

**Centre for Research into Disability and Society
School of Occupational Therapy**

**Self management Intervention for Malaysian women with breast
cancer: Enabling Quality of Life and Participation**

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Doctor of Philosophy
of
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DECLARATION

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgment has been made.

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university.

Signature:

Date:

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DEDICATION

Abided (Ecclesiastes 9:10), consoled (1 Corinthians 10:13) and empowered (Isaiah 40:29) and a quote to sum up a key experience on this long journey.....“When you know a thing, to hold that you know it; and when you do not know a thing, to allow that you do not know it— this is knowledge.” (Legge JT. *The analects of Confucius.*)

With humility, I dedicate this work to the Malaysian women with breast cancer who continues to astonish me with their strength and resilience. Also, my heartfelt dedications to my own family members battling cancer bravely, especially my brother who was diagnosed with pancreatic cancer recently and to the beloved memory of my late mum and dad who succumbed to colorectal cancer in October 1996, and lung cancer in November 1996 respectively.

ABSTRACT

Study on self-management intervention has shown enhanced quality of life in the chronic ‘non-oncology’ population, but has yet to make an impact in the field of oncology. The aim of this study was to explore, develop and evaluate the 4-week self-management intervention for women with breast cancer. The study, based on robust phased-model of a complex intervention, demonstrated an increasing research evidence from a qualitative need-assessment to a pilot study and finally to a definitive Clinical Controlled Trial. Insights and findings from the preclinical phase aided the development of the 4-week “Staying Abreast, Moving Ahead” (SAMA) program which was piloted, refined and tested using a CCT on Malaysian women (n=147) with breast cancer.

The results from the robust intent-to-treat multivariate analyses of co-variances and the univariate repeated measure analyses of variances supported the efficacy of the 4-week self-management intervention. There were significant between-group differences on Quality of life ($p=0.005$), Social Relationship (0.015), Psychological symptoms ($p=0.001$) at post test, and self-efficacy and proactive coping for both Post-test and Follow-up ($p<0.001$). There were significant differences over time within the experimental group for Quality of life ($p<0.001$), Participation, ($p=0.04$), Psychological outcomes ($p<0.001$), as well as the Cancer self-efficacy scales ($p<0.001$ to $p=0.02$) and Proactive coping ($p<0.001$).

A key implication of this study is that the theory-led SAMA program (which was developed based on the perspectives from the fields of Psychosocial oncology and Patient self-management for chronic conditions) can be disseminated to enable better Quality of life. SAMA is a potential blueprint for a feasible, timely and effective self management program for women diagnosed with breast cancer.

LIST OF ABBREVIATIONS

ACS	American Cancer Society
Anx	Anxiety
BMI	Body Mass Index
BMR	Basal Metabolic Rate
Ctrl	Control group (arm)
CBI	Cancer behavioural inventory –a self efficacy coping scale
CBT	Cognitive-Behavioral Theory
CCM	Chronic Care Model
CCT	Clinical Controlled Trial
CDSM	Chronic Disease Self-management
CI	Confidence Interval (95%)
CS	Clinical Significance
CSE	Cancer Self Efficacy
CT	Chemotherapy
DASS	Depression, Anxiety, Stress Scale
Dep	Depression
DV	Dependent variables
Exp	Experimental group (arm)
FR	Family role
GLM	General Linear Model
ICF	International Classification of Functions
IOM	Institute of Medicine, USA
IPA	Impact on Participation and Autonomy
IQR	Interquartile range
ITT	Intention-to-treat (Approach to Analysis)
IV	Independent Variables

PIQ	Patient Information Questionnaire
QOL	Quality of Life Multivariate Analysis of Covariance
MANCOVA	Mental Component Score - Short Form-36 Health Survey
MCS	Medical Research Council, United Kingdom
MRC, UK	National Health Medical Research Council
NHMRC	National Health Medical Research Centre
NCI	National Cancer Institute
NCR	National Cancer Registry, Malaysia
PCI	Proactive Coping Inventory
PCS	Physical Component Score - Short Form-36 Health Survey
RCT	Randomised Control Trials
SAMA	<i>'Staying Abreast, Moving Ahead'</i>
SCT	Social Cognitive Theory
SD	Standard Deviation
SE	Self-efficacy
SESES	Stanford's Emotional Self-Efficacy Scale
SF 36	Short Form-36 Health Survey
SR	Social relationship
SPSS	Statistical Packaging for Social Sciences
SUPPH	Strategy used by people to promote health- self efficacy scale
T1	Time 1 (Baseline measurement)
T2	Time 2 (Post test or post intervention measurement)
T3	Time 3 (Follow up measurement)
UMMC	University Malaya Medical Centre
WHO	World Health Organization
η_p^2	Partial Eta squared

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LIST OF OPERATIONAL TERMS

This section briefly outlined the operational context of the common terms used within the thesis.

‘Attribute’ of self-management: The essential elements linked to the concept of self-management such as patient education, skills, and broad areas of tasks are categorized as attributes of self-management (Nikki Embrey, 2006),

‘Complex intervention’ refers to “an intervention that consists of several phases and each phase is a progression to the next” (MRC, 2000).

‘Enablement’ includes “both things that clinicians can do for patients to remove barriers to self-management, as well as helping patients be more autonomous and care for themselves” (Epstein RM, 2007)

‘Endpoints’: as per consort statements (Altman et al., 2001). Also mean outcome measures. The primary endpoints refers to the outcome measures of QOL, IPA and DASS and the secondary endpoints refers to the cancer self efficacy and proactive copings (i.e. ‘attribute’ of self-management intervention).

‘Empowerment’: “the taking control of their lives by setting their own agendas, gaining skills, increasing confidence, solving problems and developing self reliance” (Currie & Wiesenberg, 2003, p. 896). It is “a consequence of self-management” (Nikki Embrey, 2006, p. 513).

‘Manulised’: refer to a program which follows a specific manual to guide the delivery of the intervention.

‘Proactive coping’: refers to the cognitive and behavioral processes that enable people to foresee potential threats to their goals and to undertake efforts to prevent them (Aspinwall & Taylor, 1997). A proactive health professional (as opposed to a reactive health professional) is one who acts promptly on the current situation in a forward thinking plan even before the potential problem materialize.

‘Self-efficacy’: refers to beliefs in one’s capabilities to organize and execute the courses of actions required to produce given attainments” (A. Bandura & Adam, 1997, p. 3).

‘Usual care’ here refers to the usual medical treatment that most women with breast cancer will go through i.e. surgery, adjuvant therapy (chemotherapy and/or radiotherapy) and /or targeted therapy, i.e. the common medical care outlined in the Malaysia’s Clinical practice Guideline for Breast cancer.

‘Pretest’ refers to measurement at baseline (T1), and **‘post test’** (T2) refers to measurement at post intervention whilst **‘follow up’** (T3) refers to 4 weeks after post test or 8 weeks after baseline.

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1

INTRODUCTION

“The function of protecting and developing health
must rank even above that of
restoring it when it is impaired”
(Hippocrates)

1.0 Introduction

Today, chronic diseases account for more than half of the global disease burden (WHO, 2004) rendering them a major healthcare problem and cause of disability as well as contributing up to 70% of healthcare expenditure (Hoffman, Rice, & Sung, 1996). An estimated 41 million people will die from chronic conditions in the year 2015, with about 80% of deaths occurring in low-middle income countries (WHO, 2006). However, many developing countries' health systems have not addressed these epidemiological and demographic changes of a rising chronic illness. Most healthcare practices are based on the traditional model of acute, episodic care (Glasgow et al., 2002; Pruitt & Epping-Jordan, 2005).

Adding to the challenge is the influx of breast cancer cases, now increasingly being seen as a chronic illness (LJ. Fallowfield, 2004) and with many persistent medical and non-medical related problems following treatment (Loh & Yip, 2006). The need to improve service delivery for this group is critical (NM. Clark, 2003). In short, the steep rise of chronic illnesses constitutes a primary challenge with an increasing impact for health and social policy (Cheah, 2001; Chew, Van Der Weyden, & Martin, 2003; Epping-Jordan, Bengoa, Kwar, & Sabate, 2001; Groves & Wagner, 2005).

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In addition, for a long time in medicine, the focus is on the disease rather than on the person behind the disease (Cardol, De Haan, De Jong, Van Den Bos, & De Groot, 2001). Likewise, in oncology, the target is the tumor rather than the individual (Schnipper, 2001). The current socio-political movement where the individual experience of illness is seen to be as important as the disease itself signifies a patient-care approach. This is a shift from a predominantly medical one to one in which psychological and socio cultural aspects are equally important (Wade & De Jong, 2000). This conceptual shift is highly pertinent in developing countries, including Malaysia, where the healthcare system is still entrenched within a hierarchical medical model system which is physician-centered care rather than patient-centered. The latter is expounded by the Institute of Medicine as the approach for improving the quality of healthcare (IOM, 2001) since patient-centered care is highly pertinent for the management of chronic conditions. With this background that patient-centered care is the approach for managing chronic conditions, this study which is an innovative direction in healthcare delivery for Malaysian women with breast cancer is pertinent for several reasons. Firstly, the study is conceptualized along the recent health-care advances in terms of current health concept and rehabilitation construct. It considers the development and progression of a patient self-management model to complement traditional medical care. Empowering people with self-management skill facilitates them to act in advance to be proactive in preventing further deterioration and improving quality of life (QOL).

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Secondly, the approach of this study reflects a shift away from the traditional medical model of healthcare. Medical model interventions are essentially fragmentary (rather than holistic), and focus predominantly on symptom alleviation, causing a disregard for the broader meaning of life (Cardol et al., 2001). As such, care along a patient-centered approach is more pertinent and is in line with the IOM's rules for the 21st century healthcare system (IOM, 2001). This approach ensures that patient-identified problems are considered. Also, the focus is a shift away from 'dysfunction' to a 'function' view (WHO, 2001). This reflects a healthy shift from a view that magnifies what people cannot perform to one that focuses on what people can perform and/or on how to enable people to self manage and perform.

Thirdly, relevant frameworks are used to explain the processes guiding the development of the intervention. This study adopts a phase-approach to ensure a process of increasing evidence is followed through, and it uses a mixed method study in order to conduct a thorough study. Intervention based on theoretical models is being recognized as more beneficial and effective as they can better identify the processes that contribute to success of the intervention.

Fourthly, the study adopts a proactive stance of preparing patients to plan ahead, cope via self-management approach with a focus on building health rather than take a typical reactive stance.

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Lastly, it is a comprehensive effort to train patients in self managing the broader aspects of illness and health, rather than focusing narrowly on mere management of symptoms. The sections below present the background of the study, the research problem and its significance for clinical practice. The UK Medical Research Council's framework for complex intervention was adopted as a guide for the entire study and the overall structure of the thesis.

1.1 Background of the Study

“Self-management education complements traditional patient education in supporting patients to live the best possible quality of life with their chronic condition”
(T. Bodenheimer et al, 2005, p2469)

The World Health Organization has exerted that interventions for women must be unique to the health needs of women (M. Cohen, 1998). More importantly, it must also cover broader issues like family, participation and life experiences (Cardol et al., 2001). Participation in everyday occupations has a positive impact on health and wellbeing (WHO, 2002). Emphasis on women's health has been slow, particularly in developing countries. In the early 90s, the Human Development Index showed that no country treated its women as well as its men despite recognizing women as key resources to society (World Bank, 1992).

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Sadly, even media coverage of women's health showed a preoccupation in society with women's reproductive role (Shugg & Liamputtong, 2002) with much gender disparity and inequalities (Luddy, 2007; Schoen & Doty, 2004; Schoen, Simantov, Gross, Brammli, & Leiman, 2003). However, there has been enormous media attention and funding provided for breast cancer disease which is highly prevalent in women worldwide (American Cancer Society, 2005; Globocan, 2002). Unfortunately, even with this attention, medical care for women with breast cancer continues to focus narrowly on detection and survival. Even in follow-up visits, medical care seems to focus solely on detections of recurrence, without consideration of many other aspects that affects functioning. In many developed countries, care for women with breast cancer has been predominantly on the less visible psychosocial aspects (Faulkner, 2000; Giudice, Leszez, Pritchard, & Vincent, 1997; E. Lev, Eller, & et.al., 2004) and ironically may be the overall focus for women with breast cancer (NHMRC, 1999).

Research has shown that the health of disadvantaged women is compromised due to a lack of education, lack of information and lack of awareness of factors that contribute to the disease (Luddy, 2007). In reference to cancer, research shows that prompt, continuing education and emotional support are fundamental basic needs of patients (Gore-Felton & Spiegel, 1999). However, in most developing countries like Malaysia, education and emotional support are hardly essential parts of the clinical practice guidelines.

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This neglect is serious since women with breast cancer require intense and prolonged treatments (P. Ganz & Hahn, 2008; Hortobagyi, 1998). With many chronic conditions, effective management of significant morbidity from illness and its treatment which reduces QOL have taken on increasing importance (Erickson, Pearson, Patricia, Adams, & Kahn, 2001). A comprehensive, broad-based intervention to address these consequences has yet to be implemented in Malaysia.

Gaining momentum is the concept surrounding the self-management model. Despite its popularity, the term 'self-management' is ambiguous and has been used interchangeably to mean patient-education, self-care, patient-centered-care, skills, support, as well as, relationships between patient and health providers. Added together, these terms do reflect a concept of total care approach, i.e. one that is towards a patient-centered care by focusing on the patients' problem, and empowering patient participation and close collaboration with the health professional. The International Alliance of Patient Organization (IAPO, 2006a) championing for patient-centered care, contends that:

HEALTH SYSTEMS IN ALL WORLD REGIONS ARE UNDER PRESSURE AND CANNOT COPE IF THEY CONTINUE TO FOCUS ON DISEASE RATHER THAN THE PATIENTS; THEY REQUIRE THE INVOLVEMENT OF INDIVIDUAL PATIENTS WHO ADHERE TO THEIR TREATMENTS, MAKE BEHAVIOURAL CHANGES AND SELF-MANAGE (p1).

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Recent studies on people with chronic conditions have examined the provision of information (Stiegelis et al., 2004), psycho-educational program for managing major side-effects (Golant, Altman, & Martin, 2003) and also psycho-educational program for women with an increased risk of breast cancer (Appleton, Garcia-Minaur, M., J., & et.al., 2004). However, despite the many beneficial psycho-educational programs for women with breast cancer (Burke & Kissane, 1998; Hewitt, Herdman, & Holland, 2004), the recognition that breast cancer condition as an emerging chronic illness means that the needs of woman may need to be addressed beyond psychosocial interventions which place emphasis on managing emotions. In short, although these tasks such as managing emotions are usually addressed in psychosocial groups, the other important aspects on management of illness and daily roles (J. Corbin & Strauss, 1988) may not be fully integrated.

The background of this study is based on the clear acknowledgement that strictly addressing one aspect such as mere medical factors, and/or mere emotional factor are often not the most effective approach for treatment, particularly for people with chronic conditions. There seems to be a gap between what women with breast cancer expect in terms of healthcare, and what the Malaysian healthcare system has offered. There is a need to understand this gap in order to fill it with a more effective intervention – i.e. one that is broad-based and able to address the vast array of self-management needs of women with breast cancer.

1.2 Statement of the Problem

A greater declining rate of mortality are seen in people with breast cancer (Greenlee, Murray, Bolden, & Wingo, 2000; Mettlin, 1999) than in people with many other types of cancer (Jemal et al., 2006). 86% of patients survive for at least 5 years after diagnosis and this figure contributes to more than two million women living with a history of the disease in the United States (Ries, 2006). In Malaysia, population data are incomplete but estimates of incidence (and survivorship) are expected to rise in Malaysia. The influx of women with breast cancer (Avis, Assmann, Kravitz, Ganz, & Ory, 2004; Benyamini, McClain, Leventhal, & Leventhal, 2003; Berglund, Nystedt, Bolund, & et.al., 2001; Derogatis et al., 1983; Erickson et al., 2001; LJ. Fallowfield, 2004; L. Fallowfield, Fleissig, Edwards, West, & et.al., 2001; L. Fallowfield, Hall, Maguire, & Baum, 1990; Hunter, 1998) warrants a comprehensive program to be put in place in order to help them.

Women diagnosed with breast cancer face very stressful life events (Carver et al., 1993; Faulkner, Maguire, & Regnard, 1994; McDaniel, Musselman, Porter, Reed, & Nemeroff, 1995) and uncertainties of recurrence (Klee, Thranov, & Machin, 2000). Although 'staging of the breast cancer illness' allows some certainty in predicting prognosis, many life domains are affected which necessitate women to manage their surviving life period. This challenge is magnified as chronic conditions often occur as co-morbidities (T. Bodenheimer, Lorig, Holman, & Grumbach, 2002; E. Wagner et al., 2001; E. H. Wagner et al., 2001).

Introducing Self-management in Malaysia

Chronic disease is best treated by a balance of traditional medical care and the day-to-day practice of self-management skills (K. Lorig, 1994). Population-wide approach as the central strategy for preventing chronic disease epidemics should be combined with comprehensive, integrated and coordinated care at the primary care level to focus on those at high risk and those with established diseases (WHO, 2005c). Self-management program is a proven effective approach for chronic illnesses and may provide better care for women with breast cancer, and this has not been explored in Malaysia. The rationale to start self-management in primary care is to prepare people to self manage the consequences of living with a long term condition. Primary healthcare has been recognised as an ideal setting for supporting chronic disease self-management (A. Williams et al., 2007). This is because the defining features of primary care: i.e. continuity, coordination, and comprehensiveness are highly suited to chronic illness care (Rothman & Wagner, 2003). In Malaysia, most people with chronic diseases are already receiving their care at the primary care level (AS Ramli & Taher, 2008). However, what is perhaps even more essential is the timing of introducing self management rather than the setting where it is implemented. This is because changes in behavior are required and thus, early intervention is the rational approach to ensure effective delivery of collaborative care for two reasons: i) to equip patients from the beginning to deal with the condition which involves indefinite period of self care, and ii) to reduce healthcare cost and long term health utilization.

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How does the Chronic Disease Trajectory fits culturally for Malaysian?

The Corbin and Strauss Chronic Illness Trajectory Framework addresses the fluctuating course of the illness over time and emphasised health promotion and illness prevention, as well as global influences on health care (JM. Corbin, 1998). Malaysia, like many other low-middle income countries is of no exception in terms of the impact of urbanization, globalization, population ageing and other determinants responsible for changing pattern of diseases. The WHO estimated that chronic diseases in Malaysia has accounted for 71% of all deaths in 2002 (WHO, 2005b). Life expectancy at birth for males and females has increased to 70.6 years and 76.4 years respectively in 2005 with about 63% Malaysians now living in urban areas and approximately 11.6 million Malaysian adults have at least one risk factor for chronic disease (Department of Statistics Malaysia, 2005). Although there are some sporadic efforts in Malaysia to manage diabetes and hypertension in a more systematic way, many patients with chronic diseases do not achieve optimal disease control (AS. Ramli & SW., 2008) hampered due to untrained personnel and a health system orientated towards acute, episodic illnesses. A smart partnership with the 'expert patients' is ideal but Asian patients need to be encouraged to move out of their passive role and health staff need to learn to collaborate with patients. More self management education can empower patients so that they are not curtailed by cultural myths and traditional beliefs about fatality of cancer, and the toxicity of cancer treatment. There are compelling evidence on feasibility of such program even in low-middle income countries including South African, Peru and Haiti (AS. Ramli & SW., 2008) and within multiethnic groups in Australia (Swerissen et al., 2006) or Chinese

Self-management intervention program for Women with breast cancer ethnic in China (Fu, Fu, McGowan, & et.al., 2003) suggesting that the chronic disease trajectory is applicable globally.

1.3 Significance of the Study

Many research evidences have shown that consumers are dissatisfied and disillusioned with many aspects of healthcare (Coulter, 2005; J. Shapiro, Mosqueda, & Botros, 2003; Shea et al., 2007). The major healthcare systems worldwide, have revealed deficiencies in health system delivery to patients with chronic illnesses, while a burgeoning literature has increasingly promote self-management as the intervention effective for people with chronic illnesses (K. R. Lorig et al., 1999; Von Korff, Gruman, Schaefer, Curry, & Wagner, 1997; EH. Wagner, Davis, Schaefer, Von Korff, & Austin, 1999).

The government in the United Kingdom has endorsed the expert patient program i.e. a self-management program, as the centre piece of the NHS approach to chronic disease management for the 21st century (Donaldson, 2003). In Australia, the government projected that chronic diseases will contribute to over 80% by the year 2020 and chronic disease self-management has been focussed as a national priority (Jordan & Osborne, 2007). In the recent 2006-07 Australian government budget, an unprecedented allocation of over 250 million dollars was allocated for the implementation of chronic disease self-management activities (Jordan & Osborne, 2007 ; A. Williams et al., 2007).

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In Malaysia, research reports on self-management of chronic diseases are scarce. Thus, in line with the international policy context of self-management, this study contributes to a crucial milestone for Malaysian health delivery systems, especially for women with breast cancer. This study is the first attempt to study self-management for women with breast cancer with timely acknowledgement of its chronic status. This study is urgent, as increases in life expectancy also leads to an increase burden of chronic diseases to rise sharply in the years to come (Kols, 2002; WHO, 2003) as older women are far more at risk for the disease (Forbes, 2001).

The study is also significant for the following reasons:

Firstly, the study focuses on women with breast cancer, the most prevalent cancer among women worldwide (Globocan, 2002) The risk of breast cancer in developed countries has increased by two percent annually (Forbes, 2001). Cancer registries are alerting us that age-standardized incidence rates are rising even more rapidly in Asia (Sasco, 2001) as women adopt lifestyles resembling those in developed countries (Deapen, Liu, Perkins, Bernstein, & Ross, 2002; Ziegler & Hoover, 1993).

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Secondly, the study is in line with current research trends to study self-management, self-efficacy and positive striving like proactive coping. Self-efficacy is the key mechanism in social cognitive theory and is fundamental to behavioral changes (Bandura, 2004). It also acts as a predictor of disease management (NM. Clark & Dodge, 1999). A notable future direction for self-efficacy research (Pajares, 2005) is towards the aspects of specific self-efficacy. Studies on these attributes are crucial to help us understand health behaviors.

Thirdly, the study adopts a robust phase-approach using mixed-method study to develop and test a complex intervention. It incorporates service-users' input to identify crucial issues to be addressed so that outcomes are relevant (Faulkner, 2000). Based on theory-driven work, the study provides increasing research evidence as the study progresses through each phase of this phase-approach which would be discussed later.

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Fourthly, the study addresses the broader participation in life roles and quality of life issues, away from a narrow 'symptom-focus' (a reflection of the reductionist view of the medical model). The focus on participation and occupation (self care/ self-management of roles) is reflective of the unique field of occupational therapy, and is also in line with the current International Classification of Functioning's (ICF) framework (ICIDH-2, 1999).

Fifthly, specific to occupational therapy practice, there is a lack of clinical practice protocol for therapists to train patients to self-manage their condition. Self-management programs have a role in empowering the survivor to participate in their own healthcare, leading to a substantial positive contribution in improving the clients' quality of life (QOL) and a reduction in healthcare cost and utilisation.

Finally, findings of the study may contribute to the knowledge base on how to integrate behavioral-psychological approaches together with the outdated medical model approach which greatly influences positive health outcomes.

1.4 Approach to the Study

This section outlines the UK Medical Research Council's (MRC, 2000) framework and the flow chart of the entire study which is based on this framework.

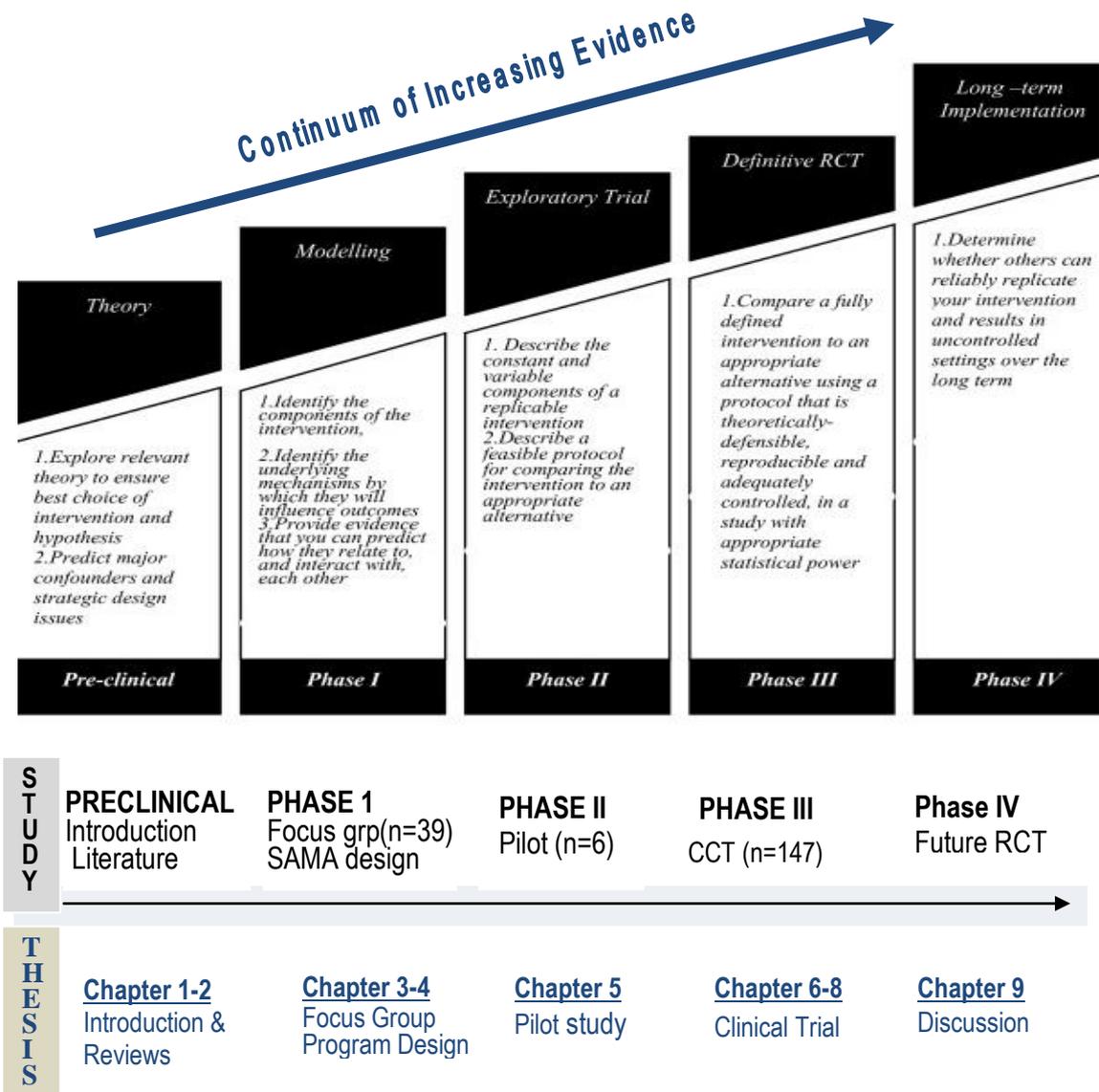
1.4.1 The Medical Research Council's Framework for Complex Intervention

Figure 1.1 shows the MRC framework (MRC, 2000) for evaluating complex interventions, and which was adopted to guide this study on women with breast cancer. The MRC's phase-approach, separates the different questions being asked so that progression is along a continuum of 'increasing evidence' to ensure effective delivery during the trial (M. Campbell et al., 2000). The framework guides the examination of the theoretical hypothesis at each phase of the study. In the preclinical phase, examination of the guiding principles and hypothesis on hypothesised effectiveness led the conceptualisation of a program to be tested. In Phase One of this study, focus group was utilised to assess the complexities of patient satisfaction issues (Schwartz, 2000), and provided insights into aspects which may be feasible to study using conventional quantitative methods (RS. Barbour, 2005). Such lay involvement has been proposed as politically mandated (Entwistle, Renfrew, Yearley, Forrester, & Lamont, 1998).

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Figure 1.1

Phases of development for a Complex Intervention



Ref: Framework for the development of a complex intervention (MRC, 2000)

In Phase Two, a pilot study was used as the mean to test the viability of the newly developed clinical program (Stein & Cutler, 2000), and the insights obtained were used to further support the design for the clinical trial. In Phase Three, the clinical-controlled-trial (CCT) was planned to evaluate the efficacy of the new program. Evaluation was planned based on methodological standards on issues such as sample size, inclusion and exclusion criteria and block-design method. A protocol to ensure and develop a “theoretically defensible, reproducible, and an adequately controlled study with appropriate statistical power” (M. Campbell et al., 2000) was developed within the manual for the facilitator which was in line with the workbook for the participants.

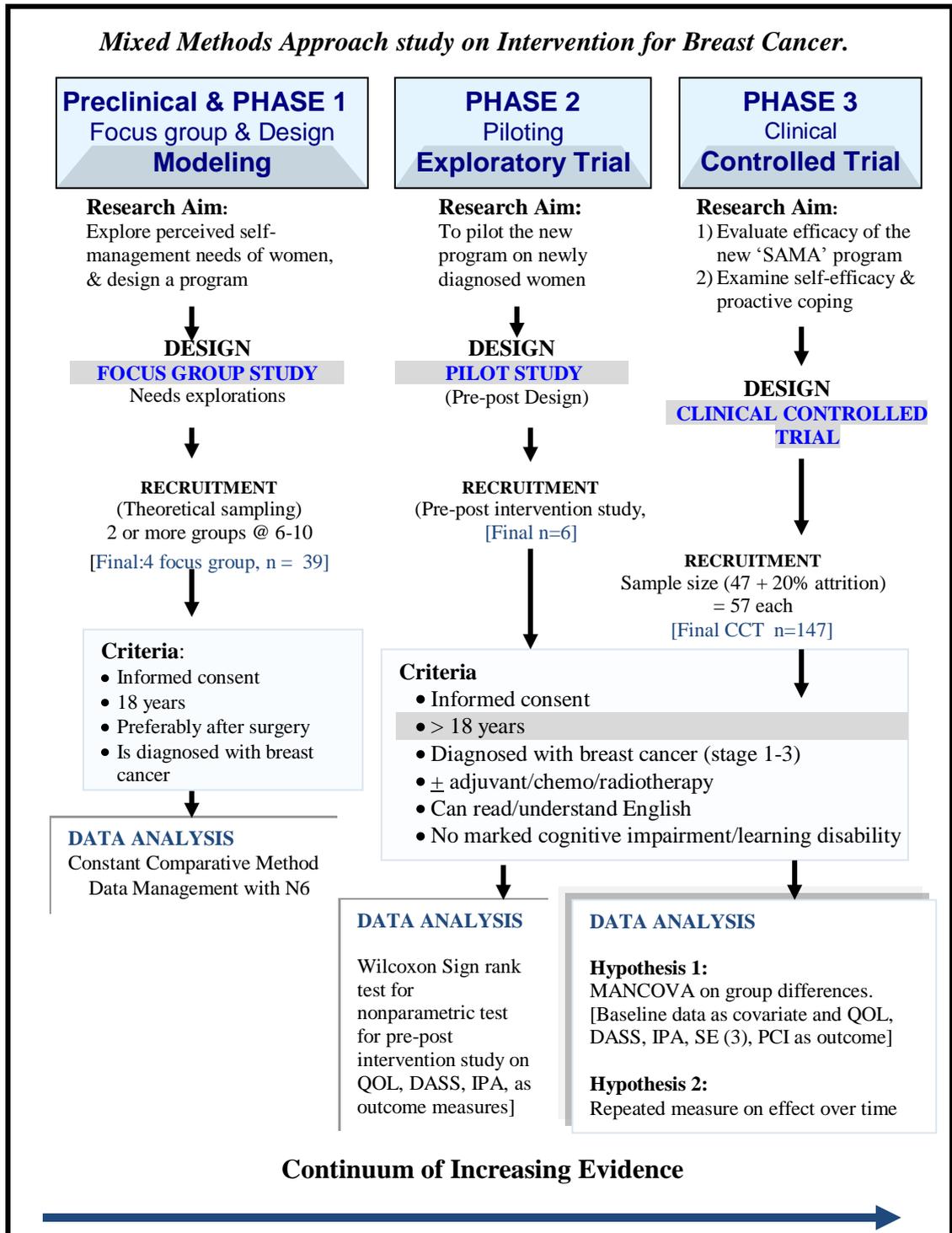
1.4.2 A Mixed-methods Approach

Figure 1.2 shows the progression and use of a mixed, qualitative followed by quantitative approach to the study. This ‘mixed-methods-research’ (Johnstone, 2004; Moffatt, White, Mackintosh, & Howel, 2006) was used to address the complexity of research in healthcare in order to overcome the limitations from using quantitative methods alone. When incorporated into traditional trial design, a mixed-method improves the sensitivity to the priorities of patients and enhances the quality of the evidence base for informing policy and practice (Dixon-Woods, Agarwal, Young, Jones, & Sutton, 2004; Moffatt et al., 2006).

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Figure 1.2

Flow Chart of the Mixed-method Study



Self-management intervention program for Women with breast cancer

Qualitative research is an ‘artful complement’ to aid researchers in accessing information beyond that obtained by quantitative methods (Tate, 2006). It is particularly appropriate for researching a previously unexplored topic but is relatively under-represented in medical research (R. Barbour, 2001; RS. Barbour, 2005; Green & Britten, 1998; Pope, Ziebland, & Mays, 2000). It may capture more meaning as medical care today needs to be patient-centered (IOM, 2001a, 2007).

Therefore, such mixed–methods research are (1) facilitatory – as one strategy facilitates or ‘assists’ the other, (2) complementary - because two strategies are used to investigate different aspects of a problem, as well as (3) triangulatory – because it involves corroboration in which one method is used to verify the findings of the other (Brannen, 2005; Hammersley, 1996).

1.5 Aim and Objectives of the Study

The aim of this study was to explore, develop and evaluate a self-management intervention for women newly diagnosed with breast cancer. The objectives of the study are presented below according to the specific phases of this study.

Self-management intervention program for Women with breast cancer

1.5.1 Preclinical: Reviews of Pertinent Literatures

The aim of this section was to review literature pertaining to self-management, chronic care and breast cancer epidemiology and intervention. The review focused on challenges /threats faced by people, as a consequence of having breast cancer, within the three areas of self-management tasks commonly encountered by people with chronic conditions. The purpose was to identify the therapeutic components for inclusion in a self-management intervention for women newly diagnosed with breast cancer.

1.5.2 Phase I: Needs Assessment and Program Development

A needs assessment via focus groups for the purpose of exploring the perceived self-management needs from the women's perspectives was conducted. The aim was to identify the intervention components (and underlying mechanisms that may influence outcomes) in order to inform the development of a self-management intervention program for Malaysian women with breast cancer.

1.5.3 Phase II: Piloting

A pilot study on a small cohort of women with breast cancer was conducted to test the newly developed program, and to prepare for the clinical controlled trial.

1.5.4 Phase III: Intervention Evaluation using a Clinical Controlled Trial (CCT).

A CCT was conducted to evaluate the impact of the program on women's QOL, limitation in participation in life roles, psychological symptoms, as well as specific self efficacy and proactive coping at immediately post-intervention (post-test/ T2) and at follow up (T3), with baseline (T1) adjusted. The posttest (T2) is 4 week after baseline and the follow up test (T3) is 4 week from T2 or 8 weeks from baseline.

1.6 Overview on Thesis

This section delineates the presentation of this thesis based on the entire study as illustrated in Figure 1.2. Chapter One introduces the background to the study. Chapter Two covers the literature review which leads to the conceptual framework underlying the study. Chapter Three details the need assessment via focus groups whereby the perceived needs and concerns of Malaysian women with breast cancer are reported. Chapter Four presents the development of the SAMA intervention. Chapter Five presents the pilot study to explore feasibility and acceptability of the newly developed program by a cohort of women with breast cancer. Chapter Six to Eight present the Clinical Controlled Trial (CCT). Finally, Chapter Nine presents the discussion and the conclusion of the study.

2

LITERATURE REVIEW

Medical care alone is insufficient for managing chronic conditions
(T. Bodenheimer et al., 2002).

2.1 Epidemiology of Breast Cancer

Chronic physical and mental health conditions accounted for 47% of the global burden of the disease in 2002. It is predicted that it will account for nearly 80% of worldwide diseases by the year 2020 (World Health Organisation, 2003) with poorer health outcome and increase burden for cancer survivors (M. Brown, Lipscomb, & Snyder, 2001; Yabroff, Lawrence, Clauser, Davis, & Brown, 2004). Chronic diseases are estimated to consume about 70-80% of US health-care spending (Coleman & Newton, 2005). Chronic diseases are the major cause of death and disability in Malaysia, accounted for 71% of all deaths and 69% of the total burden of disease (AS Ramli & Taher, 2008)

Cancer together with heart disease, stroke and depression have been identified as the most common cause of death (Epping-Jordan, Pruitt, Bengoa, & Wagner, 2004; Jemal et al., 2005; Yach, Hawkes, Gould, & Hofman, 2004). Breast cancer, among all cancers, is the leading cause of cancer mortality in women worldwide. Out of the 35 million people who died from chronic disease in 2005, half were under 70 years and half were women (WHO, 2005a). Breast cancer is primarily a woman's disease, although among males there is a minimal risk of developing breast cancer as well, with a ratio of 1:100 as reported by the American Cancer Society (American Cancer Society, 2005).

Self-management intervention program for Women with breast cancer

Breast cancer today is highly curable if detected early, but unfortunately about 80% of the cases are detected at advanced stages in developing countries (Boutayeb & Boutayeb, 2005). Incidence and mortality rates of women with breast cancer vary considerably by world region with at least a 10-fold variation in incidence rates worldwide (Bray, McCarron, & Parkin, 2004; Parkin & Fernandez, 2006). In general, the incidence is high (greater than 80 per 100,000) in developed regions of the world and low (less than 30 per 100,000) in developing regions (Bray et al., 2004; Parkin & Fernandez, 2006).

With over 100 years of research, it is now well known that breast cancer is a disease driven by hormones, genetics (sex, body compositions, genes), and lifestyle (Washbrook, 2006). Studies showed that there is a rapid rate of increase in incidence rates before menopause (ages 40–50) and then a decline in rates (Bray et al., 2004). Higher level of physical activity (Blair et al., 1989; Sandvik et al., 1993) and weight maintenance has been linked to lower rates, possibly due to the diminishing levels of circulating estrogens.

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Two factors which have often been blamed for increasing the risks of having a breast cancer are stress and food. However, recent evidence found inconclusive evidence of job stress and increased risks of breast cancer (Schernhammer et al., 2004). There is even a report of lower risk with high strain job (Nielsen et al., 2005) as stress impairs estrogens synthesis. In contrast, a case control study (n=622) reported that exposure to more than one life event is positively associated with breast cancer [odds ratio(OR):1.62; 95% CI: 1.09-2.40], and that a general feeling of happiness and optimism has a "protective effect" on its etiology (OR-0.75, 95% CI:0.64-0.86) (Peled, Carmil, Siboni-Samocho, & Shaham-Vardi, 2008).

Related to food, diet and weight - one study (n= 88647) found that intake of meat or fish during mid-life was unrelated to risk of breast cancer (Holmes et al., 2003). However, weight gain after menopause increases the risk of developing breast cancer condition (Chu et al., 1991; A. Eliassen, G. Colditz, B. Rosner, W. Willett, & S. Hankinson, 2006; Van den Brandt et al., 2000). A large cohort study (n=49 514 postmenopausal women) within the Nurses' Health study found that 15.0% (95% CI, 12.8%-17.4%) of breast cancer cases were attributed to weight gain of 2.0 kg or more since the age 18 years, and 4.4% (95% CI, 3.6%-5.5%) were attributed to weight gain of 2.0 kg or more since menopause (A. Eliassen et al., 2006).

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Low fat diet among postmenopausal women have been reported to correlates with lower recurrences (Stuart, Brennan, French, Houssami, & Boyages, 2006); as fat-tissue increased the risk of recurrences and decreased survival of women with breast cancer (Goodwin & Boyd, 1990; Rock & Demark-Wahnefried, 2002). Evidence shows that environmental lifestyle factors such as diet and exercise are prominent risk factors (Bray et al., 2004; Deapen et al., 2002; Ziegler & Hoover, 1993). In short, the evidence suggests that women need to self manage their weight and may benefit from self monitoring their BMI status, physical activity and dietary habits. However, a recent study by the American Cancer Society found that cancer survivors were not pursuing healthy lifestyles (CM. Blanchard, Courneya, & Stein, 2008). Managing lifestyle is as important as managing the illness in women with breast cancer. These findings thus argue for health education on the important linkage between diet and disease (Khor & Gan, 1992), and for woman to take an active role in managing these modifiable factors and pursuing a healthy lifestyle behaviours.

2.1.1 Incidence of Breast Cancer Worldwide

The most prevalent cancer in the world is breast cancer , with 4.4 million survivors living up to 5 years following diagnosis (D. M. Parkin, F. Bray, J. Ferlay, & P. Pisani, 2005). One in 8 women will develop breast cancer before the age of 75 years (Globocan, 2002).

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By 2020, the total number of cases of cancer is projected to increase by 29% and 73% in the developed and the developing countries respectively. This is largely a result of an increase in the number of old people, urbanization and change in dietary habits (Boutayeb & Boutayeb, 2005).

There are marked geographical variations, with an age-standardised incidence of between 95 per 100,000 in the developed countries and 20 per 100,000 in less developed countries (D. Parkin, F. Bray, J. Ferlay, & P. Pisani, 2005). Incidence rates are high in most developed countries (except for Japan, where it is third after colorectal and stomach cancers), and modest in Eastern Europe, South America, Southern Africa, and Western Asia.

Around Asia, the incidence rate is reported as modest (Pisani, Parkin, Bray, & Ferlay, 1999). Breast cancer is the most common cancer for women in all the Asian regions (Rojas et al., 2005). In Singapore, there has been an annual increase of 3.6% between 1968 and 1992 (Bray et al., 2004; Parkin & Fernandez, 2006). The incidence rates are about 5-fold lower in reports around the Asian region compared to Western countries (Lacey, Devesa, & Brinton, 2002). However, it has also been reported that the rates are rising alarmingly in Asia (Sasco, 2001).

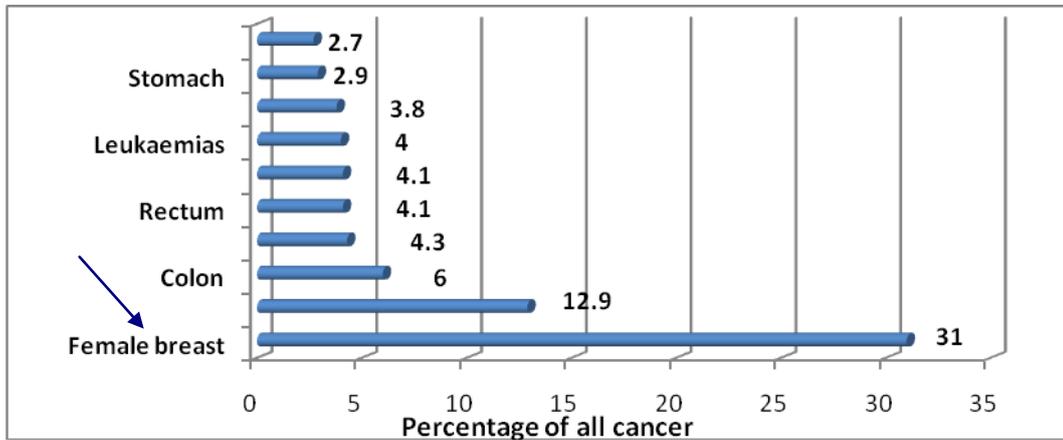
2.1.2 Incidence of Breast Cancer in Malaysia

Malaysia is a multi-racial country with a population of approximately 23 million people, comprising of Malays (58%), Chinese (24%), Indians (8%) and others (10%). The International Agency for Research in Cancers estimated that the incidence of breast cancer in Malaysia as 34.8 per 100,000 with almost 4,000 new cases in the year 2000 (Globocan, 2002).

It was reported that there were 3738 new cases of breast cancer in 2003 (National Cancer Registry, 2003). This is an estimate of 46.2 per 100,000 age standardized incidence rate, which translates to a 1 in 19 chance of Malaysian women developing breast cancer in their lifetime. At a percentage of 30.4% of all newly diagnosed cases of cancer in Malaysian women, breast cancer is the most common cancer in women as depicted in Figure 2.1 (NCR, 2003). In 2002, 52.3% of newly diagnosed women were younger than 50 years old (National Cancer Registry, 2002). Among the three main races, 1 in 16 Chinese women, 1 in 16 Indian women and 1 in 28 Malay women will develop breast cancer in their lives respectively (Lim & Halimah, 2004). Table 2.1 present the variation in the incidence rates according to age and ethnicity.

Figure 2.1

The Most Prevalent Cancers in Females, Malaysia 2003



The Second national cancer Registry, 2003 (National Cancer Registry, 2003)

Available at <http://www.acrm.org.my/ncr/documents.pdf>

Table 2.1

Breast Cancer Incidence (per 100, 000) by Age

RACE	Age Group (age = 'x' and below)								Cumulative Ratio
	9	19	29	39	49	59	69	70+	
Chinese	0	0.2	2.7	45.5	154.1	190.2	188.1	117.5	6.3
Indian	0	0	2.6	26.5	90.3	204.3	201.1	224.5	6.3
Malay	0	0.2	2.4	27.7	86.5	125.1	82.0	61.2	3.5

The Second National Cancer Registry, 2003 (NCR, 2003)

Available at http://www.acrm.org.my/ncr/documents/NCR_2nd_Report/Chapter1.pdf .

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Within the Klang Valley, two major hospitals offering treatment to women with breast cancer are the Kuala Lumpur Hospital (KLH) and the University Malaya Medical Centre (UMMC). In the case of KLH, the majority of the patients are Malay where an alarming 50-60% of new diagnosis are at advanced stages (stage 3-4), with an average tumor size of about 5.4 cm (Hisham & Yip, 2003). In the case of UMMC, for the period 1998 to 2001, out of the 752 new cases of breast cancer; the majority were Chinese predominantly around 40 to 49 years, about 30% to 40% of them in late stages with an average tumor size of 4.2 cm (Hisham & Yip, 2003). In short, incidence rates are highly prevalent in the 40-49 years age group and more than 50 percent of cases are below 50 years old. In general, the incidence rates among Chinese and Indians are higher compared to the Malay ethnic. However, the Malay patients are found to have larger tumors and are usually at the advanced stages when diagnosed.

2.2 Breast Cancer as a Chronic Condition

2.2.1 Acute versus Chronic status

Some breast cancer such as ‘carcinoma in-situ’ type may be categorized as an acute condition, i.e. typically short-lived, has no permanent disruption of functioning and cure is often the predictable outcome.

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The more advanced-staged are categorized as ‘terminal’ conditions since morbidity is high and definite. Overall, most other breast cancer may be considered an evolving chronic condition.

Chronic conditions are often defined in terms of duration, prognosis, pattern and sequelae (Delaware Healthcare Association, 1998; Dowrick, Dixon-Woods, Holman, & Weinman, 2005; O'Halloran, Miller, & Britt, 2004; Von Korff et al., 1997). The World Health Organization defines chronic diseases as having one or more of the following characteristics (Delaware Healthcare Association, 1998; Zwar, Harris, Griffiths, & Roland, 2005) which includes whether the disease:

- i) is permanent,
- ii) involves residual disability,
- iii) caused by non-reversible pathological alteration,
- iv) requires special training or rehabilitation, or a long period of supervision, observation, or care.

Therefore, based on reviews on survivorship and challenges faced over indefinite periods, breast cancer condition can be classified as a form of chronic illness.

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Using the TNM (Tumour, Node, Metastasis) Classification System, illness is staged depending on factors like the size of the tumor, lymph node involvement, and distant spread of cancer cells. According to the Bloom-Richardson cancer grading system, a score of Grade 1 shows that the cells are least aggressive and a Grade 3 suggests aggressive cells (Woodward et al., 2003). A stage_I breast cancer refers to a small tumor (T1), without spread while a Stage IV is refers to a metastatic disease. Treatment decisions are made on the basis of these stages and grades. Early detection and better treatment have enhanced survival rate up to above 50% compared to a decade ago (American Cancer Society, 2005), with as high as 90% for noninvasive cancer (Peto, Boreham, Clarke, Davies, & Beral, 2000). Table 2.2 showed the survival rate of women with breast cancer at the five year milestone following treatment for precancerous and early_staged breast cancer.

Table 2.2

Disease-Free and Survival by Stage of cancer at 5 years

Stage at diagnosis	Disease-free survival (%)	Breast cancer specific survival (%)
DCIS	90-95	98-100
I*	80-95	80-98
II*	50-75	50-70
III	50-66 (15-35*)	30-60 (15-40*)
IV-metastatic	0-5	5-20

Data from Stuart et al, Australian Family Physician, 35 (4), 2006 (*treated with breast conserving technique). DCIS+Ductal carcinoma in situ, stageI-III: early breast cancer, stageIV= advanced cancer

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In the USA, data taken in 2005 from the Surveillance, Epidemiology, and End Results (SEER) showed that 86.8% of women diagnosed 5 years ago are still alive, 77.3% of those diagnosed 10 years ago are still living, while 52.2% of those diagnosed 20 years ago are still living (Ries et al., 2005b). These reports on survival rates and age (at diagnosis) showed that 5-year survival rates for women under 45 is 83%, for women aged 45-54 is 87% and for women 55 years and older is over 88% (Ries et al., 2005a).

Today in the United States, breast cancer survivors account for 23% more than 10 million cancer survivors (P. Ganz & Hahn, 2008). The rate of survivorship is still increasing and today, there are an estimated 4.4 million survivors up to 5 years following diagnosis compared to only 1.4 million survivors from lung cancer (D. Parkin et al., 2005). Elsewhere, survival rates range from 49% - 74%, with Australia-New Zealand (68%) and Japan (74%) among the highest (Pisani et al., 1999). In Malaysia, the 5-year survivor rate is generally unknown, with estimates of about 63 percent, 57 percent and 46 percent for the Chinese, Indian and Malay respectively, and over 81 percent for stage I disease (Yip, Nur Aishah, & Mohamed., 2006). Thus, the general trend of breast cancer conditions in terms of duration, prognosis, sequelae seems to be increasingly towards a chronic condition presentation. Advances in the detection and treatment of cancer, with an increasing aging population means an increase in the numbers of cancer survivors in the near future (IOM, 2005).

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Women with breast cancer face a myriad of survivorship issues, compounded by co-morbidities common in the older age group. They have a higher risk for other co-morbidities like other cancers, cardiovascular disease, osteoporosis, diabetes, and accelerated physical-cognitive decline (Ahles et al., 2005; P. Ganz, 2001; Silliman, Prout, Field, Kalish, & Colton, 1999). Estimates on the burden of illness in cancer survivors in a national, population-based sample in the USA, cited that cancer survivors reported significantly higher burden and reported their health as fair or poor (31.0% versus 17.9%; $p < .001$) compared to matched control subjects (Yabroff et al., 2004). In fact, it was reported that survivors faced a wide array of physical, psychosocial, economic-occupational threats to their psychological adjustment in the treatment and survival period (Chirikos, Russell-Jacobs, & Jacobsen, 2002; Katz, Irish, & Devins, 2004; NHMRC, 2001). The Long-Term Medical Conditions Alliance (LTMC, 2004)'s recognized the effects of long-term conditions on people's emotional and social well-being, and the opportunities available to improve a person's quality of life (Chew et al., 2003; J. Wilson, 1999). Thus, it is essential for survivors to be actively collaborating in the management of these multiple presentations of symptoms which interfere with life activities. The ultimate goal of intervention for breast cancer as a chronic condition is the maintenance of pleasurable and independent living, not cure (Holman & Lorig, 2000; IOM, 2007).

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Like other chronic conditions, for women with breast cancer to maintain pleasurable and independent living, they need to access to high quality information, continuous care, symptom management and support in managing the social, economic and psychological consequences of their symptoms (Holman, 2005 ; Macdonald, Bruce, Scott, Smith, & Chambers, 2005; Stuart et al., 2006), as well as how to reduce the risk of recurrence (IOM, 2001a). The following sections review the arrays of self-management needs which women with breast cancer must manage to maintain independent living.

2.3 Self-management Needs of women with Breast cancer

Applying the chronic illness trajectory model developed by Corbin and Strauss (1988), the self-management needs for persons with chronic conditions can be divided into three types: medical management, role management, and emotional management (T. Bodenheimer et al., 2002; Von Korff et al., 1997). In chronic illnesses, the day-to-day care responsibilities by patients and their families are real challenges that need to be dealt with, and these challenges need to be managed collaboratively with healthcare providers (Coleman & Newton, 2005).

2.3.1 Needs within the Medical-related Self-management Tasks

Table 2.3 summarizes the common physical side effects from the various medical treatment for breast cancer like surgery, radiotherapy, chemotherapy and the two main hormonal therapies (Stuart et al., 2006). These threats that need to be managed, range from the commonly reported incidence of pain, fatigue and insomnia, to less commonly reported effects like menopausal and sexual impairment. After surgery, post-mastectomy pain syndrome (PMPS), continues in about 50% of women (particularly in the young and obese) right up to an average of 9 years post-surgery (Macdonald et al., 2005). In a random sample of 744 breast patients, axillary dissection (AD) and axillary radiotherapy (RT) after dissection were significantly related to the occurrence of arm symptoms (odds ratio for AD = 3.3, $p < .001$; odds ratio for RT = 3.1, $p < .001$) (Winkle Kwan et al., 2002).

Lymphedema, a chronic condition with incidence rates ranging from 6 to 83 percent (B. Clark, Sitzia, & Harlow, 2005) can occur even 20-30 years after breast axillary treatment (Coates et al., 2000). Lymphedema increases with the amount of surgery and radiation to the lymph node areas, as well as with increased chemotherapy treatment (Brezden, Phillips, Abdolell, Bunston, & Tannock, 2000; Hayes, Janda, Cornish, Battistutta, & Newman, 2008).

Self-management intervention program for Women with breast cancer

During chemotherapy, positive correlations between anxiety and depression in patients undergoing chemotherapy were found (Pandey et al., 2006; Schreier & Williams, 2004). Using depression and pain as the strongest predictor of fatigue in cancer survivors, n=1957 (JE. Bower et al., 2000), it was found that about 34% of breast cancer patients (n=763) reported significant fatigue at 1-5 years following diagnosis, (J. Bower, Ganz, Desmond, & et.al., 2006).

Insomnia, another common complaint in patients with breast cancer has been shown to have a host of psychological and medical correlates and consequences (Fiorentino & Ancoli-Israel, 2006). Furthermore, a randomized study on fatigue and exercise (n=120, mean age 52 years) from five large cancer centers, demonstrated that 30% reported poor quality sleep even before the start of treatment (Poniatowski, 2001).

Table 2.3.1 presents a tabulated list of some commonly reported challenges from cancer treatment that complicates the tasks that women need to manage. Less commonly reported challenges include menopausal symptoms like hot flushes and dyspareunia (Leining et al., 2006) which are potential medical management tasks that also needs attention.

Table 2.3

Common challenges from cancer treatment

Surgery	
Pulling-over-scar/ pain/discomfort, Scar contracture Paraesthesia at axilla, medial upper arm Lymphedema Physical imbalance, neck pain from breast tissue loss (those with large breasts) Intermittent, jabbing breast pains Intermittent pain at upper arm on the side of an axillary clearance (3–6 months)	
Radiotherapy	Chemotherapy
Breast edema and tenderness Hyper-pigmentation in the first year (Later, a greater density of tissue) Decrease in size of residual breast	Tiredness/fatigue Hair loss Bitter taste in mouth (few weeks) Peripheral neuropathy may persist
Hormonal therapy (Tamoxifen)	Hormonal therapy (Aromatase)
Hot flushes Tender breasts Gastrointestinal upset Vaginal dryness and discharge Decreased libido Abnormal vaginal bleeding	Hot flushes Musculoskeletal pain Vaginal dryness Osteoporosis

Table adapted from Stuart et al, 2006.

Apart from managing illness related challenges, these women need to manage risk reduction behaviors (IOM, 2001b) in order to improve health. Women especially the 50-69 year old need to adopt routine mammography and clinical breast examination (Baxter, 2000). A study reported when more of the health-recommendations guideline are met by cancer survivors, their health-related quality of life increases (CM. Blanchard et al., 2008).

Self-management intervention program for Women with breast cancer

The relationship between breast cancer and weight gain is common in older women and women need to manage an ideal body weight while managing the psychological-emotional distress simultaneously. A case control study in Poland (n=4502) reported that breast cancer risk is reduced by 30-40% with moderate-vigorous exercise, OR = 0.74; CI = 0.62-0.89 (Peplonska et al., 2008) and women need to increase physical activity (Courneya, Mackey, & Jones, 2000; Tabenkin, Goodwin, Zyzanski, Stange, & Medalie, 2004). Unfortunately, a recent study found that of the various cancer survivors (n=9105), only 30-47 percent are meeting the recommended 150 minute exercise per week (CM. Blanchard et al., 2008). In fact, studies have shown that even stress and depression can inhibit efforts made to lose weight (Hainer, Kabrnova, Aldhoon, Kunesova, & Wagenknecht, 2006). Quality of life (QOL) is also strongly linked to weight loss suggesting the importance of dietary management in patients with cancer (Nourissat et al., 2008). Thus, managing threats, risks and the health promotion aspects reduces state anxiety, enhance functioning and QOL (CM. Blanchard et al., 2008; Blanchard CM., Courneya KS., & Laing D., 2001).

In short, consideration for the needs to manage illness tasks must be balanced with the needs to manage the health task that encompasses the work that people living with chronic condition must manage in their lives. The next two sections present the needs to manage emotional and role-related tasks.

2.3.2 Needs within Emotion-related Self-management Tasks

Emotional distress as a core indicator of a patient's wellbeing has been promoted as the sixth vital sign in cancer care (Bultz & Carlson, 2005). Emotional distress varies in level of intensity, depending on severity of disease and phase of treatment (Simonton & Sherman, 1998). It has also been reported that the onset of reactive anxiety and depression also often coincides with the fatigue experienced with daily radiation treatments (Rowland & Holland, 1990). Thus, management of emotion is crucial as one quarter to one third of women undergoing chemotherapy experienced distress (Campora, Naso, & Vitullo, 1992; S. Newell, Sanson-Fisher, Girgis, & Ackland, 1999).

Up to 50% of women with breast cancer experience psychiatric morbidity (A. Hall, Fallowfield, & A'Hern, 1996), coupled with anxiety and depression commonly faced right from the moment they are diagnosed with breast cancer (Dow, 2000). In a cohort study on breast cancer patients (n=2943), the post-hoc multivariate analysis revealed that chemotherapy (HR: 1.2; 95% CI: 1.0 – 1.5), and hormonal receptor positive status (HR: 1.2; 95% CI: 1.0 – 1.5) were significantly and independently associated with an increased risk for developing depression (K. Lee, Ray, Thomas, & Finley, 2007).

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Cancer and its treatment are linked to many psychosocial factors like anxiety and depression can also impair social functioning roles and an adversely affect the quality of life (Velanovich & Szymanski, 1999). There are evidences which suggest that distress in cancer patients is highly prevalent, under-recognized and consequently under-treated (Cull, Stewart, & Altman, 1995; PB. Jacobsen, 2007; Zabora et al., 2001). It is also more pronounced in some subgroups, such as during the first year after breast cancer diagnosis (P. Ganz et al., 2004), and in younger patients than in older ones ($\rho = 0.20, p=0.49$). Untreated psychological distress adversely affects many areas of patient functioning and participation in life which in turn lowers their QOL.

In a large cross-sectional study of patients screened for emotional distress at Johns Hopkins Kimmel Cancer Center in Baltimore, United States (Zabora et al., 2001) and at the Tom Baker Cancer Centre, Canada (Carlson, Speca, Patel, & Goodey, 2004), high levels of fatigue (49% of all patients), pain (26%), anxiety (24%), depression (24%), and financial hardship were found. Women with breast cancer ($n=723, 801$) when compared to women in the general population, were 37% more likely to commit suicide and the elevated risk of suicide persisted even long after diagnosis (Schairer, Brown, Chen, & al., 2006).

Nevertheless, a systematic review from 31 studies revealed some parameters of psychosocial factors which have positive health enhancing impact such as social support, marriage and others (Falagas & et.al., 2007). Social support has been identified as a health-enhancing factor in cancer care (CG. Blanchard, Albrecht, Ruckdeschel, & et.al., 1995; Lehto, Ojanen, & Kellokumpu-Lehtinen, 2005).

Therefore, emotional management tasks should also consider strategies for health enhancing factors like self-efficacy and social support. In sum, the ability to manage changing emotions is crucial, as emotional functioning means the ability to enjoy life which gives strength to commit to treatment (Luoma & Hakamies-Blomqvist, 2004).

2.3.3 Needs within Role-related Self-management Tasks

Evidence suggests that cancer characteristics and cancer treatment may also affect life performances. Chemotherapy treatment for women with breast cancer can lasts for many months and interferes with childcare, social relations, role functioning such as continuing employment (E. Maunsell, Brisson, Dubois, Lauzier, & Fraser, 1999) and performances of domestic work (Luoma & Hakamies-Blomqvist, 2004).

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Results of a comparative study of interviews with 102 women (61 white, 41 black) suggest that black women have more difficulty in social-role functioning, especially the resumption of household activities (Bourjolly & Nuamah, 1999). In addition, breast cancer survivors were more likely to be functionally impaired at the five-year benchmark, more likely to reduce work effort and experience greater downturns in market earnings (Chirikos et al., 2002). Indirectly affecting household roles is the financial burden and strains from the costly treatment of breast cancer. In about 20-30 percent of women with breast cancer, an over expression of the growth factor receptor (HER2) increases aggressiveness of their cancer cells (Slamon et al., 2001). These women required targeted therapy which cost around RM 100-180 per course. This huge financial burden (Sasser et al., 2005) that aggravates household expenses has an impact on the women's role tasks.

Juggling home and work roles and maintaining their role as a major care provider in the family is increasingly common for women today. Maintaining, adapting and creating meaningful life roles, such as those of mother and caring for aged parents, are pertinent life tasks for women with breast cancer since older women are more at risk of the disease (Forbes, 2001). In fact, patients with higher disease-stages have more unmet needs (A. Hall et al., 1996) and this also has an impact on social, marital and family relationship.

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The psychosexual role issues of women are also affected, aggravated and/or contributed by depression, use of hormone therapy, chemotherapy and fatigue (NHMRC, 2001; Schag et al., 1993). Sexual functioning has been found to significantly affect women (n=558) who received chemotherapy compared to those who did not, regardless of the type of surgery ($p < 0.001$) (P. Ganz et al., 2004). A study examining the sexual problems of women below 50 years (n=209), revealed problems in four areas (lack of interest in sexual activity, difficulty becoming aroused, difficulty relaxing and enjoying sex, and difficulty achieving orgasm), with a lack of interest being the main challenge (Burwell, Case, Kaelin, & Avis, 2006). These needs are critical but research suggests they have been ignored in a medical model delivery system. For example, a study in Japan (n=102) found that discussing body image and sexuality were disregarded in therapeutic decision-making situations in breast cancer patients (Adachi, Ueno, Fujioka, Fujitomi, & Ueo, 2007).

2.3.4 Needs within Quality of life- related Issues

As the medical treatments for people with chronic illnesses are increasingly being evaluated for life extension and quality of life issues (EL. Lev & Owen, 1996), it is thus imperative to review how cancer affects one's health-related quality of life (QOL) and participation in life roles across the illness trajectory period.

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For women diagnosed with breast cancer, improvements in their life expectancy have led to a greater emphasis on QOL (Rampaul et al., 2003; Stanton, 2006). QOL assessment can be used in diagnosis, predicting prognosis, assessment, patient monitoring, clinical decision-making, communication and treatment (Perry, Kowalski, & Chang, 2007). However, there is limited information about QOL of Malaysian women which could be possibly due to a lack of research and lack of valid, reliable and responsive instruments to measure patient-reported outcomes (Pusic et al., 2007) .

Evidence showed that about 20-30% of survivors reported a disruption in their quality of life through loss of roles, functional abilities and problems with social relationships (Irvine, Brown, Crooks, Roberts, & Browne, 1991). Lower QOL has also been found specifically related to menopausal symptoms and problems with relationships, sexual functioning, and body image (Avis, Crawford, & Manuel, 2005). Impaired QOL have also been found in postoperative patients, where up to 70 percent of stage I to III women below 50 years (n=202) reported deterioration in their QOL lasting up to several years post diagnosis (Avis et al., 2005).

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Ganz & Goodwin (2005) found that when assessing the QOL of women with breast cancer, their stage of disease should be taken into account. However, studies have shown that the more important factors to be considered are the non-medical psychosocial and age factors. Past chemotherapy was a statistically significant predictor of a poorer current level of QOL, $p = 0.003$ (A. Ganz et al., 2002). In another study on post adjuvant therapy ($n=86$), QOL was reported as generally favorable (Lindley, Vasa, Sawyer, & Winer, 1998), while one study ($n=763$) found it to be associated with poorer functioning in several dimensions of QOL (A. Ganz et al., 2002).

Research on QOL in women with breast cancer are needed in order to evaluate if there is some subset of breast cancer survivors where prevention or rehabilitation is needed due to a functional status decline (Schmitz, Cappola, Stricker, Sweeney, & Norman, 2007; Silliman et al., 1999). For example, a large study ($n=1082$) from a pool of 120 thousand recruited for the Nurses' Health study found that young women who developed breast cancer experienced the largest relative decline in QOL and across multiple domains of physical roles, bodily pain, social functioning and mental health (Kroenke, Chen, Kawachi, Colditz, & M.D., 2004) when compared to the middle-aged and elderly women.

Impairment in QOL had been linked to psychosocial factors like menopausal symptoms, problems with relationships, sexual functioning, and body image (Avis et al., 2005; Burwell et al., 2006; Leining et al., 2006); as well as problems with relationship and body-image challenges (E. Maunsell, Drolet, Brisson, Robert, & Deschenes, 2002) and being of younger age (Kroenke et al., 2004). Impairment in QOL has also been linked to psychological symptoms like anxiety, depression and adjustment disorder (Fawzy, 1999; Ryan et al., 2005), and recurrences of breast cancer (Arndt, Merx, Stegmaier, Ziegler, & Brenner, 2005). In cases of cancer recurrences, a significant decline was found in many domains of QOL like physical functioning, general health, and social functioning after recurrence (A. Ganz et al., 2002; Oh et al., 2004). Impairment in QOL had also been linked to physical factors like treatment related consequences of affected arm morbidity and lymphedema incidence (Kuehn et al., 2000; W. Kwan et al., 2002; Velanovich & Szymanski, 1999).

Thus, there is a need to consider what aspect of rehabilitation that needs more focus. To elaborate, the level of social integration (a potential focus for rehabilitation) was found to explain more of the variance in QOL than the treatment or tumor characteristics among the breast cancer survivors (Michael, Berkman, Colditz, Holmes, & Kawachi, 2002)

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Overall, the presentation of needs using Corbin and Stauss (1988)'s framework provides a new insight of looking beyond the challenges encountered within the medical tasks. This recognition that the health of women involves empowering them towards emotional, social, cultural, spiritual and physical well-being (M. Cohen, 1998; Currie & Wiesenber, 2003) has not been fully considered by the traditional medical health model, and thus must be addressed. Rightly, these complex needs require a balance of traditional medical care and some form of self-management skills over time, akin to other chronic disease management as proposed by Lorig (1994).

The review, thus far provides an understanding on the extensive needs of women with breast cancer as a chronic condition. It highlights the reasons on why the management of women with breast cancer warrants an innovative, broad based approach so as to address the multiple needs of these women. The understanding of the background of chronic care, the model for chronic care approach and the evidences for self-management intervention in chronic care are presented in the next section. In fact, a recent finding from breast cancer patients themselves showed they regarded themselves as living with a 'chronic condition' (M. Oxlad, TD. Wade, L. Hallsworth, & B. Koczwar, 2008a). This sets the scene on why we need a new model of care for breast cancer condition and this model of chronic illness care may be the way for managing breast cancer today in Malaysia and elsewhere around the world.

2.4 Self-management and the Chronic Care Model (CCM)

This section reviews the Chronic Care Model (CCM), an organizational approach in primary care for managing chronic conditions, as the background to self-management support. It highlights how self-management fits in this bigger picture, presents the concept and attribute, and examines its application to breast cancer care.

2.4.1 The Chronic Care Model (CCM)

The CCM is a system approach used in primary care settings to improve chronic disease management (T. Bodenheimer, Wagner, & Grumbach, 2002; EH. Wagner, 1998; E. Wagner, 2000). Chronic disease management aims to manage chronic conditions using a systematic care approach (Weingarten et al., 2002).

Figure 2.2 depicts how self-management support - one of the six interrelated components, fits into the model. There are three elements of relevance for this study: i) the self-management support, ii) the informed-activated patient and iii) the prepared-proactive team and they interact productively toward functional and clinical outcomes (Coleman & Newton, 2005).

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Unlike acute diseases management where the patients are passive recipient of care, the management of a chronic disease is characterized by an active role and responsibilities that a patient need to take (KR. Lorig & Holman, 2003; Newman, Steed, & Mulligan, 2004) in partnership with health staff. This partnership is not just a resource for understanding health problems; it is the basis for prevention and intervention (E. H. Wagner, 2000).

Figure 2.2

The Chronic Care Model



Figure 2.1 CCM - Ref: WAECPO815477, Feb 12 2008 (EH. Wagner, 1998).
Permission granted for reproduction by American College of Physician (see Appendix E).

2.4.2 *The Self-management Support*

The term 'self-management' was first introduced by Thomas Creer in the 1960s (KR. Lorig & Holman, 2003). Within the CCM at the system level, the term, 'self-management support' was used to refer to the process of making multilevel changes in healthcare systems and in the community to facilitate patient self-management (R. Glasgow, C. Davis, M. Funnell, & A. Beck, 2003). It arose as a support of the inability of the health system to cope with escalating chronic conditions. Thus, it attempts to enhance the ability of patients to successfully self-manage the day-to-day challenges of their condition with health professionals (JH. Barlow, Sturt, & Hearnshaw, 2002).

Self-management is a formalized patient-education program within the parameters of the medical regime (Tyreman, 2005) and to improve people's confidence to deal with medical, role and emotional management tasks (Adams, Greiner, & Corrigan, 2004). It refers to the learning and practicing of skills necessary to carry out an active and emotionally satisfying life in the face of a chronic condition (K. Lorig & Holman, 1993). A recent concept-analysis study of self-management in long term condition, defined self-management as an intervention in healthcare which increases a patient's power and responsibility for making decisions to help ensure that necessary health-care actions are taken (Embrey, 2006).

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A more pragmatic definition (adopted for this study and used as a guide in the design of the 4-week SAMA) is Gruman and Von Korff's 1996 (McGowan, 2005) broad concept of self-management (tasks/ activities) which is:

INVOLVES THE PERSON WITH THE CHRONIC DISEASE, ENGAGING IN ACTIVITIES THAT PROTECT AND PROMOTE HEALTH, MONITORING AND MANAGING OF SIGNS-SYMPTOMS OF ILLNESS, MANAGING THE IMPACTS OF ILLNESS ON FUNCTIONING, EMOTIONS AND INTERPERSONAL RELATIONSHIPS, AND ADHERING TO TREATMENT REGIMES (p2).

This definition implies work to be done by the patients at both the interpersonal and intrapersonal levels. It implies that the patient needs to make whatever cognitive, behavior and emotional changes in order to maintain a satisfactory QOL. The delineated tasks help us appreciate the need to supplement medical care with educational-cognitive-behavioral interventions, which is now a key feature in many healthcare delivery systems in many countries. (JH. Barlow, Bancroft, & Turner, 2005; JH. Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002; BMA, 2007; T. Bodenheimer, Davis, & Holman, 2007; Holman & Lorig, 2000; May, 2005; Von Korff, Glasgow, & Sharpe, 2002). The key attribute of self-management, or 'essential elements linked to the concept' (Embrey, 2006), on the three broad areas of tasks and the five core skills are presented below.

2.4.3 Core self-management Tasks and Skills

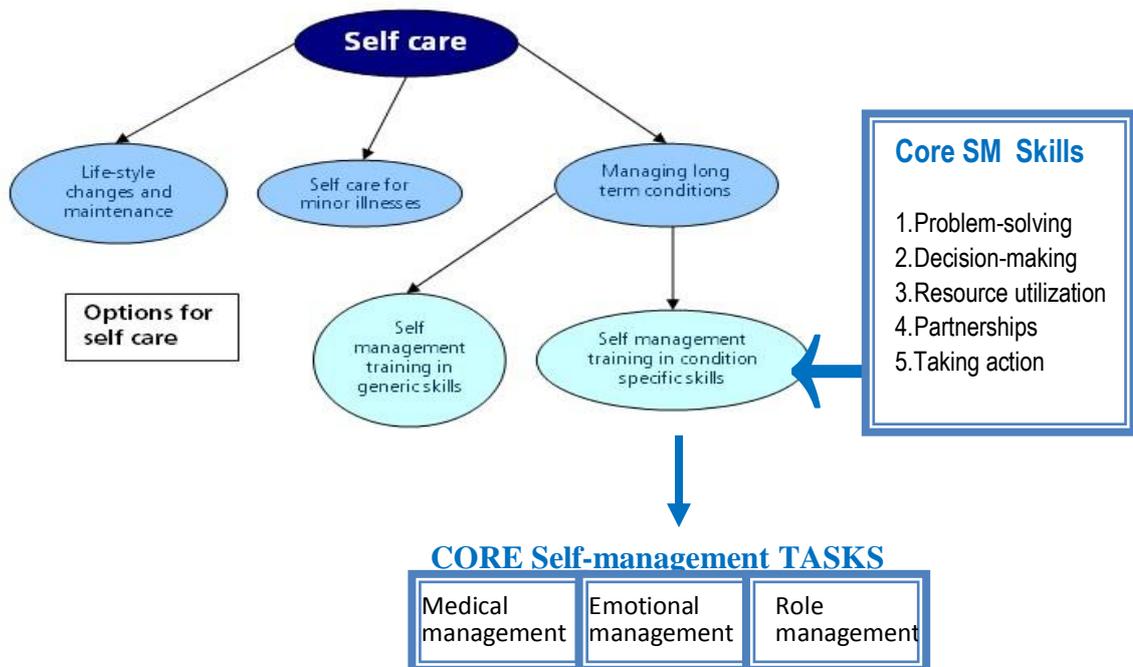
Figure 2.3 illustrates the subtle differences of self-management from the self care concept. Both terms have been used interchangeably and confusingly, because although different, the distinction is not clear. Both refer to a range of methods and behavior that enables people to manage their health and illness, leading to a range of positive outcomes (DOH, 2006). Self care refers to actions and decisions which are taken independent of interaction with a health professional (NM. Clark & et.al., 1991).

Self-management is regarded as a subgroup of self care which take place in the context of a recognized medical F with a level of health service input (Department of Health, 2006) and emphasizing patient-health professional collaboration for better care management. The five core skills (K. Lorig, 1996) and the three broad tasks (J. Corbin & Strauss, 1988) were added in the Figure 2.3 to highlight the self-management concept. The three broad tasks are medical, emotion and role management tasks, while the self-management skills includes, problem-solving and decision-making, resource utilization, developing effective partnerships with healthcare providers and taking action. These attribute of self-management (Embrey, 2006) can be learned to improve self-management of a chronic condition (Paula. Sherwood et al., 2007).

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Figure 2.3

Comparison on 'Self-management' and 'Self care'



Adapted from 'Option for Self Care, BMA 2007'. Available at <http://www.bma.org.uk/ap.nsf/Content/selfmanagementresource>

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Although education is one of the essential core components in self-management, the inclusion of self-management skills to patient education is one of the features that differentiates self-management education from the traditional patient education (T. Bodenheimer et al., 2002). People with chronic conditions must perform day-to-day management of their illnesses (T. Bodenheimer et al., 2002), and thus would need training and support (besides these skills), more than mere patient-education (Coleman & Newton, 2005; EH. Wagner, BT. Austin, & M. Von Korff, 1996b). Learning these three common sets of self-management tasks, ie. the medical, emotion and role tasks, facilitate restoration of a sense of control in life and enhances quality of life (K. Lorig, 1996; KR. Lorig & Holman, 2003).

2.4.4 Evidence of Effectiveness of Self-management Intervention

Self-management has been widely promoted as a mean to improve the quality of life of people with chronic physical conditions (Embrey, 2006). The efforts to improve systems of care for people with chronic illness, have resulted in rapid promotion and provision of self-management style programmes in the past few years (Coleman & Newton, 2005; K. R. Lorig et al., 1999; Von Korff et al., 1997; EH. Wagner, BT. Austin, & M. Von Korff, 1996a), especially the hospital-based programmes led by health professionals (JH. Barlow, Sturt et al., 2002).

Self-management intervention program for Women with breast cancer

From a healthcare cost utilization perspective, meta-analyses (67 studies) show that the self management program are effective economically particularly with severely ill enrollees (Krause, 2005). It has been reported that self-management has yielded health savings up to over \$2,000 per patient per year (Bourbeau, Collet, Schwartzman, & et.al., 2006), and is a viable answer to the increasing healthcare cost in cancer care (Meropol & Schulman, 2007). Meta-analysis involving 53 self-management studies (26 diabetes, 14 osteoarthritis, and 13 hypertension) reported a statistically and clinically significant pooled effect size of -0.36 (95% CI, -0.52 to -0.21) for hemoglobin and blood pressure levels in diabetes and hypertension (Chodosh et al., 2005) better glycemic control ($n=41$ studies) in primary care (Renders et al., 2001). For asthma, there were reduced symptom and hospitalization in 36 trials on adult asthma (Gibson, Powell, Coughlan, Wilson, & et.al., 2004). For diabetes, there was a report of significant reduction of BMI (-0.77 kg/m²) and systolic blood pressure (-6.2 mmHg), with implications that it was effective in reducing cardiovascular risk in newly diagnosed Type-2 diabetic patients (B. Thoolen et al., 2007).

Overall, evidence are suggesting that self-management interventions have small to moderate effects for some chronic disease (Warsi, Wang, LaValley, Avorn, & Solomon, 2004a).

Self-management intervention program for Women with breast cancer

In oncology, the National Cancer Institute, USA, recently acknowledged self-management as important for generating functional outcomes (Epstein & Street, 2007), even though it was viewed as a part of the helping relationships. Although chronic disease is acknowledged as best treated by a balance of traditional medical care and day-to-day practice of self-management skills (K. Lorig, 1994), there is a critical lack of study on self-management for women with breast cancer.

Despite all these favorable evidence, self-management programs have been reported as the least implemented and the most challenging area of chronic disease management (R. Glasgow et al., 2003), even in chronic non-oncology field. Perhaps one reason is that, researchers could not identify what types of self-management program features or characteristics are the most effective predictor for successful outcomes (Chodosh et al., 2005).

Therefore, the following sections review the theoretical underpinning of self-management intervention and their related attributes which may be potent mechanisms responsible for change at the interpersonal and intrapersonal levels.

2.5 Theoretical Underpinning of Self-management intervention

Theory gives planners the tools to move beyond intuition in designing health intervention based on understanding of behaviors (K. Glanz, Rimer, & Sharyn, 2005). The theory that is often linked to self management interventions and psychosocial interventions include social cognition, cognitive-behavioural and group development theory. Social cognition theory (SCT) addresses the processes of behavioral changes at the interpersonal level, while Beck's cognitive-behavioral theory (CBT) addresses the processes at the intrapersonal level (K. Glanz et al., 2005).

From a clinical perspective, theory-led focused programs are regarded as the best models for healthcare intervention (IOM, 2007). Von Korff, Gruman, et al. (1997) asserted that the theoretical underpinnings of effective self-management programs should be based on Social-cognition and Cognitive-behavioral theories. From a group perspective, Tuckman's theory is a useful guide for facilitator-led group. It has been applied in the training of health professionals to become effective members of an interdisciplinary team (P. Hall & Weaver, 2001; J. Walker & Mathers, 2004; Weber & Karman, 1991) and also in patient groups (Donelson, 2007). The key principles of the Tuckman's model will be discussed in chapter 4 while the SCT and CBT will be reviewed here.

2.5.1 The Socio-Cognitive Theory – Interpersonal level

Bandura's Social Cognitive theory explains that behavior is influenced by a triadic reciprocal-interaction of i) personal factors, ii) aspect of the behavior itself, and iii) the environment (Bandura, Adams, & Beyer, 1977). Within SCT, the three main factors that will affect the likelihood that a person will change his health behavior are: i) self-efficacy, ii) goal, and iii) outcome expectancies (K. Glanz et al., 2005; Marks & Allegeante, 2005). Studies have shown that SCT provides a theoretical framework for evaluating improved quality-of-life outcomes through interventions with physical chronic conditions (CS. Burckhardt, Archenholtz, & Bjelle, 1993; Damush et al., 2003; Fu et al., 2003; Karlein et al., 2003; K. R. Lorig et al., 1999), and recently, with cardiac diseases (NM. Clark & Gong, 2000), and breast cancer illness (Cimprich et al., 2005; Graves, Carter, Anderson, & Winett, 2003).

SCT also provide a guide for strategies to increase self-efficacy (that motivates and regulate behaviors), via skill mastery, role modelling of the targeted behavior, rehearsing the behavior and providing feedback on the performance (Adams et al., 2004; Elder, Ayala, & Harris, 2002; Marks & Allegeante, 2005). There are also postulations that many of the changes in health behaviors required strategies informed by cognitive behavioral theory.

2.5.2 *The Cognitive Behavioral Theory – Intrapersonal level*

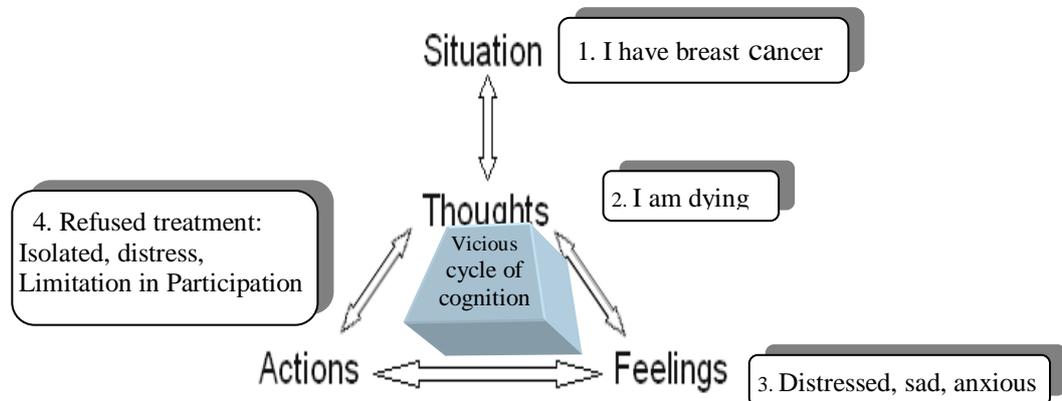
The Cognitive Behavior Theory (A. Beck, 1976) operates at the intrapersonal level (K. Glanz et al., 2005). Beck hypothesized that emotions arise from *how* they are appraised, which is influenced by underlying cognitive structures that cause faulty /biased interpretations of events. The terms Cognitive Therapy and Cognitive Behavior Therapy (CBT) are often used interchangeably as it is usual for cognitive-based therapy to incorporate behavioral techniques as well. The inclusion of cognitive-behavioral principles in intervention is essential as it in line with the prevailing psychosocial impact surrounding women with breast cancer (NHMRC, 2003). This is often of greater significance in contrast with the requirement in the physically-related chronic conditions (NM. Clark, Janz, Dodge, & Sharpe, 1992; N. Williams, Wilkinson, Stott, & Menkes, 2008). Recent studies found that CBT was effective for depression (ES = 1.2; 95%CI = 0.22-2.19), anxiety (ES = 1.99; 95% CI = 0.69-3.31), and QOL (Osborn, Demoncada, & Feuerstein, 2006).

Cognitive behavioral interventions utilize a multimodal approach and are particularly effective in decreasing symptom severity for patients with cancer (MH. Antoni et al., 2001; Dodd & Miaskowski, 2000; P. Sherwood et al., 2007). Cancer diagnosis lead to enduring feelings of vulnerability (JE. Bower et al., 2005), resulting in cognition errors and faulty beliefs which can lead to distress and interfere with physiologically ready states for self-management. As an illustration, women are more prone to ‘jump to conclusions’ when they are in distress as depicted in Figure 2.4.

Self-management intervention program for Women with breast cancer

Figure 2.4

The CBT Applied to Women with Breast Cancer



Self-management with CBT strategies offers an extra tool for managing emotion, via challenging self-defeating thoughts and relaxation techniques. CBT strategies have been proven better than supportive counselling for delivering effective treatment for stress disorder (Litz, Engel, Bryant, & Papa, 2007). Culturally, some Chinese scholars even hypothesized that CBT may be more compatible to Asian cultures and beliefs system than many other therapies (Hwang, Wood, Lin, & Cheung, 2006; Lin, 2001), because CBT is more structured, directive and symptom focused (Hong & Ham, 2001)

Issues beyond health literacy may include language difficulties, lack of understanding, ethnic identity issues (negotiating cultural aspects of self), and difficulties negotiating unmet expectations (Hwang et al., 2006). However, techniques aligning with the client's background, cultural beliefs and needs can increase CBT adherence (e.g. recommending Qi Gong, Tai Chi as the healthy activities common in Chinese culture instead of golf or tennis).

Self-management intervention program for Women with breast cancer

CBT with supportive education has been proven as effective intervention for cancer patients (Bottomley, Hunton, Roberts, Jones, & Bradley, 1996 ; Edelman & Kidman, 1999; Lustman, Griffith, Freedland, Kissel, & Clouse, 1998). A recent meta analyses involving adult cancer survivors (n= 1492) found CBT to be effective for depression (ES = 1.2; 95% CI = 0.22-2.19), anxiety (ES = 1.99; 95% CI = 0.69-3.31), and for improving QOL (Osborn et al., 2006). With breast cancer, the use of cognitive behavioral strategies has been associated with improved symptom management, i.e lowered symptom severity and depression (MH. Antoni et al., 2001; P. Ganz, Greendale, Petersen, & et.al., 2000; EL. Lev et al., 2001), improved immune response after surgery (McGregor et al., 2004), and increased sleep efficiency (Quesnel, Savard, Simard, Ivers, & Morin, 2003).

Cognitive behavioral strategies have also been found to improve independence in symptoms management by patients with stages I-III cancer undergoing radiation (Benor, Delbar, & Krulik, 1998). Due to its effectiveness, Newman (2004) proposed that training for health professionals (leading self-management program) should include cognitive behavioral techniques besides group facilitation, goal setting, and problem-solving.

2.5.3 *The Attribute of Self-management*

Theoretically, ‘defining attribute’, are characteristics appropriate to, or belonging to a concept (L. Walker & Avant, 1995). Apart from the established five core self-management skills listed above; the other attribute of self-management are self efficacy belief and knowledge (Embrey, 2006).

A recent addition to the concept is ‘proactive coping’ which is being acknowledged in the field of self-management (Karlein et al., 2003; B. Thoolen, de Ridder, Bensing, Gorter, & Rutten, 2008). The attribute or related-concept of self-management is often regarded as the underlying mechanism of change which contributes to the success of self-management program.

i. Self-efficacy

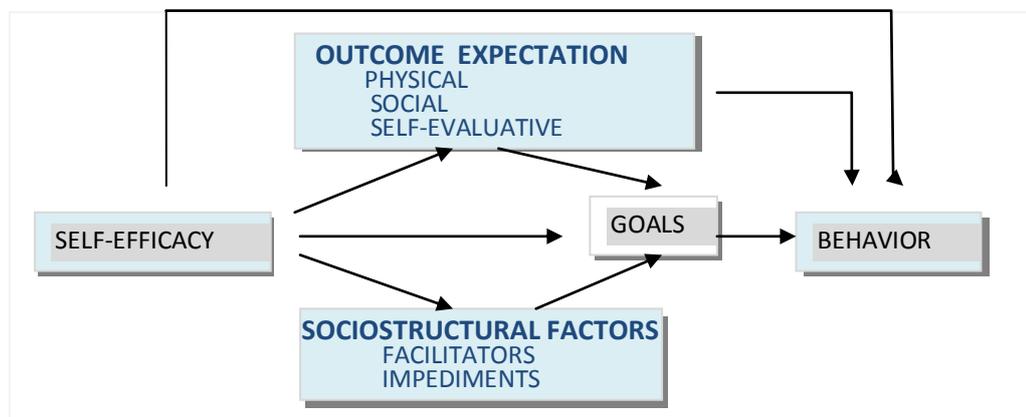
Self-efficacy, a key mechanism (K. Lorig, 1996) or attribute (Embrey, 2006) of self-management is embedded in successful self-management programs. Self-efficacy is the belief or confidence an individual has in her ability to perform a specific cognition or behavior (Bandura, 1986). People with self-efficacy are more likely to feel that they are able to control challenging environmental demands by adopting adaptive actions (Bandura, 2001).

Self-management intervention program for Women with breast cancer

Self-management of chronic diseases, via self-efficacy theory has been promoted as effective health models for chronic conditions (Bandura, 2004). A person who feels confident in her ability to control challenges (or threats), is more likely to implement successful actions (R. Schwarzer, 1993). Perceived self-efficacy is a stronger predictor of future behavior than previous experience for a given tasks (Bandura, 1982, 1998). It is a mediator for traumatic experiences (Benight & Bandura, 2004) and has been found to be consistent across race/ethnicity and health literacy levels (Sarkar, Fisher, & Shillinger, 2006). Bandura hypothesized self-efficacy as the fundamental mechanism to lifestyle change (A. Bandura, 1977) as it affects health habits both directly and indirectly as illustrated in Figure 2.5

Figure 2.5

Structural path on how Self-efficacy Affects Health Behaviors



Ref: Bandura (2004) Health Education & Behavior, Vol. 31(2):143-164, April 2004.
Available from <http://heb.sagepub.com/cgi/reprint/31/2/143>.

Self-management intervention program for Women with breast cancer

One goal of self-management is that people have the confidence to deal with the medical, emotional and role management tasks related to their condition (Adams et al., 2004). This perceived self-efficacy, as explained by Bodenheimer et al (2002) is the confidence to carry out behavior necessary to reach a desired goal. Such ability to self-manage have led researchers to believe that increased levels of self-efficacy is responsible for positive outcomes in people with ctional disability (Davis, Leveille, Favaro, & LoGerfo, 1998). In cancer care, emotional regulation tasks are common and optimal emotional outcome is not affective homeostasis, but rather, a dynamic flexibility in emotional experience (Diamond & Aspinwall, 2003).

Evidence linking self-efficacy and health behaviors are reported as strong (R. Schwarzer & Fuchs, 1995), where self-efficacy has been demonstrated to enhance QOL outcomes (Giese-Davis, Koopman, Butler, & al., 2002), improved survival in advanced cancer diagnoses, $p < 0.001$ (T. V. Merluzzi, R. C. Nairn, K. Hegde, M. A. M. Sanchez, & L. Dunn, 2001), improves symptom management (EL. Lev et al., 2001) and lowered mood disturbance in breast cancer survivors (Giese-Davis et al., 2002). Self efficacy have also mediates to improve dietary and exercises practice in survivors (Mosher et al., 2008).

Sources of development of Self-efficacy

Bandura, delineates four sources of information which affect the development of self-efficacy (Bandura, 1986). These strategies have been used to promote behavioral change in women with breast cancer (Burgess et al., 2008), and in chronic disabilities (Marks & Allegrante, 2005). The source of this self-efficacy which plays a meditational role in regulating human behavior can be achieved via four sources:

i) Mastery experience: Experiences gained from mastery performances is the strongest influence on self belief (Bandura, 1998). Successful past performance and present outcomes interpreted as successful, contribute and raise self-efficacy while those interpreted as failures lowers it (Bandura, 1997).

ii) Vicarious experience: Behavior produced from observing others provides a short cut in learning skill without the need for personal experimentation (Maddux, 1995). This is a weaker source compared to mastery experience, and has a negative impact if the role model fails (Bandura, 1997).

iii) Verbal persuasion: Persuasion from peers and health professionals, and the ability to talk oneself into doing something has a role in enhancing self-efficacy (C. Burckhardt & Jones, 2005; Holman & Lorig, 1992). It is easier to weaken self-efficacy beliefs through negative appraisals than to strengthen it through positive encouragement (Bandura, 1997).

iv) Physiological states: The fourth way (the least potent way) of modifying self-beliefs of efficacy is to reduce people's stress reactions and alter their negative emotional states (Bandura, 1994) via somatic pathways like physiological cues of heart rate and level of anxiety.

High-arousal decreases one's ability to convince oneself that something is possible (Bandura, 1986, 1997) especially so when confronting stressful diagnosis like cancer (Gurevich, Devins, & Rodin, 2002). Psychological stress processes have also been linked to down-regulation of biological immune activity in cancer (Kiecolt-Glaser & Glaser, 1999) and thus needs to be managed.

Self efficacy as predictor of health behaviours

Self-efficacy has been postulated as the mechanism for change and it relates to better health, higher achievement, and more social integration (A Bandura, 1977; R. Schwarzer & Fuchs, 1995). As a key attribute of self-management (Embrey, 2006), self-efficacy is postulated as the mechanism whereby it influences the behaviors necessary to reach desired goals (T. Bodenheimer et al., 2002; R. Schwarzer & Fuchs, 1995).

Self-management intervention program for Women with breast cancer

People with a chronic disease may need to constantly adjust their life style which often leads to low self-esteem, increased levels of stress (Nodhturft et al., 2000) and negative physiological states which then reinforce feelings of incompetency (Bandura, 1986).

Many studies have shown that self-efficacy is a potent predictor of health behaviours (NM. Clark & Dodge, 1999; PS. Fry, 2001; PS. Fry & Debats, 2002; Seydel, Taal, & Wiegman, 1990; Siu, Chan, Poon, Chui, & Chan, 2007; Wu, Tang, & Kwok, 2004). As a predictor, specific self-efficacy has been associated to perceived QOL (PS. Fry, 2001), psychological distress and loneliness (PS. Fry & Debats, 2002) in the elderly, while general self-efficacy has been predictive of low psychological distress in elderly Chinese women with chronic physical illnesses (Siu et al., 2007; Wu et al., 2004). In women with breast cancer, self-efficacy has been shown to predict the intention to engage in behaviors such as breast self examination (Seydel et al., 1990). Specific self-efficacy like emotional self-efficacy for cancer (SESES) has been demonstrated to significantly ($p < 0.05$) predict problem interacting with health staff (Han et al., 2005). High self care self-efficacy (SUPPH) has been found to predict better QOL and lower symptoms (EL. Lev et al., 2001). For cancer behavior coping self-efficacy (CBI), high CBI is associated with higher QOL (T. V. Merluzzi et al., 2001).

ii. *The Proactive Coping*

Proactive coping is a recent addition to self-management support (Steeverink, Lindenberg, & Slaets, 2005; Bart Thoolen, de Ridder, Bensing, Gorter, & Rutten, 2007). In fact, perceived self-efficacy has been regarded as a form of personal coping resource (Lazarus, 2000; R. Schwarzer & Scholz, 2000).

Proactive coping style is attributed to about half of the variance in psychological adjustment to cancer (K. Glanz & Lerman, 1992). Thus, it is a potentially potent mechanism for behavioral change. It is one of the competencies that assist goal-setting and planning of health behavior (Schreurs, Colland, Kuijer, de Ridder, & van Elderen, 2003; Bart Thoolen et al., 2007) reflective of the effective self-management skill.

The markers of successful adaptation has been found to include – i) maintaining active-involvement in daily life, ii) reducing the disruptions to one's life roles, iii) regulating the normal emotional-reactions to the illness, and iv) managing feelings of hopelessness, helplessness, worthlessness, and/or guilt (Spencer, Carver, & Price AA., 1998). These markers are important in cancer management and may promote self-management in cancer patients.

Self-management intervention program for Women with breast cancer

The idea that coping promotes health and QOL is intricately relevant in oncology but relatively new in the field of self-management. According to Folkman (Folkman, 1997), coping theory needs to be modified in order to take into account the positive psychological states. He reviewed 13 tools that measured various aspects of coping, and recommended 'proactive coping' as an approach that taps the innovative aspects of positive copings (eg mastery of future challenges). Avis and colleagues (2005) found that coping skills, in general, affect life after breast cancer. They also found that younger women who are less able to cope showed poorer QOL.

Specifically, proactive coping reflects on goal management in difficult situations. The extent to which an individual employs proactive coping is said to be an indicator of self regulation. The skills in proactive coping include planning, regulation of negative emotions invoked by thinking about a threat/stressor and mental simulation (Aspinall & Taylor, 1997). It thus facilitates 'future-oriented' self regulation behavior (Steverink et al., 2005) and this idea of a 'forward move' is also in line with Wagner's (1998) CCM model which is essentially proactive in its approach. Patients move from a 'passive', helpless role to a 'proactive' stance (Halper, 2001), such as focusing on keeping people as healthy as possible (EH. Wagner, 1998).

Self-management intervention program for Women with breast cancer

Findings suggest that people high on the Proactive Coping subscale are resourceful, responsible and principled (R. Schwarzer, Greenglass, Dagmara, Fiksenbaum, & Taubert, 1999) and have beliefs that are rich in potential for change, particularly in ways that would result in improvement of oneself and one's environment (E. Greenglass, Schwarzer, Jakubiec, Fiksenbaum, & Tauberts, 1999). This in a way complements the self-management skills. Coping, for the proactive individual is not a single response, but a view of oneself and one's world i.e. a belief that things will work out (not because of luck or other uncontrollable factors) because one takes responsibility for outcomes.

A feeling of threats is a prerequisite for people to become motivated to engage in proactive coping as shown with a group of focus group participants (n=47) (Ouwehand, De Ridder, & Bensing, 2001). One benefit of proactive coping is that threats are encountered in an early stage which lessen the impact when the threats fully emerged (Aspinall & Taylor, 1997). Consequently, the threats consume much less resources which means that the resources are available for other activities.

Self-management intervention program for Women with breast cancer

One study showed that proactive behavior prospectively protects against disease progression in patients (n=177) with HIV (Ironson et al., 2005). Proactive behaviours have been shown to improve goal achievement and self-efficacy in self-management tasks when taught to 180 diabetic patients (S. Brown, 1999; B. Thoolen et al., 2008). As such, recent educational interventions have been designed to improve proactive skills in elderly and in diabetic patients (Bode, de Ridder, & Bensing, 2006; B. Thoolen et al., 2008). Proactive coping was also found to be consistently and negatively associated with depression, leading to the conclusion that depression is less likely to be an outcome in a proactive individual (ER. Greenglass, 2001). However, research into proactive coping as an important attribute of self-management is relatively new. Conceptualizing proactive coping as a set of competencies allows it to be implemented in self-management program and to be examined by researchers.

iii. Education

Education and knowledge are often used interchangeably in self-management to denote information needs. Self-management education is viewed as the essential foundation for the empowerment approach (Funnell & Anderson, 2004), and empowerment is the taking control of one's life by setting one's own agendas, increasing confidence, gaining skills, solving problems and developing self reliance (Currie & Wiesenber, 2003).

Self-management intervention program for Women with breast cancer

Self-management education provides the knowledge and a mechanism for change, since knowledge increases people's confidence about health decisions (Fries, Everett, Sokolov, Beadle, & Wright, 1997; McDonald et al., 2004), leading to empowerment (Funnell & Anderson, 2004; Hughes, 2004; McGowan, 2005). Self-management education is thus a potent mechanism for change.

The provision-of-information has been viewed as an essential cancer intervention service (Burke & Kissane, 1998) since it reduces distress. People with chronic conditions need to access high quality information, personal medical information, and multidisciplinary rehabilitation (L. Beck, 2003; Hunter, 1998; C. H. Kroenke, L. D. Kubzansky, E. S. Schernhammer, M. D. Holmes, & I. Kawachi, 2006). As examples, women with breast cancer who have better knowledge of the disease and treatment options were found to have greater satisfaction with their decision-making (Whelan et al., 2003).

In contrast, women with breast cancer who had poorer knowledge of symptoms and risk factors were strongly associated with delay in help-seeking (Grunfeld, Ramirez, Hunter, & Richards, 2002). In one study, it was found that about 30% of women delayed in seeking treatment for 12 weeks or more after a self-discovery of a breast symptom and the delay intervals were associated with poorer survival (Grunfeld et al., 2002).

Self-management intervention program for Women with breast cancer

Knowledge gained can lead to better problem-solving and decision-making (Hughes, 2004). This enables them to actively engage in health behaviors (McGowan, 2005; EH. Wagner et al., 1996b) like a healthy diet, exercise, monitoring and managing adverse symptoms (Demark-Wahnefried, Pinto, & Gritz, 2006; IOM, 2007). Although knowledge is a mechanism for promoting change in behaviour but by itself, it is insufficient. (Coulter, 2005; Coulter, Entwistle, & Gilbert, 1999; R. Glasgow, E. , C. Davis, L. , M. Funnell, M. , & A. Beck, 2003), particularly where changes in health behaviors (often complex) are needed.

Fundamentally, for changes in health behaviors to take place, some forms of skills are needed. In patient education, information is provided but now the self management skills. The educational processes in self-management interventions include these required skills of – goal-setting, self-monitoring and developing self-efficacy for the acquisition of the desired health behaviors (Cameron & Best, 1987).

Self-management education has enhanced improvements in knowledge coping behavior, adherence, self-efficacy and symptom management (T. Bodenheimer et al., 2002; Angela. Coulter & Jo. Ellins, 2006; A. Coulter & J. Ellins, 2006).

Self-management intervention program for Women with breast cancer

In self-management support, another key attribute is collaborative care. This partnership approach demands some form of educational-facilitation skills from the health professional and necessitates a proactive health professional with understanding of chronic care and how to effectively guide patients in these processes. This is one reason why self-management led by peers may be less effective than those led by health professionals (Warsi, Wang, LaValley, Avorn, & Solomon, 2004b).

The training process for health professional has been reviewed as crucial (Daniels & Kissane, 2008) and, it should include group facilitation, cognitive behavioral goal setting (Newman et al., 2004) and other attribute or elements of self-management. Knowledge gained from both the professional and expert patients in self-management programs cannot be undervalued (Embrey, 2006) as it contributes towards skill development in problem-solving and decision-making (Hughes, 2004).

iv. *Group Delivery*

Self-management programs can take place on a one-to-one basis or in group settings led by either health providers or lay persons (McGowan, 2005). Group education (K. Calzone et al., 2005; Rickheim, Weaver, Flader, & Kendall, 2002b) and group work has been extensively used in psychology and more recently in oncology (Ball et al., 2002; Deakin, 2006; Stangier, Heidenreich, Peitz, Lauterbach, & Clark, 2003; Tang, Funnell, & Anderson, 2006). Group development from initiation to termination studied by theorists such as Schutz, Bion, Yalom and Tuckman provides useful guide on how to maximize client participation, facilitate group interaction and reinforce learning (Cole, 2005). Many researchers identify group therapy as the preferred route for treating distress in cancer patients because of the reduced cost since a greater number of patients can be treated simultaneously (Carlson & Bultz, 2003). Studies suggest mixed benefits of psychoeducational groups (Hakala, Karvetti, & Rönnemaa, 1993). Several studies suggest that groups produce greater benefits than individual therapy, e.g. in weight loss programs (Renjilian et al., 2001), gastrointestinal symptom reduction (Vollmer & Blanchard, 1998) and in the level of QOL of breast cancer patients (Sakiko et al., 2000). One study (n=91) found significant improvement in depression (p=0.0001), anxiety (p=0.0001) and QOL (p=0.0009) following a structured support group intervention (Lindemalm, Strang, & Lekander, 2005).

Self-management intervention program for Women with breast cancer

Another study concluded that the effectiveness of the individual therapy was diminished in a group format delivery (Stangier et al., 2003). Others have demonstrated that significantly more time was spent per patient in individual sessions (1.25 hours) than in group education (0.74 hours) (K. A. Calzone et al., 2005) but with greater improvements in self-management (Rickheim, Weaver, Flader, & Kendall, 2002a). Group self management also reduced anxiety and distress for women newly diagnosed with breast cancer (M. Antoni et al., 2006). However, other studies showed no differences between group or individual delivery, e.g. a randomized comparison study showed no benefit differences between group education-counseling versus individual therapy (K. A. Calzone et al., 2005),

It is simply inadequate to judge effectiveness of any intervention based solely on whether it is an individual or group format as it depends on factors including aim and resources. As an example, a clinical trial showed education-based group interventions facilitated the *initial adjustment* (aim) of women with early breast cancer (stage 1-3), but not from peer group intervention (Helgeson, Cohen, Schulz, & Yasko, 1999). Another study found age composition (membership status) as an important clue for effectiveness, where women diagnosed at a younger age (27-44 years) posed as a significant predictor ($p < 0.05$) of worse functioning in the social domain (Cimprich, Ronis, & Martinez-Ramos, 2002).

Nevertheless, it is undeniable that groups do offer certain therapeutic values not found in many individual deliveries. The recent healthcare cost effectiveness move has also led to a resurgence of interest in group deliveries and teamwork (Grumbach & Bodenheimer, 2004). With theory-informed intervention and facilitation style such as those informed by Tuckman's theory (1965), the effectiveness of psychoeducational group intervention can be further enhanced (Cole, 2005).

2.6 Non Pharmacological Interventions for Breast Cancer

This section describes the present intervention for women with breast cancer which are basically psychosocially orientated and the justification for a broad based intervention that extend beyond medical care or mere psychosocial care.

2.6.1 Present Interventions and Limitations

There are many models of care that have been established in oncology. For example, psycho-educational groups primarily aim to increase understanding of condition-specific information (Cunningham, Lockwood, & Cunningham, 1991), while supportive-psychotherapy aims at emotional catharsis and generating a sense of support through empathic listening and encouragement (Spiegel & Spira, 1991).

Self-management intervention program for Women with breast cancer

Cognitive-behavioral therapy aims at training to reframe attitudes, problem-solving and stress management (Kissane, Bloch, & Miach, 1997). For decades, psychological concerns have been the predominant focus in intervention of women with breast cancer (Burke & Kissane, 1998; Hewitt et al., 2004), accompanied by an even greater recent recognition for psychosocial intervention (Bultz & Carlson, 2005; PB Jacobsen & Jim, 2008). All these have been developed within the specialised field of psycho oncology which aim to provide better care to reflect the new enthusiasm on better care that is needed with improvement in cancer treatment resulting long-term survivors of cancer.

Psychooncology formally started in the mid 1970s. As the stigma associating cancer to fatalism reduced, people begin to discuss about diagnosis and feelings of their illness (Holland, 2002). In the 1990s quality of life issues were regarded as integral in Psychooncology (Holland & Goen-Piels, 2009). Psychosocial oncology is the study and treatment of the social, psychological, emotional, spiritual, quality of life, and functional aspects of cancer across the cancer continuum, from prevention through diagnosis, treatment, survivorship, palliative care, and bereavements (HMI, 2006). The definition of psychooncology had been holistically described by its proponents (Kissane, 2006). However, much of its clinical practices was on psychological sequelae of cancer and distress. This is in-line with the idea that cancer is not a disease but a crisis that needs to be overcome.

Self-management intervention program for Women with breast cancer

The Malaysia Clinical Practice Guidelines for management of breast cancer follows a predominantly medical model (Malaysia Ministry of Health, 2002) and focuses on medical care quite exclusively. Intervention such as provision of information (Stiegelis et al., 2004) and psycho-educational program for managing major side-effects (Golant et al., 2003) have not been integrated to meet the need of the Malaysian women. These approaches are widely used elsewhere and with increasing use of complementary therapies (i.e. relaxation, diet therapy, megavitamins, imagery, spirituality, naturopathy, immune therapy, homeopathy and acupuncture) which were used by 9-54 percent of adults with cancer (NHMRC, 2001).

Specifically, a more integrative model that integrates i) context of patients self management for chronic diseases, and ii) Corbin and Straus work on the three tasks (medical, emotion and role tasks) that people with chronic illnesses need to do, may provide better care for cancer and address cancer as a form of chronic illness. With this model, self management education is essential so that patients are informed and prepared to work collaboratively with their health professionals.

Self-management intervention program for Women with breast cancer

Meta-analyses from other studies have shown evidence of coping benefits (Andersen et al., 2004; Lesley. Fallowfield, 1995; T. Meyer & M. Mark, 1995) and survival benefits (Spiegel, Bloom, Kraemer, & Gottheil, 1989) from psychosocial interventions. Studies found reduced anxiety-depression and increased knowledge during treatment of breast cancer illness (Devine & Westlake, 1995; T. J. Meyer & M. M. Mark, 1995), lowered cortisol level (stress hormone) in stage II or III cancer (Andersen et al., 2004) and lowered psychological morbidity (Cunningham, Edmonds, & Williams, 1999; Fawzy, Fawzy, & Canada, 2000).

However, women with breast cancer require intense and prolonged treatments (Stuart et al., 2006), face persistent physical, emotional and social problems (Stuart et al., 2006), and have many unmet needs (Loh & Yip, 2006) not addressed by the current health system. In addition, prevention and management of the illness and its treatment which reduces quality of life has taken on increasing importance (Erickson et al., 2001), and particularly so in breast cancer which has the best survival rates compared to many other types of cancer (Jemal, Thomas, Murray, & et.al., 2002). The review highlight a gap in the current interventions which may be the reason/s for the inconclusive findings on which type of intervention is the best (Burke & Kissane, 1998; Devine & Westlake, 1995) since there is no available program to meet all these needs.

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Self-management intervention, which is broad based and has proven effective with other chronic conditions may be a viable option. This is because it encompasses more than mere psychosocial, or mere patient-education, but is a broader care which complements medical care (T. Bodenheimer et al., 2002; KR. Lorig & Holman, 2003). It is a patient-centered approach and holds promises that address the multiple challenges faced by women in order to live effectively with the condition. It requires active patients (not a passive stance) and partnership between patients and health staff.

Several justifications below are presented to support this notion. Firstly, breast cancer is becoming a chronic condition and requires ongoing management over a period of years (Epping-Jordan et al., 2004). Self-management which has proven effective with other chronic physical condition, have many lessons to be shared. Fundamentally, there are numerous tasks with implications that patients must self manage (BMA, 2007) which includes:

- Adhering to treatment regimes, by accessing the information they seek
- Engaging in activities that protect and promotes health, being proficient in carrying out both medically-related behaviors (e.g., doing breast self awareness steps, managing nausea,) and non-medically related behaviors (e.g., choosing a wig, interacting with one's doctor, exercising);

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- Monitoring, managing signs-symptoms of illness
- Managing the impact of illness and day-to-day functioning, emotions and personal relationships and being proficient in problem-solving
- Creating new and meaningful life roles
- Enhancing their levels of confidence (i.e., perceived self-efficacy) in their ability to engage in these behaviors

Clearly, these are not easy tasks that any lay person can perform without support. Firstly, these tasks indicate a need for a structured program with close collaboration with health staff and the tasks are suggestive of patients' active involvement rather than being a passive recipient.

Secondly, a large evaluation study of over 20 year of interventions on women with breast cancer (Burke & Kissane, 1998) and a meta-analysis of 62 psychosocial interventions on cancer (T. J. Meyer & M. M. Mark, 1995) reported inconclusive findings on program effectiveness. Although comparisons may be complicated by the varying focus, aims and/or membership, these results implied that the intervention provided thus far, are not addressing the patients' need adequately. The result further implied that an integrated system approach of greater partnership between patients and providers with requisite skills and resources are not in place.

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Thirdly, interventions are not theory-driven and thus, make it difficult to understand how things work. Reviews on theory-driven programs showed small to moderate effects for various chronic diseases (Warsi et al., 2004b), with promising outcomes in improved health status (KR. Lorig, Sobel, Ritter, & et.al., 2001; K. R. Lorig et al., 1999).

Finally, from the earlier review, self-management addresses the essential self care aspects in partnership with health professionals. It deals with education, skills, and attitudes of patients, training them to be self sufficient, proactive problem solvers and manager of all the tasks commonly dealt with by people with chronic condition. It prepares people to live healthily albeit living indefinitely with breast cancer.

The sections below draw out some of the key features of self-management design so that with a better appreciation of the feature, the right design can be applied to breast cancer care.

2.6.2 Patient Education versus Self-management.

Education is a key attribute of self-management (Fries et al., 1997), and improving patients' education is an important strategy for managing chronic disease (Gray, 2004). Health professional must understand how best to deliver education and train the patients in self management. This is because the traditional patient-education approach has been demonstrated as not improving health outcomes (Coleman & Newton, 2005; Gibson et al., 1998). An answer to this limitation is to have a clear understanding of the demarcation between patient education and self-management education. The contrasting characteristic between both approaches have been delineated by Bodenheimer, Lorig, Holman, and Grumbach (2002). Self-management education encompasses a range of emotional, cognitive, and behavioral tasks, and this acknowledgement can help us understand why patient education alone is clearly ineffective for managing chronic conditions. It extends beyond the less effective traditional patient-education (T; Bodenheimer, Wagner, & K., 2002; Angela. Coulter & Jo. Ellins, 2006). In sharp contrast to the traditional patient education that provides information and teaches technical disease-related skills, self-management education teaches skills on how to act on the self identified problems. This empowers people to take active control by applying problem-solving skills to the challenges they face (T. Bodenheimer et al., 2002).

i. Condition Specific versus Generic Self-management Education

The complexities of health behavior and needs of women with breast cancer can make intervention difficult to design and to evaluate, even though there is a common focus on the three self-management areas. Even the popular Expert Patient Program, a generic program, showed only modest psychological improvement as well as small effects in health outcomes and health utilisation (Griffiths, Foster, Ramsay, Eldridge, & Taylor, 2007). It would seem more effective then to tailor intervention to the condition-specific needs according to the NHMRC recommendation for disease-specific and stage-specific intervention (Burke & Kissane, 1998) so that needs of the specific condition can be better addressed.

From a clinical perspective, it helps to identify who benefits from what type of intervention. This will assist clinicians in knowing who to offer specific therapies and how to tailor the specific intervention to the identified group e.g. on breast cancer patients in contrast to patients with generic chronic conditions-. However, there is still a general lack of research evidence in this aspect. More studies are required to identify cost effective interventions with consideration for the current, shrinking health budget.

ii. Professional Led versus Peer Led Intervention

The IOM's published rule for the 21st century healthcare system highlight care based on a continuous healing relationships (Taylor & Fowler, 2008), which suggests health professionals' involvement. Collaborative partnership in self-management occur, "when patients and care providers have shared goals, a sustained working relationship, mutual understanding of role and responsibilities, and requisite skills for carrying out their roles" (Von Korff et al., 1997, p. 1097).

Self-management programs involving patients and health professionals are highly valued (Embrey, 2005). Drawing from both experts (patients and health providers) is the best approach to improve healthcare delivery but may need some form of skillful facilitation that group leaders should acquire. However, the self-management model promoted by Lorig and colleagues since 1980s (Fu, Ding, McGowan, & Fu, 2006; K. Lorig, 2001; KR. Lorig & Holman, 2003; K. R. Lorig et al., 1999), and the UK's Expert Patients Program (EPP) are lay-led (Department of Health, 2001).

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The questions on whether lay-led or professional-led self management program are more effective requires more research (Dowrick, 2006). In self-management, there are clearly a set of requisite skills involved which imply some sort of training for patients, and also for the health professionals so that these mandatory, prerequisite skills can be effectively imparted to patients.

Thus, it is not surprising that a focus group involving 27 leaders of 34 cancer support group in Australia have found that the non-health professional reported greater difficulties in dealing with cancer groups as well as dealing with groups in general (Kirsten, Butow, Price, Hobbs, & Sunquist, 2006). Even the traditional self help groups, usually are peer-led, have been proposed to be guided and led by health professionals with training in group facilitation and with knowledge on facilitation (Stang & Mittelmark, 2008). In contrast to the recent evidence indicating that lay-led programs have only a small effect on health outcomes (Griffiths et al., 2007), health professional-led programs (Andersen et al., 2004; Sheard & Maguire, 1999 ; Warsi et al., 2004b) shows promising results. Evidence suggest successful intervention strategies should include the use of support from a trained interventionist (Griffiths et al., 2007; Smeulders et al., 2007; Warsi et al., 2004b), with training in group facilitation, goal setting, problem-solving and cognitive behavioral techniques (Newman et al., 2004).

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Lately, there is a shift in trend with a greater interest in hospital-based programs led by health professionals (JH. Barlow, Sturt et al., 2002; JH. Barlow, Wright et al., 2002; Smeulders et al., 2007; Warsi et al., 2004b).

2.6.3 Effectiveness of Self-management Intervention

Collaborative self-management interventions have been found successful at promoting intention to self manage (V. Lee, Kennedy, & Rogers, 2006; K. R. Lorig et al., 1999; McCulloch, Price, Hindmarsh, & Wagner, 2000; Von Korff et al., 1997; EH. Wagner et al., 1999), albeit a small to moderate effect size results (Warsi et al., 2004b). Both the specific and generic self-management programs have shown some evidence of effectiveness (Bodenheimer, Lorig, Holman, & Grumbach, 2002; Cimprich et al., 2005; K. R. Lorig et al., 1999).

Self-management is a key element in the care model for long term conditions (Department of Health, 2006), and could be applied to breast cancer as a chronic condition. Based on the literature review here and the background to the study (chapter one), a conceptual framework to guide the development of a new intervention for women with breast cancer was conceptualized (Figure 2.6).

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Figure 2.6 is an overview of the plan to address the imbalances caused by the threats of breast cancer using self-management intervention (the enabler) in order to enhance the health outcome. The ‘enabler’ part within this concept will be further expanded in Chapter 4 (see Figure 4.1). Thus, with the aim to achieve the highest level of functioning and the lowest level of symptoms in cancer care (NM. Clark, 2003), this concept of self-management is a theoretically justifiable and applicable model for women with breast cancer who are living indefinitely with the condition.

2.6.4 Application of self-management Intervention on Breast cancer

Although self-management has not yet been applied on the cancer population, Lorig (Personal communication, February 8th, 2005) expressed that self-management program would be suitable for the cancer population. In recent years, the application of self-management in the field of cancer has been acknowledged (Epstein & Street, 2007). Research evidence shows that health behavior can be changed through a focused program (Murphy, 2005).

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Women diagnosed with cancer needs to manage not only the illness tasks, but also to proactively manage the risk reduction behaviors and adopting a healthy lifestyle (Oxlad et al., 2008a). For example, in the Nurses' Health Study (n= 5204) - a large epidemiological study – it was found that weight before diagnosis and weight gain after diagnosis were associated with increased breast cancer recurrence (Willett, 2006). Such lifestyle issues like, weight gain after diagnosis, and obesity at diagnosis have been demonstrated to be closely associated to breast cancer outcomes such as recurrence and survival (Chlebowski, Aiello, & McTiernan, 2002).

There are wide spectrums of medical and survivorship issues with lifelong consequences affecting the QOL of breast cancer patients (Stuart et al., 2006). Even patients with diagnoses more than 5 years ago or after initial treatment, have been shown to still need for psycho-oncological support (Holzner et al., 2001). This suggests the burden of illnesses are wide ranging, indefinite, and requires a proactive management closely drawing together the social, psychological and behavioral aspects of the way of life of the population IOM, 1982, pp. 49-50 (2001b).

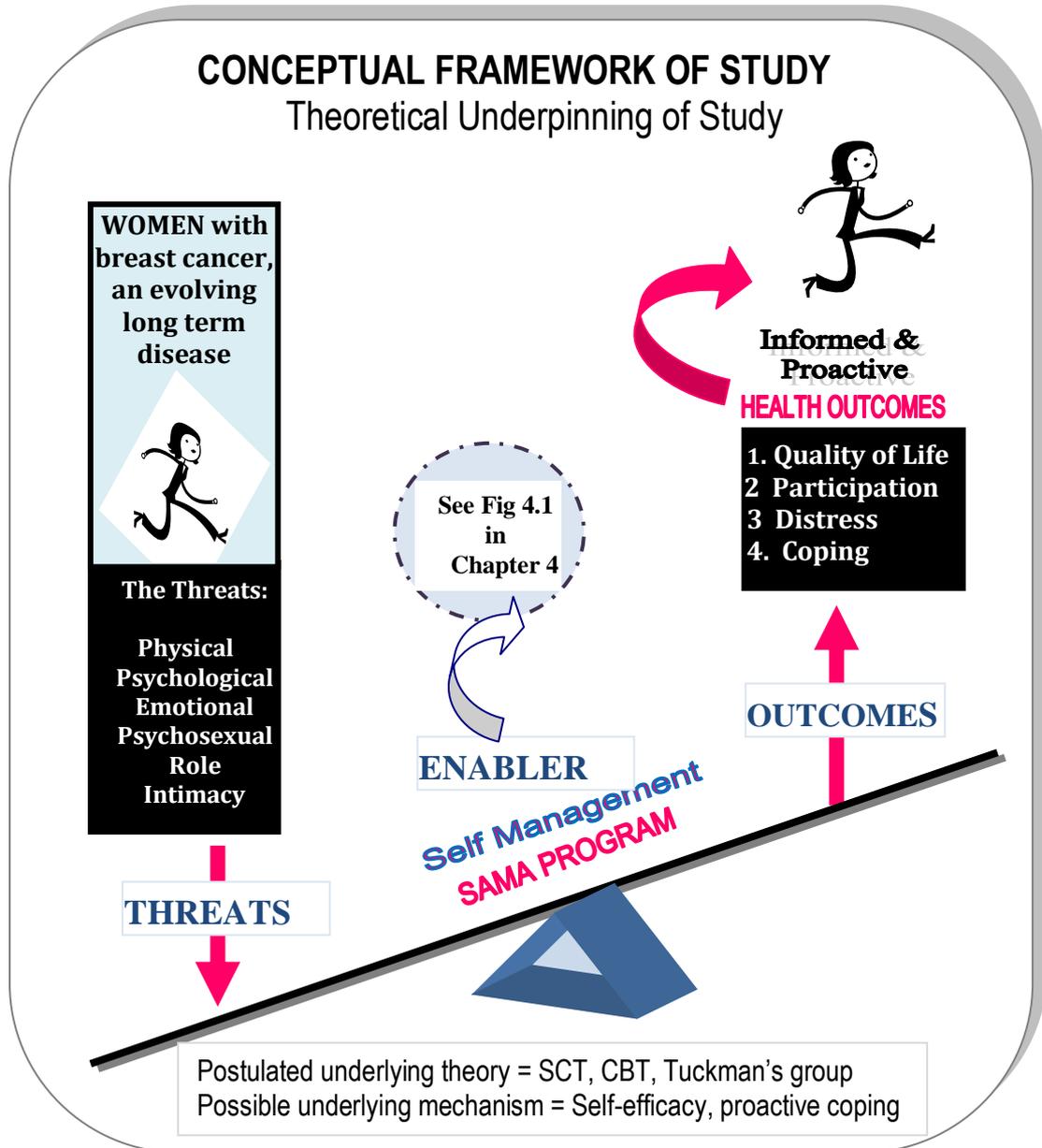
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This review of literature concludes that the present medical care alone is insufficient (T. Bodenheimer et al., 2002) and the medical model is inadequate (S. Shapiro et al., 2001). However, the usual psychosocial intervention for cancer patients is also not comprehensive enough to address all the challenges that comes with a cancer condition presenting as a form of chronic illness.

In summary, the review indicated that intervention to address any combination of emotional, cognitive, and behavioral factors (PB Jacobsen & Jim, 2008) should be theory-led as they offer perspectives to explain behavior and determinants of health (Davies, 2006). A broad-based system-focused intervention to enable patient outcomes (Coleman & Newton, 2005) such as collaborative self-management intervention is needed. The concept of enablement includes both things that clinicians can do for patients to remove barriers to self-management, as well as enabling them to be autonomous in caring for themselves (Epstein & Street, 2007). Figure 2.6 is a conceptual framework that has been proposed for consideration of a broad based intervention to address the multiple challenges faced by women with breast cancer.

Figure 2.6

Conceptual Framework- addressing imbalance with self-management.



SAMA Program: "Staying Abreast, Moving Ahead" program

3

NEEDS ASSESSMENT

(via Focus Groups)

Engaging patients in health policy decision-making
helps to ensure that policies reflect patient and caregiver needs.....
..... which ultimately leads to improved health outcomes,
quality of life and patient satisfaction.

(IAPO, 2006b)

3.1 Overview

This section describes the qualitative need assessments which represent Phase I of the UK framework for complex interventions (MRC, 2000). Ethical approvals (Appendix F) were obtained from three main governing bodies: i) the Human Research Ethics Committee of Curtin University of Technology (18/2/2005), ii) the Medical Ethics Sub-Committee, University Hospital (Ref 435.15/21.3.2005) and iii) the Malaysia Ministry of Health's Research Committee (KKM/JEPP/02 (160) 9/5/2005).

3.2 Needs Exploration via Focus Group

Examination of the literature on cancer care and chronic disease management provide useful insights to a timely intervention program for women with breast cancer. However, to enhance the effectiveness of the identified intervention within a self-management conceptual framework, focus groups can be used to conduct needs assessment (K. Lorig, 1996). More importantly, the idea of cancer self-management is still new.

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Therefore, the reasons for including focus groups were to involve the patients (i.e. the service user) as key stakeholders in the process of program planning to ensure that their voices are heard and their needs identified, addressed and met. In addition, focus group is a mean to receive direct input from service-users on pertinent issues that would help develop health intervention program.

The objectives of this qualitative phase were twofold: (i) to obtain information directly from Malaysian women who had been diagnosed with breast cancer, and (ii) to explore the issues identified in the self-management literature for chronic illnesses and in the breast cancer literature for cancer intervention. The outcome of this exploration was used to help develop self-management program for women newly diagnosed with breast cancer. Focus groups as a method to collect data (Slaughter & et al., 1999), capitalized on communication between women to generate information via processes, which included asking questions, exchanging anecdotes and commenting on each other's experiences and points of view (Kitzinger, 1995). They also allowed participation from women who were reluctant to be interviewed alone, and provided a non-threatening group environment which set the stage for investigating the perceptions and experiences about self-management issues.

3.2.1 Method

Recruitment and participants:

Once ethical approval from the various governing bodies was received, women with breast cancer were identified through their physicians. Fliers were distributed at breast cancer related agencies and at breast clinics and consultation rooms. The fliers included contact numbers for those interested to make enquiries. The women were then approached and provided with a patient information sheet (Appendix A-1) and a consent form (Appendix A-2). They were given explanations about the purpose of the focus groups.

They were screened based on the following criteria: (i) 18 years of age and above, (ii) diagnosed with early breast cancer (or Stage_1-3) and (iii) able to read and understand English and iv) provided consent. Reducing qualitative research to a list of technical procedures (such as purposive sampling, multiple coding, triangulation, and respondent validation) has been cautioned as overly prescriptive. None of these ‘technical fixes’ in itself confers rigor and there is no substitute for systematic and thorough application of the principles of qualitative research (RS. Barbour, 2005). Thus, careful consideration was given to the selection and screening of the participants, moderators, the focus guide, and the grouping of the participants as well as verification of the output generated from the focus groups.

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A concerted effort to increase rigor in this study included scheduling four homogenous groups along the illness trajectory; a newly-diagnosed group (mixed stages of breast cancer), a Stage_1 group, a Stage_2 group and a Stage_3 group. The aim was to capture the “shared trait/experience on which the discussion can build on” (Speziale, Streubert, & Carpenter, 2003). Statistical representativeness was not a prime requirement as the objective was to understand the social processes (Mays & Pope, 1995). Thus, the plan to invite as many women as possible was executed but a number of up to 12 women were targeted to allow an anticipated 20 percent of last minute absentees.

Media advertisements via clinics, national cancer associations, and the use of the snowballing technique involving requests from participants to inform other potential women about the study were used. All interested women who met the inclusion criteria and who had given consent were contacted by the researcher a week earlier, and informed about the meeting. These women were later personally invited to attend a specific focus group scheduled according to their medical stages of their breast cancer. There were four scheduled groups, each with 6 to 10 women. This number reflects the consensus of what constitutes an ideal-size as recommended by several authors (M. Campbell et al., 2000). A final total of 31 women participated in the four homogeneous (according to breast cancer stage) groups (Table 3.1).

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One group of 10 participants (Cancer Stage_2) was replaced because of audio-taping failure. A new group comprising of women with Stage_2 cancer was formed (n=8). Their ages ranged between 31 to 61 years with a mean of 47.1 years. The majority were married (80%), Chinese (67%), employed- part time or full time (65%), undergone a mastectomy (80%), and was diagnosed with a Stage_2 breast cancer (45%).

Table 3.1

Demographics of Focus-group Participants

Characteristic	Focus Group (n=31)					
	n	%	Newly diagnosed (n=9)	Stage_1 Group (n=7)	Stage_2 ² Group (n=8)	Stage_3 Group (n=7)
Ethnicity						
Chinese	21	67%	5	7	6	3
Malay	6	20%	3	0	1	2
Indian	4	13%	1	0	1	2
Marital Status						
Married	25	80%	7	6	7	5
Single	6	20%	2	1	1	2
Age Range						
31-61 years	47.1	31-51	35-61	35-61	31-61	41-61
Occupation						
Full/Part time		65%	7	4	6	3
Retired/Housewife		35%	2	3	2	4
Surgery						
Mastectomy	25	78%	7	5	6	7
Lumpectomy	6	11%	2	2	2	0
Breast cancer Stage						
Stage_1	8	25%	1	All Stage_1	All Stage_2	All Stage_3
Stage_2	14	45%	6	1	2	3
Stage_3	9	30%	2			

* Second Stage_2 group (the first contaminated Stage_2 group, n=10, was discarded)

3.2.2 Tool (The Focus Group Guide)

A focus group guide (refer Appendix A-4) was developed to guide the group discussions about the three broad self-management tasks (medical, emotional and social-roles). A diagnosis of cancer can make people feel alienated leading to difficulty in expressing experiences and needs (Younger, 1995). Evidence showed that women had difficulty expressing their expectations regarding an intervention (Ohlen, Holm, Karlsson, & Ahlberg, 2004). Thus topics were selected to prompt them. These included knowledge, beliefs and experiences of medical and health management (access to information on breast cancer, healthcare issues, patient–doctor relationship, and health issues), emotional and role (home and work) management.

3.2.3 Data Collection

The focus group meetings were held at the Faculty of Medicine, University Malaya, Kuala Lumpur, on each of the four Saturdays in the month of July 2005. Members of each of the groups were assigned according to their cancer stage, except for the newly diagnosed group. The facilitator and co-facilitator met early to discuss their roles and to ensure topic coverage.

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There was also an independent observer who helped direct or ferry the participants in the campus and to the meeting room. The women were invited half an hour earlier for tea and light refreshments in a relaxed and informal setting so that they could get to know each other. Their attention was reoriented to the aim of the study. The informed consent process was conducted and the ladies were asked to complete a brief demographic form. Once this was done, the women were ushered into the conference room next door, where participants sat in a circle to foster openness and encourage participation.

A welcome speech was provided, ground rules laid down and the participants' permission was sought to audio-tape the session to enable data transcription. This was followed by a brief round of formal introductions to ensure a conducive, informed and facilitatory group climate.

The women were prompted to respond to the issues raised by the moderators, but were informed that they had the right not to respond to any issue. At the end of the session the women were thanked for their participation, and were given a thank-you card and a small door gift (a multivitamin sample). Each focus group lasted about 1½ to 2 hours.

3.2.4 Data Management

The researcher attempted to ensure the trustworthiness of the data by keeping an audit trail and a meticulous record of interviews and observations, and documenting the process of analysis in detail. This was a conscious attempt, relating to the two main goals of qualitative researchers (Mays & Pope, 1995). These were, (i) to create an account of the methods and data that can stand independently so that another trained researcher could analyze the same data in the same way and come to essentially the same conclusions; and (ii) to produce a plausible and coherent explanation of the phenomenon under scrutiny.

Data management was assisted using the computer software N6 or the Non-numerical Unstructured Data Indexing Searching and Theorizing (Richards, 2002). The software complemented the processes and was used to extract out all similar terms or synonyms to help ensure no expressions were overlooked or misrepresented.

3.2.5 Data Transcription

After the four focus groups, the discussion was transcribed verbatim, with removal of all names so that the participants were identified by code only. Transcripts were compared with the field notes to ensure the correct context of the expressions.

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Using content analysis (Dixon-Woods et al., 2004), the data was categorized and determined for the frequencies of these categories across all groups as an audit trail and to increase credibility of their common expressions.

During the transcription, a systematic and thorough application of the principles of qualitative research (RS. Barbour, 2005) requires that transcript should be send out to participants for 'member-checking'. However, time constraints and a shortage of manpower made this impossible. Nevertheless, both the moderator and co-moderator together with a note-taker reviewed the transcripts to ensure that there were no conflicting views. Furthermore, two women from the focus group were invited to check the transcribed data. These two women participated in the pilot study and to feedback their views.

3.2.6 Data Analyses

Quotes (printed on color-coded paper to represent each group) identified from the verbatim transcriptions were cut out and spread out on a large table to be sorted manually.

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Each of the utterances that contained similar characteristics were then coded with a short ‘paraphrase or sentence’, resulting in categories of emerging themes with similar utterances (such as related to service-aspects, information-lacking, family-roles, etc).

The primary coding resulted in several smaller themes. Subsequently, the second coding resulted in more relevant and broader themes that ‘grouped’ the pool of items together. The coding of the clusters was refined by adding to, collapsing and redefining the coding categories into the three broad self-management tasks.

In order to reduce subjectivity leveled at the process of qualitative data analysis, multiple coding (the quantitative equivalent of ‘inter-rater reliability’) was conducted by organizing an independent assessment of the transcripts by three doctorate researchers. The transcripts were checked and re-coded where needed by three doctoral researchers who were assigned to particular sections according to their experience or background training. The major themes were agreed upon and verified using the experience of three other doctoral candidates.

3.3 Findings

A total of 41 Malaysian women diagnosed with breast cancer participated but the final analysis was based on only 31 participants (after the removal of the first Stage-2 group of 10 participants due to audio-taping failures). A profile of the participants was presented in Table 3.1.

Table 3.2 outlines the consensus key themes that emerged from the focus groups. Focus group methodology was used to gain a collective understanding of participants' views which were captured as themes. However, to add meanings and to illustrate the collective views, some specific quotes were used as example to highlight the shared experiences leading to the consensus themes related to the self-management needs of women with breast cancer. The collective understanding of participants' sharings are categorized as - medical management (A), emotional management (B) and role management (C) tasks. The results from each of the eight themes will be discussed separately in order to present the information comprehensively. In the report below, words within brackets [], refer to comments from the researcher and the codes at the end of the verbatim quotes are the obscured identification assigned to the informants from the group.

Table 3.2

Themes important for self managing breast cancer

<p>3.3.1 MEDICAL MANAGEMENT</p> <p>Theme 1 Unavailability of information Theme 2 Doctor and service/care related issues 2 i) personnel/expertise, 2 ii) resources-networking, 2 iii) human relationships and communication Theme 3 Medical-related socio-economic-cultural issues Theme 4 Health maintenance (Living with breast cancer)</p> <p>3.3.2 EMOTIONAL MANAGEMENT</p> <p>Theme 5 Support Theme 6 Coping i) General coping ii) Ongoing specific coping</p> <p>3.3.3 ROLE MANAGEMENT</p> <p>Theme 7 Relationships at work and home Theme 8 Sexuality and intimacy issues</p>
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3.3.1 Medical Management Tasks

Management Tasks Theme 1: Unavailability of information.

The consensus on unavailability of information on managing breast cancer emerged as a key concern, generating feelings of helplessness, loss and distress. The participants across all the groups strongly voiced the opinion that there was a serious lack of specific information on breast cancer which was not offered by health professionals in the field.

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Almost all the women reported that they did not have information to aid them in their decision-making. They expressed concern that there was an even greater need for this among women of lower socioeconomic status. About 10% of them felt they were well informed by their doctors, but the majority (90%) had to source actively for information from the internet and books or friends from overseas. The largely unmet information needs have been highlighted in other studies (Ankem, 2006; Raupach & Hiller, 2002). The women described having a diagnosis of cancer as confusing, frightening and distressing due to multiple misconceptions. Unfounded myths and misconceptions from across the groups include, the loss of a breast causes fatigue; sexual activity transfers cancer cells to a partner and sexual overexcitement can cause rapid cancer recurrence; toxins from chemotherapy are contagious and both stress and certain food as well as some tropical fruits (e.g. chicken, 'durian' and mangoes) cause cancer and cancer recurrences. These reports contribute partially to Theme 3 (Table 3.2) and are consistent with current research on the relationship between lack of information and increased uncertainty, anxiety, distress, and dissatisfaction (Van der Molen, 1999). Similarly, the level of distress in patients with a serious illness is reduced when they perceive that they have received adequate information (L. Fallowfield et al., 1990). The following are specific examples of the comments leading to the consensus on 'poor access to information'.

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“Do you know that the information given to us was mostly by the lay people? This is most frightening because they give all sort of [unreliable] frightening information” (SS1n3).

“I hunt the doctor down for information, it was along the corridor and I managed to stop her...that was the extent I had to take, rather than an access to a consultation, readily given to me...”(Ndn3).

“I went ahead with the operation, without any further information” (Ndn1).

The women offered some structural solutions to overcome ‘unavailable information’. These included the provision of structured information in groups, brochures and websites. Information sought included common pathways for treatment, available treatment options, purpose and meaning of staging and how it is done, active participation in the recovery process and where to source aids. They expressed a need for information to be culturally sensitive and linguistically appropriate to Malaysia using a combination of common vernacular language/dialects like Cantonese and Tamil. This includes health literacy linked with cultural competency so that the various multi-ethnic groups in Malaysia are better served. One idea offered was to increase the diversity of the hospital staff (which is currently predominantly staffed by one ethnic group, i.e. the Malays) while the majority of breast cancer patients are from the Chinese ethnic group.

Theme 2: Health professional (doctor, nurses etc) and service-related factors.

This second theme contributing to women's inability to self-manage effectively was derived from the views on lack of availability of health personnel and expert-services. These were later regrouped into 3 sub-themes; to reflect the consensus around (a) a general unavailability of health personnel and specialized services, (b) poor resources-networking on the hospital level, and (c) poor patient-provider communication and relationships.

The first sub-theme (2 ii) highlighted the shortfall in the workforce especially the lack of oncologists, specialized nurses, counselors, and therapists (e.g lymphedema). More than 10% of the women were concerned that their cancer was either misdiagnosed or undetected by inexperienced general practitioners, even though the women felt the lumps. An example of the quote to add meaning to this subtheme was,

"I saw this doctor three times. I have also applied 10-day leave but he refused to operate...He insisted it's not a cancer...that it's benign...and now [long sigh] I am suffering due to his misdiagnosis...but what can I do? (SS3n1).

Self-management intervention program for Women with breast cancer

Across all the groups, participants agreed that properly trained staff to perform clinical breast examinations was lacking and need to be addressed to maximize early detection. They voiced for a common system of diagnosis i.e. the TNM (tumor, node, metastasis) Classification (Greene, Page, Fleming, & et.al., 2002) for staging breast cancer to be used in all clinics, to avoid multiple staging because of different staging systems which causes confusion. Example of quotes across group and ethnicity were as highlighted below:

One Malay lady expressed,

“I was so lost! I was confused...and upset [because] I have doubt over the [conflicting] opinions of the doctors regarding my stage of breast cancer”. My second specialist’s opinion was different from my first” (Ndmn1).

Another Indian lady cried out,

“My doctors gave various staging of my cancer – I was told from having a Stage_1 to a Stage_2a, then a Stage_3!! This is very bad [stressful] for me” (Ndmn2).

Another woman concurred,

“...Yes, they each giving their separate conclusion and confused us. They should come to one conclusion and agreed on it before they informed us...” (Ndmn9).

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Many women agreed that breast cancer services were either unavailable or inadequate due to insufficient manpower. Even though counseling is listed in the clinical practice guidelines, yet the consensus from the two third of the women was that they were not offered this service which they acknowledged as essential (and as emphasized in one of the quote below).

“After we were told of the diagnosis, we need someone to help us through. We need both the psychological support expertise/services and the medical-related information” (SS2n1). “Counseling is so important..... ” (SS2n4).

Another woman claimed,

“I know I had this condition called lymphedema...I had to search the whole world [via internet and social- contacts from within and oversea] for help and for expertise to treat my lymphedematous arm” (S1n7).

Across the groups, the women acknowledged the awareness of lymphoedema but although not all had the experience, they all felt such services should be made available at all hospitals. Lymphedema, a condition that can occur years after completion of treatment (Passik & McDonald, 1998) is a common occurrence in women with breast cancer. (This service for managing lymphedema was generally unavailable. It was only in 2007 that a private organization started by the late wife of the Malaysian Prime Minister, organized the first lymphedema training course for a group of therapists).

Self-management intervention program for Women with breast cancer

The consensus about specialized care arises from discussions around the need to access core experts, and from the frustration and challenges faced in seeking consultation with, particularly the oncologists who were often represented by trainees or junior medical officers. This was expressed as a common occurrence both at public or private hospitals. In terms of solutions, they agreed that more nurses, therapists and doctors be trained specially in cancer care.

The doctor-related factors that participants would like to see improved included readily-available consultation time, collaborative decision-making, availability of health expertise and better communication skills. The need for trained health personnel, rather than reliance on survivors was clearly highlighted by one survivor who asserted that she felt so demoralized after an encounter with a long term (20-years) survivor.

The participants in the newly diagnosed, Stage_1 and Stage_2 groups expressed that there was too much reliance on the ad-hoc sharing of peer-survivors (merely using anecdotal evidence) which allowed entrenched myths and misconceptions to persist over the years. Although all informants (except one) acknowledged that survivor support was important, they mostly agreed that a clear demarcation was needed to differentiate what survivor (lay person) can offer and what health professionals should be offering.

Self-management intervention program for Women with breast cancer

This strategy were viewed as minimising distresses and in line with the idea of comprehensiveness of care. Overall, the participants voiced that, a lot of room for improvement were needed in the health delivery system.

“Sharing with other survivors is fine but they are biased by their own experience. We need the professional, who knows the overall issues to help you with the right direction...unbiased, and not to scare you, or push you into products, and other things...because you are already so confused” (SS1n1).

The second sub-theme (2ii) arise from issues related to resources and networking at the hospital grounds. The participants expressed strongly that the healthcare system must facilitate networking to address their unmet needs. In particular, more than 30 percent (all the newly diagnosed) agreed on a need for some kind of resource set up within the clinics.

“It’s good if hospitals have a place, where we can seek and get information because not everyone can get access from internet” (SS1n3).

“...A breast cancer network at the hospital itself” (SS2n3).

“...No, not the breast welfare association, but at hospital level itself, because this is our first place of contact” (SS2n7).

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With information-booklets, the women said that during the diagnosis period they were in a state of shock, and they concurred that having a booklet for them to refer to at their own time would be beneficial. The reason given was that they may not be receptive during the initial (crisis) period but need the book once they are emotionally stable.

The participants voiced that hospital staff should not only know where to direct patients to obtain wigs, prosthesis and special soap or facial care, but that the hospitals should have these things available on its premises. They concurred that a name-list 'bank' for rapid matching of newly-diagnosed woman to other survivors with similar experience as crucial since learning from other 'successful' survivors was seen as promoting adjustment.

Another woman expressed,

"I went into depression, but later I think what I need is to see people who have gone through it" (Ndmn1).

Besides survivors, they felt the resource centre should offer networking with health-professionals whom they viewed as the 'pipeline' for assurance, comfort, emotional-physical needs, camaraderie support and hope. This is not unexpected, as cancer patients have heightened vigilance and thus they need reassurance (Benyamini et al., 2003).

Self-management intervention program for Women with breast cancer

In fact, their agreed that partnership, amongst survivors and health professionals were essential and this element is a core element of the chronic care model.

These women are of the general consensus that more structural support for managing symptoms (such as hair loss, nausea, tiredness and lymphedema), with resources for family members was fundamental. This idea is very pertinent as cancer, or any other illness, is usually a family affair in Asian societies which have a strong extended family system.

“You could have a book, like on information for caregivers and then for the spouse, friends, family members, so that they are more aware, and thus more able to render the needed support” (Ndn5).

One participant said that she was well informed by the doctors and health staff regarding treatment options, and was impressed by an oncology nursing staff who ‘educated’ her on the side-effects and what to expect. On hearing this, the other women in the group nodded and affirmed that this should be the way to deliver care. Women wanted a better healthcare policy on breast cancer, emphasizing a delivery that is affordable and accessible to all. They also wanted to see more funds for quality anti-nausea drugs to improve compliance with chemotherapy.

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The 'synergism' of the focus group (Kitzinger, 1995) allowed participants to reinforce each others' vented dissatisfaction about the healthcare system, leading to a strong consensus call for service improvement.

However, with an ever increasing patient load and shrinking health budget, emphasizing a one way improvement of the delivery of health system clearly is impractical and uneconomical. Improving the services of health providers must be complemented with a strategy to improve the role of the service users. Therefore, a self-management model aimed at increasing patients' involvement may be the answer for the long term healthcare especially for chronic conditions. The women concurred that they can be good partners provided they were given the course and training,.

The third sub-theme (2c) arised from agreement related to human relationships and communication skills, Malaysian women show a tendency of not questioning their doctor's advice. There is still no enforced law in Malaysia which stipulates that a woman must be fully informed of standard treatment options, as the case in most developed countries. Many unassertive patients remained ignorant and suffered in silence, as some Malaysian doctors did not volunteer information.

Self-management intervention program for Women with breast cancer

The general consensus was that most women were not given information readily. Those who were assertive would resort to the strategy of ‘hunting’ for the busy doctor for more information. An example that represent this issue is the quote below.

“I have to hunt down the doctors for information” (Ndn1).

Nevertheless, even among the majority ‘educated’ participants, there were feelings of uneasiness in questioning the doctor. There is a general lack of fluency in navigating the Malaysian health system which still follows a traditional, hierarchical approach and a prevalent view that the doctor is the authority figure. The women are uncomfortable and/or lack the skills of questioning their doctors (a critical barrier for effective self-management.).

Illustrations of such poor communication skill were represented by the selective quotes from the informants. For example, one woman suffered anxiety for months, waiting for her surgeon to explain why she was not on Tamoxifen, unlike almost all the other women she met at the clinic.. she like many others dare not ask her doctor.

“Everyone else is on it...everyone I talked to seems to be on this tamoxifen drug..... I kept wondering [why am I different]Oh god, why not me? Is something terribly wrong with me? Why is the doctor not telling me?” (SS1n4).

Self-management intervention program for Women with breast cancer

We analysed this issue and come to the conclusion that there were at least three reasons why these women tended not to question their doctor's decision. These reasons were represented by the following three categories (each highlighted with the most representative quotes) :

- i) "Because the doctors know best" [reflecting a respect for the doctor as an authority figure],
- ii) "Too shy to ask/dare not ask" [suggesting a hierarchical medical barrier], and/or
- iii) "Difficult as the doctor is always busy/cannot be reached" [reflecting an access barrier].

This theme was recognized as highly critical. The criticalness reflect the research evidence elsewhere which emphasized that good doctor-patient communication is the most important factor in psychosocial care (Rankin, Newell, Sanson-Fisher, & Girgis, 2000). There is mounting evidence that effective-empathic communication with the cancer patient and family positively affects the patient's quality of life and medical outcomes (Baile & Aaron, 2005). To elaborate, the National Cancer Institute, USA recommended three important foci for patient-clinician communication: i) advocating and navigating, ii) supporting patient autonomy, and iii) giving guidance, skills and access to resources. Nevertheless, the acknowledgement that "patient-clinician communication can enhance self-management is a relatively new idea in cancer setting" (Epstein & Street, 2007).

Self-management intervention program for Women with breast cancer

The quotes below were selected to illustrate the inadequacy of communication skills of the health professionals which were expressed across all groups. Some of the quotes below selected from the various focus groups showed the lack of communication skills and/ or those that reflect a lack of empathy by health professionals. These selective quotes below triggered the discussions on this issue and were chosen to represent the poor collaborative partnership with the patients.

“ ... I cannot argue with the doctor, right? So, I just left it at that” (Ndn6).

“I have been going for regular check-ups for months and I was not explained on why I was not prescribed the drug (Tamoxifen),.. like the others” (SS1n2).

“My private doctor said I don't need to know all these... but to just trust him for he can take care of me” (SS2n4).

“... And while I'm still in a shock...he [surgeon] pressed... 'When can I 'fix' you for an operation!'. I was really shocked... I was trying to cope with the news but he wants immediate decision from me. I felt he should at least wait till my husband is with me. I had already telephone him and he was on the way to meet me at the hospital” (SS2n3).

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“He [the doctor] looked at me as if ..., there’s no hope...anymore. When I came out of his clinic, I was totally crying and feeling so devastated. I felt I had totally no support from him!” (Ndn6).

“..... My experience was with this young doctor..... Well, doctor, should be in the position to pacify me...but this young doctor said, ‘Oh, this is your 3rd chemotherapy, isn’t it? Well...4th and 5th is going to be worst!!!’[With an angry tone] I expect these people to give support, some hope, a little hope! Not more fears!” (Ndn8).

“The doctor explained...but it was hard to follow him [understand him], and so I left and then at home, I began to surf the internet for some information... to help me understand” (SS2n7).

“With the diagnosis, I was distraught... and in deep thoughts ...Whatever the doctor said was not registered at all in my mind” (SS3n1).

“Doctors should...go for human skills communication [practices]” (Ndn7).

“ Yeah...and nurses and others too...” (Ndn1).

Theme 3: Medical-related (socio-economic-cultural) issues.

Another cluster of issues that interfered with medical management was related to the broad ‘socio-economic-cultural’ theme.. Issues related to language difficulties, medical terminology issues and insurance-financial concerns (costs and lack of insurance coverage), and the lack of an employment act (to provide sufficient medical leave) gave rise to the theme on ‘Socio-economic barrier’. Another clusters of issues related to family and individual beliefs (on breast cancer, fear of screening, fear of treatment, and the unfamiliarity of, and lack of trust in the healthcare system) gave rise to the cultural portion of this theme.

The participants of the four groups concurred that cancer treatment were costly and the impact of the financial burden placed on the family can be difficult to manage. The financial burden was further aggravated by a lack of coverage provided by their insurance policy which has rather vague terms subject to unfair interpretation by the insurance company. Many in the group were force to being proactive in writing their wills to ensure that their children and loved ones were taken care of in the unfortunate event of their death.

Self-management intervention program for Women with breast cancer

Others talked about the need to be prudent and not excessive in battling the illness and in the management of financial aspects, as reflected in the selected quotes below to represent this issue..

“Cancer is not just emotionally draining it is a financial burden too. A real issue as the operation, and follow-up care are expensive. Herceptin can cost up to RM 200, 000 and this is not subsidized by the government” (Ndn4).

“Insurance does not provide full coverage...and clauses in the insurance policy are sometimes very tricky, i.e. '30 days after the first operation', This clause is not for cancer diagnosis, and we are on the losing end because our chemotherapy starts much later and thus will not be covered” (Ndn8).

“Also...once they [insurance company] find out you had breast cancer, they don't want to renew your policy the next year [we are blacklisted]” (Ndn4).

Many concurred they were shocked when first informed that they had cancer because they claimed they had previously led a healthy lifestyle. These led back to the discussion and rampant views and expression of myths related to breast cancer (and the misconceptions that arises from the many unavailable /unreliable sources of information).

Self-management intervention program for Women with breast cancer

The women agreed they were highly susceptible to myths in the vulnerable states of trying to find a reason to their diagnosis. Many of these myths were related to the causes of cancer, dietary issues, and intimacy during the period of receiving their chemotherapy. The quote below was representative of the common idea on the cancer related myths.

Example of a representative quote:

I am a very healthy person and I lead a very healthy lifestyle, so I can't understand why I got this [breast cancer], therefore my only conclusion is that it must be 'karma' [belief related to past deed]. Also, all my siblings are all well, so the [contributory] cause is also stress, i.e. work stress (SS3n5).

Food was a favorite topic and appears to have much significance to health in the Malaysian culture. Therefore, it was not surprising to find that taboos and convictions about certain foods was a hot topic across all the groups. There were much debates on the regime of juices to take or the list of food to avoid etc., even though some of these ideas were not substantiated by medical evidence. To illustrate, the Chinese, shared a strong cultural belief on food being classified as either 'ying' or 'yang', with certain food like durians (a tropical fruit) being considered 'yang' (heaty) and thus if consumed excessively may cause cancer.

Self-management intervention program for Women with breast cancer

Poultry meat especially chicken and duck meat was thought to be harmful because they were believed to be ingested with estrogenic hormones (eventhough there is a lack of scientific evidence on these prohibited food aspects).

Example of related quotes on some sommon fruits and foods:

“Mangoes [!] Definitely, it is mango that caused my breast cancer. I consumed so much mangoes before I was diagnosed” (SS3n4).

“I think there are lots of foods that caused cancer, for example, durians, prawns, duck meat, chicken meat.....” (SS3n3).

Most held a belief that, “... organic food is the answer to avoid cancer and cancer recurrences” (SS2n3). One Malay lady informed that she was told that people with cancer must resort to the use of “certain cooking utensils, i.e. those that are of made of stainless steel” (SS3n7).

Also commonly voiced was the confusion surrounding exercise, even among survivors who were healthcare staff. A healthcare worker shared,

“My surgeon cautioned me, he said, “no, no, no, you shouldn’t do anything [exercise] until 3 weeks later. Put your hands in the sling” (Ndn3).

Self-management intervention program for Women with breast cancer

Myths surrounding the issues of intimacy, chemotherapy and sexuality were also voiced in at least 3 groups. One participant in the Stage_3 group raised the issue about her husband's thoughts on sexual intimacy to which a few other women nodded in agreement, while another sought confirmation about it. Participants across all four groups discussed a widespread idea (fear) regarding the impact of chemotherapy on their daily functioning which they claimed was rampant among survivors.

Example of a common myth related to chemotherapy

“My husband believed that with chemotherapy, I have all the toxins all over my body, so it's better not to have it [sexual intercourse]” (SS3n3).

Another woman wanted confirmation and raised the question to the group,

“I heard that cancer patient cannot have too much sex because I heard that sexual excitement can lead to recurrence, but I don't know if it's true or not?” (SS3n4).

(Another myth on chemotherapy)

“Oh, you'll be so weak, you'll be so nauseated, you'll just be lying for the next 5 months in bed...and you must not go out at all” (Ndn9).

These expressions add strength to the current notion that changes must target at the policy levels and to ensure health intervention are sufficiently broad based to address the vast needs (including addressing issues related to cultural myths) of the service users.

Theme 4: Health maintenance issues.

The participants articulated a cluster of health related issues which give rise to the theme on maintaining health after a cancer diagnosis. These issues are critical particularly in preventing recurrences and enabling moving on in life. The women concurred that efforts were needed to enable themselves to live with a cancer diagnosis. Therefore they need to maintain efforts in reenacting lifestyle-changes and adjusting to the illness and readjusting to life with the illness.

Across the groups, these women concurred that adopting various mental (cognitive) and/or behavioral strategies must be adopted so that they can improve their health. Examples given were re-ordering priorities, greater appreciation of life, adopting coping strategies (e.g. meditation, positive-thinking and prayers), as well as adopting healthy diets and lifestyles. Infact, evidence suggest that in the Asia Pacific region, physical activity, rest, healthy diets and vitamins have been endorsed for long-term survival (Bowman, Rose, & Deimling, 2005). The discussion on food and diet, was a topic the Malaysian women wanted to discuss most. Even with reassurance from the healthcare team that they could eat anything they wanted, the participants expressed they were unconvinced.

Self-management intervention program for Women with breast cancer

Many women revealed their reservation about food, and one woman's quote (below) was reported here as it represents the general disbeliefs about food;

“We did ask the doctor... but they said we can eat anything. Now...., how can this be possible at all?!!! I know that for many other type of cancer the patients have to avoid certain food but... how come with breast cancer, we need not avoid certain food??” (SS2n4).

Many women concurred that they were confused about what they could and could not eat. In their efforts to maintain health, some paid more attention to cooking a healthy diet, while others had their entire families switch to eating pure organic food, which further strained them financially.

Another aspect of food was the use of traditional medicine to ameliorate the impact of breast cancer. The ‘Lin Zhi’ herbs (a type of mushroom) were strongly regarded as a potent cancer-curing agent in the Chinese community, despite a lack of scientific evidence. One woman revealed that she had been convinced that she should consume ‘Lin Zhi’, only to find her lump rapidly increasing in size with the increasing dosage recommended to her. The women also felt that many unscrupulous people have tried to make a fortune from their vulnerabilities and they had nowhere to turn in order to verify information about food and health-related strategies .

Self-management intervention program for Women with breast cancer

The women concurred that they have tried various forms of mental (cognitive) and behavioral strategies to adjust to life after a cancer diagnosis. The most common behavioral strategies included dietary modification, and getting more rest. The cognitive strategies mentioned in most groups included changing priorities, placing more importance on their own health and emotional needs (over material needs), and appreciating life and loved ones more. Others indicated strategies like engaging in activities to take their mind off the problem, returning to a normal routine, performing prayers, adopting exercise and starting a support group.

Changing attitudes towards life was a strategy used by majority of these women to promote health. They agreed on the need to stay happy, reframe ‘bad’ thoughts, ‘move quickly into decision-making’, and draw on religion, spirituality and family support to keep stress away as well as opening up and not hold everything inside. These wide ranging cognitive strategies used to rebalance or adjust to the cancer experience are important as they provide a sense of control in their efforts to mobilize resources and manage a shift in self-identity and a new lifestyle by balancing, pacing, planning and prioritizing events and activities (Kralik, Coates, Lee, & Paterson, 2007).

These common expressions of the various attempts to reconfigure their daily lives and self identity have been linked to the self-management process by Kralik et al (2007) who suggested that the term ‘self-management’ makes reference to their definition of how people cope, via activities undertaken to create order, discipline and control in their lives.

3.3.2 Emotional Management Tasks

There were two themes that emerged under this task domain: (i) the need for support and (ii) the need for coping skills. Coping skills were important to help women manage emotions that waxed and waned with the many treatments and their side effects. A further iteration divided coping into (1) general coping strategies and an (2) specific coping need to combat the ongoing/prevaling intrusive thoughts and fears of recurrence and death that seems intertwined with a breast cancer diagnosis.

Theme 5: Support.

In all the groups, the women spoke freely and appreciated the opportunity to share their experiences. However, some indicated that they were reluctant to discuss their emotional problems and personal feelings about their cancer with strangers, or even with siblings. They concurred that support from health care professionals were critical in helping them adjust to the traumatic experiences.

Self-management intervention program for Women with breast cancer

A diagnosis of breast cancer was traumatic and devastating as reflected in the words the women selected to describe their feelings. Strong emotions were common as in the metaphors ('world sinking', 'death warrant', 'my whole world fell apart...') used by the participants across all groups. These views reinforce the findings in the research literature. About 50% of women experienced psychiatric morbidity (A. Hall et al., 1996).

Anxiety and depression are commonly faced from the moment of diagnosis (Dow, 2000). In fact, psychosocial factors (not physical symptoms) are found to be better predictors of quality of life in people with cancer (E. Lev et al., 2004); and distressed patients accrued four times the healthcare costs of non-distressed patients (Levin, Perk, & Hedback, 1991).

Research showed that the ability to manage a wide ranging emotions is crucial, since positive emotional functioning means the ability to enjoy life, which strengthens people's commitment to undergo treatment (Luoma & Hakamies-Blomqvist, 2004). The quote below is representative of the general consensus on fatality;

"I think all of us here feel it's a death warrant! I can't find anyone... I feel so devastated" (SS1n2).

Self-management intervention program for Women with breast cancer

“I was with a cancer support group and yet when told, I’ve got breast cancer...it’s a different ballgame altogether. It was really traumatizing during diagnosis”

(Ndn7).

“...There should be someone there at first diagnosis...some info...what to do and who to see...because the first thing in our mind is ‘are we going to die?? I had nightmares...felt the whole world sinking” (SS2n1).

The women concurred that their present key source of emotional support were firstly from their husbands and families. Their second source of support were friends and relatives, and their third sources were community groups such as breast cancer welfare association, church and Qi Gong club.

Studies show a positive correlation between group support and improved psychological outcomes (Goodwin, 2005). In terms of breast cancer related support, most participants said that their illness had brought them closer to their family members. In the Malaysian society, it is widely acceptable that the family and not the individual that is often regarded as the basic functional or structural unit. Thus, any illness is seen as a family affair. The importance of family was reflected in some of their quotes.

“Family support is very, very important...without family I couldn’t have gone through my experiences with having a breast cancer” (SS3n2).

“Before my cancer, I had no time for my family. Now...there are more time together” (SS2n4).

Self-management intervention program for Women with breast cancer

“...After my diagnosis, my relationship with my husband improved tremendously...” (Ndn6).

“I have three children...they are all very supportive...especially during chemo and treatment” (SS1n5).

“My sibling was very helpful...For example during my trauma, I just take my sister’s words, I relied totally on her but of course, she relied on the doctor’s judgment” (SS3n5).

In addition, prevalent in one group (the newly diagnosed) was the notion (fear) that they did not want to join any breast cancer association because of fear-of-distress caused by the highly emotional sharing from fellow survivors. This group agreed that it would be hard to offer emotional support to other newly diagnosed women as they were in an equally vulnerable position. This group notion reflect a misconception which view the breast cancer support group are seeking their help rather than offering help or that it was both ways. The women argued that physical help could be easily rendered, but not emotional support and they needed emotional help which was often hard to obtain from the healthcare professionals. This may warrant a call for a change from the detached health professionals who are trained in a hierarchically medical-based model system.

Theme 6: Coping needs.

Another major theme of the focus groups was the specific coping with a multitude of fears related to death, recurrence, treatment and its wide-ranging side effects, diet, and reassuming work. In particular, fear of recurrence and metastases were commonly expressed by all groups. A study on the information needs of the newly diagnosed (n=70) confirmed that among the key information needed was those related to recurrences (Graydon et al., 1997).

Representative quotes includes -

“These fears are always there” (SS1n2), and many concurred that “...And it is the same...no matter whether you are diagnosed with Stage_1 or 3” (SS1n1).

“I kept getting this fear of whether the cancer has spread to the bone or elsewhere and even a slight bodily pain can trigger these fears, it is terrible and there is no peace at all” (SS1n2), [to which another person chipped in] “That's why, people said, “ It's not the breast cancer that kills you.... but THE FEAR!!” (Ndn6).

The women agreed to a suggestion for establishing networking of women with different concerns, (e.g. those needing Herceptin, those without spouses, etc); as they felt that such women were more likely to be reassured by those in similar circumstances.

Self-management intervention program for Women with breast cancer

Several working women expressed the different needs for coping with different work issues. For example, when one woman shared her initial fear, the other working women agreed that overcoming fear is a critical need that must be addressed.

“I was worried...how am I going to face the people in the office...but once I shaved my hair and bought myself a wig...I just move forward” (SS3n2).

Hearing and seeing how other survivors manage successfully provided the critical assurance. Nevertheless, being equipped with a proactive coping skill and facilitated into resuming participation in life activities enhances life adjustment. Many women expressed that successful coping means that they move on in life activities.

Factors were identified by the women that can enable them to cope by moving quickly into decision-making about treatment and about getting on in life. These were agreed as encompassing strategies like - acceptance and openness, coupled with a strong faith and strong family support.

Malaysian women's experiences with breast cancer appeared deeply rooted in religion and spirituality, as almost all participants concurred that prayers and religion helped regardless of religion.

Self-management intervention program for Women with breast cancer

Example of coping by the different ethnic members were reflected in the quotes-

“I cope by thanking the Lord...every morning I say, “Thank you, Lord...for giving me one more bonus day” (SS2n1, SS3n4).

Some women held strong spiritual beliefs that the diagnosis was willed by God, or related to ‘karma’ (a belief specific to Hindus and Buddhists) or a more general conviction that the outcome of the illness was in God’s hand. One woman appeared to place more importance on spirituality than on mainstream healthcare, because she did not take part in the treatment decision-making and left it all to her sister and the doctor. She also opted to remain ignorant of the side-effects.

This person had expressed initial difficulty in accepting the diagnosis as she had led a healthy lifestyle. Religion offered a good explanation to help her move on. She said that,

“It’s the consequences of karma, you cannot fight it. If cancer is to come to you, there is no way to avoid it...Like I say; the monk told me it was ‘karma’. You have to go through the treatment...once you finished the treatment, you will be fine...I tell myself to stay positive, and to ‘pay back this karma [past misdeed]...and since then, I have no relapse! ...Yes, prayers help...whatever religion we belong to” (SS3n6).

Other important coping strategies adopted besides the spiritual aspects, were keeping busy, having a proactive attitude, and educating oneself on the illness.

3.3.3 Role Management Tasks

Two important role-related themes emerged that were consistent across the groups were: (i) relationships at work and at home; and (ii) sexuality and intimacy issues. Cancer can be an isolating experience, thus it is not surprising that the women concurred with the need to reconnect with other people and to resume their roles at home or at work.

Getting back to their normal routines was seen as a good and crucial strategy for life adjustment, and was very crucial, even though they recognized that they were feeling fragile and perhaps insecure.

All the participants agreed that,

“The most important is to get back to normal life” (SS1n6).

“Indeed, getting back to normal routine and work was important...although deep down we are still fragile” (SS1n1).

Self-management intervention program for Women with breast cancer

“I got back to my exercise routine.....” (SS1n2).

“After I completed my treatment I went for brisk walks again...normal life”
(SS3n7).

“I resume my line dancing and when people asked [about my absence], I said, Oh, I went for a trip as I find myself still unable to talk about it [cancer]” (SS1n6).

Theme 7: Relationship at work and home.

Adjusting to breast cancer resulted in role changes for the women, such as delegating more or requesting assistance from family members, which in turn strengthened or added strain to some relationships. Going back to work was an issue that elicited varying opinions. About 50 percent felt avoiding working was better as they perceived the stress from work as a cause of their breast cancer. Although this is a common belief, at least one large study (n=6689) found lower cancer incidence positively associated with high work stress and offered the reason as due to impairment of oestrogen-synthesis induced by chronic stress (Nielsen et al., 2005). Some participants stayed away from work to spend more time on meaningful tasks that they have taken for granted. However, others felt that returning to work was therapeutic as it made them feel normal and ‘well’, while for some other, engrossing themselves in work helped them cope with nausea and other side effect from cancer and its treatment.

Self-management intervention program for Women with breast cancer

The quotes below reflect their perspective about returning to work.

“Oh....I returned to work as soon as I could, as work helped take my mind off breast cancer” (SS2n7).

“...It really helps having a job to go back to. It gives me an assurance that I am ok already” (SS3n2).

“I go [went] back to work because I was bored with nothing to do” (SS2n7).

“Oh, I value life differently now...I am more aware of healthful lifestyle, and the need to spend more time with loved ones and to take care of my daughter” (SS2n6).

“...With breast cancer, I see things from a different perspectives...Like now, I have the time to see my children go to work which I never did as I was always rushing off to work...and now I also have time to attend religious classes” (SS2n5).

There were also some fundamental issues related to returning to work like suitable attire and dealing with the prying, curious eyes of office colleagues who knew about their diagnosis. Also, for those who were not self employed, the issue of maintaining their job or looking for a new one that may require a fresh medical examination raised much concerns and anxieties. Even for those with jobs to return to, there were many issues to deal with.

Self-management intervention program for Women with breast cancer

The quotes below were representative of the various work-related issues

“How am I going to get back to work in my uniform with one breast missing?”

(Ndn3).

“...I cannot wear my tight bra, jacket and so forth, I had to get use to my new wardrobe, and it's like having a new identity with all the loose clothing” (Ndn1).

In terms of relationships at work, most women felt that their colleagues and bosses were generally supportive. (Although only one woman voiced lots of harassment from her immediate supervisor).

“I was given 6 months medical leave – very generous but I needed it...” (SS2n5).

“My colleagues, my bosses...they were all just wonderful, I was given light duties and they all helped out” (Ndn6).

In terms of relationships at home, this study found that women tended to focus their energy on families, financial aspects and household responsibilities. The concern for and the physical care of young children were reported across all groups. This is not unexpected as the incidence of breast cancer in multi ethnic Malaysia is highest in the 40 to 49 age group (Hisham & Yip, 2003).

Self-management intervention program for Women with breast cancer

Common tasks like adopting meaningful life roles such as those of mother and care of aged parents are highly pertinent tasks, since older women who are more at risk of breast disease (Forbes, 1997). Most married participants were concerned about childcare and the emotional demands associated with keeping their families in good spirits.

The effects of the women's cancer on the families, relatives and neighbors have been positive in a sense that it has brought people together, but they focus much of their energy on their families and their household responsibilities. This could also be viewed as an emotional displacement from focusing on the illness, to directing it towards families.

These are example of their utterances which reflected a common concern,

“...During treatment ...not easy to relax, children are around.... it is so very difficult, not easy at all” (SS3n4).

“ I am concerned as my children are still small, and I cannot afford not to work; cancer treatment is not cheap, and what about the possibility of a recurrence since cure is not guaranteed,..... and then we incur another round of expenses and this is a real issue as it affects funding for my children's education” (Ndn8).

“I pretended that everything was fine so that they [kids] were not worried”
(SS3n5).

“I am doing ...WELL, not too bad, but I can see that my husband is losing weight, [pause] worrying about me. He doesn't say it... you know how men are [pause], but I know him so well...it breaks my heart to see him like this”
(Ndn2).

Theme 8: Sexuality and intimacy related Needs.

In one of the groups, the women were quite open about their intimate relationships with their husband. This dispels the notion that Malaysian women in general are reluctant to talk about their private lives. However, as this was not typical in all groups, the use of focus groups may have led to their openness regarding the topic. In general, the woman felt that their intimate relationships were affected to some extent, but they felt the main reason was ‘within themselves’ rather than with their spouse whom they reported as ‘encouragingly supportive’. Factors like age and side effects of hormonal treatment causing dryness; (including myths that too much excitement can trigger the cancer cells, and toxicity of chemotherapy can ‘travel’ to their spouse during sexual intercourse) were brought out.

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Examples of rather prevalent notion related to the common sexuality issue

“...With Tamoxifen, I felt that there's dryness in my vagina ...and it does affect my sexual relationship with my spouse” (SS3n2).

“It depends on age as wellof course during chemo [chemotherapy], I abstained from sex, but it's not really an issue” (Ndn5). “I think it's more of me... it's like I don't want to do it” (SS3n3).

Related to this theme of sexuality and intimacy, was the issue of body image. The trauma of losing a breast and/or hair was a critical issue among the Malaysian women. In fact several participants felt strongly that, among the three aspects of medical, emotional and role management, sexuality and body image was the most important for them. Some women took more time than others to accept their new body image, while others were more open about it. Most women felt that it was easier to accept the hair loss, as it was a temporary problem. However, the lost of a breast was reported as more traumatic, especially for those with complete mastectomy. This issue of ‘mastectomy’ versus ‘lumpectomy’ was summarized by one woman who had lumpectomy as, *“Not a big problem, it's [my breast] just one bigger and one smaller” (Ndn4).* Being practical and open helped the woman to move forward. However, many women acknowledged that body image and sexual concerns undermines their confidence, femininity or womanhood, as well as lead to strained intimate relationships.

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Nevertheless, most women felt that the crises arose more from themselves than from their spouse or from others. They, however, affirmed that their husband's opinions and views were fundamental in helping them accept their new body image.

Women who were older were more able to accept the altered image, as expressed in their common views:

"I was 59 then, really ...it wasn't an issue" (SS2n6).

"Depending on age...of course sexuality is important but more important is...be strong and have a good mental attitude" (Ndn5).

"I asked for mastectomy as I considered my age and I [took into consideration] that I have no husband" (SS2n5).

Looking and feeling good were generally accepted as reciprocal and facilitating adjustments. The women expressed that they need to address appearance, and talking about it was considered crucial. One woman expressed that not one of the healthcare staff had ever asked her about these non-medical issues.

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“Looking good is good as it makes us feel better” (SS1n1).

“When we look good, we feel good” (Ndn6).

“Physical image is very important...nobody bothers to initiate discussion, as if it’s not important...but our lives consist of everything” “...with hair loss, you can come to terms with it [because it grows back]...lost of breast is harder” (Ndn8).

“After a while, I looked at myself in the mirror and said, so what? My priority now is life, beauty is secondary” (SS3n3).

“My husband tried to assure me that it (the breast) was not that important” (SS3n4). “I guess if my husband does not mind, then it does not matter” (SS3n1).

“No matter what my husband say...I don’t feel the same...somehow, something is missing” (Ndn8).

“I felt I was not normal” (SS1n6).

These findings show that the needs of women are wide ranging but the consensus views can be clustered into seven themes. Many were not met within the existing available services and this warrants a broad-based intervention that extends beyond merely addressing medical-related tasks.

3.4 Discussion

Overall, the qualitative needs assessment highlighted the need for a paradigm shift in the services offered to women with breast cancer. From the literature review, there were several principles useful for guiding the designing of an innovative self-management intervention for Malaysian women.

Firstly, the key findings from the focus group clearly indicate that focusing solely on medical tasks is insufficient as all three self-management tasks are equally important. A recent focus group (n=10) study found women with breast cancer acknowledged they were living with a chronic condition, not dying from it (M. Oxlad, TD Wade, L. Hallsworth, & B. Koczwara, 2008b). The women concurred that effective management of all three areas influenced their quality of life. It confirmed that the diagnosis and treatment of breast cancer impacted greatly on their daily lives, including work, home, relationships and role tasks.

Secondly, the multifaceted needs of Malaysian women with breast cancer warrant a broad-based intervention. Also, within a multicultural context, the use of intercultural communication skills poses a real challenge.

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Thus, increasing ethnic diversity among the health team members may be the most direct strategy to improve healthcare experiences for members of ethnic minority groups (Cooper et al., 2003).

There were several limitations in this study and certain issues may impact the external validity of this qualitative Phase I study. These included;

- Data saturation: Ideally there should be a minimum of two groups for each focus group (according to cancer staging). However, the aim was to explore and verify the findings in the literature to inform the designing of the intervention design for the main study.

As the aim of this focus inquiry was not to explore the differences between the ethnic groups but rather, the intention was to formulate a generic Malaysian program regardless of race. Thus, this preliminary study was adequate.

- Many of the participants were Malaysian Chinese, but this reflects the ratio of the ethnic representation of breast cancer in Malaysia.

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- All were English speaking participants. This may pose a bias as they represent the more affluent women who are more adept at navigating the resources for breast cancer. However, the focus group found that even among this group the need for information was still critically lacking.

These limitations may reduce the generalisability of the results, but it has highlighted many fundamental issues for Malaysian women with breast cancer, particularly those being treated in the Klang Valley, one of the more affluent regions in Malaysia. This study offers important contributions to the literature on breast cancer among Malaysian women. As a preliminary qualitative survey, it has accomplished several goals:

- (i) it adds to the sparse literature about Malaysian breast cancer survivors;
- (ii) it provides insightful understanding of quality of life issues for women with breast cancer; and
- (iii) it enhances the knowledge about specific cultural and socio-ecological factors (like dietary taboos, myths and misconceptions, acknowledgement of sexuality and body image concerns, and of the economic impact of breast cancer on the families).

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More importantly, this study addresses areas that have not been researched before. The focus groups provided opportunities for women to reveal how breast cancer had affected their lives and many survivors felt the focus groups were cathartic. In summary, the women experienced many common barriers hindering their life roles. They wanted help in the wider aspects of self-management, and from health professionals with networking of various resources.

The findings confirmed a consensus expression for a broader intervention in order to address the medical domain, the emotional and role domains. To sum up their idea on needs, one woman had expressed the idea succinctly:

“Sharing with other survivors is fine but they are biased by their own experience. We need someone who is unbiased, very level-headed about the whole thing, not just the medical Aspect, BUT every aspect of it [managing living with breast cancer], and the overall issues from health to food to lifestyle” (SS1n1).

3. 5 Clinical Implications

In essence, the verbatim quote above has appropriately highlighted two significant implications for planning interventions in cancer care.

- i) In this era of rising consumerism, patient participation is crucial for effective care and the collaboration of the different professional cultures (medical, therapy and nursing) and teams responsible for delivering cancer care must be better coordinated. The women wanted professional-led groups in the hospital settings rather than entrusting care responsibilities to survivors-led peer groups. Thus, the need for clear, defined boundaries, roles and responsibilities of the public, private and voluntary health organizations has never been so important (Tritter et al., 2003).

- ii) The women spoke against the present fragmented dimension of care and the need to address many unmet needs. This includes emotional management, knowledge-skill of how to manage the cancer and on how to live healthily to minimize risks, and the day-day roles and responsibilities. Thus, a program that could enable the newly diagnosed to self manages effectively, not just in the medical-tasks but also the ‘overall aspects of living with breast cancer’ was indicated.

Research evidence suggested that unmet needs scores correlates with quality of life scores ($r = 0.263$, $p = 0.008$) in breast cancer patients (Saatci, Akin, & Akpınar, 2007). Effective intervention must consider the multiple impact of breast cancer on women's life and to provide quality information (also to counteract the numerous prevailing myths on breast cancer) requires input from the 'expert patients'. Thus development of any new intervention must be based on requirements defined by women with breast cancer (Landmark, Bøhler, Loberg, & Wahl, 2008). The focus group study here found that patients wanted a broad-based intervention. This suggests planning of interventions may best be drawn from the bio-psychosocial models (versus a medical model)(Astin, Sierpina, Forys, & Clarridge, 2008; N. Williams et al., 2008), so that the best intervention can be developed and tested in a clinical trial.

3.6 Conclusion

In summary, this Phase I study provided insightful understanding of the self-management needs of women with breast cancer. As medicine has been (and still is) largely physician-centered, addressing what patients regard as important is fundamental to meet health outcomes. It adds to the sparse literature about Malaysian breast cancer survivors, by exploring needs from their perspectives.

4

DEVELOPMENT OF SAMA

People with chronic conditions commonly deal with
three sets of self-management tasks
(Corbin and Strauss, 1988)

4.1 Development of SAMA

The hardest part of any needs assessment process is the translation of the results into practice or policies that will provide beneficial change (J. Wright & Walley, 1998). This Chapter describes the translation of the results from the needs assessment and literature into the 4-week SAMA. It explains the development, rationale and framework of the design of the SAMA interventions that fall within the MRC's Phase 1 (Modeling Phase) for complex intervention. Work on the program involved the following sequential steps.

4.1.1 Review of Literature on Interventions for Breast cancer

Following the MRC (2000)'s framework on Preclinical Phase, background review of the literature on self-management programs for chronic diseases found that it has not included cancer conditions, therefore prompting the initiation of this study on breast cancer as an evolving chronic condition. There is a dearth of literature on therapy, rehabilitation and health-related quality of life (QOL) of Malaysian women with breast cancer. Adding on, the Malaysian Clinical Practice Guidelines for managing breast cancer (National Cancer Registry, 2002) is heavily focused on the traditional medical model. These reasons prompted the search for the identification of the gap in the current intervention for breast cancer.

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The literature review related to the epidemiology of breast cancer and chronic diseases, and interventions for breast cancer were presented in Chapter 2. In order to understand the gap in current interventions offered to Malaysian women with breast cancer, three additional key documents were explored :-

- i) The Malaysian Clinical Practice Guidelines (Malaysian Ministry of Health, 2002)
- ii) The Australian Psychosocial Clinical Practice Guidelines: information, support and counseling for women with breast cancer (NHMRC, 2000)
- iii) A review of interventions by specialist providers: A summary of the literature 1976-1996 (NHMRC, 1998).

The review compared these documents and the general comprehensive guidelines for adult cancer patients (NHMRC, 2000, 2001, 2005) as well as the literature on self-management for chronic diseases. The review on the interventions offered over 20 years period, confirmed that the search for the most effective intervention was inconclusive (Burke & Kissane, 1998). This step revealed a gap in the current intervention, where it is not able to meet the vast arrays of needs. Today, women with breast cancer are faced with numerous needs arising from the many challenges, threats and consequences of the disease, which is taking a form of chronic condition.

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Overall, recent reviews on the efficacy of psychosocial interventions for cancer patients have not been convincing due to lack of evidence. Meaningful meta-analyses have been difficult due to a lack of predetermine criteria for comparison of the wide variation in the nature of interventions and outcome measures (Manne & Andrykowski, 2006), and the lack of details of trial along a poor adherence to CONSORT statement (Coyne, Lepore, & Palmer, 2006), and an overall poor methodologic quality of the trials (SA. Newell, Sanson-Fisher, & Savolainen, 2002). There is a preponderance of evidence from metaanalyses (specifically on efficacy of managing distress in cancer patients, (Andrykowski & Manne, 2006; Lepore & Coyne, 2006), it is not surprising that the overall evidence for efficacy of general psychosocial intervention in cancer care is reported as weak (Burke & Kissane, 1998; Coyne et al., 2006; SA. Newell et al., 2002).

Since there was no ideal intervention, Burke and Kissane (1998) offered a guideline of ideal interventions which included: i) comprehensiveness, ii) structured program, iii) tailored to meet the needs and stage of disease, and iv) incorporating peer support, with v) a routine link to health care professionals. In addition, NHMRC (NHMRC, 1998) advised that education, stress-management, relaxation training, group support and coping skills training should be integral parts of a comprehensive medical care for women with breast cancer. The exploration highlights that the current narrow-based interventions focusing solely on psychosocial, emotional (as provided in many developed countries), or solely medical care (as in the Malaysia Clinical practice Guideline) is inadequate because women with breast cancer need to manage the multiple numerous tasks arising from living with a breast cancer diagnosis.

4.1.2 Identifying Key Messages from Focus groups Findings

Self-management program is problem-based and patient-focused (KR. Lorig & Holman, 2003). The Institute of Medicine (IOM, 2001b) has established that safe, effective, timely, efficient and equitable healthcare warrants the health professionals to provide better quality information to patients to meet their level of needs so that they are enabled to make informed decision-making on the treatment options.

The needs assessment via focus group (discussed in Chapter 3) supported the proposal for a self-management program that not only provides information but also skills for self-managing the wider aspects of life tasks. The program should address the unavailability of structured support for Malaysian women.

Thus, in line with Corbin and Strauss's framework and the IOM (2001)'s idea of education for patient-centered care, the planning steps for the educational content of SAMA begin with the needs assessment focused on patients' concerns. This was followed by the identification of the patients' perceived needs, which is a crucial step and is conducted by translating these insights from the focus group findings (i.e the derived themes) into key messages.

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Table 4.1

Derivation of key messages from Patients' perceived needs (themes)

<p>Key self-management Tasks</p> <p>Medical Tasks</p>	<p>Themes 1, 2 & 3 (needs associated with...)</p> <p>Informational Services and resources Partnership, networking Managing myths</p>	<p>Key messages</p> <p>*Breast cancer is not a death sentence! Know your breast cancer Work with your health staff Make informed decisions Monitor and manage symptoms Identify and refute myths</p>	<p> M E D I C A L</p>
<p>Emotional Tasks</p>	<p>Themes 3, 5 & 6</p> <p>The need for support The need for general coping The need for specific coping</p>	<p>*Mental health is crucial! Monitor distress with Distress Thermometer. Use strategies to promote emotional health like relaxation</p>	<p> E M O T I O N</p>
<p>Health Tasks</p>	<p>Themes 4</p> <p>The need to maintain health Learning how to live with breast cancer</p> <p>Adopt healthy habits to reduce risks</p>	<p>*Managing health is as important as managing illness. Adopt M.E.D.S: Manage risk –follow guidelines Exercise-4 hours a week, Manage Diet, BMI<25 Sleep, rest and relaxation</p>	<p> H E A L T H</p>
<p>Roles Tasks</p>	<p>Theme 7 & 8</p> <p>The need to manage and balance roles and relationships -at home -at work -in the community Addressing sexuality issues</p>	<p>*There is life after cancer! Resuming roles, reconnecting with loves ones, being proactive and into social networking are tools (means) for enabling them to move on and ahead</p>	<p> R O L E S</p>

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The purpose of key messages is to ensure that self-management education offers simple, clear, consistent and important advice (KR. Lorig & Holman, 2003). As delineated in Table 4.1, each week of the 4-week SAMA program is highlighted by the pertinent key messages. Next, the objectives for self-management program were planned to ensure they are complementary with these key messages. The last step ensure that the educational content was culturally appropriate (Gonzales & Lorig, 2001) for the Malaysian women (see Table 4.1).

The key messages to be addressed within this 4-week program included the following:

- “*Breast cancer is not a death sentence*” (and long term management is needed),
- “*Work in partnership with health professionals*” (assume active role and be proactive in action planning).
- “*Mental health is crucial*” (thus emotional management tasks are needed),
- “*Learning to live with breast cancer*” is important, (the need to engage in healthy living is as important as managing the illness and its effects)
- “*There is life after a breast cancer diagnosis* (therefore the need to manage roles and relationships and to resume them at home, work and community).

4.1.3 Delineating the Aims of the SAMA program

The main aim of SAMA was to empower women with education and skills to help them through the curative-treatment period. The secondary aim was to prepare them for a smooth transition into post-treatment period. In order to capture these concepts, SAMA was coined to represent the 4-week self-management program to enable women with breast cancer to self manage effectively.

The structured, targeted and theoretically-based intervention for women newly diagnosed with breast cancer were designed based on five clear self-management objectives drawn from the definition by Gruman and Von Korff's (1996) which were:

1. To adhere to treatment regimes for breast cancer
2. To engage in activities that protects and promotes health
3. To monitor and manage the signs/symptoms of breast cancer
4. To manage the impact of having a breast cancer illness on their day-to-day functioning, emotions and personal relationships
5. To create new and meaningful life roles

4.1.4 Organising the content (for delivery) around the key messages

The key components of SAMA are education (as in all traditional patient education programs) and the self-management skills. The identified key messages were translated into themes within Corbin and Strauss's three areas for self-management (Table 4.2). The educational content were therefore planned around these three spheres of medical, emotional and role tasks. The medical tasks were further subdivided into medical and health tasks.

The curriculum was designed in line with the patients' request for 'no more than four week duration' (Chapter Three). The content on health management was large and thus it was designed as a whole session by itself. This session relates to aspects on healthy living, diet, exercise, breast examination practices.

Therefore, there were four sessions: Session One was related to the medical tasks, Session Two - emotional tasks, Session Three - health tasks and Session Four - role-related tasks. Each session was designed for about 2 ½ - 3hours.

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Table 4.2

Key Messages and Content of SAMA Program

Key Messages	Session 1	Content	
<p>*Breast cancer is not a death sentence! Know your breast cancer Work with your health staff Make informed decisions Monitor and manage symptoms Identify and refute myths</p>	Activity 1	Breast cancer, chronic illness & SAMA	 M E D I C A L
	Activity 2	Where are you buddy?	
	Activity 3	Common treatment pathways & My breast cancer Profile	
	Activity 4	Common side effects & My symptom management chart	
	Activity 5	Common myths of breast cancer	
	Activity 6	Action planning & homework	
<p>*Mental health is crucial! Monitor distress with Distress Thermometer. Use strategies to promote emotional health like relaxation</p>	Activity 1	Feedback/problem-solving session	 E M O T I O N
	Activity 2	Introduction to normal adjustment process	
	Activity 3	Challenging self-defeating thoughts.	
	Activity 4	Monitoring with Distress Thermometer	
	Activity 5	Cancer coping strategies	
	Activity 6	Action planning & homework	
<p>*Managing health is as important as managing illness. Adopt M.E.D.S: Manage risk –follow guidelines Exercise-4 hours a week, Manage Diet, BMI<25 Sleep, rest and relaxation</p>	Activity 1	Feedback/problem-solving session	 H E A L T H
	Activity 2	Introduction to staying healthy guideline	
	Activity 3	Exercise planning	
	Activity 4	Menu planning	
	Activity 5	Weight management	
	Activity 6	Breast awareness and examination	
	Activity 7	Action planning & homework	
<p>*There is life after cancer! Resume roles, reconnect with loves ones, being proactive and social networking is a tool to moving on /ahead *Main theme of the week</p>	Activity 1	Feedback/problem-solving session	 R O L E S
	Activity 2	Communication & Reconnecting	
	Activity 3	Proactive planning –home/work	
	Activity 4	Building my support network	
	Activity 5	Reaching out, speaking out	
	Activity 6	Action planning & homework	

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There were four main themes in line with the four main aspects of self-management tasks. Theme 1 was on managing breast cancer supported by didactic educational content. To cover this theme, the information on breast cancer facts, the evolving nature of breast cancer, concept of self-management, the need to self manage, skills of self-management, role of the women in order to self manage (i.e. active, in partnership with professional) were included.

Theme 2 was on emotional management. This session's educational content included the understanding of the psychological adjustment involved in a crisis (i.e. illness), understanding the vicious circle of negative emotions, challenging self-defeating thoughts, monitoring distress with the distress thermometer, and coping strategies and what are the features of proactive coping.

Theme 3 is on managing health and healthy living behavior. The content includes information on health, exercise, diet, BMI and weight management, and breast awareness-examination.

Theme 4 is on managing roles and relationships, and the educational content includes communication tips, proactive planning in managing home and work tasks, building a supportive network, and reaching out to the community.

4.1.5 Integrating Self-management Skills in the 4week program

Planning for the five core self-management skills to ensure integration into the 4-week content was then conducted. These skills included; i) problem-solving, ii) decision-making, iii) resource utilization, iv) partnership with healthcare provider, and v) taking action (KR. Lorig & Holman, 2003). Also included in the planning were the homework and class exercises to provide opportunities on incorporating the sources of self-efficacy for skill buildings. Table 4.3 delineates the skills within the SAMA program.

Each week, skill mastery was built up by getting the women to change their behaviors using the action-planning sheet which was designed for two or three specific short term goals on something that they would like to be achieved within one week or so. Women gave feedback and shared their successes the following week and if any difficulties arose, they would use the problem-solving strategy again. This underlying theoretical mechanism is based on the self-efficacy belief discussed in the literature review. Empowerment is a consequence of self care (Ryles, 1999) and a consequence of empowerment is the development of competencies which allows people to gain control (Embrey, 2006)

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Table 4.3

Self-management skills within the SAMA* Program

Core self-management tasks				
The Content and its scheduling:	Medical Tasks	Emotiona Tasks	Health-related tasks	Role tasks
<u>Common skills</u>				
• Key messages with core theme	+	+	+	+
• Supporting your buddy		+	+	+
• Being proactive		+	+	+
• Action plans	+	+	+	+
<u>Core self-management skills:</u>				
• Problem-solving		+	+	+
• Decision-making	+	+	+	+
• Utilization of Resources	+	+	+	+
• Partnership with health staff	+	+	+	+
• Proactive Action-taking		+	+	+
<u>Core self-efficacy mechanism</u>				
• Skill/ Mastery experiences	+	+	+	+
• Social Modeling	+	+	+	+
• Social Persuasion	+	+	+	+
• Physiological-psychological symptor	+	+	+	+
	Week 1	Week 2	Week 3	Week 4
Postulated underlying theory =	Social Cognition & Cognitive Behavior			
Postulated underlying mechanism =	Cancer self-efficacy & proactive coping			
Postulated group/leadership style =	Tuckman's group stages & leadership			

*SAMA = Staying Abreast, Moving Ahead, a 4-week self-management program

4.1.6 Planning for the Facilitation Style

Next, the incorporation of a theoretical input of psycho-educational model and theory-based facilitator style was planned to ensure incremental learning and self-management processes takes place. Therefore, the model on group development first proposed by Bruce Tuckman (1965), was utilized to guide the group from ‘norming’ to the ‘performing’ stage. Table 4.4 is a summary of the phases and their correlations to the 5-stage cognitive-behavioural model of health education, i.e. relationship building, exploratory, decision-making, working stage and termination stage.

These stages are inevitable in order for the team to grow, tackle problems, find solutions, plan work, and deliver results (Read, 1997). The last phase, *adjourning*, involves completing the task and ending. During this phase, the members disperse from the formal meetings but are able to meet up informally when the needs arise. Along this team work principle, a 2-tier buddy system was carefully embedded in the program to help the participants work with each other. Each participant has the opportunity for a two-tiers buddies. The first tier buddy is a person assigned to each of them by the facilitator. Allocation of buddy was guided by shared characteristics of the participant such as undergoing chemotherapy, or having HER2 therapy.

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The second-tier buddy/ies would be self selected and the choice is up to the participants if they would like one or more buddies but are reminded that they have mutual responsibility for each other during the 4-week program. Selection are self-guided using criteria like, age, geographical areas of living, having similar clinic appointment or how easy they related to each other, or a need for mutual physical support (e.g car pooling) or a need to initiate emotional support with the person.

SAMA is a facilitator-led program. Thus, facilitation skills adopted by the SAMA facilitator are guided by Tuckman's model in accordance to the stages of group. A facilitator adopts several styles during the facilitation processes, starting with a directive style, shifting into a coaching style, and skillfully when appropriate into a delegating style and then a participating style, and finally a detached style as the group reached maturity or closure. This facilitation styles proposed for each of the group stages as presented in Table 4.4 served as a guide to the new facilitator, and is provided in the SAMA manual for the Facilitator. The progression of style in line with the stages of group and development of group, ensures the self-management intervention are delivered in sequential stages and in a planned manner. The groupwork strategies and the facilitation's style used within SAMA are thus designed carefully and embedded strategically within a matrix to enhance effectiveness of the program.

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Table 4.4

Group work Strategy and Facilitation Style

 Session	Stages of group	Group work strategy (Example of exercises from SAMA*)	Facilitator's style (Tuckman's)
Session 1 Managing my Breast cancer	F O R M i n g	Focus on Relationship building: Facilitator highlight common problems and goals. 'Buddy system'* to promote closeness - first tier buddies are assigned to encourage each other; Second tier buddies are self-selected to support each other with transportation, problem-solving etc.	Moving from a 'Directing' style,
Session 2 Managing my Emotions	S T O R M i n g	Exploratory stage: Paying attention to feelings and acknowledging them. Also, increasing the group work, from simple tasks like 'Challenging myths and self-defeating thoughts', to menu charting, diet planning, etc. Homework is used to shape the team transitions from "as is (the present)" to "to be (the future)".	↓ moving through a 'Coaching' style,
Session 3 Managing my Health	N O R M i n g	Decision-making stage: Requires more team-work with task-oriented actions e.g. finding yourself an exercise group or visiting a wig shop. (This encourages participants to look for common themes and common work). Action planning focus on health plan. (The team reaches consensus on the "to be" process).	↓ then into 'Participating' - to finishing-Delegating
Session 4 Managing my Roles and relationships	P E R F O R M i n g	Working Stage: Encourage the participants to take an active role. Group representative and members coordinate meeting dates, ensure attendance, plan food, outing, and visits to breast welfare association, breast resource centers. (The team has settled its relationship dynamics, and the overall group as well as personal expectations).	↓ and ending with almost-Detached style
	ADJOURN ing	Termination Stage: The group may be exposed to another group to expand its networking. The optional 3 rd line buddies can be initiated by any group member. (They share their improvements and personal growth).	

SAMA* = Staying Abreast, Moving Ahead, a 4-week program.

'Buddy system'* - a SAMA strategy to improve groupwork and cohesiveness of members.

4.1.7 Consolidation of the SAMA Program

Once the curriculum framework was planned, a final review of the vertical integration (SAMA content) and the horizontal integration (self-management skills and facilitation skills) is in line with the structured activities, homework and tools. The idea that empowerment is a vision rather than a technique or strategy (McGowan, 2005) is adopted here. Thus, strategies are needed to help women gain empowerment. Beside the requisite skills and support, a list of smaller information topics was planned and integrated into the specific week's session. These topics complement the main session and are delivered according to the scheduled timeline of four weeks duration.

Theory-led programs are better at identifying who benefits from what type of intervention (Devine & Westlake, 1995; Steverink et al., 2005), and for planning what to offer. The National Cancer Institute has asserted that theory-led programs are more likely to succeed than those developed without the benefit of a theoretical perspective (K. Glanz et al., 2005). In addition, the biomedical model of disease which is used extensively in the health delivery system in Malaysia, does not take into account all of the complex factors involved in cancer (S. Shapiro et al., 2001). To address this limitation, a theory-led intervention derived from the behavioral, cognitive and social model was eclectically adopted for SAMA.

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The planning resulted in a 4-week self-management program, known as SAMA or ‘Staying Abreast, Moving Ahead’. This is a theory-based program, to address the lack of ‘theory-informed intervention’ (Devine & Westlake, 1995; Steverink et al., 2005). It draws from Bandura’s SCT, Beck’s CBT and Tuckman’s group work theory to provide an eclectic intervention for women with breast cancer (a specific condition) and who are newly diagnosed with early breast cancer (a specific stage of disease). In short, it was tailored to a specific condition, and stage (e.g. early breast cancer), based on the features of what constitute ‘effective intervention’ as recommended by NHMRC (1998).

Therefore, SAMA is an innovative, self-management program aimed to help women with breast cancer maintain wellness by emphasizing the three sets of self-management tasks commonly dealt with by people with chronic conditions, as delineated by Corbin and Strauss (KR. Lorig & Holman, 2003), and as informed by the needs assessment findings via the use of focus groups.

4.2 Overview of the 4-week SAMA

Table 4.5 outlines the content of the 4-week SAMA, formulated using Corbin and Strauss's broad framework on core self-management tasks; the medical, emotional and role tasks (J. Corbin & Strauss, 1988) and delineated based on the women's expressed concerns and perceived self-management needs. Also highlighted in Table 4.4 were the stages of group development in line with several principles that bring together the concepts of a psycho-educational approach and a style of group work facilitation along the concept of a health professional-led intervention. Lastly, the bottom part of the matrix is a preview of the key themes, activities, homework and tools. A matrix was delineated to provide an overview of the integration of the two main components:

- A) A patient-education breast cancer specific-content
- B) A theory-led self-management content (education and skills).

In brief, the 4-week SAMA curriculum uses a group format for 8 to 15 women, weekly meetings of about 2 ½ - 3 hours each session, for four consecutive week and were led by a trained facilitator. Each of the four sessions was guided by a self-management theme: Medical management tasks, Emotional management tasks, Health management and Role management tasks.

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The first session was scheduled one hour earlier while the final session was scheduled one hour later than the middle two sessions, to cater for the pen-paper testing. Group work, mini lectures and homework were incorporated in each of the four sessions.

The last session also finished off with a tea and exchange of gifts to show mutual support to their new partner (or known as the SAMA buddy). The 2-tier buddy system was added to the program as an inbuilt support-mechanism for the participants to encourage each other as well as to discuss their homework.

Two volunteers (health professionals) were trained as co-facilitators. They were given the SAMA manual a month earlier for them to study. The co-facilitator training included a formal didactic lecture on breast cancer by a breast surgeon while the researcher gave a briefing on the SAMA intervention. The group development stages and the facilitation style were also presented to the co-facilitator since SAMA was a facilitator-led intervention. A checklist (Appendix B5) of facilitation skills was provided to them to generate awareness on what skills they need to work on.

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Table 4.5

Overview of the 4-week SAMA Program

SESSIONS SKILLS	Session 1	Session 2	Session 3	Session 4	GROUP	FACILITATOR	
	*A: The breast cancer Education content						
<p>*B: Core self-management skills (Lorig & Holman, 2003)</p> <ul style="list-style-type: none"> • Resource utilization • Taking Action • Decision-making • Problem-solving • Partnership 					PERFORM STORM FORM NORM	Detached Participating Delegating Coaching Directing	
	THEMES	<i>Breast cancer is not a death sentence</i>	<i>Mental health is crucial</i>	<i>How to live healthily with breast cancer</i>	<i>There is life after breast cancer.</i>	Team: Together to achieve more.	Facilitating....
	ACTIVITIES (Example)	Breast Facts	Mind-body Fact Mind-tools	Lifestyle Fact Body/health tools	Survivorship Tools for living		to enable self
	HOMEWORK (Example)	Symptom-Charting Myth-Identification Action Plan	Distress-charting Relaxation Ex Action Plan	Breast aware Diet/ weight BMI index Exercise Action Plan	Roles, relationship Advocacy. Action Plan		management skills and promoting QOL & participation in Life
	TOOLS	Resource book	Relaxation tape	Breast chart Diet menu, exercise chart.	Addresses Web visits		
WEEK	Week 1	Week 2	Week 3	Week 4			

*A: Vertical integration of patient-education materials *B: Horizontal integration of self-management skills (with cancer self-efficacy, proactive coping).

4.3 Guiding Principles of SAMA

With the content identified and integrated in the 4-week ‘Staying Abreast, Moving ahead’ (SAMA) curriculum, the section below explains the underlying principles (the why and how) of the SAMA intervention. Based on the study’s conceptual framework in Figure 2.6, this section on the ‘enabler’ (via self-management intervention) will be further elaborated here.

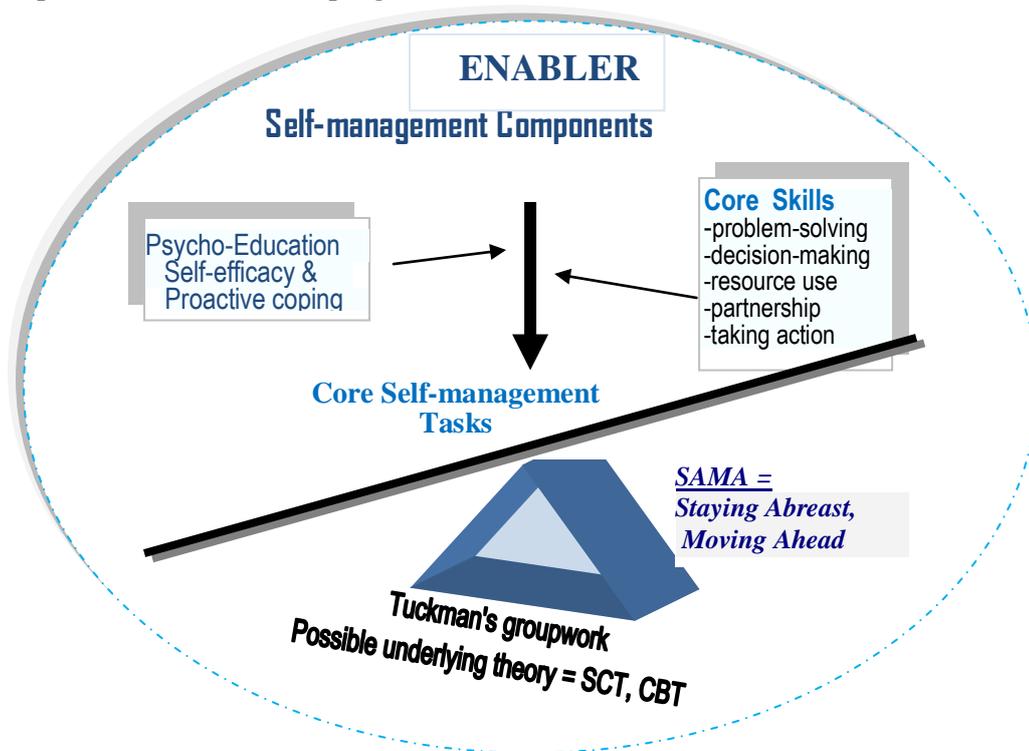
In many practice settings, health programs are often defined pragmatically and lack any clear theoretically-based science (O'Brien, Dyck, Caron, & Mortenson, 2002; Sirovich, 2002). This, in turn, limits generalisability as well as the understanding of why an intervention was successful or not (Bradley, Wiles, Kinmonth, Mant, & Gantley, 1999). In line with the call for more theory-driven experimental studies (MH. Antoni et al., 2001; Holman, 2004; T. J. Meyer & M. M. Mark, 1995), health services are increasingly drawing on ideas from other disciplines to design and deliver complex interventions (M. Campbell et al., 2000).

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Behavioral change has been conceptualized as a function of both cognitive and behavioral processes (Dowson, Marsh, & Martin, 2004). SAMA was designed as a complex intervention and its theoretical underpinnings were based on Social Cognitive Theory (SCT), Cognitive Behavioural Theory (CBT) and Tuckman's group-work, to ensure the behavior, cognitive and social realms are better addressed. Together with self-management principles and self-efficacy as its central mechanism, these principles are illustrated in Figure 4.1 as the 'Enabler' (i.e. key component enabling self management).

Figure 4.1

Components of the SAMA program – the Enabler



4.3.1 The Key Attribute of SAMA

Based on Figure 4.1, this section here highlights the attributes of SAMA. These are breast cancer education (topic identified from the focus groups and literature), cancer self-efficacy and proactive coping skills. These were consciously incorporated in the 4-week SAMA. Lorig & Holman, 2003 asserted that, a feature that distinguish self-management from other traditional patient education program is the skill of ‘self-tailoring’ or applying self-management skills and knowledge as appropriate to one’s needs. This requires an underlying confidence or efficacy which is the belief that one is capable of acting (a plan of action), as well as proactively coping by using other skills of self-management (i.e. how to act on an action plan).

The SAMA session provides opportunity for goal-setting every week, working towards achieving the medical, emotional and role management tasks. The opportunities for the development of self-efficacy belief were planned based on the four sources of development (mastery experience, vicarious experience, social persuasions and physiological states) as reviewed in Chapter Two. For example, self rating of confidence levels with action-plans was measured along a scale of 0 (totally unconfident) to 10 (totally confident). A score of 7 and above indicated there was a good chance that the action plan would be accomplished.

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Proactive coping was another attribute identified for SAMA which complements self-management behaviors. As expounded by Aspinall and Taylor (1997), the basic processes of self-regulation and social interaction come together in the stages of proactive coping. Proactive coping is a set of coping skills rather than just a coping style. It starts with a goal to build resources and skills which is called, *resource accumulation*, in advance of any specific anticipated stressor such as side effects from chemotherapy. This skill activates and prepares individuals for the resource utilization phase. In short, the three identified components of education, cancer self-efficacy and proactive coping skill, were consciously added to the protocol for planning SAMA.

4.4 The Protocol Planning of SAMA

With the content and components identified and laid out, this section presents the protocol of the 4-week SAMA. Having a protocol to ensure consistent delivery paved the way for replication of the study in future. The protocols were developed and presented in the 80 pages SAMA Facilitator's Manual. Intensive work to coordinate the Manual and to ensure its content was correlated to the simultaneously, newly developed 154 pages SAMA Participant's Workbook were conducted extensively over a period of time.

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The development of the SAMA protocol was guided by theoretical principles and strategies derived from the field of self-management. These strategies were tabled in Table 4.6. Factors affecting self-management summarized by the Royal Australian College of general Practitioners (RACGP, 2003) and the specific planning strategies from Lorig and Harris (2001) informed the planning process. The RACGP's guidelines provided the general guiding structure on factors affecting self-management delivery, while Lorig's strategies filled in the details to ensure effective delivery of SAMA.

Finally, the SAMA curriculum was developed through careful consideration of the vertical and horizontal integration of educational content and skills, that were guided by key principles from the field of self-management. The work continues for the development and refinement of the SAMA Workbook (cum resource book) for participants and the SAMA Manual for facilitator guidebook. These materials were closely examined and prepared in a way that it could be tested in a pilot study.

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Table 4.6

Protocol Planning for the 4-week SAMA Program

Factors affecting self-management (RACGP, 2003, p11)	Protocol-planning strategies (Lorig & Haris, 2001, p115-120)	Application to SAMA
Motivation	<p>Write your objectives and be sure that what you are teaching is designed to meet the objectives.</p> <p>Framing the syllabus around clients' needs</p> <p>Vary your activities</p>	<ul style="list-style-type: none"> • SAMA enables women to stay abreast and move ahead. The 5 basic self-management objectives provide the focus for the 4-week curriculum. • Objectives and weekly content were in line with key messages from clients (what they want) and on self-management (what they should have) • This is the basis of motivation for women to act on issues they can relate with. It sustains interest, also with appropriate interesting activities in between sessions.
Knowledge of condition	Providing fundamental knowledge to aid decision-making, and supplementing education with self-management strategies to facilitate improvement in health	<ul style="list-style-type: none"> • Design such as the exercise on 'My breast cancer Profile' is an aid to increase knowledge. The SAMA workbook also dealt the 'medical jargon' that is a barrier to self-management (B. Paterson, 2001).
<p>Knowledge of symptom management plan</p> <p>Identify the impact of the illness</p>	Provide information and skill on managing symptoms.	<ul style="list-style-type: none"> • Provide information on possible symptoms and prepares women to deal with them proactively. • Provides a symptom management chart for women to work on and build up and practice problem-solving skills.

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Continue ...

Belief	<p>Frame teaching around clients' beliefs</p> <p>Be consistent with key messages (one cannot teach self-management and then manage for the patient)</p>	<ul style="list-style-type: none"> • Topics and exercises, were framed to reflect concerns, address beliefs, and challenge myths • Key-messages for the week guide the content for the session, and were consistently highlighted at the start and recapitulated at the end of session to ensure that self-management is about 'self managing' and the role of the facilitator are only to facilitate.
Self-efficacy	<p>Provide opportunities for women to exercise control over their ability and desire to assume a self-management role.</p> <p>Give attention for taking positive action</p>	<ul style="list-style-type: none"> • Build on activities over several weeks: homework added in over the 4 weeks in manageable amounts. • Vicarious learning – from each other. • Lowering physiological stress • Women are commended for initiating a healthy behavior
Social Context	<p>Consider family, friends, culture, role needs.</p> <p>Give attention for positive action</p> <p>Use of same facilitator</p>	<ul style="list-style-type: none"> • Session 4 focused on roles and relationships, including home and work tasks. SAMA's two tier buddy support acts as a social tool to enhance self-management • Reward participants' efforts with praise and use vicarious models to promote self-efficacy. • Facilitator remains constant, and is conscious of duration (equality) of time between clients in the group
Promoting healthy lifestyle	<p>Use a sesame street approach – small doses of topics built over time</p> <p>Remember patients always have choices (avoid being dogmatic, remind patients that decisions are theirs)</p>	<ul style="list-style-type: none"> • Action plan activities carried over the four weeks. • Provide research evidence but let patients determine their own goals. Use specific guidelines and evidence on breast self examination, diet and exercise

RACGP =Royal Australian Clinical Guidelines for General Practitioners.

4.5 Branding of SAMA

The approach for the implementation and delivery of SAMA was studied to explore the best delivery method. One of the issues identified during this process was the branding of SAMA to promote it to patients as well as stakeholders such as breast centers and hospitals. This was also to attract patients to come forward and participate, since there were lots of reservation and challenges with recruitment during the pilot stage. The branding of this newly developed intervention was considered to ensure it is acceptable to the Malaysian women with breast cancer as well as to generate interest from relevant parties to the program. The unique features of SAMA are:

- i) A self-management educational program, (versus mere patient education sessions), with the aim to improve women's knowledge as well as their health behavior.
- ii) A condition-specific intervention, focusing on breast cancer (versus generic cancer), based on recommendation from the National Health and Medical Research Council, Australia.
- iii) Led by trained health facilitators with knowledge of group work and facilitation styles (versus peer-led), and with updated knowledge on breast cancer development as well as skills on psycho-educational model development.

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iv) guided by social cognitive and behavioral theories (versus ad hoc planning program) which are more holistic and capable of meeting the wider unmet needs of women with breast cancer,

SAMA recognizes the central role of the women for successful self-management of breast cancer that includes adopting healthy behavior. The acronym 'SAMA' was specifically used for the program as it represents the overall theme for the program: 'Staying Abreast, Moving Ahead'. SAMA which means 'same' in the Malay language, also conveys the key message (drawn from the focus group findings) that Malaysian women with breast cancer need to manage a range of similar self-management tasks daily, regardless of their age, ethnicity and cancer staging.

In conjunction with this theme, an icon of an active woman was selected as the symbol for women to model a proactive and healthy woman (despite having a breast cancer). Thus the branding of SAMA had been carefully selected during planning and publicized during the trials.

5

PILOT STUDY

A pilot, or feasibility study, is a small experiment designed to test logistics and gather information prior to a larger study, in order to improve the latter's quality and efficiency (Lancaster, Dodd, & Williamson, 2004).

5.1 Introduction

In this pilot study, the health-professional led 4-week SAMA intervention program was tested with a group of six women who had breast cancer. Tools for the program included the SAMA Participant' Workbook, the SAMA facilitator's Manual, a relaxation handbook (Loh, 2002), a relaxation tape (all developed / authored by the researcher), and a breast self examination booklet written by a Malaysian oncologist.

The rationale for this Pilot (i.e. Phase II exploratory trial within the MRC 2000's framework) was to inform decisions for the main clinical controlled trial (CCT). Thus there were two overall goals for the pilot study. The primary goal was to improve SAMA (by examining the feasibility and acceptability of it and to gather feedback from participants on the program and its workbook (process evaluation). The secondary goal was to prepare for the CCT. This includes surveying the pattern of response on the outcome tools (outcome evaluation). The tools selected, were based on careful analysis of the specific population targeted for this trial (Kantzer, Ting, Heng, Gola, & Martin, 2005), and it was decided to administer all tools in one language i.e. English.

Therefore, the research questions were:

- I) Was the program feasible for, and acceptable by women with breast cancer?
- II) What were the effects of participating in the program, as measured on the outcome tools (Quality of life, emotional distress, participation, proactive coping and self-efficacy)?

5.2 Methodology

Study Design

A single group pre-test post-test design was utilized for the developed program, assessed at baseline and at post-intervention. The aim was primarily to test the 4-week 'Staying Abreast, Moving Ahead' (SAMA) intervention.

Setting

The pilot study was conducted at the University Malaya Medical Centre (UMMC), a teaching hospital located in the Klang valley in Kuala Lumpur. UMMC runs a specialized breast clinic and has a, Breast Cancer Resource Centre, located adjacent to the surgical wards. The resource centre was established and funded by Avon Malaysia in late 2005.

5.3 Recruitment and Participants

Recruitment

The chief breast surgeon in UMMC was contacted to support the recruitment for the study. Information sheets and invitation letters (Appendix B-1 to B-3) were provided to the surgeon and her team to distribute to patients at the breast clinic.

Participants were either recruited from the wards or breast clinics, and provided the information sheet (Appendix B2) with full details of the study. The breast surgeon provided the names of the women who expressed interest in the study. This complied with the NHMRC Australian (NHMRC, 2002) which stipulates that researchers are not to contact the participants directly but interested patients can contact the researcher directly. The researcher screened the women for eligibility based on the following inclusion criteria; i) more than 18 years of age, ii) diagnosed with Stage 1-III cancer within the last 12 months (first diagnosis, and confirmed by a physician), iii) undergoing adjuvant/hormonal therapy, iv) able to read and understand English, and v) gave informed-consent. Exclusion criteria were i) marked cognitive impairment or learning disabilities (through observation/ interview) or ii) had other form of medical problems interfering with participation and attendance (from self report). The goal of the recruitment was to recruit a group of 6-10 participants to undertake the complete program and to provide feedback on the SAMA program.

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A total of 60 women were given the information, out of which only 20 were eligible. The reason for the ineligibles were, having a diagnosis outside the stage 1-3, had recurrences, unable to converse in English and/or unable to attend all four session. Of those eligible, 12 refused, and eight expressed interest and signed the consent form but the final turn up was only 6 women. In addition, one of the aims of the program was to assist the distressed, but women who were most likely to benefit (i.e., those with depression) were difficult to recruit. One woman could not get out of the feeling of gloom and wanted to be left alone; another felt she was not up to contributing (i.e. a view that the research programs are looking for help rather than helping). Many wanted to join after they had completed all treatment despite being informed that the program was designed to help them at this early stage.

Participants

The researcher screened the eight potential patients for eligibility via telephone and/or face-to-face interviews, after the surgeon confirmed these women's disease stage as part of the consent procedures. Prior to commencement they received a cover letter, consent form, and a baseline questionnaire. The eight women who consented were enrolled into the trial but two women withdrew before the testing and before receiving the intervention. The six women who consented, received a package of questionnaires to complete before the start, and a similar package at the end of the SAMA intervention.

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Thus, only six women participated in the 4-week pilot program. The dates and schedules for all the sessions were provided to the women two weeks in advance. The women were briefed about the format and delivery of the program as well as the dates before the program and this was reinforced on the onset of the session where women record and agreed on the dates before they record them down on the first page of the SAMA workbook which was provided to them. This prepared the women for proactive planning of their schedules so that full participation could be attained.

Facilitators

Facilitators were also recruited from outside the centre and two medical therapists attended the brief training. Debriefing sessions (at the end of each session or group) was scheduled for the facilitators as well as to problem solve any challenges encountered.

5.4 Instruments

5.4.1 Dependent Variables

Baseline questionnaires consisted of a demographic form, three primary tools, four secondary tools and a brief program evaluation form. There were two parts to the evaluation corresponding to the two research questions stipulated for this pilot study. These are described below under two sections: A) Process Evaluation (Research question I), and (B) Outcome Evaluation (Research question II).

A) Process Evaluation (Research question I): At the end of the program, the participants were asked for their feedback on the content and delivery of the program. Participants provided feedback using the brief program evaluation form (Appendix B-4), in terms of i) program feasibility and acceptability, ii) duration (length, timing, structure, content), iii) tools (workbook etc.), iv) other (venue, facility, facilitator) and their perceived benefits of the program. The rationale was to obtain their feedback on acceptability of the program and to gain input on improvement for the program delivery on women with breast cancer.

B) Outcome Evaluation (Research question II): In line with Research question II, the outcome tools planned for the main clinical controlled trial were tested in this pilot study as the dependent variables. The three primary endpoints were, quality of life (SF36), emotional distress (DASS), and perceived participation (IPA). The four secondary endpoints were three specific self-efficacy scales and a proactive-coping scales. Table 5.1 below is a summary of the tools, administered at baseline (T0), and at post-intervention (T1). The psychometric properties of the primary and secondary endpoints and justification for selection are presented in Table 5.1 below.

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Table 5.1

Summary of Outcome measurement scales

Variable	Tools	Scale and subscales	Descriptions /justifications
Patient Information Questionnaire	PIQ	- Personal - Health - Cancer - Treatment	Background data on personal, health, cancer profile, and cancer treatment profile
<u>Primary Endpoints</u>			
Quality of Life (QOL)	SF36v2	8 subscales, 2 total	Measures outcome reflected by medical /health management
Inventory on Participation	IPA	5 subscales	Measure outcomes reflected by role management
Emotional distress	DASS	3 subscales	Measure outcomes reflected by emotional management
<u>Secondary endpoints</u>			
Self-efficacy (self-care)	SUPPH	3 subscales, 1 total	Specific self-efficacy in cancer related tasks on self care
Self-efficacy (emotion)	SESSES	1 total scale	Specific self-efficacy in cancer related tasks on emotions
Self-efficacy (cancer behavior)	CBI	3 subscale, 1 total	Specific self-efficacy in cancer related tasks on cancer behaviour
Coping (proactive coping)	PCI	1 total scale	Specific coping required in line with self-management tasks

i. *Patient Information Questionnaire (PIQ)*

The Patient Information Questionnaire (PIQ) is a 4-page tool (Appendix D-1) to collect personal demographic data (including age, ethnic, education, income), cancer and cancer treatment profile (stage, grade, treatment), and health profile (BMI, exercise, smoking). The PIQ was designed based on sample of tools used for study on breast cancer (accessed from the web) and it was audited by the breast surgeon. The front covers of the PIQ were colored white for Baseline (T1) and green for post-intervention (T2) measures. The red color PIQ for follow-up (T3) measure in the clinical controlled trial (CCT), was not used in this pre-post design.

ii. *Quality of life (QOL)*

Health-related quality of life is an essential and a routine outcome measurement in cancer clinical trials as well as part of an optimal medical care within oncology (Carlson & Bultz, 2003; Cella, 1998; Taenzer et al., 1997). As a multidimensional construct, QOL was first developed in the social sciences and used within health-care to determine if available cancer treatments could improve patient's sense of well being (Spitzer et al., 1981).

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Wellbeing is a general term which may include physical, social, cognitive, spiritual, emotional and role functioning as well as psychological symptoms, pain and other common physical symptoms (Carlson & Bultz, 2003). QOL assessments can be used in diagnosis, predicting prognosis, assessment, patient monitoring, clinical decision-making, communication, and treatment (Perry et al., 2007).

Nevertheless, up to date, there is no single definition of 'quality of life' and this reflects the inability to capture all meaningful aspects from patients' perspectives. Studies by Ganz and Goodwin (P. Ganz & Goodwin, 2005), found that when assessing the QOL of women with breast cancer, their stage of disease should be taken into account. Ganz and Reuben (Ganz. & Reuben., 2000) compiled at least 20 examples of QOL tools used with cancer patients ranging from generic, cancer-site, and symptom-specific. Many QOL tools have been developed such as the European Organization for research and treatment of cancer (EORTC QLQ-BR23); Functional Assessment of cancer therapy-breast symptom index (FACT-B); Functional Living Index-cancer (FLIC) (Perry et al., 2007). In Malaysia, the 36-item short-form (SF-36) is one tool that has been widely considered and used in assessing quality of life (Azman et al., 2003; Sararaks et al., 2005) and this allows some references.

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The SF 36 v2 (UK) Health Survey (JE. Ware, Kosinski, & Gandek), is a 36-item self-report measure of health-related QOL in 8 domains: physical functioning (PF), role limitations due to physical problems (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role limitations due to emotional problems (RE), and mental health (MH).

The SF36 has two summary scores for its norm-based scoring; the physical composite score (PCS) and the mental composite score (MCS). It is a generic measure since it assesses health concepts that are pertinent to everyone's functional status and well-being (JE. Ware et al., 2004). However, with its physical and mental components, SF-36 revealed a clear discrimination between diseased and non-diseased groups, suggesting good construct validity. Construct validity of the SF36 tested in ten Western European countries (JE. Ware, Keller, Hatoum, & Kong, 1999) found no major differences in scores.

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The validity of the English (UK) SF-36, assessed in a community-based survey of 5,503 Chinese, Malays and Indians in Singapore (very similar to the Malaysian context of multiracial population) found that the English (UK) and Chinese (HK) SF-36 versions were valid with the multi-ethnic Asian socio-cultural context of Singapore (Thumboo et al., 2001). The SF36 version 2 was also reported as having lower ceiling and floor effects, with smaller standard deviation and higher internal consistencies (JE. Ware, 2002). The reliability for PCS has been reported as 0.92 and for MCS as 0.88 (JE. Ware, 2002). A study show that the SF-36 summary scales are valid and equivalent in an Asian population i.e. in Chinese population in Hong Kong (Lam, Tse, Gandek, & Fong, 2005). Efforts to validate the SF36 have been carried out in Malaysia (Azman et al., 2003) and in Singapore (Gao et al., 2004).

iii. Emotional Distress Symptoms

Emotional distress refers to problems such as anxiety, depression and fears around the cancer experience (Carlson & Bultz, 2003). Popular tool like the Hospital and Anxiety Depression Scale (HADS), is found suitable for screening for anxiety in a breast cancer population, but is not suitable for screening depression (Love, 2004).

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HADS as well as the Rotterdam Symptom Checklist (RSCL) have been questioned as unsuitable screening tools to detect psychological morbidity in early breast cancer (A. Hall, A'Hern, & Fallowfield, 1999).

Specific investigation into the psychometric properties of the Hospital Anxiety and Depression Scale in patients with breast cancer, led to the conclusion that the underlying factor structure comprises three distinct, correlated factors which were; i) negative affectivity (stress), ii) autonomic anxiety and iii) anhedonic depression (Jacqui, Colin, Rachel, Kate, & Mark, 2005).

The investigator suggested that if HAD is used for breast cancer population, the clinical utility may need to be enhanced by using a modified scoring procedure based on a three-factor model of psychological distress. Their proposal to alternate the scoring-method which involves regressing autonomic-anxiety and anhedonia factors onto the third factor (negative affectivity), is complicated and requires further investigation in order to establish its efficacy.

Thus, DASS-21 (Appendix D-4) is a self report questionnaire (S. Lovibond & Lovibond, 1995). It is a 21-item questionnaire which allows simultaneous assessment of three emotional states - depression, anxiety (hyper arousal) and stress. A Likert-type scale is used to rate items according to symptoms experienced in the past week, ranging from 0 (not at all) to 3 (most of the time).

Factor analysis on both clinical and nonclinical samples, have shown that the DASS21 items can be reliably grouped into three scales. Alpha value for the 7-item scales ranged from 0.73 (anxiety), 0.81 (depression) and 0.81 (stress) and has adequate convergent and discriminate validity (Crawford & Henry 2003; S. Lovibond & Lovibond, 1995). It is a valid, reliable routine clinical outcome measure of these constructs in clinical and non-clinical groups (Antony, Bieling, Cox, Enns, & Swinson, 1998; T. Brown, Chorpita, Korotitsch, & Barlow, 1997) and for inpatient setting (Ng et al., 2006). In the short-version, scores are added and doubled for each subscale. The short Depression, Anxiety, Stress scale (DASS-21, Lovibond & Lovibond, (S. Lovibond & Lovibond, 1995), is a brief version of the original 42-item tool. It has 7 items each to measure negative emotional states on three-related factors, using Likert scales of 0 to 3 ('did not apply to me' to 'applied to me most of the time') where a participant self reports the degree of negative emotional symptoms experienced during the previous week.

The psychometric properties of the DASS have been studied in samples from Australia (P. Lovibond & Lovibond, 1995) the United Kingdom (Crawford & Henry 2003), the United States (Antony et al., 1998; T. Brown et al., 1997). The internal consistency (Cronbach's alpha) of the Depression, Anxiety and Stress scale has been found to be above 0.80 for all three scales, in university students, and somewhat higher in clinical samples. Cronbach 's alpha for the UK sample was 0.89 (95% CI =0.89-0.90) for anxiety, 0.95 (95%CI =0.94-0.95) for depression, 0.933 (95% CI= 0.928 -0.937) for the stress scale and 0.966(95%CI=0.96-0.97) for total score (Crawford & Henry 2003). The DASS-21 was selected as it has been used previously in Malaysia (Musa, Fadzil, & Z., 2007).

iv. Inventory on Participation (IPA)

Understanding the impact of illness on a person's life is as important as the consideration of the disease itself (Wade & De Jong, 2000) and this concept on participation is central to a client-centered care and the self-management philosophy. In the context of human functioning and disability, participation is referred as the involvement in a life situation for an individual with a health condition (WHO, 2001). In the context of rehabilitation, it is a construct that relates to the perception of involvement in life domains whereby the ultimate aim of rehabilitation is to maximize participation (Cardol, 2001).

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Preserving participation has benefits to both the individual and the healthcare system as a whole (Lothian & Philp, 2001). The Impact on Participation and Autonomy Questionnaire (Cardol et al., 2001), is a 39-item tool designed for use with people with chronic disorders to measure perceived participation in five related (but independent) domains: autonomy indoors, family role, autonomy outdoors, social relations, and work and educational opportunities (Cardol et al., 2001). The subscales can be used separately where appropriate. It uses a Likert scale with five ordinal responses ('very good', 'good', 'fair', 'poor', 'very poor'). To calculate the average score on the subscale, the sum of the completed subscale is divided by the number of completed questions in that subscale. An average score of '0' indicates no limitation in participation and autonomy, while a score of '4' indicates very poor participation and autonomy.

The IPA (Appendix D-3) is a generic questionnaire and its test-retest reliability at the subscale level was good with all intraclass correlation coefficients (ICC) greater than 0.90; and internal reliability of the IPA was confirmed by high Cronbach alpha's on all subscales (all ≥ 0.8) (Sibley et al., 2006). The IPA was chosen as it was reported as a reliable and valid instrument for assessing participation and autonomy in people with chronic disorders (Cardol, 2001). It complements the data obtained from the SF36, and it reflects individual's perception and needs, rather than just their general abilities, tasks and roles (Cardol, 2001).

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The English version, adapted from the original Dutch version (Cardol, 2001), was reported as valid and reliable on adults with chronic conditions (Sibley et al., 2006). Cardol reported IPA, has good construct validity with homogeneity of four subscales which can be used independently. Cronbach's Alpha ranged from 0.84 (family role) to 0.87 (autonomy in self care).

v. *Specific Self-Efficacy*

This was assessed via three cancer-specific self-efficacy scales; i.e. for measuring self care (Strategies Used by People to Promote Health), cancer related behavior (Cancer Behavior Inventory) and cancer related emotions (Standford Emotional Self-efficacy Scale). These tools were selected based on the ideas that specific self-efficacy that matched behavior or specific domain/tasks targeted for change are better indicators than a generalized self-efficacy approaches. This reflects the direction for research on self-efficacy (A Bandura, 1977; Pajares, 2005). This also allows examination of which of these three self-efficacy is the best predictor for QOL. Since efficacy beliefs are task-specific, every domain of interest demands a different self-efficacy measure (EL. Lev & Owen, 1996). In this study, the self-efficacy related to i) self care, ii) cancer behaviors and iii) emotion were measured using the relevant tools described below.

a) *Strategies Used by Patients to Promote Health (SUPPH)* by E. Lev & Owen

(EL. Lev & Owen, 1996), is a specific self-efficacy scale for measuring the self care domain (Appendix D-5). It is a 29-item self-report scale to measure “self-care self-efficacy” in patients with cancer. It has three subscales and also gives a total score to indicate a total for self-care self-efficacy. The Alpha reliability for its three subscales of Positive Attitude; Stress Reduction; and Making Decisions; were reported as 0.94, 0.88 and 0.77 respectively; internal consistency ranged from 0.94 to 0.96 (EL. Lev & Owen, 1996).

The SUPPH has been used with breast cancer (n=56) and in cancer research where interventions to improve self-efficacy in self care have been found to correlate with improved QOL and reduced symptoms (EL. Lev, 2001).

b) *The Stanford Emotional Self-efficacy Scale for Cancer (SESES-C)*, by Giese-

Davis et al. (Giese-Davis et al., 2004), is a 15-item measure of perceived self-efficacy with a total score to indicate coping with the emotional aspects of illness (Appendix D-6). The alpha for the total scale was reported as 0.88-0.89. It has three subscales i.e. Communicating a full range of emotions to loved ones (alpha=0.79-0.86); Maintaining focus in the present moment without distraction or diminution of pleasure (alpha=0.78 - 0.79); and Confronting feelings and concerns related to death and dying (alpha=0.79 - 0.86) (Giese-Davis et al., 2004).

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The items are self-rated on a scale of 10-point increments ranging from 0= 'not at all' to 100= 'completely' confident. Test-retest reliability was 0.69-0.95 and predictive validity has been demonstrated in three samples of breast cancer patients. This tool was selected to measure the self-efficacy of managing emotions. In a previous study on breast cancer (n=117), patients with low emotional self-efficacy are at the greatest risk for traumatic stress symptom (Koopman et al., 2002). It has not been utilized in Malaysia or in any Asia countries, possibly because studies on self-efficacy are scarce.

c) The 14-item Cancer Behavior Inventory (CBI-B) by Merluzzi, Nairn, Hegde, Sanchez & Dunn (2001) is the brief form of the 33-items CBI tool (Appendix D-7). It was designed to measure maintenance of activity and independence, seeking and understanding medical information, stress management, coping with treatment-related side-effects, accepting cancer, maintaining positive attitude, affective regulation and seeking support (alpha from 0.80 - 0.88). They reported that the CBI's concepts on 'coping', 'resiliency', "fighting spirit", and social support were conceptualized from the perspective of self-efficacy theory, and proposed that it can be integrated into a self-management model of coping. The alpha for the entire CBI was reported as 0.94, and test-retest (1 week) reliability coefficient as 0.74 (T. V. Merluzzi et al., 2001). This tool was selected to examine specific self-efficacy for cancer behavior coping, and how it correlates with improved QOL.

vi. *The Proactive-coping scale (PCI-14)*

Proactive coping scale (PCI), a multidimensional and forward-looking coping, has 14 items and combines autonomous goal-setting with self-regulatory goal-attainment cognition and behavior, and focuses on building up resources to enable promotion of action-plans for personal growth (ER. Greenglass, 2001; E. Greenglass, 2005). The 14-item Proactive coping scale (Appendix D-6) was selected as its construct appears to be in line with self-management philosophy of an active patient, as distinguished by its three main features

1. it integrates planning-preventive strategies with goal attainment;
2. it integrates proactive goal-attainment with identification-utilization of social resources;
3. it utilizes proactive coping for goal attainment (ER. Greenglass, 2001).

The PCI scale has high internal consistency as seen in reliability measures (α) of .85 and .80 in the two samples, with good item-total correlations and factor validity and homogeneity (E. Greenglass et al., 1999). It has 14 items, and uses a Likert scoring scale ('1' = "not at all true, 2 = "barely true", 3="somewhat true" and 4="completely true"). Three items on this Proactive Coping subscale are reversed-scored. This tool was reported as a cross-cultural research instrument and has been translated into various languages including Japanese, and has been used on rehabilitation patients.

5.4.2 Independent Variables

The 4-week program, known as the SAMA program, had four sessions. Each session focused on a self-management theme, to build on their self-management knowledge, skills and confidence. SAMA covers the broad tasks of managing the illness (medical and health) tasks, emotional tasks, and role-related tasks in a group-format. The participants were introduced with the five basic but core self-management skills (i.e. problem-solving, decision-making, taking action, and resource utilization skills). Chapter 4 described the program in depth.

5.5 Data Collection

5.5.1 Ethics

Permission to conduct this study was obtained from the Curtin University Human Research Ethics Committee (OT-2005-02, 15/2/05; 9/9/06), the Medical Ethics Subcommittee, University Malaya Medical Centre (Ref435.15/21.3.05) and the Malaysian Ministry of Health's Research Committee (KKM/JEPP/02(160) 9/5/05).

Confidentiality was emphasized early in the study. However, due to the group nature of the intervention, anonymity could not be guaranteed, and all participants were informed of this issue at the start of the groups, and were reminded to respect the confidentiality of others. Results of the testing was confidential, and was not identified by names, but was coded, and only collective data were reported. All identifying or personal details will be removed from transcripts of the focus group interviews. No harm or risk factors were identified as a result of participating in this study. Participants were informed of their right to discontinue participation at any time (NHMRC, 2002). After the interview, there were no cases of any survivors who needed additional emotional support, thus, no referral for counseling was arranged. Data was stored in a locked cabinet, away from the intervention setting, and would be stored for a minimum period of 5 years.

5.6 Data Analyses

Descriptive analyses were conducted on the six participants' demographic and clinical characteristics. In order to get an overall judgement of this program, data analysis for Research question I was conducted by evaluating the participants' subjective feedback. This was to also evaluate the program in terms of acceptability and feasibility; perception of benefits and perceived potential barriers that could limit participation in the future clinical controlled trial (CCT).

Data analysis for Research question II was via the SPSS 16 analysis. As the sample size (n=6) was small; the nonparametric Wilcoxon one-sample signed rank test (a nonparametric alternative to the one-sample or paired samples parametric *t*-test) was conducted to test changes over time 1(pretest) and time 2 (posttest)

5.7 Results

5.7.1 Descriptive Statistics

The participants were comprised of Chinese (n=4) and Indian (n=2) women. Four had been newly diagnosed within the previous month while two were diagnosed about one year previously. The process of recruitment proved quite difficult as many patients had to juggle and complete many clinical-diagnostic tests and hospital appointments.

The background data of the participants are summarized in Table 5.2 below. Analysis of the demographic data showed that the participants' ages ranged from 42 to 60 years with a mean of 52.3 years. There were four Chinese and two Indian participants. Most (five) were married and had two to four children, with a mean of two children. Half (three) had education up to secondary-level and the other half had college-level education. Only two had paid jobs, while the other four were housewives. All six subjects were female, and all attended the full four week program.

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In terms of health status, data collected included those related to risk for breast cancer such as smoking, drinking, exercise and body mass index (BMI). All respondents reported they did not smoke or drink, and had some hours of exercise per week (average of 3 hours) with self-reports of 'light-activity' (50%) to 'active-activity' (50%) levels. As obesity was a risk factor, their BMI calculated from their self reported height and weight, ranged between 20.1 to 30.8 kg/m², with a mean of 25 kg/m². WHO (2004) recommended a BMI of less than 18.5 as underweight while more than 25 is considered overweight and above 30 is considered obese. Based on WHO (2004)' s guide, three women were in the overweight range with a BMI greater than 25 kg/m².

In terms of their cancer characteristics, five had invasive-ductal carcinoma and one had a rare histology of squamous cell carcinoma of the breast. The size of tumor at diagnosis ranged from 1cm to more than 5 cm, with a mean of 2cm. Half the women (n=3) had a cancer stage-I and the other half had a cancer Stage-2. In terms of grade of cancer cells, half the women were not informed while the other half had a cancer-grade of one and two. Again, half the women were unsure of their hormone receptor status and the other half had an estrogen-receptor-positive cancer. With HER2 status, half were unsure and the other half reported negative HER2 status of their cancer.

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In terms of cancer treatment, only one participant had radiotherapy treatment alone, two had chemotherapy alone, and three others had a combination of chemotherapy and radiotherapy. Most common reported treatment side-effects were nausea, anxiety and/or fatigue. Of the six women, four (77%) had breast conserving lumpectomy and two (33%) had a mastectomy.

Table 5.2

Background of Participant of Focus group (Pilot Study, n=6)

	n1	n2	n3	n4	n5	n6
Demographic Characteristic						
Age	60	50	42	57	48	51
Education Level	College	College	Secondary	Secondary	University	Secondary
Children	2	2	0	2	2	4
BMI (mean=25.2)	29 kg/m ²	22 kg/m ²	31 kg/m ²	27 kg/m ²	20 kg/m ²	22 kg/m ²
Activity level	Light	Active	Light	Light	Active	Active
Cancer Characteristic						
Duration diagnosis	3-6mths	>1 year	<3 mths	<3 mths	1 year	3-6mths
Type of Surgery	Lump.	Mastec.	Mastec.	Lump.	Lump.	Lump.
Stage of cancer	2A	2A	2	0	1	1
Type of cancer	Ductal	Mucinous	Ductal	Squamous	Ductal	Ductal
Size of cancer	2-5cm	2-5cm	>5cm	2-5cm	2-5cm	1-2cm
Grade of cancer	Unsure	Unsure	Unsure	Grade-1	Grade-2	Grade-2
Hormone-status	Unsure	Positive	Positive	Negative	Negative	Negative
Her2-status	Unsure	Negative	Unsure	Negative	Negative	Unsure

Lump = Lumpectomy; Mastec=mastectomy;
 BMI = Basal metabolic rate
 Ductal = Infiltrating ductal carcinoma of the breast
 Squamous = Squamous cell carcinoma of the breast

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5.7.2 Results of the Process Evaluation

A feedback session was conducted at the end of the program to evaluate feasibility, acceptability of the program, and potential barriers to attending the program. The participants gave feedback on the process (per guideline in Appendix B-4). Table 5.3 is the tabulated rating based on a scale of 1-10 where 1 is ‘not so useful/helpful’ and 10 is ‘very useful/ helpful’. Two women diagnosed about one year previously also contributed in one of the earlier focus group (the newly-diagnosed group). The rationale for including them was as an audit check of issues raised in the focus group to ensure coverage.

Table 5.3

Evaluation of Process

	Mean (a)	SD
<u>PROGRAM</u>		
Feasibility	8.67	0.52
Acceptability	9.25	0.61
<u>FORMAT</u>		
Length of program	8.50	0.55
Timing of session	8.17	0.98
Structure	8.67	1.21
Content	9.33	0.82
<u>TOOLS</u>		
Workbook	9.83	0.41
Homework	8.83	0.41
Breast examination book	9.00	0.63
Relaxation Tape/book	9.17	0.98
<u>OTHERS</u>		
Venue	8.33	1.03
Facility	8.50	0.55
Facilitator	9.67	0.52

(a) = Mean count of rating from 1 (useful) -10 (not useful)

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Program and Format: Integration of qualitative methods within pilot trial can help interpret the quantitative result by clarifying process (Bradley et al., 1999). All six women concurred that the 4-week intervention was feasible, acceptable, as well as timely for supporting Malaysian women with breast cancer.

Four out of six (may be more adjusted as they have the diagnosis for about one year) expressed that the format of the session with regular meetings with health professional and women were useful for clarifying things as well as to see “*how others like me are coping*”. They agreed the duration is ‘about-right’, as “*anything more than four weeks will be too challenging for women to maintain attendance*”. One woman commented on the “*rather long session*”, and suggested that light refreshments should be offered or to encourage participants to proactively bring their own snacks.

Tools: In terms of supporting tools for the program, all gave high scores for the tools. All six women reported the workbook to be useful, but disagreed on its presentation. Two women suggested all appendices be inserted within the main section, and another two preferred the present format while two others were contented with either presentation. They suggested that perhaps a clearer index for mapping the content may be the more important factor to consider.

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Three participants expressed they did not complete all the homework due to time factors and limited access to their patient-record or physicians, needed to complete their breast profile (homework from session 1). Despite this, they agreed that SAMA helped them understand their conditions better, and also about what they needed to ask about their conditions. They suggested drawing in the doctors to help them complete their profile of breast cancer as it was difficult to access their doctor without an appointment.

With regards to the breast booklet, five participants expressed that they were unfamiliar with breast self examination procedure and one woman revealed that even though she has been on follow-up for a year, no one taught her how to do it and thus she found the booklet and the practical session on breast self examination helpful. They felt the relaxation guidebook was easy to follow, but they did not have the time to practice the relaxation tape, and one woman offered the idea that it should be an option as people may be familiar with other technique like Qigong or yoga.

Other factors: With the venue and facility, some participants (n=3) complained about the faulty air-conditioning (room facility) which makes it difficult to stay longer within the enclosed room. Some felt that the venue was either too far from their house (n=1), and/or the heavy traffic was an issue for them (n=2).

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The women proposed to have the session during non-peak traffic periods (after 9am) or on weekends, or to work further on the SAMA's existing idea on pairing up people for carpooling via the 2-tier buddy's system.

Perceived Benefit: The participants expressed that the main benefit of SAMA was the peer and health professional support (n=6), which enabled learning from one another and from the facilitator. One woman voiced that the gradual, incremental learning was helpful and non-stressful (this was agreed by the other 5 participant).

They also particularly liked the buddy-system where all six adopted each other as buddies, even though they were assigned a first line buddy at the start of the program and were asked to select another women as their second line buddy.

SAMA as a professional-led program was positively regarded as a fundamental means for *“us to gain from both the participants and the health professionals (facilitators)”*, but what was crucial in their opinion was that *“we have the best of both world and we are not left to untrained survivors”*.

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Potential Barriers: The participants were prompted for feedback on at least one barrier that may limit women's participation in the SAMA program, and these include any which may or may not be encountered by themselves.

The reasons documented were juggling the many medical appointments, limited time (n=6), transportation (2), traffic jam (n=2), poor parking at UMMC (n=4), distance or lives too far (2), home-children demands (n=4), work commitment (n=3), fear of infection (n=3), distress (n=3) and language barrier (n=2).

The rationale of synthesizing these insights on barriers (see Table 5.4) was to proactively strategise to minimize them during the clinical trial. Evidence showed these are common barriers in people who had more than one chronic illness, as revealed in a study involving 10 focus groups (n= 54) (Jerant, Von Friederichs-Fitzwater, & Moore, 2005).

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Table 5.4

Potential barrier to self-management program and solution.

Barriers (number indicate patients)	Possible solutions offered by participants
1. Time Constraints: Juggling with multiple appointments - Medical visits, follow-up (all 6)	Give sufficient notice for participants to be prepared, provide sick-leave or time-off, and staff to change dates if clashes with clinic date.
2. Transportation Issues: unavailability (2), traffic jam (2), poor parking facilities (4), live too far (2)	Carpooling, Non-peak hours, program must not start too early to give enough time for people to come in.
3. Role issues: Home-children demands (4), work demands (3)	Give ample time to arrange home-task, provide time-off slip or medical sick leave. Early preparation.
4. Treatment side-effects: fear of infection (3) emotional distress (3)	Provide counseling and education, and support.
5. Limitation with English language (2)	Program offered in vernacular dialects. Staff conversant in multi-lingual.

5.7.3 Results of the Outcome Evaluation

Based on Table 5.5(descriptive) and the Figure 5.1 and Figure 5.2 (bar charts), the result showed there were no statistically significant differences between pre and post-test at the level of $p < 0.05$ for all primary and secondary endpoints.

Self-management intervention program for Women with breast cancer

Table 5.5

Mean change-scores of primary and secondary endpoints

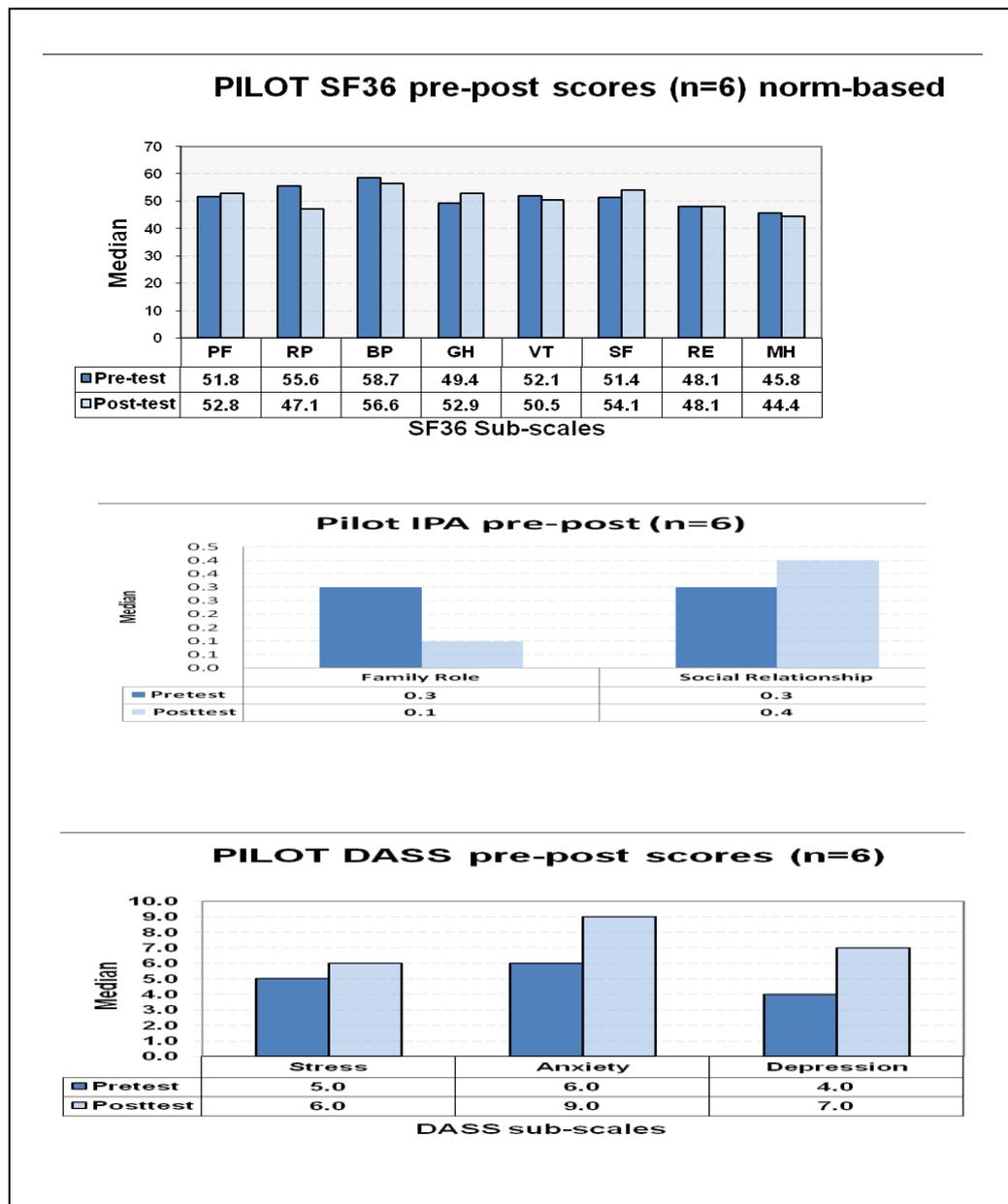
	MEDIAN SCORES (n=6)				Mean Change scores (Norm-based)			
	Pre Test	Min-max	Post Tes	Min-max	Change Score*	SD	Sig. 2-tailed	Effect size Cohen's d
Sf36 Quality of Life								
PF	51.80	(36.0-54.9)	52.80	(40.2-57.0)	2.45	1.58	0.04*	0.35
RP	55.60	(37.3-56.9)	47.10	(42.2-56.9)	-1.22	10.7	0.83	-0.15
BP	58.70	(37.2-62.1)	56.60	(46.1-62.1)	1.62	8.31	0.59	0.18
GH	49.40	(42.5-52.9)	52.90	(42.5-61.5)	3.42	7.94	0.28	0.65
VT	52.10	(39.6-58.3)	50.50	(42.7-70.8)	1.56	9.62	0.83	0.18
SF	51.40	(40.5-56.9)	54.10	(35.0-56.9)	1.82	8.21	1.00	0.23
RE	48.10	(28.7-55.9)	48.10	(40.3-55.9)	3.24	13.80	0.68	0.32
MH	45.80	(33.1-55.6)	44.40	(38.7-52.8)	0.94	8.70	0.68	0.12
Total PCS	52.50	(46.9-60.0)	53.90	(45.3-60.1)	1.18	2.48	NS	0.22
Total MCS	46.90	(33.7-55.0)	47.80	(38.0-54.6)	2.09	4.66	NS	0.28
Depression, Anxiety, Stress (DASS)								
Stress	5.00	(0.0-18.0)	6.00	(0.0-16.0)	0.67	2.42	0.48	0.10
Anxiety	6.00	(2.0-24.0)	9.00	(2.0-12.0)	-0.67	6.02	0.79	-0.10
Depression.	4.00	(0.0-26.0)	7.00	(0.0-20.0)	0.33	3.44	0.71	0.03
Impact on Participation and autonomy (IPA)								
FamilyRole	0.30	(0.0-1.4)	0.10	(0.0-1.4)	-0.14	0.20	0.08*	-0.30
SocialRelationship	0.30	(0.0-0.9)	0.40	(0.0-1.0)	0.10	0.17	0.27	0.25
Strategies used by people to promote health(SUPPH)								
Supph_positiveAttitude	58.00	(40.0-76.0)	69.00	(49.0-80.0)	8.33	14.45	0.21	0.60
Supph-stressReduction	33.00	(24.0-48.0)	37.50	(28.0-50.0)	3.67	12.66	0.35	0.40
Supph-makeDecision	10.50	(7.0-15.0)	11.00	(9.0-15.0)	0.83	2.86	0.58	0.30
SUPPH_SE(selfcare).	112.0	(71.0-128.0)	118.0	(86.0-145.0)	12.83	25.50	0.25	0.60
Cancer Behaviour Inventory (CBI)								
CBI_SE(behaviour).	105.0	(73.0-118.0)	107.0	(81.0-126.0)	4.67	10.86	0.35	0.30
Strategies Used by People to promote Health (SESES)								
Express_Emotion	82.00	(52.0-86.0)	82.00	(60.0-96.0)	5.67	6.12	0.07*	0.40
Enjoy_Presence	72.00	(48.0-96.0)	77.00	(54.0-98.0)	3.33	8.55	0.34	0.20
Confront_death	70.00	(20.0-94.0)	73.00	(56.0-100.0)	13.00	17.65	0.09*	0.50
SESES_SE(emotion).	74.50	(48.0-91.0)	77.00	(57.0-98.0)	7.50	8.78	0.12	0.40
Proactive Coping (PCI)								
Proactive Coping	42.50	(26.0-50.0)	42.50	(29.0-51.0)	1.00	3.35	0.46	0.13

* Wilcoxon Signed Ranks Test, not significant at $p < .05$; * change score= (Posttest Mean) minus (Pretest Mean)
 PCS=Physical composite Score, MCS=Mental composite Score SF36= Short form QOL; IPA=Impact on Limitation in Participation; DASS=Depression, anxiety, stress scale; SUPPH=Self care_Self-efficacy; CBI=Cancer behavior_Self-efficacy; and SESES=Self-efficacy (emotion); PCI=proactive coping

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Figure 5.1

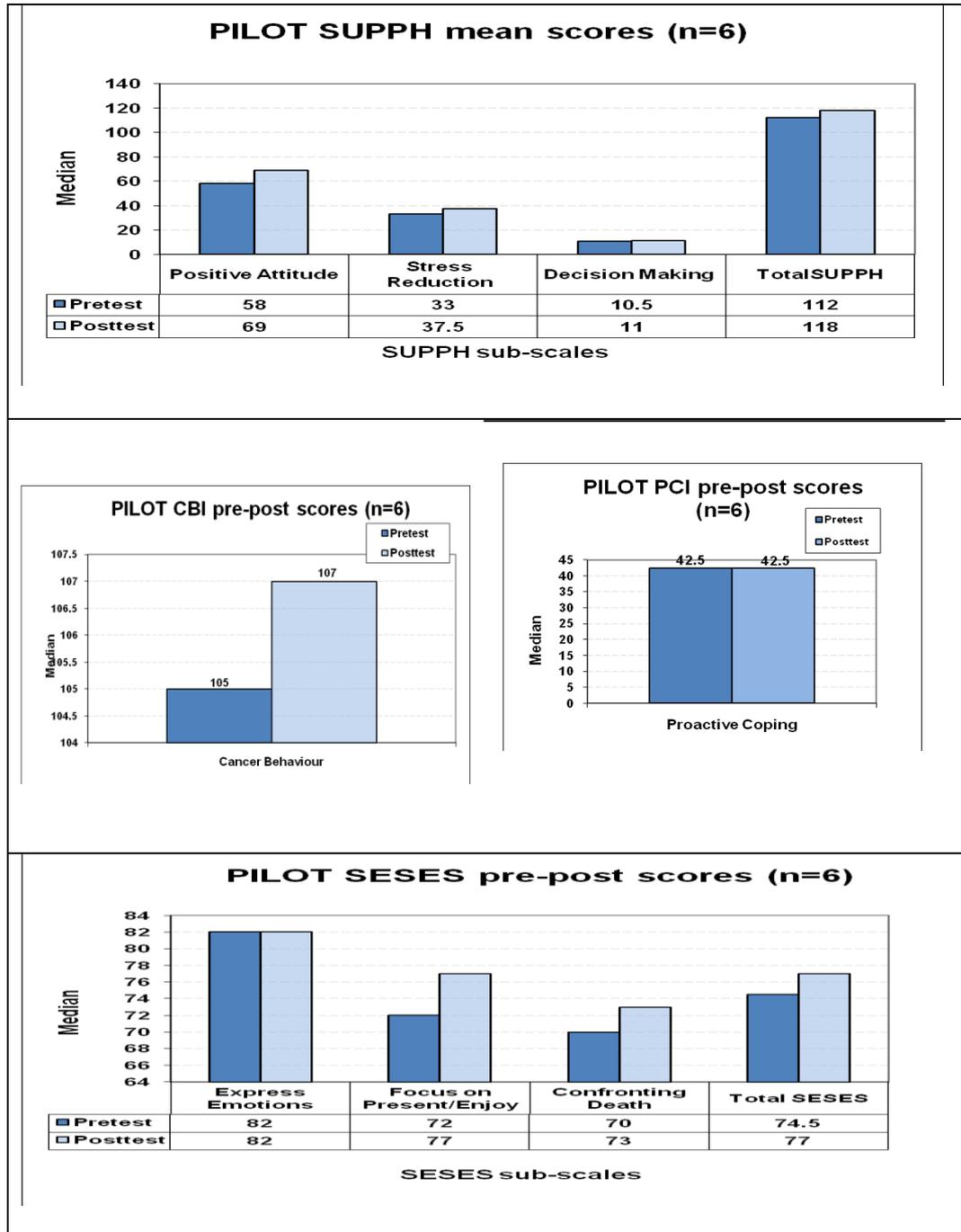
Bar Chart on Primary endpoints (QOL, IPA and DASS)



Self-management intervention program for Women with breast cancer

Figure 5.2

Bar Chart on Secondary endpoints (SUPPH, CBI, SESES, PCI)



5.8 Discussion

5.8.1 Key Findings in the Process and Outcome evaluation

The process-evaluation, based on women' experiences in the intervention, generated ideas for refinement of the program. The women provided a favorable rating for the SAMA program. The outcome evaluation showed a favorable trend as measured on most primary and secondary endpoints, although results were not statistically significant. This was expected since it was a small sample size group (n=6) and the goal was to gain feedback on the process to inform the clinical trial. As there were many subscales used and the results of subscale appeared quite similar to the total scale for measuring each variable, the final CCT will only utilized main scales.

A key difficulty experience by the women is access to their medical records and/or physicians, and as a result, they had difficulty completing the homework on "My breast cancer Profiles". Most women reported that they have not been told of their full cancer profile which they realized was crucial information to aid their treatment decision-making. They were satisfied with "My breast cancer Profile" as a tool to help them gather important information over the 4-week duration.

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These (qualitative) sharing from the women revealed barriers/challenges with time management. Four out of the six women were starting chemotherapy, and had multiple medical-related appointments (and the attendance on the SAMA sessions) to manage compared to pre intervention testing was important. Moffatt, White, Mackintosh, Howell (2006) assert that the value of collecting both types of data (mixed method) within a single study can enhance the overall quality of the evidence base. Thus, the idea of proactive coping and/or planning ahead should be emphasized in the CCT.

In fact, it has been demonstrated that data obtained from in-depth interviews uncovered some impact (psychological-emotional-social) from the perspective of the patient, even though the quantitative QOL tool revealed no statistically significant differences throughout the scores over time (Cox & Mc Garry, 2003).

5.8.2 Implications for better recruitment-strategy

Poor recruitment for cancer clinical trial had been highlighted (Cox & Mc Garry, 2003), and specifically with breast cancer patients (Maslin-Prothero, 2006). Even trials funded by the National Cancer Institute (USA) have difficulty enrolling cancer patients, with underrepresentation of racial and ethnic minorities, adolescents, the elderly, rural populations and those of low socioeconomic status (Ford et al., 2005).

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In this pilot study, there were clearly difficulties with patient recruitment even though the findings suggest positive outcomes and all six participants found the meetings therapeutic. Several insights gained by the researcher from the pilot group can help inform the planning for the CCT. Firstly, barriers and facilitators to recruitment must be addressed early as it is the basis of successful recruitment. As a strategy to recruit via information booklets has been shown to be limited (Ellis, Butow, & Tattersall, 2002), a combined approach of advertising in clinics and media involvement should be planned.

Five out of the six women who attended shared that it was their supportive husband and family who encouraged them to participate. Thus, perhaps, family involvement and their support can be engaged during recruitments since Malaysian women have tight-knit families. This implies that flexible timing or perhaps weekend sessions where husbands or siblings are free to accompany the women should be considered. Thus, the final CCT may have to incorporate both weekday and weekend sessions to enhance patient recruitment.

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Barriers and incentives for new interventions clearly do not just occur at patients' level. GroI and Wensing (GroI & Wensing, 2004) highlighted factors at the organizational level. These include, ensuring program are innovative (beneficial, feasible, and credible to clinical practice); improving the social context (network-collaboration-leadership); improving ma
npower and facilities (e.g. capacities and resources), economic and political context (e.g. policies and financing), as well as, selling the program (i.e.branding).

The multi-factorial and multi-level barriers to the recruitment are summarized below for consideration in improving recruitments for future trial (Table 5.6). Barriers like access to the doctor was highlighted and may possible contributed to the additional stress and anxiety in this pilot, as revealed with the feedback on homework related to their breast cancer profile. The intervention aimed to increase the patients' confidence and skills in approaching the health staff for information, but, perhaps health providers must change as well. As revealed by one patient: *"I know what to ask, and I am confident I don't need a bone scan, but I am afraid to cancel the appointment for my doctor might replied, "am I the doctor or are you the doctor?"*. These communication-attitude factors have to be considered and addressed to enhance the partnership in care. Jerant et al (2005) also presents other barriers like depression, weight problems, difficulty exercising, fatigue, low family support, pain, and financial problems.

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Table 5.6

Solutions for Future Recruitment Strategy

Level	Potential solutions for future recruitment strategy
Personnel	Facilitators – trained interested and available facilitators to ensure consistency. Provide education on strategies and philosophy of self-management. Recruiters – engage key nursing personnel to provide information to the patients, regarding availability of program
Organization	Engage management collaboration – promote awareness of self-management program, so that physicians are aware and able to support. Evidence based research for clinical practice – published and disseminate findings to generate interest and fundings.

5.8.3 Implications for Program Rrefinement

Two strategies for minimizing discovered during the pilot study were, i) immediate checking of the returned questionnaire and follow up with the patients by the tester, and ii) briefing the participants about potential culture-sensitive questionnaire such as ‘denial’ (in CBI), ‘death and dying’ (in SESES) to ensure response. Research indicated that questionnaires that did not ask questions that were overly personal, sensitive, or irrelevant were favored by participants (Pijls-Johannesma, Pijpe, Kempen, Lambin, & Dagnelie, 2005).

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An additional issue arising from the scheduled debriefing sessions (at the end of each session or group), indicated a need for more structured training, as even the experienced therapist was inexperienced in group-work and had some difficulty with emotions expressed by participants. Newman (2004) in proposing for self-management to be widely adopted, suggested training for trainers to include group facilitation, cognitive behavioral training, goal setting and problem-solving. Procedures for training therapists need to be considered and may include: i) reading of the manuals, ii) didactic lectures, iii) co-attendance in program run by key facilitator and also iv) briefing on group-work with self-reflection checklist on facilitator's skills (Appendix B5). The need for therapists with experiential background is complementary since the manual only does not teach skills such as how to listen, empathize, respond appropriately, and handle one's feelings.

With the participants, memory aid like marking down dates on the workbook, putting all items in the same bag each time, as well as taking turns to for telephone reminder are strategies that help in the organization of groups. Wieneke & Dienst, (1995) found that 75% of women at 6 months on completion of adjuvant chemotherapy had moderate impairment in cognitive functioning i.e. inattention, memory and mental flexibility, unrelated to changes in mood states. Therefore, preparation of participant, health professional and resources are important for smooth running of the program.

5.9 Conclusion

The pilot study described the feasibility of a new, innovative program of self-management based theory discussed in Chapter Two. It showed preliminary indications that the intervention for women with breast cancer in primary care settings is feasible and beneficial.

This chapter on the result of the pilot-study set the scene and informed the implementation of CCT which will be reported in chapter 6-8. The final CCT will utilize only the total scale, as finding here suggested having all was quite redundant. Thus, the clinical trial will utilize only four secondary endpoints i.e. all total scales of the three self-efficacy and the proactive coping scales.

In conclusion, the analysis of any type of pilot study should be mainly descriptive and results treated as preliminary and interpreted with caution (Lancaster et al., 2004). The findings from this pilot group provided preliminary evidence that warrants the SAMA program to be further tested in a larger clinical trial. This study documented benefits as well as barriers from patients' perspective and from the practical experience of conducting the pilot, to guide the main clinical controlled trial.

6

CCT *

METHODOLOGY

A Clinical Controlled Trial (CCT) is a prospective study comparing the effects of an intervention against a control (Portney and Watkins, 2000, p330)

*CCT = Clinical Controlled Trial

6.1 Study Design, Setting and Objectives

6.1.1 Study Design

A clinical trial as a prospective study comparing the effects of an intervention against a control (Portney & Watkins, 2000, p. 330) is regarded in the literature as a crucial component in the research, development and evaluation of treatment interventions within health care services (Cox & Mc Garry, 2003). A recent definition of a clinical trial is, “any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes” (WHO, 2008, p. 1).

This study is a time-series clinical controlled trial with the experimental block preceding the the control block. It was non-randomized because it was logistically more challenging to conduct a randomized controlled trial (Harris et al., 2006) which requires more manpower and funding. Also, the decision was taken based on possibility of contamination-by-diffusion, i.e. when the subjects in the control group meet and learnt from those in the experimental group. The meeting was highly likely in this study for three reasons: i) the cancer clinic is confined to a specific location, ii) intervention is not a one session but lasts for four weeks and iii) there were three testing occasions over a period of 8 weeks (baseline, post-test and follow up) which increases the probability of patients coming in contact with each other.

Having the experimental block first also reduced the risk of compensatory-rivalry and resentful-demoralisation from the control group (as there is less opportunity to share experiences by chance). It also prevented compensatory-equalisation by staff, whereby staff help the control group due possibly to guilt feelings (W. Trochim, 2002). A double blind study was also not feasible since the experimental treatment group could not be offered as a placebo as in many rehabilitation/ medical interventions. Therefore, a single-blind study was carried out where only the tester was blinded. The Consolidated Standard of Reporting Trials or CONSORT statement (Altman et al., 2001) was used to improve the methodological quality and documentations of this report. This includes minimum reporting standards like pre-specifying the endpoints, power calculation to ensure enough sample size, detailing the flow chart, use of intention-to-treat and specifying method for replacing missing data and report of effect sizes.

6.1.2 Setting

The study was conducted at the Breast Centre at the University Malaya Medical Center, an academic medical centre located centrally in Kuala Lumpur, Malaysia. It has a specialized breast clinic which is partially funded by the government and it receives referrals from all over the country. It also has a private wing, the University Malaya Specialist Centre, where fee-paying patients can expect a shorter waiting list for medical treatment.

6.1.3 Objectives

In the current study, the main objective was to test the efficacy of the 4-week Staying Abreast Moving Ahead (SAMA) program for any statistical between-group differences (experiment versus control) on the primary and secondary endpoints, using an Intention-to-treat (ITT) design. The secondary objective was to examine for any statistical differences within the group (experiment) over time. The null hypotheses relates to the two main analyses: i) the between group (experimental versus control) ITT analyses and ii) the within (experimental) group repeated-measures analyses. The specific null hypotheses of the phase three's ITT study were delineated in Chapter 8.

6.2 Participants

6.2.1 Sample-size Calculation (A Priori Power Analysis)

Using the SF36 as the main outcome criterion, the sample size was determined using the SF36 Health Survey Manual (Table 7.5, p 7:10) which indicates the sample size needed per group to detect differences between two experimental groups for post-intervention measures. Thus a sample of above 47 participants was needed to detect a 20-point difference using post-intervention measures only (JE. Ware, Snow, Kosinski, & Gandek, 2002).

However the SF36 tables do not offer sample size estimates for MANCOVA as the primary analysis. Also, the more precise way of determining the required sample size by take into account the alpha level, estimated effect size, and power based on previous similar studies in the field was also not possible as there were no data available, thus the estimates using SF36 was used. Thus the sample size required per group was 47 subjects, or a total of 114 subjects for this clinical controlled trial. With an estimated 20% rate of attrition, the final total size required was at least 136 subjects. This estimate allowed a difference of small effect size to be observed on all eight subscales. The estimates were based on Cohen (1988), assumed at an alpha of 0.05, and a power of 80% (JE. Ware et al., 2002).

6.2.2 Inclusion and Exclusion Criteria

The participants were selected based on the following eligibility criteria:

- i) more than 18 years of age
- ii) a diagnosis of Stage 1-III, confirmed by a physician
- iii) preferably has completed surgery and may or may not be undergoing chemotherapy and/or radiotherapy
- iv) may or may not be undergoing Tamoxifen (or other hormonal therapy)
- v) can read and understand English and
- vi) Able to and has given informed-consent. The study was confined to those who were newly diagnosed (within a year from date diagnosed).

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The exclusion criteria were:

- i) marked cognitive impairment or learning disabilities (through observation/ interview)
- ii) the presence of any other form of medical problem interfering with participation and attendance (from self report).

Justification for participants with Stage 1-III breast cancer: By restricting the study to a somewhat homogeneous 'early stage breast cancer' sample, the number of confounding variables was reduced and the results were more easily interpreted. (Stage III cancer were included because of the increasing survival trend even among this stage). The rationale of having women preferably after surgery is because intervention after surgery prepares the person for better tolerance for chemotherapy's dosage and side-effect (Andersen et al., 2004), and possibly results in a lower drop-out rate. Nevertheless, it was expected that there may be a few participants who would be protocol violators, i.e. those who followed the neo-adjuvant regime (operation only after chemotherapy/radiotherapy to shrink the tumor).

6.3 Instruments

6.3.1 *Dependent Variables and Tools*

This study uses two clusters of measures (i.e. the primary and secondary endpoints). The primary endpoints measured quality of life (SF36 composite scores), participation (IPA) and three psychological symptoms of distress (Depression, Anxiety, Stress Scale from the DASS tool). The secondary endpoint measures the three cancer specific self-efficacy scales and a proactive coping scale. Table 6.1 below summarises the outcome measures as described in Chapter 5.

The Patient Information Questionnaire (PIQ) contains a 4-page questionnaire which was used to collect data on the participants' personal details (age, education, income, occupation etc), health profile (exercise, weight, smoking, drinking etc), cancer profile (type, stage, size etc) and cancer treatment profile (type of surgery, chemotherapy, radiotherapy etc). Measures of the broad outcomes as well as the severity of specific symptom clusters were important for determining the efficacy of self-management intervention.

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In summary, the primary endpoint measures consist of three primary endpoints: quality of life (QOL), limitation in participation in role-related tasks (IPA) and the psychological-distress symptoms (DASS). QOL was measured using the two composite score: physical and mental scores (PCS and MCS), IPA was measured using the Family role (FR) and Social Relationship (SR) subscales. Psychological distress symptoms were measured using the Stress, Anxiety and Depression subscales.

The secondary measures were cancer-specific self-efficacy (measured via three specific cancer scales) and coping (measured with a proactive coping scale). All endpoints were taken at three timing which included one pretest and two posttest measures. The pretest (T1) is taken at baseline, whilst the two posttest were immediate post-test (T2) after the program, and another at follow-up (T3) period. The follow up test were 4 weeks from immediate post-test (T2) or 8 weeks from baseline (T1).

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Table 6.1

Summary of Outcome Measures

Measures	Subscale	Variable	Rationale
Patient Information Questionnaire		Personal Health Cancer	Demographic, Health characteristic, Cancer characteristic
<u>Primary Endpoints (outcomes)</u>			
1. Quality of Life SF36v2. Medical Outcomes Trust, Inc. (Ware JE, Kosinski, ,Dewey JE, 2000)	MCS PCS	Mental (MCS) Physical (PCS)	To gauge QOL domains, as per the self-management core area in managing illness and health.
2. Impact on Participation: (Cardol, Haan, van den Bos, de Jong, deGroot, 1999).	Social relations, Family Role	Social relations, Family Role	Family role and social relationship was deemed pertinent areas in role management.
3. Emotional Distress: Depression, anxiety, stress scale (DASS). (Lovibond & Lovibond, 995)	Stress Anxiety Depression	Stress Anxiety Depression	To measure emotional distress in line with emotional management
<u>Secondary outcomes</u>			
1. Specific self-efficacy A self care self-efficacy. Strategy used by people to promote health (SUPPH) (E. Lev & Owen, 1996)	Cancer specific: Selfcare	Self-efficacy	Based on ideas that efficacy beliefs are tasks specific and demands different measures
2.An emotional self-efficacy -Stanford 'emotional' self-efficacy (SESES)- (Giese-Davis et al., 2004)	Cancer behaviour	Self-efficacy	Postulated as an important mechanism for outcomes in behaviours
3.A cancer-behaviour self-efficacy. Cancer Behaviour Inventory (CBI)- (T. V. Merluzzi et al., 2001)	Emotions	Self-efficacy	Related to the idea that emotional distress is the 6 th vital sign in cancer care.
4. Proactive Coping Proactive Coping Inventory (PCI) (Ester Greenglass, 1999)	Coping	Coping	Postulated as enabling coping in self management

6.3.2 Independent Variables (Experimental and Control)

The independent variables were the experimental and the control groups. The covariates were the baseline measures of the primary and secondary endpoints, and the demographic variables found significant at baseline.

The Experimental Group - This is the 4-week SAMA intervention group:

Participants in the experimental group received the SAMA intervention along the usual standard medical care. The SAMA intervention was a 4-week course of about 2-3 hour per week/session.

The Control Group – This is the usual-care group: Participants in this comparative group received only the usual standard medical care, as outlined in the Malaysian's Ministry of Health Clinical practice Guideline. The usual medical care includes surgery, adjuvant therapies and may include targeted therapies. As the use of a no-treatment for the control group may be unacceptable to patients, a waiting list where all control participants would ultimately receive the intervention was offered after the research study ended.

6.4 Intervention: The 4-week SAMA Program

Table 6.2 below summarised the description of the Clinical Controlled Trial (CCT). The 4-week Staying Abreast Moving Ahead (SAMA) program comprised of a series of education-training sessions covering the medical, health, emotional and role management tasks in an educational-group format (see Table 4.5 for an overview of the 4-week SAMA program). Participants were given weekly written homework assignments related to session and skills taught each week. As the 4-week SAMA program was designed as a facilitator-led program, a short training for the co-facilitators (two external staff) was provided.

6.5 Data Collection

6.5.1 Data Collection Tools, Primary and Secondary Variables

In general there were two clusters of measurement tools and a patient information questionnaire (as described in Chapter 5) used to collect data for this study. The primary tools comprised of the SF36, IPA and DASS and were utilized to measure three primary endpoints of quality of life, limitation in participation and emotional distress. The secondary tools were SUPPH, CBI, SESES and PCI which were selected to measure the cancer-specific self-efficacy and proactive coping skills.

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Table 6.2

Summary of the CCT Intervention

TITLE	<i>Self-management intervention on women with breast cancer: impact on QOL, participation and mental distress.</i>
SETTING	The University Malaya Medical Centre, Kuala Lumpur
STUDY DESIGN	Clinical controlled trial -Block design Allocation (experimental block followed by control block)
PARTICIPANTS	Women diagnosed with stage 1-3 breast cancer, within 1-year of diagnosis
SAMPLE SIZE	N=147 [Experimental n =69, control n=78] Of the 3 protocol violators, one is more than 5 years since diagnosis, 2 were unable to complete program.
INTERVENTION	Experimental group: Professional-led, structured 4-week self-management intervention (with usual care). Use of didactic/experiential exercises within group and as home work, based on social cognitive theory and cognitive behavioral principles. Clinician’s role is one of educator and facilitator Control Group: Usual care
VARIABLE	Independent – Intervention Delivery with facilitator’s training Dependent- Primary endpoints (PCS, FR, SR, Stress, Anxiety, depression) Secondary endpoints (3 Self-efficacy and 1 coping).
TOOLS	
- Primary	Primary = Quality of Life, Participation and Emotional Distress
- Secondary	Secondary = Cancer-specific Self-efficacy and Proactive Coping
MEASURES	T1= Pre-test or baseline, T2=Post-intervention, T3=Follow-up
ANALYSIS	Intention-to-treat (ITT) analysis design (Missing data imputed via mean substitution and carry forward methods). Between-group Analyses (n=147): MANCOVA using change-scores to examine effect between groups. Within-group Analyses (n=69): Univariate RM ANOVA using raw scores on experimental group to examine effect over time.

6.5.2 Data Collection Scheme

Three measurements were taken: baseline/pretest (T1), post-intervention/ post-test (T2), and follow-up (T3). Post-intervention measure was taken immediately after the 4-week SAMA program i.e 4 weeks from baseline as intervention is a 4 week program. Follow-up test (T3) was taken at 4 weeks after completion of intervention or about 8th week from baseline. Participants who had been identified from the database for the control arm were contacted by the clinic. Those who agreed to participate came to the breast centre or at the oncology clinics where the aim of the study were explained to them. They were then given the baseline questionnaire package to fill up. The questionnaire package contains the PIQ, primary tools (SF36, DASS, IPA) and secondary tools (self-efficacy and proactive coping).

As this is a block design, the first batch of participants (n=69) was assigned to the experimental group and the next batch (n=78) was assigned to the control group. In the experimental arm, patients who gave their consent were briefed and prepared in advance for the four scheduled sessions and the baseline testing. Working women were also provided with a letter to their employer requesting support for time off during the four sessions (Appendix D-10). Those who were unable to get support from their employer, but were interested to participate in the study were given time-off certificate or medical sick leave certificates by the breast surgeon.

In the control group, patients were identified from the clinics and the breast cancer database, contacted by their surgeons, and those who consented were asked to come in to the breast centre or to the oncology clinic. At those appointments, they were further screened and the aim of the study was explained to those who met the criteria. These women were then given the Patient Information Questionnaire (PIQ) to fill up. For the two post-tests (T2 and T3), questionnaires were given to participants before or on the due dates. One week grace was provided and non-respondents received telephone reminders regarding completion of questionnaires.

6.6 Study Protocol & Fidelity Issues

The Behavior Change Consortium (Bellg et al., 2004) calls for strict adherence to fidelity at five steps (i.e. study design, provider-training, treatment-delivery, treatment receipt, and treatment skills) in behavioral trials planned for measuring health outcomes. However, Leventhal and Friedman (Leventhal & Friedman, 2004) argued that the knowledge of how intervention works is more important and the flexibility that allows assessment of variation in response to intervention across situations, providers and participants is perhaps more crucial.

Other critiques proposed a midpoint stance whereby both, i) the delivery of a theory-driven manualised program as well as, ii) the assessment of the behaviour observed in the practice (by those delivering the program) were expressed as feasible (Hardeman, Mitchie, Prevost, Fanshawe, & Kinmonth, 2005). Therefore, although the insistence of the Behavior Change Consortium has been argued as unrealistic and forcing the delivery of intervention protocol into a rigid manualised treatment, it does provide a useful set of steps that can be used to check fidelity in the SAMA program intervention. The protocol to deliver the intervention was described in the 88-pages SAMA Manual for the Facilitator, but the fidelity protocol will be reported in the following sections.

6.6.1 Facilitator Training:

Training of The SAMA facilitator was provided to the interested health professionals. The potential facilitator was selected from those with experience of group work facilitation and/or has worked in mental health or cancer care. One month before calling for a formal training, both the 88-pages SAMA Manual and 150-pages SAMA Workbook were given to allow ample time for the therapists to understand the SAMA program. A minimum of three structured lectures followed by discussions were provided.

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The content of the training sessions were outlined below:

- An overview on breast cancer in Malaysia, medical regimes and side-effects (provided by a breast surgeon),
- Lectures on self-management philosophy in the context of breast cancer as a chronic illness and the historical development of the SAMA program.
- A briefing on team-work and facilitator's style; and trainees were also given a checklist (Appendix B-5) for self-assessment of their leadership/facilitating style. The Tuckman's leadership style (Table 4.4) was adopted as a guide to explain facilitation styles alongside the process of the group development. Facilitators were also reminded of the principles of adult learning as breast cancer is prevalent among the middle-late adult population.

6.6.2 Protocol on Treatment Delivery

A summary of the protocol on treatment delivery is provided here while the details are delineated in the 80 pages SAMA Manual. Facilitators were assigned to contact the participants in about three days to a week prior to the start of the program so that arrangement could be rescheduled to ensure greater participation.

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A group attendance sheet was provided in the manual with a column for names and telephone contacts so that the facilitator could use this as a checklist and to record if the patients have been reminded of their subsequent attendance. This is important as these women have many other medical appointments. Incorporated within each of the sessions were breast-cancer related topics which included the cognitive-behavioral based exercises designed to enhance self-efficacy in the areas of managing illness, emotion, health and role tasks respectively.

Examples of these carefully planned cognitive and behavioral exercises to manage the effects of breast cancer and its treatment included ; i) monitoring self-defeating self-talk, ii) cognitive restructuring, iii) relaxation training and distracting-imagery training, and iv) behavioral role modelling.

Participants met every week for four consecutive sessions for approximately 2.5 to 3 hours. At the end of each program session, a short debriefing session for the facilitators was scheduled for the purpose of releasing and sharing any emotional residual from the group encounters, as a stress management technique.

6.6.3 Protocol of the Treatment-Receipt and Treatment Skills:

Fidelity for *receipt* and for treatment *skills*, i) implies that the patients must understand and were able to implement the new skills for the intervention to be deemed effective; and ii) requires the patients' actual performance of treatment skills in the intended situations and at the appropriate time (Bellg et al., 2004). It is this practical aspect that is perhaps the most difficult to adhere to especially for interventions that are short term and where funding only allows short term evaluation. In fact, Campbell et al. (2000) postulated that there are many reasons why interventions may be effective in achieving the desired behavior change, but could not translate into the desired clinical outcomes. Equally crucial is the logic that since behavior change interventions were designed to change behavior, the primary outcome should be behavior (Michie & Abraham, 2004). However, as only the observable behavior can be observed (and thus measurable), this leaves out many unobservable behavior. As human behavior is inherently complex, there could have been complex interplays that could made it hard to measure behaviour directly. Nevertheless, two checks on the treatment receipt were conducted for this study. These two fidelity checks were:

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- i) **Knowledge check (Shift in ‘I don’t know’ cases)** - The percentage of “I don’t know’ responses of the cancer profile, were tabulated using the baseline or pretest data (T1) and compared with post-intervention (i.e. at least 4-weeks later at T2 or T3 data from the PIQ tool (Appendix D_1). The result will be presented in Chapter 7.

- ii) **Confidence check (Shift in confidence level of health behavior)** - Using a simple pen-paper evaluation (Appendix D_9), participants self-rated their confidence level of their intentions to adopt health behaviors at before and after intervention. This check was conducted for the experimental arm at the end of the 4-week intervention. This result will also be presented in chapter 7.

The check for strict inclusion criteria for the participants was to ensure that treatment could be received. This included having the ability to understand English and thus the need to also exclude those with cognitive or psychological impairment that might interfere with treatment. Secondly, to ensure that the participants learnt from each session, related group-work and homework were built into the sessions to allow assimilation of new knowledge and skill building mastery. The facilitator checked that all program content were delivered as planned.

6.7 Statistical Analysis Methods

The statistical analyses were performed using the Statistical Package for Social Sciences, version 16 (SPSS, 2007). The demographical and clinical characteristic of the sample were described using descriptive statistics, and where appropriate, the two groups were compared using either Pearson Chi-Square (χ^2) for categorical variables or independent-samples T-tests /ANOVA for continuous variables. The justification and choice of the intent-to-treat MANCOVA and the repeated measure ANOVA tests are discussed here and the results presented in Chapter 8.

6.7.1 Primary intent-to-treat Analyses - MANCOVAs

All data analyses were carried out according to a pre established plan using intention-to-treat (ITT) analysis with missing data imputed. Four multivariate Analyses of Co-variances (MANCOVA) were conducted to examine the significant differences between the groups on the primary and secondary endpoints. The change scores (T2-T1 and T3-T1) were first computed as the units for analysis to provide the best representation of changes over time. This ensures that the variables are independent data, and this is to avoid assumption violation of MANCOVA. The two treatment groups (experimental vs control) were the independent variables. Baseline (outcome measures) scores (T1) were entered as covariates for baseline adjustments.

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The number of covariates used (i.e. 10) was within the acceptable maximum of 13 covariates per analysis for a MANCOVA on 142 subjects and on two groups (Hair, Black, Babin, Anderson, & Tatham, 2006). However, too many dependent variables can lead to Type II error where a significant result may present itself as an insignificant finding (Field, 2005). Thus the analyses for primary and secondary endpoints were run separately. Four MANCOVAs were conducted, first using primary endpoints for the T2-T1 data set and then repeated for the T3-T1 data set (Hypothesis 1). The significant demographic factors were added into the analyses to determine if any factors accounts for the differences in this cohort of sample. The procedures were repeated for secondary analyses (Hypothesis 2).

Justifications for using the MANCOVA (for Intent-to-treat analysis)

This study has several endpoints (or outcomes) based on theory driven choice of outcomes for the three broad self-management areas on medical tasks (measured by QOL), emotional tasks (measured with DASS) and role tasks (measured with IPA). Change scores were used to ensure variables were independent of each other. Thus MANCOVA is a suitable statistical choice for analysis of data (using the change scores) to test the differences in the centroid (vector) of means of the multiple interval dependents while controlling for the baseline (outcomes) covariates.

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In short, the justifications for MANCOVA were:

- i) With multiple dependents, the initial F test of MANCOVA protects against inflated Type I error rates; whereby if the Null hypothesis is true, any subsequent tests would be a Type 1 error (Tabachnick & Fidell, 2007).
- ii) With the covariance analysis, the systematic error from selection error that could result in bias can be eliminated. It also accounts for the ‘differences in the responses due to the unique characteristic of the participants’ (Hair et al., 2006, p. 406). Also, only change scores were used to ensure data were independent according to the assumption for MANCOVA.

Thus MANCOVA has the highest statistical power (Vickers & Douglas, 2001) to detect if groups differ along a combination of dimensions. Nevertheless, as MANCOVA protects only the dependent variables for which group differences exist genuinely (Pallant, 2002), an application of a Bonferroni correction to the subsequent individual ANOVAs will be conducted to ensure ‘just which group means differ significantly from others’ (Field, 2005, p. 250). Conducting multiple ANCOVA tests (over one MANCOVA) was warned against by Field (2005) because of i) the chance of Type I error increases with increasing repetition of ANCOVA tests, ii) ANCOVA only detects group differences along a single dimension.

6.7.2 Secondary Analyses

i) Effectiveness of intervention over time in experimental group

The repeated measure Analysis of Variance (RM ANOVA) was conducted using time as the independent (between group) factor, with only the experimental group (n=69) selected. This was to examine for significant within group changes over time on the primary dependent measures (Hypothesis 3) and on the secondary dependent measures (Hypothesis 4). Ten univariate ANCOVA were conducted - six with each of the primary endpoints and 4 on each of the secondary endpoints. The demographic variables found significant at baseline were added as the covariates or the between-group factor (categorical data) or as the covariates (continuous data) to examine if any of the subjects' characteristic accounts for the differences in the measures over time.

ii) Justifications for using the univariate repeated- measure ANOVA

The major benefit of repeated measure is the ability to control for the potential influence of individual differences (Portney & Watkins, 2000). This gives the confidence that any differences observed among the participants within the experimental group are more likely to reflect treatment effects and not variability between subjects.

In order to avoid violation on the assumption of independence, the special univariate RM ANOVA approach was performed. This requires the spss data to be set up similar to the randomized block design situation, allowing the 'time' factor to be used as the independent variable (IV).

The analysis of variance is robust if each of the distributions are symmetrical or if all the distributions are skewed in the same direction. ANOVA is a robust procedure especially when group sizes are equal (Field, 2005). As the pairs of measurements on the same subjects are quite equally correlated regardless of the time lag between the measurements, this design of the univariate ANOVA is valid from a statistical point of view and in fact, yields an optimal method of analysis (Gill, 1988).

In summary this chapter presents the methodology of the CCT and outlined two statistical analyses based on intent-to-treat analyses which are:

- i) the MANCOVA (between group, n=147), and
- ii) the univariate RM ANOVA (within group, n=69).

The results of the CCT will be reported in chapters 7-9.

7

CCT* RESULT I: DEMOGRAPHIC AND OUTCOME MEASURE PROFILES

The ultimate goal for intervention (for chronic conditions) is maintenance of pleasurable and independent living, not cure (Holman & Lorig, 2000; IOM, 2007).

*CCT = Clinical Controlled Trial

7.1 Overview

This chapter is the first part of the Clinical Controlled Trial (CCT) results. It details the result of the flow of the patients' recruitments, the description of the sample (personal, health, cancer and cancer treatment profiles), the fidelity checks, data cleaning procedures (missing data and extreme values), and the outcome profiles of all endpoints for the raw scores (T1, T2, T3) and for the change scores (T2-T1 and T3-T1).

7.2 Flow of Participants

7.2.1 Flow of Participants –Recruitment, Allocation, and Attrition

The recruitment for the experimental arm of the SAMA Clinical Controlled Trial started in November 2006 and ended in June 2007 while the control arm began in July 2007 and finished in February 2008. A total of 424 women newly diagnosed with breast cancer were recruited for the experimental and control arms.

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From Table 7.1, it can be seen that there were 375 responses to the letter of invitation circulated at the breast clinics and oncology-radiology clinics. An additional 49 women responded to the advertisement which was placed in the local newspaper. From this total, 72 later declined, leaving a total of 352 women.

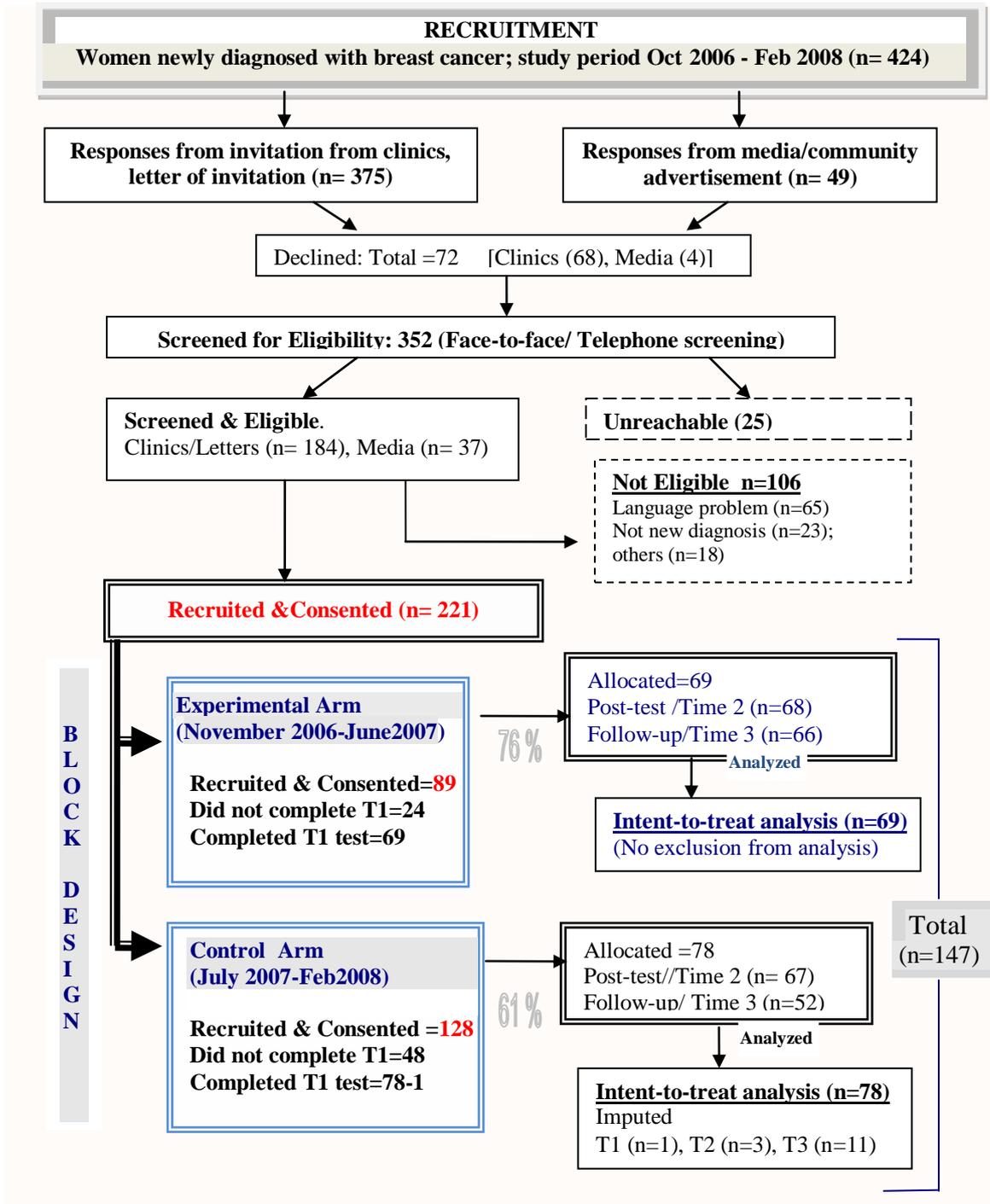
From the pool of 352 women who were screened, 221 were eligible and consented to take part in the study. Upon completion of baseline testing, 69 were allocated to the experimental arm for the SAMA intervention, while 78 were allocated to the control arm.

26 women from the experimental arm and 48 women from the control arm did not complete the baseline testing, and were thus not allocated to the study. The intention-to-treat analyses were conducted on this final total of 147 participants (69 from the experimental group and 78 from the control group).

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Table 7.1

Flow Chart showing the recruitment, allocation and follow-up of Participants



Attrition

Attrition or experimental mortality refers to the drop out of subjects from the experiment while the experiment is in progress. It is a prime concern due to the fact that fewer subjects can weaken statistical power, and often can lead to bias in the remaining data. Overall, there were 69 women on the experimental arm and 78 women on the control arm, giving rise to a total of n=147.

Within the experimental arm, 69 patients completed the baseline (T1) Patient Information Questionnaire (PIQ), 67 returned the post-test (T2) and 66 returned the follow-up (T3) evaluation. Within the control arm, 77 patients completed the baseline evaluation (one questionnaire was lost in the clinic), 67 participants returned post-test (T2) questionnaire while 52 participants returned the follow-up (T3) questionnaire. Thus, the drop outs are generally negligible although there were more drop out in the control group since they had no immediate program.

Overall, the differential loss from baseline to posttest /follow up for experimental group was 0.03 and 0.32 for control group. The percentage of missing data - ranged between 2.6-13 percent for baseline (T1), 11.3 -16.4 percent for post-test (T2), and 20.0-23.8 percent for follow-up (T3) i.e., an overall estimate of 3-24 percent. Imputation was carried out on all missing data.

7.3 Demographics Profiles

Four clusters of demographic data (Personal, Health, Cancer and Cancer treatment) of the study sample (n=147) are reported in the following sections below. The statistical chi-square and ANOVA tests were used where appropriate to examine the significance of the differences. These significant demographic covariates would be added to the MANCOVA models and the univariate RM ANOVA.

7.3.1 *Personal Demographic Profile*

Demographic data was obtained from the Patient Information Questionnaire (PIQ) and tabulated in Table 7.2. A total of 147 women participated in the study. The majority of the participants were Chinese (65%) with a mean age of 50 years (± 9 SD) and within the range of 25-75 years. Table 7.2 showed the four sub groups for age ($p=0.02$). About 78% women were between 40-60 years. Age was later collapsed and recoded into two groups of young (20-49) and old (50-79), and t-test do not show significant differences ($p=0.054$). The mean age for the experimental group was 50 ± 7 (a range between 28-64 years) and for control group, it was 49 ± 10 (a range between 25-75 years).

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More than two-third of the women were married (76%), living with their spouse and children only (68%) or together with their parents combined (the cumulative percentage was 73.5%). About 42 percent married women had one to two children, and about 44 percent women had at least a secondary education. Up to 73 percent had no extra role of looking after their aged parents. Only a negligible 6.8 percent was living alone while the rest were living with someone else. This suggests the traditional Asian practice of living within an extended family system is still highly prevalent, although families today have fewer children. More than half the women had some form of insurance policy (53%) and had a household income of 1000-5000 ringgit per month (55%). Almost half of the sample cohort was working either part-time or full-time (42%).

Comparison of the experimental group and control group showed that the backgrounds of the participants were quite similar in terms of their presentations. There were relatively more young women (20-39 years) in the control group than in the experimental group (17% versus 3%). The experimental group had a higher percentage of ethnic Chinese (78% versus 53%), and had also more women having some form of health insurance coverage (65% versus 42%). Thus, the experimental group had a higher percentage of ethnic Chinese and those with insurance coverage. The independent Chi-square tests (Table 7.2) showed only two personal demographic variables were significant at baseline. These were ethnicity ($p=0.04$) and insurance status ($p= 0.005$).

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Table 7.2

Personal Profile of the Study cohort

Variables	ALL n=147		Experiment n=69		Control n=78		Test p-value χ^2
	n	%	n	%	n	%	
Age Range							
20-39	15	10.2 %	2	2.8 %	13	16.6 %	0.022* (0.054, 2 groups#)
40-49	57	38.8 %	29	42 %	28	35.9 %	
50-59	58	39.5 %	32	46.4 %	26	33.3 %	
60-79	17	11.6 %	6	8.7 %	11	14.1 %	
Ethnicity							
Chinese	95	64.6 %	54	78.3 %	41	52.6 %	0.040*
Indian	21	14.3 %	7	10.1 %	14	17.9 %	
Malay(22) &Others(9)	31	21.1 %	8	11.6 %	13	29.5 %	
Marital Status							
Single	26	17.7 %	9	13 %	17	21.8 %	0.312
Married	111	75.5 %	56	81.2 %	55	70.5 %	
Widowed/Divorced	10	6.8 %	4	5.7 %	6	7.7 %	
Living Companion							
Alone	11	7.5 %	5	7.2 %	6	7.7 %	0.989
Spouse, kids & parent	108	73.5 %	51	73.9 %	57	73.1 %	
Parents & siblings	12	8.2 %	6	8.7 %	6	7.7 %	
Friends/Others	16	10.9 %	7	10.1 %	9	11.3 %	
Additional Roles							
Yes	40	27.2 %	16	23.2 %	24	30.8 %	0.303
No	107	72.8 %	53	76.8 %	54	69.2 %	
No. of Children							
None	33	22.4 %	14	20.3 %	19	24.4 %	0.840
<2 kids	62	42.2 %	30	43.5 %	32	41 %	
> 3kids	52	35.4 %	25	36.2 %	27	34.6 %	
Education Level							
Nil -Primary	7	4.8 %	2	2.9 %	5	6.4 %	0.999
Secondary	65	44.2 %	30	43.5 %	35	44.9 %	
College	39	26.5 %	21	30.4 %	18	23.1 %	
University	36	24.5 %	16	23.2 %	20	25.6 %	
Insurance							
Yes	78	53.1 %	45	65.2 %	33	42.3 %	0.005*
No	69	46.9 %	24	34.8 %	45	57.7 %	
Occupation							
Full time/part time	62	42.2 %	35	50.7 %	27	34.6 %	0.161
Unemployed/retired	29	19.7 %	12	17.4 %	17	21.8 %	
On MC	23	15.6 %	7	10.1 %	16	20.5 %	
Full time homemaker	33	22.4 %	15	21.7 %	18	23.1 %	
Income							
0-1000	25	17 %	9	13 %	16	20.5 %	0.501
1001-3000	49	33.3 %	22	31.9 %	27	34.6 %	
3001-5000	33	22.4 %	16	23.2 %	17	21.8 %	
>5000	40	27.2 %	22	31.9 %	18	23.1 %	

between young (20-49) and old (50-79)

7.3.2 Health Profile

The baseline health profile for the 147 women was tabulated in Table 7.3. Overall, at baseline, the weight and height of the groups were not significantly different (t-test, $p>0.05$). Participants from both groups reported that they did not smoke (95%) and did not drink (91%). Majority reported adopting up to five hours of exercise per week (80%) and took some form of food supplements (60%).

About 50 percent women had normal body weight (between 18.5 to 24.9 kg/m²), with a mean BMI of 23.6 ± 4.8 . The BMI ranged between 14.2 to 37.4 kg/m² in the overall group. Body Mass Index (BMI), was calculated using weight/height measurements (kg/m²). A trend towards significance was observed in the between group analysis for the BMI status of $22.8 + 4.2$ kg/m² - with a range between 14.6 to 33.5 kg/m² (in the experimental group) and 24.3 ± 5.2 kg/m² range between 14.2 to 37.4 kg/m²; $p=0.052$).

Overall, between the groups, two health variables were significantly different; exercise hours ($p=0.02$), and self reported activity level ($p=0.036$). The control group has more women who reported being of the sedentary type. Taking some form of health supplement although significant ($p=0.01$), had a minimum expected count of 0.4 only and was thus not included in the subsequent analyses.

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Table 7.3

Health Profile of the study cohort

	ALL (n=147)		EXPERIMENT (n=69)		CONTROL (n=77)		Sig *
	Mean+SD	Range	Mean±SD	Range	Mean ± SD	Range	
Height (feet inch)	5.14+0.4	4.10-5.80	5.2 ± 0.3	4.1-5.8	5.1 ± 0.4	4.1-5.7	
Weight (pound)	130±28	75-208	127 + 26	80-208	133 ± 29	75-207	
	ALL		EXPERIMENT		CONTROL		Sig *
	N	%	n	%	n	%	p value
<u>Smoke</u>							
Yes	0	0.0	0	0.0	0	0.0	} Fisher's 0.57
No	139	94.6	65	94.2	74	94.9	
Used to but stopped	8	5.4	4	5.8	4	5.1	
<u>Drink</u>							
Yes	6	4.1	2	2.9	4	5.1	} χ^2 0.541
No	133	90.5	62	89.9	71	91	
Used to but stopped	8	5.4	5	7.2	3	3.8	
<u>Exercise (hour/week)</u>							
0-5	129	87.8	55	79.7	74	94.9	} χ^2 0.005* MEC=4.7
6-10	18	12.2	14	20.3	4	5.1	
<u>Supplement</u>							
Yes	94	63.9	46	66.7	48	61.5	} χ^2 0.01* MEC 0.4
No	53	36.1	23	33.3	30	38.5	
<u>Activity Level</u>							
Sedentary	42	28.6	14	20.3	28	35.9	} χ^2 0.026* MEC=8.9
Light	50	34.0	16	23.2	34	43.6	
Moderate	35	23.8	23	33.3	12	15.4	
Active	20	13.6	16	23.2	4	5.1	
<u>BMI (kg/m²)</u>							
Underweight(<18.5)	18	12.2	12	17.4	6	7.7	} 0.052 MEC=1.9
Normal (18.5-24.9)	80	54.4	34	49.3	46	59.0	
Overweight(25-29.9)	33	22.4	19	27.5	14	17.9	
Obese Class1(30-39.9)	12	8.2	4	5.8	8	10.3	
Obese Class2 (>40)	4	2.7	0	0.0	4	5.1	

χ^2 = Chi-Square test of Independence. Fisher= Fisher's Exact test. Significant at $p \leq 0.05$
MEC = Minimum Expected Count

7.3.3 Cancer Profile

Table 7.4 presents the baseline data on the Cancer Profile of the participants (n=147) at baseline. The data was based on self report using the PIQ tool. Those who did not know their data were aggregated while those who knew were reported accordingly. Overall, two thirds of the women diagnosed with a stage 1-2A breast cancer (62.6%). About 30 percent had the non life-threatening ductal carcinoma in-situ (or ductal intra epithelial neoplasia) and 29% with a Bloom Richardson score of Grade 2-3 cancer. Almost 40 percent had a tumor size of 2-5cm. Most women (64%) reported having estrogen/progesterone hormonal positive cancer. Most women did not know the grade of their breast cancer tumour (64%), type (68%), or its HER2 (herceptin) status (83%).

Between the two groups, only the size of tumour was significantly different (p=0.017). About 26 percent in control group and 10 percent in experimental group were ignorant of the sizes of their tumor. At baseline, the percentages of women who were unaware of their cancer profiles were quite similar between the experimental and control groups [(HER_2 status: 84 versus 82 percent), (Grade: 62 versus 65 percent), (Type: 67 versus 69 percent), (Hormonal Receptor Status: 57 versus 54 percent)].

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Table 7.4

Baseline **Cancer Profile** of the study cohort

	All (n=147)		Experimental (n=69)		Control (n=78)		χ^2 p-value
	At baseline N	%	At baseline (T1) N	%	At baseline (T1) N	%	
Stage (TNM)							
1	42	28.6%	25	36.2 %	17	21.8 %	0.108
2A	50	34.0%	20	29.0 %	30	38.5 %	
2B	14	9.5%	8	11.6 %	6	7.7 %	
3A	18	12.3%	8	11.6 %	10	12.8 %	
3B	4	2.7%	1	1.4 %	3	3.8 %	
(?)	19	12.9%	7	10.1 %	12	15.4 %	
Type							
DCIS	1	0.7%	1	1.4 %	0	0 %	0.651
IDC	43	29.3%	20	29.0%	23	29.5 %	
ILC	3	2.0%	2	2.9 %	1	1.3 %	
(?)	100	68.0%	46	66.7 %	54	69.2 %	
Size							
0-2cm	44	29.9%	28	40.5 %	16	20.5 %	0.011* MEC =4.22
>2-5cm	58	39.5%	28	40.6 %	30	38.5 %	
>5cm	18	12.2%	6	8.7 %	12	15.4 %	
(?)	27	18.4%	7	10.1 %	20	25.6 %	
Grade (BR score)							
Grade 1	11	7.5%	6	8.7 %	5	6.4 %	0.943
Grade 2	18	12.2%	9	13 %	9	11.5 %	
Grade 3	24	16.3%	11	15.9 %	13	16.7 %	
(?)	94	64.0%	43	62.3 %	51	65.4 %	
Receptor							
ER / PR positive	47	32.0%	20	29 %	27	34.6 %	0.720
ER / PR negative	19	12.9%	10	14.5 %	9	11.5 %	
(?)	81	55.1%	39	56.5 %	42	53.8 %	
HER2							
HER2 positive	12	8.2%	5	7.2 %	7	9 %	0.925
HER2 negative	13	8.8%	6	8.7 %	7	9 %	
(?)	122	83.0%	58	84.1 %	64	82.1 %	

(?) = 'I did not know....'. ER(estrogen), PR(progesterone); HER2 (human epidermal growth factor receptor 2). BR=Bloom-Richardson's score for grading cancer cell

χ^2 = Chi-Square test. * Significant at $p \leq 0.05$ MEC = Minimum Expected Count

7.3.4 *Cancer Treatment Profile*

Table 7.5 shows the cancer treatment profile of the study sample. Most women were within 3-6 months post diagnosis (41%), had mastectomy (48%), had removal of lymph nodes (88%) and had at least 1-5 lymph nodes tested positive (51%). In terms of adjuvant therapy, half were undergoing chemotherapy (53%). 22 percent had up to 20 sessions of radiotherapy, and 27 percent were on hormonal therapy (Tamoxifen) during the trial. Tamoxifen is the usual therapy offered for endocrine-responsive disease (with more now on aromatase inhibitors).

Between the two groups, there were significant differences found for the subgroups on: types of 'present treatment' ($p=0.001$), chemotherapy drugs ($p=0.001$), hormonal therapy ($p=0.001$) and herceptine therapy ($p=0.0003$). The experimental group had significantly more women on radiotherapy (16 versus 4 percent), less on chemotherapy (41 versus 64 percent), more on Taxane - an aggressive and expensive drug (10 versus 0 percent), and less on the standard FEC drug (30 versus 49 percent). Taxane is a more aggressive chemotherapy but has greater benefits although with greater toxic effect (Levine & Whelan, 2006). Four women from the experimental group, versus two from the control group were on the costly Herceptin (Trastuzumab) monoclonal antibody, which is a form of targeted therapy (Slamon et al., 2001).

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Table 7.5

Cancer **Treatment Profile** of the study cohort

	All (n=147)		Exp (n=69)		Ctrl (n=78)		X ² p-value
	N	%	N	%	N	%	
<u>Duration Since Diagnosis</u>							
<3 months	51	34.7 %	22	31.9 %	29	37.2 %	} 0.105
3-6 months	60	40.8 %	24	34.8 %	36	46.2 %	
½ year-1 year	36	24.5 %	23	33.3 %	13	16.7 %	
<u>Type of Surgery</u>							
Lumpectomy	48	32.7 %	26	37.7 %	22	28.2 %	} 0.206
Mastectomy	70	47.6 %	33	47.8 %	37	47.5 %	
Breast Reconstruction	3	2.0 %	1	1.4 %	2	2.6 %	
Nil (Neoadjuvant)	4	2.7 %	3	4.3 %	1	1.3 %	
(?)	22	15 %	6	8.7 %	16	20.5 %	
<u>Lymph Nodes Removed</u>							
Yes	129	87.8 %	63	91.3 %	66	84.6 %	} 0.203
No	11	7.5 %	5	7.2 %	6	7.7 %	
(?)	7	4.8 %	1	1.4 %	6	7.7 %	
<u>Lymph NodesTest=Positive</u>							
< 10	90	61.2 %	49	71.1 %	41	52.6 %	} 0.01 **
>10	9	6.1 %	7	10.1 %	2	2.6 %	
(?)	48	32.6 %	13	18.8 %	35	44.9 %	
<u>Treatment Presently On</u>							
Radiation	20	13.6 %	16	23.2 %	4	5.1 %	} 0.001* MEC=1.88
Chemotherapy	78	53.1 %	28	40.6 %	50	64.1 %	
Hormonal	28	19.0 %	17	24.6 %	11	14.1 %	
Others/ Not applicable	17	11.6 %	8	11.6 %	9	11.5 %	
(?)	4	2.7 %	0	0%	4	5.1 %	
<u>Chemotherapy Drug</u>							
FEC/FAC	59	40.1 %	21	30.4 %	38	48.7 %	} 0.001* MEC=0.47
Taxol/Taxane	7	4.8 %	7	10.1 %	0	0 %	
FEC/FAC & Taxane	3	2.0 %	-	-	3	3.8 %	
AC & Taxane/Taxol	3	2.0 %	-	-	3	3.8 %	
(?)	44	29.9 %	18	26.1 %	26	33.3%	
Not applicable	31	21.1 %	23	33.3 %	8	10.3 %	
<u>Radiotherapy Session</u>							
<20	32	21.8 %	18	26.1 %	17	21.8 %	} 0.001* MEC=15.5
>20	33	22.4 %	20	29.1 %	13	16.7 %	
(?)	36	24.5 %	3	4.3 %	33	42.3 %	
Not applicable	43	29.3 %	28	40.6 %	15	19.2 %	
<u>Hormone Therapy</u>							
Tamoxifen	39	26.5 %	19	27.5 %	20	25.6 %	} 0.001* MEC=0.94
Femara/ Arimidex	5	1.6 %	3	4.3 %	2	2.6 %	
(?)	46	31.3 %	2	2.9 %	44	56.4 %	
Not applicable	57	38.8 %	45	65.2 %	12	15.4 %	
<u>Targeted Therapy/Herceptin</u>							
Yes	6	4.1 %	4	5.8 %	2	2.6 %	} 0.003* MEC=2.82
No	34	23.1 %	24	34.8 %	10	12.8 %	
(?)	107	72.8 %	41	59.4 %	66	84.6 %	

(?)= 'I did not know'. Herceptin= a humanized monoclonal antibody therapy against HER2 protein
X² = Chi-Square test. * Significant at p ≤ 0.05 MEC = Minimum Expected Count

7.4 Fidelity Report: Knowledge Check and Confidence check

The results of the fidelity protocol to ensure treatment receipts are reported here under two sections: Knowledge check and Confidence Check. Table 7.6 presents the results of the tabulated cases of participants who reported “I don’t know” (about the stage, type, size, herceptin status of their breast cancer) on their PIQ questionnaire. The percentage of ‘don’t know’ at baseline (T1) was compared with the percentage, at a period of at least 4 weeks later (i.e. at T2 or T3). It is anticipated that most women should know their cancer profile by the follow up period (T3) if not by the post-test (T2) period. Figure 7.1 shows the result of the knowledge check whilst Figure 7.2 shows the result of the confidence level check.

7.4.1 Knowledge Check - Shift in ‘I don’t know’ cases

The results showed moderate-to-large reduction of the number of - ‘*I don’t know*’ cases from the experimental group compared to the control group. Overall, changes in the knowledge level in the experimental arm were greater than in the control group. There were less people in the experimental arm than the control arm, who were still unaware of their breast profile, such as the stage of cancer (0 versus 5%), the type of cancer (20 versus 67%), the size of tumor (3 versus 12%), the grade of cancer (26 versus 54%), the hormonal receptor status of cancer (17 versus 46%) and Herceptin (HER2) the status of cancer (41 versus 74%).

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Table 7.6

Fidelity I: Knowledge of Cancer Profile at Baseline versus Pos-tests

	BASELINE (T1)				χ^2 P value	AT 4-week later (T2/T3)				χ^2 p value
	EXP		CTRL			EXP		CTRL		
	n	%	n	%		n	%	n	%	
Stage										
1	25	36.2	17	21.8	0.108	22	31.9	19	24.4	0.075
2A	20	29.0	30	38.5		21	30.4	32	41.0	
2B	8	11.6	6	7.7		13	18.8	7	9.0	
3A	8	11.6	10	12.8		11	15.9	11	14.1	
3B	1	1.4	3	3.8		2	2.9	5	6.4	
(??)	7	10.1	12	15.4	0	0	4	5.1		
Type										
DCIS	1	1.4	0	0	0.651	3	4.3	0	0	0.001
IDC	20	29.0	23	29.5		49	71.0	23	29.5	
ILC	2	2.9	1	1.3		3	4.3	2	2.6	
Others	0	0	0	0		0	0	1	1.3	
(??)	46	66.7	54	69.2		14	20.3	52	66.7	
Size										
0-1cm	7	10.1	2	2.6	0.017	6	8.7	3	3.8	0.083
1-2cm	21	30.4	14	17.9		22	31.9	20	25.6	
2-5cm	28	40.6	30	38.5		33	47.8	32	41.0	
>5cm	6	8.7	12	15.4		6	8.7	14	18.0	
(??)	7	10.1	20	25.6		2	2.9	9	11.5	
Grade										
Grade 1	6	8.7	5	6.4	0.943	12	17.4	5	6.4	0.002
Grade 2	9	13.0	9	11.5		14	20.3	17	21.8	
Grade 3	11	15.9	13	16.7		25	36.2	14	18.0	
(??)	43	62.3	51	65.4		18	26.1	42	53.8	
Receptor										
ER / PR +	20	29.0		34.6	0.720	35	50.7	31	39.7	0.000
ER / PR -	10	14.5	27	11.5		22	31.9	11	14.1	
(??)	39	56.5	9	53.8		12	17.4	36	46.2	
			42							
Her2										
Her2 +	5	7.2	7	9.0	0.925	20	29.0	10	12.8	0.000
Her2 -	6	8.7	7	9.0		21	30.4	10	12.8	
(??)	58	84.1	64	82.1		28	40.6	58	74.4	

+ = positive, - =negative, (??)= I did not know

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In terms of changes in the level of knowledge of their profile of their breast cancer condition - Table 7.7 is a descriptive statistic using frequency count. The numbers (counts) of ‘I don’t know’ at pretest are compared to the counts at post test. These frequency counts were translated as percentages and they range between 52 - 100 percent improvements in the experimental arm while only 3.7 – 67 percent improvement was found in the control arm. These reductions of ‘I don’t know’ cases are depicted in the graphs (Figure 7.1). The right graph shows a much greater shift in reduction of ‘I don’t know’ cases with the experimental group and this is a clear indication of treatment receipt.

Table 7.7

Fidelity II: Knowledge Check –Shift in the ‘I do not know’ cases

“I Don’t Know my.....”	EXPERIMENTAL ARM (N=69)					CONTROL ARM (N=78)				
	T1		T2		% change T1 to T2	T1		T2		% change T1 to T2
	n	%	n	%		n	%	n	%	
Stage	7	10.1	0	0.0	100 %	12	15.4	4	5.1	66.7 %
Type	46	66.7	14	20.3	69.6 %	54	69.2	52	66.7	3.7 %
Size	7	10.1	2	2.9	71.4 %	20	25.6	9	11.5	55 %
Grade	43	62.3	18	26.1	58.1 %	51	65.4	42	53.8	17.6%
Receptor	39	56.5	12	17.4	69.2 %	42	53.8	36	46.2	14.3 %
Her2 Status	58	84.1	28	40.6	51.7 %	64	82.1	58	74.4	9.4 %

Receptor= hormonal receptor, Her2 status=Herceptin status

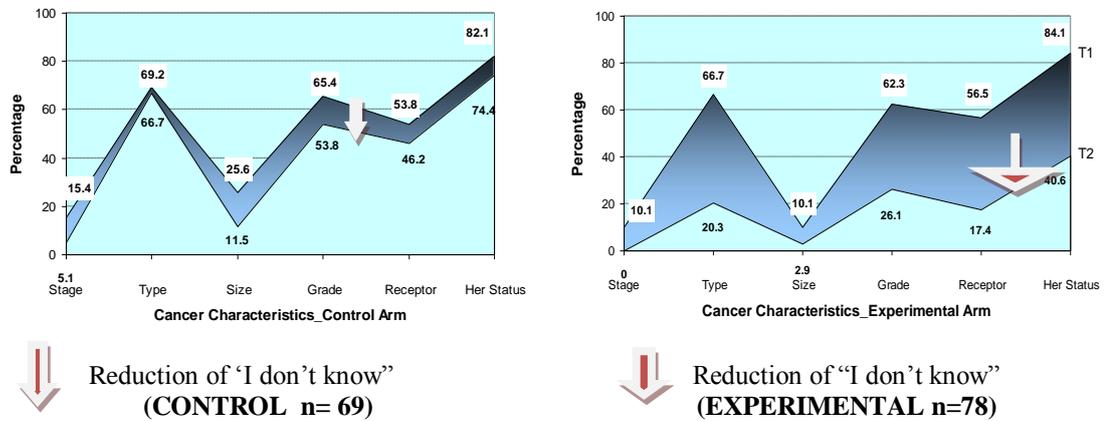
T1 = pretest or baseline

T2 = post intervention

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Figure 7.1

Fidelity I - Knowledge (Reduction in the 'I don't know*').



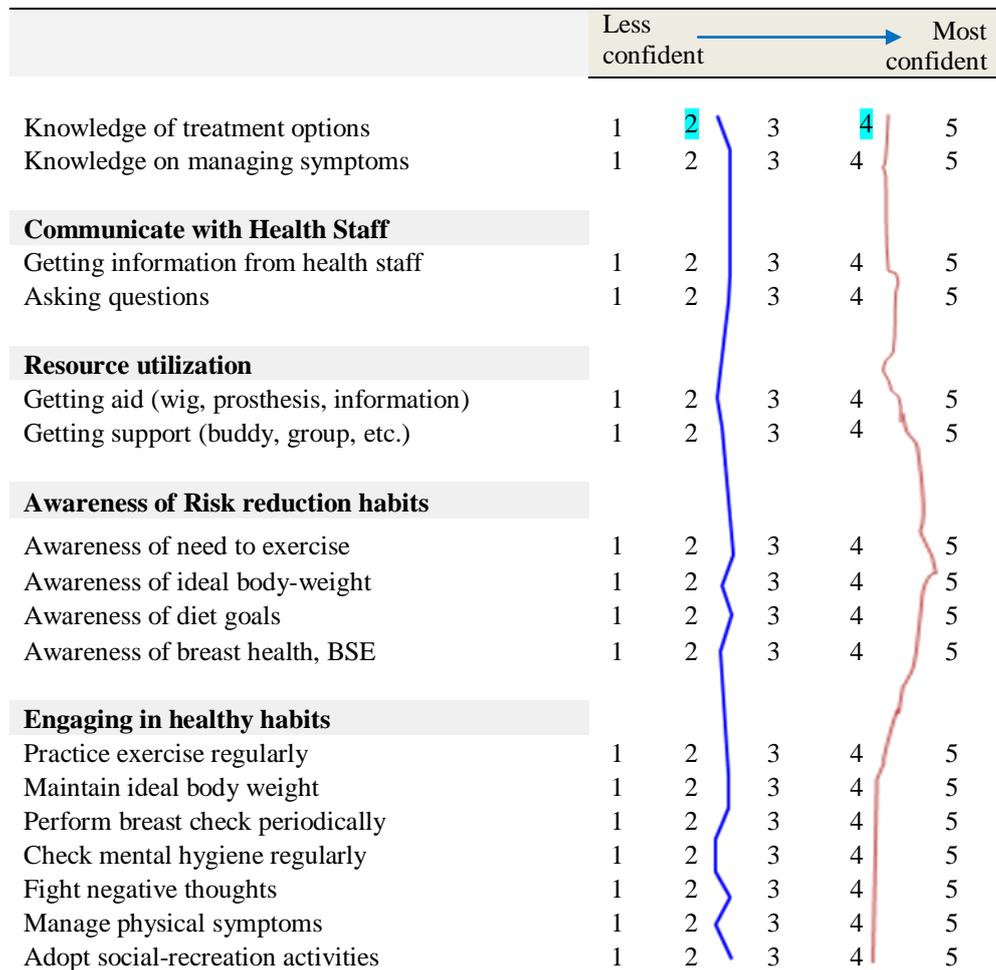
I don't know* about their cancer profile (e.g. grade, size, stage,...).

7.4.2 Confidence Check: Shift in confidence level of health behavior

Figure 7.2 depicts the changes in the perceived confidence on health behavior based on the one-page self report Evaluation (Appendix D-9) which was attached to the last page of the PIQ. This fidelity check was conducted at the end of the 4 week SAMA intervention for the experimental group (n=69). The line graph connects all the mean scores on the various items. The line on the left shows the pretest scores whilst the right shows the posttest scores, thus depicting a clear positive shift in the perceived level of confidence before and after the SAMA program. This report can also served as a triangulation method for verification of the improvement of the intervention since it matched the improved changes measured in the self-efficacy tools.

Figure 7.2

Fidelity II- Confidence (Increase Confidence in Health Behavior)



— Pre Sama (mean = 2.5 ± 0.12) — Post SAMA (mean scores = 4.5 ± 0.08)

Significant at p<0.05 using t-test

BSE = breast self examination.

(Poster P152 presented at 9th International PsychoOncology UK,17thSept 2007)

7.5 Result of Data Cleaning and Checking (Missing and Extreme values)

7.5.1 Missing Data

In line with ITT (Intention-to-treat) analyses, all missing data and missing patterns on the total 147 participants for the clinical trial were studied. Missing data were then calculated via the SPSS missing data analyzer. Appendix J-1 shows the results from the SPSS Missing Data Analyser for both the primary and secondary endpoints, before imputation.

Of all the outcome endpoints, the DASS tools presented the most missing data at post-test (T2) and at Follow-up (T3) as shown in Appendix J-2 (i-ii). It also had the most outliers detected with box plots. The most common reason for missing values was found with T3 in the control arm when participants stopped recording for various reasons.

All other endpoints with less than 20 percent missing data would not be an issue with MANOVA. In accordance with the Intent-to-treat analysis, all data were imputed using two methods of imputation strategies (mean substitution and last value carried forward).

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Tabachnick & Fidell, (Tabachnick & Fidell, 2007) argued that the pattern of missing data is more crucial than the amount missing. They advised that up to 5 percent of missing-at-random data is ignorable, but as this study uses intent-to-treat, all data had been imputed. This study had up to 25 percent missing data and all data were imputed. Data missing-not-at-random (MNAR) are non-ignorable. Table 7.8 below presents the possible reasons for the observed non-random pattern (MNAR). However, this is not a major issue since the affected item/s across tools was minimal.

Table 7.8

The Pattern of Missing data

TOOL	Item missing not-at-random, or rated as not applicable	Possible reasons
IPA	Question on intimate relationship from the social-life scale (Q6);	Many expressed the question was too personal, and left it empty.
SUPPH	Question on ‘choosing among treatment alternative recommended by my physician the one that seem right to me’ (Q11)	Many felt that doctors did not provide the alternatives, or that decisions were made for them by doctors.
SSECS	Question on ‘Talk to doctor about fear I have about dying’ (Q9)	They expressed that doctors did not have time to talk about such issues
CBI	Question on ‘using denial’(Q5)	Many felt the term was confusing and has a negative connotation to it.
PCI	I am a take charge person (Q1) When I apply for a position, I imagine myself filling it (Q10).	Many did not understand the concept of ‘take charge’.

IPA= Inventory on participation, SUPPH= selfcare self-efficacy, SESES=emotion_ self-efficacy
CBI= cancer behavior_ self-efficacy, PCI= proactive coping

7.5.2 *Extreme values:*

In descriptive statistics, the interquartile range (IQR), is a dispersion statistic defined as $IQR=Q3-Q1$ (Larson, 2006). It is robust and is not affected by the presence of extreme observations, unlike variance and standard deviation which are affected (i.e. increased).

As shown in Table 7.8, the last two columns present the number of extremes (low and high), based on the number of cases outside the range. Larson explained *mild outliers as* $x < Q1 - 1.5 * IQR$ or $x > Q3 + 1.5 * IQR$, and extreme outliers if $x < Q1 - 3 * IQR$ or $x > Q3 + 3 * IQR$ (Larson, 2006).

Based on this, DASS has the most cases of outliers, especially stress at baseline (T1) and anxiety at post-test (T2). As the analysis is intent-to-treat, the outliers were transformed to the next lower or higher non-outliers as an attempt to assume normality. Therefore, no outliers were removed from the analyses.

7.6 Outcome Profiles [Baseline (T1), Post-test (T2) and Follow-up (T3)]

These sections present a summary of the descriptive statistics at the three time points for the primary and follow by the secondary endpoints. The descriptive statistics for the primary endpoints are reported in Table 7.9, while for the secondary endpoints it is presented in Table 7.10. In this study, ‘endpoints’ refer to the outcome measures and the term is used according to the CONSORT statement (Altman et al., 2001).

7.6.1 Outcome Profiles at T1,T2,T3 (Primary endpoints)

The primary endpoints are outcome measures from the SF36 (i.e. the Physical composite score and the Mental Composite scores), the IPA (i.e. Family role and Social relationship), and the DASS (i.e. stress, anxiety and depression). Descriptive statistic on the mean scores were adjusted with the outliers transformed to the nearest highest or lowest scores (Table 7.8 and Table 7.9). The results are illustrated in the profile plots in Figure 7.3. Overall, the descriptive statistic showed a favorable increase over time [from baseline (T1) to Post-test (T2), to Follow-up (T3)] in the primary endpoints for the experimental group. In the control group - there were favorable increases in Limitation in Participation (in Social Relationship tasks). On the DASS scale, there were favorable decreases in mean scores over time in the experimental group, but in the control group - there were generally a trend of increased mean scores at T2, which then gradually reduced at T3.

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Table 7.9

Outcome Profile at T1,T2,and T3 (Primary endpoints)

	Time	EXPERIMENT n=69			CONTROL n=78			ANOVA ^A
		Mean	SE	95% CI	Mean	SE	95% CI	
PCS	T1	43.02	0.78	(41.46, 44.58)	44.09	0.88	(42.35, 45.84)	0.37
	T2	45.37	0.70	(43.98, 46.76)	43.97	0.84	(42.30, 45.64)	0.21
	T3	46.54	0.90	(44.75, 48.33)	44.51	0.85	(42.81, 46.20)	0.10
MCS	T1	44.30	1.09	(42.1, 44.30)	43.31	1.19	(40.9, 45.70)	0.56
	T2	47.70	1.01	(45.7, 47.70)	43.83	1.16	(41.5, 46.10)	0.05*
	T3	50.36	0.98	(48.4, 50.40)	44.45	1.25	(41.9, 46.90)	0.09*
FR	T1	0.97	0.08	(0.81, 1.13)	1.04	0.08	(0.88, 1.19)	0.55
	T2	0.80	0.07	(0.66, 0.95)	1.02	0.08	(0.85, 1.19)	0.18
	T3	0.71	0.07	(0.56, 0.85)	0.88	0.08	(0.70, 0.91)	0.00*
SR	T1	0.86	0.07	(0.71, 1.01)	0.80	0.06	(0.69, 0.92)	0.08
	T2	0.73	0.07	(0.60, 0.86)	0.86	0.07	(0.72, 1.00)	0.02*
	T3	0.65	0.07	(0.50, 0.79)	0.91	0.07	(0.77, 1.04)	0.03*
Stres	T1	12.67	0.99	(10.69, 14.64)	10.31	0.91	(8.49, 12.12)	0.38
	T2	9.88	0.87	(8.15, 11.62)	11.92	1.11	(9.71, 14.14)	0.00*
	T3	8.32	0.84	(6.64, 10.00)	11.33	1.12	(9.10, 13.56)	0.00*
Anx	T1	9.13	0.91	(7.31, 10.95)	7.92	0.73	(6.46, 9.38)	0.26
	T2	7.13	0.77	(5.59, 8.67)	9.05	0.90	(7.26, 10.84)	0.03*
	T3	6.29	0.71	(4.86, 7.72)	8.97	0.89	(7.21, 10.74)	0.00*
Dep	T1	9.28	1.05	(7.19, 11.36)	8.21	0.91	(6.39, 10.02)	0.40
	T2	6.17	0.81	(4.56, 7.79)	9.26	1.08	(7.11, 11.41)	0.02*
	T3	5.62	0.78	(4.07, 7.18)	9.41	1.12	(7.17, 11.65)	0.00*

PCS=Physical Composite Scores(SF36). MCS= Mental composite scores(SF36).
 IPA=Inventory on Participation and autonomy, FR=Family role, SR=Social relationship,
 DASS=Depression, Anxiety, Stress. T1=baseline, T2=post-test, T3=follow-up\
 T1= baseline, T2= post-test, T3= follow-up.

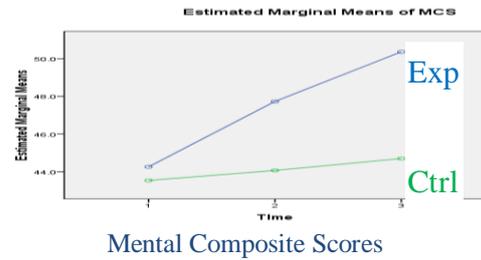
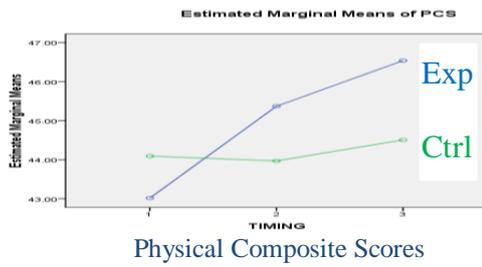
* =significant at $p < 0.05$

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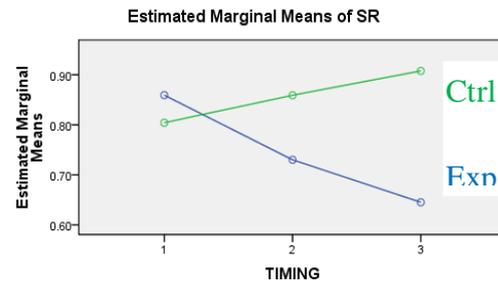
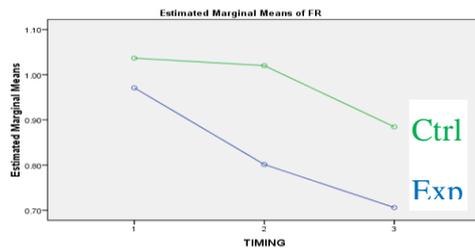
Figure 7.3

Plots on Outcome Profile at T1,T2,T3 (Primary Endpoints)

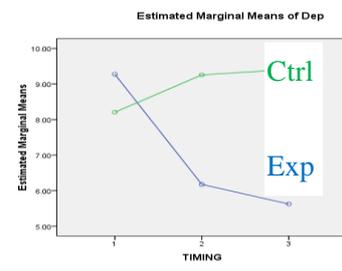
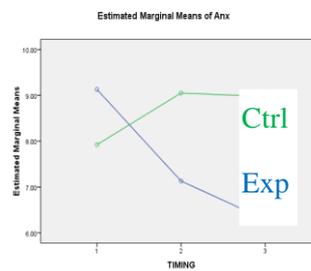
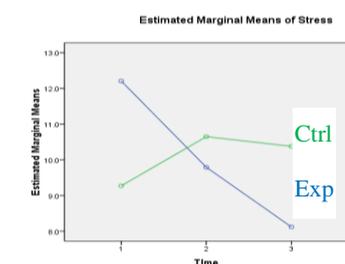
SF36 (Short form Quality of Life)



IPA (Inventory on Participation)



DASS (Depression, Anxiety, Stress Scale)



— Experimental (Exp)
— Control (Ctrl)

T1= Baseline, T2= Post-test, T3=Follow-up

7.6.2 Outcome Profile at T1,T2,T3 (Secondary endpoints)

The secondary endpoints include three specific self-efficacy: Self care_self-efficacy (SUPPH), Cancer behaviour_ self-efficacy (CBI), and Emotional_self-efficacy (SESES) and the Proactive Coping (PCI) endpoints.

Table 7.10 shows the differences of the mean scores between the groups which were significant at T2 and T3 for all these four secondary endpoints.

The profile plots in Figure 7.10 shows a distinct trend of increase over time [from baseline scores (T1) to Post-test scores (T2) and to Follow-up scores (T3)] in all the secondary endpoints in the experimental group, while a general trend of deterioration over time was found in the control group.

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Table 7.10

Outcome Profile at T1,T2 and T3 (Secondary endpoints)

Time	Experimental (n=67)			Control (n=74)			Anova (sig*)
	Mean	SE	95% CI	Mean	SE	95% CI	
SUPPH: Self care_Self-efficacy							
1	91.42	2.58	(86.20, 96.50)	101.51	2.43	(91.82, 101.51)	0.142
2	100.85	2.69	(95.40, 106.20)	96.57	2.48	(87.00, 96.57)	0.016*
3	103.96	2.87	(98.20, 109.60)	100.75	2.53	(90.69, 100.75)	0.032*
CBI: Self-efficacy_ Cancer behaviour coping							
1	84.84	2.47	(79.90, 89.70)	92.26	1.89	(84.74, 92.26)	0.235
2	91.84	2.28	(87.30, 96.40)	89.74	2.33	(79.49, 89.74)	0.020*
3	95.00	2.54	(89.90, 100.10)	92.27	2.27	(83.21, 92.27)	0.034*
SESES: Self-efficacy_ Emotion							
1	63.56	2.08	(59.40, 67.70)	64.92	1.91	(57.31, 64.92)	0.387
2	70.12	2.07	(65.90, 74.20)	66.00	2.08	(57.70, 66.00)	0.006*
3	71.64	2.21	(67.20, 76.00)	66.54	2.08	(58.26, 66.54)	0.003*
PCI: Proactive Coping							
1	39.18	0.78	(37.60, 40.70)	41.97	0.77	(38.88, 41.97)	0.265
2	41.88	0.74	(40.40, 43.30)	41.13	0.81	(37.90, 41.13)	0.034
3	43.30	0.81	(41.60, 44.90)	40.97	0.91	(37.36, 40.97)	0.001*

Secondary endpoints:

SUPPH= Strategies Used by People to Promote Health (Self care_Self-efficacy),

CBI = Cancer Behavior Inventory (Cancer behaviours _Self-efficacy_).

SESES = Stanford's Emotional Self-efficacy Scale (Emotion _Self-efficacy).

PCI = Proactive coping

T1= Baseline or pretest, T2 = Post-test, T3 = Follow-up

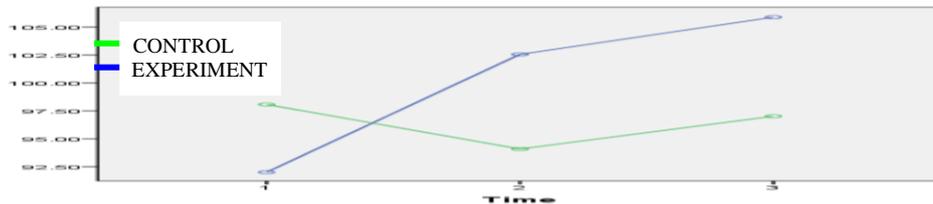
* =significant at $p<0.05$

Self-management intervention program for Women with breast cancer

Figure 7.4

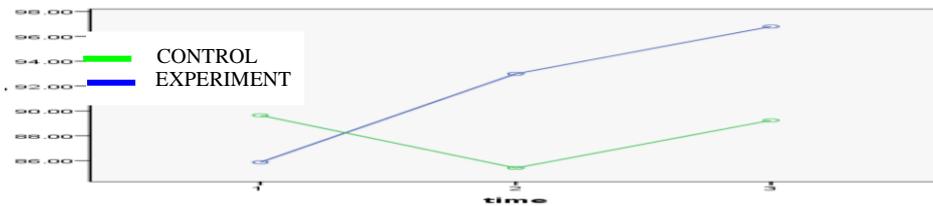
Plots on Outcome Profile at T1,T2,T3 (Secondary Endpoints)

SUPPH : Self care_Self-efficacy



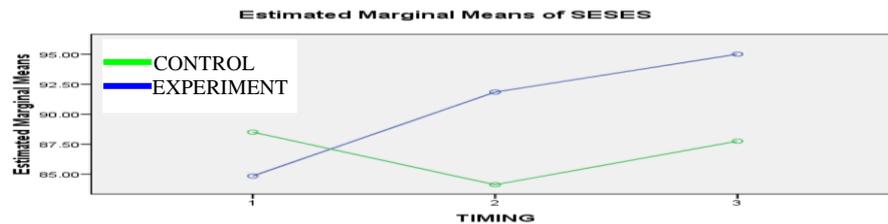
Strategies Used by People to Promote Health (Self care_Self-efficacy)

CBI : Self-efficacy_ Cancer behaviour coping



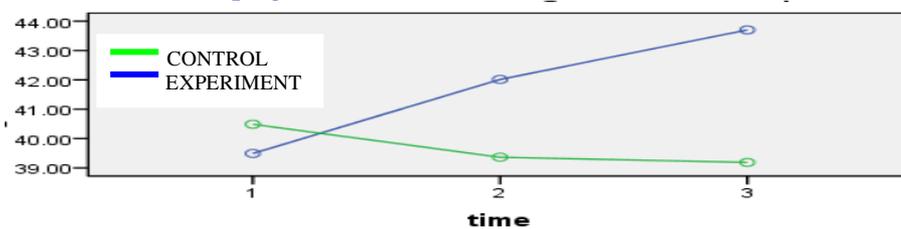
Cancer Behavior Inventory (Self-efficacy_ Cancer behaviours)

SESES : Self-efficacy_ Emotion



Stanford's Emotional Self-efficacy Scale (Self-efficacy_ Emotion).

PCI : Proactive Coping



Proactive Coping Inventory

Secondary endpoints:

SUPPH= Strategies Used by People to Promote Health (Self care_Self-efficacy),

CBI = Cancer Behavior Inventory (Self-efficacy_ Cancer behaviours).

SESES = Stanford's Emotional Self-efficacy Scale (Self-efficacy_ Emotion).

PCI = Proactive coping

7. 7 Outcome Profiles (Change Scores of T2-T1, T3-T1)

7.7.1 Outcome Profiles on T2-T1, T3-T1 score (Primary endpoint)

As change scores will be utilized in the intention-to-treat analyses using multivariate analyses of covariances (MANCOVA), the percentages of change scores at T2-T1 and T3-T1 were examined. The bar charts in Figure 7.5 show the changes in both groups, with a 5.5 % improvement in the experimental arm versus 0.27% deterioration in the control arm for the physical QOL (PCS) endpoint. About 15-32 % reduction at T2-T1 and 24-39% reduction at T3-T1 of the psychological distress were found in the experimental arm compared to an unfavorable increase in the control group (6-14 % at T2-T1; 14 to 15 % at T3-T1). The descriptive statistics is shown in Appendix J-3.

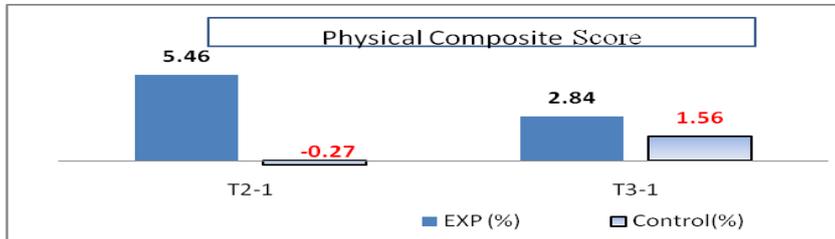
7.7.2 Outcome Profiles on T2-T1, T3-T1 score (Secondary endpoint)

The bar charts in Figure 7.7.2 for SUPPH and CBI, illustrate a trend of favorable improvements in the experimental group over the unfavorable reductions in these endpoints in the control arm. Although there were favorable change score for self-efficacy-emotion (SESES) and proactive coping skills (PCI) in both the experimental and control group - the former showed greater improvements at T2-T1 and at T3-T2. The descriptive statistics are tabulated in Appendix J-3.

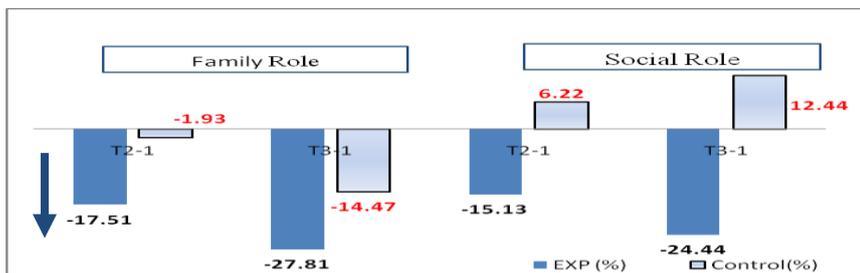
Self-management intervention program for Women with breast cancer

Figure 7.5

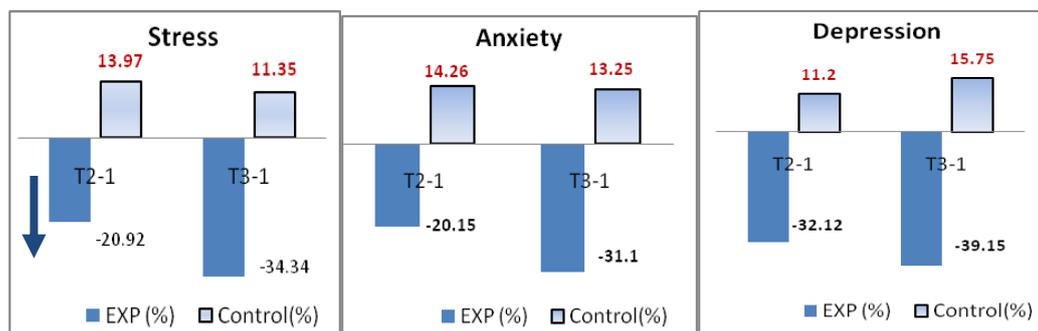
Bar chart of T2-T1 and T3-T1 change-scores (Primary Endpoints)



QOL_PCS: * Physical Composite Score at T2-T1 (p=0.005*) and T3-T1(p=0.512)



IPA: * Family Role at T2-T1(p=0.038) and T3-T1(p=0.065) & Social Role at T2-T1(p=0.034) and T3-T1(p=0.0001*)



DASS: *Stress, Anxiety, Depression at T2-T1 (p=0.001*) and T3-T1 (p=0.0001*)

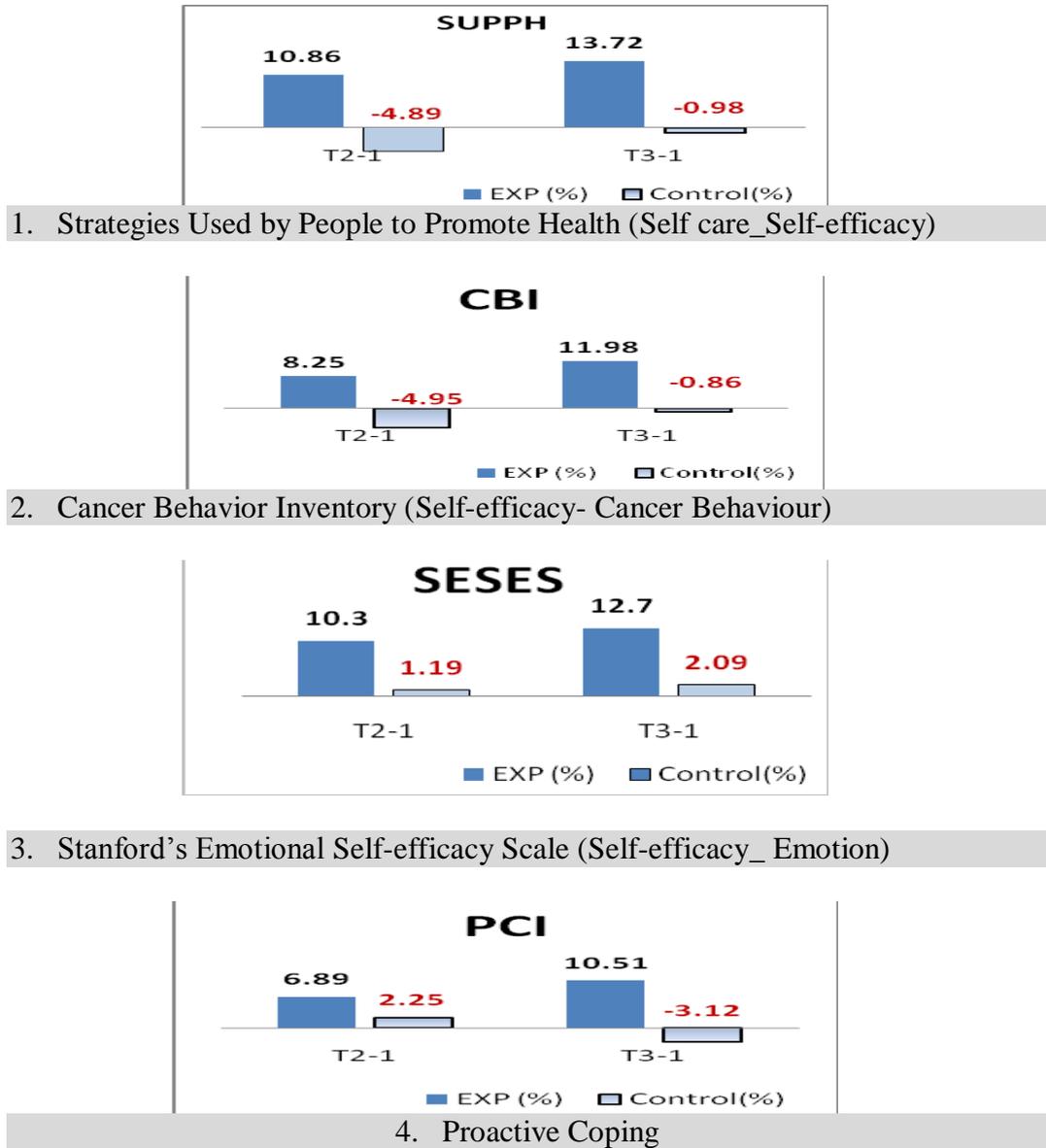
■ Experiment ■ Control

*Primary Endpoints: PCS=Physical composite scores of SF36, FR=Family role & SR= Social relationship of IPA, DASS= Stress, Anxiety, Depression of DASS

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Figure 7.6

Bar chart of T2-T1 and T3-T1 change-scores (Secondary Endpoints)



***Secondary Endpoints:**

SUPPH = Strategies Used by People to Promote Health (Self care_Self-efficacy),

CBI =Cancer Behavior Inventory (Self-efficacy_ Cancer behaviours).

SESES =Stanford's Emotional Self-efficacy Scale (Self-efficacy_ Emotion),

PCI =Proactive Coping

7.7.3 Reliable Change Index (T2-T1 and T3-T1 change scores)

The changed scores at T2-T1 and T3-T1 were scrutinized for any statistically reliable change. A reliable change index (RCI) was tabulated (Table 7.11) using the mean differences (posttest-pretest) divided by the standard error of the measure (Jacobson & Truax, 1991). RCI index of more than 1.96 signify that a change would be statistically reliable due to its magnitude of change (Jacobson & Truax, 1991). For clinical significance, Jacobson and colleagues set two criteria -i) pre-posttest change scores must exceed the RCI, and ii) post-test scores fall within the range of normative values. However, there are no agreed standard to set clinical significance among functional health measures even for the widely used SF36 (Ferguson, Robinson, & Splaine, 2002).

On the primary endpoints: the change scores were reliable for nine out of 10 variables on the experimental arm (except for PCS at T3-T1), as indicated by a RCI index of more than 1.96. On the control arm, only two measures (Stress T2-T1 and Family Role T3-T1) were reliable. On the secondary endpoints: all secondary variables on the experimental arm had a reliable change index of 1.96. For the control arm, two (SUPPH and CBI) out of four measure showed reliable change at T2-T1, and only one at T3-T1 (i.e. PCI). In summary, most of the changes in the mean-scores were found to be statistically reliable in the experimental group, especially so with the secondary endpoints.

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Table 7.11

Reliable Change Index of Primary and Secondary endpoints

		EXPERIMENT			CONTROL		
Change scores		Change scores	SE	RCI	Change scores	SE	RCI
P R I M A R Y	PCS						
	T2-T1	2.35	0.78	3.01 *	-0.12	0.63	-0.19
	T3-T1	1.22	0.67	1.82	0.69	0.40	1.73
	FR						
	T2-T1	-0.17	0.07	-2.43 *	-0.02	0.06	-0.33
	T3-T1	-0.27	0.07	-3.86 *	-0.15	0.07	2.14 *
	SR						
	T2-T1	-0.13	0.06	-2.17 *	0.05	0.05	1.00
	T3-T1	-0.21	0.06	-3.50 *	0.10	0.05	2.00
	Stress						
	T2-T1	-2.65	0.77	-3.44 *	1.44	0.68	2.12 *
	T3-T1	-4.35	0.98	-4.44 *	1.17	0.86	1.36
	Anx						
	T2-T1	-1.84	0.59	-3.12 *	1.13	0.62	1.82
T3-T1	-2.84	0.53	-5.36 *	1.05	0.65	1.62	
Dep							
T2-T1	-2.97	0.83	-3.58 *	0.91	0.59	1.54	
T3-T1	-3.62	0.85	-4.26 *	1.28	0.90	1.42	
S E C O N D A R Y	SUPPH						
	T2-T1	9.93	2.30	4.32 *	-4.73	1.63	-2.90 *
	T3-T1	12.54	2.91	4.31 *	-0.95	1.86	-0.51
	CBI						
	T2-T1	7.00	2.43	2.88 *	-4.38	1.69	-2.59 *
	T3-T1	10.16	2.47	4.11 *	-0.76	1.73	-0.44
	SESES						
	T2-T1	6.55	1.48	4.43 *	0.73	1.21	0.60
	T3-T1	8.07	1.89	4.27 *	1.28	1.33	0.96
	PCI						
T2-T1	2.70	0.57	4.74 *	-0.91	0.55	-1.65	
T3-T1	4.12	0.59	6.98 *	-1.26	0.64	-1.97 *	

PCS=Physical Composite Scores(SF36). MCS= Mental composite scores (SF36).
 IPA=Inventory on Participation and autonomy, FR=Family Role tasks, SR=Social Relationship tasks,
 DASS=Depression (Dep), Anxiety (Anx), Stress (Stres), SUPPH=Strategies Used by People to
 Promote Health (Self care_Self-efficacy), CBI=Cancer Behavior Inventory (Self-efficacy_ Cancer
 behaviours). SESES=Stanford's Emotional Self-efficacy Scale (Self-efficacy_ Emotion).
 RCI= Reliable Change Index [(Post-test - Pretest) / SEmeans] * RCI more than 1.96, and
 signify a difference is reliable

7.8 Summary

In summary this chapter summarized the four clusters of demographics of the study cohort (n=147), the outcome measure profile (primary and secondary) as well as the reliable change index of all endpoints. The overall descriptive information about the participants were rather similar in presentation for the four clusters (personal, health, cancer and cancer treatment) of profiles. Only the differences between group for: - ethnic, insurance status, exercise hours and level of physical activity were statistically significant.

Results from the fidelity checks (Figure 7.1 and Figure 7.2) provide the confidence that the fidelity protocol to ensure treatment-receipt has been successfully implemented. The raw scores of the repeated measures (T1, T2 and T3) for the primary and secondary endpoints was tabled in Table 7.9 and Table 7.10 while Figure 7.3 and Figure 7.4 illustrated the pattern of positive changes in the experimental group in contrast to the pattern of negative changes in the control group. Likewise, the percentages of change scores (Figure 7.5 and Figure 7.6) also support the preliminary evidence of the effectiveness of the SAMA program. Indepth analyses was follow- up with more definitive statistical analyses and these anlyses will be reported in Chapter 8.

8

CCT* RESULT II: Multivariate and Univariate Analyses

One goal of self-management is that people will have the confidence to deal with medical management, role management and emotional management of their conditions.

(Adams et al., 2004).

*CCT = Clinical Controlled Trial

8.1 Overview on ITT Analyses

This chapter presents the second part of the result for the Clinical Controlled Trial (CCT). The two intent-to-treat (ITT) analyses included: i) **Primary Analyses** that examined the between-group differences using multivariate analyses of co-variances (MANCOVA) and, ii) **Secondary Analyses** that examined the within-subject (experimental group) using repeated measures ANOVA. ITT design provides unbiased assessments of treatment efficacy in controlled trials (Montori & Guyatt, 2001) as it admits non-compliance and protocol deviations which thus reflects the real clinical situation (Heritier, Gebski, & Keech, 2003). The SPSS® statistical package version 16 (SPSS, Inc, Chicago Ill) was used for data analysis. The level of significance, $\alpha = 0.05$ (2-tailed) was applied to all analyses unless otherwise reported.

Briefly, Section 8.2 reports the preliminary check prior to the multivariate test. Section 8.3 reports the Primary ITT analyses using MANCOVA on both groups (n=147), whilst the four analyses -repeated with demographic covariates added to the model was presented in Section 8.4 which also shows the differences between the two sets of analyses. Section 8.5 reports the secondary ITT analyses using univariate repeated measure ANOVA on the experimental group (n=68).

8.1.1 The Null hypotheses for the study

Null Hypotheses 1 and 2 relates to the primary analyses to examine changes between-groups and were examined with four MANCOVAs.

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Hypothesis 1a and 1b relate to the six primary endpoints whilst Hypothesis 2a and 2b relate to the four secondary endpoints, at posttest and follow-up respectively. Null Hypothesis 3 and 4 relate to the secondary analyses to examine the changes within-subjects over time on the experimental group (n=69).

$H\emptyset_1$ = There are no statistical differences between the intervention and control groups, in quality of life, limitation in participation, psychological distress (**primary endpoints**) at post-test (T2) and at follow-up (T3).

[Hypothesis 1a = Post-test; Hypothesis 1b = Follow-up]

$H\emptyset_2$ = There are no statistical differences between the intervention and control groups, in self-efficacy and proactive copings (**secondary endpoints**) at post-test (T2), and at follow-up (T3).

[Hypothesis 2a = Post-test; Hypothesis 2b = Follow-up]

$H\emptyset_3$ = There are no statistical differences over any time point of the three repeated measures for any of the Quality of life, Participation or Psychological distress (**primary endpoints**) in the experimental group.

[Hypothesis 3 = Primary Endpoints]

$H\emptyset_4$ = There are no statistical differences over any time point of the three repeated measures for any of the Cancer Self-efficacy or Proactive coping scales (**secondary endpoints**) for the experimental group.

[Hypothesis 4 = Secondary Endpoints]

8.2 Preliminary Checks for Primary Analyses using MANCOVA

8.2.1 Statistical Comparison of Baselines Outcome Measures

Prior to the intent to treat analyses, differences between the mean scores of the experimental and control groups at all baseline endpoints (or outcome measures) were checked and showed no significant differences (Table 8.1). Therefore, any changes found in the subsequent analyses cannot be due to the baseline differences.

Table 8.1

Statistical comparison of baseline scores (between group)

Tools	Measures	Experimental (n=69)		Control (n= 78)		ANOVA between group (df =1, 141)	
		Mean	SD	Mean	SD	F	p-value
Primary endpoints							
SF36	PCS1	43.02	6.48	44.09	7.75	0.82	0.37
	MCS1	44.26	8.94	43.31	10.28	0.34	0.56
IPA	FR1	0.97	0.66	1.03	0.70	0.34	0.56
	SR1	0.86	0.61	0.80	0.52	0.35	0.55
DASS	Stress1	12.67	8.20	10.31	8.05	3.08	0.08
	Anxiety1	9.13	7.57	7.92	6.47	1.09	0.30
	Depression1	9.28	8.69	8.21	8.04	0.61	0.44
Secondary endpoints							
SE	SUPPH1	91.42	21.49	96.67	21.48	2.18	0.14
	CBI1	84.84	20.50	88.50	16.68	1.42	0.24
	SESES1	63.57	17.26	61.12	16.89	0.75	0.39
Coping	PCI1	39.19	6.49	40.42	6.84	1.25	0.27

Baseline scores of primary and secondary endpoints were not significant at the level $p < 0.05$, $p < 0.01$ *

Primary endpoints : PCS=Physical Composite Scores, FR=Family Role; SR=Social Relationship,
Secondary endpoints: SUPPH =Self care_Self-efficacy, CBI=self-efficacy (cancer behavior),
SESES=self-efficacy (emotion), PCI= Proactive coping

8.2.2 *Checks on Assumptions of MANCOVA*

Examination on the assumptions of MANCOVA such as independence of subjects, normality, correlations between covariates, multi-collinearity and homogeneity of variance-covariance matrices (Allen & Bennet, 2008) were checked for both sets of change scores (T2-T1 and T3-T1). Change scores, instead of raw data were used so that the data is independent of each other.

Univariate normality was assessed with Shapiro Wilk's test and boxplots. The result showed that Shapiro Wilk's statistic was significant for all dependent variables except for a few variables (PCS, SESES, PCI on T2-T1 change scores; and PCS, SUPPH, SESES, PCI, CBI on T3-T1), thus the data were log-transformed (Log10). However, this procedure did not improve the results of the Shapiro Wilk's statistic. Examination of each of the box plots showed roughly symmetrical presentations, suggesting that univariate normality could be assumed (Allen & Bennet, 2008). There were multiples univariate outliers (4 on T2-T1 and 14 on T3-T1) on the DASS scales, one at SUPPH T2-T1 and two at PCS T3-T1. These outliers were then transformed to the next lowest/highest values (Psychwiki, 2008). The Mahalanobis-distance confirmed no multivariate outlier in both sets of change scores.

8.2.3 Comparison of Internal Reliability Coefficients

The consistencies of measurement or internal reliabilities of the scale were also computed on the database of this study cohort and the alpha coefficients were compared with the developers’ alpha. Table 8.2 presents the differences between the alpha (internal consistency reliability) of the tools on this sample with that from the developers. Almost all scales were 0.7 and above except for mental composite score (MCS= 0.2). This scale was dropped from all subsequent analyses.

Table 8.2

Internal consistency of Measurement Scale – Comparison between study’s and developers’ Alpha

	Items	<u>SAMA's alpha</u> (n=142)	<u>Developer's alpha</u>
Primary Endpoints at pretest			
Physical composite (PCS)	21	0.65	0.92 (Ware, 2002)
Mental composite (MCS)	14	0.25	0.88 (Ware, 2002)
Family Role (FR)	7	0.91	0.80 (Cardol, 2002)
Social Relationship (SR)	7	0.87	0.80 (Cardol, 2002)
Stress	7	0.87	0.81 (Lovibond, 1995)
Anxiety	7	0.77	0.73 (Lovibond, 1995)
Depression	7	0.88	0.81 (Lovibond, 1995)
Secondary Endpoints at pretest			
SUPPH	29	0.96	0.70-0.90 (Lev, 1996)
CBI	14	0.92	0.94 (Merluzi, 1999)
SESES	15	0.92	0.90 (Giese-Davis,
PCI	14	0.87	0.80 (Greenglass,1999)

PCS = Physical Composite scores. MCS = Mental Composite scores
 FR= Family Role; SR= Social Relationship
 Anx=Anxiety, Dep= Depression
 SUPPH = self care_self-efficacy
 CBI = cancer behavior_self efficacy
 SESES = emotional_self efficacy
 PCI = Proactive coping

8.2.4 Comparison of the R Square of Correlation Coefficient (R^2)

The R squared (R^2) from the MANOVA tests between the raw data and the log-transformed data for all dependents were compared. R^2 is the proportion of variability in a data set that is accounted for by a statistical model. It is the statistical measure of how well the regression line approximates the real data points (goodness of fit).

Table 8.3 showed the R^2 coefficients were better on the raw data sets, whereby an R^2 of 1.0 indicates that the regression line perfectly fits the data. There were higher values in both sets of the raw data, when compared to its equivalents on the log-transformed data, confirming that the raw scores were better. Thus, the raw data was utilized for all subsequent analyses.

Table 8.3

Comparison of the R^2 raw-data and R^2 log-transformed data

	T2-T1 data-- set		T3-T1 data-set	
	R^2 (raw)	R^{2**} (log)	R^2 (raw)	R^{2**} (log)
PCS	0.388	0.388	0.273	0.273
FR	0.276	0.276	0.377	0.352
SR	0.257	0.280	0.283	0.272
Stress	0.300	0.294	0.342	0.330
Anxiety	0.282	0.311	0.330	0.244
Depression	0.350	0.405	0.380	0.340
SUPPH	0.403	0.220	0.351	0.351
CBI	0.379	0.234	0.314	0.314
SESES	0.231	0.170	0.274	0.274
PCI	0.261	0.215	0.290	0.290

$R^{2(\text{raw})}$ =Not log transformed; $R^{2**(\text{log})}$ =Log transformed (Log10) $R^2 = \frac{SS_{\text{reg}}}{SS_{\text{tot}}}$

PCS=Physical Composite Scores, FR=Family Role; SR=Social Relationship, SUPPH = self care_self-efficacy CBI = cancer behavior_self efficacy SESES = emotional_self efficacy PCI = Proactive coping

8.2.5 *Multicollinearity, Homoscedasticity and Equality of variance*

Table 8.4 – Table 8.6 below showed the correlations between: the covariates (ranging from 0.40 -0.65), change-scores of T2-T1 (0.26 -0.74), and change-scores of T3-T1 (0.28-0.74). As there were all less than 0.8, we can assume that the assumptions of multicollinearity were not violated.

Box's M (homoscedasticity assumption in MANOVA) for the four sets of data (Primary T2-T1 and T3-T1; Secondary T2-T1 and T3-T1) were not significant at the 0.001 level indicating that homogeneity of variance-covariances matrices could be assumed.

Levene's Test of Equality of variance were not significant for T2-T1 data, but was significant for PCS, Anxiety and Depression at T3-T1 and for CBI and SESES T3-T1. Pallant (2002, p259) suggests a conservative alpha of 0.025 or 0.01 to determine the significance of those variables that violated this assumption. Finally, MANCOVA is robust against violation of normality and equality of variance if the cell sizes exceed 30 (Allen & Bennet, 2008) and are of equal cell sizes.

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Table 8.4

Correlations between covariates (T1)

	PCS1	FR1	SR1	Stress1	Anx1	Dep1	Supph1	CBI1	PCI1
Physical Comp Score (PCS)	1.00								
Family Role (FR)	-0.46**	1.00							
Social Relationship (SR)	-0.24**	0.57**	1.00						
Stress	-0.34**	0.42**	0.35**	1.00					
Anxiety	-0.38**	0.45**	0.30**	0.73**	1.00				
Depression	-0.33**	0.41**	0.41**	0.81**	0.65**	1.00			
SUPPH	0.07	-0.35**	-0.44**	-0.26**	-0.18*	-0.40**	1.00		
CBI	0.16	-0.39**	-0.49**	-0.31**	-0.25**	-0.39**	0.67**	1.00	
SESES	0.18*	-0.37**	-0.34**	-0.19*	-0.23**	-0.32**	0.57**	0.64**	1.00
PCI	0.12	-0.18*	-0.35**	-0.03	-0.14	-0.17*	0.63**	0.50**	0.52**
Max	0.46	0.57	0.50	0.81	0.65	0.40	0.67	0.64	0.52

** p< 0.01 level (2-tailed), * p <0.05 level (2-tailed);

PCS=Physical Composite Scores, FR=Family Role; SR=Social Relationship,

Anx=Anxiety, Dep= Depression, SUPPH=Self care_Self-efficacy, CBI=cancer behavior-self efficacy,

SESES= emotional self efficacy, PCI = Proactive coping

Table 8.5

Correlations between T2- T1 change-scores

	PCS	FR	SR	Stress1	Anx	Dep	Supp	CBI	SESES
Physical Comp Score	1								
Family Role	-0.30**	1							
Social Relationship	-0.16	0.63**	1						
Stress	-0.23*	0.45**	0.38**	1					
Anxiety	-0.27*	0.26**	0.21**	0.67**	1				
Depression	-0.35**	0.35**	0.33**	0.74**	0.62**	1			
SUPPH	0.28**	-0.25**	-0.36**	-0.25**	-0.19*	-0.31**	1		
CBI	0.26**	-0.29**	-0.44**	-0.24**	-0.18*	-0.35**	0.53**	1	
SESES	0.24**	-0.18	-0.14	-0.17*	-0.15	-0.26**	0.38**	0.51**	1
PCI	0.10	-0.16	-0.25**	-0.13	-0.08	-0.22*	0.37**	0.33**	0.26**
Max	0.35	0.63	0.44	0.74	0.62	0.35	0.53	0.51	0.26

** p< 0.01 level (2-tailed), * p <0.05 level (2-tailed)

SUPPH=Self care_Self-efficacy, CBI=cancer behavior-self efficacy, SESES= emotional self efficacy,

PCI = Proactive coping

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Table 8.6

Correlations between T3- T1 change scores

T3-T1	PCS	FR	SR	Stress	Anx	Dep	Supph	CBI	SESES
PCS	1								
FR	-0.18*	1							
SR	-0.07	0.50**	1						
Stress	-0.14	0.47**	0.50**	1					
Anx	-0.18*	0.40**	0.43**	0.74**	1				
Dep	-0.28**	0.18*	0.12**	0.37**	0.27**	1			
SUPPH	0.06**	-0.26*	-0.40**	-0.32**	-0.14	-0.17**	1		
CBI	0.11	-0.41*	-0.54**	-0.40**	-0.27**	-0.09	0.55**	1	
SESES	0.12	-0.28*	-0.26**	-0.24**	-0.18*	-0.17**	0.38**	0.64**	1
PCI	0.16	-0.20	-0.40**	-0.32**	-0.30**	-0.16**	0.51**	0.51**	0.52**
Max	0.28	0.50	0.54	0.74	0.27	0.17	0.55	0.64	0.52

** p< 0.01 level (2-tailed), * p <0.05 level (2-tailed);

PCS = Physical Composite Scores, FR=Family Role; SR=Social Relationship,
 Anx = Anxiety,
 Dep = Depression,
 Supph = Self care_Self-efficacy,
 CBI = Cancer behavior-self efficacy,
 SESES = Emotional self efficacy,
 PCI = Proactive coping

8.3 Primary ITT Analyses: Between-group Multivariate Analyses

8.3.1 Overview - Primary Analyses without demographic covariate

These sections present the results of primary analyses via four multivariate analyses of covariances (MANCOVA) on the dependent variables (DVs). There were two types of covariates involved

- i) baseline covariates i.e. baseline T1 endpoints, used for both sets of MANCOVA,
- ii) demographic covariates –used only in the second set of the repeated MANCOVA.

There were four hypotheses delineated and these were examined via four MANCOVA - two for the primary endpoints (Hypothesis 1a and 1 b), and another two for the secondary endpoints (Hypothesis 2a and 2b) to examine for the differences between the groups at posttest (T2-T1) and at follow-up (T3-T1) respectively. Using the change scores separately ensures that the assumption of independence of data was not violated. Thus the T2-T1 analyses were performed separately from the T3-T1 analyses.

In order to understand the data better as there were multiple dependent variables, the four MANCOVA were repeated with demographic covariates added to the model. These findings are reported in section 8.4.

8.3.2 Hypothesis 1a: Quality of life, Participation and Distress at Post-test

The first MANCOVA showed a significant effect of the SAMA intervention on the combined dependent variables (DVs) at post-test (using T2-T1 change scores). Table 8.7 shows the overall F test: $F(6, 134) = 3.45, p < 0.03$; Wilks' Lambda = 0.87, partial eta squared (η_p^2) = 0.13. Close examination of the individual DVs using a Bonferroni adjusted alpha level of 0.008 (i.e. $0.05/6$ dependents) showed statistically significant differences in the Physical Composite scores (PCS) and three symptoms of Psychological distress scales. The effect sizes of 0.0 to 0.1 is small (J. Cohen, 1988) and indicates that the mean of the treated group is at the 50-54 percentile of the untreated group. The Partial Eta squared are estimates of the degree of association for the sample.

PCS : $F(1, 135) = 8.22, p = 0.01, \eta_p^2 = 0.06$

Stress : $F(1, 135) = 12.7, p < 0.001, \eta_p^2 = 0.08$

Anxiety : $F(1, 135) = 12.2, p < 0.001, \eta_p^2 = 0.08$

Depression: $F(1, 135) = 14.5, p < 0.001, \eta_p^2 = 0.09$

Comparing the experimental and control group, there are greater improvement in the change scores of PCS with greater reduction in all three distress symptoms.

PCS [2.32 (1.12, 3.52; 95% CI) versus -0.01 (-1.22, 1.03; 95% CI)]

Stress [-2.35 (-3.74, -0.95; 95% CI) versus 1.16 (-0.15, 2.48; 95% CI)]

Anxiety [-1.79 (-2.96, -0.62; 95% CI) versus 1.08 (-0.01, 2.18; 95% CI)]

Depression [-2.77 (-4.07, -1.46, 95% CI) versus 0.73 (-0.50, 1.95; 95% CI)].

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Table 8.7

Group Differences in Quality of life, Participation, Distress (T2-T1)

Multivariate Tests (MANCOVA 1)

Effect		Value	F	Sig.*	Partial η^2	Power
Treatment Group	Wilks' Lambda	0.87	3.45	0.03	0.13	0.94

*Computed using alpha = 0.05; df (6, 134)

Univariate Tests: *Quality of life, Participation and Distress at Post-test*

Source	Dependent Variable (DV)	Type III Sum of Squares	Mean Square	F	Sig.a	Partial η^2	Power
Treatment Group (IV)	PCS.t2-1	201.51	201.51	8.22	0.01*	0.06	0.81
	FamRoleT2-T1	1.06	1.05	4.40	0.04	0.03	0.55
	Social R'ship	0.84	0.83	4.57	0.03	0.03	0.56
	Stress.T2-T1	422.98	422.97	12.69	0.00*	0.08	0.94
	Anxiety.T2-T1	283.14	283.14	12.18	0.00*	0.08	0.93
	Depress.T2-T1	419.39	419.39	14.47	0.00*	0.09	0.97

a Computed using alpha = 0.05, df (1, 135). * Significant at $p \leq 0.008$ (Bonferroni adjusted)

Estimated marginal means: *Quality of life, Participation and Distress at Post-test*

Tools	Dependent variable (DV)	IV	Mean	Std. Error	95% CI	
					Lower	Upper
SF36	PCS.t2-1	experimental	2.32 ^a	0.61	(1.12,	3.52)
		control	-0.01 ^a	0.57	(-1.22,	1.03)
IPA	FamRoleT2-1	experimental	-0.18 ^a	0.06	(-0.30,	-0.06)
		control	-0.01 ^a	0.06	(-0.12,	0.11)
	SocRshipT2-1	experimental	-0.11 ^a	0.05	(-0.22,	-0.01)
		control	0.04 ^a	0.05	(-0.06,	0.14)
DASS	Stress.T2-1	experimental	-2.35 ^a	0.71	(-3.74,	-0.95)
		control	1.16 ^a	0.66	(-0.15,	2.48)
	Anxiety.T2-1	experimental	-1.79 ^a	0.59	(-2.96,	-0.62)
		control	1.08 ^a	0.55	(-0.01,	2.18)
	Depress.T2-1	experimental	-2.77 ^a	0.66	(-4.07,	-1.46)
		control	0.73 ^a	0.62	(-0.50,	1.95)

Covariates appearing in the model are evaluated at the following values: Physical composite score = 43.5901, Family role T1 = 1.0058, Social relationship T1 = .8299, StressT1 = 11.4150, anxietyT1 = 8.4898, depressionT1 = 8.6531.

PCS=Physical Composite Scores, FamRole =Family Role, Supp =self-efficacy(self care), IV = Independent variables. DV= Dependent variables

8.3.3 Hypothesis 1b: Quality of life, Participation, Distress at follow-up

Results from the second MANCOVA using T3-T1 change-score (see Table 8.8), showed a significant effect of the intervention on the combined dependent variables (primary endpoints) at follow-up (using T3-T1 change scores). The overall test are: $F(6, 134) = 4.05, p < 0.001$; Wilks' Lambda = 0.85, $\eta_p^2 = 0.15$.

Univariate analysis of the dependent variables at the conservative Bonferroni adjusted alpha level of 0.008 was not statistically significant for Physical composite score, Family role and depression. Only three variables show significant differences ($p < 0.008$) and these were Social Relationship, Stress and Anxiety.

$$\left. \begin{array}{l} \text{Social relationship: } F(1, 139) = 11.6, \eta_p^2 = 0.08; \\ \text{Stress: } F(1, 139) = 13.2, \eta_p^2 = 0.09; \\ \text{Anxiety: } F(1, 139) = 20.26, \eta_p^2 = 0.13. \end{array} \right\} p < 0.001$$

Overall, the result showed significant differences on three primary endpoints at follow-up, compared to four at immediately post-test. A comparison of both groups showed that experimental group had better reduced scores than the control group for these measures:

$$\begin{array}{l} \text{SR} \quad : [-0.2 (-0.3, -0.09; 95\% \text{ CI}) \text{ versus } 0.09 (-0.01, 0.19; 95\% \text{ CI})] \\ \text{Stress} \quad : [-3.85 (-5.57 \text{ to } -2.13; 95\% \text{ CI}) \text{ versus } 0.73 (-0.89, 2.34; 95\% \text{ CI})] \\ \text{Anxiety} \quad : [-2.67 (-3.85 \text{ to } -1.49; 95\% \text{ CI}) \text{ versus } 0.90 (-0.21, 2.01; 95\% \text{ CI})] \end{array}$$

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Table 8.8

Group Differences in Quality of life, Participation, Distress (T3-T1)

Multivariate Tests (MANCOVA 2)

Effect		Value	F	Sig.*	Partial η^2	Power
Treatment Group	Wilks' Lambda	0.85	4.05 ^a	0.00*	0.15	0.97

Computed using alpha = 0.05; df (6, 134)

Univariate Tests - Quality of life, Participation, Distress at Follow-up

Source	Dependent Variable (DV)	Type III Sum of Squares	Mean Square	F	Sig.	Partial η^2	Power
Treatment Group (IV)	PCS.T3-1	10.78	10.78	0.44	0.51	0.00	0.10
	FamRoleT3-1	0.26	0.26	0.74	0.39	0.01	0.46
	SocRshipT3-1	2.50	2.50	11.60	0.00 *	0.08	0.97
	Stress.T3-1	858.31	858.31	13.15	0.00 *	0.09	0.96
	Anxiety.T3-1	540.39	540.39	20.26	0.00 *	0.13	0.99
	Depress.T3-1	20.69	20.69	0.87	0.35	0.01	0.97

*Computed using alpha = 0.05; df (1,139) ** Significant at p<0.008 (Bonferroni adjusted)

Estimated Marginal Means - Quality of life, Participation, Distress at Follow-up

Tools	Dependent Variable (DV)	IV	Mean	Std. Error	95% CI	
					Lower	Upper
SF36	PCS.t3-1	experimental	1.21 ^a	0.55	(0.12,	2.29)
		control	0.70 ^a	0.52	(-0.32,	1.72)
IPA	FamRoleT3-1	experimental	-0.29 ^a	0.06	(-0.41,	-0.17)
		control	-0.13 ^a	0.06	(-0.24,	-0.02)
	SocRshipT3-1	experimental	-0.20 ^a	0.05	(-0.30,	-0.09)
		control	0.09 ^a	0.05	(-0.01,	0.19)
DASS	Stress.T3-1	experimental	-3.85 ^a	0.87	(-5.57,	-2.13)
		control	0.73 ^a	0.82	(-0.89,	2.34)
	Anxiety.T3-1	experimental	-2.67 ^a	0.60	(-3.85,	-1.49)
		control	0.90 ^a	0.56	(-0.21,	2.01)
	Depress.T3-1	experimental	-3.38 ^a	0.83	(-5.02,	-1.74)
		control	1.07 ^a	0.78	(-0.48,	2.61)

a. Covariates appearing in the model are evaluated at the following values:

Physical comp score1 = 43.5901, Family role T1 = 1.0058, Social relationship T1 = .8299, StressT1 = 11.4150, anxietyT1 = 8.4898, depressionT1 = 8.6531.

PCS=Physical Composite Scores, Family Role=Family Role; Social Relationship =Social Relationship
IV = Independent variables. DV= Dependent variables

8.3.4 Hypothesis 2a: Cancer specific self-efficacy, Proactive coping at Post-test

A third MANCOVA to test the significant effect of SAMA intervention was conducted on the combined DVs (secondary endpoints) at post-test (using T2-T1 change scores). The overall multivariate F test showed: $F(4, 138) = 8.43, p < 0.001$; Wilks' Lambda = 0.80, partial eta squared (η_p^2) = 0.2.

Based on Table 8.9, significant results were found on all individual dependent variables for Self care_Self-efficacy (SUPPH), Cancer behaviour_Self-efficacy (CBI), Emotional_Self-efficacy (SESES) and Proactive copings (PCI):

SUPPH	: $F(1, 141) = 25.2, \eta_p^2 = 0.2;$	} $p < 0.001$
CBI	: $F(1, 141) = 12.9, \eta_p^2 = 0.08;$	
SESES	: $F(1, 141) = 11.38, \eta_p^2 = 0.08$	
PCI	: $F(1, 141) = 16.1, \eta_p^2 = 0.10.$	

At T2-T1 period, there were significant differences between-groups with a greater improvement in change-score on the experimental group for all variables than in the control group. The control group generally showed deterioration except for slight improvement in emotional self efficacy.

SUPPH: [9.05 (5.36, 12.72; 95% CI)] versus [-3.95 (-7.41, -0.49; 95% CI)]

CBI: [5.86 (2.21, 9.51, 95% CI)] versus [-3.38 (-6.81, 0.05; 95% CI)]

SESES: [6.85 (4.16, 9.54: 95% CI)] versus [0.47 (-2.06, 2.99, 95% CI)]

PCI: [2.42 (1.32-3.51: 95% CI)] versus [-0.66 (-1.69, 0.36; 95% CI)].

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Table 8.9

Group Differences in Self-efficacy, Proactive copings (T2-T1)

Multivariate Tests (MANCOVA 3)

Effect		Value	F	Sig.*	Partial η^2	Power
Treatment Group	Wilks' Lambda	0.80	8.43 ^a	0.00	0.20	1.00

*Computed using alpha = 0.05; df (4, 138)

Univariate Tests - *Cancer specific self-efficacy and Proactive coping at Post-test*

Source	Dependent Variable (DV)	Type III Sum of Squares	Mean Square	F	Sig.a	Partial η^2	Power
Treatment Group	SUPPH.T2-T1	5850.59	5850.59	25.19	0.00	0.15	1.00
(IV)	CBI.T2-T1	2955.77	2955.77	12.94	0.00	0.08	0.95
	SESES.T2-T1	1409.75	1409.75	11.38	0.00	0.08	0.92
	PCI.T2-T1	328.67	328.67	16.06	0.00	0.10	0.98

df = (1, 141) * Significant at p<0.012 (Bonferroni Adjusted)

Marginal means *Cancer specific self-efficacy and Proactive coping at Post-test*

Tools	Dependent Variable (DV)	IV	Mean	Std. Error	95% CI	
					Lower	Upper
Cancer Self-efficacy	SUPPH.T2-1	experimental	9.05 ^a	1.86	(5.36,	12.72)
		control	-3.95 ^a	1.75	(-7.41,	-0.49)
	CBI.T2-1	experimental	5.86 ^a	1.85	(2.21,	9.51)
		control	-3.38 ^a	1.73	(-6.81,	0.05)
Coping	SESES.T2-1	experimental	6.85 ^a	1.36	(4.16,	9.54)
		control	0.47 ^a	1.28	(-2.06,	2.99)
	PCI.T2-1	experimental	2.42 ^a	0.55	(1.32,	3.51)
		control	-0.66 ^a	0.52	(-1.69,	0.36)

Covariates appearing in the model are evaluated at the following values: SUPP-29: sum of all items T1 = 94.2041, cancer-behaviourT1 = 86.7823, SESES_sumT1 = 62.2653, Proactive-coping T1 = 39.8435

SUPPH = Self care_Self-efficacy, CBI= Cancer behavior_self-efficacy, SESES= Emotional _self-efficacy, PCI=proactive coping.

IV = Independent variables. DV= Dependent variables

8.3.5 Hypothesis 2b: Cancer specific self-efficacy, Proactive coping at Follow-up

A fourth MANCOVA to test the significant effect of the SAMA intervention was conducted on the combined dependent variables (secondary endpoints) at follow-up (using T3-T1 change scores). The overall F test statistic was: $F(4, 138) = 8.67$, $p < 0.001$; Wilks' Lambda = 0.80, partial eta squared (η_p^2) = 0.2. Table 8.10 showed significant between-group on all individual variables of the secondary endpoints:

SUPPH	: $F(1,141) = 14.2$, $\eta_p^2 = 0.09$	} $p < 0.001$
CBI	: $F(1,141) = 11.1$, $\eta_p^2 = 0.07$	
SESES	: $F(1,141) = 12.6$, $\eta_p^2 = 0.08$	
PCI	: $F(1,141) = 34.1$, $\eta_p^2 = 0.20$	

There were significant differences between the two groups, where a much greater improvement in the change-score was found in the experimental group on the three self efficacy scales:

SUPPH	= [11.69 (7.20 to 16.18, 95%CI) versus -0.20 (-4.42 to 4.02, 95%CI)],
CBI	= [9.30 (5.34 – 13.26, 95%CI) versus 0.0 (-3.72 to 3.72, 95%CI)];
SESES	= [8.67 (5.49 to 11.84, 95%CI) versus 0.76 (-2.22 to 3.73, 95%CI)].
PCI	= [4.00 (2.74 to 5.25, 95%CI) versus -1.15 (-2.33 to 0.03, 95%CI)].

Using Cohen (1988) guide of effect size of 0.2 as small, 0.5 as medium and 0.8 as large, the effect sizes were small (0.1 to 0.2), indicating the mean of the treated group is at the 54-58 percentile of the untreated group.

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Table 8.10

Group Differences in Self-efficacy, Proactive copings (T3-T1)

Multivariate Tests (MANCOVA 4)

Effect		Value	F	Sig.*	Partial η^2	Power
Treatment Group	Wilks' Lambda	0.80	8.67 ^a	0.00	0.20	1.00

Computed using alpha = 0.05; df (4, 138)

Univariate: *Cancer specific self-efficacy and Proactive coping at Follow-up*

Source	Dependent Variable (DV)	Type III Sum of Squares	Mean Square	F	Sig.	Partial η^2	Power
Treatment Group	SUPPH.T3-1	4895.39	4895.39	14.16	0.00*	0.09	0.96
	CBI.T3-1	2994.54	2994.54	11.13	0.00*	0.07	0.91
	SESES.T3-1	2167.29	2167.29	12.56	0.00*	0.08	0.94
	PCI.T3-1	919.57	919.57	34.07	0.00*	0.20	1.00

df= (1, 141) * significant at p < 0.02 (Bonferroni Adjusted)

Marginal Mean: *Cancer specific self-efficacy and Proactive coping at Follow-up*

Tools	Dependent Variable (DV)	IV	Mean	Std. Error	95% CI Lower --- Upper
Cancer Self-efficacy	SUPPH.T3-1	experimental	11.69 ^a	2.27	(7.20, 16.18)
		control	-0.20 ^a	2.13	(-4.42, 4.02)
	CBI.T3-1	experimental	9.30 ^a	2.00	(5.34, 13.26)
		control	0.00 ^a	1.88	(-3.72, 3.72)
Coping	SESES.T3-1	experimental	8.67 ^a	1.61	(5.49, 11.84)
		control	0.76 ^a	1.51	(-2.22, 3.73)
	PCI.T3-1	experimental	4.00 ^a	0.64	(2.74, 5.25)
		control	-1.15 ^a	0.60	(-2.33, 0.03)

a. Covariates appearing in the model are evaluated at the following values: SUPP-29: sum of all items T1 = 94.2041, cancer-behaviourT1 = 86.7823, SESES_sumT1 = 62.2653, proactive-copingT1 = 39.8435.

SUPPH = Self care_Self-efficacy, CBI= Cancer behavior_self-efficacy, SESES=Emotional_Self-efficacy, PCI=proactive coping.

IV = Independent variables. DV= Dependent variables

8.4 Primary ITT Analyses: Between-group Multivariate Analyses (with demographic covariates)

8.4.1 Overview - Primary Analyses with demographic covariate

This section reports the four MANCOVA repeated with the demographic covariates added to the model. The demographic factors found significant at baseline, were entered as the independent between-group factors together with the group factor (experimental and control).

Data from the cancer profile were not tested as the data were considered 'incomplete' with the "I don't know" cases. The age group was re-coded into two subgroups of young (20-49 years) and old (50-79 years), and cross tabulation using chi-square test found no significant differences at baseline ($p=0.054$). This factor was dropped from the analyses. Therefore, there were only four demographic covariates added to the model, which were: Ethnicity: Chinese ($n=162$ versus Indian ($n=21$), versus Malay ($n=24$); Insurance: Insured ($n=135$) versus non-insured ($n=72$); Activity level: Sedentary-light($n=132$) versus Moderate($n=30$) versus Active ($n=45$); Exercise hours: (0-5hours ($n=165$) > 5 hours per week ($n=42$).

8.4.2. Results of Primary Analyses with demographic covariates

The four set of MANCOVA tables, with demographic-covariates were collated in Appendix J-5 (i-iv). When controlled for the demographics, the overall F test for the four MANCOVA were significant at post-test (T2-T1) and at follow-up (T3-T1) for at least one primary endpoints ($p = 0.02$, $p < 0.001$), as well as for all the secondary endpoints ($p < 0.001$, and $p < 0.001$ respectively), suggesting that there were significant between-group differences.

Primary endpoints, T2-T1 with demographic covariate

With the primary endpoints, when controlled for the demographic characteristics, the six measures using T2-T1 scores showed that only the psychological distress symptoms i.e. stress, anxiety depression were significant at the more conservative Bonferroni adjuster $p < 0.008$ ($0.05/6$). Social relationship was significant at the usual $p < 0.05$ level but not at the more conservative level of 0.008 level; and Physical composite score, Family role and social relationship measures were no longer significant. However, the power of these three variables are also low [(48 %, 45%, 69%) as shown in Appendix J-5 (i)].

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Primary endpoints, T3-T1 with demographic covariate adjusted

At follow-up (using T3-T1 change scores) to examine the between-subject groups [experiment (exp) versus control (ctrl)] for the primary endpoint, the overall multivariate F showed that i) groups (exp versus ctrl) and ii) insurance (insured versus non-insured) were significant at $p < 0.05$. Using the conservative Bonferroni adjusted $p = 0.008$ level, the univariate tests showed three measures demonstrate between-group significance. These were social relationship, stress and anxiety.

Social relationship: [F (1, 146) = 11.6, eta squared = 0.08, power of 92%]	} p=0.008
Stress: [F(1, 146) = 13.1, eta squared = 0.09, power of 95%]	
Anxiety: [F(1, 146) = 20.3, eta squared = 0.001, power of 99%]	

Secondary endpoints, T2-T1 with demographic covariate adjusted

The overall multivariate F was significant ($p < 0.001$) for the T2-T1 scores. The univariate tests showed significance for three secondary measures (Selfcare_self efficacy, Cancer behavior_self efficacy and the Proactive coping) at the Bonferroni adjusted $p < 0.001$. Emotional_Self-efficacy was not significant (SESES, $p = 0.05$).

Secondary endpoints, T3-T1 with demographic covariate adjusted

The overall multivariate F was significant ($p < 0.001$) for the T3-T1 scores. Similar pattern was found in the univariate T3-T1 scores which showed statistical significance for all variables except for SESES ($p = 0.036$).

8.4.3 Comparison of Results - With and without the Demographic Covariates

Overall, the Table 8.11 below summarized the differences found at, before and, after demographic covariates were adjusted in the MANCOVA models. Findings were quite consistent except for Physical composite score (T2-T1) and Social relationship (T2-T1) measures and emotion_self efficacy (T2_T1). Physical composite score and emotional_self-efficacy became not significant after the demographic covariates were adjusted. Social relationship variable showed significance at $p < 0.05$, it was not significant at the more conservative bonferroni adjusted $p < 0.008$. At follow up using T3-T1 scores, no changes were observed in the primary endpoints. In the secondary endpoints, the emotional self efficacy became non-significant after adjustment for demographic covariates.

The multivariate F test indicated statistically significant differences between the insurance group: $F(6, 129) = 2.77, p = 0.015$. Individually, the univariate results (Appendix J-5 ii) showed that 'insured' group ($n=78$) had a lower stress scores than the non-insured group ($n=68$) with a mean difference of -3.68 (95% CI -6.5 to -0.88), $p=0.01$.

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Table 8.11

MANCOVA – Comparison of the ‘with’ and ‘without’ demographic covariates

Primary Endpoints	MANCOVA 1 Table 8.3.1 (-without-)	MANCOVA 1* (rpt) (with covariates) Appendix J-5 (i)	MANCOVA 2 Table 8.3.2 (-without-)	MANCOVA 2* (rpt) (with covariates) Appendix J-5 (ii)
Physical CS	0.005**	0.056	0.51	0.46
Family role	0.034*	0.068	0.39	0.26
Social R'ship	0.038*	0.015 **	0.001**	0.001**
Stress	0.001**	<0.001**	<0.001**	<0.001**
Anxiety	0.001**	0.003**	<0.001**	<0.001**
Depression	0.001**	0.003**	0.35	0.31
Secondary Endpoints	MANCOVA 3 Table 8.3.3 (-without-)	MANCOVA 3* (rpt) (with covariates) Appendix J-5 (iii)	MANCOVA 4 Table 8.3.4 (-without-)	MANCOVA 4*(rpt) (with covariates) Appendix J-5 (iv)
SUPPH	< 0.001***	0.001***	0.001***	0.001***
CBI	< 0.001***	< 0.001***	0.001***	0.001***
SESES	0.001***	0.046 *	0.001***	0.036 *
PCI	< 0.001***	0.001***	0.001***	0.001***

* significant at $p < 0.05$; ** significant at $p < 0.008$; *** significant at $p < 0.012$
 NS= not significant

SUPPH = Self care_ self efficacy
 CBI = Cancer behavior_ self efficacy
 SESES = Emotion_ self-efficacy
 PCI = Proactive coping

MANCOVA 1-4 : with no ‘demographic covariate’ added
 MANCOVA 1-4 : with ‘demographic covariates’ added

8.5 Effectiveness of Intervention over time (experimental group)

8.5.1 Overview and Preliminary check for RM ANOVA

This section reports the series of univariate repeated measure ANOVA (RM ANOVA) design or a within-subject design or referred also as a *split-plot in time* analysis (Gill, 1988). The SPSS data was set up similar to the randomized block design situation to compare the 69 experimental subjects' rating on all primary and secondary endpoints. The within-subjects factor is Time (three levels indicating the baseline, posttest and followup) and the dependent variables were physical composite, family role, social relationship (primary endpoints) and cancer specific self efficacy and proactive coping (secondary endpoints) scores. By adding demographic covariates to the usual fixed-effects model, the extent to which a subject characteristic accounts for individual responses to a treatment can be examined.

The reorganization of data as randomized blocks with time as the independent was to avoid the violation of independence of subjects. of the other two timing. Normality test showed that Shapiro–Wilk were mostly significant, but close examinations of the box plots showed the plots were roughly symmetrical, except for depression which had floor effects. Thus, post-hoc comparison was conducted with the Games Howell test for variables (i.e. PCS, FR, Anxiety and Depression) with significant Levene's test. For variables with equal variances assumed, the Turkey test was used.

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Table 8.12

Correlations between Primary endpoints

	PCS 1	PCS 2	PCS 3	FR 1	FR 2	FR 3	SR 1	SR 2	SR 3	Stres 1	Stres 2	Stres 3	Anx 1	Anx 2	Anx 3	Dep 1	Dep 2
PCS1	1.0																
PCS2	.44**	1.0															
PCS3	.43**	.68**	1.0														
FR1	-.43**	-.31**	-.29*	1.00													
FR2	-.17	-.32**	-.22	.59**	1.0												
FR3	-.27*	-.38**	-.51**	.54**	.65**	1.0											
SR1	-.29*	-.20	-.22	.69**	.45**	.57**	1.0										
SR2	-.16	-.27*	-.28*	.42**	.63**	.60**	.60*	1.0									
SR3	-.22	-.36**	-.45**	.47**	.51**	.74**	.64**	.80**	1.0								
Stres1	-.33**	-.35**	-.36**	.52**	.26*	.30*	.45**	.28*	.28*	1.0							
Stres2	.01	-.17	-.12	.22	.38**	.35**	.37**	.48**	.40**	.61**	1.0						
Stres3	-.19	-.35**	-.44**	.26*	.36*	.58**	.35**	.42**	.52**	.44**	.61**	1.0					
Anx1	-.27*	-.36**	-.37**	.47**	.44**	.37**	.37**	.34**	.34**	.76**	.58**	.45**	1.0				
Anx2	.03	-.22	-.12	.29*	.36**	.28*	.27*	.27*	.22	.57**	.75**	.45**	.71**	1.0			
Anx3	-.08	-.27*	-.35**	.36**	.38**	.39**	.27*	.28*	.32**	.58**	.59**	.67**	.79**	.72**	1.0		
Dep1	-.36**	-.24*	-.36**	.54**	.30*	.37**	.46**	.32**	.34**	.85**	.50**	.43**	.68**	.49**	.54**	1.0	
Dep2	-.04	-.27*	-.26*	.41**	.43**	.45**	.39**	.52**	.48**	.53**	.72**	.48**	.56**	.75**	.59**	.58**	1.0
Dep3	-.14	-.33**	-.44**	.38**	.33**	.57**	.39**	.51**	.59**	.46**	.54**	.75**	.47**	.49**	.63**	.56**	.73**
MAX	0.44	0.68	0.51	0.69	0.65	0.60	0.64	0.80	0.59	0.61	0.72	0.70	0.79	0.72	0.63	0.58	0.73

*. Correlation is significant at the 0.05 level (2-tailed).

** . Correlation is significant at the 0.01 level (2-tailed).

PCS=Physical Composite Scores, FR=Family Role; SR=Social Relationship, Stres= Stress, Anx=Anxiety, Dep= Depression

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Table 8.13

Correlations between Secondary endpoints

	SUPP 1	SUPP 2	SUPP 3	CBI 1	CBI 2	CBI 3	SESES 1	SESES 2	SESES 3	PCI 1	PCI 2	PCI 3
SUPP1	1.00											
SUPP2	0.56**	1.00										
SUPP3	0.43**	0.77**	1.00									
Cbi1	0.72**	0.39**	0.39**	1.00								
Cbi2	0.52**	0.80**	0.64**	0.48**	1.00							
Cbi3	0.39**	0.67**	0.72**	0.52**	0.76**	1.00						
SESES1	0.68**	0.41**	0.35**	0.75**	0.59**	0.51**	1.00					
SESES2	0.54**	0.58**	0.48**	0.56**	0.76**	0.63**	0.75**	1.00				
SESES3	0.44**	0.49**	0.52**	0.47**	0.66**	0.79**	0.61**	0.74**	1.00			
PCI1	0.61**	0.54**	0.48**	0.53**	0.43**	0.38**	0.56**	0.51**	0.35**	1.00		
PCI2	0.43**	0.56**	0.52**	0.35**	0.56**	0.46**	0.42**	0.49**	0.42**	0.71**	1.00	
PCI3	0.43**	0.59**	0.63**	0.39**	0.54**	0.62**	0.38**	0.49**	0.57**	0.72**	0.79**	1.00
Max	0.72	0.80	0.71	0.75	0.76	0.78	0.74	0.74	0.57	0.72	0.79	-

*. Correlation is significant at the 0.05 level (2-tailed).

**.. Correlation is significant at the 0.01 level (2-tailed).

SUPP = Self care_Self-efficacy

CBI = Cancer behaviour_Self-efficacy

SESES = Emotional_Self-efficacy

PCI = Proactive coping

1 = Time 1 / baseline/ pretest

2 = Time 2 / post intervention / posttest (4 weeks from baseline)

3 = Time 3 /follow up (8 weeks from baseline or 4 weeks from T2)

Table 8.12 – 8.14 showed the correlation matrices of the variables. Low correlations prevent an inflated Type I error (Field, 2005, p324). The descriptive and post-hoc results were presented in Appendix J-6 i-iv (primary endpoints) and J-7 i-iv (secondary endpoints). The RM ANOVA indicated a significant time effect in the experimental group for most endpoints except for for Social relationship (Table 8.14). There were statistically significant differences in at least one of the time points for Physical composite scores, Family role, and on the three psychological distress symptoms (stress, anxiety and depression).

8.5.2 Hypothesis 3: *Quality of life, Participation and Distress at T1, T2 and T3*

i. Quality of Life (QOL) measure via physical composite scores (PCS)

Based on Table 8.14 and Figure 8.1, the RM ANOVA indicated a significant time effect in the experimental group for PCS: $F(2, 198)=8.07, p=0.0001$. Pair-wise comparison revealed significant differences between - i) T1 and T2 ($p=0.05$) and ii) T1 and T3 ($p=0.001$). Mean score at T2 and at T3 were higher than baseline indicating an increasing QOL scores immediately after intervention. The scores were even higher at follow-up (T3) compared to baseline (T1).

With the demographic covariates, ethnicity accounted for the significant differences in the PCS measures: $F(2, 198) = 7.442, p = 0.001$. Pair wise comparison (and depicted in Figure 8.1) showed that the Malays-others and the Chinese had the highest QOL scores across time compared to Indian. Overall, the QOL for the majority Chinese and the minority Malays (inclusive of the few Eurasians) were higher than the Indian in this study cohort.

ii) Participation in Family Role (FR) and Social Relationship (SR) Tasks:

For family role variable, the RM ANOVA (see Table 8.14 and Figure 8.1) indicated a significant time effect [$F(2, 198) = 3.18, p = 0.04$] on the experimental subjects. Pair-wise comparison for time effect showed a significant difference exist between time at pretest and at follow-up ($p = 0.041$).

With the demographic covariates, 'insurance status' accounted for the significant differences in Family Role (FR) as shown by the overall F test: [$F(1, 198) = 4.18, p = 0.04$]. There were decreasing means scores over time (from T1 to T3) in the limitation in Family role. Pair-wise comparison for insurance status in the experimental group showed that the insured ($n = 45$) present with a significantly lower scores for limitation in participation for Family role tasks than the non-insured ($n = 24$).

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For the Social relationship variable; the RM ANOVA found no significant effect of time. However, the 'Physical Activity' covariate, accounted for the significant difference in social relationship as shown by the overall F test: $F(2, 198)=3.61$, $p=0.029$. The pair-wise comparison found the sedentary-light (physical activity) group ($n=30$) had the highest limitation in social relationship tasks but this was not significant at $p<0.05$.

iii) Psychological Distress Symptoms (Stress, Anxiety and Depression):

Based on Table 8.14 and Figure 8.1, the RM ANOVA indicated that there was a significant time effect for the stress variable as shown by the F test: [$F(2,198) =6.85$, $p=0.001$]. Pairwise comparison showed the stress scores decreases over time, with significant differences between T1 and T2 ($p=0.05$), and T1 and T3 ($p=0.001$).

With the demographic covariates added, Ethnicity and Physical activity accounted for the significant differences on the three symptoms of distress as reported below -

i) Ethnicity: [$F(2,198) =6.86$, $p=0.0001$], and ii) Physical effect: [$F(2,198) =3.27$, $p=0.004$]. Stress scores was significantly lowest in the Chinese ethnic and highest in the Malay ethnic ($p=0.01$). Stress scores was also lowest in the Active (physical activity) group, compared to the sedentary (physical activity) group ($p=0.07$).

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For Anxiety, there was a significant main effect of time [$F(2,198) = 3.69, p=0.02$], and pairwise comparison showed the anxiety scores decreases over time with significant differences between T1 and T3 ($p=0.02$). The demographic covariate that accounted for the individual responses to the treatment on this variable was: ethnicity [$F(2,198) = 5.71, p<0.01$]. Pairwise comparison showed the anxiety scores was significantly lowest in Chinese and highest in Malay ($p=0.01$).

For Depression, there was a significant effect over time [$F(2,198) = 5.72, p<0.01$]. Pairwise comparison showed the depression scores decreases over time, with significant differences between T1 and T2 ($p=0.02$) and between T1 and T3 ($p<0.01$). The demographic covariate that accounted for the individual responses to the treatment on this variable was: ethnicity [$F(2,198) = 6.33, p<0.01$]. Pairwise comparison showed that depression was lowest in Chinese compared to Indian ($p=0.02$) and when compared to Malay ($p=0.02$).

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Table 8.14

Effectiveness at Within Group - Quality of Life, Participation, Distress

Dependent Variables	Source	Type III Sum of Squares	Mean Square	F	Sig.	Partial Eta Squared	Power ^b
Physical Composite Score (QOL)	TIME	534.67	267.33	8.07	0.00	0.07	0.95
	Ethnic	492.98	246.49	7.44	0.00	0.07	0.93
Family Role (IPA)	TIME	2.23	1.11	3.18	0.04	0.03	0.60
	Insurance	1.46	1.46	4.18	0.04	0.02	0.53
Social Relationship	Physical activity	1.93	0.96	3.61	0.02	0.03	0.66
Stress	TIME	664.85	332.42	6.85	0.00	0.06	0.91
	Ethnic	666.36	333.18	6.86	0.00	0.06	0.91
	Physical activity	317.70	158.85	3.27	0.04	0.03	0.61
Anxiety	TIME	277.05	138.52	3.69	0.02	0.03	0.67
	Ethnic	428.09	214.05	5.71	0.00	0.05	0.86
Depression	TIME	500.35	250.18	5.72	0.00	0.05	0.86
	Ethnic	553.98	276.99	6.33	0.00	0.06	0.89

a. Computed using alpha = 0.05; df (2, 198)

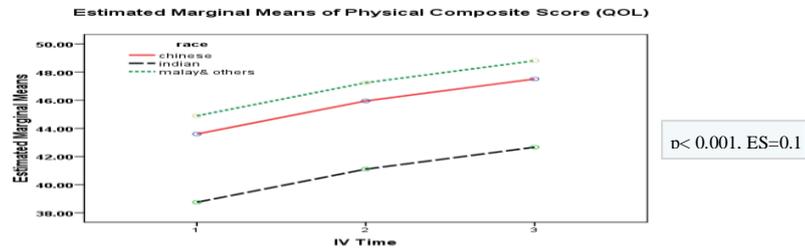
(See Appendix J-6 i-iv for descriptive and pairwise comparison on primary endpoints)

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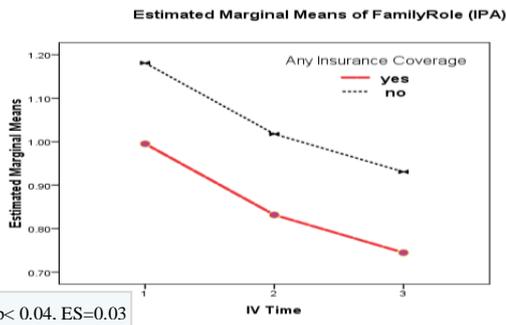
Figure 8.1

Effectiveness within group - Quality of life, Participation, Distress

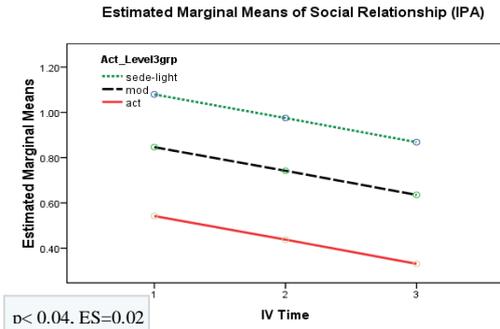
QOL: Physical composite role



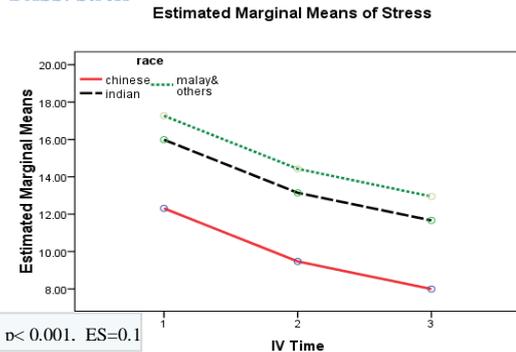
IPA: Family role



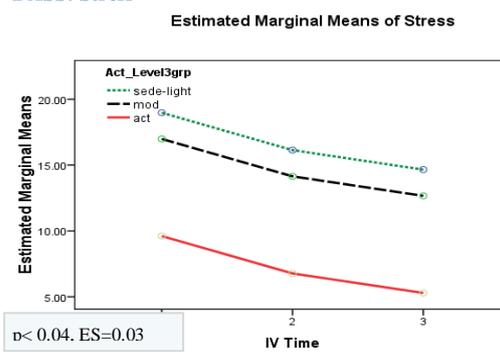
IPA: Social Relationship



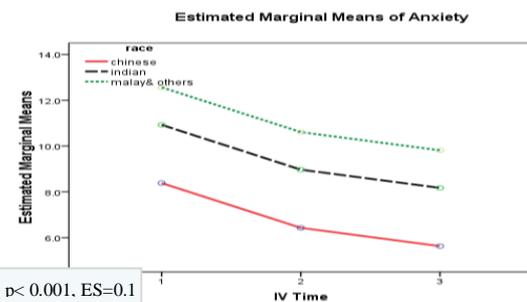
DASS: Stress



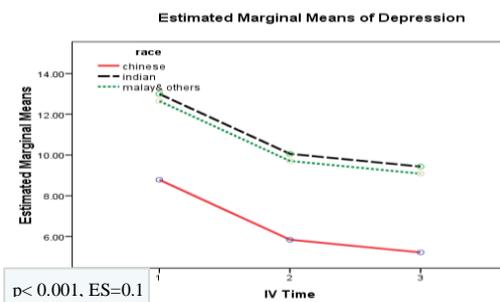
DASS: Stress



DASS: Anxiety



DASS: Depression



Levene's test significant for PCS, FR, Anxiety and Depression (Games Howell's equal variance not assumed used for posthoc multiple comparison). For others, posthoc comparison using Tukey

8.5.3 Hypothesis 4: Self efficacy and Proactive Coping at T1, T2 and T3

Table 8.15 and Figure 8.2 showed the Univariate RM ANOVA tests on the four secondary dependent variables. As Levene's test was not significant, suggesting equal variances for all the four variables, the Tukey's test was used. Tukey's test examined large number of means and controls Type-I error rate well but lacks statistical power (Field, 2005, p340). The RM ANOVA indicated that there were significant time effect for all the cancer specific self-efficacy ($p < 0.001$, $p = 0.01$, $p = 0.02$, $p < 0.001$) and for proactive coping ($p = 0.04$, $p = 0.05$, $p = 0.04$, $p = 0.03$). The covariates accounting for the significant differences in the secondary endpoints were reported below.

i) *Self care_Self-efficacy (SUPPH)*

The RM ANOVA showed significant differences in at least one time point in the main effect of : Time- $F(2, 198) = 6.12$, $p = 0.003$; Ethnicity- $F(2, 198) = 4.43$, $p = 0.013$; and Physical activity- $F(2, 198) = 3.25$, $p = 0.041$. Post-hoc comparison for 'time' showed a significant increase of scores over time, between T1 and T2 ($p = 0.04$) and between T1 and T3 (0.001) indicating that the SAMA intervention improves the specific self-efficacy at immediate and at follow up. Self care_self efficacy of the Indian were found higher than the Chinese ($p = 0.01$), while physically-active women showed higher self efficacy than the sedentary-light women ($p = 0.04$).

ii. Cancer behaviour _self-efficacy (CBI)

The RM ANOVA showed significant differences in at least one time point in the main effect of Time: $F(2, 198) = 4.83, p=0.009$ and Physical activity $F(2,198) = 3.11, p=0.047$. Post-hoc comparison for the effect of 'time' showed a significant increase of scores over time, between T1 and T2 ($p=0.037$) and between T1 and T3 (0.003) indicating that intervention improves the CBI at immediate and at follow up. Post hoc for the physical activity factor showed that the active group had significantly highest CBI scores and the sedentary-light group had the lowest scores ($p=0.045$).

iii. Emotional _self efficacy (SESES)

The RM ANOVA showed significant differences in at least one time point in the main effect of Time: $F(2, 198) = 4.26, p=0.015$ and Physical activity $F(2,198) = 3.29, p=0.039$. Post-hoc comparison for the effect of 'time' showed a significant increase of scores over time, between T1 and T3 ($p=0.02$) only. The physically-active women were found to have highest SESES scores than the sedentary-light group ($p=0.04$).

iv. Proactive Coping(PCI)

The RM ANOVA indicated that there were significant time effect [$F(2, 198)= 8.39, p<0.001$], ethnic effect [$F(2, 198)= 15.35, p < 0.001$], and physical activity effect [$F(2, 198) = 3.76, p=0.025$].

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Post hoc comparison for effect of time showed increased PCI scores between T1 and T2 ($p=0.03$) and T1 and T3 ($p<0.001$). Ethnicity accounted for the individual responses to the treatment on the PCI where the Indian are found with significantly higher proactive coping than Chinese ($p <0.001$) as well as higher than the Malay ($p<0.001$). With physical activity as covariate, women with a moderate-level of physical activity had higher PCI than the women who were sedentary ($p< 0.001$).

Table 8.15

Effectiveness at within-group - Self-efficacy, Proactive copings

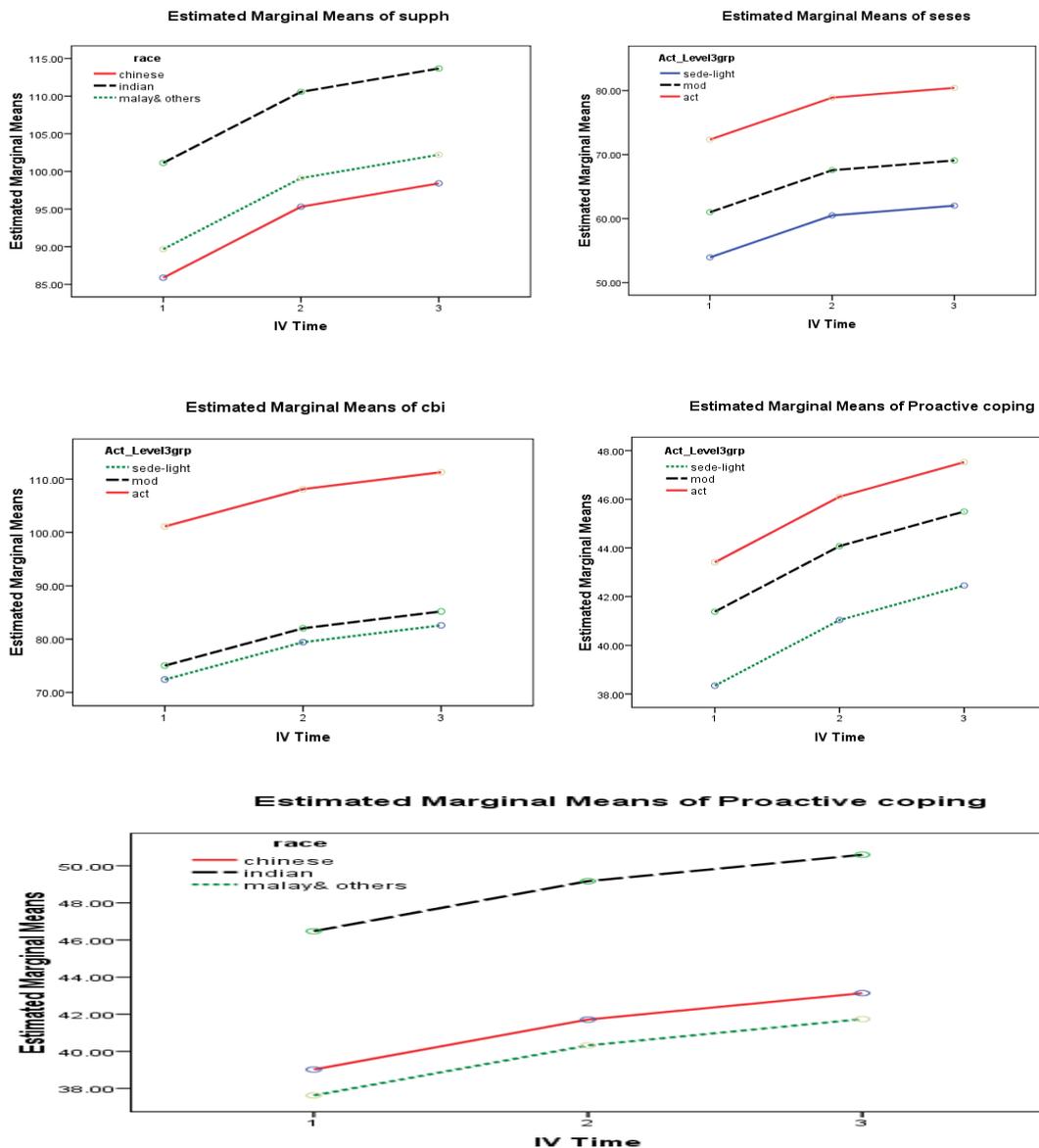
Dependent variable	Source	Type III Sum of Squares	Mean Square	F	Sig.	Partial Eta Squared	Observed Power ^b
SUPPH	TIME	5883.19	2941.59	6.11	0.00	0.05	0.88
	Ethnic	4260.08	2130.04	4.43	0.01	0.04	0.75
	Physical activity	3119.83	1559.91	3.24	0.04	0.03	0.61
CBI	TIME	3730.50	1865.25	4.83	0.01	0.04	0.79
	Physical activity	2402.77	1201.30	3.11	0.05	0.03	0.59
SESES	TIME	2539.02	1269.51	4.25	0.02	0.04	0.73
	Physical activity	1962.75	981.37	3.29	0.04	0.03	0.62
Proactive Coping	TIME	603.16	301.58	8.39	0.00	0.07	0.96
	Ethnic	1103.80	551.90	15.35	0.00	0.13	0.99
	Physical activity	270.35	135.17	3.76	0.03	0.03	0.68

a. Computed using alpha = 0.05; df (2, 198)
 (See Appendix J-7 i-iv for descriptive and pairwise comparison)

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Figure 8.2

Effectiveness at Within-group - Self efficacy and Proactive coping



Levene's test not significant for all secondary endpoints (Tukey's equal-variance assumed used for posthoc multiple comparison).

Secondary endpoints:

- SUPPH= Self care_Self-efficacy
- SESES = emotional_Self-efficacy
- CBI = self-efficacy_cancer behaviour
- PCI = Proactive coping

8.6 Summary

8.6.1 Primary ITT Analyses – Between-groups Multivariate Analyses

This chapter presents the results of the i) Primary Analyses: the between-group analyses from the four MANCOVA ‘without’ and ‘with’ demographic covariates added to the model, and ii) Secondary Analyses: the within group analyses using univariate repeated measure ANOVA (split-plot design). The results were almost similar except for the Physical composite scores of the QOL measure.

The first MANCOVA (between-groups at post-test using T2-T1 change scores) showed that the differences between the groups were significant for only four dependents (Social Relationship, and the three Psychological Distress symptoms). The between-group differences were not statistically significant for the Physical composite (PCS) and the Limitation in Family role (FR) scores. With the demographics covariates added, the differences between-groups at follow up (using T3-T1 change score) were not significant for PCS, FR and depression.

8.6.2 Secondary ITT Analyses - Within group Univariate Analyses (RM ANOVA)

The ten independent analyses of RM ANOVA with demographic covariates added to the model involved - six analyses for primary endpoints and four for secondary endpoints. The demographic covariates were added to the model to examine the extent to which a subject-characteristic accounts for individual responses to a treatment. Overall, significant time effect was found in most primary endpoints (except social relationship) and in all secondary endpoints. By convention, the f^2 effect sizes (for analysis of variance) of 0.02, 0.15, and 0.35 are considered small, medium and large effect respectively (M. Cohen, 1998). Thus the effect sizes of the differences were small to medium.

Of the four demographic covariates, ethnicity accounted for the significant treatment effect at four of the primary endpoints (Table 8.14) and at two of the secondary endpoints (Table 8.15). Physical Activity accounted for the significant effect in all four secondary dependents, but only the differences between sedentary-light group versus active group were significant for selfcare_self-efficacy (SUPPH, $p=0.04$) and cancer-behaviour_self-efficacy(CBI, $p=0.05$). The active group showed higher mean scores suggesting that the physically active responded better to treatment in terms of improved cancer self-efficacy (self care and cancer behaviour).

9

DISCUSSION AND CONCLUSION

Theory-led interventions are more likely to be successful
than those developed without the benefit of
a theoretical perspective
(K. Glanz et al., 2005).

9.1 Overview

This chapter presents the discussion, conclusion and implications of this study. The discussion and conclusion in this chapter encompasses the exploration, development and evaluation of a self-management intervention for women newly diagnosed with breast cancer. The findings from this study, starting at the preclinical theory phase to the modeling phase and progressing to the exploratory phase and finally at the definitive CCT phase have yielded a continuum of increasing research evidence. The preclinical phase involved the integration of input from the theoretical explorations of breast cancer care, self-management philosophy for chronic conditions and the qualitative findings from a cohort of Malaysian women with breast cancer. The modeling phase involved the planning of a self-management program based on insights and findings from the preclinical phase, resulting in the development of a 4-week SAMA ('Staying Abreast, Moving Ahead') program with its Participant's Workbook and a Facilitator's Manual. In the exploratory phase, the pilot study was used to evaluate the SAMA intervention process which informed and verified the needs for it to be tested further on a larger scale Clinical Controlled Trial (CCT). The CCT used a block design to test the differential impact of the SAMA program with an experimental and a control group. The results of the intent-to-treat between-group multivariate analyses and the within-group univariate Analyses of variances were presented in Chapter 8. Overall, several conclusions can be drawn from this study.

9.2 Discussion of Key Findings

9.2.1 Self-management Intervention for Women with breast cancer

This study is one of the first studies to develop and evaluate a comprehensive program of a self-management intervention with women newly diagnosed with breast cancer. The initial needs assessment study verified that women need a broad based intervention to help them deal with the wider aspects of living with breast cancer. It verified that intervention should covers, not just the medical aspect (common in medical care approach) or the psychosocial aspects (common in cancer care), but a holistic program that encompasses all medical, health, social and emotional tasks (Loh, Packer, Yip, & Low, 2007).

The CCT provide the evidence to support the importance of self-management education and psychosocial support, and is consistent with the growing body of literature highlighting the positive effect of systematic efforts to increase patients' knowledge, skills, and confidence in managing the condition (Norris, Engelgau, & Narayan, 2001).

9.2.2 Impact of SAMA on Women with breast cancer

This study has provided strong level evidence of the comparative effectiveness of the SAMA intervention program in enabling self management. Compared to usual-care (control), the 4-week SAMA program was successful in significantly reducing stress, anxiety and depression, reducing limitation in social-relationship participation and improving the cancer-specific self-efficacy as well as proactive coping (elaborated under its specific headings below). Overall, the differential impact of the 4week SAMA program intervention and the Usual Care for a cohort of Malaysian women with breast cancer have been positively supported by the statistically significant findings from the multivariate analyses of co variances. At post-intervention, the experimental group when compared with patients receiving usual care, showed significantly better scores on the Physical Composite scores, with a large percentage of change scores differences (Figure 7.5) at T2-T1 (5.46% versus -0.27%, $p= 0.014$) and also (but lesser) at T3-T1 (2.84% versus 1.56%, $p=0.49$). This suggests that SAMA program had a greater impact at immediate post intervention compared to the 4-week follow-up. Furthermore, the efficacy of the program is supported by the women's report on their improved level of confidence in their knowledge about breast cancer via the fidelity check. This suggests that with an increased knowledge, their confidence level increased and as such their self management skills also improved.

i. Impact of SAMA on the Quality of Life

The multivariate analyses with demographic covariates adjusted showed a non-significant between-groups difference for physical composite scores on the Quality of Life scale at post-test ($p=0.056$, power= 48%) and at follow-up ($p=0.46$, power = 10%). Univariate RM ANOVA of within-subjects in the experimental group showed that the favorable changes over time in QOL were significant ($p=0.0001$).

Several points related to the findings are discussed here. Firstly, the physical composite scores showed low power (48% at post-test and 10% at follow-up) and low internal reliability PCS ($r = 0.65$). Secondly, the within group and reliable change index showed significant favorable changes in the experimental group, and this was tested in the RM ANOVA. These statistics raised doubts whether the PCS scale was able to represent QOL in women with breast cancer, since the MCS had been dropped due to low internal reliabilities ($r= 0.2$). As there is doubt that the SF-36 summary scales may not accurately summarise underlying subscales (D. Wilson, Parsons, & Tucker, 2000), perhaps a better scale is needed or the component scores should be interpreted with caution and only in combination with profile scores (Taft, Karlsson, & Sullivan, 2001).

In another study involving about 75 chronic (atopic dermatitis) patients, QOL and disease control were found to be related with low scores in SF-36 ($r^2=0.20$) and with greater correlation for SF-36 mental components (Coghi, Bortoletto, Sampaio, de Andrade, & Aoki, 2007). This study provided the research evidence which demonstrated that the mental component, and not the physical component, showed the greatest impact on scores for quality of life. Since the use of the SF36 summary scores had been cautioned as not accurately reflecting underlying subscales (Reed, 1998; D. Wilson et al., 2000), replication of this study is warranted. However, more importantly, the use of a wider profile from the QOL subscales should be included and studied together instead of mere reliance on the sole PCS scale.

ii. *Impact of SAMA on Participation*

The differential impact on participation in life roles were measured using two measures: i) Family Role (FR) and ii) Social Role (SR). This study found that intervention had statistically significant impact on social relationship role but not on family role. Having an insurance coverage accounts for the differences between the subgroups, where the insured showed less limitation in family role [FR: $F(2, 198) = 4.18, p=0.042, \text{power of } 53\%$].

Multivariate covariance analyses showed that the between-group differences in Family role were not significant (after Bonferroni adjustment) at posttest (T2-T1: $p=0.068$, power = 45%) and at follow-up (T3-T1: $p=0.26$, power= 20%), suggesting that there were no real differences between the groups. However, the power of the tests was rather low. Univariate RM ANOVA showed there was significant time effect in the experimental group, with a greater reduction at limitations of family-role across time. Figure 7.3 showed a lesser reduction in the control group. One postulation on the changes found is that, in the context of Asian extended families, illnesses draw families together as revealed in the focus groups (chapter 3) and house roles are shared. Also, the statistically low power of family role variable (FR=45% and 20%) may suggest a likelihood of Type II error (J. Williams, Hathaway, Kloster, & Layne, 1997).

For Social relationship roles, differential impact of the SAMA program on the between group scores were significant at post-test (T2_T1: $p=0.015$, power of 69%) and also at follow-up (T3-T1: $p<0.001$, power of 94%), indicating that the impact of intervention was immediate and had improved further at follow-up. In constrast, increased limitation was found in control group (see Figure 7.3). Nevertheless, the effect sizes (partial eta square) were small. For within group effect, the Univariate RM ANOVA showed that the reduction in limitation of social-relationship in the experimental group was not significant over time.

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Doubt is cast on the sensitivity of the IPA tool used to measure outcomes in women with breast cancer population (a non traditional group of chronic disease) as the results showed low variability in both Family role and Social relationships scales. Correspondence with the IPA developer (Cardol, 2004) on 20th March 2008, confirmed that it was designed for a more physically chronic population.

However, a possible reason for the improvement in Social relationship is that the tool specifically measures improvement in intimate relationships (see appendix D-3, item 6f). The 4-week SAMA program addresses issues related to the myths surrounding fear of intimacy as revealed in the focus group (see Chapter 3). Thus women in the experimental group received information to correct these myths, enabling better intimate relationships and enhancing social support. These findings support that the factors associated with participation in treatment and in life situations are potentially modifiable (P. Ganz, Desmond, Belin, Meyerowitz, & Rowland, 1999; Maly, Umezawa, Leake, & Silliman, 2004). As an example, social support has been linked with better self-management skills (Falagas & et.al., 2007; Gallant, 2003; Lehto et al., 2005). Social support is a health enhancing parameter in cancer care, since socially isolated women have higher mortality (C. Kroenke, L. Kubzansky, E. Schernhammer, M. Holmes, & I. Kawachi, 2006).

iii. Impact of SAMA on Psychological Distress Symptoms

Multivariate analyses showed significant differences between groups on all three measures of the psychological distress at post-test, but for only stress and anxiety (not depression) at follow-up (whether the demographic covariates were adjusted or not in the MANCOVA models). Univariate RM ANOVA showed significant improvement over time in the stress ($p < 0.01$), anxiety ($p = 0.02$) and depression ($p < 0.01$) variables. The study found that the usual care (control) group showed deterioration while the experimental group improved on their psychological wellbeing (see Figure 8.1).

The fact that there were improvements and no overall psychological deterioration within the experimental group suggests that the SAMA program had important, beneficial effects since lowered psychological morbidity promotes adjustment (Cunningham et al., 1999; Fawzy et al., 2000). There may be a need to study the effect of reduced psychological distress especially on whether a reduced depression can be sustained at follow up (T3) or even longer period. The importance of lowered depressive symptoms had been demonstrated in a study predicting survival in cancer patients ($n = 205$), whereby the depressive symptom had been shown to be the most consistent psychological predictor of shortened survival time (K. Brown, Levy, Rosberger, & Edgar, 2003).

In summary, the three theoretically-driven choices of outcome measures showed that these outcome variables were closely related to one another. The findings from this study are supported by research findings whereby anxiety, depression, and/or impaired social functioning roles have been showed to subsequently and adversely affected quality of life (Hansson, 2002; Shim et al., 2006). With the secondary endpoints, this study's concurrent findings show a reduced psychological distress with an increased self-efficacy and proactive coping. Studies have shown that perceived self-efficacy correlated highly with health behaviours (R. Schwarzer & Fuchs, 1995). Specifically, low emotional self-efficacy correlates with higher risk for traumatic stress symptoms (Koopman et al., 2002).

iv. Impact of SAMA on self-efficacy and proactive copings

Multivariate analyses controlled for the demographic covariates (race, insurance, exercise and activity levels) were found to show significant between-group differences for two specific self-efficacy measures and proactive coping after the Bonferroni adjustment at $p=0.0125$. The specific self-efficacy involved were: i) self care (SUPPH) and ii) cancer behavior (CBI). The other specific self efficacy i.e. emotional_self-efficacy was not significant after Bonferroni adjustment (SESES, $p=0.046$ at post-test and $p=0.036$ at follow-up).

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The univariate RM ANOVA showed significant improvement over time in all these four variables in the experimental group ($p < 0.001$ to $p = 0.02$). This reduced psychological distress and the improved self-efficacy in the experimental group is supported by research findings that self-efficacy is predictive of low psychological distress (Siu et al., 2007; Wu et al., 2004). The finding here is also supported by a systematic review conducted by the Australian Primary Health Care Research Institute on managing chronic diseases in primary care - self-management programs found to be most effective were those that developed self-efficacy in relation to specific behaviours rather than those that were more general (Zwar et al., 2005).

In addition, the proactive coping style – reported as attributed to about half of the variance in psychological adjustment to cancer (K. Glanz & Lerman, 1992), was found improved with the 4-week intervention. In one study ($n = 180$ Type II diabetes) that uses both self-efficacy and proactive coping in its intervention, it was demonstrated that significant improvement occurred for proactive skills, goal attainment and confidence in dealing with self-management issues (B. Thoolen et al., 2008). Therefore, proactive coping should also be regarded as an important component in women's self management for breast cancer.

v. Participants' characteristic accounting for the Impact

The multivariate analyses and univariate RM ANOVA with race, insurance status, exercise status and physical activity (demographic covariates) added have found that ethnic group, insurance and physical activity seems to be influential and accounted for significant outcomes in the univariate models. In this sample, participants having chemotherapy were higher in control group than the experimental group (64 % versus 41%) and those having radiotherapy were higher in experimental group (23% versus 5%). Both chemotherapy (Campora et al., 1992; S. Newell et al., 1999; Schreier & Williams, 2004) and radiation (Rowland & Holland, 1990) have been linked to higher anxiety and depression in patients.

However, the univariate RM ANOVA showed that women who participated in the SAMA program showed lowered psychological distress over time, indicating that intervention had an impact on distress level. Post-hoc results indicated that ethnicity accounted for some significant changes in the subjects' outcome measures. The Chinese ethnic group had significantly lower level of stress compared to the Indian group ($p=0.08$), and compared to the Malay group ($p=0.01$). They also showed lower level of depression compared to the other two ethnic group (Malay group, $p=0.02$ and Indian group, $p=0.02$).

In this study, there were slightly more single and younger women in the control group than in the experimental group. Studies have shown that younger women are more distressed and have poorer adjustment (Avis et al., 2005; Lehto et al., 2005). However, age was not a significant confounding factor for this study cohort as demonstrated in both the multivariate and univariate analyses.

Demographically, the control group had more women with larger tumours (>5cm; 15 versus 9 % in experimental). However, there were more newly diagnosed cases within three months in the experimental group, and more women with lymph nodes tested positive (10% versus 3% in control), and undertaking the costly Taxol drug (10% versus 0% in control) and/or expensive Herceptin therapy (6% versus 3% in control). Also, there were more working women in the experimental group (51% versus 35% in control, although it has been argued that work could both be a health enhancing factor or a source of distress in the focus groups (Chapter 2). These factors may have contributed to the higher percentage of women in the experimental group who were clinically stressed (at baseline) although the clinically anxious and depressed patients were roughly proportionate for both groups. The findings in this study are supported by studies which confirmed that psychosocial variables are the more important determinants of health outcomes than cancer type or cancer treatment (Lehto et al., 2005; Michael et al., 2002).

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In addition, this study found that the active women (n=16) have lowered stress levels compared to the sedentary-light group, have increased self care_self-efficacy [p=0.04, power 61%] and increased cancer behavior_self efficacy [p=0.05, power 59%]. A breast cancer risk reduction of 25-30% -accrued from 47 out of 62 studies was demonstrated in people with increased physical activity (CM. Friedenreich & Cust, 2008). Data from 4393 cases of invasive breast cancer also demonstrated that weight loss after menopause is associated with a decreased risk of breast cancer (A. H. Eliassen, G. A. Colditz, B. Rosner, W. C. Willett, & S. E. Hankinson, 2006). Another study showed that physical activity is correlated with significant improvement in quality of life ($p < 0.001$) in cancer survivors (Burham & Wilcox, 2002). The outcome linking women who exercise with low level of stress and high self-efficacy is a favourable finding as evidence suggests that exercise influences other aspects of the cancer experience including cancer detection, coping, rehabilitation and survival after diagnosis (CM. Friedenreich & Orenstein, 2002). Thus, physical activity as a modifiable risk factor should be included in the self-management education. These evidences from other research studies provide support the findings on physical activity from this study, and they underline the importance of promoting physically active lifestyles in patients. The content on risk reduction (to include weight management strategies) should be incorporated in all self-management intervention.

9.3 Contribution of this study

9.3.1 Contribution 1: Theory-led Intervention for Breast cancer

This study in part addresses the call from previous researchers for theory-led self-management intervention so that the factors that contribute to the effectiveness of the intervention can be better understood.

By acknowledging breast cancer condition as a chronic condition, this study which incorporated self-management philosophy and perspectives on cancer care showed that the newly developed program (informed by theory and needs assessment) is feasible and timely. Its corresponding Manual and Workbook, gives planners the tools to move beyond intuition in designing health intervention based on understanding of behaviors (K. Glanz et al., 2005).

9.3.2 Contribution 2: Self-management support in multicultural Malaysia

The study showed that a 4-week self-management program for the multicultural-multiethnic Malaysian women with breast cancer was feasible and acceptable. The cross-cultural contributions from this study (using an early intervention approach) include i) providing a platform where women of different background come together to learn, challenge each other misconception and support each other on the three common tasks. The small group approach allows each women the opportunity to reappraise their beliefs by looking for research evidence to refute, accept or to reach a consensus on the best way to self manage the illness. This is an economical and a practical early-intervention program for addressing issues simultaneously in a group setting and drawing resources from the expert-patients and from evidence-based research finding.

Promoting and encouraging self-management intervention is regarded as a Level-II research evidence from at least one properly-designed randomised controlled trial (RACGP, 2003). Many studies have also demonstrated that self-management program is successful across ethnic groups in Hong Kong (Siu et al., 2007), China (Fu et al., 2003) and across culturally and linguistically diverse populations in Australia (Swerissen et al., 2006). This SAMA program is a potential blueprint for bridging the unmet needs of women not address by the medical-model health system.

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The Lesson from Malaysia

Self management education provided the multiethnic and information-lacking Malaysian women a chance to learn proactively and to self manage at a very early stage during the disease. The lesson from Malaysia is that self management for women with breast cancer implemented early and proactively in a group approach can facilitate their medical, emotional and role adjustments, and improves health outcomes. This is inspite of the heterogeneity in ethnicity, culture, belief, religion and a prevailing acute model of healthcare system.

The Lessons for Malaysians.

Adjustment to a diagnosis of cancer depends on many factors related to patient-derived (intrapersonal and interpersonal), cancer-derived (severity and treatment), society-derived (open discussion, knowledge and popular beliefs) factors (Holland & Gooen-Piels, 2002). Specific lessons for Malaysia can be derived from the spectrum of breast cancer presentation.

- i. The mean tumor size at presentation is 5.4 cm, whilst 50-60% of the newly diagnose cases are at stage 3 and 4 (Abdullah & Yip, 2003). About 52.3% of the new cases in 2002 were women below 50 years old (National Cancer Registry, 2003), and peak around 40-49 years (Abdullah & Yip, 2003).

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Unfortunately, prognosis of breast cancer in young women is generally considered to be unfavourable. Early detection of breast cancer offers the most promising possibility to optimize the diagnosis and treatment of breast cancer and, as a result, reduce breast cancer mortality and improve health related quality of life in women (Ute-Susann, Altland, Duda, Engel, & al., 2009). Thus, a lesson here is for Malaysian women to be vigilant and aim for early detection.

ii. Women in Malaysia have a 1 in 19 chance of getting breast cancer, and a 1:16 for Chinese, 1:16 for Indian, and 1 in 28 for Malay in their lifetime (NCR, 2003). Although all three aspects of medical, emotion role tasks were regarded as fundamental needs by Malaysian women, studies are needed to determine if Malaysian adjusted similarly and if not, which ethnic group adjusts better. Thus, study on the differences in the rates and patterns of how Malaysian women adjust; what are the barriers and facilitators that promote adjustment; and also how the prevailing cultural myths hinder adjustment are needed.

iii) With only 16 breast clinic for 23 million population in Malaysia, we are way below the guide of 1:16 million (Abdullah & Yip, 2003). The lesson here for Malaysia is that we need more expertise services and more clinics to facilitate early detection-treatment. There are many cases where women still kept their breast even when oversized tumors are fungated with bad odour. A shift in the cognitive mindset from a reactive to a preventive action is crucial. Malaysians are far behind the concept of prophylactic mastectomy.

9.3.3 Contribution 3: The role of cancer self-efficacy in cancer care

Self-efficacy is regarded as a key psychological resource in adapting to chronic physical illness, but the construct has received less attention among individuals coping with cancer (Manne et al., 2008). This study uses a cluster of specific cancer self-efficacy which showed significant differences between groups, as well as, significant differences in the within-group changes consistently in these three scales in the CCT. Thus, it give rise to a postulation that perhaps the cancer self-efficacy variables may be reciprocally related and/or mutually reinforcing in cancer care.

The study raises many research questions on cancer self efficacy and provides the preliminary evidence to support the role of cancer self efficacy in cancer care. In short, integration of cancer specific self-efficacy in intervention should be considered as they have potential benefits. Future exploratory and confirmatory factor analysis should be explored to improve understanding of the causal effect of the relationships of the scales and/ or to generate a one factor cancer self-efficacy tool.

9.4 Strengths and Limitations

9.4.1 Strengths of the Study

Firstly, this study adopted a rather rigorous approach by utilizing the MRC (UK) framework for complex intervention which provides a continuum of increasing research evidences. The study investigated the effect of the SAMA program on women newly diagnosed with breast cancer. SAMA derived from a theory-driven initiative based on a strategic planning framework and thus, is more likely to succeed (Brazil, Ozer, Cloutier, Levine, & Stryer, 2005; K. Glanz et al., 2005).

Secondly, recognizing that attrition rate has always been an issue in any cancer trial, strategies were employed to ensure minimal dropouts from the intervention. These strategies (repeated reminders, proactive planning of timing of data gathering just before the first session and just after the last session, encouragements from buddies) were pursued bearing in mind that imputation of missing values is not a substitute for complete data and cannot be rectified with an Intent-to-treat analyses (C. Wright & Sim, 2003), even though ITT may give an unbiased estimate of treatment effect (Heritier et al., 2003). However, it was more difficult to prevent missing data from the repeated measures in the control arm where the women do not receive the program.

Thirdly, the selection of the tools relied on theory-informed choices. Thus ensuring that the clusters of tools measure outcomes as well as the postulated mechanism for change (i.e self efficacy, education, copings)

Fourthly, the study adhered to the recommended strategy for evaluation of evidence (Rychetnik, Frommer, Hawe, & Shiell, 2002) by distinguishing between the fidelity of the evaluation process in detecting the success or failure of the SAMA intervention program (reported in Chapter 7) and the success or failure of the intervention itself (reported in Chapter 8).

Finally, the analyses followed the conservative approach of ‘intention to treat’ design to reduce the bias in favor of treatment (which occurs in ‘on-protocol’ analysis). Having no statistically between-groups differences in the 10 outcome variables at baseline also strengthened the confidence of all subsequent findings. The use of MANCOVA was justifiably the most effective for multiple dependents as it equates groups on extraneous variables (Portney & Watkins, 2000) and to reduces Type 1 errors (Pallant, 2002) so that the effect of independent variable can be seen more clearly.

9.4.2 Limitations of study

Firstly, although the study involved a control group, it does not include having a third (placebo) group to receive an alternative intervention (e.g. yoga etc), which can ensure a clearer effect on the SAMA program. However, given that the nature of the self-management intervention is a new concept in Malaysia, the researcher felt that any changes in this initial study would be adequate.

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Secondly, although double-blind study would be better, this was not feasible since the treatment could not be offered as a placebo as in many rehabilitation intervention. Thus, a single-blind study was carried out where only the tester is blinded.

Thirdly, true randomization to reduce the threats to external validity offered by a randomized controlled trial, although not impossible, was found to be rather challenging for this study. With limited funding, resources and manpower, the CCT block design was adopted in favour of the gold standard RCT. CCT reduces threats on internal validity as the possibility of diffusion (contamination) is high due to three issues.

One, the breast cancer clinic is normally confined.

Two, intervention continues for 4 weeks and thus increases the chances for patient contacts. Three, the risk of compensatory rivalry and resentful demoralization from the control group, and/or compensatory equalization by staff who helped out (W. M. K. Trochim, 2002) is higher when the control group meets the experimental group.

9.5 Clinical Implications and Recommendations for Future Studies

9.5.1 Clinical Implications

The findings of this study address both the treatment effect for the SAMA program and the needs that have emerged from the review in the preclinical phase. The SAMA program evidenced positive findings as measured in all primary and secondary endpoints, albeit low effect sizes and some low statistical test power.

The SAMA program with its favourable results can be disseminated throughout breast care centres in Malaysia as an early-intervention strategy. Further effort are needed to ensure SAMA is not a stand-alone program, as this was cautioned as an ineffective approach (Glasgow et al., 2002). Thus, efforts to integrate SAMA into routine medical care for women with breast cancer should be implemented along a concept of a total care. Primary healthcare is reported as an ideal setting for supporting CDSM and attempts in other countries to incorporate self-management education activities into the healthcare sector have faced setbacks due to inadequate integration into primary care (Jordan & Osborne, 2007). However, the more critical factor is perhaps the timing of the program i.e. the when and not where, since women newly diagnosed should be targeted earlier.

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The strength of the SAMA program is in its eclectic blend of techniques with consideration on the needs to address breast cancer from a psychosocial oncology care perspective, and from, a broad-based self-management care perspective. Also, one of the hallmark of the management of chronic illnesses is the patient and provider partnerships (T. Bodenheimer et al., 2002) which is an intended feature of the SAMA program in accordance with the expressed needs of women.

The 4-week SAMA program addresses the cancer specific self-efficacy to enhance self-management. This beneficial effort is supported by research evidence indicating that high self-efficacy promote symptom management (Giese-Davis J, Koopman C, L, & al., 2002) and behavioral change in women with breast cancer (Burgess et al., 2008; EL. Lev, 2001; T. Merluzzi et al., 2001).

This finding can be used to optimize clinical practice (Kottke et al., 2008) so that training is targeted at the potential role of cancer self-efficacy as a potent mechanism for successful self management behaviors in women.

Self-management intervention program for Women with breast cancer

This study provides the evidence that the SAMA, as a broad based, self-management intervention program for women with breast cancer is beneficial. The evidence that both medical and nonmedical tasks are important should prompt a special task force to review the Malaysian Clinical Practice Guidelines (CPG) for women with breast cancer or to develop a specific CPG for self-management care of women, ensuring that the wider needs of women are acknowledged.

Also, distress level is reduced considerably with the 4 week SAMA program, indicating that the 4 week program has significant effect on the subjects ($p < 0.000$ Bonferroni adjusted). In this study, the Chinese women and the physically active women seemingly benefitted most from the intervention. Why and how the other ethnic groups responded is inconclusive due to small representation, but it must be noted that women in general reported the same level of need for cancer knowledge, skills and support as found in the focus groups.

This study has also found that a high prevalence of distress at baseline of up to about 30 percent. From a clinical perspective, the detrimental results in the control group (see Figure 7.3 and Figure 7.4) suggest that support is needed. This provided the evidence for supporting the call for distress to be recognized as the 6th vital sign in cancer care (Bultz & Carlson, 2005) There is a need for distress to be routinely monitored like other vital signs to reduce the threats of cancer in daily living. Patients, families, and treatment teams should be informed that management of distress is an integral part of total medical care (NCCN, 2008).

9.5.2 Recommendations for Future Studies

This research has raised as many questions as it has potentially answered. It is encouraging that the consistency with which the fidelity test and results from the intent-to-treat analyses of the clinical trial supports the conceptual framework.

Firstly, future studies should consider using randomization if replicating this study. It should also look at the predictor variables as well as the moderators of treatment outcomes amongst the specific self-efficacy and proactive coping in order to determine the role of these potential mechanisms of self-management.

Secondly, there are inconclusive findings related to ethnicity in the RM ANOVA. The sample was predominantly Chinese, and the collapse of the minority Malay ethnic subgroup with the others (predominantly Eurasian or mixed nationals) may not be representative of the ethnic Malays. Generalizability of the results is therefore limited. A replication of study with larger representation using multi-sites should be considered. This study raised questions in identifying which group is really distressed, suffers lowered QOL and has limitation in life roles participation after a diagnosis of breast cancer. Is it only confined to certain demographics, like age, marital status, etc. or is it across all groups? Is self-management equally effective for all ethnic groups or only across certain demographic group? These and other pertinent questions relevant to multiethnic Malaysia, hopefully can be answered by research stimulated by this report.

Thirdly, this study has opened the research path to examine further how specific cancer self-efficacy contributes to effective self-management behaviours. Specific domains of cancer-related self-efficacy have been demonstrated as mostly and closely related to relevant areas of adaptation when considered cross-sectionals (Manne et al., 2008). However, which constructs are more influential in explaining successful outcomes? Is there a single construct for cancer self-efficacy for cancer adaptation?

Finally, addressing health literacy in chronic illness has been associated with better outcomes (Coleman & Newton, 2005), but language and health literacy is a real challenge in a multicultural and a developing country like Malaysia. Future research may look at what other language or its combinations (e.g. using bilingual facilitators) are needed to enhance delivery of the self-management education.

9.6 Conclusion

This study utilizing robust methodology has accomplished three goals: i) it has reinforced the evidence of effectiveness of the self-management findings from chronic non-cancer fields regarding the inevitable patient self-management in health care and the important role of self-efficacy, ii) it has added to the sparse literature concerning the self-management needs of multi ethnic Malaysian women with breast cancer, and iii) the findings supported the philosophy of self-management as relevant in non-western culture and as a broad-based intervention to address the varied needs of women with breast cancer. More importantly, this study has addressed areas that have not been studied before, which is, a comprehensive study of a self-management intervention program to address breast cancer condition as a chronic illness.

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- G-5 International Survivorship Conference, Malaysia 10-12 Aug 2007
- G-6 7th Biennial Asian Association of Social Psychology 25-28 July 2007
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Appendix A: FOCUS GROUP



THE SELF-MANAGEMENT INTERVENTION FOR WOMEN WITH BREAST CANCER

- Appendix A-1 : Information sheet on Focus Group**
- Appendix A-2 : Consent form for Focus Group**
- Appendix A-3 : Invitation Letter to Focus Group**
- Appendix A-4 : Focus Group Guide**

Appendix A-1



*“Helping Women
with breast cancer
to help themselves”*
[FOCUS GROUP]

Information Sheet on Focus Group

Please read the following information about the focus group

Introduction to Breast Cancer focus group:

You are invited to participate in a study that will help us to understand how women with breast cancer manage their breast cancer, emotions and daily roles. We are inviting you to this study because of your experiences with breast cancer, and with our health services.

What is the purpose of this group?

The aim is to explore what enables women to best manage their breast cancer to enhance better quality of life. Your feedback will be used to inform the development of a 4-week Self-management program. [Self-management, is a structured patient-education program aimed at providing women the information and skills to help them manage their condition, and take control of the emotional and social consequences in a proactive way]

What happens if I decide to take part?

You will be given this information sheet and will be asked to sign a consent (agreement) form. We will arrange a time and place to meet together in a group of about 10 people. Taking part is voluntary and it is important in two ways. First, you will meet and share experiences and opinions with other women like yourself. Secondly, your feedback will help us develop a specific self-management program tailored to women with stage 1-3 breast cancer.

What will happen in the focus group?

The group meeting will last about 2 hours. A moderator, using a list of questions, will explore the topic of self-management for breast cancer. We will audiotape for accurate record of what is said. There is no right or wrong answers and the important thing is for you to share your opinions freely. Thus, there will be ground rules to establish a permissive environment whereby views are not judged and consensus are not sought. We will stress confidentiality. You will also be asked to respect the confidentiality of others by ensuring the discussion is within the group. If findings are presented or published, no individual will be identified as only group information will be reported.

What is the benefit of participating?

You will have opportunity to contribute towards the development of a self-management program aim to help other women like yourself. Your contribution will assist researchers and therapists to better design a SM program to enable better self-management of the breast cancer in terms of:

1. adhering to treatment regimes
2. engaging in activities that protect and promote health
3. monitoring and managing symptoms and signs of illness
4. managing the impact of illness and day-to-day functioning, emotions and personal relationships
5. creating new and meaningful life roles

What if I need more information?

This project is being carried out by Ms Loh Siew Yim, a doctoral candidate with the University of Curtin, Australia and currently on the International Postgraduate Scholarship from Australia and on study leave from University Malaya. This study is being supervised by Professor Tanya L. Packer, Director of Centre for Research into Disability and Society.

This study has been approved by, i) the Curtin University Human Research Ethics Committee, ii) the Medical Ethics Sub-Committee and iii) University Hospital and the Ministry of Health's Research Committee. If needed, verification of approval can be obtained either by writing to Curtin University Human Research Ethics committee, Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth 6845.

If you need any further information, kindly contact the researchers:

1. Loh Siew Yim

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3. Professor Yip Cheng Har

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Appendix A-2



*"Helping Women
with breast cancer
to help themselves"*
[FOCUS GROUP]

Consent Form for Focus Group

**Please complete this consent form if you agree to participate in this study.
See also the attached "Information sheet".**

- I _____(PLEASE PRINT NAME) agree to take part in the research project called focus group for women with breast cancer.
- I understand the purpose of this focus group is to gather information from women like you about your experience and opinion regarding how you had self managed or could have better self -manage when diagnosed and faced with breast cancer.
- I understand that the group will last approximately 2 hour, discussing around issue on enabling women to better self-manage in terms of:
 1. adhering to treatment regimes
 2. engaging in activities that protect and promote health
 3. monitoring and managing symptoms and signs of illness
 4. managing the impact of illness, day-to-day functioning, emotions and roles
 5. creating new and meaningful life roles
- I understand that the discussion will be taped, and confidentiality will be maintained. Any information or quotations taken from the discussion and used in writing the project summary will be general. I will not be identified by my name or by any other defining characteristic, and I agree to respect the confidentiality of information given by others in the group.
- I have read the information sheet and had the project fully explained to me and my consent is fully given. I voluntarily agree to participate and understand that I may stop taking part at any time or decline to answer some questions. I am at least 18 years of age.

Signature of participant: _____

Date: _____

Signature of person obtaining consent: _____

Date: _____

Appendix A-3

Invitation Letter to Focus Group



Dear Ladies,

This letter is sent to women like you, encouraging you to make a contribution with researchers from University Malaya & University of Curtin who are currently conducting a study on women with breast cancer. We will conduct a focus group discussion that gives women like yourself, an opportunity to contribute in terms of experiences or opinions on services, care or circumstances that may improve your participation and quality of life.

This project aims at developing self-management program for women with breast cancer. We feel it is essential to include the opinions and attitudes of women like you, who have experience breast cancer. A group facilitator will ask a series of questions that will promote a discussion around this issue on enabling better self-management in terms of:

1. adhering to treatment regimes
2. engaging in activities that protect and promote health
3. monitoring and managing symptoms and signs of illness
4. managing the impact of illness and day-to-day functioning, emotions & relationships
5. creating new and meaningful life roles

If you would like more information about this project, you may call us. We look forward to hear about your views and experiences.

With Best Wishes,

1. Loh Siew Yim

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2. Professor Tanya L. Packer

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3. Professor Yip Cheng Har E-mail: yipch@um.edu.my

Dept of Surgery, Faculty of Medicine, University Malaya, Kuala Lumpur

Appendix A-4

Focus Group Guide

A. BEFORE FOCUS GROUP - CHECKLIST

Location and physical set-up:

- Easy to find – appropriate place to hold the discussion?
- Relaxed, neutral place with no distractions (audio-taping must be unobtrusive)
- Round seating arranged for participants to face each other

What do I need?

- Participant consent forms and honoraria receipts (if honorarium is available)
- A notepad for note takers/observers & 2 quality (90 minute) audio tapes & recorder
- Moderator's Interview guide - What are some (about 3) good questions to ask?

Determining Participants and moderator:

- Consider and plan proactively how to recruit participants?
- Consider how people in this general category are alike or different?
- Consider what kind of person should moderate?

Getting Participants to attend.

- Contact potential participants by phone (or in person) about 2 weeks prior to the session. Contact 10 to 25% more people than needed to counteract no shows.
- Send an invitation after contact to confirm. Have a map with good directions and on an official letterhead and a real signature at the bottom.
- Contact each person the day or two, before the focus group as a reminder.
- Consider if incentives are need to encourage participation

Determining the focus group interview guide:

- Facilitate patients to discuss retrospectively, issues relating to their experiences and perceptions of supportive care throughout their cancer journey.

B. DURING FOCUS GROUP - CHECKLIST

Organisation:

Venue	: e.g. The breast cancer Association/ UMMC
Duration	: e.g. 1-2-hour session
Group size	: e.g. 6-10 people
Independent observer	: e.g. 1 to monitor process for internal validity

No of sessions

It is common that opinions will differ within and between group, regardless of their apparent homogeneity. Because of the very subjective nature of focus groups it is recommended that a minimum of two groups be held with each segment to confirm any findings. (i.e. if young and old people, or married or single are seen as distinct, important segments, then two groups would be assembled in each age segment – four in total).

Introduction and Background:

Welcome (tea, coffee) and Introduction on background and purpose of meeting
Inform on the purpose of this SM project, why these sessions are being conducted, who the sponsor is and how the info is going to be used).

Example: “This is a SM project to improve quality of life of women with breast cancer. The term self-management typically refers to any formal patient-education program aimed at providing the patient with the information and skills necessary to manage their condition within the perimeters of the medical regime. Self-management skills are skills to help people to take control of the emotional-social consequences of living with a long-term illness, which is very pertinent in breast cancer and has high stigma (i.e. the lingering perception is still very strong in the society)”.

Self-management intervention program for Women with breast cancer

Purpose of focus group:

“I am inviting you because of your experience with breast cancer and the health services. You will be one in a small group contributing ideas to inform a program for women with breast cancer.

Ground rules:

Paraphrase: e.g. “There are no right or wrong answers, the key thing is for you to share your opinions and all answers will be audio-taped and analysed for emerging themes. Everything said is to remain within this group”.

Topic Guide:

Paraphrase: e.g. “The idea of SM program is basically to enable better self-management of the condition in terms of the following topic which we will be focusing on:

- adhering to treatment regimes & engaging in activities that promote health
- monitoring and managing symptoms and signs of illness
- managing the impact of illness, emotions and personal relationships
- creating new and meaningful life roles.

In short I am interested in how you can better manage emotion that comes with the illness, the side-effect, following treatment regimes and managing your chores and roles”.

Question Guide: (These 2-5 questions are usually the most important and require the most attention in analysis).

Q1: “Breast Cancer can be an emotionally draining experience for some women. In your opinion, what were some of the emotions that you all went through when you were first diagnosed and subsequently during treatment? “

- How did you cope? Did you feel the services available were sufficient?
- Was there anything you would recommend to help other women like cope better?

Self-management intervention program for Women with breast cancer

Q2: Most women have some form of difficulty coping with the illness and treatment such as; from side effect of treatment (like nausea, vomiting etc) or from the complication of treatment (like swelling of arm, pain and fatigue). What was your experience and how did you overcome does experience.

- Did you find adherence to treatment easy? Can be made easier?
- How do you think healthcare could assist? What would be helpful?
- What would you like to see to be included in the health services?

Q3: Some women may have difficulty adjusting to their roles. Did you have problems managing your work at home, with the children or housework or going to work etc.?

- What were the main challenges /difficulty?
- What could have been made better?
- How do you think the health service could help? (information/ skills/ therapy?)

Ending Question:

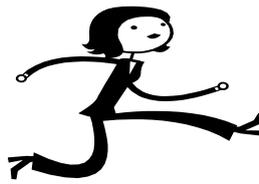
Of all the things we have discussed today, which of the three aspects of Self-management tasks do you think is the most important to enable women with breast cancer to manage with better participation and quality of life.

Final Question: Facilitator gives a short overview of the project as well as a summary of the discussion. The final question is “have we missed anything?” and allowed about 10minutes for participants to answer this question.

C. AFTER FOCUS GROUP - CHECKLIST

- Thank the participant
- Transcribe the transcript.
- Immersion and coding the transcript for key ideas/words/terms
- Data Management with N6
- Analyse the data

Appendix B: PILOT GROUP



THE SELF-MANAGEMENT INTERVENTION FOR WOMEN WITH BREAST CANCER

- Appendix B-1 : Invitation Letter to Pilot Group**
- Appendix B-2 : Information sheet for Pilot Group**
- Appendix B-3 : Consent form on Pilot Group**
- Appendix B-4 : Evaluation of Process (Pilot Group)**
- Appendix B-5 : Checklist-Assessing My Skills as a facilitator**
- Appendix B-6 : Sample Action Plan (Medical Management)**

Appendix B-1



*"Helping Women
with breast cancer
to help themselves"*
[PILOT GROUP]

Invitation Letter to Pilot Group

Dear Ladies,

This letter is sent to women like yourself, encouraging you to participate in a 4-week facilitated program developed for women newly-diagnosed with stage 1-3 breast cancer. We would like to invite you to a newly develop program (based on the findings from interviews with groups of Malaysian women with breast cancer, held from July-August 2005 at University Malaya).

The program, known as the SAMA program (the acronym for 'staying abreast-moving ahead') will be offered only to women with stage 1-3a breast cancer who have completed surgery.

We like to offer the program to you, where we will support you with training sessions in group format, for about 2 hours up to 4 weeks. You will learn tasks like monitoring symptoms and signs of illness, managing the impact of emotions, engaging in activities that protect and promote health, and meaningful life roles. You will also received a **workbook cum resource book** (free of charge), **a relaxation book with a tape to practice at home**. There will be two testing, one at the start and another at the end of program, to evaluate how you have benefited as well as how we can further refine the program for women with breast cancer.

We feel you will benefit by participating because many women expressed that it helps to talk about their breast cancer, to learn from the experiences of others and to learn the skills of self managing the illness. We welcome you to take this first step to 'take charge' of your life, living well with a diagnosis of breast cancer, by participating and working with us to help yourself.

With Many Best Wishes,

1. Loh Siew Yim

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2. Professor Tanya L. Packer

The Centre for Research into Disability and Society (Tel: + 618 9266 4651)

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Appendix B-2



*“Helping Women
with breast cancer
to help themselves”*
[PILOT GROUP]

Information sheets for Pilot group

Please read this information about the Self-management program for breast cancer

Introduction to study:

A diagnosis of breast cancer can be an emotionally, physically and socially challenging for most women. Findings from several focus groups with Malaysian women with a diagnosis of breast cancer, verified a lack of information and support to help them through this stressful period. We, therefore, would like to offer a new program for women who are recently diagnosed with a stage I/ II/ III breast cancer.

What is the purpose of study:

This SAMA program (an acronym for “Staying Abreast-Moving Ahead”) is being offered as a part of a research study for women with breast cancer (Stage 1-3 who has completed surgery). It was developed in order to address the many issues and concerns brought up by women who participated in the earlier focus group interviews.

What happens if I decide to take part?

You will be asked to sign a consent (agreement) form, and invited to attend four 2-hourly group sessions held once a week, where you will be supported by us and a ‘buddy’ throughout the 4 weeks. The program entails sharing, discussion, reflections, homework and skill building. There will also be two (paper and pencil) testing (before and after the program). Your name and medical information will remain completely confidential regardless of your participation in the program. If you decide not to take part, it will not affect the medical care given to you.

What is being tested?

The study will also test how a self-management program can help women manage the tasks of managing emotions, managing the illness and managing daily roles. We will measure your quality of life, anxiety-depression-stress level, perceived-participation, proactive coping skills and your level of self-efficacy or confidence in coping. All information will be kept confidential. If findings are presented or published, no individual will be identified as only group information will be reported.

What are the benefits of participating?

You will learn information and skills, in a supportive and an affirmative environment, to help you better manage the condition, to refocus on engaging in activities that protect and promote health, managing symptoms and signs of illness, managing the impact of illness, emotions and roles, by being informed.

You will have opportunities to share and learn many valuable life lessons with many others in similar situations, and to receive and/or bring strength, hope and enrichment to each other. Also, you will indirectly help other women like yourself through your valued participation and contribution of your experiences to the program so that more women with breast cancer can be enabled.

What if I need more information?

This project is being carried out by Ms Loh Siew Yim, a doctoral candidate with the University of Curtin, Australia (currently on the International Postgraduate Scholarship from Australia and on study leave from University Malaya). This study is being supervised by Professor Tanya L. Packer, Director of Centre for Research into Disability and Society and Professor Yip Cheng Har and Professor A Passmore.

This study has been approved by, i) the Curtin University Human Research Ethics Committee, ii) the Medical Ethics Sub-Committee and iii) University Hospital and the Ministry of Health's Research Committee. If needed, verification of approval can be obtained either by writing to Curtin University Human Research Ethics committee, Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth 6845 or by telephoning 9266 2784.

If you need any further information, kindly contact the researchers:

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2. Professor Tanya L. Packer

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3. Professor Yip Cheng Har

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Appendix B-3



*“Helping Women
with breast cancer
to help themselves”*
[PILOT GROUP]

Consent Form on Pilot Group

Please complete the following consent form if you agree to participate in this study.

See also the attached participant information sheet.

I _____ (PLEASE PRINT NAME) agree to take part in the research project called Self-management (pilot group) for women with breast cancer.

I understand the **purpose** of this pilot group is to test out a Self-management program for women with breast cancer. I understand the once a week session is a 4-week program, lasting approximately 2 hours each session. I also understand there will be two testing conducted (before the program, immediately after the program). After the program, I may be called to contribute on how the program can be made better for enabling women with breast cancer.

I understand that **confidentiality** will be maintained, and I agree to respect the confidentiality of information given by others in the group. I also understand that any information or quotations taken from the discussion and used in writing will be general and I will not be identified by my name.

I understand that there is **no risk** to participation, but sharing my experience **may** make me feel somewhat uncomfortable, which is understandable. [We want you to feel comfortable while participating, you can let us know if you are uncomfortable and we can discuss about it].

I have read the information sheet and had the project fully explained to me and my consent is fully given and I **voluntarily agree** to participate. I am at least **18 years of age**.

Signature of participant: _____ Date: _____

Signature of person obtaining consent: _____ Date: _____

Appendix B-4

Evaluation of the Process (Pilot Group)

1 2 3 4 5 6 7 8 9 10

PROGRAM:	Not so helpful ←-----→ Very Helpful (Ideas to improve?)
Feasibility	_____
Acceptability	_____

1 2 3 4 5 6 7 8 9 10

FORMAT	Not appropriate ←-----→ Very appropriate (Ideas to improve?)
Length,	_____
Timing	_____
Structure	_____
Content	_____

1 2 3 4 5 6 7 8 9 10

TOOLS	Not so helpful ←-----→ Very helpful (Ideas to improve?)
Workbook	_____
Homework	_____
Breast Book	_____
Tape/Handbook	_____
Homework	_____

1 2 3 4 5 6 7 8 9 10

OTHERS	Not appropriate/helpful ←-----→ Very Helpful (Ideas to improve?)
Venue	_____
Facility	_____
Facilitator	_____

PERCEIVED BENEFITS: (any comment about the SAMA program) _____

POTENTIAL BARRIERS (any barrier/s limiting participation in SAMA).

Name: (Telephone/Email:)

Appendix B-5

Checklist on Skills of a Facilitator

Reflect on the following statements, check areas where you would like to work on Rating: [Poor 1...2...3...4... Good]		Please Circle			
1	Do I know myself (i.e. confident, some anxiety to stay alert)	1	2	3	4
2	Do I know the subject matter (i.e. prepared, know the topic area)	1	2	3	4
3	Do I know the audience (know a bit of everyone's background)	1	2	3	4
4	Do I respect the participant (e.g. can you call by their first name?)	1	2	3	4
5	Do I respect differences in opinions and lifestyles (non judgemental)	1	2	3	4
6	Do I use a variety of vocal qualities (vary the pitch, rate and volume)	1	2	3	4
7	Do I use my body well (posture, gestures, expressions to reinforce subject matter)	1	2	3	4
8	Do I make my remarks clear and easy to remember (present one idea at a time, show relationships/ summarize/ paraphrase..)	1	2	3	4
9	Do I enhance my presentations with illustrations (with group's age and background)	1	2	3	4
10	Do I understand group dynamics (aware of conflict resolutions)	1	2	3	4
11	Am I inclusive (facilitate people to share and participate in the learning experiences)	1	2	3	4
12	Am I culturally sensitive (recognize that participants' cultures shapes their perspectives)	1	2	3	4
13	Am I enthusiastic and caring (engage the listeners and challenge their thinking but at the same time be aware of their feelings)	1	2	3	4
14	Am I flexible (in charge but without being overly controlling)	1	2	3	4
15	Am open to new ideas? (recognize that you can learn from participants as well as offer them new ideas).	1	2	3	4
16	Am I humble? (aware that you do not have all the answers)	1	2	3	4
17	Am I compassionate? (be aware that the cancer-related material have an emotional impact on the participants)	1	2	3	4
18	Am I empathetic? (understand the participants' emotional reactions)	1	2	3	4
19	Am I motivated (interested in improving my presentations)	1	2	3	4
20	Am I available to people (Do I set reasonable time for them to call and reach in times of needs)	1	2	3	4

Adapted from Training the trainers (NCI, 2004)

Appendix B-6 Sample on Action Plan



Collaborative Action-planning (for individual action plan).

Short-term goal 1

Short-term goal 2

Short-term goal 3

The Problem-solving steps:

The problem is : _____

The goal is: _____

The Problem-solving steps are:

Step 1: _____

Step 2: _____

Step 3: _____

Step 4: _____

How confident are you to follow through with these activities before your next visit?

Not Confident 1 3 3 4 5 6 7 8 9 10 **Very Confident**

Reflect on the problems and solutions for rating below 5.

a. What might prevent you from completing these activities prior to your next visit?

b. Solution(s) to the above barriers:

Reassess your confidence level

Not Confident 1 3 3 4 5 6 7 8 9 10 **Very Confident**

**APPENDIX C:
CLINICAL CONTROL TRIAL (CCT)**



**THE SELF-MANAGEMENT
INTERVENTION FOR
WOMEN WITH BREAST CANCER**

- Appendix C-1 : Invitation Letter to CCT**
- Appendix C-2 : Information sheet on CCT**
- Appendix C-3 : Consent form for CCT**
- Appendix C-4 : Advertisement for CCT**

Appendix C-1

Invitation Letter to CCT Group



UNIVERSITY MALAYA

Fakulti Perubatan, Universiti Malaya

LEMBAH PANTAI, 50603 KUALA LUMPUR, MALAYSIA
TEL.: 603 – 7967 6612/ 2639 FAKS:603 – 7967 4766



8hb Sept 2006

Dear Ladies,

This letter is sent to women newly diagnosed with breast cancer, to inform about a free program that aimed at improving participation and your quality of life after a diagnosis of breast cancer.

The program was developed based on the findings from four group-interviews with Malaysian women diagnosed with breast cancer, held from July to August 2005 at University Malaya. This program, known as the **S.A.M.A.** Program (short for 'staying abreast moving ahead'), is open to all women with stage 1-3 breast cancer who had completed surgery. If you agree, you will be assigned to either: (i) a 4-week SAMA program (about 2½hour session per week, over four weeks) and a series of paper-pencil testing; or (ii) a series of paper-pencil testing at three different timing.

We urge you to take this first step to take control of your life, by participating so that you can help us to improve care for women with breast cancer and/or to help yourself whilst we support you. We recognize that this is stressful period, and would like to send out the message that you do not have to be alone during this period.

Best Wishes,

Loh Siew Yim

Siewyim.loh@postgrad.curtin.au

Information Sheet on CCT Group

Please read the following on the rehabilitation program for breast cancer

Introduction to study:

A diagnosis of breast cancer can be physically, emotionally, and/or socially challenging experience for most women. Findings from focus groups with Malaysian women with a diagnosis of breast cancer, verified that a lack of information, support and skills to help them through this stressful period. We, therefore, would like to offer a newly developed program for women who are recently diagnosed with stage I- III breast cancer.

What is the purpose of study:

This SAMA program (an acronym for "Staying Abreast-Moving Ahead") is being offered as a part of a clinical study for women with breast cancer. We want to provide you the much needed support as you go through your cancer treatment.

What happens if I decide to take part?

If you decide to participate, you will be either assigned to the 4-week SAMA program – four sessions of about 2½hourly group-session, weekly over 4-week (with testing); or to just a series of testing with your normal treatment. If you decide not to take part, it will not affect the medical care given to you. Your name will remain completely confidential regardless of your participation. All information will be kept confidential. If findings are published, no individual will be identified as only group information will be reported

What are the benefits of participating?

You will learn information and skills to help you self manage within a supportive environment. You will have opportunity to share-learn with other women, and to receive (and bring) strength and enrichment to the group. Your participation can also help us understand how best to help women with breast cancer.

What if I need more information?

This project is being carried out by Ms Loh Siew Yim, a doctoral candidate with the University of Curtin, Australia. This study has been approved by; the Curtin University Human Research Ethics Committee, the Medical Ethics Sub-Committee University Hospital and the Malaysian Ministry of Health's Research Committee. If needed, verification of approval can be obtained from any of the above or, either by writing to Curtin Human Research Ethics committee, Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth 6845.

Appendix C-3

"SAMA:
Staying Abreast,
Moving Ahead"



Consent Form for CCT Group

Please complete the following consent form if you agree to attend the program.
Please read the attached information sheet for details.

- I _____ (PLEASE PRINT NAME) agree to **attend** the breast cancer program called the SAMA program, a self-management intervention for Malaysian women with breast cancer. This is a 4-week program to help women self-manage the life changes that come with a diagnosis of breast cancer.
- I understand that I will be **assigned to**, either the SAMA program whereby I will participate in the group session for 4 weeks (with testing); or to the series of testing only
- I have read the **information sheet** and had the **project fully explained to me and my consent is fully given.**
- I **voluntarily agree** to participate and understand that I may stop taking part at any time or decline to answer some questions.
- I am at least **18 years** of age.
- I have been informed that **confidentiality** will be ensured to the extent that it is possible, and that I will not be identified in any publications where my personal information will not be divulged.

Participant signature: _____ Date: _____

Telephone: (H) _____ (O): _____ (M) : _____

Person collecting consent: _____

Appendix C-4



Advert for CCT Group

ANNOUNCEMENT

CALLING WOMEN NEWLY-DIAGNOSED WITH BREAST CANCER

IF YOU

- have been diagnosed with Stage 1 or 2 or 3 Breast Cancer,
- have preferably completed surgery,
- are currently undergoing chemo/radiotherapy or hormone therapy, &
- can read and understand English.

OFFERING YOU A REHABILITATION PROGRAM

Curtin University, Australia and University Malaya, Malaysia have developed a program for breast cancer. You are encouraged to attend this free 4-week clinical research program to help you self manage your breast cancer. If you decide to attend, you will either: attend a 2½ hour weekly group session for over four weeks period, or participate in a series of paper-pencil testing.

What are the benefits?

You will gain information and skills. You will have the opportunities to share and learn many valuable life lessons with other women. Participants receive and bring strength, hope and enrichment, to each other. Your participation can help us improve services for many other women with breast cancer. We believed in a partnership approach to help you so that you do not have to be alone during this stressful period.

What if I am interested?

If you would like more information regarding the project and dates and time for the groups, please contact: siewyim.loh@postgrad.curtin.edu.au

With Best Wishes,
LOH SIEW YIM

Appendix D

PATIENT INFORMATION QUESTIONNAIRE (PIQ)



THE SELF-MANAGEMENT INTERVENTION FOR WOMEN WITH BREAST CANCER

Appendix D-1	: Patient Demographic Questionnaire
Appendix D-2	: Quality of Life (SF-36 UK)
Appendix D-3	: Participation and Autonomy (IPA-E)
Appendix D-4	: Depression, Anxiety, Stress (DASS)
Appendix D-5	: SE-Self care (SUPPH)
Appendix D-6:	: SE-Cancer behaviour (CBI-B)
Appendix D-7	: SE- emotion (SSECS)
Appendix D-8	: Proactive Coping Scales (PCI)
Appendix D-9	: Evaluation of SAMA & Confidence
Appendix D-10	: Letter to Employer

Self-management intervention program for Women with breast cancer

B: MEDICAL HISTORY

10. When were you diagnosed with breast cancer? __ (day) / __ (month) / ____ (year)

11. How long has it been since the diagnosis was made:

1. < 3 months ago 2. 3-6 months 3. 6-12 months 4. more than 1 year

12. Do you know your stage of breast cancer?: No Yes (Stage: I / II / III)

1. Stage 0 3. Stage 2A 4. Stage 3A 5. I do not know
2. Stage 1 3. Stage 2B 4. Stage 3B

13. What TYPE of breast cancer did you have?

1. DCIS (Ductal Carcinoma in situ) 4. Others: _____
2. IDC (Invasive Ductal Carcinoma) 5. I do not know
3. ILC (Invasive Lobular Carcinoma)

14. What was the SIZE of your tumor?

1. 0 – 1cm 2. >1-2cm 3. >2 - 5cm 4. >5cm 5. I do not know

15. What was the GRADE of your tumor? (this is from histo-pathology lab result)

1. Grade 1: well-differentiated (G1) 4. I don't know
2. Grade 2: moderately-differentiated (G2)
3. Grade 3: poorly-differentiated (G3)

16. Estrogen/Progesterone Receptors result:

1. ER positive / PR positive 2. ER negative/ PR negative 3. I dont know

17. HER-2/neu (gene) presence?

1. HER-2 positive 2. HER-2 negative 3. I do not know

C: TREATMENT

18. If surgery, what did you had?

1. Lumpectomy [] 4. Lumpectomy & Breast Reconstruction []
2. Mastectomy [] 5. Mastectomy & Breast Reconstruction []
3. I do not know []

19.a. Did you have any lymph nodes removed? 1. Yes (How many? = _ _ _)

2. No 3. I do not know

b. Was the lymph nodes tested positive for cancer?

1. Yes (How many? = _ _ _) 2. No 3. I do not know

Self-management intervention program for Women with breast cancer

20. What treatment regimes have you received? (Tick one or more)

1. Surgery only 3. Surgery & Chemotherapy
2. Surgery & Radiation 4. Others _____
5. I do not know

21. What treatment are you presently on?

1. Radiation 2. Chemotherapy 3. Hormonal 4. Others: _____
5. I do not know

22. What CHEMOTHERAPY are you on? (check on those that apply)

1. FEC / FAC 4. Taxol / Taxotere
2. CMF 5. Others : _____
3. AC 6. I do not know

23. HORMONE THERAPY (check those that apply): [AI = aromatase inhibitor]

1. Tamoxifen
2. Femara: (AI: letrozole) [for postmenopausal, receptor positive]
3. Arimidex (AI: anastrozole) [for early stage BC]
4. Aromasin (AI: exemestane) [for early, post-menopausal & HR +ve]
5. I do not know

24. IMMUNOTHERAPY / TARGETED THERAPY:

Are you on Herceptin? 1. Yes 2. No 3. I do not know

D: SIDE EFFECT FROM TREATMENT

- | | | |
|---|---|--|
| 1 <input type="checkbox"/> Anxiety | 6 <input type="checkbox"/> Depression | 11 <input type="checkbox"/> Fatigue |
| 2 <input type="checkbox"/> Nausea/Vomiting | 7 <input type="checkbox"/> Pain | 12 <input type="checkbox"/> Alopecia (hair loss) |
| 3 <input type="checkbox"/> Stomatitis (mouth sores) | 8 <input type="checkbox"/> Neutropenia (low white blood cell) | |
| 4 <input type="checkbox"/> Weight Loss | 9 <input type="checkbox"/> Diarrhoea | 13 <input type="checkbox"/> Constipation |
| 5 <input type="checkbox"/> Sleep problem | 10 <input type="checkbox"/> Sexual Problem | 14 <input type="checkbox"/> Shortness of Breath |

For question 25-29, refer to the index in the box above. Write the relevant numbers here.

25. Which of these side effects (below) you had during/after **surgery**:

26. Which of these side effects that you had from **chemotherapy**:

27. Which of these side effects you had from **radiotherapy**: _____

28. Which of these side effects you had from **targeted therapy**: _____

Self-management intervention program for Women with breast cancer

E: LIFE-STYLE & HEALTH INDEX:

30. Do you smoke? 1. Yes 2. No 3. Used to but stop now
31. Do you drink? 1. Yes 2. No 3. Used to but stop now
32. Do you exercise? 1. Yes 2. No 3. Sometimes
33. How long do you exercise in an average week? ____ hours (Total hours for the week)

ACTIVITY LEVEL: Tick the box that describes your present daily activity level?

- | | |
|--|---|
| 1. <input type="checkbox"/> Sedentary | I participate in little or no daily exercise. Most of my time is spent in low-intensity activities e.g. watching television, driving, doing a desk job |
| 2. <input type="checkbox"/> Light | I mostly sit through the day, but perform light exercises 1-2 days/week. |
| 3. <input type="checkbox"/> Moderate | I lead a moderately active lifestyle . It includes light exercises 1-2 days/week. |
| 4. <input type="checkbox"/> Active | I follow an active lifestyle that includes either light exercise for more than 3 days per week or intense physical activity for 1-2 days per week. |

HEALTH INDEX (Ask for tester to measure you if you are unsure):

35. BMI Calculator: (body fat based on ht and wt)

Height : _____ft _____inches
Weight : _____pound
Classification: _____ (between 18-25 score)

36. BMR Calculator: (energy burn, to calculate daily calorie need)

Height : _____ft _____inches
Weight : _____pound
Age : _____

-Thank you for completing -

Appendix D-2



Quality of Life (SF-36 UK)

Appendix D- 3



**Inventory on Participation and Autonomy-
English version (IPA-E)**

Self-management intervention program for Women with breast cancer

Inventory on Participation and Autonomy
(IPA)

() ACTIVITIES IN AND AROUND THE HOUSE (with or without aids or assistance)
The next questions are about the tasks and responsibilities you have at home, and the way your health or disability influences these. We would like to know whether you can decide when and how something is done, even if you don't do it yourself.

Score
for
office
use
only

3a. My chances of contributing to looking after my home <i>the way</i> I want to are			
	Very Good	<input type="checkbox"/>	0
	Good	<input type="checkbox"/>	1
	Fair	<input type="checkbox"/>	2
	Poor	<input type="checkbox"/>	3
	Very Poor	<input type="checkbox"/>	4
3b. My chances of getting light tasks done around the house (e.g. making tea or coffee), either by myself or by others, <i>the way</i> I want them done are			
	Very Good	<input type="checkbox"/>	0
	Good	<input type="checkbox"/>	1
	Fair	<input type="checkbox"/>	2
	Poor	<input type="checkbox"/>	3
	Very Poor	<input type="checkbox"/>	4
3c. My chances of getting heavy tasks done around the house (e.g. cleaning), either by myself or by others, <i>the way</i> I want them done are			
	Very Good	<input type="checkbox"/>	0
	Good	<input type="checkbox"/>	1
	Fair	<input type="checkbox"/>	2
	Poor	<input type="checkbox"/>	3
	Very Poor	<input type="checkbox"/>	4
3d. My chances of getting housework done, either by myself or by others, <i>when</i> I want them done are			
	Very Good	<input type="checkbox"/>	0
	Good	<input type="checkbox"/>	1
	Fair	<input type="checkbox"/>	2
	Poor	<input type="checkbox"/>	3
	Very Poor	<input type="checkbox"/>	4
3e. My chances of getting minor repairs and maintenance work done in my house and garden, either by myself or by others, <i>the way</i> I want them done are			
	Very Good	<input type="checkbox"/>	0
	Good	<input type="checkbox"/>	1
	Fair	<input type="checkbox"/>	2
	Poor	<input type="checkbox"/>	3
	Very Poor	<input type="checkbox"/>	4

Self-management intervention program for Women with breast cancer

3f. My chances of fulfilling my role at home as I would like are			
	Very Good	<input type="checkbox"/>	0
	Good	<input type="checkbox"/>	1
	Fair	<input type="checkbox"/>	2
	Poor	<input type="checkbox"/>	3
	Very Poor	<input type="checkbox"/>	4
3g. If your health or your disability affect your activities in and around your home, to what extent does this cause you problems?			
	No problems	<input type="checkbox"/>	0
	Minor problems	<input type="checkbox"/>	1
	Major problems	<input type="checkbox"/>	2
(4) LOOKING AFTER YOUR MONEY (with or without aids or assistance)			4/
The next questions deal with the effect of your health or disability on the control <u>you</u> have over spend your own money.			
4a. My chances of choosing how I spend my own money are			
	Very Good	<input type="checkbox"/>	0
	Good	<input type="checkbox"/>	1
	Fair	<input type="checkbox"/>	2
	Poor	<input type="checkbox"/>	3
	Very Poor	<input type="checkbox"/>	4
(6) SOCIAL LIFE AND RELATIONSHIPS			5/
The next questions are about the quality and frequency of your social relationships. We like to know whether your 'health problems or disabilities' affect your relationships.			
6a. My chances of talking to people close to me on equal terms are			
	Very Good	<input type="checkbox"/>	0
	Good	<input type="checkbox"/>	1
	Fair	<input type="checkbox"/>	2
	Poor	<input type="checkbox"/>	3
	Very Poor	<input type="checkbox"/>	4
6b. The quality of my relationships with people who are close to me			
	Very Good	<input type="checkbox"/>	0
	Good	<input type="checkbox"/>	1
	Fair	<input type="checkbox"/>	2
	Poor	<input type="checkbox"/>	3
	Very Poor	<input type="checkbox"/>	4
6c. The respect I receive from people who are close to me is			
	Very Good	<input type="checkbox"/>	0
	Good	<input type="checkbox"/>	1
	Fair	<input type="checkbox"/>	2
	Poor	<input type="checkbox"/>	3
	Very Poor	<input type="checkbox"/>	4

Self-management intervention program for Women with breast cancer

6d. My relationships with acquaintances (friends) are	Very Good	<input type="checkbox"/>	0
	Good	<input type="checkbox"/>	1
	Fair	<input type="checkbox"/>	2
	Poor	<input type="checkbox"/>	3
	Very Poor	<input type="checkbox"/>	4
6e. The respect I receive from acquaintances is	Very Good	<input type="checkbox"/>	0
	Good	<input type="checkbox"/>	1
	Fair	<input type="checkbox"/>	2
	Poor	<input type="checkbox"/>	3
	Very Poor	<input type="checkbox"/>	4
6f. My chances of having an intimate relationship are	Very Good	<input type="checkbox"/>	0
	Good	<input type="checkbox"/>	1
	Fair	<input type="checkbox"/>	2
	Poor	<input type="checkbox"/>	3
	Very Poor	<input type="checkbox"/>	4
6g. My chances of seeing people as often as I want are	Very Good	<input type="checkbox"/>	0
	Good	<input type="checkbox"/>	1
	Fair	<input type="checkbox"/>	2
	Poor	<input type="checkbox"/>	3
	Very Poor	<input type="checkbox"/>	4
9a . My chances of helping and supporting people in any way are:	Very Good	<input type="checkbox"/>	0
	Good	<input type="checkbox"/>	1
	Fair	<input type="checkbox"/>	2
	Poor	<input type="checkbox"/>	3
	Very Poor	<input type="checkbox"/>	4
6h. If your health or disability affect your social life & relationships, to what extent does this cause you problems?	No problems	<input type="checkbox"/>	0
	Minor problems	<input type="checkbox"/>	1
	Major problems	<input type="checkbox"/>	2

** Family roles (3a-f, 4a) ** Social Relationship: (6a -6f, 9a)

Appendix D- 4

DEPRESSION, ANXIETY, STRESS (DASS-21)

Please read each statement and circle a number 0, 1, 2 or 3 that indicates how much the statement applied to you *over the past week*. There are no right or wrong answers. Do not spend too much time on any statement. **The rating scale is as follows:**

- 0 Did not apply to me at all
- 1 Applied to me to some degree, or some of the time
- 2 Applied to me to a considerable degree, or a good part of time
- 3 Applied to me very much, or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (eg, in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

Appendix D- 5

SELF-EFFICACY –SELF CARE (SUPPH)

How much confidence do you have in doing these behaviors? Rate your confidence using this scale:					
	1	2	3	4	5
	VERY LITTLE	CONFIDENCE		QUITE A LOT	
1- Excluding upsetting thoughts from my consciousness	1	2	3	4	5
2- Using relaxation techniques to decrease my anxiety	1	2	3	4	5
3- Finding ways of alleviating my stress	1	2	3	4	5
4- Using a specific technique to manage my stress	1	2	3	4	5
5- Doing things that helped me to cope with previous emotional difficulties	1	2	3	4	5
6- Practicing stress reduction techniques even when I'm feeling sick	1	2	3	4	5
7- Managing to keep anxiety about illness from becoming overwhelming	1	2	3	4	5
8- Thinking of myself as better off than people who became ill when they were younger than I am now	1	2	3	4	5
9- Focusing on something not associated with my illness as a way of decreasing my anxiety	1	2	3	4	5
10- Believing that using a technique to manage treatment stress will actually work	1	2	3	4	5
11- Choosing among treatment alternatives recommended by my physician the one that seems right for me	1	2	3	4	5

[Lev & Owen, 1996]

Self-management intervention program for Women with breast cancer

Making my own decision regarding treatment alternatives	1	2	3	4	5
Deciding for myself whether or not to have treatment	1	2	3	4	5
Experiencing life's pleasures since I became ill	1	2	3	4	5
Doing special things for myself to make life better	1	2	3	4	5
Convincing myself I can manage the treatment stress	1	2	3	4	5
Helping other people going through illness and treatment	1	2	3	4	5
Convincing myself the treatment is not so bad	1	2	3	4	5
Keeping my stress within healthy limits	1	2	3	4	5
Appreciating what is really important in life	1	2	3	4	5
Believing I can find strength within myself for healing	1	2	3	4	5
Convincing myself I'll be O.K.	1	2	3	4	5
Finding a way to help me get through this time	1	2	3	4	5
Believing that I really have a positive attitude about my state of health	1	2	3	4	5
Doing things that helped me to cope with previous physical difficulties	1	2	3	4	5
Doing things to control my fatigue	1	2	3	4	5
Finding ways of helping myself feel better if I am feeling blue	1	2	3	4	5
Managing the side effects of treatment so that I can do things I enjoy doing	1	2	3	4	5
Dealing with the frustration of illness and treatment	1	2	3	4	5

[Lev & Owen, 1996]

Self-management intervention program for Women with breast cancer

Appendix D- 6

SELF-EFFICACY - CANCER BEHAVIOUR (CBI-B)

Please read each numbered item. Then rate that item on how confident you are that you can accomplish that behavior. Circle a number on the scale. If you circle a "1" you would be stating that you are not at all confident that you can accomplish that behavior. If you circle a "9" you would be stating that you are totally confident that you can accomplish that behavior. Numbers in the middle of the scale indicate that you are moderately confident that you can accomplish that behavior.

RATE AS BEST AS YOU CAN EVEN IF YOU ARE NOT SURE ABOUT AN ITEM

		NOT AT ALL CONFIDENT			MODERATELY CONFIDENT			TOTALLY CONFIDENT
1	Maintaining independence.	1	2	3	4	5	6	7 8 9
2	Maintaining a positive attitude.	1	2	3	4	5	6	7 8 9
3	Maintaining a sense of humor.	1	2	3	4	5	6	7 8 9
4	Expressing negative feelings about cancer.	1	2	3	4	5	6	7 8 9
5	Using denial. (putting things out of my mind at times *).	1	2	3	4	5	6	7 8 9
6	Maintaining work activity.	1	2	3	4	5	6	7 8 9
7	Remaining relaxed during treatments and not allowing scary thoughts to upset me.	1	2	3	4	5	6	7 8 9
8	Actively participating in treatment decisions.	1	2	3	4	5	6	7 8 9
9	Asking physicians questions.	1	2	3	4	5	6	7 8 9
10	Seeking consolation.	1	2	3	4	5	6	7 8 9
11	Sharing feelings of concern.	1	2	3	4	5	6	7 8 9
12	Managing nausea and vomiting.	1	2	3	4	5	6	7 8 9
13	Coping with physical changes.	1	2	3	4	5	6	7 8 9
14	Remaining relaxed while waiting at least one hour for my appointment.	1	2	3	4	5	6	7 8 9

*the clause was inserted to improve clarity by the developer on Feb2008 (after CCT completed)

Self-management intervention program for Women with breast cancer

Appendix D- 7

SELF-EFFICACY – EMOTION (SESES)

Please rate how confident you are in your ability to do the following. Rate your degree of confidence by filling in a bubble from 0-100 on the scale below each statement.

1. Let my friends know when I am angry because of something they did. Not at all confident	0	10	20	30	40	50	60	70	80	90	100	Completely confident
2. Directly consider the thought that I might die. Not at all confident	0	10	20	30	40	50	60	70	80	90	100	Completely confident
3. Be with people or do things without being distracted by painful emotions or anxious thoughts. Not at all confident	0	10	20	30	40	50	60	70	80	90	100	Completely confident
4. Ask for the emotional support I need from my spouse/partner or closest friend. Not at all confident	0	10	20	30	40	50	60	70	80	90	100	Completely confident
5. Focus my full attention on one thing at a time. Not at all confident	0	10	20	30	40	50	60	70	80	90	100	Completely confident
6. Consider any issue at all while remaining calm and feeling centered. Not at all confident	0	10	20	30	40	50	60	70	80	90	100	Completely confident
7. Express love, affection, caring to my spouse/partner or closest friend. Not at all confident	0	10	20	30	40	50	60	70	80	90	100	Completely confident
8. Talk about my possible death with my spouse/partner or closest friend. Not at all confident	0	10	20	30	40	50	60	70	80	90	100	Completely confident
9. Talk to my doctor about fears I have about dying. Not at all confident	0	10	20	30	40	50	60	70	80	90	100	Completely confident
10. Stay calm while waiting for the results of medical tests. Not at all confident	0	10	20	30	40	50	60	70	80	90	100	Completely confident
11. Face my fears about the thought that I might die without feeling anxious all day or all night. Not at all confident	0	10	20	30	40	50	60	70	80	90	100	Completely confident
12. Truly enjoy activities or people that are meaningful to me. Not at all confident	0	10	20	30	40	50	60	70	80	90	100	Completely confident
13. Express sadness or cry with my family members. Not at all confident	0	10	20	30	40	50	60	70	80	90	100	Completely confident
14. Cry or express other emotions I feel about dying when I am talking with someone close to me. Not at all confident	0	10	20	30	40	50	60	70	80	90	100	Completely confident
15. Ask for the emotional support I need from family members. Not at all confident	0	10	20	30	40	50	60	70	80	90	100	Completely confident

Stanford Emotional Self-Efficacy Scale--Cancer(Giese-Davis, et al, 2004)

Appendix D– 8

PROACTIVE COPING SCALE

This questionnaire is about the way you cope. Please rate all the statements according to how best they described you presently.

SCORING:

1 =“not at all true, 2 = “barely true”, 3 =“somewhat true”, 4 =“completely true”

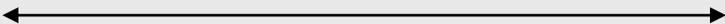
	Please Circle
1 I am a "take charge" person.	1 2 3 4
2 I try to let things work out on their own. (-)	1 2 3 4
3 After attaining a goal, I look for another, more challenging one.	1 2 3 4
4 I like challenges and beating the odds.	1 2 3 4
5 I visualise my dreams and try to achieve them.	1 2 3 4
6 Despite numerous setbacks, I usually succeed in getting what I want.	1 2 3 4
7 I try to pinpoint what I need to succeed.	1 2 3 4
8 I always try to find a way to work around obstacles; nothing really stops me.	1 2 3 4
9 I often see myself failing so I don't get my hopes up too high. (-)	1 2 3 4
10 When I apply for a position, I imagine myself filling it.	1 2 3 4
11 I turn obstacles into positive experiences.	1 2 3 4
12 If someone tells me I can't do something, you can be sure I will do it.	1 2 3 4
13 When I experience a problem, I take the initiative in resolving it.	1 2 3 4
14 When I have a problem, I usually see myself in a no-win situation (-)	1 2 3 4

- Reverse items

Appendix D- 9

Evaluation of Confidence Level (Treatment-receipt)

We would like to know how confident you are in doing certain health activities
Rate how confident you are that you can initiate a behaviour change in each of these areas- before, and after, participating in the 4-week SAMA intervention

RATING
No confidence 1...2...3...4...5 Most confident


	BEFORE SAMA	AFTER SAMA
Knowledge		
• Knowledge of treatment option	1...2...3...4...5	1...2...3...4...5
• Knowledge of managing symptom	1...2...3...4...5	1...2...3...4...5
Communicate with health professionals		
• Get information from health care staff	1...2...3...4...5	1...2...3...4...5
• Asking questions	1...2...3...4...5	1...2...3...4...5
Resources Utilisation		
• Getting aid (wig, prosthesis, information)	1...2...3...4...5	1...2...3...4...5
• Getting support (buddy, group, etc.)	1...2...3...4...5	1...2...3...4...5
Awareness of Risk reduction habits		
• Awareness on need to exercise	1...2...3...4...5	1...2...3...4...5
• Awareness of ideal body weight	1...2...3...4...5	1...2...3...4...5
• Awareness of my diet goals	1...2...3...4...5	1...2...3...4...5
• Awareness of breast health, BSE procedures	1...2...3...4...5	1...2...3...4...5
Engaging in Healthy habits		
• Practice exercise regularly	1...2...3...4...5	1...2...3...4...5
• Maintain Ideal body weight	1...2...3...4...5	1...2...3...4...5
• Perform breast check periodically	1...2...3...4...5	1...2...3...4...5
• Check 'mental hygiene'	1...2...3...4...5	1...2...3...4...5
• Fight negative (self defeating) thoughts	1...2...3...4...5	1...2...3...4...5
• Manage physical symptoms	1...2...3...4...5	1...2...3...4...5
• Adopt social recreation activities	1...2...3...4...5	1...2...3...4...5

.....THANK YOU & MANY BEST WISHES

Appendix D- 10

Letter to Employer



UNIVERSITY MALAYA

Fakulti Perubatan, Universiti Malaya
LEMBAH PANTAI, 50603 KUALA LUMPUR, MALAYSIA
TEL.: 603 – 7967 6612/ 2639
FAKS: 603 – 7967 4766



28hb Nov 2006

Dear Employer,

The University of Curtin, Australia and the University of Malaya, Malaysia is collaborating on a clinical research program designed for women newly diagnosed with (stage 1-3) breast cancer. The aim is to help women to self manage their breast cancer condition so as to improve their participation and quality of life.

This 4-week facilitated-program was developed based on the findings from group-interviews held between June -August 2005 with Malaysian women diagnosed with breast cancer. The outcome of that is the **S.A.M.A.** Program ('Staying abreast Moving ahead'), which is open to all women with stage 1-3 breast cancer and able to converse in English. The schedule of about 3-hour session per week, over four weeks is as stipulated below).

Dates for the four Thursday / Saturday: _____, _____, _____ and, _____

Time : 9.00 - 1.30 noon

Venue: Breast center, 6th Floor, Menara Utama University Malaya Medical Centre

We would like to urge all employers to support their female employee/s who have volunteered to attend the program. With your support of approved 'time off' or annual leave, we hope more ladies can take this first step to take charge of the illness by self managing the condition, whilst we support them. We thank you for your kind support to the ladies. Please do get in touch with us should you need further clarification.

With Many Best Wishes,

Ms Loh Siew Yim PhD candidate, Curtin University, Australia
Ms Umi/ Ms Ong 7949 2639 (Breast Cancer Resource Center)

Appendix E

PERMISSION BY AMERICAN COLLEGE OF PHYSICIAN (Wagner's Chronic Disease Management Model)

/2008 TUE 14:46 FAX 2153512644 ACP WUBIR5570

001/0

ACP

AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | Doctors for Adults

February 12, 2008



WAACP0815477

Siewyim Ioh
o/o Centre for Research into Disability and Society
School of Occupational Therapy
Curtin University of Technology
GPO Box U1987
Perth, Western Australia 6845
AUSTRALIA

Dear Mr. Ioh:

Thank you for your request to reproduce the following from *Effective Clinical Practice*:

Figure 1 from Wagner EH. Chronic Disease Management: What Will It Take to Improve Care for Chronic Illness? *Effective Clinical Practice*. 1998;1:2-4.

Permission is granted to reproduce the preceding material with the understanding that you will give appropriate credit to *Effective Clinical Practice* as the original source of the material. Any translated version must carry a disclaimer stating that the American College of Physicians is not responsible for the accuracy of the translation. This permission grants non-exclusive, worldwide rights for this edition in print and electronic formats for not-for-profit, educational use only. ACP does not grant permission to reproduce entire articles or chapters on the Internet unless explicit permission is given. This letter represents the agreement between ACP and Siewyim Ioh for request WAACP0815477 and supersedes all prior terms from the requestor.

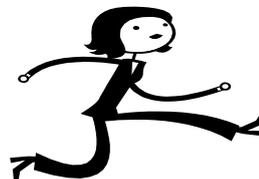
Thank you for your interest in *Effective Clinical Practice*. If you have any further questions or would like to discuss the matter further, please contact me at 215-351-2678 or fax 215-351-2438.

Sincerely,

Susan Klumb
Permissions Coordinator

Your reference #:ocm model

Appendix F
ETHICS APPLICATION APPROVAL



**THE SELF-MANAGEMENT
INTERVENTION FOR
WOMEN WITH BREAST CANCER**

**Appendix F-1: Ethics Approval from University of Curtin,
Perth, Australia**

**Appendix F-2: Ethics Approval from Ministry of Health,
Kuala Lumpur, Malaysia**

**Appendix F-3: Ethics Approval from University of Malaya,
Kuala Lumpur, Malaysia**

Self-management intervention program for Women with breast cancer

Appendix F-1

Ethics Approval from University of Curtin, Australia

Division of Health Sciences

9th February 2006

Ms Siew Yim Loh
School of Occupational therapy
Curtin University of Technology

Dear Siew Yim

Re: Ethics Application

We are pleased to advise that your Progress Report/Application for Renewal (Form B) for the project ***Self-management and intervention for Malaysian women with breast cancer: Enabling quality of life and participation*** has been approved.

This change in the measurement tool is seen as having no effect on the outcome of the project.

If at any time any further changes/amendments occur, or if a serious or unexpected adverse event occurs, please advise me immediately. The approval number for your project is **OT-2005-02**. Please quote this number in any future correspondence.

Please Note: The following standard statement must be included in the information sheet to participants:
This study has been approved by the Curtin University Human Research Ethics Committee. If needed, verification can be obtained either by writing to the Curtin University Human Research Ethics Committee, C/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth 6845 or by telephoning 9266 2784.

If you have any questions regarding the above, please do not hesitate to contact me.

Yours sincerely



PROFESSOR TANYA L. PACKER PHD
Professor and Director
Centre for Research into Disability and Society
School of Occupational Therapy
Curtin University of Technology

Curtin University of Technology

Centre for Research into Disability and Society

School of Occupational Therapy

GPO Box U1987
Perth Western Australia 6845

Telephone +61 8 9266 4651
Facsimile +61 8 9266 3636

CRICOS Provider Code 00301J

Appendix F-2

Ethics Approval from Ministry of Health, Malaysia



PEJABAT TIMBALAN KETUA PENGARAH KESIHATAN MALAYSIA
(PENYELIDIKAN & BOKONGAN TEKNIKAL)
KEMENTERIAN KESIHATAN MALAYSIA

OFFICE OF THE DEPUTY DIRECTOR GENERAL OF HEALTH MALAYSIA
(RESEARCH & TECHNICAL SUPPORT)
MINISTRY OF HEALTH MALAYSIA

Alamat (Address)
d/a Institut Penyelidikan Perubatan
(c/o Institute for Medical Research)
Jalan Pahang, 50688 Kuala Lumpur, Malaysia
Tel: 03-25988820 Fax: 03-25920675
Kawar (Cable): RESEARCH KUALA LUMPUR
E-mail: ksmak@mhc.gov.my

MEDICAL RESEARCH & ETHICS COMMITTEE
MINISTRY OF HEALTH MALAYSIA
C/o Institute for Medical Research
Jalan Pahang
50688 Kuala Lumpur

Ruj. Tuan :

Ruj. Kami

KKM/JEPP/02 (100)

Tarikh : 9 May 2005

Protocol Title :
Self management of women with breast cancer

Principal Investigator: Ms Loh Siew Yim
Department of Allied Health
University of Malaya

Documents received and reviewed with reference to the above study:

1. Borang JTP/KKM 1-2
2. Research Proposal
3. Participant Information Sheet and Consent Form

The Medical Research & Ethics Committee, Ministry of Health Malaysia operates in accordance to the International Conference of Harmonization Good Clinical Practice Guidelines.

Comments (if any): Project Sites: UMMC

Decision by Medical Research & Ethics Committee:

- Approved
 Conditionally Approved
 Disapproved

Date of approval : 9 May 2005

On behalf of :

DATO' DR ZAKI MORAD MOHD ZAHER
Chairman
Medical Research & Ethics Committee
Ministry of Health Malaysia

Appendix F-3

Ethics Approval from University of Malaya, Malaysia

 <p>PUSAT PERUBATAN UNIVERSITI MALAYA ALAMAT: LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA TELEFON: 03-79564422, 03-79574422 KEBEL: UNIHOS, KUALA LUMPUR FAX NO: 6-03-79545682</p>	
NAME OF ETHICS COMMITTEE/IRB: Medical Ethics Committee, University Malaya Medical Centre ADDRESS: LEMBAH PANTAI 59100 KUALA LUMPUR	ETHICS COMMITTEE/IRB REFERENCE NUMBER: 435.15
PROTOCOL NO: TITLE: Self-Management Intervention For Malaysian Women With Breast Cancer: Enabling Quality Of Life & Participation.	
PRINCIPAL INVESTIGATOR: Loh Siew Yim TELEPHONE:	SPONSOR: KOMTEL:
The following item <input checked="" type="checkbox"/> have been received and reviewed in connection with the above study to be conducted by the above investigator.	
<input checked="" type="checkbox"/> Borang Permohonan Penyelidikan <input type="checkbox"/> Study Protocol <input type="checkbox"/> Investigator Brochure <input checked="" type="checkbox"/> Participants Information Sheet & Consent Form(Focus Group) <input checked="" type="checkbox"/> Letter of Inviting Participation to Focus Group <input checked="" type="checkbox"/> Participants Information Sheet & Consent Form (Pilot Group) <input checked="" type="checkbox"/> Letter of Inviting Participation to Pilot Group <input checked="" type="checkbox"/> Participants Information Sheet & Consent Form (Clinical Controlled Trial) <input checked="" type="checkbox"/> Letter of Inviting Participation to Clinical Controlled Trial <input type="checkbox"/> Advertisement/Payment & Compensation to Subjects <input checked="" type="checkbox"/> Investigator(s) CV's (Loh Siew Yim)	Ver date: 21 March 2005 Ver date: Ver date: Ver date: Ver date: Ver date: Ver date: Ver date: Ver date:
and have been <input checked="" type="checkbox"/>	
<input type="checkbox"/> Approved <input checked="" type="checkbox"/> Conditionally approved (identify item and specify modification below or in accompanying letter) <input type="checkbox"/> Rejected (identify item and specify reasons below or in accompanying letter)	
Comments: Pengkaji diminta melantik seorang pakar klinikal sebagai Penyasat Bersama bagi kajian ini.	
Date of approval: 20 th April 2005	
c.c Ketua Jabatan Sains Kesihatan Sekutu Timbalan Dekan (Penyelidikan) Fakulti Perubatan, Universiti Malaya Setiausaha Jawatankuasa Penyelidikan Pusat Perubatan Fakulti Perubatan, Universiti Malaya	 PROF. LOOI LAI MENG Chairman Medical Ethics Committee

Appendix G

LISTS OF RELATED CONFERENCES

Poster Conference Venue	Breast Cancer as a chronic illness International Conference on Health Sciences (Malaysia) Kuala Lumpur, Malaysia. May 7 th 2005
Poster Conference Venue	Breast Cancer As a Chronic Illness: Implication for Rehabilitation Mark Leweris Health Seminar (Australia) Curtin University, Perth Australia. Nov 10 th 2005
Paper Conference Venue	Barriers to self-management in women with breast cancer National Breast Cancer Education Summit (Malaysia) Kuala Lumpur. Malaysia. July 1-2 nd 2006
Poster Conference Venue	Breast Cancer As a Chronic Illness: Implication for Self-management The UICC World Cancer Conference (USA) Washington DC, USA. July 8-14 th 2006
Paper Conference Venue	Patient Self-management - Innovations for cancer care? International Survivorship Conference (Malaysia) Kuala Lumpur Crown Plaza. Malaysia. August 10-12 th 2007
Poster Conference Venue	‘Exploring self-management needs of women with breast cancer’ 7th Biennial Asian Association of Social Psychology (Malaysia) Kota Kinabalu, Sabah. Malaysia. July 25-28 th 2007
Poster Conference Venue	A Clinical Controlled Trial – Self management for Breast Cancer As a Chronic Illness The Asia Pacific Occupational Therapy Conference (Hong Kong) Hong Kong 21-17 Jun 2007
Poster Conference Venue	‘A self-management Clinical trial: Addressing breast cancer as a chronic illness’ 9th International PsychoOncology 2007 (UK) London Imperial College, United Kingdom. 15-21 th September 2006
Poster Conference Venue	The Self management Needs of Malaysian women with breast cancer: a qualitative study International PsychoOncology 2007 (UK) London Imperial College, United Kingdom. 15-21 th September 2006

Appendix H

LISTS OF RELATED PAPER/ BOOK PUBLISHED

- 1 SY Loh, T Packer, WY Low, CH Yip (2007).
The Perceived Needs of Malaysian women with Breast Cancer.
The Asia Pacific Journal of Public Health 18 (3) p52-7 (2007)
- 2 SY Loh & CH Yip (2006).
Breast cancer as a chronic illness: Implication for Rehabilitation and Medical Education.
Journal of University Malaya Medical Journal 9 (2) p 3-11 (2006)
- 3 SY Loh, T Packer, A Passmore, CH Yip, S Dhalwali (2006). Breast cancer as a chronic illness: implication for self-management intervention.
The UICC World cancer Congress Education/ Abstract Book, p 232 (Poster No 84-32)
- 4 SY Loh, T Packer, APassmore, CH Yip, S. Dhalwali (2007).
A self-management Clinical Controlled Trial: addressing breast cancer as a chronic illness (poster P1-152).
Journal of the Psychological, Social and Behavioural Dimension of cancer. Vol 16 Number 9 (Supplement) September 2007
- 5 SY Loh, T Packer, WY Low, CH Yip (2007)
Malaysian women with breast cancer: Exploring Needs of Self-management (P2-36)
Journal of the Psychological, social and behavioural dimension of cancer. Vol 16 Number 9 (Supplement) September 2007
- 6 Baseline adjustment for statistical efficiency on a Clinical Controlled Trial.
Journal of University Malaya Medical Journal 2009
- 7 SY Loh (2002) - Book
Relaxation: Enhancing Your Mental Wellbeing
Leeds Publication (M) Ltd
ISBN: 983-2431-16-6

Appendix I

AWARDS



THE SELF-MANAGEMENT INTERVENTION FOR WOMEN WITH BREAST CANCER

Appendix I-1: IPRIS, Australia

Appendix I-2: UICC Scholar, USA

Appendix I-3: IPOS, UK

Appendix I_1

IPRIS SCHOLARSHIP AWARD, AUSTRALIA

Office of Research and Development

COPY

Curtin
University of Technology

Application ID: 987

23 November 2007

ABN 99 143 842 569
Building 100 Level 1 West
Dumas Rd Bentley
GPO Box U1987 Perth
Western Australia 6845
Telephone +61 8 9266 7863
Facsimile +61 8 9266 3793
Web <http://research.curtin.edu.au>
CRICOS Provider Code 00301J

TO WHOM IT MAY CONCERN

This hereby confirms that **Ms Siew Loh**, is in receipt of an Endeavour International Postgraduate Research Scholarship (EIPRS) at Curtin University of Technology.

The Endeavour IPRS is funded by the Department of Education, Science and Training (DEST) and is tenable for a period of 3 years with the possibility of up to 12 months extension (6 months at a time).

As an Australian Government scholarship, the Endeavour IPRS provides the following benefits to the recipient:

- ❖ *Waiver of visa application fees for the recipient and their dependants* (See DIMIA form titled 990i –Charges);
- ❖ *Payment of IPRS Student Fees - DEST will pay the course costs for the duration of the scholarship i.e. three (3) years with the possibility of up to one (1) year extension;*
- ❖ *Overseas Student Health Cover (OSHC) – DEST will cover the cost of a standard OCHC policy for the student and their dependants.*

Ms Loh commenced her EIPRS 9th August 2004 and it is currently due to expire 9th February 2008. Ms Loh has had one extension of 6 months approved but is eligible to apply for a second extension of 6 months closer to the current end date of the award.

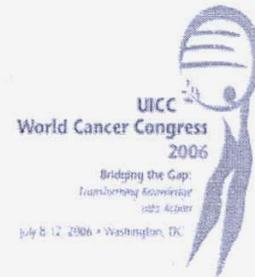
Should you require any further information regarding Ms Loh's Endeavour IPRS scholarship, please do not hesitate to contact this office by e-mail (scholarships@curtin.edu.au) or by phone (+61) 8 9 266 3119.

Yours sincerely


Delia Giggins
Manager, Scholarships

Appendix I_2

UICC SCHOLAR SCHOLARSHIP, USA



March 15, 2006

SIEW YIM LOH
Via Email: syioh@um.edu.my

Dear SIEW YIM LOH,

On behalf of the 2006 UICC World Cancer Congress (WCC) Scholarship Committee, we are pleased to inform you of your acceptance for a scholarship to the UICC World Cancer Congress to be held in Washington, DC from July 8 – 12, 2006. The World Cancer Congress agenda includes educational courses, scientific programs and papers by experts in the field of cancer control.

Enclosed please find a Confirmation of Acceptance Form to be completed and returned to Celeste McNair, Meeting Manager, at cmcnair@talley.com or fax 1-856 423-3420. Forms must be received no later than Wednesday, March 22, 2006.

The Congress organizers welcome your attendance at these events. We are working with the U.S. Department of State to alert U.S. embassies and consulates of the important nature of this conference. Please note that this letter does not guarantee that the consulate will issue a visa. While we are happy to provide documentation of your attendance and participation in the conference for visa purposes, visa issuance is at the sole discretion of the consular officer.

We have also included with this letter essential information that clarifies costs and describes important responsibilities that you have in accepting this scholarship.

If you have any questions, please feel free to contact Celeste McNair 1-856 423-7222 x 224 or at cmcnair@talley.com.

We are delighted to welcome you to the 2006 WCC Scholars program.

Sincerely,

Cathy Swaney
Program Manager, ACS University
American Cancer Society, Inc.

Appendix I_3

IPOS TRAVEL AWARD, UK



3 August 2007

via e-mail

Siew Yim Loh
Dept of Rehabilitation Medicine
Faculty of Medicine
50630, Kuala Lumpur
Malaysia

Re: IPOS 9th World Congress of Psycho-Oncology

Dear Ms. Loh:

The International Psycho-Oncology Society (IPOS) 2007 International Scientific Committee is pleased to invite you to attend the IPOS 9th World Congress of Psycho-Oncology and Psychosocial Academy, 16 – 20 September 2007 in London, United Kingdom. IPOS hereby offers you a scholarship to assist you with payment for all of your financial expenses associated with this Congress, including but not limited to food, transportation, accommodations and insurance while you are in the UK and your air fare from Malaysia to the UK and back. IPOS sincerely hopes that the British Embassy will assist you to its fullest capability in gaining an entry visa to attend the 9th World Congress of Psycho-Oncology.

Your attendance at the Congress will provide a valuable opportunity to increase the diversity of psycho-oncology professionals who attend and will encourage the promotion of psycho-oncology in all parts of the world. Please do not hesitate to contact IPOS Headquarters with any questions.

Sincerely,

A handwritten signature in black ink that reads 'Jennifer M. Allhisi'.

Jennifer M Allhisi MA Ed
IPOS Program Director

Appendix J

AWARDS



THE SELF-MANAGEMENT INTERVENTION FOR WOMEN WITH BREAST CANCER

- Appendix J-1 : SPSS missing values
- Appendix J-2 : Box plots
- Appendix J-3 : Change scores –primary endpoints
- Appendix J-4 : Change scores-secondary endpoints
- Appendix J-5 : MANCOVA with demographic covariates
- Appendix J-6 : Univariate RM ANOVA- primary endpoints
- Appendix J-7 : Univariate RM ANOVA- secondary endpoints

Appendix J-1

SPSS Missing Value Analyzer Report for all endpoints

		N	Mean	SD	Missing		No. of Extremes ^a	
					Count	%	Low	High
Primary Endpoints: SF36, IPA, DASS								
SF36	PCS_1	147	43.60	7.18	2	2.00	3	8
	PCS_2	147	44.60	6.71	12	8.20	7	8
	PCS_3	147	45.40	7.52	24	16.30	5	6
	MCS_1	147	42.90	10.43	2	1.40	8	7
	MCS_2	147	45.00	9.95	12	8.20	3	3
	MCS_3	147	46.80	10.23	24	16.3	5	4
IPA	FR_1	145	1.01	0.73	2	1.40	0	0
	FR_2	137	0.92	0.76	10	6.80	0	3
	FR_3	128	0.72	0.65	19	12.90	0	0
	SR_1	145	0.79	0.64	2	1.40	0	2
	SR_2	137	0.77	0.67	10	6.80	0	0
	SR_3	128	0.73	0.65	19	12.90	0	1
DASS	Stress_1	146	11.31	8.25	1	0.70	0	13
	Stress_2	136	10.82	8.68	11	7.50	0	3
	Stress_3	125	9.55	8.26	22	15.00	0	2
	Anxiety_1	146	8.37	6.88	1	0.70	0	1
	Anxiety_2	136	8.03	7.32	11	7.50	0	13
	Anxiety_3	125	7.57	7.23	22	15.00	0	6
	Depression_1	146	8.70	8.37	1	0.70	0	7
	Depression_2	136	7.77	8.39	11	7.50	0	5
	Depression_3	125	7.10	8.37	22	15.00	0	5
Secondary Endpoints: SUPPH, CBI, SESES, PCI								
SE ¹	SUPPH1	143	93.90	22.03	4	2.70	3	0
	SUPPH2	137	96.20	22.51	10	6.80	0	0
	SUPPH3	128	101.90	22.30	19	12.90	0	0
SE ²	CBI 1	144	86.90	18.97	3	2.00	0	0
	CBI 2	137	88.30	20.46	10	6.80	0	0
	CBI 3	128	93.70	20.19	19	12.90	0	0
SE ³	SESES1	144	62.60	17.33	3	2.00	0	0
	SESES2	135	66.40	17.90	12	8.20	0	0
	SESES3	127	69.50	17.79	20	13.60	0	0
PCI	PC1	144	39.70	6.92	3	2.00	3	0
	PC2	133	40.30	7.04	14	9.50	2	0
	PC3	128	41.80	7.30	19	12.90	0	0

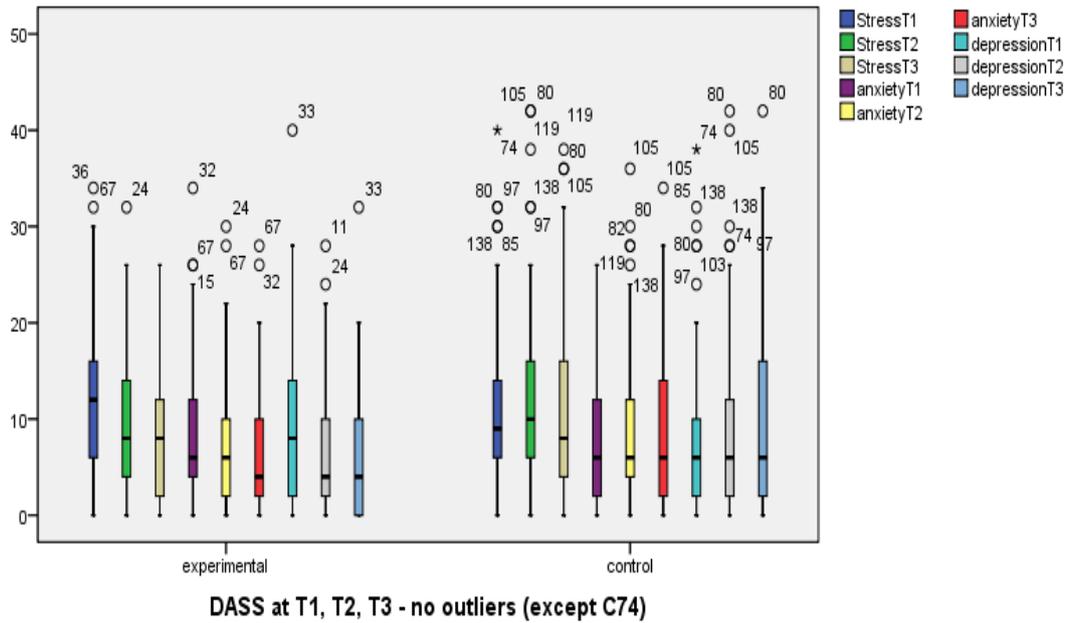
^a =number of cases outside the range (Q1 - 1.5*IQR, Q3 + 1.5*IQR);

Appendices

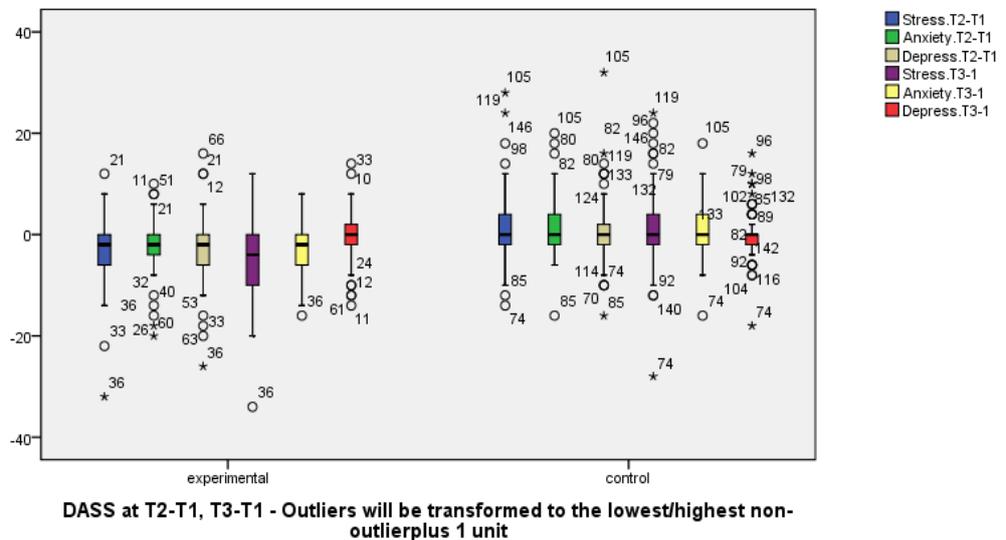
Appendix J-2 (i)

Boxplots: Mean scores of DASS at T1, T2, T3

Before transformation



After transformation-



Self-management intervention program for Women with breast cancer

APPENDIX J-3

Table 7.8.1 Change scores at T2-T1 and T3-T1 (Primary Endpoints)

			Mean	SD	SE	95% CI	% Change score	F	Anova Sig	
T2-T1										
PRIMARY	PCS T2-1	EXP	2.35	6.50	0.78	(0.79, 3.91)	5.46	6.15	0.014	
		CTRL	-0.12	5.59	0.63	(-1.38, 1.14)	-0.27			
	FR T2-T1	EXP	-0.17	0.57	0.07	(-0.31, -0.03)	-17.51	3.00	0.085	
		CTRL	-0.02	0.50	0.06	(-0.13, 0.10)	-1.93			
	SR T2-T1	EXP	-0.13	0.51	0.06	(-0.25, -0.01)	-15.13	5.69	0.018	
		CTRL	0.05	0.43	0.05	(-0.04, 0.15)	6.22			
	Stres T2-T1	EXP	-2.65	6.42	0.77	(-4.19, -1.11)	-20.92	15.9	0.001	
		CTRL	1.44	5.98	0.68	(0.09, 2.79)	13.97			
	Anx T2-T1	EXP	-1.84	4.90	0.59	(-3.02, -0.66)	-20.15	11.9	0.001	
		CTRL	1.13	5.45	0.62	(-0.10, 2.36)	14.26			
	Dep T2-T1	EXP	-2.97	6.86	0.83	(-4.62, -1.32)	-32.12	15.1	0.001	
		CTRL	0.91	5.19	0.59	(-0.26, 2.08)	11.20			
	T3-T1									
	PRIMARY	PCS T3-1	EXP	1.22	5.55	0.67	(-0.12, 2.55)	2.84	0.48	0.49
CTRL			0.69	3.51	0.40	(-0.10, 1.48)	1.56			
FR T3-1		EXP	-0.27	0.61	0.07	(-0.41, -0.12)	-27.81	1.30	0.25	
		CTRL	-0.15	0.58	0.07	(-0.28, -0.02)	-14.47			
SR T3-1		EXP	-0.21	0.48	0.06	(-0.33, -0.10)	-24.44	17.6	0.001	
		CTRL	0.10	0.44	0.05	(0.00, 0.20)	12.44			
Stres. T3-1		EXP	-4.35	8.16	0.98	(-6.31, -2.39)	-34.34	17.9	0.001	
		CTRL	1.17	7.60	0.86	(-0.55, 2.88)	11.35			
Anx T3-1		EXP	-2.84	4.41	0.53	(-3.90, -1.78)	-31.10	20.8	0.001	
		CTRL	1.05	5.75	0.65	(-0.25, 2.35)	13.25			
Dep. T3-1		EXP	-3.62	7.03	0.85	(-5.31, -1.93)	-39.15	15.6	0.001	
		CTRL	1.28	7.91	0.90	(-0.50, 3.07)	15.75			

PCS=Physical Composite Scores, FR=Family Role; SR=Social Relationship, Anx=Anxiety, Dep=Depression, Supp=Self care_Self-efficacy.

APPENDIX J-4

Table 7.8.2 Change Scores at T2-T1 and T3-T1 (Secondary Endpoints)

			Mean	SD	SE	95% CI	Change Score (%)	F	Anova Sig.
		T2-T1							
S E C O N D A R Y	SUPPH T2-T1	EXP	9.93	19.10	2.30	(5.34, 14.52)	10.86	28.0	0.001
		CTRL	-4.73	14.37	1.63	(-7.97, -1.49)	-4.89		
	CBI. T2-T1	EXP	7.00	20.19	2.43	(2.15, 11.85)	8.25	15.4	0.001
		CTRL	-4.38	14.89	1.69	(-7.74, -1.03)	-4.95		
	SESES. T2-T1	EXP	6.55	12.33	1.48	(3.59, 9.51)	10.30	9.4	0.003
		CTRL	0.73	10.67	1.21	(-1.67, 3.14)	1.19		
	PCI. T2-T1	EXP	2.70	4.78	0.57	(1.55, 3.84)	6.89	20.5	0.001
		CTRL	-0.91	4.85	0.55	(-2.00, 0.18)	2.25		
		T3-T1							
S E C O N D A R Y	SUPPH. T3-1	EXP	12.54	24.20	2.91	(6.72, 18.35)	13.72	15.9	0.001
		CTRL	-0.95	16.41	1.86	(-4.65, 2.75)	-0.98		
	CBI T3-1	EXP	10.16	20.49	2.47	(5.24, 15.08)	11.98	13.6	0.001
		CTRL	-0.76	15.28	1.73	(-4.20, 2.690)	-0.86		
	SESES. T3-1	EXP	8.07	15.68	1.89	(4.31, 11.84)	12.70	8.95	0.003
		CTRL	1.28	11.76	1.33	(-1.37, 3.93)	2.09		
	PCI. T3-1	EXP	4.12	4.92	0.59	(2.93, 5.29)	10.51	37.5	0.001
		CTRL	-1.26	5.63	0.64	(-2.52, 0.01)	-3.12		

SUPPH=Strategies Used by People to Promote Health (Self care_Self-efficacy), CBI=Cancer Behavior Inventory (Self-efficacy_ Cancer behaviours). SESES=Stanford's Emotional Self-efficacy Scale (Self-efficacy_ Emotion), PCI= Proactive coping.

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APPENDIX J-5 (i)

MANCOVA 1 Quality of life, participation and Distress at Post-test (T2-T1)

Multivariate Between group: **QOL, Participation and Distress at Post-test (T2-T1)**

Effect	Value	F	df	Error df	Sig.	Partial Eta Squared	Power ^b	
Factor Grp	Wilks' Lambda	0.89	2.64 ^a	6, 146	133.00	0.02	0.11	0.85

b. Computed using alpha = .05

d. Design: Intercept + fActiveorGrp + Ethnic + Xinsuran + exercise + Activeivity_Level

Univariate Between group: **QOL, Participation and Distress at posttest**

Source	Dependent Variable	Type III Sum of Squares	Mean Square	F	Sig.	Partial Eta Squared	Power ^b
Factor Grp	PCS.t2-1	128.14	128.14	3.67	0.06	0.03	0.48
	FamRoleT2-T1	0.99	0.99	3.38	0.07	0.02	0.45
	SocRshipT2-T1	1.33	1.33	6.07	0.02	0.04	0.69
	Stress.T2-T1	587.90	587.90	12.74	0.00	0.09	0.94
	Anxiety.T2-T1	277.59	277.59	9.19	0.00	0.06	0.85
	Depress.T2-T1	429.20	429.20	9.02	0.00	0.06	0.85

Df= (1, 146) Bonferroni adjusted p=0.008.

Pairwise Comparisons: QOL, Participation and Distress at post-test

Dependent Variable	(I) IV group	(J) IV group	Mean Difference (I-J)	Std. Error	Sig. ^a	95% CI for Difference ^a	
						Lower	Upper
PCS.T2-1	experimental	control	2.02	1.05	0.06	-0.06	4.10
FamRoleT2-T1	experimental	control	-0.18	0.10	0.07	-0.37	0.01
SocRshipT2-T1	experimental	control	-0.21 [*]	0.08	0.02	-0.37	-0.04
Stress.T2-T1	experimental	control	-4.32 [*]	1.21	0.00	-6.72	-1.93
Anxiety.T2-T1	experimental	control	-2.97 [*]	0.98	0.00	-4.91	-1.03
Depress.T2-T1	experimental	control	-3.69 [*]	1.23	0.00	-6.13	-1.26

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

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APPENDIX J-5 (ii)

MANCOVA 2 Quality of life, participation and Distress at Follow-up (T3-T1)

Multivariate Between group: QOL, Participation and Distress at follow-up

Effect		Value	F	(df, error)	Sig.	Partial Eta Squared	Power ^b
Factor Grp	Wilks'	0.847	3.99 ^a	6, 133	0.00	0.15	0.97
insuran	Lambda	0.897	2.53 ^a	6, 133	0.02	0.10	0.83

b. Computed using alpha =0 .05

Design: Intercept + fActiveorGrp + Ethnic + insuran + exercise + Activeivity_Level

Univariate Between group: QOL, Participation and Distress at follow-up

Source	Dependent Variable	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Power ^b
Group	PCS.t3-1	13.11	1	13.11	0.54	0.46	0.00	0.11
	FamRoleT3-1	0.46	1	0.46	1.28	0.26	0.01	0.20
	SocRshipT3-1	2.64	1	2.64	12.44	0.00	0.08	0.94
	Stress.T3-1	757.21	1	757.21	11.67	0.00	0.08	0.92
	Anxiety.T3-1	476.18	1	476.18	17.69	0.00	0.11	0.99
	Depress.T3-1	24.94	1	24.94	1.06	0.31	0.01	0.18
insuran	PCS.t3-1	13.70	1	13.70	0.57	0.45	0.00	0.12
	FamRoleT3-1	0.34	1	0.34	0.95	0.33	0.01	0.16
	SocRshipT3-1	0.21	1	0.21	0.97	0.33	0.01	0.17
	Stress.T3-1	438.53	1	438.53	6.76	0.01	0.05	0.73
	Anxiety.T3-1	88.64	1	88.64	3.29	0.07	0.02	0.44
	Depress.T3-1	2.42	1	2.42	0.10	0.75	0.00	0.06

df = (1, 146) Bonferroni adjusted p=0.008.

Pairwise Comparisons: QOL, Participation and Distress at follow-up

DV:	(I) IV group	(J) IV group-	Mean Difference (I-J)	Std. Error	Sig. ^a	95% CI for Difference ^a	
						Lower	Upper
GROUP							
SocRshipT3-1	experimental	control	-0.29	0.08	0.00	-0.45	-0.13
Stress.T3-1	experimental	control	-4.91	1.44	0.00	-7.75	-2.07
Anxiety.T3-1	experimental	control	-3.89	0.93	0.00	-5.72	-2.06
INSURANCE							
Stress.T3-T1	yes	no	-3.68	1.42	0.01	-6.49	-0.88

a. Adjustment for multiple comparisons: Bonferroni adjusted p=0.008.

*. The mean difference is significant at the .05 level.

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APPENDIX J-5 (iii)

MANCOVA 3 Self-efficacy and Proactive coping at post-test (T2-T1)

Multivariate: Self-efficacy and Proactive coping at post-test (T2-T1)

Effect	Value	F	(Df, error df)	Sig.	Partial Eta Squared	Power ^b
Factor Grp Wilks' Lambda	0.84	6.62 ^a	(4, 135)	0.00	0.16	0.99

a. Computed using alpha = .05

b. Design: Intercept + fActiveorGrp + Ethnic + Xinsuran + exercise + Activeivity_Level

Univariate: Self-efficacy and Proactive coping at post-test (T2-T1)

Source	Dependent Variable	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Power ^b
Factor Grp	SUPPH.T2-T1	4961.78	1	4961.78	16.85	0.00	0.11	0.98
	CBI.T2-T1	3525.12	1	3525.12	11.36	0.00	0.08	0.92
	SESES.T2-T1	519.90	1	519.90	4.05	0.05	0.03	0.52
	PCI.T2-T1	322.30	1	322.30	14.07	0.00	0.09	0.96

Df (1, 146) Bonferroni adjusted p=0.012.

Pairwise Comparisons: Self-efficacy and Proactive coping at post-test (T2-T1)

Dependent Variable	(I) IV group-allocation	(J) IV group-allocation	Mean Difference (I-J)	Std. Error	Sig. ^a	95% CI for Difference ^a	
						Lower	Upper
SUPPH.T2-T1	experimental	control	12.56 [*]	3.06	0.00	6.51	18.61
CBI.T2-T1	experimental	control	10.59 [*]	3.14	0.00	4.38	16.80
SESES.T2-T1	experimental	control	4.07 [*]	2.02	0.05	0.07	8.06
PCI.T2-T1	experimental	control	3.20 [*]	0.85	0.00	1.51	4.89

*. The mean difference is significant at the .05 level

a. Adjustment for multiple comparisons: Bonferroni p=0.012

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APPENDIX J-5 (iv)

MANCOVA 4 Self-efficacy and Proactive coping at follow-up (T3-T1)

Multivariate Between group: Self-efficacy and Proactive coping at follow-up

Effect		Value	F	(df, error)	Sig.	Partial Eta Squared	Power ^b
Factor Group	Wilks' Lambda	0.84	6.44 ^a	(4, 135)	0.00	0.16	0.99

b. Computed using alpha = .05

d. Design: Intercept + fActiveorGrp + Ethnic + Xinsuran + exercise + Activeivity_Level

Univariate Between group: Self-efficacy and Proactive coping at follow-up

Source	Dependent Variable	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Power ^b
Factor Group	SUPPH.T3-1	4195.93	1, 141	4195.93	10.13	0.002	0.068	0.885
	CBI.T3-1	2755.54	1, 141	2755.54	8.65	0.004	0.059	0.831
	SESES.T3-1	815.38	1, 141	815.38	4.47	0.036	0.031	0.556
	PCI.T3-1	657.81	1, 141	657.81	24.13	0.000	0.149	0.998

Bonferroni adjusted p=0.012.

Pairwise Comparisons: Self-efficacy and Proactive coping at follow-up

Dependent Variable	(I) IV group-allocation	(J) IV group-allocation	Mean Difference (I-J)	Std. Error	Sig. ^a	95% CI for Difference ^a	
						Lower	Upper
SUPPH.T3-1	experimental	control	11.55 [*]	3.63	0.00	4.38	18.73
CBI.T3-1	experimental	control	9.36 [*]	3.18	0.00	3.07	15.65
SESES.T3-1	experimental	control	5.09 [*]	2.41	0.04	0.33	9.85
PCI.T3-1	experimental	control	4.57 [*]	0.93	0.00	2.73	6.41

*. The mean difference is significant at the .05 level

a. Adjustment for multiple comparisons: Bonferroni

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APPENDIX J-6 i

i) Univariate RM ANOVA: Effect over time on QOL, Participation and Distress

DV	IV Factor		Mean	SE	95% CI (lower -upper)	
Physical Composite Score (QOL)	Time	T1	42.42	1.10	40.24	44.60
		T2	44.77	1.10	2.59	46.94
		T3	46.33	1.10	44.15	48.50
	Ethnic	Chinese	45.69	0.89	43.93	47.44
		Indian	40.84	1.49	37.91	43.78
		Malay& others	46.98	1.36	44.30	49.66
Family Role (IPA)	Time	T1	1.09	0.11	0.86	1.31
		T2	0.93	0.11	0.70	1.15
		T3	0.84	0.11	0.61	1.06
	Insurance coverage	yes	0.86	0.10	0.66	1.05
		no	1.04	0.12	0.81	1.27
Social Relationship	Time	T1	0.82	0.10	0.63	1.02
		T2	0.72	0.10	0.52	0.91
		T3	0.61	0.10	0.42	0.81
	Physical activity level	sedentary-light	0.97	0.17	0.64	1.31
		moderate	0.74	0.19	0.37	1.11
		active	0.44	0.16	0.11	0.76
Stress	Time	T1	15.19	1.34	12.56	17.82
		T2	12.35	1.34	9.72	14.98
		T3	10.87	1.34	8.24	13.50
	Ethnic	Chinese	9.92	1.08	7.80	12.05
		Indian	13.60	1.80	10.05	17.15
		Malay& others	14.88	1.65	11.63	18.13
	Physical activity level	sedentary-light	16.59	2.27	12.10	21.07
		moderate	14.60	2.53	9.61	19.58
		active	7.22	2.20	2.88	11.57
Anxiety	Time	T1	10.63	1.17	8.31	12.94
		T2	8.67	1.17	6.36	10.98
		T3	7.87	1.17	5.56	10.18
	Ethnic	Chinese	6.81	.95	4.95	8.68
		Indian	9.36	1.58	6.23	12.48
		Malay& others	11.00	1.45	8.14	13.85
Depression	Time	T1	11.48	1.27	8.98	13.98
		T2	8.54	1.27	6.04	11.04
		T3	7.91	1.27	5.41	10.41
	Ethnic	Chinese	6.62	1.02	4.60	8.63
		Indian	10.83	1.71	7.46	14.20
		Malay& others	10.48	1.56	7.40	13.57

APPENDIX J-6 ii

ii) Pair-wise comparison on the Primary Dependent measures (QOL)

Quality of Life Measure

Dependent Variable: Physical Composite Score (PCS)

FACTOR	(I)	(J)	(I-J)	SE	Sig. ^a	95%CI(Lower-Upper)	
TIME	1	2	-2.35	0.98	0.05	-4.71	0.01
		3	-3.91	0.98	0.00	-6.27	-1.54
	2	3	-1.56	0.98	0.33	-3.92	0.80
Ethnic	chinese	indian	4.84	1.35	0.00	1.56	8.12
		malay& others	-1.29	1.27	0.93	-4.37	1.78
	indian	malay& others	-6.13	1.74	0.00	-10.35	-1.92

APPENDIX J-6 iii

iii) Pair-wise comparison on the Primary Dependent measures (Participation)

Limitation in Participation Measure

Dependent Variable: FamilyRole (IPA)

FACTOR	(I)	(J)	(I-J)	SE	Sig. ^a	95%CI(Lower-Upper)	
TIME	1	2	0.16	0.10	0.31	-0.08	0.40
		3	0.25	0.10	0.04	0.00	0.49
	2	3	0.08	0.10	1.00	-0.15	0.33
INSURANCE	yes	no	-0.18	0.09	0.04	-0.36	-0.01

Dependent Variable: Social Relationship

FACTOR	(I)	(J)	(I-J)	SE	Sig. ^a	95% CI	
						Lower	Upper
Physical activity level	sedentary-light	moderate	0.23	0.10	0.09	-0.02	0.49
		Active	0.53	0.30	0.24	-0.25	1.27
	mod	active	0.30	0.31	1.00	-0.46	1.06

APPENDIX J-6 iv

iv) Pair-wise comparison on the Primary Dependent measures (Distress)

Psychological Distress measures

Dependent Variable: Stress

FACTOR	(I)	(J)	(I-J)	SE	Sig. ^a	95%CI(Lower-Upper)	
TIME	1	2	2.84	1.18	0.05	-0.02	5.70
		3	4.31	1.18	0.00	1.45	7.18
	2	3	1.47	1.18	0.64	-1.38	4.34
ETHNIC	chinese	indian	-3.67	1.64	0.08	-7.64	0.29
		malay& others	-4.95*	1.54	0.00	-8.68	-1.22
	indian	malay& others	-1.28	2.11	1.00	-6.38	3.81
PHYSICAL ACTIVITY LEVEL	sedentary-light	moderate	1.99	1.43	0.50	-1.48	5.46
		Active	9.36	4.14	0.07	-0.63	19.36
	Moderate	active	7.37	4.26	0.25	-2.93	17.67

Dependent Variable: Anxiety

FACTOR	(I)	(J)	(I-J)	SE	Sig. ^a	95%CI(Lower-Upper)	
TIME	1	2	1.95	1.04	0.18	-0.55	4.47
		3	2.75	1.04	0.02	0.23	5.27
	2	3	0.79	1.04	1.00	-1.71	3.31
ETHNIC	chinese	indian	-2.54	1.44	0.24	-6.03	0.94
		malay& others	-4.18	1.35	0.01	-7.46	-0.90
	indian	malay& others	-1.64	1.85	1.00	-6.12	2.83

Dependent Variable: Depression

FACTOR	(I)	(J)	(I-J)	SE	Sig. ^a	95%CI(Lower-Upper)	
TIME	1	2	2.94*	1.12	0.02	0.22	5.66
		3	3.56*	1.12	0.00	0.84	6.28
	2	3	0.62	1.12	1.00	-2.09	3.34
ETHNIC	chinese	indian	-4.21*	1.56	0.02	-7.98	-0.44
		malay& others	-3.86*	1.46	0.02	-7.40	-0.32
	indian	malay& others	0.34	2.00	1.00	-4.49	5.18

Mean Difference (I-J)

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

*. The mean difference is significant at the .05 level.

APPENDIX J-7 i

UNIVARIATE RM ANOVA SECONDARY ENDPOINTS

i) Univariate RM ANOVA: Effect over time on Self-efficacy and Proactive copings

Dependent Variable:	IV Factor		Mean	Std. Error	95% CI	
					Lower	Upper
SUPPH	Time	T1	92.22	4.20	83.94	100.51
		T2	101.66	4.20	93.37	109.94
		T3	104.76	4.20	96.47	113.04
	Ethnic	chinese	93.20	3.39	86.50	99.89
		indian	108.45	5.67	97.26	119.63
		malay& others	97.00	5.18	86.77	107.22
	Activity levels	Sedentary-light	87.85	7.15	73.73	101.96
		Moderate	89.89	7.95	74.20	105.57
		Active	120.91	6.93	107.22	134.59
CBI	Time	T1	82.85	3.76	75.43	90.28
		T2	89.85	3.76	82.43	97.28
		T3	93.01	3.76	85.59	100.44
	Activity levels	Sedentary-light	78.14	6.41	65.49	90.79
		Moderate	80.75	7.12	66.69	94.80
		Active	106.83	6.21	94.57	119.09
SESES	Time	T1	62.43	3.30	55.90	68.95
		T2	68.98	3.30	62.45	75.50
		T3	70.50	3.30	63.98	77.03
	Activity levels	Sedentary-light	58.82	5.63	47.70	69.93
		Moderate	65.88	6.26	53.53	78.23
		Active	77.21	5.46	66.44	87.99
Proactive Coping	Time	T1	41.04	1.14	38.77	43.30
		T2	43.73	1.14	41.47	46.00
		T3	45.15	1.14	42.89	47.42
	Activity levels	Sedentary-light	40.60	1.95	36.75	44.46
		Moderate	43.65	2.17	39.36	47.93
		Active	45.67	1.89	41.93	49.41

APPENDIX J-7 ii

ii) Post-hoc comparison on univariate RM ANOVA for SUPPH

Dependent Variable: **SUPPH**

	(I)	(J)	Mean Difference (I-J)	Std. Error	Sig. ^a	95% CI	
						Lower	Upper
TIME	1	2	-9.43 [~]	3.73	0.04	-18.44	-0.42
		3	-12.53 [~]	3.73	0.00	-21.54	-3.52
	2	3	-3.10	3.73	1.00	-12.11	5.91
ETHNIC	chinese	indian	-15.24 [~]	5.17	0.01	-27.74	-2.75
		malay& others	-3.79	4.86	1.00	-15.53	7.94
	indian	malay& others	11.45	6.64	0.26	-4.59	27.49
Activity level	Sedentary-light	moderate	-2.04	4.52	1.00	-12.97	8.88
		Active	-33.06 [~]	13.03	0.04	-64.53	-1.58
	moderate	active	-31.02	13.43	0.07	-63.45	1.41

APPENDIX J-7 iii

iii) Post-hoc comparison on univariate RM ANOVA for CBI

Dependent Variable: **CBI**

	(I)	(J)	Mean Difference (I-J)	Std. Error	Sig. ^a	95% CI	
						Lower	Upper
TIME	1	2	-7.00	3.34	0.11	-15.07	1.07
		3	-10.15 [~]	3.34	0.01	-18.23	-2.08
	2	3	-3.15	3.34	1.00	-11.23	4.91
Activity level	sedentary-light	moderate	-2.60	4.05	1.00	-12.39	7.18
		Active	-28.69 [~]	11.68	0.05	-56.89	-.49
	moderate	active	-26.08	12.03	0.10	-55.14	2.97

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APPENDIX J-7 iv

iv) Post-hoc comparison on univariate RM ANOVA for SESES

Dependent Variable: SESES

	(I)	(J)	Mean Difference (I-J)	Std. Error	Sig. ^a	95% CI	
						Lower	Upper
TIME	1	2	-6.55	2.94	0.08	-13.64	0.55
		3	-8.07 [*]	2.94	0.02	-15.17	-0.98
	2	3	-1.52	2.94	1.00	-8.62	5.58
Activity level	Sedentary-light	moderate	-7.06	3.56	0.15	-15.67	1.55
		Active	-18.39	10.26	0.22	-43.18	6.39
	moderate	Active	-11.33	10.57	0.86	-36.87	14.21

APPENDIX J-7 v

v) Post-hoc comparison on univariate RM ANOVA for PCI

Dependent Variable: Proactive coping

	(I)	(J)	Mean Difference (I-J)	Std. Error	Sig. ^a	95% CI	
						Lower	Upper
TIME	1	2	-2.69 [*]	1.02	0.03	-5.16	-0.23
		3	-4.11 [*]	1.02	0.00	-6.58	-1.65
	2	3	-1.42	1.02	0.50	-3.88	1.04
Ethnic	chinese	indian	-7.45 [*]	1.46	0.00	-10.99	-3.91
		malay& others	1.39	1.37	0.94	-1.93	4.72
	Indian	malay& others	8.85 [*]	1.88	0.00	4.30	13.39
Activity level	sedentary-light	moderate	-3.04 [*]	1.23	0.05	-6.02	-0.05
		Active	-5.07	3.56	0.47	-13.67	3.53
	moderate	Active	-2.02	3.67	1.00	10.89	6.83

Based on estimated marginal means Adjustment for multiple comparisons: Bonferroni.

*. The mean difference is significant at the .05 level.

Significant pairwise

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