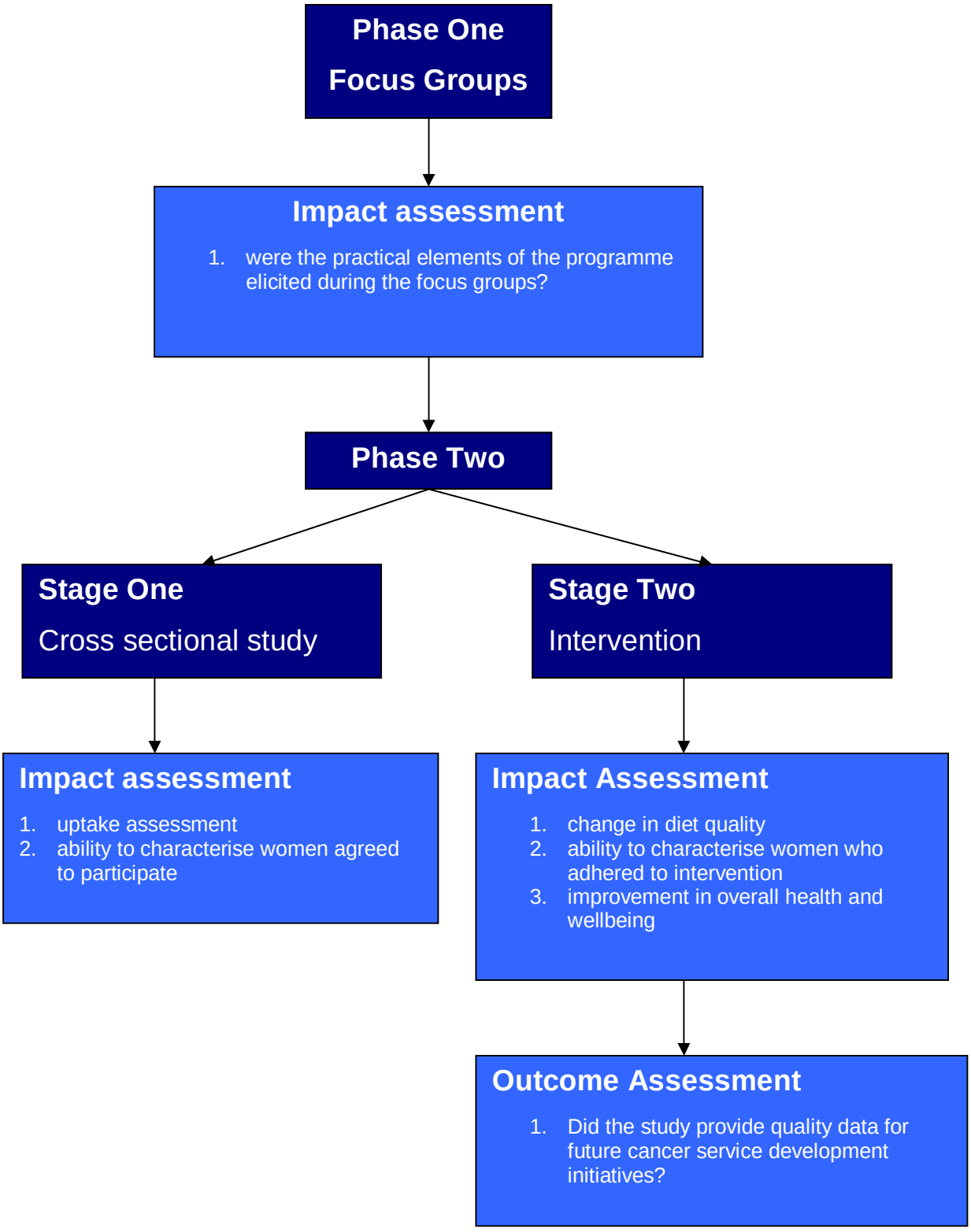

Figure 6-2 Summary of impact and outcome assessment

6.3.2. Impact assessment

6.3.2.1. Assessment - Study One

The goals and objectives for the focus groups were met. Specifically, the practical aspects of the study as proposed by the focus group participants were incorporated into the study intervention.

6.3.3. Summary

Despite not achieving the number of focus groups planned, the one which was conducted elicited the information needed to develop the programme which was to be tested in phase two.

Overall, phase one achieved its desired impact

6.3.4. Lessons learned

In future, when planning focus groups, alternative methods of recruiting patients would be investigated.

6.3.4.1. Study Two – Stage One

6.3.4.1.1. Uptake

Today, more and more people are surviving their cancer diagnosis, leading to a growing need for health providers to offer services that better meet the long term health needs of this group.

Over the last two to three decades, several research groups have become focussed on providing evidence that demonstrates health benefits ranging from enhanced quality of life through to improved relapse free and overall survival when adopting healthy lifestyle behaviours after a cancer diagnosis. As a clinical dietetic practitioner, it was apparent that if such evidence once established were to be translated into practice, such programmes would have to been acceptable to the women for whom they were intended. As such, a gap was identified in the literature leading to the present study, the first to assess uptake in a group healthy eating programme for newly diagnosed postmenopausal women with breast cancer.

Over a period of six months, 58 newly diagnosed postmenopausal women with breast cancer were invited to enrol in a group health eating programme. Of those invited, eleven (21%) agreed to participate. With feasibility established at 50%, the results indicate that interest in such a programme fell well short of the benchmark set, suggesting that such a programme would not be a feasible addition to services currently offered by NHS dietetic departments.

As a stand alone study, where the outcome of interest was to measure participation rates in a health promotion activity whereby all patients were eligible to enrol, direct comparisons to other data cannot be made. Data however does exist from other dietary intervention studies with select subsets of this patient group and these are presented below.

Of the studies reviewed in chapter two, only two, the Womens Healthy Eating and Living Study (WHEL) and the Womens Intervention Nutrition Study (WINS), both conducted in the US reported uptake data.

In the WHEL study, of the 4708 eligible patients identified, 1601 (34%) did not participate in the study with 1284 (27%) declining to participate, 315 (7%) failing to complete the run-in period, and 2 (0.04%) refusing randomisation after completing the run-in period. The remainder, 3107 (66%) went on to be randomised. Recruitment for this study took five and a half years.

For the WINS study, the following participation rates were found. Of the 5466 eligible, 2537 (45%), went on to be randomised, leaving 55% of all eligible women declining participation. The recruitment period for this study took seven years.

In unpublished data from the Womens Intervention and Nutrition Study (UK), of the 1528 women invited to take part, 301 (19.7%) consented to the study with the remainder (80.3%) declining participation.

In the studies presented above, participation rates ranged from 19% in this study to 64% in the WHEL study. Two possible explanations are suggested to explain such disparities. Firstly, the WHEL study with the highest recruitment rate of 64% did not require participants to attend dietary counselling sessions as these were conducted over the telephone. This suggests that participant burden may significantly impact on uptake in dietary interventions for this group.

Secondly, women enrolling in the WINS and WHEL studies were aware that both studies were investigating the role of diet in improving survival from breast cancer. Such knowledge may have been a powerful motivator for enrolment. In both the WINS UK and this study, participants had no such incentive, with the WINS UK investigating the feasibility of adopting a low fat diet, and the present study assessing interest in a health eating programme.

The preceding discussion highlights the problems faced by the health service providers in developing future services. Not only is there a paucity of evidence as to the likely interest in health promotion activities, existing evidence varied markedly, largely due to differences in the type of dietary

intervention, low fat (WINS US and WINS UK) and healthy eating (WHEL and this study), mode of intervention, telephone counselling (WHEL), and group sessions (WINS US, WINS UK and this study), and length of intervention, (months to years).

6.3.4.1.2. Characteristics that predict uptake

Although statistical tests were applied to the data showing no differences between women who agreed to participate and those who refused in predicted health behaviour determinants, due to insufficient sets of data, conclusions cannot be reliably drawn.

6.3.4.2. Summary

Clearly, the impact of stage one on the overall project was undermined by poor accrual. Only since closing the study have the challenges of trial recruitment come to light. What is now apparent is that failing to meet recruitment targets is a widespread problem in clinical research and for that reason recruitment rates have been extensively researched.

Two main areas have been addressed. Firstly, the reporting of recruitment rates have been investigated as this has important implications for researchers when predicting both target numbers and time taken to meet recruitment targets.

Gross[113] et al conducted a systematic review of 172 randomised controlled clinical trials published in 1996-2000 and found only 52% of studies reported the numbers of patients who were screened for eligibility, of which less than half went on to report numbers meeting eligibility requirements. The authors concluded that random and incomplete reporting of the recruitment process was common.

Whilst acknowledging the guidelines for reporting clinical trials have been greatly improved, largely due to the publication of the CONSORT guidelines, the reporting of recruitment data remains a problem.

Of the data that does exist, recent commercial clinical trial data report <30% of UK based trials reach their recruitment targets.[112] For non industry sponsored trials[114] the picture is similar with 45% reaching their recruitment targets and one-fifth recruiting less that 25% or their recruitment target.

Secondly, the reasons for non-participation have been investigated so that barriers to recruitment can be identified and subsequently addressed, potentially resulting in greater recruitment rates.

Whilst the reasons for non-participation are wide ranging, three key areas have been identified to explain poor recruitment; clinician characteristics, patient characteristic and protocol eligibility.

On the clinician side, several reasons have been cited and include; lack of interest in research, time demands, availability of suitable study, resource constraints and ethical considerations. Patient factors including age, ethnicity, gender and socio-economic status have been identified as potential reasons for non participation. Practical issues such as time demands and transport for extra visits can be barriers to participation. In addition, patients often report poor understanding and/or hold negative views of the clinical trial process which in turn leaves them reluctant to participate. Lastly, in many cases study protocols exclude large numbers of patients in order to maintain internal reliability.[113 115-123]

Together, these published data suggest that currently recruitment to clinical trials is generally poor. Further there is no clear evidence outlining successful strategies to improve clinical trial participation rates.[124]

With an ever growing push, due to both the high profile research agenda as outlined in "Best Health for Best Research" and a greater understanding of the causes of disease, new opportunities for research into prevention, cures and palliation exist. In our "evidence based" health culture, this means an ever increasing number of clinical trials are being established and the impact therefore of poor recruitment cannot be underestimated. In the commercial sector alone, there has been a 20% growth in the number of clinical drug trials between the years 2000-2005.

In future, sites that have a reputation as "good recruiters" may be targeted by commercial research organisations as the ability to conduct a study within proposed timeframes is paramount to cost effective practice. If future trials are focused in such "research hubs", an inequitable system will occur whereby patients who are not seen at these sites will not have access to new and promising treatments. Secondly, with more trials opening, it will create competition to enrol patients on studies within these "research hubs" potentially compromising individual trial recruitment targets.

Clearly this is situation that should be avoided and highlights barriers to recruitment as an important area for future research. The research agenda may benefit by expanding its scope to include investigations on the effect of specific interventions and disease type on recruitment rates.

Overall, the impact of phase two, stage one was poor.

6.3.5. Lessons learnt

In retrospect, given the complexities of trial recruitment, the research question “what is the likely interest in a group healthy eating programme” could not reliably be gained through a clinical trial and in effect, the outcomes were unachievable even before implementing the programme.

6.3.6. Study Two - Stage Two

6.3.6.1. Change in diet quality

Unable to assess due to numbers and quality of data.

6.3.6.2. Characteristics that predicted adherence to the programme

Unable to assess due to numbers and quality of data.

6.3.6.3. Improvement in overall health and well-being

Unable to assess due to numbers and quality of data.

6.3.6.4. Summary

Significant numbers of missing and incomplete data were found (see tables 10-1and 10-2). In total of the 105 sets of data that should have been completed, 23 (22%) was missing and all 17 (100%) food frequency questionnaires were unable to be analysed due to incomplete data.

Data form	Incomplete	Missing
Food frequency questionnaire	**17/21**	4/21
Multidimensional health locus of control	1/21	4/21
Self rated diet	0/21	6/21
Body mass index	0/21	2/21
Self esteem	0/21	5/21

Table 6-1 Summary of incomplete/missing data at baseline

Data form	Incomplete	Missing
Food frequency questionnaire	8/10	2/10
Body mass index	0/10	3/10
Self esteem	0/10	2/10

Table 6-2 Summary of incomplete/missing data at six-month follow-up

Despite both verbal and written instructions on the procedures for collecting data, clearly, serious problems with data collection was evident. As the data was not handed over to the CI until recruitment for the study had closed, these problems were not identified until it was too late. As per the study protocol, all data forms were to be scanned independently and therefore no provision was made for early collection of forms. In hindsight, a random sample of the data forms should have been collected for quality assurance purposes. Had this occurred, the issue of poor data would have been identified at an earlier date and could have been rectified.

A search of the scientific literature revealed little evidence for the scope and nature of poor data quality and therefore the extent to which it affects the overall integrity of research is difficult to assess.

In 2004 Wood et al[125] reviewed all published randomised trials over a six month period in 2001 from four high impact journals to examine how missing outcome data was both reported and examined. In total 71 trials were analysed, of which 89% reported missing outcome data and of these only 40% reported reasons for the missing data. 20% reported more than one-fifth of the outcome data missing. In concluding, the authors state missing outcome data is common in randomised controlled trials and often these missing data are inadequately dealt with in the statistical analysis.

Both the local research ethics committee and NHS trust R&D department were contacted requesting information on recruitment rates and prevalence of missing or incomplete data in locally conducted trials. On both counts no information was forthcoming.

The impact of the study could not be assessed as the problems which occurred during implementation compromised the ability of the study to achieve its goals and objectives

6.3.7. Lessons learned

The success of any health promotion programme is inextricably linked to how well the implementation phase has been executed. The belief that careful planning would ensure successful implementation

was ill-founded. Clearly, equal importance must be placed on ensuring the protocol is carried out as planned. Ultimately, failure to do this led to the failure of the study to meet its goals and objectives. In future, an impact assessment will be designed a priori and form part of any further research proposals.

6.3.8. Outcome assessment

The purpose of outcome evaluation is to demonstrate that the intervention was effective, affordable and well implemented. If these elements can be demonstrated, the intervention can lead to programme replication studies thus resulting in large scale evidence based health promotion activities. Clearly, the current study did not provide this evidence.

6.3.9. Assessment

Outcomes were not achieved

6.3.10. Lessons learnt

Poor implementation led to the failure of this study emphasising the importance of ensuring adequate quality control measures during the implementation phase are in place prior to commencement. This in turn will improve the likelihood that outcomes are achieved.

6.4. Evaluation summary

The following table sets out lessons learned whilst conducting this study which will be carried through when planning future research.

Type of evaluation	Lesson
Formative evaluation	Ensure good local support for the study Ensure good understanding of procedures for adopting studies in local research portfolios
Process evaluation	Test methods prior to implementation Ensure clear job roles and responsibilities are set up and agreed if outsourcing work
Outcome evaluation	Ensure implementation phase is well executed Ensure adequate quality assurance methods are in place for data collection

Table 6-3 Summary of lessons learnt

6.5. Chapter summary

The results of this study suggest that in this cohort of postmenopausal women newly diagnosed with breast cancer, interest in attending a group healthy eating was limited. However, given the lack of statistical power due to inadequate screening procedures identifying and subsequently inviting women to participate, the observed recruitment rates cannot be generalised to all postmenopausal women newly diagnosed with breast cancer.

Further, for those women who participated in the programme, the effects of the programme were undeterminable due to poor data quality.

Not only should the results of this study be interpreted with caution for the reasons aforementioned, but in addition, it is plausible that the results of this study reflect interest in clinical trial participation as opposed to interest in a group healthy eating programme as highlighted by the scientific literature on the challenges in clinical trial recruitment.

Overall the failure of the study in meeting its aims and objectives can be attributed to the lack of women invited to attend the group health eating programme. This came about largely due to the withdrawal of one site from the study and inadequate screening procedures at the remaining NHS trust. Both these problems could have potentially been avoided had appropriate procedures been in place to identify and deal with non compliance to the study's protocol. Failure to ensure such safeguards were in place prior to implementation was due to inexperience on the part of the chief investigator who in assessing the risk benefit ratio of intervening in the working environment of the NCRN staff and policies, and in the interest of future collaborations, chose the path of least resistance. This proved to be a costly judgement.

Chapter Seven

Conclusions

7.0 Conclusions

In undertaking the current study, it was clear that conducting clinical research in the NHS, particularly as a sole local investigator posed many challenges. During the course of this Doctoral programme, research culture in the UK has gone through many changes. For example ethical and NHS trust approval has been streamlined with a central application replacing the two application process which was in practice during this study. Had such measures been in place, study approvals would have been much timelier, potentially allowing more time (several months) to appropriately assess and rectify non compliance to the study protocol. One potential outcome may have been to restart recruitment once it was known that not all women were being identified and subsequently being invited to attend the group healthy eating programme.

Secondly, in very recent times there has been a move to ensure transparency and accountability for all research staff including employees of the National Cancer Research Network with the publication of the Cancer Research Network Measures (as part of the Manual for Cancer Services) and the proposed Model Clinical Trials Agreements being extended to include non-commercial research. Further, plans are underway to ensure appropriate training and certification of research nurses. In totality, these measures will ensure improvements in the conduct and therefore the outcomes of clinical research in the UK, a key goal if the UK is remain a competitive environment for multi-national research programmes.

7.1. Direction of future research

Given the study was unable to estimate what level of interest newly diagnosed women with breast cancer have in a group healthy eating programme, and whether attending such a programme led to improvements in overall health and well-being, should this study be undertaken again?

To answer this question, the assumptions that underpinned this trial must be revisited. At the time of conceiving this project, several key drivers were identified including; Current services failing to meet the long term health needs of this patient group, patient interest and improving patient health outcomes.

7.1.1. Current NHS services

Since this project started there has been no change in health service provision for breast cancer patients. Health service policy continues to highlight the need for expansion and diversification of cancer services and the issue remains high on the NHS agenda.[126] [127]

Further, with the 2007 recommendation[19] by the worlds leading cancer charity (WCRF) that all new cancer patients receive nutrition counselling, it could be argued that research in the role for diet in secondary cancer prevention remains current and valid.

That said, in the period between submitting this thesis for examination and addressing reviewer's comments, an important document has been published by the Department of Health in relation to this issues.

On December 17, 2008 the Rehabilitation Measures as part of the revised Manual for Cancer Services 2008 were issued.[128] These measures mandate the establishment of a network cancer rehabilitation lead and a network cancer rehabilitation group. The remit of the cancer rehabilitation team is to:

1. conduct a baseline mapping of the current provision of cancer rehabilitation
2. develop cancer site specific rehabilitation pathways
3. develop a service specification
4. conduct a service needs assessment
5. develop a training and education strategy from the outcomes of the needs assessment

The above rehabilitation measures apply specifically to four allied health professions; Physiotherapy, Occupational Therapy, Speech and Language Therapy and importantly **Dietetics**.

These measures should ensure that future services better meet the needs and expectation of cancer patients. Specifically, if the baseline mapping and subsequent needs assessment process is conducted as planned, nutrition education should become, in future part of routine care pathway.

7.1.2. Patient interest

As discussed previously little evidence exists to estimate the likely interest in health promotion activities for newly diagnosed breast cancer patients. Inferences can only be drawn from intervention studies with outcomes not focused on uptake in health promotion activities. As the rehabilitation measures are introduced, service evaluation will provide this evidence.

7.1.3. Improving patient health outcomes

With survival rates from breast cancer continuing to rise to unprecedented levels, the need to look at ways to provide health care that addresses the long term needs of this patient group remains as it was prior to commencing this study.

Prior to commencing this study, two large scale randomised controlled trials were underway in the US to determine if dietary modifications could influence survival rates in postmenopausal women diagnosed with breast cancer. During the course of this study, both those trials published their findings. In the WHEL study, no link between a healthy diet and breast cancer outcomes were found, and in the WINS study, the authors report an effect with a low fat diet on recurrence and survival however these findings remain controversial in the literature. Therefore, currently no strong scientific evidence exists to show that changing dietary behaviours after diagnosis influences breast cancer outcomes.

7.1.4. Summary

In summary, the implementation of the Rehabilitation Measures for Cancer Services will ensure future service provision will address the broader health needs of cancer patients therefore negating the need for future research into the level of interest in health promotion programmes in this patient group. Providing the implementation of the measures is evaluated as planned, this information will be available for future service development initiatives.

7.2. Personal statement

At times I struggled with the fact that this study failed to meet its aims and objectives. However the many and varied challenges I was presented with during the course of this project and the lessons learnt from dealing with those challenges, provided me with an exceptional learning opportunity.

Specifically, I gained valuable experience in; applying for research funding, applying for ethical approval, applying for trust approval, setting up a steering group, setting up a research team, conflict resolution, communicating with and providing feedback to a wide range of health professionals and patients alike and lastly project management skills.

As such I feel satisfied that despite the fact the project failed to achieve its outcomes, the funding scheme which was set up to support the development of researchers did achieve its aims and objectives and in the words of Henry Ford " ***Failure is only the opportunity to begin again more intelligently".***

Chapter Eight

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Chapter Nine

Appendices

9.0 Appendices

9.1. Details of randomised controlled trials

Trial		Publications	Year of publication	Publication Title	Type of dietary intervention	Objectives	Primary Outcome
1.	**WOMENS INTERVENTION NUTRITION STUDY**						
Stage I	NAS (Nutrition Adjuvant Study)						
	Trial results	Chlebowski et al[25]	1987	A breast cancer nutrition adjuvant study (NAS): protocol design and initial patient adherence	Low fat diet	Reduce dietary fat	Total daily dietary intake of fat in grams
	As above	Chlebowski et al[26]	1990	Current Status: Evaluation of dietary fat reduction as secondary breast cancer prevention			
Stage II	Feasibility study	Chlebowski et al[27]	1993	Adherence to dietary fat intake reduction therapy for early breast cancer	Low fat diet	To evaluate the feasibility of integrating a program based on dietary fat intake reduction into adjuvant treatment strategies for postmenopausal women receiving therapy for early breast cancer	Dietary fat reduction to 20% of total energy – revised during intervention to 15%
Stage III	RCT	Chlebowski et al[28]	2007	Dietary fat reduction and breast cancer outcome: Interim efficacy results from the Women's Intervention Nutrition Study	Low fat diet	To test the hypothesis that a dietary intervention targeting fat intake reduction would prolong relapse-free survival in women with resected breast cancer	Relapse free survival

Table 9-1 Trial characteristics

Trial		Publications	Year of publication	Publication Title	Type of dietary intervention	Objectives	Primary Outcome
2.	**WOMENS HEALTHY EATING AND LIVING STUDY**						
	Feasibility study	Pierce et al[29]	1997	Feasibility of a randomized trial of a high-vegetable diet to prevent breast cancer recurrence	High vegetable, reduced fat, and increased fibre diet	To examine the feasibility of a randomized trial of diet intervention involving several major changes in the overall dietary pattern to reduce recurrence of breast cancer	Dietary change Dietary adherence
	Interim analysis on 1010 women enrolled on trial	Rock et al[129]	2001	Reduction in fat is not associated with weight loss in most women after breast cancer diagnosis: evidence from a randomized controlled trial	High vegetable, reduced fat, and increased fibre diet	Examine weight change in response to diet intervention	Weight change
	Trial Design Paper	Pierce et al[130]	2002	A randomized trial of the effect of a plant-based dietary pattern on additional breast cancer events and survival: the Women's Healthy Eating and Living Study	High vegetable, reduced fat, and increased fibre diet		
	Interim analysis of 393 women enrolled on trial	Rock et a[131]l	2004	Plasma triacylglycerol and HDL cholesterol concentrations confirm self-reported changes in carbohydrate and fat intakes in women in a diet intervention trial	High vegetable, reduced fat, and increased fibre diet	To examine the effect of increased carbohydrate and reduced fat intakes on plasma lipids	Change in plasma lipid and serum insulin concentrations
	Interim analysis of 291 women enrolled on trial	Rock et al[132]	2004	Effects of a high-fiber, low-fat diet intervention on serum concentrations of reproductive steroid hormones in women with a history of breast cancer	High vegetable, reduced fat, and increased fibre diet	To examine the effects of a high vegetable, high-fiber, low-fat diet intervention on serum concentrations of reproductive steroid hormones	Change in serum hormone and sex hormone binding globulin concentrations

Table 12-1 Trial characteristics (cont.)

Trial	Publications	Year of publication	Publication Title	Type of dietary intervention	Objectives	Primary Outcome
Results from 2970 women who had completed 1-year follow-up and had not had a breast cancer event	Pierce et al[133]	2004	Telephone counselling intervention increases intakes of micronutrient and phytochemical rich vegetables, fruit and fiber in breast cancer survivors	High vegetable, reduced fat, and increased fibre diet	Describe the effectiveness of this intervention protocol in achieving major changes in the overall dietary pattern	Change in dietary intake Change in plasma carotenoid concentrations
Subset of 77 women enrolled on trial	Thomson et al[134]	2005	Longitudinal changes in body weight and body composition among women previously treated fro breast cancer consuming a high-vegetable, fruit and fiber, low-fat diet	High vegetable, reduced fat, and increased fibre diet	To investigate the association between reported changes in dietary intake and body weight and body composition measures	Change in anthropometric and body composition measurements over 4 year period
Reporting of baseline to twelve month dietary change in 739 'on counselling' protocol Participants (adherers)	Newman et at[135]	2005	Achieving substantial changes in eating behaviour among women previously treated fro breast caner – An overview of the intervention	High vegetable, reduced fat, and increased fibre diet	Reporting of baseline to 12-month dietary change and achievement of select Healthy People 2010 dietary objectives	Change in intake of vegetables, vegetable juice, fruit, fiber and fat and the association between cooking classes attended and overall dietary adherence
Subset of 202 women enrolled on WHEL	Thomson et al[136]	2005	Diet and Biomarkers of Oxidative Damage in Women Previously Treated for Breast Cancer	High vegetable, reduced fat, and increased fibre diet	To explore the relationship between dietary intake and oxidative DNA damage	Effect of diet on oxidative damage biomarkers

Table 12-1 Trial characteristics (cont.)

Trial	Publications	Year of publication	Publication Title	Type of dietary intervention	Objectives	Primary Outcome
3. Djuric et al and Jen et al						
	Djuric et al[31]	2002	Combining weight loss counselling with the weight watchers plan for obese breast cancer survivors	Energy restriction	To develop and test individualised methods for effective weight loss in obese breast cancer survivors	Weight change
	Jen et al[32]	2004	Improvement of metabolism among obese breast cancer survivors in differing weight loss regimens	Energy restriction	To examine the possible beneficial effects of three weight loss regimens on insulin resistance and blood lipid and leptin levels in obese breast cancer survivors	Change in cholesterol, insulin and leptin levels
4. Holm et al and Nordevang et al						
	Holm et al[33]	1990	Dietary intervention as adjuvant therapy in breast cancer patients a feasibility study	Low fat diet (20-25% of total energy)	To evaluate the feasibility of using a low fat diet as a component of adjuvant therapy for breast cancer patients	Change in dietary fat intake
	Nordevang et al[34]	1990	Dietary intervention in breast cancer patients: effects on dietary habits and nutrient intake			
	Nordevang et al[35]	1992	Dietary intervention in breast cancer patients: effects on food choice			

Table 12-1 Trial characteristics (cont.)

Trial		Publications	Year of publication	Publication Title	Type of dietary intervention	Objectives	Primary Outcome
5.	**BRIDGES**						
		Herbert et al[36]	2001	Change in Women's diet and body mass following intensive intervention for early-stage breast cancer	Low fat (20%), high fiber and micronutrients from plant sources	To report on the effect of an intensive dietary intervention on dietary factors	Change in dietary fat intake
6.	**de Waard et al**						
		De Waard et al[37]	1993	A feasibility study on weight reduction in obese postmenopausal breast cancer patients	Low fat diet	Feasibility study of weight reduction in obese postmenopausal women	Weight change
7.	**BCDIP**						
		Kristal et al[86]	1997	Feasibility of using volunteer research staff to deliver and evaluate a low-fat dietary intervention: the American cancer society breast cancer dietary intervention project	Low fat diet	To examine whether a randomized trial using community volunteers could recruit study participants, deliver and monitor the intervention and achieve intervention goals	Change in dietary fat intake

Table 12-1 Trial characteristics cont.

	Study Title or Author	Group allocation	Details of nutrition intervention	Dietary Assessment Method	Duration of diet intervention	Duration of Study	Dietary Assessment schedule
1.	**WOMENS INTERVENTION NUTRITION STUDY[24-28]**						
Stage I	Nutrition Adjuvant Study	1. Attention Control	Fortnightly for 1st 3 months then once a month up to one year	4 day food records	1 year	1 year	0,3,6,12 months
		2. Intervention	Fortnightly for 1st 3 months then once a month up to one year				
Stage II	Feasibility study	1. Attention Control	Fortnightly for 1st 3 months then once a month up to one year	3 unannounced, 24-hr dietary recalls	1 year	1 year	0,3,6,12 months
		2. Intervention	Fortnightly for 1st 3 months then once a month up to one year				
Stage III	RCT	1. Control		24 hr diet recalls	2 years	5 years	
		2. Intervention					
2.	**WOMENS HEALTHY EATING AND LIVING STUDY[29 30]**						
	Feasibility study	1. Control	Not reported	Repeated 24-hr diet recall	Not reported	1 year	0,6,12 months
		2. Intervention					
	RCT	1. Control	Telephone counselling - Cooking classes - monthly Print material - monthly	24 hour diet recall and FFQ		5 years	0,6,12,24,36,48,72 months
		2. Intervention					

Table 9-2 Intervention details

	Study Title or Author	Group allocation	Details of nutrition intervention	Dietary Assessment Method	Duration of diet intervention	Duration of Study	Dietary Assessment schedule
3.	**Djuric et al and Jen et al[31 32]**						
		1. Attention Control	Written materials on healthy eating	3 day food records	1 year	1 year	0,3,6,12 months
		2. Weight Watchers (WW)	Encouraged to attend WW with no other diet or exercise instruction				
		3. Individualised counselling	Weekly telephone contacts by dietitian for 1st 3 months, biweekly for months 3 and 6 and monthly thereafter. Plus monthly meeting where written information was distributed				
		4. WW and individualised counselling	Weekly telephone contacts by dietitian for 1st 3 months, biweekly for months 3 and 6 and monthly thereafter. Plus encouraged to attend WW meetings.				
4.	**Holm et al and Nordevang et al[33-35]**						
		1. Control 2. Intervention	Individualised dietary counselling to reduce fat over 4-6 sessions over two months	Diet history interview 4 day food records	2 months	2 years	0,3,6,9,12 and 24 months

Table 12-2 Intervention details (cont.)

	Study Title or Author	Group allocation	Details of nutrition intervention	Dietary Assessment Method	Duration of diet intervention	Duration of Study	Dietary Assessment schedule
5.	**BRIDGES[36]**						
		1. Control	Usual care - no intervention	7 day diet recall using FFQ		1 year	0,4,12
		2. Nutrition Intervention	2 x individual sessions, 1st (60 mins) at beginning of program and 2nd (30 mins) at the end of the program and 15 (14 x 150 mins and 1 5.5 hour) x dietetic led group sessions. Sessions were held weekly.				
		3. Stress reduction intervention	Equivalent contact time with psychologists. There was no nutrition material presented.				
6.	**de Waard et al[37]**						
		1. Control	Not reported	Not reported	Not reported	1 year	Not reported
		2. Intervention					
7.	**BCDIP[38]**						
	Kristal et al	1. Control	6 x one hour weekly individual sessions then monthly 1 hour group sessions x 10	4 day food record	1 year	1 year	0,3,6 and 12 months
		2. Intervention					

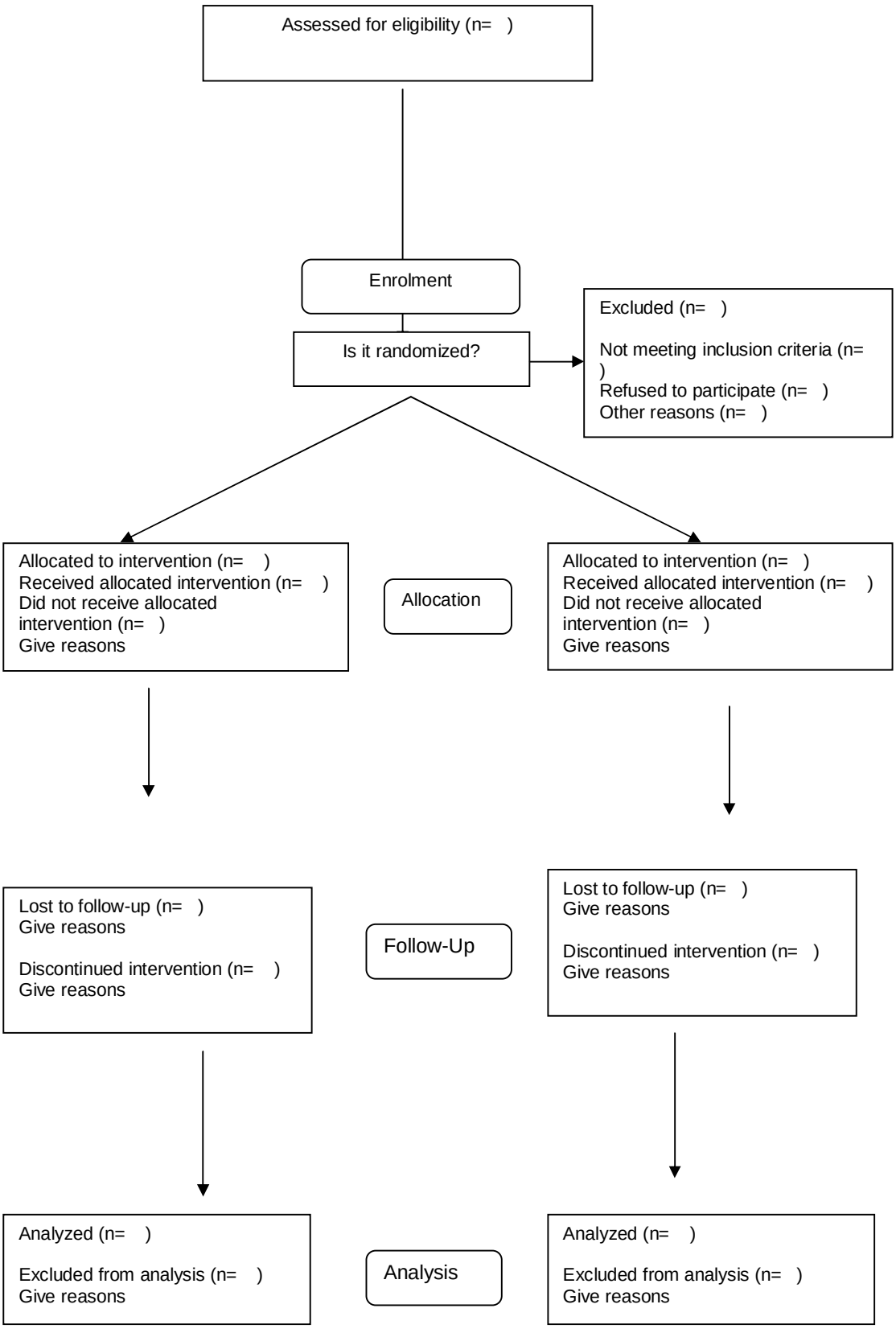
Table 12-2 Intervention details (cont.)

9.2. CONSORT Checklist

PAPER SECTION And topic	Item	Description
TITLE & ABSTRACT	1	How participants were allocated to interventions (*e.g.*, "random allocation", "randomized", or "randomly assigned").
INTRODUCTION Background	2	Scientific background and explanation of rationale.
METHODS Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.
Objectives	5	Specific objectives and hypotheses.
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (*e.g.*, multiple observations, training of assessors).
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (*e.g.*, blocking, stratification)
Randomization -- Allocation concealment	9	Method used to implement the random allocation sequence (*e.g.*, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.
RESULTS Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned,

		together with reasons.
Recruitment	14	Dates defining the periods of recruitment and follow-up.
Baseline data	15	Baseline demographic and clinical characteristics of each group.
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (*e.g.*, 10/20, not 50%).
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (*e.g.*, 95% confidence interval).
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.
Adverse events	19	All important adverse events or side effects in each intervention group.
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.
Generalizability	21	Generalizability (external validity) of the trial findings.
Overall evidence	22	General interpretation of the results in the context of current evidence.

The Consort E-Flowchart Aug. 2005



9.3. Recruitment matrix for focus groups

1	Single Person Household, Working, no children, recently diagnosed
2	Single Person Household, Working, no children, diagnosed 1-3 yrs ago
3	Single Person Household, Working, no children, diagnosed >5 yrs ago
4	More than 1 Person Household, working, no children, recently diagnosed
5	More than 1 Person Household, working, no children, diagnosed 1-3 yrs ago
6	More than 1 Person Household, working, no children, diagnosed >5 yrs ago
7	Single Person Household, Working, with children, recently diagnosed
8	Single Person Household, Working, with children, diagnosed 1-3 yrs ago
9	Single Person Household, Working, with children, diagnosed >5 yrs ago
10	More than 1 Person Household, working, with children, recently diagnosed
11	More than 1 Person Household, working, with children, diagnosed 1-3 yrs ago
12	More than 1 Person Household, working, with children, diagnosed >5 yrs ago
13	Single Person Household, Retired, recently diagnosed
14	Single Person Household, Retired, diagnosed 1-3 yrs ago
15	Single Person Household, Retired, diagnosed >5 yrs ago
16	More than 1 Person Household, Retired, recently diagnosed
17	More than 1 Person Household, Retired, diagnosed 1-3 yrs ago
18	More than 1 Person Household, Retired, diagnosed >5 yrs ago

9.4. Covering letter for focus groups

Date:

Dear

Re: Study entitled 'Reshaping Breast Care Services – A Role for Dietitians?'

I am writing to inform you that our Breast Unit has agreed to take part in a small study to identify:

- if Breast Cancer patients would like to have nutrition education as part of their standard care pathway
- if so, what type of programme would they like implemented.

The study will take the form of a focus group, which will be held on (date).

I am enclosing a copy of the patient information sheet for your information. However, if you have any questions please do not hesitate to contact the lead investigator, Jillian Milne.

With kind regards

Consultant Breast Surgeon

✂_____

Reply slip

Please reply by…….. A phone call or email will do instead of the reply slip.

To: Jillian Milne
State Registered Dietitian
Tel (direct line)
Email

I will be attending the focus group on

Name ……

If you are coming to the group, please could you give a contact phone number so that Jillian can contact you if necessary. Please contact Jillian if you have any questions about the group or need directions.

Please note: As some participants may still be having treatment for their breast cancer, we would be grateful if you would consider others by not attending the meeting if you have an acute infection. If this is the case we would ask that you notify us on the day.

9.5. Patient information sheet

Reshaping Breast Care Services – A Role for Dietitians?

My colleague (Consultant Surgeon) is forwarding this information sheet to you on my behalf. My name is Jillian Milne and I am a State Registered Dietitian. I have recently begun postgraduate studies with the School of Medicine at the University of Southampton looking at the care given to Breast Cancer Patients in the NHS.

This letter is to invite you to consider participating in my study. Before you decide if you would like to take part it is important that you understand what your participation may involve. I would therefore be grateful for a few moments of your time to read the following information and to discuss it with your family and/or friends if you so wish.

Background

In my previous position as the Research Dietitian with the Winchester and Eastleigh NHS Trusts Breast Care Unit, I had the opportunity to meet many breast cancer patients, some of whom expressed their concern about the lack of nutrition advice given at the time of their diagnosis. Now that a holistic approach to care is being taken and diet for a general healthy lifestyle is an area of interest to Breast Cancer patients, I applied for and have received funding from the Department of Health to conduct some research on piloting a nutrition education programme for newly diagnosed breast cancer patients.

The study will be conducted in three parts and I am writing to you today to ask if you would be interested in taking part in the first stage of the study. The first stage of the project will be conducting group discussions called 'focus groups' with around 10-12 current and past breast cancer patients. The purpose of these discussions is to get your views and opinions on the type of nutrition programme you would like to see in the NHS, as ultimately the success of the programme will depend on its acceptance to breast cancer patients.

What would participation involve?

The focus group I am inviting you to attend is to be held on (date). During this time I would like you and the other participants to discuss and comment on the type of nutrition programme you would like to see offered to breast cancer patients.

We are very interested in your views and want to make sure we capture all the comments made during the focus group and for this reason the discussion will be audio taped. The audio will be analysed to draw out the main themes at a later date and this information along with some handwritten notes taken during the focus group will be compiled into a report detailing recommendations for the development of the nutrition education program to be run in stage two. The audio tapes will be stored for 15 years in line with the data protection policy of the University of Southampton. All information from the discussion will be anonymised and therefore no personal details will be retained.

Will I benefit from the study?

This study will have no direct benefit to you as you have either begun or finished your treatment and the programme will be aimed at newly diagnosed breast cancer patients. However the information obtained will help to inform my colleagues and myself as to how we can improve things for future patients.

What do I need to do if I decide to take part?

Please return the reply slip to me in the enclosed envelope (retain this copy of the patient information sheet for your future reference). On the day I will then ask you to sign a consent form. This is nothing to be alarmed about. The consent form gives your permission for me to share the information with colleagues outside of (Relevant NHS Trust) The information that I will obtain will not contain any of your personal details; therefore you anonymity will be assured.

What if I decide not to take part?

If you decide not participate in the study you need take no further action.

Who do I contact if I have any further questions?

Please feel free to telephone me on the above number, which is a direct line. I would be more than happy to discuss this study in more detail with you.

Thank you for your time in reading this information sheet.

Jillian Milne

9.6. Consent form for focus groups

Title of Project: Reshaping Breast Care Services – A Role for Dietitians?

Name of Researcher: Jillian Milne

Please initial box

1. I confirm that I have read and understand the patient information sheet dated ..... (version .....) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that sections of any of my medical notes may be looked at by responsible individuals from [hospital/institution] or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

4. I agree to take part in the above study. ☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent (if different from researcher)	Date	Signature
_____	_____	_____
Researcher	Date	Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes

9.7. GP letter for focus groups

Date

Dear Dr ……..

Re: Patients Name ……..
DOB ……/……/……

I are writing to inform you that this lady has agreed to take part in a focus group looking at ways to improve current services offered to breast cancer patients. Please find enclosed a leaflet regarding this Study.

……. will be attending a group session on …….. at ……..

Ethical approval for this Study has been obtained and it is funded by the Department of Health's - National Co-ordinating Centre for Research Capacity Development.

I would be pleased to discuss any aspects of this Study with you should you require any more information.

Yours sincerely

Jillian Milne SRD
Research Dietitian

Enc – Patient Information Sheet

9.8. Rosenberg Self-Esteem Scale (Rosenberg, 1965)

Trial Number	:	☐☐☐☐☐
Date	:	☐☐ / ☐☐ / ☐☐☐☐

The scale is a ten item Likert scale with items answered on a four point scale - from strongly agree to strongly disagree. The original sample for which the scale was developed consisted of 5,024 High School Juniors and Seniors from 10 randomly selected schools in New York State.

Instructions:

Attached is a list of statements dealing with your general feelings about yourself. If you strongly agree, circle **SA**. If you agree with the statement, circle **A**. If you disagree, circle **D**. If you strongly disagree, circle **SD**.

	Strongly Agree	Agree	Disagree	Strongly Disagree
1. On the whole, I am satisfied with myself	SA	A	D	SD
2. At times, I think I am no good at all	SA	A	D	SD
3. I feel that I have a number of good qualities	SA	A	D	SD
4. I am able to do things as well as most other people	SA	A	D	SD
5. I feel I do not have much to be proud of	SA	A	D	SD
6. I certainly feel useless at times	SA	A	D	SD
7. I feel that I'm a person of worth, at least on an equal plane with others	SA	A	D	SD
8. I wish I could have more respect for myself	SA	A	D	SD
9. All in all, I am inclined to feel that I am a failure	SA	A	D	SD
10. I take a positive attitude toward myself	SA	A	D	SD

The scale may be used without explicit permission. The author's family, however, would like to be kept informed of its use:

The Morris Rosenberg Foundation
c/o Department of Sociology
University of Maryland
2112 Art/Soc Building
College Park, MD 20742-1315

References

References with further characteristics of the scale:

Crandal, R. (1973). The measurement of self-esteem and related constructs, Pp. 80-82 in J.P. Robinson & P.R. Shaver (Eds), Measures of social psychological attitudes. Revised edition. Ann Arbor: ISR.

9.9. Multidimensional Health Locus of Control Questionnaire

Trial Number : ☐☐☐☐☐

Date : ☐☐ / ☐☐ / ☐☐☐☐

This is a questionnaire designed to determine the way in which different people view certain important health-related issues. Each item is a belief statement with which you may agree or disagree. Beside each statement is a scale which ranges from strongly disagree (1) to strongly agree (6).

For each item we would like you to circle the number that represents the extent to which you disagree or agree with the statement. The more strongly you agree with a statement, then the higher will be the number you circle. The more strongly you disagree with a statement, then the lower will be the number you circle. Please make sure that you answer every item and that you ***circle only one number per item***. This is a measure of your personal beliefs: obviously, there are no right or wrong answers.

Please answer these items carefully, but do not spend too much time on any one item. As much as you can, try to respond to each item independently. When making your choice, do not be influenced by your previous choices. It is important that you respond according to your actual beliefs and not according to how you feel you should believe or how you think we want you to believe.

	Strongly Disagree	Moderately Disagree	Slightly Disagree	Slightly Agree	Moderately Agree	Strongly Agree
1. If I get sick, it is my own behaviour which determines how soon I get well again	1	2	3	4	5	6
2. No matter what I do, if I am going to get sick, I will get sick	1	2	3	4	5	6
3. Having regular contact with my doctor is the best way for me to avoid illness	1	2	3	4	5	6
4. Most things that affect my health happen to me by accident	1	2	3	4	5	6
5. Whenever I don't feel well, I should consult a medically trained professional	1	2	3	4	5	6
6. I am in control of my health	1	2	3	4	5	6
7. My family has a lot to do with my becoming sick or staying healthy	1	2	3	4	5	6
8. When I get sick, I am to blame	1	2	3	4	5	6
9. Luck plays a big part in determining how soon I will recover from an illness	1	2	3	4	5	6
10. Health professionals control my health	1	2	3	4	5	6
11. My good health is largely a matter of good fortune	1	2	3	4	5	6
12. The main thing which affects my health is what I myself do	1	2	3	4	5	6
13. If I take care of myself, I can avoid illness	1	2	3	4	5	6
14. When I recover from an illness, it's usually because other people (for example, doctors, nurses, family, friends) have been taking good care of me	1	2	3	4	5	6
15. No matter what I do, I'm likely to get sick	1	2	3	4	5	6
16. If it's meant to be, I will stay healthy	1	2	3	4	5	6
17. If I take the right actions, I can stay healthy	1	2	3	4	5	6
18. Regarding my health, I can only do what my doctor tells me to do	1	2	3	4	5	6

9.10. Food Frequency Qestionnaire (HEA3)

Trial Number	:	☐☐☐☐☐
Date	:	☐☐ / ☐☐ / ☐☐☐☐

This is a questionnaire designed to assess your **USUAL** diet.

The questionnaire contains a list of foods and beverages. Please mark YOUR '**AVERAGE' SERVING / PORTION SIZE** (small, medium, large) for different foods, and **HOW OFTEN** you eat them. If you do not normally eat the food please put a zero (0) in the month column.

This is followed by some additional questions asking for more detailed information about the types of foods you eat and the cooking methods you use. Finally we would like you to rate how healthy you believe your usual diet is.

EXAMPLE SHOWN AT TOP OF TABLE: This person eats a large bowl of cereal four times a week and 2 slices of bread per day.

TBLSP = rounded tablespoon. TSP = rounded teaspoon.

Food	Medium Serving	Your Serving Size			How Often		
		S	M	L	Day	Week	Month
Example: Bread	2 medium slices	☒	☐	☐	1		
Example: Cereal	Average bowl / 3 TBLSP	☐	☐	☒		4	
BREAD / CEREAL / POTATOES							
Bread / toast	2 medium slices	☐	☐	☐			
Breadfast cereal	average bowl / 3 TBLSP	☐	☐	☐			
Crackers / crispbread	3 Crackers / slices crispbread	☐	☐	☐			
Bun / roll	1 Bun / roll	☐	☐	☐			
Pitta / Chapati	1 small piece(not "mini")	☐	☐	☐			
Rice / pasta / noodles	average serving (=6 TBLSP)	☐	☐	☐			
Plaintains / green bananas / sweet potatoes	1 Plaintains or green bananas / 2 sweet potatoes	☐	☐	☐			
Potatoes (not chips)	3 egg-sized potatoes	☐	☐	☐			
FRUIT / VEGETABLES							
Vegetables (fresh/frozen/tinned)	medium serving (2 TBLSP)	☐	☐	☐			
SaladBreadfast cereal	medium serving (3 TBLSP)	☐	☐	☐			
Stewed or tinned fruit	medium serving (3 TBLSP)	☐	☐	☐			
Fresh fruit	1 apple, orang or banana / small bunch grapes / slice melon	☐	☐	☐			
Fruit juice	average glass (160ml)	☐	☐	☐			
MEAT / ALTERNATIVES							
Lean meat / fish / chicken (no skin)	4oz / 4 fish finger (=small pack of playing cards)	☐	☐	☐			

Food	Medium Serving	Your Serving Size			How Often		
		S	M	L	Day	Week	Month
Sausages, burgers, luncheon meat etc.	3 small sausages, 2 burgers, 2 slices luncheon meat	☐	☐	☐	☐	☐	☐
All other meat (e.g. beef, chops etc. with visible fat, chicken with skin, bacon etc.	4oz (=small pack of playing cards size)	☐	☐	☐	☐	☐	☐
Sausage rolls / meat pie	1 individual pie, 2 sausage rolls	☐	☐	☐	☐	☐	☐
Eggs	2 medium	☐	☐	☐	☐	☐	☐
Beans/ lentils / dhal	3 TBLSP	☐	☐	☐	☐	☐	☐
Nuts / peanut butter	1 TBLSP / small bag	☐	☐	☐	☐	☐	☐
CAKES, PUDDINGS AND SNACKS							
Donut, cake	1 piece	☐	☐	☐	☐	☐	☐
Pudding, fruit pie, danish pastry	1 piece / average bowl	☐	☐	☐	☐	☐	☐
Biscuits	3 small biscuits	☐	☐	☐	☐	☐	☐
Chocolate	small bar	☐	☐	☐	☐	☐	☐
Ice cream	1 scoop, 1 choc-ice, 1 King cone	☐	☐	☐	☐	☐	☐
Crisps, peanuts etc.	1 small bag (25g)	☐	☐	☐	☐	☐	☐
SUGAR							
Sugar	1 TSP	☐	☐	☐	☐	☐	☐
DRINKS							
Squash / frizzy drinks	1 can (330ml), average glass (250ml)	☐	☐	☐	☐	☐	☐
diet / slimline / sugar free drinks	1 can, 1 average glass	☐	☐	☐	☐	☐	☐
tea	1 cup	☐	☐	☐	☐	☐	☐
coffee	1 cup	☐	☐	☐	☐	☐	☐
alchoholic drinks	1 glass wine, 1/2 pint beer, 1 tot spirits / liqueur (pub measure)	☐	☐	☐	☐	☐	☐

Food	Medium Serving	Your Serving Size			How Often		
FATS		**S**	**M**	**L**	**Day**	**Week**	**Month**
Fried or oily food	e.g. medium portion chips (3/4 cup), 2 fried eggs, 2 rashes fried bacon	☐	☐	☐	☐	☐	☐
Margerin or butter	1 pat	☐	☐	☐	☐	☐	☐
low fat spread	1 pat	☐	☐	☐	☐	☐	☐
cooking oil / fat / ghee	1 level TBLSP	☐	☐	☐	☐	☐	☐
Mayonnaise / oily salad dressing	1 level TBLSP	☐	☐	☐	☐	☐	☐
MILK AND DAIRY							
Full fat milk	1/3 pint (200ml)	☐	☐	☐	☐	☐	☐
Semi-skimmed milk	1/3 pint (200ml)	☐	☐	☐	☐	☐	☐
Skimmed milk	1/3 pint (200ml)	☐	☐	☐	☐	☐	☐
Cheese	small matchbox	☐	☐	☐	☐	☐	☐
Yoghurt / cottage cheese / fromage frais	small pot	☐	☐	☐	☐	☐	☐

Please Turn Over

ADDITIONAL QUESTIONS:

1. Do you usually use wholemeal / high finer / granary bread? ☐ Yes ☐ No

   If yes, Please specify type: _____

2. Do you use a high fiber breakfast cereal? ☐ Yes ☐ No

   e.g. Alpen, museli, all bran, Jorden's crunchy, shredded wheat, weetabix, porriadge oats, shreddies, fruit n' fiber

   If yes, Please specify type: _____

3 a) Do you usually use brown or wholegrain rice or pasta or eat potatoes with skins on? ☐ Yes ☐ No

   If yes, Please specify type: _____

   b) If yes, please tick whichever you normally eat:

   I) Wholegrain rice ☐ Yes ☐ No

   II) Wholewheat pasta ☐ Yes ☐ No

   III) Potatoes with skin ☐ Yes ☐ No

4 a) Do you use low fat spread, low fat cheese or low fat yoghurt? ☐ Yes ☐ No

   b) If yes, please tick whichever you normally eat / use:

   I) low fat hard cheese ☐ Yes ☐ No

   Specify type here _____

   II) low fat soft cheese ☐ Yes ☐ No

   Specify type here _____

   III) low fat yoghurt ☐ Yes ☐ No

   Specify type here _____

   IV) low fat spread ☐ Yes ☐ No

   Specify type here _____

   V) very low fat spread ☐ Yes ☐ No

   Specify type here _____

5. What sort of oil / fat do you usually use for frying?	**(pleae tick ONE only)**	
I) lard / dripping / butter or ghee	☐ Yes	☐ No
II) blended vegetable oil	☐ Yes	☐ No
III) polyunsaturated oil e.g. sunflower	☐ Yes	☐ No
IV) monosaturated oil e.g. olive, nut	☐ Yes	☐ No
6. What kind of spreading fat do you usually use?	**(pleae tick ONE only)**	
I) Butter	☐ Yes	☐ No
II) ordinary margerin (e.g. Stork)	☐ Yes	☐ No
III) polyunsaturated margerin (e.g. sunflower)	☐ Yes	☐ No
IV) monosaturated margerin(e.g. olive, rapeseed)	☐ Yes	☐ No
V) low fat spread (e.g. Gold, Delight)	☐ Yes	☐ No
VI) very low fat spread (e.g. Gold Lowest)	☐ Yes	☐ No
7. a) Do you use salt in cooking?	☐ Yes	☐ No
b) Do you add salt to food at the table?	☐ Yes	☐ No
*If **YES**, do you add salt at the table without tasting?*	☐ Yes	☐ No

8. To what extent do you agree or disagree that you have a healthy diet overall? **(please tick ONE only)**

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
☐	☐	☐	☐	☐

9.11. Fact-ES Questionnaire (Version 4)

Trial Number	:	☐☐☐☐☐
Date	:	☐☐ / ☐☐ / ☐☐☐☐

Attached is a list of statements that other people with your illness have said are important.

By circling one (1) number per line, please indicate how true each statement has been for you **during the past 7 days.**

PHYSICAL WELL-BEING	*Not at all*	*A little bit*	*Some-what*	*Quite a bit*	*Very Much*
1. I have a lack of energy	0	1	2	3	4
2. I have nausea	0	1	2	3	4
3. Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
4. I have pain	0	1	2	3	4
5. I am bothered by side effects of treatment	0	1	2	3	4
6. I feel ill	0	1	2	3	4
7. I am forced to spend time in bed	0	1	2	3	4

SOCIAL / FAMILY WELL-BEING	*Not at all*	*A little bit*	*Some-what*	*Quite a bit*	*Very Much*
1. I feel close to my friends	0	1	2	3	4
2. I get emotional support from my family	0	1	2	3	4
3. I get support from my friends	0	1	2	3	4
4. My family has accepted my illness	0	1	2	3	4
5. I am satisfied with family communication about my illness	0	1	2	3	4
6. I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box here ☐ *and go to the next section.*					
7. I am satisfied with my sex life	0	1	2	3	4

EMOTIONAL WELL-BEING	*Not at all*	*A little bit*	*Some-what*	*Quite a bit*	*Very Much*
1. I feel sad	0	1	2	3	4
2. I am satisfied with how I am coping with my illness .	0	1	2	3	4
3. I am losing hope in the fight against my illness	0	1	2	3	4
4. I feel nervous	0	1	2	3	4
5. I worry about dying	0	1	2	3	4
6. I worry that my condition will get worse	0	1	2	3	4

FUNCTIONAL WELL-BEING	*Not at all*	*A little bit*	*Some-what*	*Quite a bit*	*Very Much*
1. I am able to work (include work at home)	0	1	2	3	4
2. My work (include work at home) is fulfilling	0	1	2	3	4
3. I am able to enjoy life	0	1	2	3	4
4. I have accepted my illness	0	1	2	3	4
5. I am sleeping well	0	1	2	3	4
6. I am enjoying the things I usually do for fun	0	1	2	3	4
7. I am content with the quality of my life right now	0	1	2	3	4

ADDITIONAL CONCERNS	*Not at all*	*A little bit*	*Some-what*	*Quite a bit*	*Very Much*
1. I have hot flushes	0	1	2	3	4
2. I have cold sweats	0	1	2	3	4
3. I have night sweats	0	1	2	3	4
4. I have vaginal discharge	0	1	2	3	4
5. I have vaginal itching/irritation	0	1	2	3	4
6. I have vaginal bleeding or spotting	0	1	2	3	4
7. I have vaginal dryness	0	1	2	3	4
8. I have pain or discomfort with intercourse	0	1	2	3	4
9. I have lost interest in sex	0	1	2	3	4
10. I have gained weight	0	1	2	3	4
11. I feel lightheaded (dizzy)	0	1	2	3	4
12. I have been vomiting	0	1	2	3	4
13. I have diarrhea	0	1	2	3	4
14. I get headaches	0	1	2	3	4
15. I feel bloated	0	1	2	3	4
16. I have breast sensitivity/tenderness	0	1	2	3	4
17. I have mood swings	0	1	2	3	4
18. I am irritable	0	1	2	3	4
19. I have pain in my joints	0	1	2	3	4

9.12. Covering letter for healthy eating programme

Date

Dear

I am writing to you as our Breast Unit is participating in a research study with the University of Southampton. The study is looking at whether a group healthy eating programme would be of interest for women who have had a recent diagnosis of breast cancer.

I have enclosed a patient information sheet which provides complete details about the study including the contact details of the research team.

Yours sincerely

CONSULANT BREAST SURGEON

9.13. Patient information sheet for healthy eating programme

University of Southampton

Patient information sheet

Uptake and response to dietary intervention

in women with breast cancer

PART 1

You are being invited to take part in a research study to see whether a group "healthy eating" programme would be beneficial for newly diagnosed breast cancer patients. Before you decide whether or not to participate it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and talk to others such as family or friends about the study if you wish.

- Part 1 tells you the purpose of this study and what will happen to you if you take part
- Part 2 gives you more detailed information about the conduct of the study

Please do not hesitate to ask me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

In my previous position as the Research Dietitian with the Winchester and Eastleigh NHS Trusts Breast Care Unit, I had the opportunity to meet many breast cancer patients, some of whom expressed their concern about the lack of nutrition advice given at the time of their diagnosis.

Now that a holistic approach to care is being taken by the NHS and diet for a general healthy lifestyle is an area of interest to breast cancer patients, I applied for and subsequently received funding from the Department of Health to conduct research into the benefit of a group "healthy eating" programme for newly diagnosed breast cancer patients.

At an individual level, the purpose of the study is to help you improve your diet which in turn could improve your overall health and well-being. At a broader level the study will allow us to identify the demand for a healthy eating programme and secondly to identify whether the programme was helpful in improving women's diets. The results of this study may be used by NHS service development units when planning improvements to cancer services.

Why have I been chosen?

All postmenopausal women at (*name of trust*) diagnosed with breast cancer during a period of six months starting from February 2007 are being invited to participate in the study.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do, you should keep this information sheet and before we collect any information you will be asked to sign a consent form.

You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

You will be contacted by phone from a nurse in your Breast Unit's team within the next seven days to see if you are interested. If you are, the nurse from the Breast Unit will arrange to meet with you at your next appointment. At this meeting you will be asked to sign the consent form and we will begin to collect information from you which are outlined below.

The study itself will be conducted in two stages. I have included a diagram which might be helpful to look at when you are reading the following section.

Stage One

You will be asked to complete three questionnaires looking at your current diet and other health behaviours which consider the reasons for your desire to participate in this study or not. The questionnaires will take approximately fifteen minutes to complete. Your height and weight will also be measured by the nurse at this time.

Stage Two

To find out if providing "healthy eating" classes is helpful in improving your diet, we need to put people into two groups, half the people will attend the group "healthy eating" programme and the other half will receive normal services. Currently in the NHS newly diagnosed breast cancer patients are not offered any nutrition advice as part of their care package. To try and ensure the groups are the same to start with each patient is put into one of the two groups by chance (randomly). This is done by a computer. At the end of the study the results are compared. You will have a one in two or a 50% chance of being placed in the "healthy eating" programme.

If you are selected to attend the group "healthy eating" classes you will be invited to attend 4 x two-hour small (maximum 12) group nutrition education classes held over the course of six months. We would like you to attend these classes once a month however we understand that there may be times during the course of your treatment when you may not be able to attend classes. By giving you six months to complete the four classes this allows some flexibility to pick and choose which classes suit you the most.

The classes will be conducted by a State Registered Dietitian. The classes will be based on the Government's "Eat*well*: Your Guide to Healthy eating" programme as currently, we do not know what type of diet will delay or prevent your cancer from returning. We do know however that following a healthy diet can benefit your general health and well-being.

Other topics such as common nutrition problems that occur during cancer treatment and discussions about alternative diets and supplements will be addressed. The classes will be very interactive and will encourage group participation. They will be held during working hours at the Macmillan Centre facilities.

Before you start attending classes, in addition to the three questionnaires you completed in stage one you will be asked to fill in one further Quality of Life questionnaire which will take about five minutes to complete. At the end of the six month study period we will ask you to repeat the same measurements taken in both stages one and two so that we can compare the results.

After we have collected this information there will be no further follow-up required for this study.

For those women who are not placed into the nutrition education classes at the time of allocation, we will be offering 2 x half-day "healthy eating" seminars where you will be given all the information outlined above that was taught to the "healthy eating" group once the study is over.

Expenses and Payments

We will not be able to offer any reimbursement for travel expenses incurred in attending the group "healthy eating" classes.

Will I benefit from the study?

We cannot promise the study will help you, however adopting a healthier diet has been shown to improve general health and well-being.

The information we collect might help improve the services offered to future Breast Cancer Patients.

What if there is a problem?

Any complaint about the way you have been dealt with during the study will be addressed. The detailed information on this is given in Part 2.

Contact number for complaints is
Jillian Milne
Chief Investigator
Telephone: 023 8079 6539

Will my taking part in the study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2.

Contact Details

Jillian Milne
Research Fellow
Institute of Human Nutrition
Level E (MP893) Centre Block
Southampton General Hospital
Tremona Rd
Southampton
SO16 6YD

Tel +44 (0)23 8079 6539
Fax +44 (0)23 8079 5102
Mobile 07960 607149

This completes Part 1 of the Information Sheet. If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

PART 2

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time; however we will contact you six months after starting the program to ask if you would be willing to:

- Complete the end of study questionnaires
- Have your weight measured

You may accept or decline one or all of these requests without affecting the standard of care you receive.

What if there is a problem

Complaints

If you have a concern about any aspect of this study, you should ask to speak with the researcher who will do her best to answer your questions (023 8079 6539).
If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

Harm

Participation in the study carries no significant risk of physical or psychological harm. However if you are harmed due to someone's negligence, you may have grounds for a legal action for compensation against The University of Southampton and the University of Southampton NHS Hospitals trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?

Any information which is collected about you during the course of the research will be kept strictly confidential. Any personal details about you will be kept by the research nurse at the Breast Unit who will give you a unique study number. All data collected by the research team will contain only this study number. No personal information will be passed onto the research team.

The data collected will be used to compare the results between the two groups for measures of dietary patterns, weight and quality of life scores. The data will be held for 30 years and then destroyed securely in accordance with NHS Policy. The data will not be used for any future studies.

Involvement of the GP

With your consent, we will notify your GP that you are participating in the study.

What will happen to the results of the research study?

At the end of the study we will write to you outlining the main findings of the study.

The results from this study will also be submitted for publication to relevant medical journals and presented at conferences for health professionals.

Participants will not be identified in any report or publication.

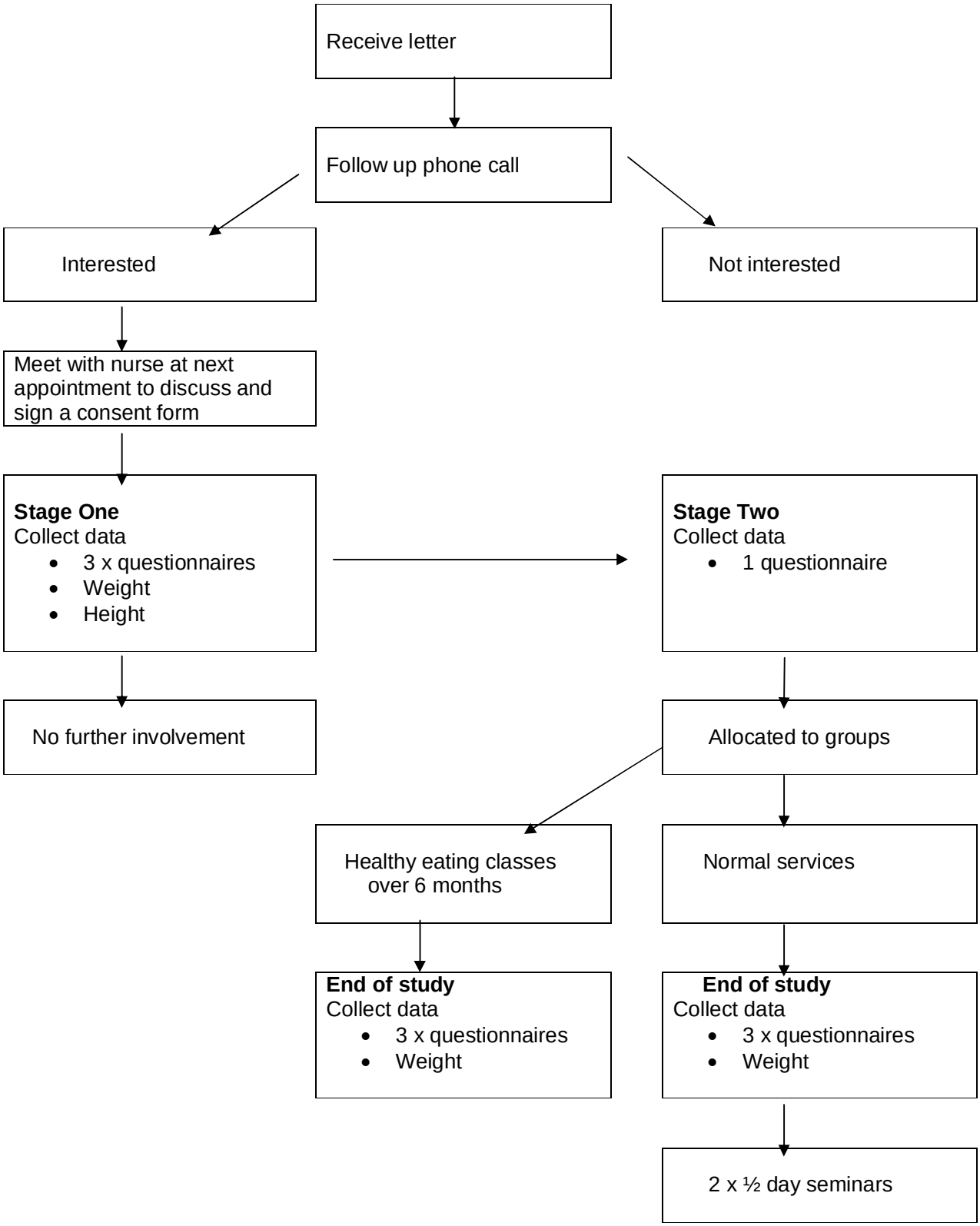
Who is organising and funding the research?

The study is funded by the Department of Health's' National Co-ordinating Centre for Research Capacity Development. The Researcher, Jillian Milne has received a Researcher Development Award which covers salary costs along with a small research budget. The sponsors of this study, the Southampton University's Hospital NHS trust and the University of Southampton will not receive any money for including you in the study.

Who has reviewed the study?

This study was given a favourable ethical opinion by the Southampton & South West Hampshire Research Ethics Committee B (REC Reference Number: 06/Q1704/144)

Thank you for your time in reading this information sheet.


Receive letter
Follow up phone call
Interested
Not interested
Meet with nurse at next appointment to discuss and sign a consent form
Stage One
Collect data
3 x questionnaires
Weight
Height
Stage Two
Collect data
1 questionnaire
No further involvement
Allocated to groups
Healthy eating classes over 6 months
Normal services
End of study
Collect data
3 x questionnaires
Weight
End of study
Collect data
3 x questionnaires
Weight
2 x ½ day seminars

9.14. Consent form for healthy eating programme

Title of Project: Uptake and response to dietary intervention in women with breast cancer

Name of Researcher: Jillian Milne

Please initial box

1. I confirm that I have read and understand the information sheet dated 11, December, 2006 (version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected ☐

3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the University of Southampton, regulatory authorities or from the NHS trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records ☐

4. I agree to my GP being informed of my participation in the study ☐

5. I agree to take part in the study ☐

Name of Patient	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes

9.15. GP Letter for healthy eating programme

Date

Dear Dr ……..

Re: Patients Name ……..

DOB ……/……/……

I are writing to inform you that this lady has agreed to take part in a study looking at ways to improve current services offered to breast cancer patients. Please find enclosed a leaflet regarding this Study.

(name of patient) will be attending group sessions at the Macmillan Cancer Support Centre, Southampton General Hospital.

Ethical approval for this Study has been obtained and it is funded by the Department of Health's - National Co-ordinating Centre for Research Capacity Development.

I would be pleased to discuss any aspects of this Study with you should you require any more information.

Yours sincerely

Jillian Milne SRD
Research Dietitian
02380 798924

Enc – Patient Information Sheet

9.16. Steering Group Member List

Table 9-3 Invited steering group members

Name	Organisation	Role
Mr Mark Mullee	RDSU Southampton University Hospital Trust	Director and Statistician
Dr Rachel Thompson	Institute of Human Nutrition	Senior Research Fellow/Public Health Nutritionist
Dr Sian Robinson	Medical Research Council Epidemiology Unit	Senior Research Fellow
Mr Richard Rainsbury	Winchester and Eastleigh Healthcare Trust	Consultant Breast Surgeon
Mr David Rew	Southampton Universities Hospital Trust	Consultant Breast Surgeon
Ms Lorraine Brown	Winchester and Eastleigh Healthcare Trust	Breast Care Nurse
Professor William Rosenberg	Wellcome Trust Clinical Research Facility	Director
Professor Alan Jackson	Institute of Human Nutrition	Director
Professor Martin Wiseman	WCRF (World Cancer Research Fund)	Consultant
Professor Tony Kendricks	NCCRCD	Chair of the Researcher Development Awards
Ms Anne Croudass	NCRN (National Cancer Research Network)	Network Lead Nurse
Ms Pat Dawney	Consumer Research Panel	Consumer Representative
Ms Fran Williams	MacMillan Cancer Relief	Service Development Manager
Ms Janice Gabriel	Research Ethics Committee	Committee member
Professor Lesley Fallowfield	Brighton and Sussex Medical School	Professor in Psycho-Oncology
Mrs Hilary Warwick	Nutrition and Dietetics	Director
Dr Deborah Fenlon	Southampton University, School of Nursing and Midwifery	Senior Research Fellow

9.17. Birmingham Clinical Trials Unit Peer Review Report

24th November 2006

Dear Sir

Re: Reshaping Breast Cancer Services – A Role for Dieticians?

This study forms part of a PhD project and aims to understand the factors that influence enrolment and subsequent participation in a "healthy eating" program for postmenopausal women newly diagnosed with breast cancer, and then plans to assess if a group "healthy eating" program improves diet in these women.

Previous breast cancer research has focused mainly on prevention, with the findings that the risk of breast cancer can be reduced by taking regular exercise, adopting a healthy diet, not smoking and drinking alcohol in moderation. The prevention of breast cancer remains a priority, as it still affects one in eight women in the United Kingdom. However, with the number of women now surviving a diagnosis of breast cancer having increased in the last ten years, there has been a shift towards addressing the needs of cancer survivors (with cancer survivorship labelled a national priority by the National Cancer Research Institute).

Whilst the role of nutrition in the primary prevention of cancer has been the subject of several reviews, the role of lifestyle changes in the secondary prevention of breast cancer remains unanswered. Research shows that women newly diagnosed with breast cancer are interested in and do make lifestyle changes, reasoning that if diet can reduce the risk of breast cancer, then diet might also reduce the risk of disease recurrence. However, despite this, currently the National Health Service does not offer nutrition advice to these women. Further, with many women overweight or obese at time of diagnosis, any improvement in diet would be of benefit to their general health (and reduce the risk of other complications such as diabetes and cardiovascular problems).

The randomised controlled trial part of the study compares a group "health eating" program with usual care. The planned intervention is cheap and relatively easy to implement both in the clinic and at home by the patient. Importantly, the results from this part of the study will help inform health care providers of the needs and expectations of breast cancer patients.

The primary outcome of the study is diet quality, which will be assessed using the Diet Quality Index-Revised (DQI-R), and aims to detect a 10 point improvement in the DQI-R (with 90% power). The study plans to recruit 200 patients, which would actually provide statistical power to detect a smaller difference (between 5 and 6 points). However, by recruiting 200 patients, this allows for patient drop-out and loss to follow-up, but also the confidence intervals for the primary outcome will be tighter and analysis of the secondary outcomes will be more robust.

My main criticism of the proposed study is the possibility of contamination in those patients randomised to routine care (the control group). There is the potential for these women to make changes to their diet outside the realms of the trial, which could potentially dilute any treatment effect. However, this is a pragmatic study and the authors are aware of this problem, and the trial is powered to detect a smaller difference than stated in the protocol.

In summary, the proposal is well-written and thought out (they have discussed the project with a variety of leading experts within the field), and asks an interesting question (with an easy to implement intervention) in an important disease area.

Yours faithfully

Natalie Ives

Senior Statistician, BCTU

9.18. Results Study Two

9.18.1. Study two - Stage two – Participation

Due to the small number of women enrolled to participate in the group healthy eating programme, insufficient data was generated to enable meaningful statistical analyses to be conducted. The following section instead details the outcomes from each of the proposed protocol sections as described in the methods. The reason for this is that each of these sections will form the basis of a large part of the following chapter, the discussion, in order to identify the reasons for the study's failure to meet its aims and objectives.

9.18.1.1. Study outcomes

Study outcomes were not achieved. The reasons for this are systematically reviewed in Chapter Six (Discussion).

9.18.1.2. Randomisation

Randomisation was achieved as planned via telephone utilising the services of the Birmingham Clinical Trials Unit.

9.18.1.3. Data collection

Data was not collected as per protocol (see section 5.7.5.2 below for further details).

9.18.2. Intervention schedule

Due to poor recruitment numbers, only one group was formed and subsequently completed the group healthy eating programme as per protocol.

9.18.3. Quality control

9.18.3.1. Screening and recruitment

9.18.3.2. Data

Significant numbers of missing and incomplete data were found (see tables 5-16 and 5-17). In total of the 105 sets of data that should have been completed, 23 (22%) was missing and all 17 (100%) food frequency questionnaires were unable to be analysed due to incomplete data.

Data form	Incomplete	Missing
Food frequency questionnaire	**17/21**	4/21
Multidimensional health locus of control	1/21	4/21
Self rated diet	0/21	6/21
Body mass index	0/21	2/21
Self esteem	0/21	5/21

Table 9-4 Summary of incomplete/missing data at baseline

Data form	Incomplete	Missing
Food frequency questionnaire	8/10	2/10
Body mass index	0/10	3/10
Self esteem	0/10	2/10

Table 9-5 Summary of incomplete/missing data at six-month follow-up

9.18.3.3. Dietary intervention

The healthy eating classes were delivered in accordance with the protocol.

9.18.4. Study period

The study was open for recruitment as planned for six months between April 2007 and September 2007.

9.18.5. Data collection

Data was collected at the correct time periods as per protocol however procedures for data collection were violated.

9.18.6. Data analysis

Due to the small data sets, electronic scanning was not performed. All completed data collection forms were manually entered into SPSS by the CI and as planned, the CI conducted all analyses.

9.19. Procedures Manual for NCRN staff

Reshaping Breast Care Services –

A Role for Dietitians?

Procedures Manual

Table of contents

1.0 Introduction

Survival rates for breast cancer have improved dramatically over recent years largely due to earlier detection and more effective treatments. Currently over 80% of postmenopausal women diagnosed with breast cancer can expect to survive their diagnosis.

Not surprisingly, these women are becoming increasingly interested in how they can improve their overall health and well-being. One area of particular interest patients consistently report in the literature is diet, as cancer patients view nutrition as an important part of their cancer therapy. The literature shows that significant numbers of these women make changes to their diets after their diagnosis and cite frustration with the lack of support from health care providers in adopting these changes.

Currently a unique opportunity exists in the National Health Service to develop health promotion activities for breast cancer survivors. With the recent shift in focus from a NHS that does things “to” and “for” its patients to one that is “patient led” the foundations had been laid to identify, plan and deliver services that better meet the needs and expectations of patients.

This study will pilot a group healthy eating program with newly diagnosed postmenopausal women with breast cancer. The results from this study will help future cancer service development initiatives.

2.0 Overall aims

Title	Reshaping Breast Care Services – A Role for Dietitians?
Overall Aims	1. To understand the factors that influence **enrolment** and subsequent **participation** in a "healthy eating" program for newly diagnosed postmenopausal women with breast cancer. 2. To assess if a group "healthy eating" program improves the diets of newly diagnosed postmenopausal women with breast cancer
Purpose	To inform cancer service development initiatives
Design	This "mixed method" study will be conducted in two stages Stage 1: Cross-sectional study Stage 2: Randomised controlled trial .

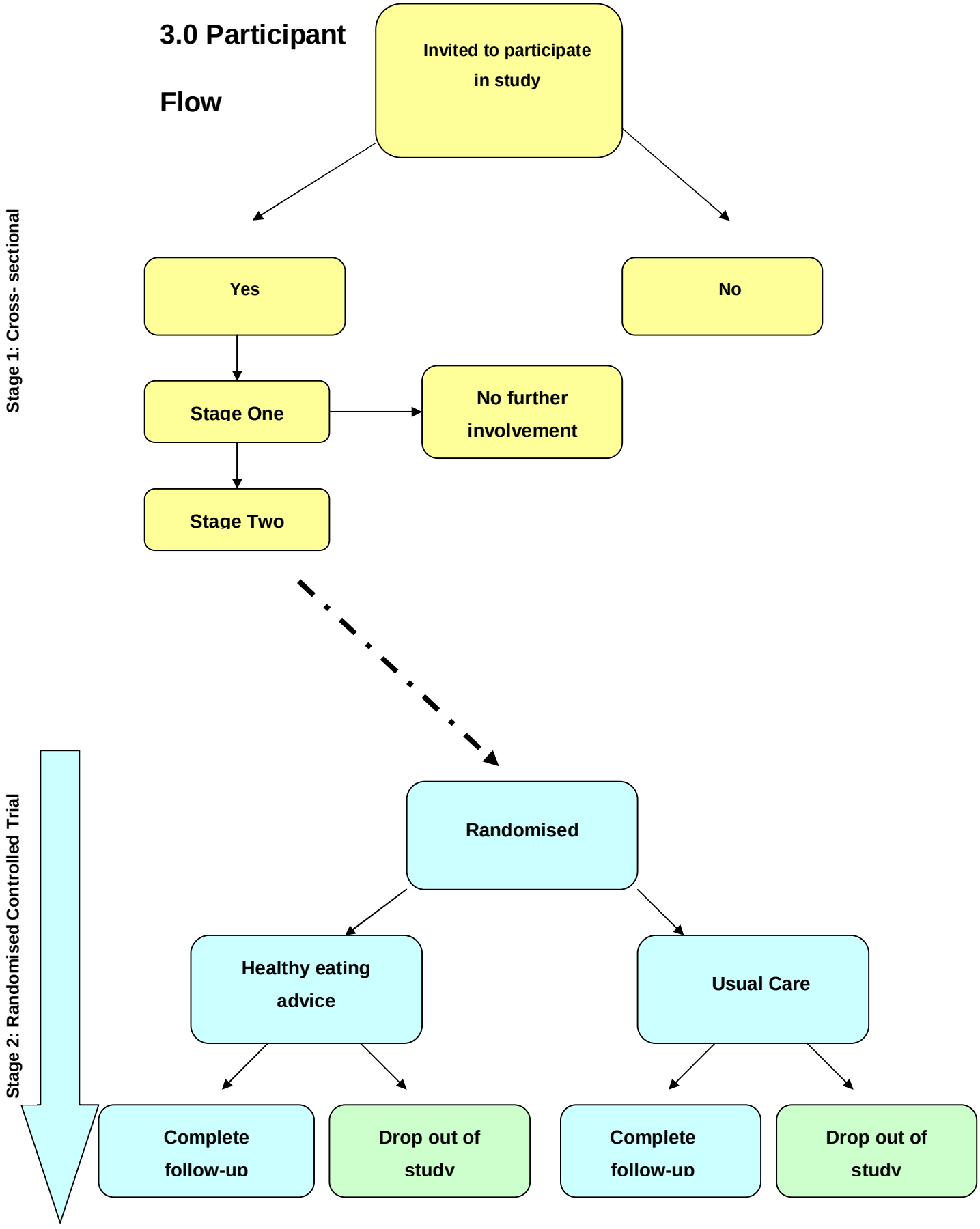
2.1 Aims and Objectives – Study One

Study 1 – Cross-sectional study	
Aims	3. To estimate the proportion of newly diagnosed postmenopausal women with breast cancer who will enrol on a group "healthy eating" program 4. To understand the factors that influence **enrolment** in a "healthy eating" program
Objectives	3. To invite 400 newly diagnosed postmenopausal women with breast cancer to a group "healthy eating" program during the recruitment period of six months 4. To describe the factors that determine whether or not newly diagnosed postmenopausal women with breast cancer enrol on a "healthy eating" program
Hypothesis	50% of newly diagnosed postmenopausal women with breast cancer will enrol in a "healthy eating" program

a. Aims and Objectives – Study Two

Study 2 – Randomised Controlled Trial	
Aims	3. To assess if a group "healthy eating" program improves the diets of newly diagnosed postmenopausal women with breast cancer compared with usual care 4. To determine the impact of participating in a "healthy eating" program on self reported quality of life scores compared with usual care 5. To understand the factors that influence **participation** in a "healthy eating" program
Objectives	4. To compare change in overall diet quality scores in the "healthy eating" group with usual care 5. To compare change in weight in the "healthy eating" group with usual care 6. To compare self reported quality of life scores in the "healthy eating" group with usual care 7. To describe the factors that determine whether or not newly diagnosed postmenopausal women with breast cancer complete a "healthy eating" program
Hypothesis	3. Difference in change of overall diet quality scores will be 10 points higher for women in the "healthy eating" group compared to women in usual care. 4. Difference in change in weight over the course of the intervention will be 3 kgs less in women enrolled in the "healthy eating" group compared to women in usual care.
Intervention	A group "healthy eating" program of 4 x 2 hour sessions over a six-month period
Study Groups	Usual care Healthy Eating Group

3.0 Participant Flow



4.0 General information

- All the data collection forms are specially designed to be scanned. Therefore please DO NOT PHOTOCOPY them as the information will not be recognised by the scanning computer
- Only information recorded in the boxes will be picked up by the scanner so please do not write information outside these boxes. If you make a mistake in a box you will have to start another form.
- I can't stress how important it is that ALL postmenopausal women be invited. If women are missed the study will be deemed invalid. If you think there is going to be a problem with achieving this PLEASE contact Jocelyn Walters and myself ASAP so that we can try and sort something out.

5.0 Screening and Recruitment Schedule

5.1 Screening

Identify all postmenopausal women newly diagnosed with breast cancer.

How you do this is entirely up to you. Obviously the least time consuming method would be the most appropriate. I believe each trust has a different system for recording new diagnoses. I would suggest you speak with the data manager because numbers of new diagnoses are uploaded to the Department of Health on a regular basis so the data manager must get this information from somewhere.

- Allocate a study number (1- 200 at Portsmouth and 201- 400 at SUHT)
- Complete demographic information for data collection sheet
- Record study number, name and hospital number on a password protected computer file. (This will be the only patient identifiable information gathered and is the linking file between study numbers and names. You will be the only one to access this file)

5.2 Post invitation packs

- ALL postmenopausal women receive an invitation
- The invitation should be sent out ONE WEEK AFTER DISCHARGE from primary surgery
- The packs are made up. The only thing missing is the invitation letter which MUST be printed on BREAST UNIT LETTERHEAD and be SIGNED by THE CONSULTANT (MR ROYLE for SUHT and MR WISE for Portsmouth)
- DO NOT USE HANDWRITING on the envelope. Please insert the name and address in the space provided in the word document which should automatically line up with the window on the envelope.
- The packs are pre numbered. PLEASE ensure you match up the persons study number with the correct envelope

5.3 Follow-up phone call

- **Phone** patient a few days after sending the invitation
- **Record** phone call in phone log
- Ask patient if they are interested in joining the study. If there are any queries that you can't deal with please direct them to me. My contact details are on the patient information sheet
- **RECORD OUTCOME ON THE DATA COLLECTION FORM**

- If they agree to participate in either the one off questionnaires (stage one) or decide to join the classes (Stage two) please arrange to **meet them** at their **next appointment** which should be in a few days (Results clinic)
- If they decline any participation PLEASE ask them if they would mind letting us know why and this information is important when conducting research. **RECORD the reason** on the DATA COLLECTION FORM
- **FOR ALL PATIENTS please encourage** them to complete the optional form in the pack asking them to write down their thoughts/feelings about the trial. There is a pre stamped envelope for them to return the form

5.4 Meeting to consent and collect baseline data

Information to collect at meeting

- Consent form
- Height and weight
- **Questionnaires**
    - MHLC
    - FFQ (HEA3)
    - ROSENBERG SELF ESTEEM
    - ***FACT-ES only*** *for those joining the classes*
- Once you have all the data phone the randomisation unit for group allocation
- Please give all patients randomised a study number card for their wallets.
- If allocated to the group healthy eating classes, please give patient class schedule

5.5 Six month follow-up

For those who were allocated to the classes, one month before their six month follow-up is due, check patient's next appointment. If this coincides approximately to six months, arrange to meet them at this appointment to collect follow up data. If not, please schedule an appointment to collect data.

The following data must be collected at this time

- **Treatment order** (from medical record) e.g. surgery + chemo + rxt
- Height and weight
- **Questionnaires**
    - MHLC
    - FFQ (HEA3) – assessing USUAL diet (before their diagnosis!)
    - ROSENBERG SELF ESTEEM

- FACT-ES

THIS DATA MUST BE COLLECTED FOR ALL PATIENTS ALLOCATED TO THE CLASSES EVEN IF THEY DIDN'T ATTEND.

6.0 Record keeping

6.1 Patient – study number linking file

Please keep a password protected file linking patient identifiable data (name, hospital number) with the allocated study number. This file will be the ONLY record as I will only receive numbered information. It is really important this is kept up to date.

6.2 Study file

This file will be handed over to me at the end of the study so it MUST NOT have patient identifiable data on it. The excel file has been set up and sent to you electronically. The fields are as follows:

Study Number
Date letter dispatched
Date of phone call
No to any involvement
Yes to stage one only
Yes to stage two
Date of consent and baseline data collection
Treatment order
Date for six – month follow up

Please keep this record up to date