Developing A Text Messaging Intervention To Support Medication Adherence To Endocrine Therapy In Adjuvant Breast Cancer: 
*An Interpretive Description Approach*

By

Soha Mahmoodi Ahrari

A thesis submitted in conformity with the requirements for the degree of Master of Science

Graduate Department of Pharmaceutical Sciences

University of Toronto

© Copyright by Soha Mahmoodi Ahrari 2017
Developing a Text Messaging Intervention to Support Medication Adherence to Endocrine Therapy in Adjuvant Breast Cancer: *an Interpretive Description Approach*

Soha Mahmoodi Ahrari  
Master of Science  
Graduate Department of Pharmaceutical Sciences  
University of Toronto

**Abstract**  
2017

Most adjuvant breast cancer patients are prescribed long-term endocrine therapy; however, not all patients continue these medications long term. Text messaging programs have been shown to be a low cost means of increasing medication adherence in a wide variety of chronic conditions, but have not been extensively studied in the breast cancer setting. The primary objective of this study was to develop a text messaging intervention to support long term endocrine therapy adherence. First, we sought to understand the breast cancer survivorship experience in the context of endocrine therapy. Second, we were interested in women’s experiences when using a theoretically grounded text messaging intervention. Participants were recruited from a single large academic centre. The initial text messaging intervention was informed by the Medication Adherence Model. Data collection comprised of two semistructured interviews with eight participants, as well as enrollment in the text messaging intervention. Two main themes arose regarding the experience of breast cancer survivorship. First, fear of recurrence and the worry about returning to normal after breast cancer treatment were dominating emotional experiences. As a result, a high degree of uncertainty permeated their lives, and learning to manage uncertainty was identified as a critical coping skill. When participants were asked regarding preferences for a text messaging intervention, women stated they were interested in an intervention that would act as a supporting friend, sending positive messages about overall wellness. In addition, message tailoring was recognized as an important characteristic in order to increase program usefulness. These findings are useful in shaping future work ensuring long term medication adherence to endocrine therapy.
Acknowledgements

This thesis would not have been possible without support and encouragement of many people. It’s true what they say – it takes a village to raise a child. And it takes an amazing support network to write a thesis. I am especially indebted to my supervisor Dr Carlo DeAngelis, who encouraged my pursuit of academic passions and provided me with so many amazing opportunities to expand my abilities as a pharmacist and as a researcher. A heartfelt thanks also to my Dr Kelly Grindrod and Dr Zubin Austin for your support and guidance. Sincere thanks to the amazing pharmacy team at the Odette Cancer Centre for welcoming me as a colleague and as a friend. Alia and Susan – your passion for patient care inspires me.

I cannot go without a special thanks to my cheerleaders outside of the pharmacy world. My parents, for your unrelenting enthusiasm and encouragement. Maryam, for knowing to never ask how my thesis is going. Pedram, for seeing the best in me and helping me through the highs and lows. My family and friends, for being the best team anyone could ask for.

Thank you.
Preface

Ethical approval for this study was obtained from Sunnybrook Health Sciences Centre Research Ethics Board on July 21, 2015. The Ethics Certificate number is 233-2015.
## Table of Contents

Abstract                                                                                      ......................................................... ii
Acknowledgements                                                                                  ......................................................... iii
Preface                                                                                           ............................................................... iv
Tables and Figures                                                                                       .............................................................. vi
List of Appendices                                                                                  .............................................................. vi
List of Acronyms                                                                                  .............................................................. vii
Chapter 1: Introduction and Overview                                                             ....................................................... 1
Chapter 2: Literature Review                                                                         ....................................................... 9
Chapter 3: mHealth Intervention Development                                                        ............................................... 16
Chapter 4: The Intervention Mapping Approach                                                         ............................................... 19
Chapter 5: Research Design                                                                         ....................................................... 28
Chapter 6: Results                                                                                 ....................................................... 46
Chapter 7: Discussion                                                                             ....................................................... 53
Tables and Figures

Figure 1: Medication Adherence Model Schematic .................................................................15
Table 1: Performance Objectives for Self-Regulation of Adherence ..................................21
Table 2: Determinants of Behaviour Change ......................................................................24
Table 3: Participant Characteristics .....................................................................................47

List of Appendices

Appendix A: Initial Interview Guide ....................................................................................66
Appendix B: Sample Text Messages for Initial Interview ..................................................67
Appendix C: Baseline Data Collection Form ......................................................................68
Appendix D: Final Interview Guide ....................................................................................69
Appendix E: Consent Form ................................................................................................70
Appendix F: Privacy/Security Education for Participants ...................................................76
Appendix G: Data Preparation and Transcription Protocol ...............................................77
Appendix H: Sample Final Library of Text Messages .........................................................79
Appendix I: Summary of Findings and Discussion ..............................................................82
List of Acronyms

AI  Aromatase Inhibitor
ET  Endocrine Therapy
MAM  Medication Adherence Model
mHealth  mobile Health
SERM  Selective Estrogen Receptor Modulator
SMS  Short Message Service
WHO  World Health Organization
Chapter 1: Introduction and Overview

*We look for medicine to be an orderly field of knowledge and procedure. But it is not. It is an imperfect science, an enterprise of constantly changing knowledge, uncertain information, fallible individuals, and at the same time lives on the line... The gap between what we know and what we aim for persists. And this gap complicates everything we do.* - Atul Gawande

1.1 Introduction

This thesis is a summation of my exploration into the relationship breast cancer survivors have with endocrine therapy. I used the findings to inform development of a text messaging program to support long term medication adherence. It is not possible to generalize the data summarized in this research to all breast cancer survivors; however, this deeper understanding of the survivorship experience may improve the efficacy of adherence interventions such as the one described here as it more accurately addresses issues breast cancer survivors face.

This chapter will introduce the thesis by providing the reader with a background on the problem, followed by study rationale, study aims, research questions, and a discussion of study significance.

1.2 Study Background

1.2.1 Breast Cancer Incidence, Prevalence, and Treatment

Breast cancer is the most commonly diagnosed cancer in Canadian women, making up over one quarter of all female cancers\(^1\), and is the leading cause of female cancer death\(^2\). At least 60% of all breast cancers are hormone receptor positive (HR+), requiring estrogen/progesterone stimulation for growth\(^2\). Generally, initial treatment for early invasive and locally advanced breast cancer involves a combination of surgery, radiation, and/or chemotherapy\(^3,4\). Adjuvant endocrine therapy to reduce the risk of breast cancer recurrence is considered for all patients with HR+ tumours, and can result in a 50% reduction in breast cancer mortality in the twenty years following initial diagnosis\(^5\).
Endocrine therapy (ET) in the adjuvant setting involves the use of selective estrogen receptor modulators (SERMs) or aromatase inhibitors (AIs) for several years following breast cancer diagnosis and treatment\textsuperscript{5,6}. Tamoxifen is the most commonly used SERM, antagonizing the effect of estrogen on estrogen receptors in breast tissue\textsuperscript{2}. AIs such as anastrozole, exemestane, and letrozole reduce estrogen synthesis which results in an estrogen-deprived state in the body\textsuperscript{2}. Both SERMs and AIs significantly improve long term survival, and there is growing evidence to support their use for up to 10 years after initial cancer treatment\textsuperscript{6,7}. All of these medications require patients to take one tablet daily.

Breast cancer incidence has remained stable for the past several years\textsuperscript{1}. However, cancer is more likely to occur in older adults, meaning that as Canada’s population continues to age\textsuperscript{8} the actual number of breast cancer patients will continue to increase. This rise in the number of breast cancer patients and survivors increases the pressure on an already fiscally-constrained public healthcare system, raising questions as to how we can increase quality and efficiency of care.

1.2.2 Medication Taking Behaviour

One of the most important factors in ensuring oral medication efficacy is appropriate and consistent use. As C. Everett Koop, former US Surgeon General, put it, “drugs don’t work in patients who don’t take them”\textsuperscript{9}. There are three related terms that have been used to describe this behaviour: compliance, adherence, and concordance. Each of these terms represent a paradigm shift in the patient-provider relationship, moving from a more paternalistic model to one that increasingly values patient autonomy\textsuperscript{10}. Compliance is defined as the extent to which patients follow healthcare provider recommendations\textsuperscript{11}. Adherence then integrates patient autonomy into the decision-making process\textsuperscript{11}. Therefore, medication adherence is a measure of how closely patients uphold the decision made collaboratively with the healthcare provider. In contrast, concordance focuses on the decision-making process itself, recognizing the ultimate primacy of the patient’s decision\textsuperscript{11,12}. Therefore, I explicitly chose
the term medication adherence throughout this thesis as it best fit both my research interests and my personal perspective as a Canadian-trained pharmacist, which is further discussed in section 5.3.

1.2.3 Medication Adherence

Medication adherence is generally defined as “the extent to which a person’s behaviour – taking a medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a healthcare provider”\textsuperscript{13}. There is currently no gold standard of adherence measurement, nor is there a widely accepted and reliable operational definition. For example, many researchers divide medication adherence into four sub-behaviours: initiation, implementation, discontinuation, and persistence\textsuperscript{14}. Adherence to initiating therapy refers to the time taken from receiving a new prescription to starting therapy\textsuperscript{14}. Implementation refers to the medication-taking itself, such as whether patient dosing corresponds to the prescribed dosing\textsuperscript{14}. Discontinuation occurs whenever patients choose to stop taking their medications. Finally, persistence refers to the length of time between initiation and discontinuation\textsuperscript{14}. These sub-behaviours are not consistently measured, and there is a significant amount of research that consists of measuring a single sub-behaviour, such as persistence, and extrapolating it to characterize overall medication adherence in a population. For example, one study of breast cancer patients showed that 33\% of patients had been classified as nonadherent. Of that 33\%, only one third were intentionally non-adherent, while the rest of the patients appropriately discontinued endocrine therapy prematurely due to intolerable side effects, breast cancer recurrence, other medical reasons independent of cancer, and death, thus showing an underestimation of adherence\textsuperscript{15}. At the same time, studies of patient self-report and pill counts have been found to overestimate adherence compared to electronic pill caps which record the number of times a bottle is opened, and presumably the medication is taken\textsuperscript{16}. 


The operational definition of adherence has also differed based on the situation in question. Historically, adherence research tended towards defining adherent behaviour as taking over 80% of doses as prescribed, although some studies used rates as high as 95%\textsuperscript{9,17}. In the context of cancer treatment, intravenous chemotherapy standard of practice requires doses to be within 5% of clinical guidelines in order to maximize efficacy while minimizing toxicity risk\textsuperscript{18}, and it follows that this standard is an appropriate goal for the duration of all cancer treatments. However, adherence research done in ET after breast cancer has used 80% adherence based on past precedent in other chronic disease medication adherence studies\textsuperscript{19}.

1.2.4 Cost of Low Medication Adherence

Medication adherence has been recognized as an essential concern in patient care. Poor adherence is associated with higher healthcare costs due to poor control of chronic and acute conditions, resulting in up to $290 billion dollars in excess spending annually in the United States\textsuperscript{20}. In a recent economic review of medication adherence, the authors recognized that although non-adherence reduces overall healthcare costs by lowering drug expenditure in the short term, this is outweighed by the increased cost that stems from disease progression of a potentially controllable disease\textsuperscript{21}. One Canadian report found that approximately 5% of hospitalizations were directly due to medication nonadherence, costing hospitals up to $1.6 billion dollars annually, and the healthcare system up to $7-9 billion annually\textsuperscript{22,23}. These large costs are of significant concern for healthcare providers and payers, resulting in a high degree of interest in interventions that improve medication adherence and prevent worsening of chronic conditions. General reasons for poor medication adherence have previously been identified. The most common barriers to adherence have been grouped by the WHO into five categories:
socioeconomic, patient, healthcare provider, therapy, and education\textsuperscript{13,14}. However, despite continued interest, researchers have not been able to identify strong predictors of poor medication adherence at the initiation of therapy to target for intervention development.

Medication adherence studies in other chronic conditions have shown that nearly 50% of patients are sub-optimally adherent, resulting in poorer outcomes and increased health care costs\textsuperscript{9,24}. Similar to other chronic conditions, nonadherence rates to ET range from 15 to 50% in the breast cancer survivor population\textsuperscript{2,25-30}. Low adherence has been linked to the development of resistance to ET\textsuperscript{31}, resulting in increased rates of cancer recurrence and overall mortality\textsuperscript{32,33}. The variation in adherence rates reported in the literature is indicative of the variability in measurement tools and operational definitions used to quantify adherence, as discussed in section 1.2.3.

In addition, persistence rates to ET decrease over time\textsuperscript{34}, resulting in a significant proportion of patients who do not complete five years of treatment\textsuperscript{29,34}. This trend will likely continue its annual decline as healthcare providers increasingly prescribe ET for ten years\textsuperscript{35}. Adherence rates tend to decrease dramatically in the first year but then continue a linear decline over time\textsuperscript{34}, indicating that continued monitoring and intervention is necessary for this patient population. One effective way of increasing medication adherence is ensuring a positive relationship with the healthcare team, with frequent points of contact\textsuperscript{36}. However, current guidelines recommend a reduction in follow-up appointments over time, from 2-3 appointments per year for the first 3 years down to 1-2 appointments per year for year 4 and 5 of endocrine therapy\textsuperscript{37}. In order to maintain adequate adherence, another means of increasing communication opportunities is required.

As researchers continue to study nonadherence patterns in breast cancer patients on ET, some general trends have been noted. First, patients who felt there was little benefit to their treatment, as described
by the Health Belief Model, had lower rates of medication adherence compared to those with more positive health beliefs about ET. In addition, one survey found the main patient-reported reason for premature ET discontinuation was side effects. Finally, Bandura’s concept of self-efficacy has also been shown to be closely tied to adherence to cancer treatment. There is evidence to show that good patient-provider communication and satisfaction with care can improve health beliefs and self-efficacy. This can be accomplished through continued and close monitoring by healthcare professionals.

However, as discussed above, guidelines recommend a reduction in follow-up appointments over time. This reduction in patient-provider communication opportunities plays a part in reducing medication adherence over time. In order to maintain adequate adherence monitoring and ensure patients feel supported while on treatment, with opportunities to address health beliefs and side effects, despite the reduction in appointments (and therefore close monitoring), another approach is needed.

Text messaging interventions have been used in a variety of healthcare settings to encourage adherence to medications and to other healthcare provider recommendations. Intervention efficacy tends to be dependent on how well the intervention meets the needs of the target audience. In the case of breast cancer patients, a text messaging program may play a part in increasing connectivity to the healthcare team. In conclusion, despite the variability in current research measures of adherence, clinicians and researchers recognize that nonadherence to endocrine therapy continues to be a problem.

1.3 Study Rationale

There is a large group of women who survived breast cancer and are now being treated with ET. A significant proportion of them stop taking their medications prematurely, meaning that they are at increased risk of breast cancer recurrence. The likelihood of prematurely stopping treatment...
increases over time\textsuperscript{31}, while at the same time patients see their oncology healthcare team less frequently.

In order to address this issue with a minimal increase in healthcare expenditure, I used a mobile health approach to engage with patients. Mobile health interventions such as text messaging programs have been successful in the past in improving medication adherence while at the same time requiring minimal human oversight, making it an ideal adjunct to current clinical practice.

1.4 Study Aims
My primary aim in this thesis was to develop a text messaging intervention focused on medication adherence to ET. This thesis will first explore the evidence behind medication adherence interventions, discuss the initial text message content development, and then summarize the process by which semistructured interviews were conducted to inform the final text messaging intervention.

1.5 Research Questions
1) What is the breast cancer survivorship experience in the context of continued endocrine therapy treatment?

2) What are women’s preferences for a text messaging intervention that supports medication adherence to endocrine therapy?

1.6 Significance of the Study
The aim of this study is to explore breast cancer survivors’ current experiences with endocrine therapy and work closely with them to improve a theoretically grounded text messaging intervention aimed at improving adherence to endocrine therapy. A real-life understanding of the survivorship experience in the context of endocrine therapy can be informative for other researchers and intervention developers. In addition, text messaging interventions have only slowly come into use over the last
twenty years, meaning intervention developers are still studying how to best develop and optimize interventions. This research can contribute to a better understanding of intervention development in chronic disease in general as well as breast cancer survivors on endocrine therapy in particular.

1.7 Conclusion

This chapter has briefly described the background of the project and its significance for patients and healthcare providers. I also introduced the study aims, research questions, and study significance.

The rest of this thesis is organized into seven chapters. Chapter 2 is a literature review of mobile health.

It also introduces the theoretical behaviour models being used to describe medication adherence.
Chapter 2: Literature Review

The art of medicine consists of amusing the patient while nature cures the disease – Voltaire

2.1 Introduction

In the previous chapter I provided background on breast cancer incidence, prevalence, and treatment. I then defined medication adherence and outlined the evidence behind adherence to ET. I also reviewed the costs associated with medication nonadherence in chronic disease and with ET in particular. Finally, I summarized the study rationale, aims, and research questions.

In this chapter I present the current knowledge around mobile phone use in the modern world and the development of mobile health in the last 20 years. I then review a theoretical behaviour model of medication adherence which helped shape intervention development.

2.2 Mobile Phones

Mobile phones are a relatively new technology that have drastically affected human interactions, with an estimated 8 billion active mobile phones globally connecting the world. Text messaging technology was first developed in 1992, and in less than thirty years has become the most commonly used nonvoice application on mobile devices. It is widely used for social communication, and its use as a health promotion and management tool is increasingly becoming recognized.

2.2.1 Mobile Health: A historical perspective

Mobile health, or mHealth, is a term that was first used in 2005. There is currently no standardized definition for this term. The WHO has adopted the following definition of mHealth:

Medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices.

Text messaging as a component of mHealth has existed from its inception. According to Head et al, the first formal evaluation of an mHealth intervention was a text messaging intervention published in
2002\(^{50}\), while the first randomized controlled trial for a health promotion mHealth intervention was published in 2005\(^{51}\). Since then, there have been numerous pilot studies and randomized interventions which have appeared in the literature.

Text messaging interventions have been of increasing interest as an adjunct health intervention that improves health outcomes in a scalable, low cost way. In addition, research has shown that message tailoring, interactivity, personalization, and/or high message repetition has increased the success of text messaging interventions in the past, suggesting that researchers are still looking for the optimal combination of strategies that improve intervention quality and efficacy\(^{52}\).

2.2.2 Mobile Health in Breast Cancer

Text messaging, and other mobile media, has fundamentally changed the way with which individuals interact with the world. Mobile media creates perpetual contact with peers, resulting in changes in the ways social circles behave\(^{53}\). For example, the Mobile Interface Theory discusses how mobile devices have created a new social space for individuals to interact within. Researchers have shown that breast cancer patients require more time with their healthcare providers in order to meet their educational and support needs. As this time cannot be provided face-to-face, an alternative means of connecting is through this new social space. Text messaging has been harnessed in order to deliver health care interventions that range from lifestyle modification support to disease management, with a strong body of literature focusing on diabetes and HIV treatment adherence. There is also growing interest in other chronic conditions like hypertension and asthma\(^{45}\). In meta-analysis, medication adherence interventions had large effect sizes when the text messaging programs were bi-directional and personalized to an individual’s clinical need\(^{45}\).

Text messaging interventions, in addition to improving medication adherence directly, can act as an efficient means to identify patients having adherence issues. This continued close monitoring would
ensure clinicians can provide more resource-intensive interventions to a smaller number of patients that require additional care. Early identification of non-adherent oncology patients and provision of additional care for a short period of time at the critical initial period of non-adherence has shown to be effective in the past in improving long term adherence\textsuperscript{54}.

Technology interventions in the oncology setting, which are highly scalable and low-cost, have not been studied extensively. Currently, there are a small but growing number of clinical trials underway looking at various facets of patient acceptance of text messaging interventions and their impact on adherence to ET\textsuperscript{55-7}. However, despite strong recommendations from federal institutions\textsuperscript{58} to conduct user-centred research to validate theory-based content for these interventions, this guiding principle has not been followed in the research conducted to date, meaning that interventions are not optimized to provide the content and interactivity that patients desire.

2.3 The Medication Adherence Model

*He who loves practice without theory is like the sailor who boards ship without a rudder and compass and never knows where he may cast.* - Leonardo da Vinci

As mentioned in section 1.2.4, a theoretical model of the target behaviour needs to be adopted in order to shape development of any text messaging intervention. In order to adequately describe the components of medication adherence behaviours that needed to be addressed in the initial intervention, I chose to use the Medication Adherence Model\textsuperscript{59} (MAM). This model was initially developed to evaluate medication adherence for individuals with hypertension, but is applicable to other long-term medications that manage chronic conditions such as endocrine therapy. Both endocrine therapy and antihypertensives are characterized by the similarity in their purpose, namely, that both aim to prevent the target condition (cancer, or a cardiac event) from occurring. This differs significantly from medications taken to control symptoms of a current chronic condition. There have been many other health behaviour models developed to address adherence concerns in situations that pose a high
threat to individual health, but these were not designed to address adherence concerns when threat is low, as in chronic disease management. The impact of nonadherence to insulin for type 1 diabetes, for example, can be felt by patients within hours. The repercussion of nonadherence to antihypertensives or endocrine therapy may take years to manifest, meaning that the behavioural theory needed describe medication adherence in this context needs to take into account both short and long term effects of taking a medication while the patient is asymptomatic to the target condition.

The MAM is a midrange theory that was developed using constructs from the Health Belief Model, Bandura’s Social Cognitive Theory, the Theory of Reasoned Action, and the Self-Regulation Model. While the first three theories have all been shown to be integral to making healthcare decisions, the construct of self-regulation is integral in addressing the repetitive process of appraising chronic disease progression and management over long periods of time. Based on these models, critical cognitive concepts involved in explaining adherence include patient perception of illness severity/susceptibility, medication benefits/barriers, and self-efficacy.

2.3.1 Core Constructs of the Medication Adherence Model

The MAM is a framework consisting of three core processes describing medication adherence to an asymptomatic condition. It was developed through content analysis of adherence to chronic medications incorporating theoretical models of human behaviour. The three core processes are (1) Purposeful Action, (2) Patterned Behaviour, and (3) Feedback.

**Purposeful action** is the degree to which patients choose to take medication(s) based on perceived need. Patients weigh the perceived benefits, such as their estimation of how well the medication is working (effectiveness), against perceived risks, such as medication safety or experience and severity of side effects. If an individual perceives that a medication is needed to promote health or prevent disease, they will be more likely to take medications.
Purposeful Action is a cognitive process that can be mapped closely to the Health Belief Model; both incorporate perceived illness susceptibility and severity, as well as perceived medication effectiveness and safety. The result of purposeful action to stop medications is intentional non-adherence, or choosing to alter dosing or stop medications with/without consulting the healthcare team.

**Patterned Behaviour** is the degree to which patients create routines to ensure every medication dose is taken as prescribed. When patterned behaviours are not adequately developed, it can result in unintentional non-adherence. Although patients have the intention to take their medication, and thus are undertaking Purposeful Action, there may be unintentional non-adherence due to factors such as (1) inability to access medication, (2) interruption of routine, and (3) a lack of reminders.

**Access** can be defined as the patient’s ability to obtain, store, and self-administer a medication as prescribed. Although it involves having the cognitive and physical ability to take medications, it is not considered a cognitive component in MAM because of the external forces involved. Factors that can reduce access include economic barriers (lack of insurance, reduced income), geographic barriers (patient remoteness from healthcare providers and pharmacies), and physical/cognitive abilities to obtain, store, and administer medications.

**Routine** is defined as the patient’s ability to create a pattern in their daily life to ensure medications are taken as prescribed. Routines are meant to be tailored to an individual’s lifestyle. Patients that are highly adherent tend to link medication taking behaviours to other behaviours critical to their daily life. They also tend to link medications to specific times, locations, or behaviours (i.e. with meals, in the bedroom, or every time they enter a specific area of their home). Care must be taken to ensure the medication routine is linked to a behaviour/time that is integral to daily life; this reduces the chance of an interruption that causes a dose to be missed.
Finally, *reminders* are used to minimize the chances of missing a dose through interruptions in routine. Reminders can include alarms or pill boxes meant to act as prompts to take medication. This concept is also described in the Health Belief Model under the cue domain.

Patterned behaviour is a domain that is not fully described in traditional medication-taking behaviour models. However, it is necessary to describe the full process of chronic medication management. Although the cognitive domain, enshrined here under Purposeful Action, may indicate that a patient intends to take a medication, they may become unintentionally non-adherent due to lack of components that make up Patterned Behaviour, making it a valuable component of the MAM.

**Feedback** is the degree to which information, prompts, or events can reinforce or change medication-taking behaviours. Purposeful Action and Patterned Behaviour are continually being influenced by patient experiences. Feedback sources can include experiences with side effects, media messages, or comments by healthcare providers/laypeople. Positive Feedback experiences, such as new information about the benefits of continuing endocrine therapy, may incentivize good adherence. In contrast, negative Feedback experiences, such as a perception of medications being ineffective or unsafe, may decrease adherence. In addition, Feedback involves self-awareness in order to explicitly identify factors that may influence adherence and includes a process of allowing these observations to change adherence behaviour.

Feedback is closely tied to the Self-Regulation Model. The Self-Regulation Model can be described as three separate but intertwined behaviours of self-observation, self-evaluation, and self-reaction which are integral to understanding how health behaviours are sustained or change over time. In the MAM, Feedback implicitly includes these ideas and asks whether effects, events, or prompts affect medication adherence through indirect changes in Purposeful Action or Patterned behaviour.
2.3.2 Conclusion

The three main constructs that make up the MAM come together to elegantly describe the process of medication adherence over time. First, Purposeful Action means that patients must make a deliberate decision to start endocrine therapy. Once this decision is made, a patient will develop a Patterned Behaviour over time so that medication-taking becomes a natural part of life that requires little cognitive input. These two domains constantly interact in a patient’s life as new experiences occur or new information is learned. The Feedback domain describes the feedback loop that affects their decision to act and the behavioural patterns established. Figure 1 is adapted from Johnson et al. 2002\textsuperscript{59} to describe the relationship between these constructs.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{medication_adherence_model.png}
\caption{Medication Adherence Model Schematic}
\end{figure}

2.4 Conclusion

In this chapter, I briefly the historical beginnings of mobile health. I also introduced the Medication Adherence Model, a theoretical health behaviour model that describes medication adherence to chronic medications used to reduce risk of serious health outcomes. In the following chapter I will be further expanding the current methods used to develop mobile health interventions.
Chapter 3: mHealth Intervention Development

3.1 Introduction

In the previous chapter I presented a short history of the changes that have occurred in the mHealth field since its inception over 20 years ago. I then presented the Medication Adherence Model, which can be used as a basis for adherence intervention development. In this chapter, I will be presenting the formalized intervention development approach that has been widely adopted by mHealth intervention developers, and then using this approach to develop the initial text messaging program to be used in my study. As the mHealth research field grows, researchers have recognized that the efficacy of a text messaging intervention is dependent on how well it meets the needs of the target audience. These needs can be met through varying the content, messaging style, and interactivity of the intervention. In consequence, researchers now recommend that the intervention be developed through a formalized pretesting process, and their recommendations are summarized below\textsuperscript{58,67-9}.

3.1 Formative Research

The first step in formative research for intervention development includes developing a strong understanding of the target audience as well as the target health behaviour. This research would follow similar parameters as research done for other healthcare communication materials development. The target behaviour needs to be well understood and key behaviour change mechanisms in the population of interest need to be defined. A theoretical model of behaviour change, if available, can be adopted. In this thesis, I chose to use the Medication Adherence Model (MAM), which has been described in section 2.2.3.

3.2 Designing the Program

Program design is a complex process. Experienced intervention developers recommend starting with identification of a clear behaviour change goal and target audience\textsuperscript{69}. In this case, I identified the
behaviour change goal and target audience as maintaining medication adherence in breast cancer survivors taking endocrine therapy.

The next step in designing the program involves choosing specific communication objectives and behavioural techniques to promote medication adherence. Communication objectives are developed using the chosen theoretical model of behaviour change, in this case the MAM, to identify important beliefs, attitudes, and knowledge that patients would ideally gain. As the MAM involves developing positive attitudes in order to maintain Purposeful Action, positive Behaviour Patterns to maintain adherence, and providing a mechanism for Feedback to ensure continued medication adherence, these constructs were used both to design the text messaging intervention development framework and when creating the text message library. Program design and intervention development is discussed in more detail in Chapter 4.

3.3 Pretesting

Pretesting the text messaging intervention is the first step that involves members of the target audience. Pretesting can involve focus groups, semi-structured interviews, or surveys with participants. The purpose of this step is to assess both the concept/content/messages included in the program as well as the degree of engagement participants have with the program. This helps us better understand how participants use the intervention, whether there were particular aspects or messages that were viewed as especially helpful, and perhaps provide a preliminary understanding of potential behaviour change. This thesis involves both intervention development and pretests the theoretically-informed text messaging program. The pretesting process took the shape of participant interviews, as further discussed in Chapter 5.
3.4 Future steps

The next steps in intervention development including conducting pilot studies and randomized controlled trials. Pilot studies are constructed as opportunities to test study logistics such as participant recruitment, enrollment, and technical aspects of text message delivery and data collection. Next, a larger multi-site randomized controlled trial is done in order to assess intervention efficacy prior to more wide-spread real-world application. Ideally, this randomized trial would be pragmatic as a real-world setting would more accurately reflect future wide-spread use of the intervention. These components of developing a text messaging intervention are beyond the scope of this thesis.

3.5 Conclusion

In this chapter I briefly described the formal intervention development approach that is becoming widely accepted in mobile health. In the next chapter, I will further expand on the steps taken to develop my initial text messaging intervention.
Chapter 4: The Intervention Mapping Approach

*Intervention Mapping is the product of its authors’ frustration in teaching students the processes in developing theory- and evidence-based health promotion*.\(^{70}\)

### 4.1 Introduction

While researching mHealth intervention development, I found numerous general recommendations to include a theoretical behaviour model in the development of mHealth interventions. However, I found it challenging to operationalize these recommendations as the mHealth literature has not yet described a method to systematically apply theory during the development of an intervention\(^{71}\). Therefore, I searched the health intervention literature more broadly in order to identify a specific method that can guide theory-informed intervention development. In my research, I identified the *Intervention Mapping Approach*\(^{72}\), a framework which allows intervention developers to systematically apply theory in their interventions. This approach is also beneficial in that it creates a space to discuss the development and rationale for decisions in the intervention development process\(^{73}\). It has mostly been used in general health promotion interventions, but recently has also been used to develop a mobile phone/internet delivered program to support smoking cessation\(^{74}\). Intervention mapping involves a set of six highly structured yet iterative steps that help guide intervention from development to full-scale implementation. The steps are summarized as follows\(^{75}\):

1. Conduct a needs assessment
2. Create a matrix of change objectives
3. Link change objectives to theoretical methods and practical strategies
4. Design and organize the intervention program
5. Program Adoption and implementation
6. Program evaluation
Interestingly, after using the intervention mapping approach to develop my intervention, I identified a recent article by Abroms and colleagues that recommended steps to specifically develop a text messaging intervention for behaviour change. Their recommendations were derived both from a review of the literature and the authors’ own experiences with creating and evaluating text messaging programs for behaviour change internationally. Although I did not follow their recommended steps a priori while developing my intervention, they closely mirror my intervention mapping-inspired approach and thus support my methodological decisions.

4.2 Needs Assessment

The first step in intervention mapping involves a thorough needs assessment. This assessment ensures that the central problem, in this case medication adherence, is thoroughly understood by intervention developers. It calls for a brainstorming process to list all possible determinants of the behaviour in question, and then review of the literature to identify additional determinants based on past research and general constructs of behaviour change theories.

In this study, medication adherence has been characterized by the MAM (see section 2.3), which has been informed by a number of theoretical models of behaviour change. The process of selecting the MAM involved a review of the literature and clinical assessment of an appropriate model for medication adherence to endocrine therapy.

4.3 Developing the Matrix of Change Objectives

The second step in the intervention mapping approach is to create the matrix of change objectives that provide a framework for the intervention. At this stage, the information gathered in the needs assessment is used to specify desired outcome behaviours that can be influenced by the intervention. Then, performance objectives are selected to describe exactly what an intervention participant needs to do in order to reach the outcome behaviours. Finally, determinants of behaviour change are selected.
These determinants are changeable components of health behaviours that have been associated in the needs assessment with the outcome behaviour in question.

In this study, the outcome behaviour is specified as medication adherence to endocrine therapy in breast cancer survivors.

4.3.1 Performance Objectives

The performance objectives in this study were created by breaking down the general intervention goal into a series of sub-behaviours. This allowed for selection of important and changeable internal and external determinants of each of these behaviours or environmental conditions.

In this study, I used the MAM to derive three performance objectives, which are listed in Table 1. The performance objectives encompass the three parts of the MAM: Purposeful Action, Patterned Behaviour, and Feedback. Each performance objective was also broken down into sub-goals informed both by the MAM and previous research in barriers and facilitators of medication adherence\textsuperscript{13,15}.

<table>
<thead>
<tr>
<th>Table 1: Performance Objectives for Self-Regulation of Adherence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>Purposeful Action</strong>: Increase understanding of disease and treatment</td>
</tr>
<tr>
<td>a. Accept breast cancer as part of patient’s history</td>
</tr>
<tr>
<td>b. Acknowledge the potential for breast cancer recurrence</td>
</tr>
<tr>
<td>c. Acknowledge that endocrine therapy is meant to reduce breast cancer recurrence risk</td>
</tr>
<tr>
<td>d. Recognize medication side effects</td>
</tr>
<tr>
<td>2. <strong>Patterned Behaviour</strong>: Prepare and implement behavior patterns that support good medication adherence</td>
</tr>
<tr>
<td>a. Schedule medication doses to be a convenient part of daily routine</td>
</tr>
<tr>
<td>3. <strong>Feedback</strong>: Maintain good medication adherence over time</td>
</tr>
<tr>
<td>a. Recognize poor medication adherence</td>
</tr>
<tr>
<td>b. Identify reasons behind reduced adherence</td>
</tr>
<tr>
<td>c. Manage side effects appropriately</td>
</tr>
</tbody>
</table>
4.3.2 Determinants of Behaviour Change

The second component required to create the matrix of change objectives identification of the determinants of behaviour change. These determinants are derived from theories of behaviour change that are most relevant to the outcome behaviour in question.

In this study, after reviewing the literature, I again used the MAM along with the Integrated Theory of Behaviour Change\textsuperscript{76} to describe medication adherence. I then used theories to derive the major determinants of building or maintaining positive medication adherence behaviours. The major determinants of health behaviour change include: knowledge and beliefs, social facilitation, and self-regulation skills.

\textit{Knowledge and Beliefs}: Knowledge is defined as factual information, whereas beliefs incorporate personal perceptions of this information. Enhancement of knowledge is linked to increased self-efficacy towards a specific behaviour. As self-efficacy\textsuperscript{77} has been identified as a key component of operationalizing knowledge and health beliefs\textsuperscript{76}, this theoretical construct was also included as a separate determinant of behaviour change.

\textit{Social facilitation}: Social facilitation includes social influence and social support. Social influence occurs when an authority figure sways beliefs and motivation, leading to changes in the target behaviour. Social influence can come from healthcare providers, family, friends, media, and other print/electronic communications. Social support consists of emotional and practical support that a patient receives; this can facilitate or hinder target behaviours.

\textit{Self-regulation Skills}: Self-regulation skills include the ability to plan a behaviour and enact it. The process of goal planning, reflective thinking, and self-evaluation are important components of...
selfregulation. These activities are strongly influenced both by knowledge and social facilitation determinants described above.

4.3.3 Final Matrix

The next task in using the intervention mapping approach is to combine the performance objects with the determinants of behaviour change, and to populate the resulting matrix with specific and relevant change objectives. The intervention mapping approach does not require that each component of the matrix be completed, rather, it is important to complete relevant and avoid extraneous change objectives75.

The resulting matrix (Table 2) is a result of my previous literature search, focusing on the research cited in this thesis, combined with clinical experience as a pharmacist trained to provide pharmaceutical care.
<table>
<thead>
<tr>
<th>Performance Objectives</th>
<th>Determinants of Behaviour Change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Performance Objectives</strong></td>
<td><strong>Determinants of Behaviour Change</strong></td>
</tr>
<tr>
<td><strong>Knowledge</strong></td>
<td><strong>Beliefs/Attitudes</strong></td>
</tr>
<tr>
<td>1. Increase understanding of disease and treatment</td>
<td>Describe why breast cancer occurs, how past therapies have treated disease, and how endocrine therapy works</td>
</tr>
<tr>
<td>1a. Accept breast cancer as part of patient’s history</td>
<td>Express positive attitude about medical history</td>
</tr>
<tr>
<td>1b. Acknowledge the potential for breast cancer recurrence</td>
<td>State breast cancer recurrence risk</td>
</tr>
<tr>
<td>1c. Acknowledge that endocrine therapy is meant to reduce breast cancer recurrence risk</td>
<td>State breast cancer recurrence risk reduction with and without endocrine therapy</td>
</tr>
<tr>
<td></td>
<td>Express confidence in endocrine treatment efficacy</td>
</tr>
<tr>
<td></td>
<td>Acknowledge that a large proportion of breast cancer patients take endocrine therapy</td>
</tr>
<tr>
<td>1d.</td>
<td>Recognize medication side effects</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>effects sources of information to check for full list of side effects</td>
</tr>
<tr>
<td>2.</td>
<td>Prepare and implement behaviour patterns that support good medication adherence</td>
</tr>
<tr>
<td>2a.</td>
<td>Schedule medication doses to be a convenient part of daily routine</td>
</tr>
<tr>
<td>3.</td>
<td>Maintain good medication adherence over time.</td>
</tr>
<tr>
<td>3a.</td>
<td>Recognize poor medication adherence</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>3b.</td>
<td>Identify reasons behind reduced adherence (i.e. cost and access issues)</td>
</tr>
<tr>
<td>3c.</td>
<td>Manage side effects appropriately</td>
</tr>
</tbody>
</table>
4.4 Intervention Development

The intervention development process as discussed by Bartholomew and colleagues\(^\text{75}\) involves both creation of initial content for participants to review, as well as the sequence that the program would be delivered over time. In the development of this intervention, my methodology diverged from the intervention mapping approach; the program structure was not shaped by intervention developers prior to study initiation, but rather was an important question that participants were to answer. As such, this step in the intervention mapping approach involved simply the creation of an initial library of text messages that could address each component of the matrix of change [Table 2]. The shape of the intervention, consisting of the timing and content of the messages, was decided by individual participants during their initial and final interviews.

4.5 Program Adoption/Implementation and Evaluation

The goal of program adoption/implementation is to identify key potential adopters and implementers in the program, specify determinants of adoption and implementation, and then create an implementation plan for widespread program dissemination\(^\text{75}\). Following this, it is essential to conduct formal program evaluation. This evaluation involves assessment to determine whether program objectives have been met. Both of these steps, though vital to wide-scale intervention adaptation, are beyond the scope of this thesis, which aims to simply create an initial intervention program.

4.6 Conclusion

In this chapter I review the formal steps in the Intervention Mapping Approach. I used these formal steps in order to create my initial text messaging intervention, which was then implemented in order to gather feedback from my research participants. The next chapter reviews the pretesting design to assess and improve the initial text messaging intervention.
Chapter 5: Research Design

[Words] break the shackles of time...they are proof that humans are capable of working magic. – Carl Sagan

5.1 Introduction

In the previous chapter I discussed the initial development of a text messaging intervention for this study.

In this chapter I discuss the development of my methodology and outline the interpretive description approach as a tool to focus my work. Next, I present a reflexivity statement encompassing the experiences and training that colour my research perspective. Following this, the participants, study recruitment methods, setting, and data collection protocol is described. Finally, I discuss the analysis process used in this study. The chapter concludes with a section discussing ethical considerations and trustworthiness of the data.

Prior to study commencement the research protocol and supporting documentation was submitted to the hospital research ethics board for approval. It was approved after minor technical changes that did not affect the overall study design. Ethical considerations for this study followed the guidelines set forward by the Tri-Council Policy Statement published by the Canadian Government.

5.2 Methodology

In the present study I explored the experiences of breast cancer survivors on endocrine therapy and used these insights to develop and pilot an intervention that aims to improve endocrine therapy adherence.

This research has been conducted within a constructivist paradigm, recognizing the importance of each woman’s unique realities and bringing their insights together in order to inform clinical practice and intervention development. A qualitative design, as opposed to a quantitative design, was selected for
this project as it was the most appropriate means to study a subjective human experience. Previous work in the mHealth intervention development literature has also identified the importance of a nuanced understanding of patient experiences in order to inform intervention development. A qualitative approach is especially suited to this type of research question as it requires the researcher to approach the study from the perspective of the research participant. This is in contrast to quantitative approaches that have a positivist or post-positivist interpretation of the world, requiring a theory to be either confirmed or denied without allowing for the possibility of discovering or co-creating new ideas that better address the issues of the target audience. Therefore, the methods most appropriate to my research question fall within the qualitative paradigm, leading me to focus on Thorne’s interpretive description approach as means to frame my methodological decisions.

5.2.1 Interpretive Description

Interpretive description is a “generic” qualitative method originally developed by clinician researchers in order to advance meaningful disciplinary knowledge and to understand perspectives and experiences relevant to applied health disciplines. Generic qualitative approaches, which encompass Interpretive Description and Qualitative Description, are those that do not fall under the conventional phenomenological, grounded theory, or ethnographic approaches taken in qualitative work. It takes a constructivist epistemological approach to understanding truth; the researcher and research participant are understood as influencing one another, working together to co-create knowledge. Implicit in interpretive description is the goal of understanding clinical phenomena in order to translate research findings into practices that improve patient care.

Interpretive description uses an inductive analytic approach, allowing ideas to organically emerge from the data. Rather than acting as a prescriptive tool, it provides guidance to applied clinical researchers as they navigate complex clinical questions through the dual lens of researchers and health practitioners. In
contrast, other traditional qualitative methodologies do not consider the breadth of the clinician researcher’s experience. For example, grounded theory requires researchers to approach a study without expectations or clinical knowledge, phenomenology requires bracketing of expectations while conducting a detailed coding of participants’ experiences, and ethnography requires long-term immersion into the target group of interest. Interpretive description appreciates the clinical experiences that clinician researchers bring to their research question, and instead focuses on guiding the description and interpretation process in an attempt to portray relevant participant perspectives and inform clinical practice. A more detailed discussion of data analysis is summarized in the following section.

Interpretive description was therefore chosen because of the strong influence that pharmacy practice had on my work. This approach also emphasizes the importance of combining a theoretical background with experiences from the field. As such, I was able to incorporate my experience as a pharmacist providing care to cancer patients on endocrine therapy with what I learned from a review of the literature and interviews with research participants. This research project has a practical goal of cocreating knowledge that may enhance our understanding of how to support breast cancer patients as they transition to survivors and move care from specialized oncology practice back to their communities.

5.2.2 Thematic analysis

Thorne’s discussion of interpretive description also provides guidance on data analytic methods most appropriate to the types of methodologies suited to clinical practice research. In this study, I focused on thematic analysis. Thematic analysis is a method of identifying, analyzing, and reporting patterns identified in a data set. As such, it can be used as a means of interpreting aspects of a research project. Thematic analysis can either take an inductive or a deductive approach. The deductive approach is a theoretical strategy particularly useful when answering a highly specific research question. In contrast,
an inductive strategy requires the researcher to analyze a data set and create categories which eventually solidify into themes and sub-themes. Thorne recommends an inductive approach to interpretive description at is more epistemologically aligned the clinician researcher’s perspective.

Thematic analysis began after the first interview. I continued to analyze each interview as it was conducted and returned to the data repeatedly throughout the interviews to identify themes as they emerged in order to develop these ideas more carefully. I use the phrase ‘emerging themes’ throughout my thesis; by this I mean that I thoughtfully recognized patterns and applied labels to them. This does not mean that the themes were lying latent in the data, waiting to be discovered, as this idea is not in keeping with my personal philosophical orientation. Rather, the process of identifying emerging themes was a challenging intellectual exercise, bringing together patterns that I recognized in the data with my own experiences as a clinician and researcher.

5.3 Reflexivity and Positionality Statement

Reflexivity is a crucial component to understanding the researcher as the instrument through which research is conducted. In Thorne’s book, *Interpretive Description*, the concept of turning the researcher lens back onto the researcher is described in two ways. First, the researcher ought to locate their own theoretical positioning. This includes an explication of pre-research attitudes and individual biases. Second, she emphasizes the importance of situating the researcher’s discipline within the project, as interpretive description is explicitly located in the applied disciplinary domain. Thorne describes how a disciplinary lens affects the research project and from its conception, and affects the researcher’s philosophical orientation. She suggests that the researcher’s health discipline should actually be viewed as one of the “theories” that explicitly shape the research work. Using these recommendations, I have turned the researcher lens back on myself.
As a pharmacist, I spend the majority of my professional life thinking about medications. Medication adherence is a central tenet of chronic disease management, and is of particular concern when medications are prescribed to lower the risk of a disease recurrence. My training in the undergraduate pharmacy program also strongly emphasized the importance of adherence, even including it as one of the four components of a systematic pharmaceutical care workup. Therefore, from a theoretical perspective, I feel that the pharmacy profession is strongly primed to be focused on medication adherence, and the influence of my past training can clearly be seen in my own interest in taking on this project.

Over the past several years, both as a pharmacist and as a pharmacy student, I have worked closely with an interdisciplinary team to provide effective supportive care to cancer patients. This close-knit team of colleagues has provided me with ample opportunities to reflect on clinical experiences and research findings with more experienced clinicians. I have felt a growing dissonance between understanding medical literature, particularly with regard to medications used for risk reduction, and actual application in clinical practice. As I gained experience in my clinical pharmacist role in the breast cancer clinic, I found it challenging to reconcile risk reduction from long term medication adherence with the short term challenges patients face with daily medication use. My frustration is mostly centred around working with patients who experienced significant side effects on a daily basis. I continue to question how I can reconcile the pressure to apply population-level data derived from large randomized trials with the patient sitting in front of me. I had previously understood risk as an abstract concept, and with more work experience found it a growing challenge to apply this concept to clinical practice. In order to reduce the number of situations where this occurs, I recognized I needed to provide support much earlier in the process of care in order to improve quality of life while still maintaining the risk reduction benefits of taking medication(s). My position as an “insider researcher” with medical and personal knowledge about the patients’ medical condition provides an interesting research orientation.
In my years of working with the cancer population, I have also gained some biases that are important to point out prior to data collection and analysis. First, I am inclined to favour a text messaging program. I recognize that in order to provide excellent patient care a significant amount of time is needed, which is usually sorely lacking. I have felt on numerous occasions that patients have been suffering from side effects for far too long without the proper care and attention to alleviate their burdens. Secondly, my pre-research attitudes also encompass professional attitudes. This strongly predisposes me to encourage patients to continue taking medications, even during an interview, and thus change the interaction from that of a curious researcher/participant to a healthcare provider/patient encouraging positive health behaviours. This was a challenge I was aware of and documented about extensively in my field notes.

5.4 Sources of Data

My primary sources of data were semi-structured interviews that I conducted with breast cancer patients on ET. Women over 18 years of age, diagnosed with hormone receptor positive stage I-III breast cancer, who were currently taking and planned to continue taking ET for the next 6 weeks were eligible for the study. I used semi-structured open-ended questions during the interview [see Appendix] and interviews were audio recorded with participant’s consent. The consent forms, recruitment procedures, and letters of approval are also located in the Appendix. My secondary sources of data include informal discussions with the clinical team, made up of breast cancer centre pharmacists, nurses, social workers, and medical oncologists. I also observed clinical discussions in the team meeting rooms regarding other patients and their experiences, and drew from my own experiences with patients taking endocrine therapy.

The second major source of data is the text messages that have been developed and then analyzed by patients during interviews. These text messages were theoretically developed using the general process described in chapters 3 and 4.
Participants were excluded if they were unable to speak English or were unable to provide informed consent for the study. An ethical discussion of the inclusion/exclusion criteria is summarized in section 5.10.

5.5 Sample Size

Sample size is an important consideration in all research studies. For this study, participants were purposively sampled and approached. Purposive sampling was done to increase variability in participant characteristics; this ensures a broad understanding of the barriers perceived by all intended recipients of a text messaging adherence intervention.

The purposive sampling considerations I used in this study were two-fold. First, acceptance of a text messaging intervention may vary depending on familiarity to mobile technologies. Younger age is correlated to higher rates of mobile phone use, meaning that sampling both older and younger patients is important to ensuring a text messaging intervention is acceptable. In addition, the experience of older and younger women differs regarding the number and types of side effects they experience while on endocrine therapy. For the purpose of this study, “older” is defined as > 50 years while “younger” is defined as ≤ 50 years. This age cut-off, which is similar to the age of menopause, also changes the types of side effects women experience while on endocrine therapy, making it an interesting consideration in this population. Second, length of time a patient has been on endocrine therapy may reflect a need to change the approach to supporting adherence, as reflected in the Transtheoretical Model of Behaviour Change. Early on in therapy, patients may be still forming their new medication taking behavior, meaning that the intervention needs to include reinforcement of education and identification of potential barriers to medication adherence. Later on, in order to maintain a behavior that has already been well-established, continued support and encouragement may be needed. This potential variation
in needs regarding a text messaging program required further exploration. Therefore, I purposefully recruited at least two participants that reflected both the age and duration of time on therapy variables.

Only breast cancer survivors are able to articulate their experiences with endocrine therapy and with the proposed intervention. It should be noted that as this is a qualitative study with a limited sample of patients, the results lack generalizability. Given that the purpose of this study is to gain insight into the survivor experiences and receive feedback on the text messaging program this was deemed not to be a problem. In addition, although results are not generalizable, pretesting text messaging program prior to widespread implementation has been shown to improve general acceptance68,69.

5.6 Recruitment
Recruitment occurred either in a breast cancer follow-up clinic, in the waiting room, or the pharmacy within the recruitment site. Patients were approached during their follow-up appointment or when filling a prescription at the pharmacy. The clinical team (physician, nurse, and pharmacist) was aware of my research project and introduced me to patients that met inclusion criteria. As I was also part of the clinical team for one of the medical oncologists, I also screened patients for eligibility in the clinic I practiced in. I felt it was inappropriate for me to approach patients that I had a previous therapeutic relationship with. I separated my clinical work from my research work by identifying patients who were eligible for recruitment and asking a colleague within the circle of care to introduce me as a researcher to the patient. Therefore, I was only viewed as a researcher rather than as a part of the clinical team.

Recruitment was open for 3 months longer than the anticipated 6 months. This was due to the unanticipated challenge of having more than 1-2 participants in the study at a single point in time. Having less concurrent participants provided me with the time required to analyze, understand, and implement participant recommendations iteratively with each subsequent participant.
There were four potential participants approached who declined participating in the study. One participant declined because, despite having a mobile device that she uses to communicate with family and friends, she felt that the program would remind her too much of being a cancer survivor. This was not something she wanted to focus on. Two participants declined participation because they were not comfortable with English and receiving text messages in English. Other reasons cited for declining included feeling overwhelmed by concurrent social issues.

5.7 Setting

This study was conducted in a teaching hospital in a large urban centre in Canada. This particular setting is known to have a higher proportion of high income patients than other hospitals in the same urban setting\(^9\). This difference in socioeconomic status could affect interest and buy-in into a text messaging program, which could influence study findings.

5.8 Data Collection

5.8.1 Interviews

I conducted interviews using semi-structured interview guides [see Appendix]. The semi-structured interview allows participants to expand within topic areas freely and thus delve into unanticipated areas and ideas.

The interview guide was developed by reviewing the literature to assess interview guides from similar studies. Questions were derived from a review of the literature using PubMed, Medline, Embase, and PsychInfo. Search terms included ‘text messaging intervention’, ‘text messaging’, and ‘intervention development’. Study findings along with clinical experience and an expert review by a peer pharmacist shaped the semi-structured interview guide.

Each participant chose the time and place of the interview. Six participants were initially interviewed in a quiet room at the recruiting site, while two were interviewed at a coffee shop of the participant’s
choosing. Although all were given the option to conduct the interview in their own home or at a public space near their home, they all felt more comfortable with conducting the initial interview at the recruitment site, which was viewed as a neutral ground. All follow-up interviews were conducted over the phone as per participant preference. Interviews lasted between 30 and 75 minutes, with most ranging from 45 minutes to an hour.

Interviews were recorded using a single digital recorder. If necessary, the study mobile device was available as a back-up recording device against recorder failure, but this was not necessary for any of the interviews. Participants had the opportunity to ask for their transcripts or the recordings, but none chose to do so.

Attrition is a common occurrence in research, particularly when asking participants to continue to engage over time. Due to the short duration of the program and the high degree of engagement of study participants, attrition did not occur in this study. As I presented the study as an iterative text messaging program that required patient engagement in order to improve it, participants took a strong degree of ownership over their experience. I believe attrition was also partially avoided by specifically asking participants about their level of interest in the study the number of text messaging interactions per week changed according to patient preferences.

5.8.2 Field Notes

After each interview I created field notes to supplement interview data. The field notes included thoughts I had during the interview as well as my feelings and impressions of each interview. I also included a description of the setting and other potentially relevant non-verbal communication or other information that may be relevant for future analysis. Finally, the last part of my field notes include my reflections of my own performance as a novice interviewer and included a list of thoughts and impressions that will influence future interviews. This was particularly relevant for the initial interview
with participants, as I knew I would likely have a second opportunity to clarify any thoughts or ideas I had after reflecting on that interview.

These field notes were attached to each interview transcript, which became important supplements during data analysis.

5.8.3 Text Message Interactions

Initial example text messages that were used as part of the first interview are listed in the appendix. Based on the results of the initial interview, I then mapped out six weeks of messages that were to be sent to each study participant based on the baseline messages but incorporating expressed participant interests and preferences. These messages, along with participant responses, were documented in an encrypted database. This allowed me to review the particular timing and messages being sent to participants, as well as better understand when patients were responding to them. These results formed a basis for my second semi-structured interview, acting as prompts to better understand the effect of particular messages.

5.8 Transcription

All interviews were transcribed verbatim within 3 days of the interview. All interviews were listened to at least twice in their entirety. The first time, I paused and re-listened to portions of the recording frequently in order to ensure I recorded each word spoken to the best of my ability. The second time, I listened to the audio file in order to double check the accuracy of transcription as well as to annotate potential feelings or moments of interest.

Prior to starting transcription I deliberately selected the components of the interview that were to be transcribed. Although transcriptions can become extremely technical, using specific symbols to demarcate speech and preserve all components of the audio file, I felt that I needed to preserve the naturalness of transcription. Mergenthaler and Stinson⁹², in their discussion of principles of
transcription, recognized that transcriptions need to have a natural structure and intellectually elegant rules in order to adequately meet researcher needs. In addition, McLellan et al. discuss the importance of having the level of transcription complement the level of analysis. As my analysis was intended to explore themes in the content and not the specific accents or slang used in the interview, I included transcription rules that would allow me to systematically transcribe each interview without allowing the transcription process and final product to distract from my ability to remain close to the data. These rules changed slightly over time in order to help me preserve the naturalness of the transcript, requiring me to return to previous transcripts and ensure they conformed to my transcription rules. These rules have been strongly influenced by Poland’s recommendations, and are summarized in the Appendix.

As I had the opportunity to be both the interviewer and transcriber for this project, I also added in my own reflections during the transcription process as an addendum in the side panel of the transcript. This became part of the field notes used during analysis.

### 5.9 Data Analysis

Data interpretation in qualitative research is not a discrete step. As I conducted and transcribed the interviews I used these opportunities to begin looking for patterns or highlight interesting ideas that arose. Once transcripts were completed, I loaded them into a computer-assisted qualitative data software, in this case Quirkos®. However, I soon felt that the software itself was acting as a barrier to really understanding and absorbing what was happening in each transcript and field note. Upon reviewing the literature I found that this was a common concern among qualitative researchers, who recognized that specialized software, while useful to organize large data sets, can be an impediment for a researcher not familiar with the software. As the number of interviews was limited and I was familiar with the transcripts through the transcription process, manual analysis was possible and was in fact preferred to limit my distance from the data.
As I was taking an interpretive description approach, I was influenced by practical inductive methods of data analysis outlined by Thomas. He outlined that his purpose in undertaking analysis was to concisely summarize textual data and establish transparent, defensible links between summary findings and the original research objectives.

While recognizing that data analysis is an evolving part of qualitative work, involving an inquisitive mind from the moment of study conception to its completion, the coding process can be described as a discrete step in the analysis process. My inductive coding began with a thorough and close reading of the completed transcripts and associated field notes. I identified and highlighted sections of the text that contained meaningful units of data and assigned them to categories. Thomas, in his discussion practical strategies for inductive coding, said that initial general categories will likely be derived from evaluation of the study aims. Additional categories were derived from multiple readings of the data, or in vivo coding. The highlighted sections were then grouped into various categories, which eventually resulted in developing themes from the data. As I conducted this coding process, Thomas continued to influence my work by bringing me back to my central purpose and trying to better understand links between my study goal and that of the themes that arose. I also tried to uncover and understand the core meanings in the text, which were to aid with the coding process.

5.10 Ethical Considerations

I am known to some breast cancer patients due to my present role as an oncology pharmacy fellow working in the breast cancer clinic. In order to reduce the impact of previous pharmaceutical care they received from me during the study, I avoided enrolling patients that I had previously met in my capacity as a pharmacist. In order to enroll patients, I asked a health care provider within the circle of care to introduce me to the patient in my capacity as a researcher.
5.10.1 Informed Consent

Potential participants were approached while waiting for their oncologist appointment or while waiting for a prescription in the pharmacy. They were provided with written information and an informed consent form regarding the study and given as much time as they needed to consider the written information. Participants who were interested in participating provided their mobile phone numbers. All participants signed the informed consent form in my presence, after which I either turned on the voice recorder to begin the first interview or we arranged a time and location to conduct the first interview.

5.10.2 Confidentiality

Confidentiality was protected in several ways. First, each participant was provided with a unique identifier which was used throughout the transcription and coding process. The unique identifier was only linked to the participant’s name and telephone number in the password protected master-linking document. During the transcription process, the participant name was replaced with their unique identifier and any other names, locations or identifying features were replaced with descriptive nouns. The recording device and all signed consent forms and identifying documents were stored in a locked filing cabinet in a secure office. All transcripts and audio files were stored in a password-protected encrypted server. After completion and acceptance of this thesis, all data (signed consent forms and study documents) will be stored in a secure office or server for 10 years after which they will be destroyed or deleted, as per institutional ethics review board requirements.

5.10.3 Exclusion Criteria

There were several decisions made regarding exclusion criteria that I feel requires an ethical discussion. First, I excluded non-English speakers from study participation. This could be construed as inequitable and therefore unethical. However, the research team did not have access to a professional medical interpreter service. An alternative means of communicating is using family members as informal
interpreters; however, this is a violation of privacy and therefore challenging from an ethical perspective. In addition, all text message content would need to be translated to the target language, and there are concerns that meanings may be lost in translation resulting in a reduction in the value of the feedback being provided. Therefore, both for participant confidentiality and study feasibility reasons non-English speakers were excluded. It is anticipated that future research with larger sample sizes may involve non-English speaking participants, but would require professional translation services to maintain the integrity of the developed text messaging program.

I also excluded potential participants who were unable or unwilling to use a mobile device. This may result in a bias against older people or against people of lower socio-economic status, both of whom may be less likely to use a mobile device regularly. I also chose not to provide participants with a studiespecific mobile phone. Although this would reduce barriers for people who do not have their own device, I felt that providing an additional device would not simulate a real-world text messaging program. Participants may like/dislike the program based on the quality of the provided mobile device or their comfort level with using a new device. Instead, I chose to use a participant’s own device in order to prevent the issue of comfort level with technology to disrupt study participation. In addition, future larger studies and real-world application of the developed text messaging program use patients’ own mobile devices, making it reasonable to use this population of women in the current study. As most Canadians already own a mobile device, and the proportion who do so continues to rise, I feel that excluding the proportion of potential participants will not detract from the findings of this small study.

5.11 Data Representation

The resulting data from this study was presented as written accounts of themes. In the results section, themes are outlined and relevant quotes were included to illustrate each theme. Participant anonymity was protected by using identification numbers for each quotation.
5.12 Trustworthiness

Qualitative validity and reliability are established, in qualitative research, through a discussion of credibility, transferability, and dependability\(^1\). In addition, interpretive description is a qualitative method that recognizes that study validity is not simply a result of rigidly adhering to protocols, but is fully recognized when results can pass the “thoughtful clinician test”, or what one author described as passing the “cardiac validity” and “lacrimal validity” tests\(^1\). The following sections will discuss these ideas further.

5.12.1 Credibility

Credibility is the concept that seems to parallel internal validity in quantitative research. It is established through a discussion of the data collection and analysis methods. A credible study presents results that are of facts stated in the interviews.

Credibility, in this study, was enhanced through the use of audio-recordings and a summarized database of all sent and received text messages. These procedures ensured all participants interactions are captured for analysis. The resulting themes are presented with supporting quotes in order to support authenticity.

In addition, I used a portion of my field notes as a reflexive journal in order to keep track of my evolving personal biases that influenced interactions with participants. I also used the second interview conducted with each participant as an opportunity to reflect with participants about emerging themes or ideas that seemed to arise during the first interview. This provided an opportunity for participants to expand on or clarify their own views of the endocrine therapy experience.

An interesting finding, both from my field notes and the interviews themselves, was participants’ comfort with providing both positive and negative feedback. This ability to critique both the intervention
and the healthcare system more broadly is indicative of a level of comfort that lends credence to the findings of this study.

5.12.2 Transferability

Transferability can be viewed as analogous to external validity in quantitative research. It is a recognition of the extent to which the findings of this study can be applied to other contexts\(^9\). In this study, transferability can be recognized in the descriptions I have provided of the context of this study. These results can be applied to other patients on endocrine therapy in relatively wealthy urban centres, or can be used to develop a text messaging program that can be piloted in a wider number of research sites.

5.12.3 Dependability

Dependability is the consistency in the way data was collected and analyzed. Dependability was enhanced during interviews by using the same interviewer and maintaining a similar interview style using the same interview guide as per protocol.

5.12.4 Other considerations

All interviews were conducted and transcribed by the researcher, which enhances consistency of the data. During data analysis, potential themes that arose out of the data were discussed with the clinical team in order to bring a second perspective to the data and act as a “thoughtful clinician test”.

Clinical team members that afforded expert peer review throughout the process included:
- A registered nurse who acted as a patient navigator for patients with breast cancer for over a decade
- Three oncology pharmacists who had worked closely with breast cancer patients for 3 to 10+ years
- A breast cancer medical oncologist
As I shared my themes and sub-themes with the experts as they arose, I asked if they seemed to resonate with their experiences with this population. Experts expressed agreement, and felt that they resonated with the themes. When asked, they stated that they did not feel that the results were self-evident or inaccurate.

5.13 Conclusion

This chapter has discussed the overall methodology as well as the particular interpretive description and thematic analysis methods chosen. It then reviewed the process used to collect data and recruit study participants. Finally, ethical and trustworthiness considerations were discussed. The next chapter introduces the themes that I found most pervasive in my interviews. It also highlights the changes made to the text messaging program in order to meet the needs of study participants.
Chapter 6: Results

6.1 Introduction

The purpose of this study was to develop a text messaging intervention aimed at improving endocrine therapy adherence in breast cancer survivors. The results are presented by first giving a background of the participants in the study. The findings are then presented in the context of the two main research questions in order to first explore how participants experienced endocrine therapy and then their preferences for a text messaging program. Supporting quotes are included that best illustrate the concepts identified.

6.2 Demographic Information

In total, eight women participated in the study. All participants were cognitively capable of providing informed consent, and were able and willing to use their mobile devices for the duration of the study. Participant age ranged from 31 to 56 years. They were taking between two and ten medications at baseline, with a median of three natural products/over the counter medications and two prescription medications. All but one woman in this study were married, and all the currently married participants had at least one child.
Table 3: Participant Characteristics

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Number (total = 8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, female</td>
<td>8</td>
</tr>
<tr>
<td>Endocrine therapy</td>
<td></td>
</tr>
<tr>
<td>Tamoxifen</td>
<td></td>
</tr>
<tr>
<td>Exemestane</td>
<td>2</td>
</tr>
<tr>
<td>Exemestane + leuprolide</td>
<td>2</td>
</tr>
<tr>
<td>Tamoxifen + leuprolide</td>
<td>3</td>
</tr>
<tr>
<td>Total number of medications</td>
<td></td>
</tr>
<tr>
<td>Prescription medications (median, range)</td>
<td>6 (2-10)</td>
</tr>
<tr>
<td>Over-the-counter medications (median, range)</td>
<td>2 (1-4)</td>
</tr>
<tr>
<td>Natural health products (median, range)</td>
<td>2 (1-3)</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Age (median, range)</td>
<td>42 (31-56)</td>
</tr>
<tr>
<td>Months on endocrine therapy (median, range)</td>
<td>11 (1-28)</td>
</tr>
<tr>
<td>Family status</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td></td>
</tr>
<tr>
<td>Children</td>
<td>7</td>
</tr>
</tbody>
</table>

6.3 Main Findings

As mentioned above, the main findings are arranged in the context of the two main research questions, “what is the breast cancer survivorship experience in the context of using endocrine therapy?” and “what are women’s preferences for a text messaging intervention while receiving endocrine therapy?”. The main themes identified in the breast cancer survivorship experience included (1) the emotional reaction in survivorship and (2) uncertainty as a state of mind. The theme *the emotional reaction in survivorship* was manifested in three ways, as guilt and fear about the diagnosis and recurrence, perceived inability to take action, and the stress of burdening social supports. The theme *uncertainty as a state of mind* was conceptualized as a continuum. On one end were participants who had strong negative feelings about their medical history and consequently felt uncertain and anxious about making decisions regarding health management. On the other end of the spectrum were participants who recognized and embraced the uncertain nature of breast cancer recurrence. Consequently, these
participants articulated their decision-making process, which involved a conscious weighing risks and benefits to reach a resolution.

The main themes identified in answer to the second research question included (1) personifying the program and (2) tailoring messages. Personifying the program was discussed by numerous participants as creating a friendlier and broadly embracing program that focused on holistic wellness rather than cancer management. They were also strongly interested in connecting more closely with other survivors and in participating in peer networks. Tailoring messages was described in two ways. Participants preferred content that was specific to the symptoms and issues they were currently experiencing, and articulated various means by which this tailoring could occur within a text messaging program.

6.3.1 The Emotional Reaction to Survivorship

In response to the first research question, women took a more broad view of breast cancer survivorship than simply the endocrine therapy in particular. By the time endocrine therapy is started, women have completed their more active phases of treatment. They have therefore transitioned into a more passive phase of treatment and survivorship requiring less healthcare provider oversight. As a result, the themes identified are not specific to endocrine therapy but rather reflect the overall phase in treatment in which these women are experiencing.

The first theme described in this section is the emotional reaction that permeates this phase of survivorship. These emotions can be broken into (1) fear and guilt of occurrence and recurrence, (2) frustration and self-blame around “why can’t I take action?”, and (3) the stress of burdening social supports in an ongoing manner. The second theme is a recognition that uncertainty as a state of mind is a pivotal component of psychological aspect of survivorship. The state of uncertainty in individuals seems to fall on a continuum, resulting in drastically different outcomes.
6.3.1.1 The Emotional Life of Passive Survivorship

The fear of recurrence was a strong driver of participants’ decisions to continue on endocrine therapy at the time of the study. In addition, some participants talked about guilt being a strong component of their cancer experience. The feeling that the original cancer diagnosis was somehow caused by something participants did in the past was a common sentiment. One woman talked about her previously poor diet and physical activity level, and strongly felt that she brought on her diagnosis as a result of her previous actions.

This guilt was also sometimes manifested in actions that should be taken in the present. One participant brought the guilt of past and present actions together when talking about her struggles with implementing a regular exercise program: “I’m trying to do some exercises. I feel guilty, like that’s what I failed before too...”

Finally, some participants also talked about the worrying burden they continued to place on social supports. Women were accustomed to being independent and being the caretakers of those close to them. The cancer experience resulted in a change in this caretaker status, causing participants to require assistance when none was previously needed. One woman described a return to a more dependent state with her mother and the associated guilt that arose on both sides of that relationship: “I feel so bad – I feel like, you know, I’ve put [my mom] through hell because of everything I’ve gone through. And you know, she blames herself for a lot of it.”

6.3.1.2 Uncertainty as a State of Mind

All participants talked about managing uncertainty in different ways, most commonly in reference to breast cancer recurrence. In a sense, the management of uncertainty can be conceptualized as a state of mind. Depending on where women fell on a continuum of management of uncertainty, their discussion of fear and anxiety widely varied.
On one end of the spectrum were a few participants who were unable to cope with the uncertainty of breast cancer recurrence. One woman described this state of mind in this fashion: “I don’t know, I’m really surprised at what to change, since I got this sickness I don’t know what this – what happened, why I got this. So [I’m] still very anxious...”

In contrast, some participants recognized the uncertainty of breast cancer recurrence that loomed over their heads, but were able to move past it. These participants took time to articulate the weighing of risks and benefits during their decision making process. One woman described her thought process as she decided to follow a naturopathic doctor’s recommendations in conjunction with her oncologist’s treatments during chemotherapy:

“If someone tells me that it’s going to prevent recurrence, I’d do it. You know what I mean? I don’t listen to everybody, but if my naturopath tells me, why not? What can I lose, really? I mean what can be worse than cancer...I mean I understand kidney stone with vitamin C, but still...But maybe if I were desperate I would try [the vitamin C]. Because...you get to a point where you’re like ‘I have nothing to lose’. And it’s true, it’s like what can go wrong, really?”

Her management of uncertainty resulted in confident decisions, and recognition that as her life situation changes she may decide to make changes with a lower degree of anxiety.

6.3.2 Shaping the Text Messaging Intervention

Overall, participants expressed positive feedback regarding the text messaging program. In order to better meet individual needs, participants discussed the possibility making the program more humanlike. This included ensuring text messages were written in a positive and familiar tone. They also requested the program be not exclusively focused on endocrine therapy, but rather addressed healthy lifestyle factors important to breast cancer survivors. Changing the program to reflect a more holistic
view of healthy living, implicitly taking into account breast cancer history, was viewed as a step in the right direction. Finally, the importance of message tailoring was discussed.

6.3.2.1 Personifying the Program

Participants were accepting of the current tone and message structure, with some participants particularly asking for messages to be written in a positive or neutral tone while avoiding negative or fear-mongering messaging. For example, one participant asked one of the text messages to be removed: “‘Natural’ doesn’t always mean safe. If you’re thinking of using natural products (herbs, supplements), make sure your cancer care team knows – call us at [pharmacy phone number]. We can make sure it’s safe and right for you.” She viewed this message as negative, and felt that the fear tactic behind this message went too far.

Some participants also talked about the intimacy of text messaging, which was viewed as a means of communication with loved ones. “Like when you’re getting a text message from a friend, from someone that you love that you’re close to and it just makes you happy even if you don’t see each other, even if it’s a short message”. One participant even recommended giving the program a name as she viewed the program as potentially acting like a friend who is checking in on her and concerned about her well-being.

In addition, all participants had a strong preference for a more holistic approach to survivorship, recognizing that general mental and physical well-being, in addition to the endocrine therapy, need to be addressed. Participants described varying ways in which this could be accomplished, such as sharing “interesting facts and things that related to the whole, not just cancer...things about flowers. Something that cheers you up, something that makes you laugh.” Another woman talked about providing a “tidbit for the day... some people get ... bible verses... Or they get...daily jokes.”

Finally, some participants expressed interest in connecting more closely with other survivors, as demonstrated by their previous activities seeking survivor communities for support. As one participant
put it, they sought out peers “because they [the healthcare team] are talking from an analytical perspective because they haven’t been through, they’ve only done what they’ve done in school and that’s the stuff they’re feeding you. Versus someone that has actually gone through their journey”.

6.3.2.2 Tailoring the message

There was a strong desire to manage uncertainty in the cancer experience, which was partially manifested as a desire to control program content. Participants preferred messages tailored to their specific needs, for example by addressing particular side effects they were currently experiencing. One woman, when receiving a message about a topic she didn’t request, remarked “that text message that wasn’t for me”, pointing out the importance of bidirectional messaging that asks women about their experiences and providing content most relevant to them.

Participants also preferred content that promoted self-efficacy, allowing them to gain skills that knowledge that facilitates decision-making. For example, in reference to the content about safe natural health product selection, one participant stated “I learned something new-something I could actually use...So that was great”.

6.4 Conclusion

This chapter provided a detailed overview of the findings from this study. They were presented according to the general breast cancer survivor experience while on endocrine therapy and then in focused in on the mobile phone experience. The next chapter will provide a discussion of the findings, including how the text messaging program could be changed in order to better address the recommendations made. Study strengths, limitations, and potential implications will also be discussed.
Chapter 7: Discussion

This chapter discusses findings in the context of the main research question guiding the project and in light of relevant literature. To date, there have been few research projects addressing text messaging programs in oncology, and the majority of these projects have been focused on feasibility and have been quantitative in nature. The purpose of this study was to better understand the education and supportive care needs of breast cancer survivors on endocrine therapy and use this knowledge to develop a useful and relevant text messaging program to support medication adherence. The results of this study provides important information for future intervention developers as well as to clinicians providing survivorship care, allowing care providers insight into some of the supportive care needs of this population. This chapter will also present suggested modifications to a text messaging program for use in future research. Finally, a discussion of study strengths, limitations, and potential implications are also summarized.

7.1 The Emotional reaction to Survivorship

7.1.1 Diagnosis and Recurrence

Guilt and fear were emotions prevalent in the survivorship literature, particularly in regards to diagnosis and recurrence. Fear of recurrence has been recognized as an almost universal experience in breast cancer survival\textsuperscript{97,98}, with almost 90% of women experiencing these fears at least occasionally\textsuperscript{100}. Allen and colleagues\textsuperscript{101} recognized that this fear could be triggered by new physical symptoms. In addition, the transition from active treatment with close physician monitoring to a more passive monitoring can result in a hyper-alert state which can substantially reduce wellbeing\textsuperscript{102}. The reasons identified for this distress included the feeling of vulnerability as treatment is withdrawn, decreased medical professional monitoring, and uncertainty about self-monitoring. In this study, participants expressed similar negative emotions related to diagnosis and recurrence despite the continued use of endocrine therapy.
7.1.2 Why can’t I take action?

Guilt stemming from participants’ lack of action of key recommendations was another common phenomenon. This guilt can be interpreted as low self-efficacy. The MAM includes a self-efficacy construct\(^{59}\), reaffirming the good fit of this model and the importance of addressing self-efficacy in an adherence intervention.

7.1.3 Social Support

The final aspect of the emotions associated with breast cancer diagnosis was the stress stemming from a perceived burdening of social supports for potentially years after diagnosis. Some women articulated their perceived social role as that of a caregiver, rather than a care receiver, and found this continued shift in social roles challenging to reconcile. They felt that by the time of the interviews, which occurred months after surgery, chemotherapy, and/or radiation were completed, they should have returned to normal. Instead, they continued to require additional support. This theme, which could be viewed as a component of reconciling a “new normal” status, is one that arises in the breast cancer survivorship literature\(^{101,103}\). Recognition of the “new normal” is a critical component of psychosocial wellbeing in order to ensure survivors are open to receiving assistance from their support networks for as long as necessary.

Women described instances in which their social networks expressed relief that the active part of treatment was over, and that things could now return to normal. However, some women recognized that they had to establish a “new normal”, one that adjusts for lingering symptoms and factors in the additional social support required\(^{101,103-6}\). In this study, women expressed the guilt with continuing to require social support and not returning to normal, thus paralleling existing literature.
7.2 Uncertainty as a State of Mind

Uncertainty was a common phenomenon that manifested itself in a number of ways. For some women, the uncertainty stemmed from not understanding how they initially developed breast cancer, and led to a place wherein women felt that if they could not prevent the initial occurrence of breast cancer, they were likely not going to be able to prevent a recurrence of the disease. However, this uncertainty seems to have been dealt with in numerous ways, leading to widely varying outcomes.

The uncertainty surrounding recurrence is a common theme in the survivorship literature, appearing almost universally in breast cancer survivors. The conceptualization of uncertainty being a continuum parallels the results of other cancer survivorship research. Allen found that on one end of the spectrum were a group of women who had removed uncertainty from the equation and viewed recurrence as only a matter of time, while others accepted and moved beyond uncertainty with a new appreciation for life. The chronic disease literature more generally seems to support this idea. Mishel and colleagues describe a theory about uncertainty in the chronic illness trajectory and suggest ways that uncertainty can be mitigated. They start with a postulation that uncertainty in the chronic disease trajectory is a fundamental challenge to the Western worldview, which values predictability and certainty. The implicit assumption here is that each individual ultimately desires certainty. In order to adapt and accommodate uncertainty, a new worldview is required, one that accepts the uncertainty inherent in the disease trajectory. In other words, patients need to transition from a mechanistic worldview of cause and effect to a probabilistic one that is comfortable with ambiguity. This allows them to establish a new equilibrium. Those that continue with a mechanistic worldview conceive of uncertainty as an adversary that needs to be conquered, and therefore result in a highly anxious, sometimes paralyzed state. Those that have transitioned to a probabilistic worldview have the ability to reach a new equilibrium and embrace their present and future.
7.3 Putting it all together

The ideas discussed above – guilt, low self-efficacy, adjusting to a new normal, and managing uncertainty – can all be considered in the context of improving the text messaging program. Message content can be expanded to include information about diagnosis and recurrence risk. The results reaffirm the importance of including tools and knowledge that bolster self-efficacy as per the MAM. Finally, the text messaging program needs to continue to normalize the idea of the “new normal”. It also would likely benefit from messages that use probabilistic, rather than mechanistic, language.

7.4 Changing the Text Messaging Intervention

The second research question resulted in two main themes: (1) the desire to personify the existing program and expand its content, and (2) the requirement to tailor content.

7.4.1 Personifying the Program

The emerging theme in participant responses to the text messaging program was the desire for positive messaging that emulates a conversation between friends. This is line with other work in mHealth development. In addition, the desire for a more holistic program was reflective of work done in breast cancer survivorship. The American Society of Clinical Oncology goals and American College of Surgeons’ commission of cancer requirements include the need to provide survivorship care plans that support a wide variety of general health concerns that tend to arise as a consequence of breast cancer. As a result, the text message library became dominantly about increasing exercise, healthy eating, natural health products, and side effect management.

7.4.2 Program Tailoring

mHealth tailoring has been recognized in previous systematic reviews to be an integral component of an effective program. The results of this thesis are reflective of this result, and provided insight into the type of tailoring most desired. Bidirectional messaging that asked...
participants specific questions about their current concerns and potential side effects, and then
provided tips or resources to manage these issues, were viewed as the most valued type of tailoring.

7.4.3 Final Thoughts

As a result of participant input, the resulting program bears little resemblance to the initial intervention.
However, the fundamental purpose of the text messaging program remains the same – to be able to
monitor and encourage medication adherence. In order for an intervention to have any effect, patients
have to continue to participate in the program long term. Therefore, the importance of these adjunct
messages that do not simply focus on medication adherence become all the more important. The quality
and applicability of each message allows intervention developers to encourage continued participation
in the text messaging intervention over a long period of time.

Continued patient monitoring will let healthcare providers who administer the program know when
patients are in trouble, and will likely result in a phone conversation or a clinic visit. In this way, text
messaging interventions can act as adjuncts to the important support patients receive from their
healthcare team.

The results of this study speak to a larger need in breast cancer survivorship – to continue to provide
holistic care whenever possible.

7.5 Limitations

There were two major limitations to this study. The first was the challenge related to sampling. Despite
efforts to recruit participants, a smaller sample than anticipated was obtained. This was partially due to
the unanticipated high degree of involvement required throughout the six weeks of patient enrollment.
More interviews could have expanded the findings of the study. Another limitation is the theoretical
sampling parameters initially established. As a result, study participants were younger than the majority
of breast cancer survivors. It would be interesting to examine whether the interest in a text messaging
program changes drastically with age in order to better understand the value of such a program in the larger population.

7.6 Conclusions

The findings of this study illustrate some of the concerns women have during endocrine therapy, as well as their preferences for a text messaging program. The strongest emotional reactions during breast cancer survivorship were worries about the original diagnosis, recurrence, lack of action, and stress on social support. Uncertainty was an embedded part of the way participants viewed the world. As a result, participants stressed the need to have a personified program with bidirectional messaging that addresses both holistic wellness and issues specific to them. Future research areas include determining the duration women persist with a text messaging program as well as its impact on medication adherence.
References


50. Neville R, Greene A, McLeod J, Tracy A. Mobile phone text messaging can help young people

51. Rodgers A, Corbett T, Bramley D, Riddell T. Do u smoke after txt? Results of a randomised trial of
smoking cessation using mobile phone text messaging. Tobacco. 2005.

MA: Jones & Bartlett Publ.; 2010.

53. Rice R, Hagen I. Young Adults’ Perpetual Contact, Social Connectivity, and Social Control through


55. Yale University. Pilot for The Breast Cancer Endocrine Therapy Adherence (BETA) Trial.

56. Michigan State University. Text Messaging to Improve Adherence to Oral Chemotherapy Agents.

57. Southwest Oncology Group. Text-Messaging Intervention to Reduce Early Discontinuation of AI
Published 2012.

58. Willoughby JF, Furberg R. Underdeveloped or Underreported? Coverage of Pretesting Practices
and Recommendations for Design of Text Message–Based Health Behavior Change Interventions.

Accessed April 24, 2015.

60. Conner M, Norman P, eds. Predicting Health Behavior: Research and Practice with Social

61. Leventhal H, Leventhal E, Contrada R. Self-regulation, health and behavior: a perceptual-cognitive


66. Meyer D, Leventhal H, Gutmann M. Common-sense model of illness:The Example of

Health Knowledge, Behaviors, and Outcomes: An Environmental Scan. Rockville, Maryland; 2014.

68. Whittaker R, Merry S, Dorey E, Maddison R. A development and evaluation process for mHealth


Berger R. Now I see it, now I don’t: researcher’s position and reflexivity in qualitative research. Qual Res. 2015;15(2):219-234.

Appendix A: Initial Interview Guide

Part 1 – General mobile phone use

A. What is your current comfort level with technology? What types of technology do you use, and how often? (i.e. phones, computers, tablets, etc.)
   a. Which of these devices do you prefer?
   b. Do you use any particular apps for communication (i.e. BBM, WhatsApp, SMS, email) and if so what do you prefer and why?

B. With regards to mobile phones,
   a. What do you use it for?
   b. How often do you send/receive messages? How quickly do you normally respond to messages?
   c. Who are you most commonly in contact with (i.e. spouse, children, family, friends)?
   d. Are there any barriers to using your phone (i.e. visual impairment etc.)?

Part 2 – Education delivered through text messaging

A. We are thinking of creating a program where you would receive text messages about your medication.
   a. Do you have any concerns that you feel need to be addressed before opting into a text-messaging program?
   b. What types of things would you like to read about in these messages?
   c. Why would you like to receive messages? (i.e. to learn more about your pill, to remind you to take your pill)
   d. What types of things would you like to learn about your medication?
   e. What types of questions did you have about your medication when you went home? (if applicable)
   f. Can you give some examples of messages that you would like to receive?

B. “Here’s a list of 10 potential text messages that we could be sending you. Please share your overall impressions, and perhaps we can also go over each message individually.
   Overall impression
   a. Overall, can you rank these messages in order from most to least interesting/helpful?
   b. How often and when would you like to get these types of messages?
   For each text message
   c. What did you find most interesting about the message?
   d. What did you find least interesting about the message?
   e. Was there anything confusing about what you just read?
   f. Was there anything in particular that you liked/disliked?
Appendix B: Sample Text Messages for Initial Interview

1) If you’re having trouble remembering to take your pill, try pairing it with a daily habit (like breakfast, or brushing your teeth!)

2) Pills should not be stored in the bathroom. Humidity (i.e. from showers) can ruin them. Try keeping them in your bedroom, away from where kids can reach them.

3) Over the last 7 days, how many days were you able to take your pill exactly as prescribed? Please answer with a number from 1-7.
   
   If 7 → “That’s great! This pill reduces the chance that your breast cancer will come back.” If 1-6 → “Is there any reason why?”

4) Your pill can be taken with food or on an empty stomach (whatever is easier). Make sure to take it with a glass of water or juice.

5) The most common side effect with your pill is hot flashes (sudden sweating and feelings of warmth). Have you experienced any?
   
   If yes → Hot flash tip: avoid tobacco and heavy alcohol use, it makes hot flashes worse. Want some more tips?

6) In order to battle fatigue, try going for a 5-10min walk outside. Exercise can reduce feelings of fatigue

7) “Natural” doesn’t always mean safe. If you’re thinking of using natural products (herbs, supplements), make sure your cancer care team knows – call us at ____ (pharmacy phone number). We can make sure it’s safe and right for you.

8) A workout for strong bones doesn’t have to be boring. You can try a new dance class, go hiking, or take a walk. Want more exercise tips?

9) Have you thought about improving your diet? Plant-based diets are full of “phytochemicals” that reduce the risk of developing cancer. Try introducing beans/lentils in your diet by adding small amounts into your favorite recipes.

10) Today is the start of a new week! Consider getting a pedometer (some smartphones can double as pedometers!) and set a daily step goal for yourself.
Appendix C: Baseline Data Collection Form

<table>
<thead>
<tr>
<th>Study ID:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>BC Stage:</th>
<th>Date:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Endocrine Treatment (start date):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Allergies:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Special needs: (sight, hearing, mobility, literacy, disability, ostomy)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Social history: (highest level of education completed)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Health Habits: (caffeine, smoking PPD, diet, alcohol, illicit drug use, exercise)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Past cancer history: (date of diagnosis, staging, treatments)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Other Medical Conditions:</th>
</tr>
</thead>
</table>

### Medication history

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Dose</th>
<th>Route</th>
<th>Frequency</th>
<th>Comments</th>
<th>Start date</th>
<th>Stop date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Non-Prescription Medications (e.g., Over-the-counter products, herbals, others)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Dose</th>
<th>Route</th>
<th>Frequency</th>
<th>Comments</th>
<th>Start date</th>
<th>Stop date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Non-Prescription Medications (e.g., Over-the-counter products, herbals, others)</th>
<th>Dose</th>
<th>Route</th>
<th>Frequency</th>
<th>Comments</th>
<th>Start date</th>
<th>Stop date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix D: Final Interview Guide

A. Can you describe your experience with receiving the text messages over the past few weeks? a. Was there anything annoying? 
b. Can you tell me particular messages you liked or didn’t like? 
c. How do you feel about sharing the messages with your family/friends? (Did you share the messages with anyone?)
d. How did you feel about the timing and frequency of messages? How can we better time messages to fit with your life? (Would you want them more/less often? Would you want timing to vary or stay the same?)
e. How did you feel about having to respond to some messages? What about getting acknowledgement for your responses? 
f. In your opinion, what is a reasonable way to communicate with you on an ongoing basis about your medication through your mobile phone? (i.e. WhatsApp, email, SMS, etc.)? 
g. What did you learn from the text messages? 
h. What challenges did you face with reading all the messages that we sent you?   
B. How did the program change your perception of your healthcare team? 
a. In what way did the program make you feel more/less connected to your healthcare team? C. What were the financial barriers to participating in this program? 
a. How would your willingness to participate in such a program be influenced by a pay-per-message plan?
Appendix E: Consent Form

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Full Study Title: Assessment of patient acceptability of an SMS model of care delivery to improve oral endocrine therapy adherence in breast cancer

Principal Investigator: Dr. Carlo De Angelis, Pharmacy Department, Clinician Scientist – Oncology, 416480-6100 ext. 1085

Funding Source: Cancer Centre Pharmacy Department Research Fund

INFORMED CONSENT

You are being asked to consider participating in a research study. A research study is a way of gathering information on a treatment, procedure or medical device or to answer a question about something that is not well understood yet.

This form explains the purpose of this research study, provides you with information about the study procedures, possible risks and benefits, and the rights of the participants (you).

Please read this form carefully and ask any questions that you may have. You may have this form and all information about the study explained to you. If you wish, someone may be available to verbally translate this form into your preferred language. You may take as much time as you wish to decide whether or not to participate. Feel free to discuss it with your friends and family or your doctor.

Please ask the study staff or one of the investigator(s) to clarify anything that you do not understand or would like to know more about. Make sure that all of your questions are answered to your satisfaction before deciding whether to participate in this research study.

Participating in this study is completely your choice (voluntary). You have the right to choose not to participate or to stop participating at any time.

INTRODUCTION

You are being asked to consider participating in this study because you are currently taking a hormone medication for treatment of breast cancer.

Some people choose to stop taking or reduce the dose of their hormone therapy against their doctor’s recommendation because of personal reasons. This means that they may not have as much of a benefit from taking their hormone medication.
Past research has shown that text-messaging programs about medications increases the chances that patients will choose to take their medications consistently. However, we aren’t sure what type of information breast cancer patients would like to receive about their hormone therapy.

**WHY IS THIS STUDY BEING DONE?**

The purpose of this study is to understand what patients would want out of a text messaging education program about their hormone medications.

**WHAT WILL HAPPEN DURING THIS STUDY?**

If you agree to participate in this study, a member of the research team will talk to you about the best time and place to interview you. This interview will be up to 60 minutes long, and will go over your current mobile phone usage, and ask you for feedback on sample text messages we would be sending you. Next, you will receive at least three text messages from the research team per week for 6 weeks. Some text messages will only contain information, while others will ask you to text back your responses. After 6 weeks, you will be contacted again by a study investigator to see what you thought about the messages we sent you. This conversation can occur over the phone or in-person at the Odette Cancer Centre and is anticipated to take up to 60 minutes of your time. All interviews will be audio-recorded and transcribed for later analysis.

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

It is anticipated that about 25 people will participate in this study at the Sunnybrook Odette Cancer Centre. The length of this study for each participant is about 2 months. The entire study is expected to take about 12 months to complete and the results should be known 4 months from completion.

**WHAT ARE THE RESPONSIBILITIES OF THE STUDY PARTICIPANTS?**

If you decide to participate in this study, you will be asked to do the following:
- Provide demographic information – this will happen at your first meeting with a study investigator.
- Answer questions in person – this will happen at your first meeting with a study investigator.
- Receive at least 3 text messages per week for 6 weeks – you will be asked to read and sometimes reply to the text messages the research team sends you.
- Answer questions in person or over the phone – this will happen 2 weeks after the text messages are finished.

**WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?**

There are no medical risks to you from participating in this study, but answering questions or receiving text messages may make you feel uncomfortable. You can refuse to answer any questions, stop the interviews, and ask us to stop sending you text messages at any time.
You will be told about any new information that might reasonably affect your willingness to continue to participate in this study as soon as the information becomes available to the study staff.

**WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?**

You may or may not benefit directly from participating in this study. However, possible benefits include added education about your medication through text messages, and additional time talking to a pharmacist or member of the research team and an opportunity to ask questions about your treatment. Your participation may or may not help other people understand more about their breast cancer medications in the future. Your participation may or may not help researchers better understand what patients want in a text messaging program designed to educate patients on their medications. There are no medical benefits to you from taking part in this study.

If you decide not to participate in this study, you will continue to receive the same treatment that you would regularly.

**CAN PARTICIPATION IN THIS STUDY END EARLY?**

The investigators may decide to remove you from this study without your consent for any of the following reasons:

- The investigators decide that continuing this study would be harmful to you
- You are unable or unwilling to follow the study procedures
- Answering interview questions becomes too stressful for you

If you are removed from this study, the investigators will discuss the reasons with you.

You can also choose to end your participation at any time without having to provide a reason. If you choose to withdraw, your choice will not have any effect on your current or future medical treatment or health care. If you withdraw voluntarily from the study, you are encouraged to contact Soha Ahrari, [soha.ahrari@sunnybrook.ca](mailto:soha.ahrari@sunnybrook.ca). You may be asked questions about your experience with the study. If you withdraw your consent, the information about you that was collected before you left the study will still be used. No new information about you will be collected without your permission.

**WHAT ARE THE COSTS OF PARTICIPATING IN THIS STUDY?**

Participation in this study may involve additional costs to you, depending on the text-messaging plan you have on your personal mobile phone.

By signing this consent form, you do not give up any of your legal rights.

**ARE STUDY PARTICIPANTS PAID TO PARTICIPATE IN THIS STUDY?**

72
If you decide to participate in this study, you will be reimbursed $50 for some study related expenses such as transportation, parking, and additional mobile phone costs. You will receive payment at the end of the study.

**HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?**

You have the right to have any information about you and your health that is collected, used or disclosed for this study to be handled in a confidential manner.

If you decide to participate in this study, the investigators and study staff will look at your personal health information and collect only the information they need for this study. “Personal health information” is health information about you that could identify you because it includes information such as your

- name,
- address,
- telephone number,
- date of birth,
- new and existing medical records, or
- the types, dates, and results of various tests and procedures.

You have the right to access, review, and request changes to your personal health information.

The following people may come to the hospital to look at your personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

- Representatives of the Sunnybrook Research Institute, Sunnybrook Health Sciences Centre, or the Sunnybrook Research Ethics Board, because they oversee the ethical conduct of research studies at Sunnybrook

Access to your personal health information will take place under the supervision of the Principal Investigator.

“Study data” is health information about you that is collected for the study but does not directly identify you.

Any study data about you that is sent outside of the hospital will have a code and will not contain your name or address, or any information that directly identifies you.

Study data that is sent outside of the hospital will be used for the research purposes explained in this consent form.
The investigators, study staff, and the other people listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

The Principal Investigator will keep any personal health information about you in a secure and confidential location for 10 years and then destroy it according to Sunnybrook policy.

When the results of this study are published, your identity will not be disclosed.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please provide your name, address, and telephone number to one of the study staff.

DO THE INVESTIGATORS HAVE ANY CONFLICTS ON INTEREST?

There are no conflicts of interest to declare related to this study.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You have the right to receive all information that could help you make a decision about participating in this study. You also have the right to ask questions about this study and your rights as a research participant, and to have them answered to your satisfaction, before you make any decision. You also have the right to ask questions to receive answers throughout the study.

If you have any questions about this study, you may contact the person in charge of this study (Principal Investigator): Carlo De Angelis, Pharmacy Department, Clinician Scientist - Oncology, 416-480-6100 ext. 1085.

The Sunnybrook Research Ethics Board has reviewed this study. If you have questions about your rights as a research participant or any ethical issues related to this study that you wish to discuss with someone not directly involved with the study, you may call the Chair of the Sunnybrook Research Ethics Board at (416) 480-6100 ext. 88144.

DOCUMENTATION OF INFORMED CONSENT

You will be given a copy of this informed consent form after it has been signed and dated by you and the study staff.

Full Study Title: Assessment of patient acceptability of a SMS model of care delivery to improve oral endocrine therapy adherence in breast cancer

Name of Participant: ________________________________________________________________

Participant
By signing this form, I confirm that:
- This research study has been fully explained to me and all of my questions answered to my satisfaction

- I understand the requirements of participating in this research study
- I have been informed of the risks and benefits, if any, of participating in this research study
- I have been informed of any alternatives to participating in this research study
- I have been informed of the rights of research participants
- I have read each page of this form
- I authorize access to my personal health information, medical record, and research study data as explained in this form

- I have agreed to participate in this research study

Name of participant (print)  Signature  Date

Person obtaining consent
By signing this form, I confirm that:
- This study and its purpose has been explained to the participant named above
- All questions asked by the participant have been answered
- I will give a copy of this signed and dated document to the participant

Name of person obtaining consent (print)  Signature  Date
Appendix F: Privacy/Security Education for Participants

PRIVACY/SECURITY WITH MOBILE PHONES

Security Tips for Mobile Phone Safety

Tip #1: Lock your phone

If your phone falls into the wrong hands, a password is your first line of defense to protect your privacy. Make sure it also locks automatically after 1 or 5 minutes of non-use.

Tip #2: Set up a phone tracking service

‘Find My iPhone’ or equivalent services allow you to lock, track, or wipe lost phones remotely. This protects your data, and can help you recover a lost/stolen phone.

Tip #3: Hide text messages so they don’t appear on your lock screen

This prevents people from reading your messages over your shoulder, and keeps your communications private.
Appendix G: Data Preparation and Transcription Protocol

General Text Formatting

- Calibri, 11 point font
- One-inch top, bottom, left, and right margins
- All text will begin at left-hand margin, no indents
- All text will be left justified

Interview Labeling

Each transcript document will have a cover (title) page, consisting of:

- Participant ID
- Interview name (Initial or Final Interview)
- Interview date
- Interview setting (i.e. participant’s home, coffee shop, recruitment site)
- Interviewer ID
- Transcriber ID

Participant and interviewer names will only be documented in the master spreadsheet in order to maintain anonymity.

File Naming Conventions

All files will be named according to the following conventions:

- The audio file of the interview will be [participantID]_[interviewdate]_[initial/final]interview.mp3
- The transcript document will be [participantID]_[initial/final].docx
- Associated field notes or analytical memos will be saved as [participantID]_fieldnote[note#].docx

Transcription Format

Each voice will be identified with the speaker’s ID followed by a colon and space before transcribing the content each person says.

Managing Crosstalk

When two voices overlap in the audio, the transcriber will include the annotations “[crosstalk]” and “[crosstalk ends]” to demarcate the duration of crosstalk for both voices. Inaudible Information

For sections of audio that are difficult to transcribe, the annotation “[inaudible]” will be used.

Managing Silence
When pauses are less than three seconds, ellipses will be used; for longer pauses the annotation “[pause]” will be used.

Nonverbal and background sounds

Nonverbal and background sounds will be included as descriptions within square brackets. Filler words will be transcribed. In addition, as the transcription process is being completed by the interviewer, any additional context that has not been included in the analytical memo will be added in as an annotation in square brackets. This includes any changes in emotion or tone as they are identified. This allows for data analysis to begin during the transcription process.

Improving Transcription Quality

All audio files will be reviewed at least twice in their entirety in order to ensure accuracy.
## Appendix H: Sample Final Library of Text Messages

<table>
<thead>
<tr>
<th>Message type</th>
<th>Text Message Content</th>
</tr>
</thead>
</table>
| Introduction | Hi [Name]! Thanks for joining the TMS (text messaging study) about your [medication name] medicine! To confirm your number, plz text back “y”. – the TMS team  
Thanks! If you have urgent questions don’t hesitate to call the Sunnybrook nursing line [insert number]. |
| Reminder     | If you’re having trouble remembering to take your pill, try pairing it with a daily habit (like breakfast, or brushing your teeth!)  
Missed a dose? Take it as soon as you remember. If it’s over 12 hours since your missed dose, skip the dose for that day and go back to your regular schedule.  
Tip: although it’s ideal to take pills at the same time daily, you can actually take it as soon as you remember and then go back to your regular time the next day  
Pills are best stored away from heat, light, and moisture – so best to keep them out of the bathroom and away from the kitchen stove! Have you thought about where you store your pills?  
Pills should not be stored in the bathroom. Humidity (i.e. from showers) can ruin them. Try keeping them in your bedroom, away from where kids can reach them.  
Have you checked the expiry dates on all the pills/supplements at your house? Expired pills might not work as well; time to buy some new ones! Despite the name, the medicine cabinet is usually the worst place to keep medicine! Where do you store your pills?  
Response: Great! That’s a good place. The weather is warming up 😊. Tip: don’t leave medicine in the car! The temperature can get really high, damaging your pills. Keep them in a separate bag or purse that you take with you when traveling. |
| Interactive  | Over the last 7 days, how many days were you able to take your pill exactly as prescribed? Please answer with a number from 1-7.  
1) If 7 ➔ “That’s great! Sounds like you have some good habits built in.  
2) If 1-6 ➔ Is there any reason why? |
| Drug information | The most common side effect with your pill is hot flashes (sudden sweating and feelings of warmth). Have you experienced any? Your pill can be taken with food or on an empty stomach (whatever is easier). Make sure to take it with a glass of water or juice. |
| Side effect management | Hot flash tip: avoid tobacco and heavy alcohol use, it makes hot flashes worse. Want some more tips?  
Hot flash tip: Try rhythmic breathing exercises to help you meditate and relax. Click [here](#) for more info |
Hot flash tip: Take your pill at bedtime
If your pill interferes with sleeping, try taking it in the morning.

Hot flash tip: Some people find avoiding alcohol, spicy food, and caffeine (coffee, tea, cola, chocolate) helps

Hot flash tip: Try keeping your environment cool

Hot flash tip: Wear layers! If you have a hot flash, you will have something to take off.

Tip: If side effects continue to bother you, call _____ (nursing or pharmacy line?) for help

Your pill might cause headaches – try acetaminophen (e.g. Tylenol®) every 4-6 hours if needed. If it continues to bother you, call us _____(nursing line/pharmacy line)

A side effect of your pill can be fluid retention (hands and feet might swell). If this is a problem, try to elevate your feet when you sit, and avoid tight clothing. Call us if this continues to bother you ___ (nursing line/pharmacy line)

Hot flash tip: Regular exercise might reduce hot flashes. Exercising can be easy – start by parking your car on the other side of the parking lot to increasing your walking distance.

In order to battle fatigue, try going for a 5-10 min walk outside. Exercise can reduce feelings of fatigue

If you’re having muscle or joint pain, try ibuprofen (e.g. Advil®) or acetaminophen (e.g. Tylenol®) every 4-6 hours. If it continues to bother you, call us ____ (nursing line/pharmacy line)

If you experience nausea (upset stomach) after taking your pill, try taking it after eating.

Lifestyle management
Calcium and vitamin D are important for bone health. Did you know almonds, brazil nuts, and sunflower seeds are all great sources of calcium?

High salt diets can weaken your bones. Check nutrition labels, and try to limit salt to less than 2100mg per day.

Maintaining a healthy weight reduces the risk of breast cancer coming back, and has added benefits of reducing heart disease, diabetes, and cancer risk.

Want to calculate your healthy weight? Try a BMI calculator like this one.

Thinking of revamping your diet? Consider Legumes (beans, lentils, dry peas)! They are plants that are high protein, low fat, and full of iron and cancer-fighting phytochemicals. What a superfood!

Diet tip: When you go to a restaurant, ask for sauces and salad dressing on the side. That way, you can control how much you eat.

Did you know the cancer centre pharmacy can check your natural supplements to make sure they are safe and right for you? Call them at _____ during regular business hours.

This pill might cause vaginal dryness – did you know you could get special lubricants to help? Call ___ (pharmacy) for more info, or text “Y” to learn more.

Goal setting
A workout for strong bones doesn’t have to be boring. You can try a new dance class, go hiking, or take a walk.
<table>
<thead>
<tr>
<th><strong>Have you thought about tracking your steps? 1300 steps = 1 km.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Today is the start of a new week! Consider getting a pedometer (some smartphones can double as pedometers!) and set a daily step goal for yourself.</strong></td>
</tr>
<tr>
<td><strong>Exercising (like walking) 3-5 hours weekly improves breast cancer survival. Have you thought about setting an exercise goal?</strong></td>
</tr>
<tr>
<td><strong>Slow and steady wins the race! Weight loss of 1-2 lbs (0.5-1kg) per week is safe and healthy, and helps you keep the weight off. Have you thought about setting a weight loss goal?</strong></td>
</tr>
<tr>
<td><strong>Have you thought about improving your diet? Plant-based diets are full of “phytochemicals” that reduce the risk of developing cancer. Try introducing beans/lentils in your diet by adding small amounts into your favorite recipes.</strong></td>
</tr>
<tr>
<td><strong>Have you thought about buying an activity tracker to count your steps? If you have a step counter or smartphone app, let us know how many steps you took today!</strong></td>
</tr>
</tbody>
</table>
Appendix I: Summary of Findings and Discussion

Emotional Reaction to Survivorship
- Fear of recurrence
  - Fear is universal experience
- Why can’t I take action
  - Low self-efficacy
- Guilt around social support
  - Recognize the “new normal”

Uncertainty
- Uncertainty in Chronic Illness theory
  - Probabilistic language

Personification
- Positive language
- SMS as intimate
- Holistic program
- Bi-directional messages
- Educate only on requested topics
- Building self-efficacy
- Name the program
- General survivorship topics