SHARED DECISION MAKING: MANAGING NON-CRITICAL CHRONIC ILLNESS BY COMBINING BEHAVIOURAL & DECISION THEORY WITH ONLINE TECHNOLOGY

by

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DEDICATION

I am most grateful to my family and friends for releasing me with love, to pursue higher education. I could not have accomplished this without your continual support.

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ABSTRACT

Shared decision making between patient and provider is considered the cornerstone of patient-centred care but transpires in only 10% of face-to-face encounters. Technology interventions have been explored as a means of filling the shared decision making gap but fall short in patient engagement. Recent studies indicate that combining multiple approaches could lead to greater commitment towards achieving positive health outcomes. The objective of this study is to demonstrate that a behavioural theory and decision theory can complement one another within a technology intervention for shared decision making. This novel approach integrates multiple theories within a single computerized ontology knowledge model that is flexible, expressive and extensible. A mixed method study assessed the solution using goal-based scenarios for hypertension reduction. Usability data was captured primarily using the "think aloud protocol". Both quantitative and qualitative data were analyzed independently and in combination, revealing two-thirds of the study participants favoured the technology intervention.

LIST OF ABBREVIATIONS USED

AMA – American Medical Association

ANCHOR – A novel approach to cardiovascular health by optimizing risk management

API – Application programming interface

ASE – Attitude - Social Influence – Self-efficacy (behavioural model)

CA – Choice architecture

CHEP – Canadian Hypertension Education Program

CPG – Clinical practice guideline

CVD – Cardiovascular disease

ER Model – Entity relationship model

HRM – Halifax Regional Municipality

I-Change – Integrated change (behavioural model)

ISO – International Organization for Standardization

JNC8 - Eighth Joint National Committee

LM – Lifestyle medicine

Mg – Milligrams

MmHg – Milligrams of mercury

NICE – National Institute for Healthcare Excellence

NICHE - kNowledge Intensive Computing for Healthcare Enterprises (research group)

ODSF – Ottawa decisional support framework

REACH - Reducing risk with e-based support for adherence to lifestyle change in hypertension

REB – Research ethics board

SDM – Shared decision-making

SWRL – Semantic web rule language

TAP – Think aloud protocol

TTM – Trans-theoretical model

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CHAPTER 1: INTRODUCTION

Shared decision making (SDM) empowers patients to be more informed and to actively participate in the choices related to their own health. Through patient-provider collaboration, consensus is reached on the best avenue for health improvement. It is a meeting of the experts in which the physician is the expert in medicine and the patient is the expert in his or her own life, values and circumstances [1]. SDM gives patients the opportunity to make the best individualized care decisions, while allowing healthcare providers to feel confident that options were presented and the best care prescribed. SDM can improve the patient's quality of life [2], quality of care and safety [3] while lowering healthcare costs [4]. The premise of SDM rests on the belief that a better choice for health improvement is made when the patient and healthcare provider share the decision making role. SDM is considered desirable because of its potential to a) reduce overuse of options not clearly associated with benefits for all (e.g., prostate cancer screening); b) enhance the use of options clearly associated with benefits for the vast majority (e.g., cardiovascular risk factor management); c) reduce unwarranted healthcare practice variations; d) foster the sustainability of the healthcare system; and e) promote the right of patients to be involved in decisions concerning their health [5].

Shared decision making is a promising paradigm shift for healthcare. However, despite its benefits and being touted as the cornerstone of patient-centred care [6], literature shows that only 10% of face-to-face clinical consultations involve shared decision making [3]. Consequently, technology interventions (decision aids) are seeking to fill the SDM gap [7, 8]. Decision aids can improve decision quality; reduce decisional conflict, increase participation and increase choices consistent with the patient's values [7]. Patient decision aids incorporate individual profiles and preferences to make the decision support more personalized. Recent innovations allow patients to use technology aids on mobile, tablet and other internet technologies. This encourages interactive and informed decision making that is feasible, accessible and cost-effective [8].

Behavioural theories can improve the success rate of health interventions. In the ANCHOR study, behavioural strategies were shown to reduce the risk of cardiovascular disease through lifestyle change rather than increasing patient medication [9]. Internet and mobile-based interventions for increasing physical activity in cardiac rehabilitation have successfully combined user's needs with health behavioural models to effect health improvements [10]. Lifestyle medicine (LM), as it has been coined, is a new behavioural approach for the prevention and treatment of non-communicable diseases such as hypertension using low-risk lifestyle change along with monitoring of cardiovascular health metrics [11]. According to the American College of Lifestyle Medicine, "there is a growing body of scientific evidence that has demonstrated that lifestyle intervention is an essential component in the treatment of chronic disease that can be as effective as medication, but without the risks and unwanted side-effects" [12]. LM has become the preferred method for prevention of hypertension and other chronic diseases but remains primarily an outpatient prescription (used by primary care providers before hospitalization). Hence, behavioural theory that can lead to LM decisions before even the outpatient concerns arise (i.e., in the pre-hypertension stages) can be a catalyst for proactively reducing hypertension and the potential hospitalization (as an inpatient) if untreated.

Decision theory is also making inroads to effect health behaviour change and improve decision making in the health domain. A study on decision-making to improve drug adherence recommends choice architecture (CA) as a complimentary technique for improving health behaviour and decisions [13]. CA is a decision theory from behavioural economics, which alters behaviour (choices) in a predictable way without preventing any options or significantly changing preferences or incentives [14]. It persuades the patient away from complacency (doing nothing), satisficing (taking the route of least resistance) or at the other extreme, becoming overconfident. According to Sunstein, "faced with important decisions about their lives, people often make pretty bad choices—choices they would not have made if they paid full attention and possessed complete information, unlimited cognitive abilities and complete self-control" [15].

Thus, CA is a rich toolkit of choice strategies that can be borrowed from economic theory to influence a patient towards a more optimal decision or path based on their preferences. It includes strategies such as presenting default options and pre-ordering of choices based on preferences, focusing on gains not costs, using anchor messages to frame expectations, providing incentives to continue adherence to their choice, message repetition and more.

An SDM technology intervention with embedded behavioural theory and choice constructs could dually encourage patients towards optimal decisions that yield positive health outcomes. Prior studies suggest that reinforcement through multiple methods may increase motivation and adherence [13, 14, 16]. Thus, this research study assesses whether a technology intervention employing behavioural theory and choice architecture can facilitate SDM to manage a non-critical chronic illness. A cardiovascular risk factor (hypertension) will be used to validate the technical feasibility and usability of the proposed technology lifestyle intervention. Hypertension (high blood pressure), the most common chronic cardiovascular risk factor, is prevalent in 22% of Canadian adults aged 20 to 79 years [17]. It affects approximately 1 billion individuals worldwide [18] and can be managed by non-pharmacological means, such as increasing exercise, reducing smoking and reducing sodium intake.

1.1. Research Problem

This research thesis combines and embeds the Integrated Change (I-Change) behavioural theory [19] with choice architecture [15] within the *í*heart web application to facilitate shared health decision making. The research develops a seamless, online application that empowers a patient to make lifestyle choices and share decisions necessary to reduce hypertension.

From a knowledge modelling perspective, the research problem in this thesis explores how to formally model behavioural theory with choice architecture for deployment in an integrated shared decision making tool. The resulting model should be flexible and allow multiple participants, be applicable to any disease condition, and link to domain specific interventions and relevant domain content. The model will be used to inform the application development and allow complimentary behavioural and choice constructs to be utilized to advise and bring the patient to a readiness state to share decisions with a healthcare provider. The shared decisions are then acted upon by the patient to endorse a lifestyle behaviour change that reduces hypertension.

The I-Change behavioural theory and choice architecture constructs used in this thesis are evidence-based and have been used in other research and practical applications [13, 14, and 19]. This research is not about proving the effectiveness of the theories; instead we demonstrate that a behavioural theory and decision theory can be integrated within a single knowledge model without losing the integrity and validity of the theories. The research validates the knowledge model which is used to inform the development of a shared decision making application to reduce hypertension.

The *í*heart web application developed in this thesis presents a “proof of concept” that shared decision making can transpire through a technology intervention when guided by behavioural theory and decision theory. The success criteria for *í*heart are therefore its ability to engage patients to make lifestyle choices and participate in online discussions with a healthcare provider to formulate shared decisions. As *í*heart is a prototype system, its use in a clinical setting is not considered an evaluation criterion for this research. This research is a pilot study of *í*heart to determine the technical feasibility and usability of the application from the patient’s perspective. Feedback gained from the study serves in refining *í*heart for future study. Creating a clinical implementation of online shared decision making is outside the scope of this thesis.

1.2. Research Objectives

This research seeks to answer three questions:

i) Can behavioural theory and decision theory be combined within a single computerized knowledge model (ontology) that is flexible, expressive and extensible to inform the development of a shared decision making tool while keeping the respective theories intact and valid?

ii) Is the íheart application, combining behavioural theory (I-Change model) and decision theory (choice architecture), a useful tool for engaging patients to share health decisions?

iii) What would enhance the use of iheart for shared decision making? Sub-elements of the secondary research question include:

a. What are potential feasibility and usability challenges in using iheart for SDM?
b. Is the information content, choice delivery and SDM useful for the patient?
c. Do the participants perceive iheart as an effective alternative or supplement to traditional clinical interactions (face-to-face encounter) for shared decision making?
d. What modifications are needed to improve the iheart application?

To answer the research questions, this thesis will:

1. Create an SDM ontology model integrating I-change behavioural theory with choice architecture
2. Develop the íheart application based on the resulting SDM ontology model
3. Conduct a technical feasibility and usability pilot study with 8-10 participants
4. Use the think aloud protocol to gather participant feedback (qualitative data)
5. Use inductive thematic analysis to code and evaluate the qualitative data
6. Further evaluate the feasibility and usability of the íheart application from the participant's perspective using a post-study questionnaire (quantitative data)

1.3. Research Challenges

To accomplish the research objectives, the following challenges need to be addressed:

i. Identifying proven theories that are suitable for shared decision making and can be modeled and computerized.

ii. Integrating multiple theories within a single knowledge model without impacting the integrity of each respective theory.
iii. Designing a knowledge model that is flexible, scalable and patient-centred.
iv. A credible means of measuring the participant's I-change behavioural state.
v. Integration of a user-friendly, validated and secure sodium calculation is needed. The average person may not be capable of self-assessing their daily salt consumption or set a salt reduction goal in quantitatively measurable terms (milligrams) without assistance.
vi. A simple, seamless and effective means of chatting online in real time with a healthcare provider is needed within the *í*heart application.
vii. Recruiting 8-10 hypertensive participants without access to medical records requires targeting the desired population through recruitment advertisements.
viii. Designing a research study to objectively measure usability of the intervention.

1.4. Research Solution

The research is based on the vision in Figure 1.1 that three key elements can induce patients to share decisions to reduce hypertension through lifestyle change. First, theory-driven and evidence-based strategies for behavioural modification can reduce cardiovascular risk [9]. Second, choice architecture alters behaviour in a predictable way without preventing any options or significantly changing preferences or incentives [15]. Third, decision aids such as technology decision tools can reduce decisional conflict resulting in fewer patients remaining passive or undecided [7]. Together, the three elements can synergistically inform, support and engage the patient to be actively involved in their shared health journey and decision making.

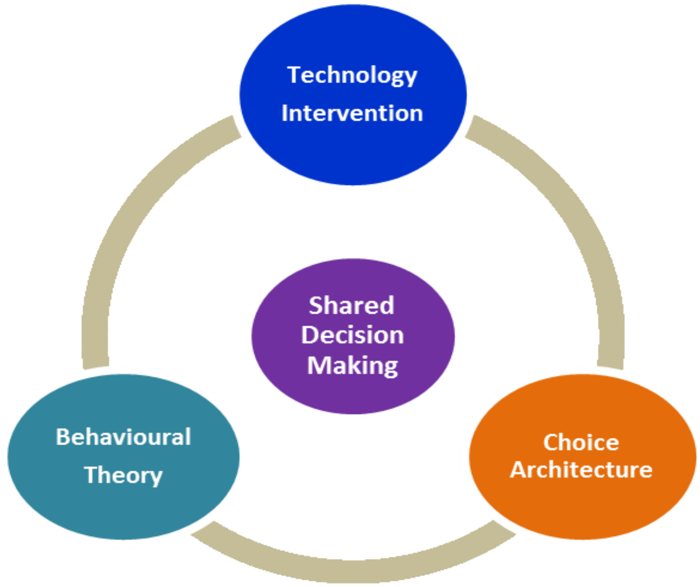

Figure 1.1 - Conceptual Model for SDM

An ontology model is used to integrate the core components of the conceptual model for SDM. The ontology model is then used to inform the computerization of the iheart web application. The model is to be scalable and flexible and should accommodate any disease condition, multiple participants, the selection of different theories for behaviour change and also different choice architecture concepts. The ontology model should be patient-centric and contain the core constructs, relationships, and description logic that will form the foundation upon which the technical solution will draw its elements and processing logic.

The technology solution envisioned is a web-based interface storing information on a centralized server within a secure relational database. A web application framework is used to produce a rich internet application that includes a mechanism for chat sessions that enable online shared decision making. The technical solution relies on the ontology model constructs to present the behavioural theory, choice and domain content as a seamless shared decision making process between patient and healthcare provider.

To assess the research solution's usability, a section of a post-study questionnaire and the "think aloud protocol" (TAP) [20] will be used. TAP is a systematic qualitative technique for assessing usability of a technology product. As Benbunan-Fich describes in her use of TAP to assess the usability of an online website, "the think aloud method is a qualitative research technique, well suited to determine how users interact with websites, how users feel about a site, and how and when usability problems occur."[20] The TAP method will be used to capture participant's usability feedback while they complete goal-based scenarios. Having users openly verbalize their cognitive thoughts, feelings and opinions about the solution gives insight into their true reaction to it. It results in a more complete picture of the problems encountered and reduces bias that can transpire with structured, after-the-fact data collection techniques such as questionnaires. In a mixed method study, TAP provides a good cross-check on consistent user feedback regarding usability.

1.5. Contribution

In this thesis, we create a prototype of a shared decision making intervention incorporating both behavioural and decision theory within an online technology solution. Literature demonstrates that behavioural theory, decision theory and technology can independently support patient engagement for shared decision making [9, 13]. Studies evaluating one or two of these approaches are common [10]. In our study, we take a novel approach of combining all three components in a single intervention to reduce hypertension. This research is a preliminary study to assess the technical feasibility and usability of the proposed shared decision making solution combining multiple theories.

1.6. Thesis Organization

The remainder of the thesis is organized as follows: Chapter 2 presents the background and main concepts related to the research question. Chapter 3 outlines the evolution of the research solution from its conception to its assessment through a pilot study. Chapter 4 describes the various forms of evaluation applied to the study data. Chapter 5 is a discussion of the study findings, vision and research limitations. Chapter 6 explores future work that could potentially build on this research. Chapter 7 includes a review of the research contribution and concluding remarks.

CHAPTER 2: BACKGROUND

2.1. Shared Decision Making

Shared decision making is not necessary in every clinical encounter, but is pertinent when the patient is presented with alternative choices that require weighing benefits and harms. The patient is then faced with decisional conflict and must draw on their preferences and potentially advice of others including their healthcare provider for decisional support. Shared decision making is a process during which clinicians (experts in medicine) and patients (experts in their own life, values and circumstances) collaborate to make health decisions, considering both the best available evidence and patients' preferences [21]. The common ground is that both parties wish to achieve a positive health outcome for the patient. Hence, shared decision making shows promise in many health disciplines and practical areas such as cancer screening and treatment, diabetes, cardiovascular disease prevention, mental health and other areas where a patient may be faced with a crucial but difficult decision.

2.1.1. Lifestyle Medicine

Lifestyle medicine (LM) is a rapidly emerging medical practice that uses lifestyle interventions in the treatment and management of diseases. Interventions such as exercise, smoking cessation, stress management and diet improvement are proving effective for the prevention and treatment of lifestyle diseases such as diabetes, hypertension, heart disease, obesity, osteoporosis and several types of cancer [12]. It is a pioneering approach in which healthcare providers and patients "take action by bridging the gap from treating consequences to focusing on upstream determinants of health [22]." LM is gaining momentum but currently remains primarily a clinical practice (outpatient basis). With an aging population seeking homecare, it has merit as a residential intervention. LM is used either as an alternative to medications or a reduction in prescribed medications. Lifestyle medicine is an ideal arena for the use and expansion of shared decision making. Patients and healthcare providers must make choices regarding the type or combination of lifestyle changes to be made, overcoming barriers to change, determining intensity of change, goal setting and more. The growth of lifestyle medicine could arguably be dependent on the use of shared decision making and vice versa. The challenge is moving away from paternalistic or traditional medicine to a patient-centred focus.

To address the shared decision making challenges in lifestyle medicine, health interventions, especially web-based decision aids are becoming more prevalent. The wide reach and low cost of leveraging the internet is seen as a means to reform patient-centred care —leading to increased patient autonomy, improved collaborative patient–provider interactions, and ultimately better health outcomes and patient satisfaction [23]. A one-year study of online lifestyle modification for weight loss revealed several features that make an online intervention successful. These include: fostering encouragement, responsiveness from online provider, personalization, specialized content about lifestyle modification, sense of accountability for participant and use of behavioural strategies [23].

2.2. Hypertension

Hypertension, the medical term for high blood pressure, is a growing risk factor for cardiovascular disease (CVD). Hypertension affects 22% of the Canadian adult population [17] and remains one of the most important modifiable risk factors for cardiovascular disease globally [24]. The prevalence of hypertension in Canada continues to increase and is predicted to reach 7.5 million people in 2012/2013 with more than 1000 people newly diagnosed with hypertension every day [24].

Hypertension is a condition where shared decision making about lifestyle choices presents an opportunity. Hypertension can be reduced by proper diet, exercise, reduction in smoking, reduction in alcohol consumption, reduction in sodium intake and stress management as viable alternatives or supplements to medications. In fact, shifting clinical guidelines for hypertension highlight the opportunity for personalized shared decision making. The Eighth Joint National Committee (JNC 8) in the US recently recommended that evidence does not support initiating treatment (medication) for individuals over 60 until their blood pressure surpasses 150 over 90 mm Hg [25]. Aggressive treatment of hypertension in the elderly is perceived by JNC8 as being high risk [25]. Hence, alternative means and tools to regulate hypertension are desirable. Persons in high risk groups in the US with lower elevated blood pressure stand to benefit from personalized, patient-provider shared decisions about lifestyle modification.

Despite the changes in the US, the Canadian clinical practice guideline (CPG) for hypertension has not been adjusted to reflect the recommendations of its US counterparts. Instead, the Canadian CPG recommends scheduling a visit and tests to assess hypertension for a blood pressure measurement of 140 over 90 mm HG [24]. This applies across the board with no differentiation for any high risk groups. For non-severe cases of hypertension, the guideline recommends clinic (outpatient), ambulatory or home blood pressure monitoring after a second elevated reading that is non-severe [24].

Still, the Canadian clinical practice guideline advocates lifestyle changes endorsed by Hypertension Canada's, Canadian Hypertension Education Program (CHEP) [26]. The lifestyle changes endorsed include modifying: 1) physical exercise 2) weight reduction 3) alcohol consumption 4) dietary intake 5) sodium intake and 6) stress level to manage hypertension [24]. Of particular interest, the guideline proposes that "first, non-pharmacological management should be instituted in all patients and, if successful, can potentially normalize BP levels without the need for drug therapy." [24]

2.3. Health Behaviour Change

In recent years, health behaviour change has become central to lifestyle interventions aimed at prevention, public and chronic health concerns. The principle behind health behaviour change is that an individual can abandon health-compromising behaviours and adopt health-enhancing behaviours. Health behaviour change is the premise for Lifestyle Medicine and the National Institute for Health and Care Excellence (NICE) has formalized a pathway for a person-centred health behaviour change approach [27]. The pathway takes into account the individual's social, cultural and economic context, motivation and skills, including any potential barriers they face to achieving and maintaining behaviour change [27]. A vast amount of literature is accumulating on health behaviour change, and studies indicate a mix of both successes [28, 29] and challenges [30, 31] to date.

Evidence shows that health behaviour change especially when making lifestyle modifications is a challenge for most people to accomplish without support or supplemental aids [32]. The average person aims with good intentions to improve their lifestyle when faced with health concerns. Often, short term gains are realized but long term adherence is difficult to achieve. Adherence can be rated as 1) non-adherence 2) lapse/re-adoption 3) adherence. To achieve sustained adherence, literature suggests the use of cognitive or behavioural theory [33] and also shared decision making [34].

2.3.1. Behaviour Change Models

Behavioural change theories explain how human behaviours may change. Each theory or model uses different factors or stages to demonstrate the change evolution or process. Common behavioural change theories include: the self-efficacy model, social cognitive theory, theory of planned behaviour, trans-theoretical model and health belief model. In developed countries, a significant portion of mortality is due to specific behaviour patterns and the belief is these behaviour patterns are modifiable [35]. Thus, there has been a growing application of behaviour change theories in preventative medicine and public health within recent years. The old model of healthcare, a reactive system that treats acute illnesses after the fact, is evolving to one more centred on the patient, prevention and the ongoing management of chronic conditions [36]. This includes application of health-enhancing behaviours (i.e. increased exercise), health-protective behaviours (i.e. cancer screening) and avoidance of health-harming behaviours (i.e. smoking). A unifying theme across the various change theories is that behaviour change can have long term effects and the individual has partial control over changing their behaviour [37].

Many different types of behavioural frameworks exist. Behaviour theories are classified as to their key determinants (e.g., values, attitudes, self-efficacy, etc.), the scale at which the model can be applied (e.g., individual versus organisational/societal), or whether it focuses on understanding or changing behaviour [37]. One of the most common forms of behaviour theories are "stage theories". These theories suggest that an individual progresses through discrete levels or phases of change represented by stages to achieve a desired outcome (behaviour). Although different stage theories have different quantities and categories of discrete stages, they all commence with the individual considering change then increasingly moving toward that change and ending with fruition when the behaviour is acted upon and maintained. Stage theories recognize behaviour as an outcome of competing influences weighed and decided upon by the individual [38] and that different cognitive factors are used at different stages [37]. Behaviour change is complex and dependent on many intrinsic and extrinsic factors such as our personal values, preferences, efficacy, motivation, income, availability, family and peer influences to mention a few. The foci of stage-based interventions are to transition an individual from one stage to the next while overcoming the competing interests and barriers to change. Hypothetically, the individual moves through the stages in order but may relapse to an earlier stage. They may also cycle through the stages more than once before reaching the goal of sustained behaviour change.

A systematic review of international literature by the New Zealand government in 2011 [39] showed that seven randomized control trials had used behavioural models to improve hypertension. The health interventions based on the Cognitive Behavioural Theory or Social Learning Theory (also referred to as Social Cognitive Theory) were found to be the most effective at improving target behaviours in people with hypertension. Behaviour change frameworks were most effective at changing behaviours related to management of blood pressure, increased physical activity and improving medication adherence.

Other studies have revealed counseling interventions using behavioural theory can result in lifestyle changes that reduce the risk of cardiovascular disease and its modifiable factors, such as hypertension. The ANCHOR study [9] used behavioural theory and shared decision making in the clinical setting using face-to-face visits. The study concluded that global cardiovascular risk can be effectively decreased through lifestyle changes that are informed by readiness to change assessments and personalized counseling. In contrast, the REACH study [40] aims to use a web-based lifestyle counselling intervention to reduce hypertension. The randomized control trial will issue tailored e-messages to its study group based on their stage of readiness for change. The stage of change will be assessed using Prochaska's Transtheoretical algorithm (TTM) [40]. The final results of this research have yet to be published; however, it highlights the use of a staged behaviour change theory within a web-based intervention aimed at reducing hypertension.

2.3.2. I-Change Model

There are many different behavioural change models each having their own benefits and critiques. The model selected for this research study is the Integrated Change or I-Change model, which is a staged model. Staged models follow a discrete progression from one stage to another to account for behaviour change. I-Change is a model that evolved from the Attitude-Social Influence-Self-efficacy (ASE) model [41] that integrates aspects of several theories including the Theory of Planned Behaviour, Social Cognitive Theory, Transtheoretical Model and Health Belief model [41].

The I-Change model consists of three discrete stages: awareness (being cognizant a change is needed), motivation (desiring the change) and action (taking steps to complete the change). For each phase, different factors are relevant. In its full complexity, as shown in Figure 2.1, the I-Change model hypothesizes that pre-disposing factors and informational factors drive our awareness of change by presenting knowledge, cues to act or some form of risk perception. Awareness may then lead to motivating factors for change based on the ASE model (attitude, social influences and efficacy). Motivation drives intention and in this stage the individual pre-contemplates, contemplates and prepares for the change similar to the TTM. Past this point, ability factors and overcoming barriers to change are essential to acting on the behaviour change which can either be as a trial (short term) or maintained (long term adherence).

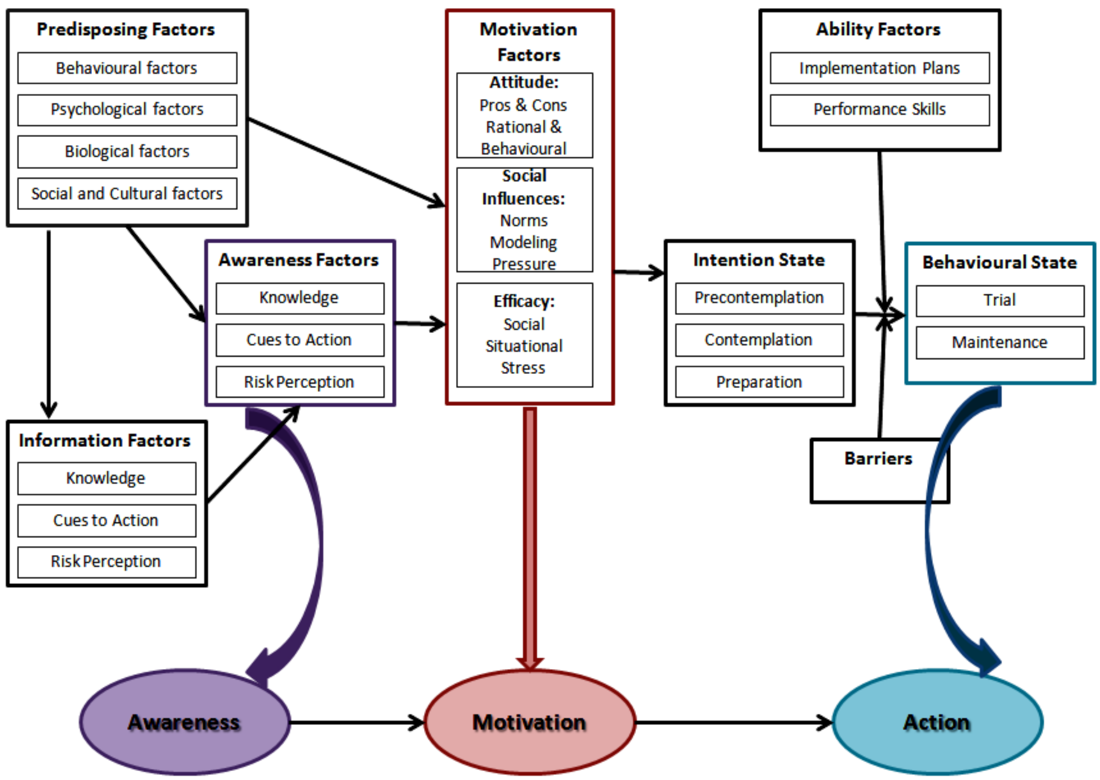

Figure 2.1 – Integrated Change Model

I-Change is a relatively new model that is gaining popularity in the health domain. It was first applied by De Vries and collaborators in 2005 to study the patient education needs of the general public regarding hereditary cancer [19]. It has been used in subsequent health studies by De Vries and other independent researchers. Voogt C. et al (2013) used the I-Change model recently to develop a web-based intervention for reducing heavy drinking among college students in the Netherlands where drinking starts at an early age [42].

In reviewing the various behavioural change models, I-Change was selected for this thesis as it evolved from other well established, evidence-based behavioural change models. Further, in the New Zealand systematic review of behaviour change on chronic care, Cognitive Behavioural Theory and Social Learning/Cognitive Theory were found to be effective for modifying target behaviours that reduce hypertension [39]. Since the I-Change model is based on Social Cognitive Theory, evidence suggests it's a good candidate for use. Its three simple states: awareness, motivation and action, are also easy to assess and manipulate. Having fewer states makes it easier to devise and validate a scoring instrument to determine the current behaviour state. This produced a ripple effect as it also reduces the complexity needed to program the online application. For instance, programming a questionnaire and scoring algorithm based on three states is less complex than five states. It is also beneficial to design systems that reduce the cognitive load on a chronically ill patient. The simpler and shorter the behavioural questionnaire embedded within the application, the lesser the cognitive load for the patient. For these reasons, I-Change is well suited for a technology-based intervention to reduce hypertension.

2.4. Decision Theory

Decision theory explains how human beings make decisions in complex, real-world situations. It is an interdisciplinary subject pursued by economists, mathematicians, cognitive psychologists, politicians and philosophers. Decisions can be spontaneous or take considerable time to formulate. Regardless of duration, individuals make decisions based on their values, preferences and influences. Decision theories attempt to understand the rationale involved in making optimal decisions under both certainty and uncertainty.

In general, there are three components to any decision [43]:

1. the state of nature (uncertainty)
2. the choices available (alternative courses of action)
3. the payoffs (anticipated outcomes)

Decisions progress through a cognitive and behavioural process (Figure 2.2) whereby the individual is presented with a situation (event) requiring a decision, they must evaluate and select the best course of action (act) and accept the gain or loss (outcome). The types of decisions that are suited to decision theory are: choice under uncertainty, having competing and equally desirable choices, inter-temporal choice and complex choice. Inter-temporal choice is when a current decision will affect the options that become available in the future.

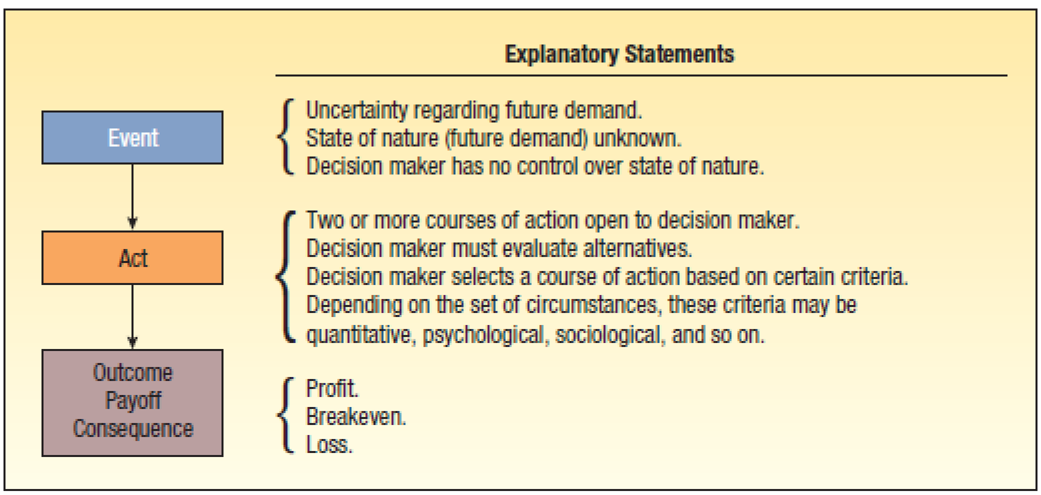

Figure 2.2 – Decision Progression

In healthcare, patients must often make difficult decisions under uncertainty, choose between competing and equally desirable choices or navigate complex decisions. In some health circumstances, inter-temporal choice[1] comes into play. Determining diagnostic testing, treatment paths, lifestyle decisions, adherence, etc.

[1] Inter-temporal choice is a concept that describes how an individual's current decisions affect what options become available in the future. For example, an individual decides to get breast screening and is found to have Stage I cancer. Early stages of cancer can be treated with a mastectomy, radiation and hormone therapy. If the same individual opts out of breast screening and is not detected until Stage III, they may face mastectomy, radiotherapy, hormone therapy and chemotherapy. [44]

represent typical health related choices facing patients. Interestingly, decisional quality is found to be worse with a greater quantity of options and contradicts a basic assumption of patient-centred care, which promotes giving the patient more options and more information [45]. Hence, it is important that the decision theory selected is evidence-based. It should have practical application in the healthcare setting and be effective in improving decision quality; reducing decisional conflict and increasing choices consistent with the patient's values [46]. For example, the Ottawa Hospital Research Institute has been leading the way by devising evidence-based patient decision aids using their Ottawa decisional support framework (ODSF) [47] which is based on behavioural and economic decision theories. These decision aids aim to prepare the patient for active interaction with their healthcare provider in a face-to-face encounter so both parties can jointly select the optimal path for the patient's condition.

2.4.1. Choice Architecture

Choice architecture (CA) is a decision theory originating from the field of economics [48] and has been successfully used in healthcare. It serves to fill the well-known intent-behaviour gap [49], characterized by a disconnect between intention and actual behaviour. Essentially, choice architecture presents and guides an individual to make optimal choices based on their values and preferences without making the choice for them. It is a subtle means of informing and empowering the patient during the decision making process.

An empowered patient is one that is prepared to ask questions, seek additional information for decision making, challenge and assert their needs and expectations regarding diagnosis and treatment for their specific health circumstance. Too often, healthcare providers or patients will resort to "satisficing" [50] whereby the parties simply accept an available option (prescription) as satisfactory even within the realm of evidence-based medicine. Patient safety data alone indicates that less than optimal decisions are sometimes made in medicine [50]. Choice architecture is a method of overcoming satisficing by presenting appropriate, evidence-based alternatives for maintaining or improving patient outcomes.

CA is essentially a toolkit of different approaches that support making better decisions. It nudges individuals in a suitable direction through the use of its components which include: default options, anchoring, providing feedback, expecting error, understanding mappings, giving incentives and structuring complex choices into simpler choices [15]. Four components from the CA set will be used in this research. These are default options, anchoring, providing motivating feedback and giving incentives. A brief description of each CA feature to be used is provided next.

Default Options: When faced with decisions, many people opt for the path of least resistance. It implies that for a specific choice, there is one that the majority of people would choose. Therefore, it makes sense to present the "normal" option as the default and allow the decision-maker to override it and choose differently if necessary. It ensures that complacency (doing nothing) is eliminated from the choice. Default options can be very powerful [51], especially when tied to the individual's preferences. Default options derived from a patient's profile aim to increase the likelihood the individual will choose what is logically best for them based on the information they have provided. For instance, a person making meal choices uses an online tool for assistance. They enter their gender, age, BMI, weight loss target and allergies. The web tool can then offer several meal ideas and portion sizes to match their profile and weight loss goals. Proposed daily meals (breakfast, lunch, dinner) from the full meal set would be highlighted as default options based on the individual's profile. This removes the possibility of eating unhealthy food (no diet change).

Anchoring: When people have to guess during decision making, bias often comes into play. For example, Thaler & Sunstein describe people from Chicago and people from Green Bay being asked the population of Milwaukee [51]. People from Chicago know Milwaukee is smaller than their city. Hence, they typically guess it is one-third the size of Chicago or one million people. People from Green Bay know Milwaukee is larger than their city and typically guess it is three hundred thousand. The anchor (city they come from) biases their answer according to the authors. The population of Milwaukee is approximately 580,000 people. The example demonstrates how anchoring can influence choices. Similarly, if an individual wanted to take the path of least resistance to weight loss, they may set their target goal (behaviour change) far too low to effect any real change. With anchoring, either messages or options are customized to set the individuals expectations realistically based on evidence at the onset of making the decision.

Motivating Feedback: Giving feedback is one of the best ways to improve performance or outcomes. It serves a dual purpose: 1) to keep us from becoming discouraged and 2) at the other extreme keeps us from becoming overconfident or optimistic. An excellent example is how the Department of Transportation in Canada uses the choice architecture technique of motivating feedback to slow down drivers in high risk locations. Digital signs that register and publicly display a driver's speed are placed before toll bridges or other risky locations where speed could result in a serious accident involving multiple vehicles. When an excessive speed is detected (i.e. 70 km/hour in a 50 km/hour zone), the sign will show the speed and flash "slow down" with a quick frequency to alarm the driver. This feedback makes the driver cognizant of their speed long before approaching the high risk area. The same concept applies in healthcare. For weight loss, online tools track an individual's daily caloric intake and weight loss progress. Graphs giving feedback to the online user along with positive messaging encourages adherence to a continued diet change.

Incentives: Incentives increase the gain or reduce the loss of taking an unwanted action. It is a basic economic concept that moves an individual further towards enrolment or sustained adherence towards a change. An example of a technology-based incentive is found in Dr. Joseph Cafazzo's BANT iPhone app [52]. BANT helps teens to manage Type 1 Diabetes by using iTune store credits as an incentive. Adolescents are reluctant to prick their finger with a blood glucose monitor (glucometer) and take readings at school several times a day. The Bant app rewards teens with iTunes store credits every time they use their glucometer. It uses Bluetooth to transfer their glucometer reading to the BANT app on their iphone. Once the reading is successfully uploaded they receive their iTunes credit.

Choice architecture and its various components have been successfully used in different aspects of healthcare. It has been widely used by public health agencies to promote healthy food choices [53]. Food guides use choice architecture concepts such as structuring complex diet choices into simpler choices (i.e. categorization of food groups), recommending defaults (daily servings for each food group) and providing incentives such as improved health, quality of life and longevity. Food guides also strive to eliminate unhealthy food choices by not mentioning them as options. Another area of health where CA has been effectively used is to improve adherence to medication use [13] and it has even been considered as a means for altering population health behaviour [14]. In the US, choice architecture has been used to enable consumers to make health insurance purchases that match the individual’s custom level of health services required [54]. Thus, CA is an economic-based decision theory that has proven through evidence that it can enable better health decision making.

2.5. Combining Multiple Theories

Behavioural theories are commonly used in preventative medicine to help patients make better lifestyle decisions that extend life. Stage theories such as the I-Change model are suited for health interventions that modify behaviour, especially those that are technology-based. For instance, the Netherlands devised the “What Do You Drink” web-based intervention to detect and reduce heavy drinking among young adults [42]. It used both intervention mapping and parts of the I-Change behavioural model. The web intervention moved young adults from heavy drinking to low-risk drinking by transitioning them through the I-Change behavioural stages. Most stage-based behavioural interventions will capture either pre-intervention and/or post-intervention behavioural states. In a technology intervention, the individual’s behaviour state is easily determined by embedding a validated, behavioural questionnaire within the system. The scoring of the questionnaire determines the individual's current behavioural state. The score can then be used to tailor or personalize the application based on the known readiness state for behaviour change. Thus, behaviour change readiness is an easily acquired input to improve shared decision making involving lifestyle change.

Other inputs can also influence better shared decision making. Shared decision making is ideal in situations of uncertainty or where multiple competing options exist. Thus, decision theory, which is designed to navigate complex decisions and uncertainty, can also be a contributing success factor for SDM. The decision framework used by the Ottawa Hospital Research Institute described in Section 2.4 is evidence of economic-based decision theory supporting SDM. By embedding decision theory within technology decision aids, it fosters patient engagement and enables better shared decision making. Further, when the decision theory draws on health evidence within a technology aid involving SDM, it levels the playing field by offering the health evidence to both the patient and healthcare provider. Choice architecture is a decision theory that can support SDM and is well suited for technology decision aids. For example, a default option can be programmed based on the patient's preferences and values through logic rules or a decision table. Providing feedback or incentives can be achieved in creative ways through screen messages, visual objects or points earned. Likewise, the breakdown of complex choices into simpler choices can also be accomplished in many ways through software programming.

As described above, literature shows that behavioural theory, specifically the I-Change model is suitable for technology interventions that modify lifestyles [42]. Evidence also demonstrates that decision theories such as choice architecture can spur behaviour change [13], influence decision making [55] and are suited for technology interventions [48]. Furthermore, reinforcement through multiple methods may increase motivation and adherence [16]. In fact, in their study on medication adherence

[13], Nease, Frazee and Miller recommend the marriage of patient engagement strategies with choice architecture solutions. The researchers suggest that the theories are complimentary and further research should be done to explore the combination of patient engagement strategies such as behavioural theory and choice architecture. Hence, this research proposes a technology intervention employing the I-Change behavioural theory and elements of choice architecture, to reduce a cardiovascular risk factor (hypertension) using SDM.

CHAPTER 3: MATERIALS AND METHODS

The iheart web application was developed as a "proof of concept" to determine whether making shared decisions for the management of a non-critical chronic illness such as hypertension, using a technology intervention based on behavioural and decision theory, proves usable. ***Usability*** according to the ISO 9241 standard is the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use [56]. The research methodology used to determine the technical feasibility and usability of the iheart solution involved ten components:

1) A literature review examined the prevalence, success and challenges of shared decision making. This review identified solutions for addressing the gaps with SDM. The solutions included use of behavioural theory, decision theory, technology decision aids and further, that combined methods should be explored to improve adherence to health lifestyle modifications. The findings from the literature review were documented in a concept map (Appendix A);

2) The solution for the research problem (Sections 1.1 to 1.4) was conceptually defined in a patient-centric process flow depicting the steps and shared decisions that could empower a patient to make a desired lifestyle modification to improve their health;

3) The identification of appropriate lifestyle modifications for reducing hypertension included review of the Canadian clinical practice guideline along with other evidence-based recommendations, domain specific content and education materials;

4) The development of a single knowledge model combining behavioural and decision theory to support SDM;

5) The creation of decision logic to recommend lifestyle modifications for reducing hypertension based on patient demographics and health markers. This component included a comparison of different methods for storing and processing decision logic;

6) The logical design of the iheart application using system design techniques;

7) The discovery of an application development framework that enabled online, real-time shared decision making along with secure storage of data for web access from any location;

8) The creation of test plans and their execution by various stakeholders;

9) The generation of case-based scenarios to evaluate iheart;

10) The creation of an evaluation strategy for the iheart prototype and areas for improvement; this included assessment of the technical feasibility and usability of iheart.

The ensuing chapter describes the evolution of the iheart web intervention in terms of phases. The phases include a conceptual phase, design phase, development phase and assessment phase.

3.1. Conceptual Phase

During the literature review for this research, a concept map was devised as shown in Appendix A. The concept map delineated the different concepts, theories and constructs that literature revealed are relevant to shared decision making. The concept map visually illustrated the relationships between concepts and ideas that are woven into the iheart solution. It was a useful way for the researcher to organize distinct concepts (theories, patient engagement, interventions, etc.) and how they combine to achieve both the goal (shared decision making) and the desired outcomes (adherence, improved health, etc.).

3.1.1. Conceptual Process Flow

The concept map was expanded into a blueprint for the iheart technology intervention, employing the I-Change behavioural theory and choice architecture. This was accomplished by defining a conceptual process flow diagram. The diagram (figure 3.1) visually outlined the patient navigation for the proposed technology intervention, indicating the different choices and shared decision making steps between patient and provider. A patient-centred approach was used to determine the sequence of steps in the process. This included data to be entered and decisions to be made that would inform shared decision making to reduce hypertension.

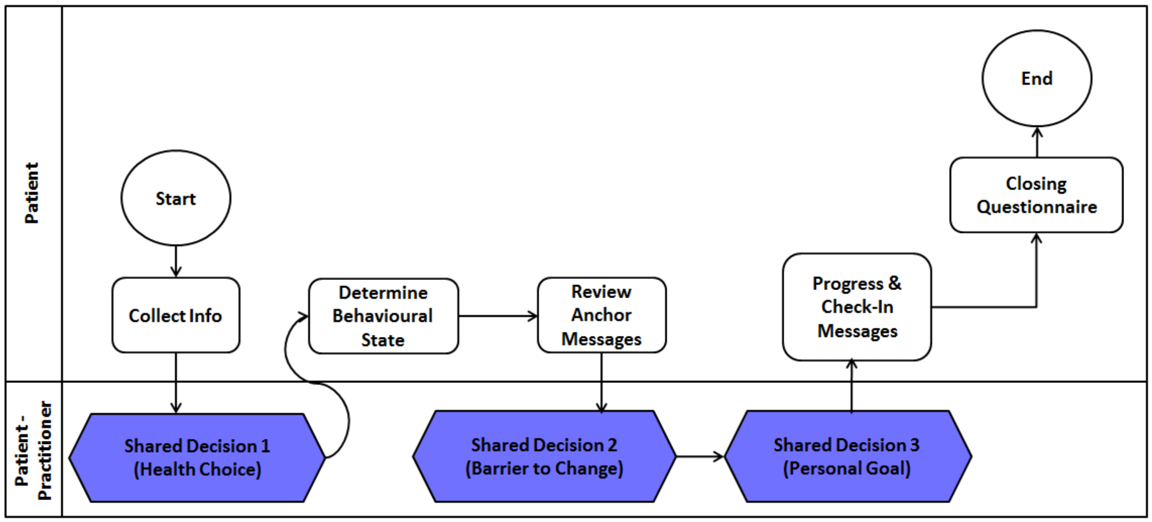

Figure 3.1 – Conceptual Process Flow

The steps in the process flow were:

Information Collection: Demographics including age, gender and ethnicity along with health markers for current exercise, smoking and sodium intake are collected for use in the subsequent choice architecture.

Shared Decision 1 (Health Choice): A health choice (lifestyle intervention) is the first shared decision made towards reducing hypertension. Based on the Canadian clinical practice guideline [24], three lifestyle modifications were selected from the full set of recommended options for the purpose of this research: to increase exercise, reduce smoking or reduce sodium intake.

Behavioural State: A validated questionnaire captured the behavioural state of the patient (awareness, motivation or ready to act) using the I-Change behavioural model.

Anchor Messages: CA anchor messages motivated behaviour change by framing the importance of the intervention and setting expectations without impacting preferences.

Shared Decision 2 (Identify Main Barrier to Change): A second shared decision prompted the patient to identify and discuss overcoming inhibiting psychological barriers. Overcoming barriers is essential for altering lifestyles successfully [41, 57].

Shared Decision 3 (Personal Goal Setting): A third shared decision set a realistic personal goal for the intervention.

Progress and Check-In Messages: Entry of systolic and diastolic blood pressure measurements were made while receiving a concurrent motivational check-in message.

Closing Questionnaire: The patient evaluated their experience with iheart.

Walking through the conceptual process flow demonstrates the patient-centric nature and theory behind iheart. First, the patient enters their demographic data (age, gender and ethnicity) along with their current health markers related to hypertension reduction. The behaviour change choices (shared decision 1) include increasing exercise, reducing smoking or reducing sodium. Depending on their current lifestyle (smoking, sodium consumption & exercise), the patient is presented with one or more of these options (although they are able to select any of them), and chooses one based on shared decision making with their healthcare provider. Afterwards, the patient fills out a behavioural questionnaire, which scored their initial I-Change behavioural state. Importantly, the behavioural state (awareness, motivation or action) informs elements of the choice architecture (CA), a decision theory that attempts to fill the intent-behaviour gap. In particular, based on the patient's behaviour state, appropriate CA anchor messaging is presented, adapted to the patient's readiness for making the selected behaviour change (e.g., quitting smoking cuts your risk of dying from smoking-related heart disease in half). An expert in Industrial-Organizational Psychology devised and validated the behavioural questionnaire. Questionnaires, content and informational messages were further reviewed by a nurse to ensure they were patient appropriate and also met patient education readability guidelines [58]. The patient then discusses their main barrier to making the lifestyle change selected in shared decision 1.

This is done in collaboration with their healthcare provider (shared decision 2). The patient then sets a concrete goal with their healthcare provider (shared decision 3) given their health choice (e.g., reduce a certain number of cigarettes per day). Once the patient completes all three shared decisions, they enter a series of progress updates, namely their systolic and diastolic blood pressure measurements, and concurrently receive their daily check-in messages. After each patient completes their use of iheart, a questionnaire is completed to evaluate the technology intervention.

3.1.2. Evidence-Based Fields and Content

Fields and content based on evidence or public health guidelines were identified and implemented within iheart. Fields refer to an element of data entered in the system (i.e. person's age). For the purpose of this research, the fields and content specifically related to hypertension, although iheart could apply to other health conditions and domains besides cardiovascular disease. The sources and content for various aspects of iheart are described in detail below and were used in the system design.

The demographic information collected in the patient profile (screen P2 in Appendix B) was selected based on the Canadian clinical practice guideline [24] (CPG), Public Health Agency of Canada [59] and the Heart and Stroke Foundation of Canada [60]. The demographics selected for entry were: age range, gender and ethnicity. The Canadian CPG notes that age is important in considering hypertensive treatment. In particular, in the elderly age group (age 80 and above), caution is advised for treatment of frail persons [24]. Gender is another important factor for hypertension. In adults, hypertension is comparatively the same for men and women for most age groups. However, the rates for prevalence of hypertension in women are increasingly higher than men, from age 55 and above [59]. This demonstrates the importance of knowing both age and gender. A 2006 study by the Heart and Stroke Foundation of Ontario, the University of Ottawa Heart Institute and Statistics Canada found that persons of South Asian or African descent are three times more likely to be hypertensive than the general population. They are also prone to developing it at a younger age [60]. Hence, we selected age, gender and ethnicity as relevant demographic factors for the shared decision making between patient and healthcare provider. Although the patient already knows their demographics, it was essential that the healthcare provider be aware of the patient demographics (by viewing the patient profile) during the shared decision making.

The health markers entered in the patient profile were selected based on the Canadian clinical practice guideline [24] (CPG), which recommends several lifestyle modifications that can reduce hypertension. The three lifestyle choices presented within iheart (screen P4 in Appendix B): increasing exercise, reducing smoking and reducing sodium intake, are a subset from the Canadian hypertension CPG. Other information from the Heart and Stroke Foundation and Health Canada also contributed to iheart. For instance, Health Canada describes adult exercise in terms of light, moderate and vigorous effort [61]. Thus, the same established convention was used in the iheart intervention to collect exercise levels of patients. Based on evidence, Health Canada recommends that an adult Canadian should not exceed a maximum of 2,300 mg of sodium per day [62]. This is a relevant fact used within the decision logic of iheart. The evidence described informed the data collection for the patient profile and informed the choice architecture within iheart. Specifically, the default options for recommended lifestyle changes (shared decision 1) were based on the patient's profile.

Additional educational content was included within iheart. The information for CA anchor messages was based on Canadian public health content and guidelines. To ensure that system users were aware of the hypertension stages and recommended systolic blood pressure (SBP) and diastolic blood pressure (DBP) readings, the chart [63] in Appendix B (screen P11) was incorporated in the iheart design. The blood pressure chart educates the patient about their condition with the intent of increasing adherence to their desired lifestyle change.

3.2. Design Phase

The conceptual process flow (figure 3.1) and evidence-based content (Section 3.1.2) informed the iheart application design. The design phase produced three artefacts: an ontology knowledge model, decision logic and the logical system design. The logical system design included both an entity-relationship diagram and mock application screens. The design artefacts are described further in the next sections.

3.2.1. Ontology Model

The theory and shared decision making steps from the conceptual process diagram were represented in a single ontology knowledge model using Protégé 3.5. The ontology model shown in figure 3.2 contains the behavioural, choice and domain specific content. An ontology model was used for several reasons:

i) It integrated behavioural and decision theory in a single model.

ii) It created a semantic vocabulary for shared decision making and theory constructs.

iii) It allowed knowledge sharing between the designer and software developer.

iv) It separated the domain knowledge from the operational application deployment.

v) It produced a flexible, scalable and reusable model.

Knowledge representation as a computerized ontology using an ontology editor such as Protégé was instrumental in overcoming some of the research challenges (Section 1.3, ii and iii). Formally representing the knowledge related to shared decision making and theories made it easier to design and build the iheart application. The ontology model formed the bridge between the conceptualization (figure 3.1) and the subsequent design artefacts. The mock screens (Section 3.2.3) were easy to define once the formalized model existed including semantic vocabulary and content. Similarly, the entity-relationship model (Section 3.2.4) was a quick extension from the ontology model which included a fair amount of granularity. For instance, figure 3.2 shows that various behavioural models exist within the ontology. The I-Change model has a behaviour_state property that includes its three possible states.

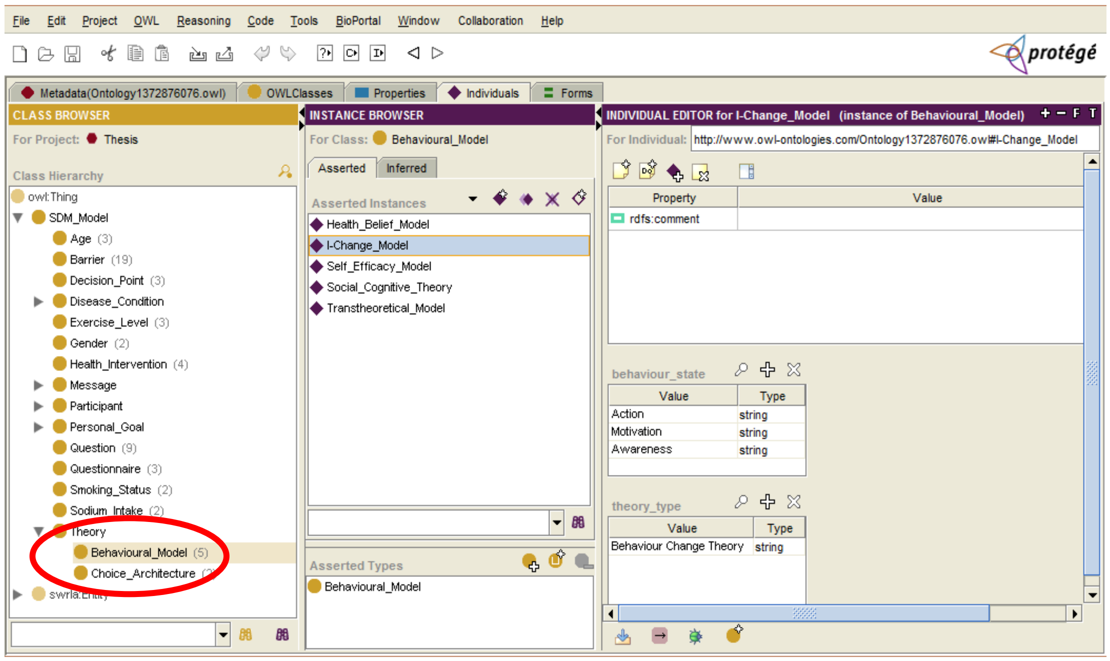

Figure 3.2 – Ontology Knowledge Model for Shared Decision Making

The ontology model was built to be flexible, accommodating any disease condition, the selection of different behaviour theories (red ellipse in figure 3.2) and choice architecture concepts; as well as scalable, to support multiple health care providers and patients (red ellipse in figure 3.3).

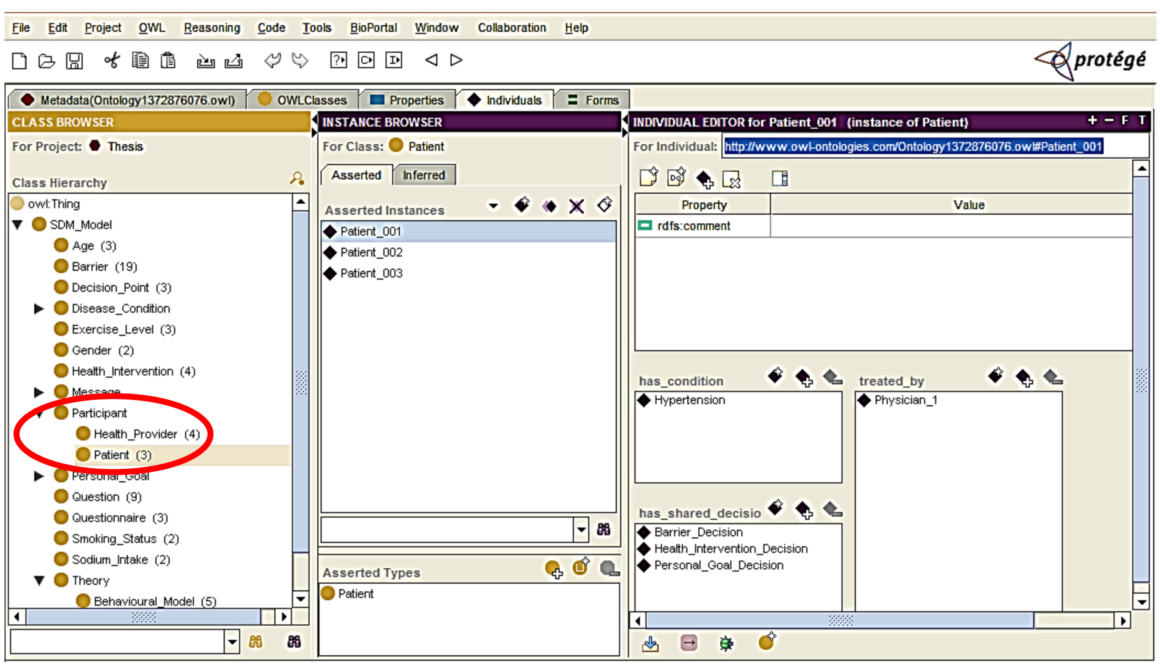

Figure 3.3 – Participant Flexibility within Ontology Model

This patient-centric model further contained the core constructs, relationships, content, messages and description logic that formed the foundation for the technical solution. The ontology model contained classes that were flexible and expansive. For instance, figure 3.4 shows the Disease_Condition class can be expanded to include any disease or condition that can be addressed using lifestyle modification through an online SDM intervention. The Cardiovascular disease subclass contained both Hypertension and Blood Cholesterol for demonstration purposes. The Diabetes subclass contained Type I Diabetes and Type II Diabetes. Similarly, the Participant class contained subclasses for patient and healthcare provider but this could be expanded to include the full continuum of care needed for the lifestyle modification (i.e. nutritionist, therapist, etc.). Shared decision making in healthcare can be a one-to-one or one-to-many relationship (one patient to many healthcare providers) and the iheart ontology model was designed to accommodate either configuration.

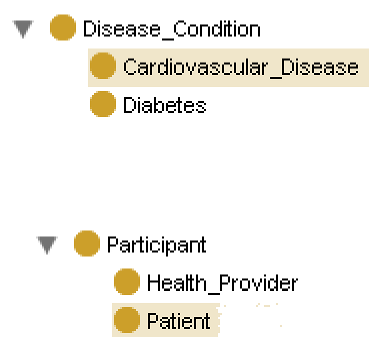

Figure 3.4 – Ontology Class Subset

Instances were created within subclasses to further define the contents or item set that belonged to the class. For example, the Decision_Point class contained three instances: Health_Intervention_Decision, Barrier_Decision and Personal_Goal_Decision. These instances represent the three shared decisions from the conceptual flow diagram in figure 3.1. Object and datatype properties were also used to further define the domain, range and values of properties. In figure 3.5, the datatype property "choice_methods" shows the different choice architecture techniques (see Allowed values drop down list) that can be used to build a specific CA toolset for combined use with a specific behavioural theory (i.e. I-Change theory) within an online health intervention.

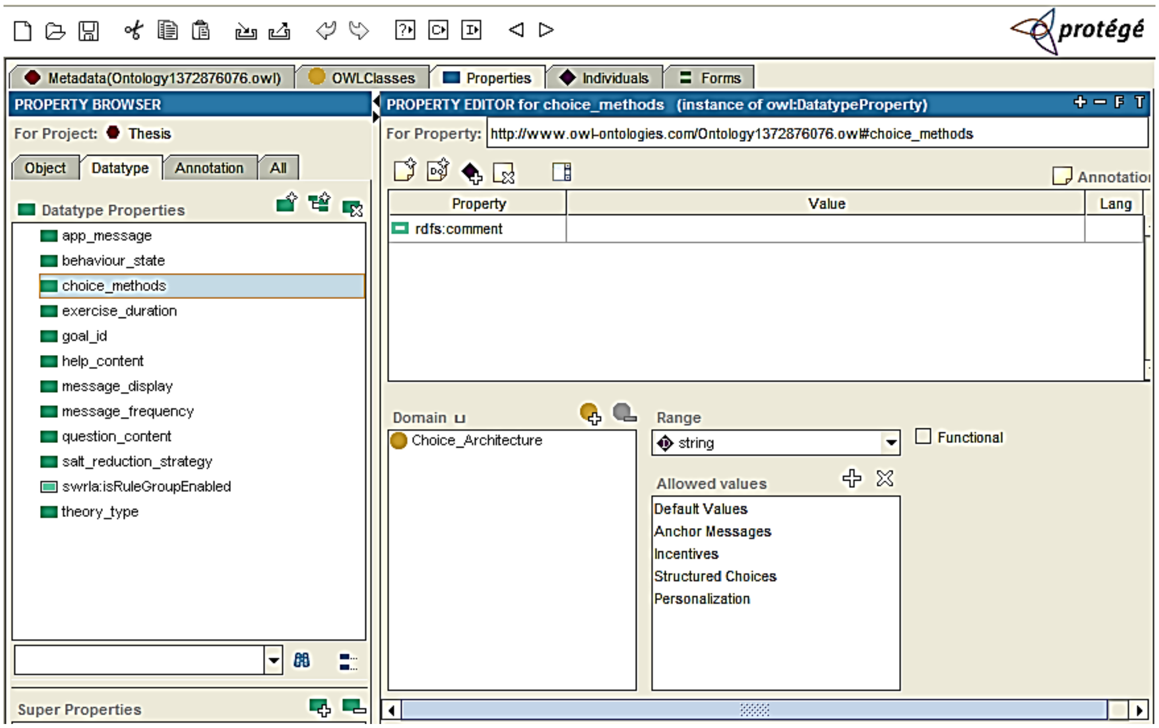

Figure 3.5 – Ontology Datatype Properties for choice methods

3.2.2. Decision Tables

The logic rules for the application, including the shared decision making logic, were documented externally in decision tables, along with domain specific messaging. The Semantic Web Rule Language (SWRL) was assessed as a means for storing and executing rules for shared decision making within iheart. Although SWRL is a common rules language used with ontologies, the iheart application integrated decision logic in only two areas (shared decision 1 and CA anchor messaging). Instead of using SWRL, a decision table was used to formalize the decision logic in order to increase the expressivity of the model that was subsequently incorporated within the application. The decision table for determining the recommended health choices (lifestyle changes) based on the patient's profile is shown in table 3.1. For example, if a patient had entered Exercise Level = Low, Smoking = Non-Smoker and Sodium Intake > 2300 mg/day, then smoking would not be a recommended lifestyle change and only increasing exercise and reducing sodium would appear in the list of suggested choices.

PROFILE PROMPT SELECTIONS			AVAILABLE CHOICES (Shown in Choice list)
EXERCISE LEVEL	**SMOKING STATUS**	**SODIUM INTAKE**	
Low	Smoker	≤ 2300 mg/day	Increase Exercise; Reduce Smoking
Low	Smoker	> 2300 mg/day	Increase Exercise; Reduce Smoking; Reduce Sodium
Low	Non-Smoker	≤ 2300 mg/day	Increase Exercise
Low	Non-Smoker	> 2300 mg/day	Increase Exercise; Reduce Sodium
Moderate	Smoker	≤ 2300 mg/day	Increase Exercise; Reduce Smoking
Moderate	Smoker	> 2300 mg/day	Increase Exercise; Reduce Smoking; Reduce Sodium
Moderate	Non-Smoker	≤ 2300 mg/day	Increase Exercise
Moderate	Non-Smoker	> 2300 mg/day	Increase Exercise; Reduce Sodium
Vigorous	Smoker	≤ 2300 mg/day	Reduce Smoking
Vigorous	Smoker	> 2300 mg/day	Reduce Smoking; Reduce Sodium
Vigorous	Non-Smoker	≤ 2300 mg/day	Should not be a candidate in the study – review profile
Vigorous	Non-Smoker	> 2300 mg/day	Reduce Sodium

Table 3.1 – Decision Table for Health Intervention Choice

Simple decision logic was also used to inform the CA Anchor messaging based on the patient's behavioural state. The messages are shown in table 3.2 and the decision logic determined the number of messages displayed (reinforcement). An example of the anchor messages being shown in the application is presented in screen P6 of Appendix B for an individual in the motivation state.

HEALTH CHOICE	MESSAGE ID	MESSAGE
Exercise	MSG_ EX1	30 minutes of exercise each day (walking) can lower your blood pressure.
	MSG_ EX2	Regular exercise can reduce blood pressure and prevent diseases.
	MSG_ EX3	After 3 months of regular exercise, you may have better health, strength and a more positive outlook on life.
Sodium	MSG_ NA1	Too much salt (> 2300 mg/day) in your diet can lead to high blood pressure.
	MSG_ NA2	Most people eat too much salt and are at risk of developing high blood

HEALTH CHOICE	MESSAGE ID	MESSAGE
		pressure and other diseases.
	MSG_ NA3	High blood pressure can increase your risk of developing heart disease and stroke.
Smoking	MSG_ SM1	Smoking or being around smokers can increase your risk of developing heart disease and stroke.
	MSG_ SM2	If you quit smoking, your risk of dying from smoking-related heart disease is cut in half.
	MSG_ SM3	If you quit smoking, your risk of dying from lung cancer is cut in half.

Table 3.2 – Anchor Messages

A person in the awareness state was shown all three anchor messages. A person in the motivation state was shown the first two messages. A person that was already in the action state was shown only the first message. Essentially, the farther the person was from the action state, the more messages they received. The following decision logic regulated the level of reinforcement through incremental messaging.

IF behaviour_state = AWARENESS OR

behaviour_state NOT IN (AWARENESS, MOTIVATION, ACTION)

THEN display all 3 messages for the HEALTH_CHOICE selected

IF behaviour_state = MOTIVATION

THEN display first 2 messages for the HEALTH_CHOICE selected

IF behaviour_state = ACTION

THEN display first message for the HEALTH_CHOICE selected

3.2.3. Mock Screens

We devised mock screens based on the ontology model and decision logic. The mock screens and ontology model served as a communication tool between the designer and software expert for refining the iheart intervention. Having a documented expression of the iheart application's physical presentation and functions introduced "usability" in a tangible manner. Using mock screens, the designer was able to abstract and assess whether a patient could reasonably use iheart for its designated purpose of reducing hypertension through shared decision making. The mock screens laid out the progression and number of screens to be presented. Overburdening patients with data entry and questionnaires was a concern to the designer. Care was taken to keep data entry and questions clear, succinct and necessary. The sample mock screen for shared decision 1 is shown in figure 3.6. Shared decision screens were denoted with the "handshake" symbol with notes on where behavioural theory or choice architecture was used and additional notes for the software developer to establish decision logic or embed special features (i.e., shared decision making chat session).

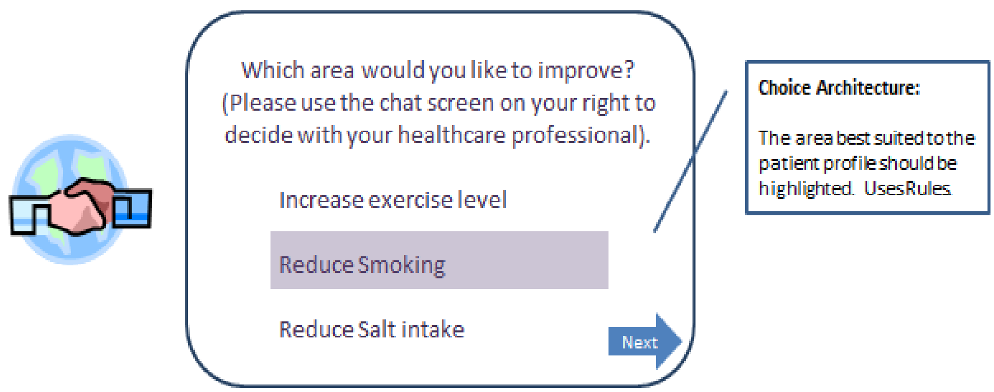

Figure 3.6 – Sample Mock Screen for Shared Decision 1

The mock screens represented a first-cut at the presentation layer in paper form. It defined the web application's look and feel, desired level of user-friendliness, navigation, messaging, data entry and content. As an example, the mock screens for capturing the patient's health markers (part of their profile) is shown in figure 3.7. It confirmed the order of data entry and the designer's expectations for the presentation layer. For instance, the questionnaire to determine the patient's I-Change behavioural status was moved during the mock screen process to appear after the selection of the health choice (shared decision 1). The questionnaire is dependent on the specific lifestyle behaviour change and asks questions such as "Do you think you are putting your health at risk with your current level of **exercise**?" It allowed the designer to see that the I-Change questionnaire is choice specific and not generic, thus logically must follow shared decision 1.

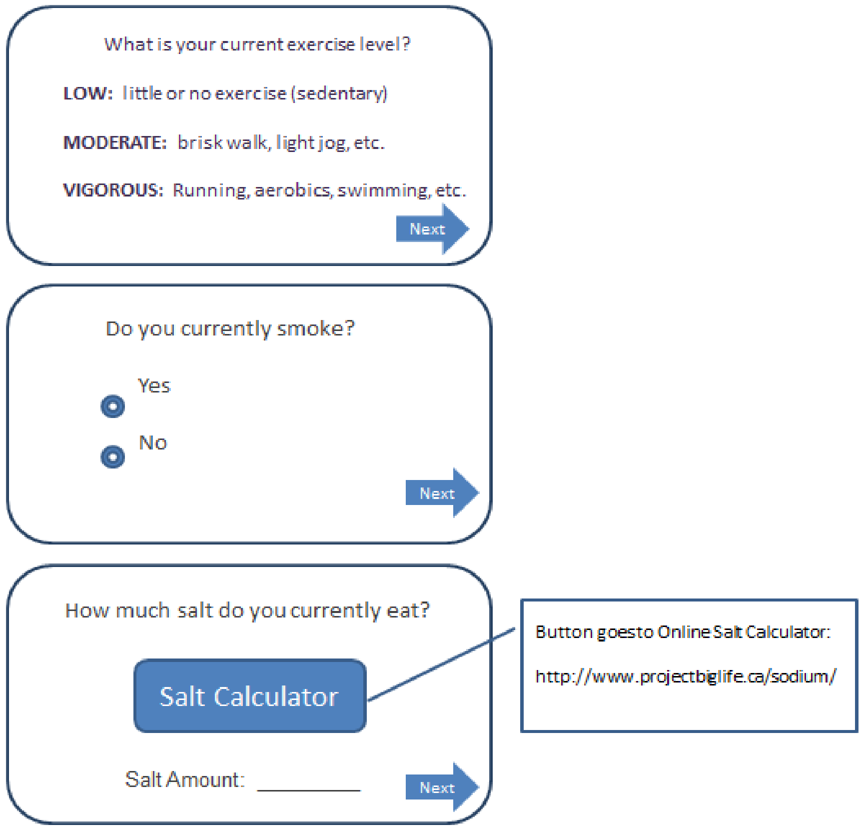

Figure 3.7 – Mock Screen Design for Capturing Health Markers

3.2.4. Entity-Relationship Model

An entity-relationship model (ER model) defined the underlying data and information for the application. The ER model was forward engineered using the ontology model and mock screens. The MySQL Workbench was used to create, maintain and manage the ER model. The ER model is an abstract representation that is translated into a relational database. It was used by the software developer to create the logical and physical database. It shows the entities, data elements, primary keys, indexes, relationships between entities and their cardinality. During the test phase

(Section 3.5), the data model was adjusted to reflect requested changes if they impacted the database. An excerpt of the ER model is shown in figure 3.8.

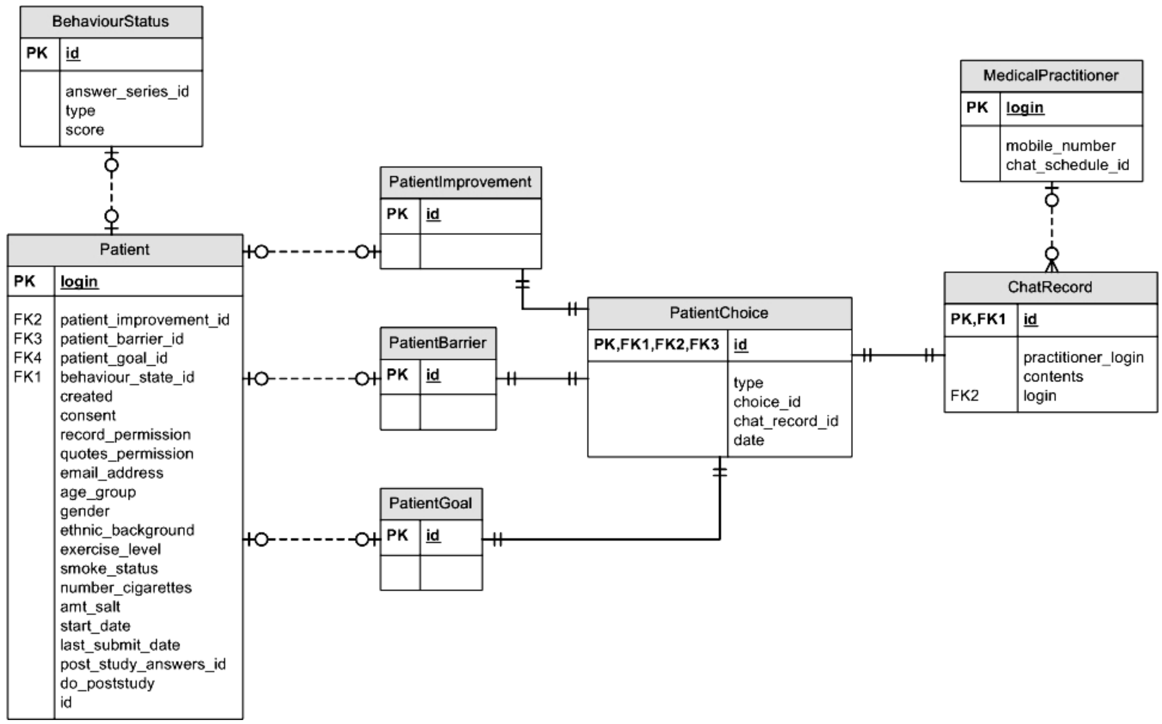

Figure 3.8 – Excerpt of ER Model

Two areas of the research are demonstrated in the ER model excerpt. First, we see that each patient has a behaviour state (tables on far left). The “answer_series_id” field in the Behaviour Status table represents a link to a set of answer tables (not shown in the ER model excerpt). The ”type” field tracks the form of behaviour change being made such as exercise, smoking or salt intake. The “score” field stores the total score from the behavioural questionnaire. The total score determines which behaviour state: awareness, motivation or action the person is currently demonstrating towards the behaviour change (type of lifestyle change) they desire. Each patient will also make choices (three shared decisions) represented by the Patient Improvement, Patient Barrier and Patient Goal tables. These three tables relate back to the “Decision Point” class in the ontology model (figure 3.2) which relates back to the three shared decisions in the conceptual process flow (figure 3.1). Each aspect of the ontology was similarly modeled to create the underlying database for the iheart application.

3.3. Application Development

All of the artefacts from the design phase were used to communicate the iheart requirements to the software developer. The ontology model, mock screens and ER Model informed the build of the physical application including its logic, features, content and presentation layer. The decision tables were incorporated in the actual physical solution (described in Section 3.4, System Architecture). Several iterations of testing (described in Section 3.5, Application Testing) refined the application.

3.3.1. Presentation Layer

The actual presentation of the iheart application is shown in the sample screen in figure 3.9. This screen shows shared decision 1 on the left. The “suggested areas” for lifestyle modification are based on the health markers entered by the patient and the decision table logic in table 3.1. The patient can override the suggested choices and choose one that appears in the “other areas” list. These were low priority choices based on the decision table logic. The large box on the right side of the screen shows the chat box for patient and provider to engage in making shared decision 1. The information message (blue circle with an “i” on the left side) instructs the patient to chat with their healthcare provider to engage in a shared decision. Once the patient has completed a chat with their provider and reached a conclusion on the best decision, they would select their lifestyle modification choice (behaviour change to complete shared decision 1).

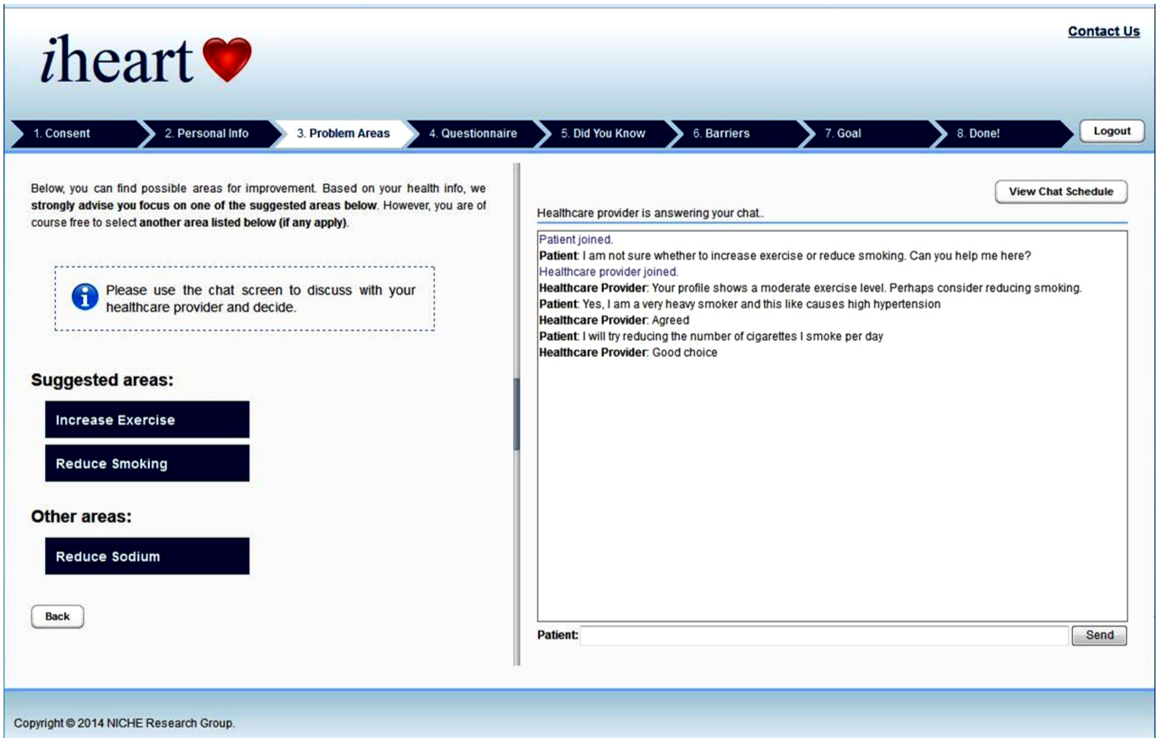

Figure 3.9 – Sample Application Screen

The iheart application also incorporated a variety of features to ensure it was user-friendly. The patient view included a series of tabs across the top menu bar showing the navigation path (progressive steps to take) and the user's current step (highlighted in white) within the application. The steps are listed in table 3.3, and aside from step 1 (study consent); the steps were informed by the conceptual process flow in figure 3.1 and ontology model in figure 3.2.

No.	Menu Item (Step)	Purpose	Screen Reference (Appendix B)
1	Consent	Display study details and acquire participant consent	P1
2	Personal Info	Capture patient demographics and health markers	P2
3	Problem Areas	**Shared Decision 1:** Suggest areas for improvement and discuss using patient-provider chat session	P4
4	Questionnaire	I-Change behavioural questionnaire (scored by the	P5

No.	Menu Item (Step)	Purpose	Screen Reference (Appendix B)
		application logic and informs choice architecture)	
5	Did You Know	CA anchor messages displayed	P6
6	Barriers	**Shared Decision 2:** Discuss and select main barrier to change using patient-provider chat session	P7
7	Goal	**Shared Decision 3:** Set goal for behaviour change selected in step 3 using patient-provider chat session	P8
8	Done! Enter Progress	Enter daily progress (blood pressure measurements)	P9
9	Done! Post-Study Questionnaire	Complete post-study questionnaire to assess iheart	P12

Table 3.3 – Menu Navigation

The application had three views based on the end-user's role. The roles included an administrative role, healthcare provider role and patient role. The administrative role could create, view and manage new end-user accounts (i.e. create patient and practitioner login accounts) using a single screen. The health provider role could view the patient profiles and engage in chat sessions using two separate screens. The patient role completed the steps shown in table 3.3 and information entered in the 12 patient screens shown in Appendix B.

Behavioural theory is incorporated in screens P5 and P7. Screen P5 determines the I-Change behaviour state of the patient using the questionnaire shown in Appendix B. The application scored the responses to determine if the patient was in the awareness, motivation or action state. The behaviour state identified would then inform the choice architecture (i.e. anchor messages to display). The anchor messages set the patient's expectations for the behaviour change (so they are not too low or too high). For instance screen P6 in Appendix B shows that for increasing exercise, a message frames the expectations to be in the vicinity of 30 minutes of exercise. Doing less (i.e. 10 min per day) would have little impact on reducing hypertension. Similarly, doing too much (i.e. > 60 min per day) could lead to burnout or other health concerns. The number of anchor messages was also relevant. It served to move the patient from a lesser behavioural state towards the action state using the decision logic described in Section 3.2.2.

Another aspect of the I-Change behavioural model was incorporated in screen P7. The I-Change model in figure 2.1 shows that before reaching the action state, it is important to overcome the barriers to change. Furthermore, psychological research shows that overcoming barriers is essential for altering lifestyles successfully [41, 57]. Through a shared decision in screen P7, the patient contemplates their barriers to change and identifies the main one for a chat discussion with their healthcare provider. Help content was embedded in the iheart application to assist here. By hovering the mouse over the barrier list on screen P7, a more detailed explanation was provided for each individual item. Similar help content is available in other areas of the application such as screen P4. Further explanation is given to assist the patient to understand the meaning of each health intervention choice.

Choice architecture components are found on the following screens: P4, P6, P9 and P10. Screen P3 uses the CA concept of presenting default options and pre-ordering the options based on the patient's profile. This was done using the decision table in table 3.1 and presenting the higher priority areas for improvement under "suggested areas" and the lesser areas under "other areas". For example, if a patient had entered a low exercise level, non-smoker and sodium less than 2300 mg/day, then the "suggested areas" on screen P4 would show "Increase Exercise" and the "other areas" would show "reduce sodium". Reducing smoking would not be shown as it is not a viable option for a non-smoker. In Screen P5, the CA concept of anchor messages was used. The CA concepts of message repetition, motivational messages and incentives are used in screen P9. Each day the patient received a new motivational message on the progress screen where they entered their blood pressure measurements. They would also receive a heart (incentive) in the status bar across the top of the screen for each day they entered their progress. This encourages long term adherence through a visual incentive. Screen P10 also used feedback to motivate the patient towards long term behaviour change adherence. This was accomplished using graphs of the patient's blood pressure measurements and health change progress (i.e. increasing exercise).

The provider role had two screen views: Patient Chats and Patient Overview shown in figure 3.10 and 3.11 respectively. The provider could easily toggle between these two views using the buttons in the top left corner underneath the main iheart logo.

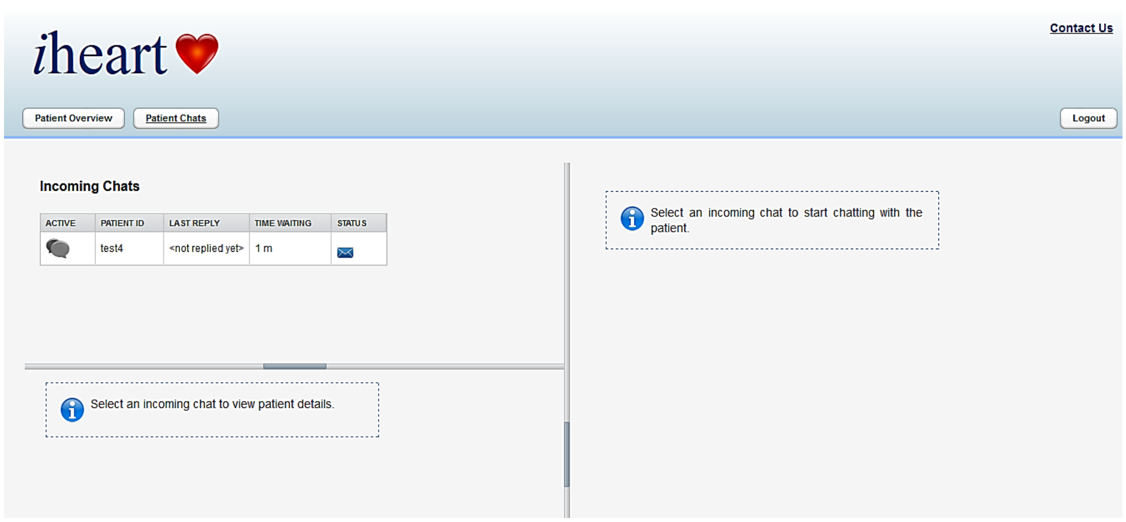

Figure 3.10 – Patient Chat Screen within Provider Role

The Patient Chat view presented a list of all the incoming chats from patients. In this study, the patient-provider interactions were one-to-one. However, the application is designed such that multiple patients and multiple providers could be using the application at any given point in time and engaging in multiple chats. Thus, if a provider logged into the application, it is possible that they would see several incoming chats from their various patients. They could respond to each chat by highlighting the patient (the chat box would then appear on the right hand side of the screen in figure 3.10). This makes it simple to respond and juggle incoming chats from multiple patients very quickly. The status symbol (envelope) in the Incoming Chat table on the screen would flash with a green plus sign whenever a patient sends a new chat message in their session. This way, the provider can tell which chat sessions are idle and which are actively awaiting a response. Patients know when their provider is available for chatting by looking up the provider's chat schedule on screen P4, P7 and P8. All of the shared decision making screens have a "View Chat Schedule" button above the chat box. This displays the provider's availability for chats in a pop-up window. For example, a healthcare provider may choose to block one hour a day for patient chats between 3:00 – 4:00 pm. This would be reflected in their availability schedule in iheart.

The Patient Overview shown in figure 3.11 provides a quick summary of the patient's profile. By highlighting a patient on the left side, their profile would appear on the right side. This showed their demographics, health markers for exercise, smoking and salt intake. It also showed the shared decisions they had completed (and which ones might still be outstanding) and the progress they had entered to date.

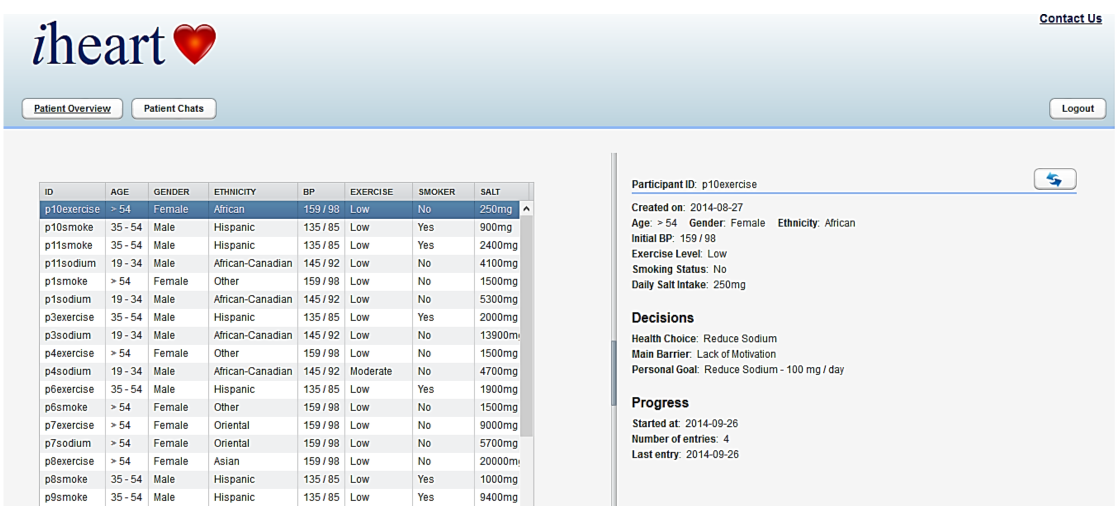

Figure 3.11 – Patient Overview within Provider Role

3.3.2. Outsourced Components

The iheart solution was conceived and designed by the author of this research thesis including creation of the conceptual process flow (figure 3.1), knowledge model (figure 3.2), decision tables (i.e., table 3.1), content and messaging (i.e., table 3.2) and mock screens (i.e., figure 3.7). These artefacts were essential to the development of the online tool which was programmed by a member of the NICHE Research Group. The entity-relationship model (figure 3.8) was a joint collaboration between the author and application developer.

Two other components of the iheart application were outsourced to ensure valid domain expertise was incorporated in the research solution. First, the I-Change behavioural questionnaire along with its scoring mechanism was devised by an expert in Industrial-Organizational Psychology from St. Mary's University in Halifax, Canada. Second, the salt calculator was an existing product devised by the Ottawa Hospital Research Institute and Dr. Douglas Manuel. A formal agreement was signed between the author of this research thesis and the creators of the salt calculator for its authorized use within the iheart application.

The I-Change behavioural questionnaire is a concise set of questions. The questionnaire for the behaviour change of increasing exercise is shown in screen P5 of Appendix B. All questions had a dichotomous answer (Yes / No) where a "yes" response would be given a value of one and a "no" response a value of zero. The total score determined the appropriate behaviour state using the scale below:

- **No awareness:** Score 0
- **Awareness:** Score 1
- **Motivation:** Score 2
- **Action: Score** 3

The questionnaires and questions were presented during a focus group to seven other psychology peers for review and adjustment. There were three questionnaires (one for each behaviour change type: increase exercise, reduce smoking, reduce salt intake). Each behavioural questionnaire had three questions to score. Thus, a total of nine unique questions supported the three questionnaires. The final draft of each questionnaire was incorporated in the system design, namely ontology model and informed the application development. The behavioural change questionnaires were modeled using two ontology classes: Questionnaire (3 instances) and Question (9 instances). An object_type property "has_question" linked each Questionnaire to its behaviour-specific questions. The example shown in figure 3.12 demonstrates that Questionnaire_1 has questions (Question_1, Question_2, and Question_3). Questionnaire_1 pertained to increasing exercise and its associated questions were:

1. Do you think you are putting your health at risk with your current level of exercise? [Y|N]
2. Do you intend to increase your amount of exercise over the next month? [Y|N]
3. Have you made a specific plan to increase your amount of exercise over the next month? [Y|N]

The questionnaires and associated questions in the ontology model informed the development and content presented in screen P5.

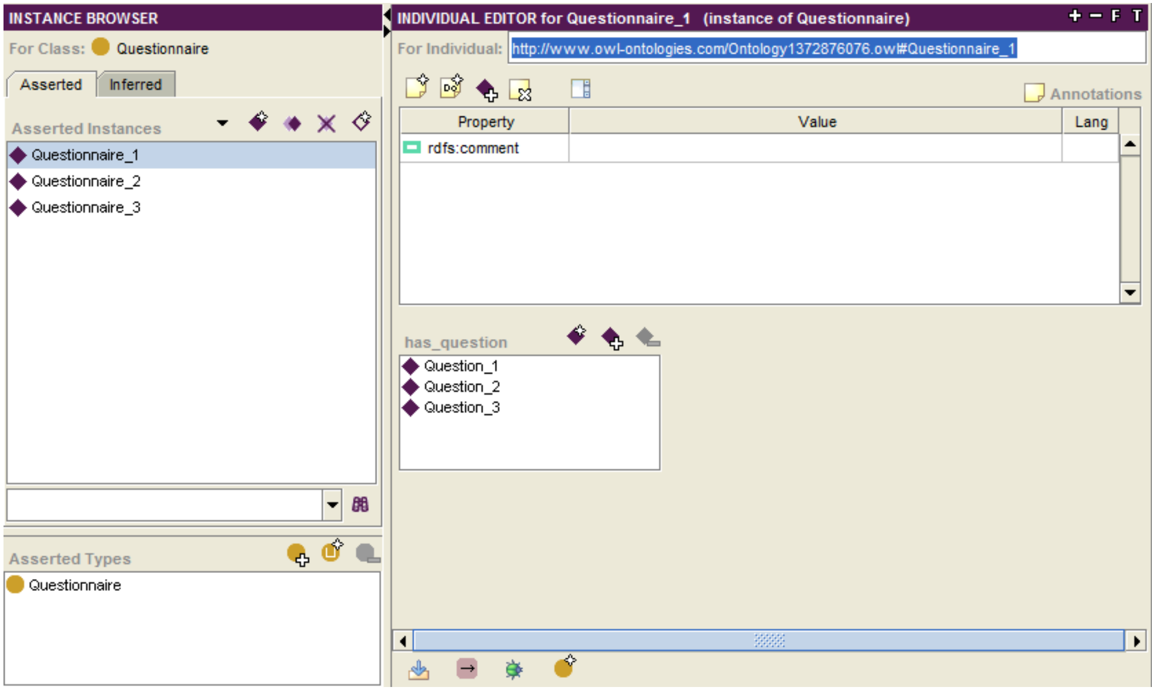

Figure 3.12 – Instances for Questionnaire Class within Ontology Model

The other main external component embedded within the iheart application is the salt calculator. The BigLife Sodium Calculator [64] was selected to assist patients in determining their daily salt consumption. This is a freely available online salt calculator that required a mandatory input value, age, and asked twenty-three questions about dietary sodium intake. After answering the required questions, pressing the "calculation" button returned the person's daily sodium consumption in milligrams per day. An excerpt of the BigLife Sodium Calculator embedded within the iheart application is shown in screen P3 of Appendix B. The salt calculator could be invoked in two ways. On first entry to screen P2, the patient was prompted to answer "How much salt do you currently eat?" The question could only be answered by pressing the "calculate my salt intake" button next to the question. Once their salt intake was calculated using the embedded sodium calculator, the value in mg per day populated the salt intake field. The "calculate my salt intake" button then moved below the previously calculated value in case the patient wanted to re-calculate their sodium intake during the process.

The BigLife Sodium Calculator was selected for personalized salt calculation within iheart since it is a Canadian tool that incorporates current Canadian guidelines for sodium intake. It is also a validated tool endorsed by public health agencies such as the Ontario Stroke Network [65], Kidney Foundation of Canada [66] and the Middlesex-London Health Unit [67]. The BigLife Sodium Calculator was launched in March 2013 and as of May 31, 2013 a total of 39,598 salt calculations had been performed by 31,315 unique individuals using the online tool [68]. The salt calculator is comprised of 23 questions: 3 on restaurant foods, 19 on packaged foods and 1 on added salt. The embedded BigLife Sodium Calculator and full question set are shown in Appendix C. The service agreement for the BigLife Sodium Calculator is referenced in Appendix F.

3.4. System Architecture

The iheart application was an open-source solution. It consisted of a web-based interface storing information on a centralized server within a secure relational database. The full system architecture for iheart is shown in Figure 3.13. The Vaadin open source web application framework [69] was used to produce a rich internet application accessible on PCs and mobile devices. Vaadin was used to create the three main screens for the patient, healthcare provider and system administrator. Vaadin contains a plug-in for chat sessions that enabled online shared decision making in real time. The chat feature was formerly shown on the right-hand side of figure 3.9. The iheart data was physically stored in a MySQL database [70] on a secure server. Eclipselink [71] was used to automatically persist application objects in the database, and implements the Java Persistence API (JSR 317) [72]. The Drools business rule management system [73] implements the Java Rules Engine API (JSR 94) [74], and was used for implementing the decision logic based on the decision tables in Section 3.2.2. These tables contributed to both the shared decision making and choice architecture messaging. The data loaders were custom scripts created by the application developer to load the various .csv data files. The data summarizers were queries created to extract data from the MySQL database for analysis. For instance, the post-study questionnaire and the chat summaries were reviewed in detail during the study evaluation. Finally, the Big Life Sodium Calculator was made accessible from within iheart, and estimated the participant's daily sodium consumption. The system architecture worked seamlessly behind the scenes while the patient was only aware of the presentation layer (front-end screens).

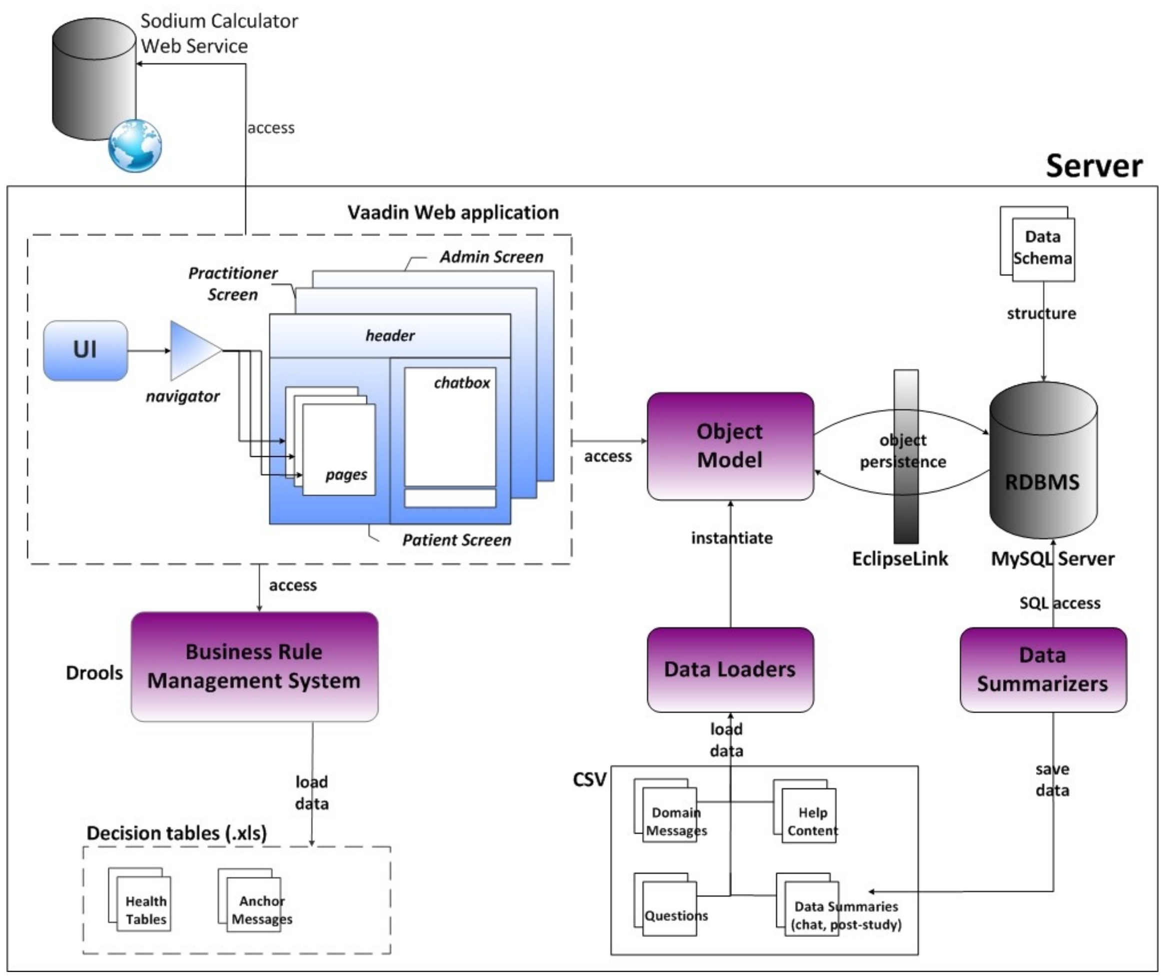

Figure 3.13 – iheart Application Architecture

While establishing the system architecture, two different reasoning methods were considered. Both SWRL rules within an ontology model and the Drools Business Management System were compared as a means for processing the application rules. SWRL rules are defined within an ontology model and executed using a reasoner. Both methods have pros and cons that should be weighed for the specific application. The two reasoning methods were scientifically compared in a research study using a telecardiology decision support system [75]. Ontology-based reasoning is simpler to implement and maintain since the rule components are managed in the ontology model and not hard-coded within the rules. Reasoning based on Drools provides greater expressiveness [75] and is easier to adopt in a business setting. The researchers concluded that Drools and Ontology/SWRL reasoning are both valid approaches with comparable performances. Another study based on five years of industrial research presented valid challenges in adopting ontologies in the enterprise. SWRL is an ontology based solution and presented pragmatic deterrents. The main barriers were modeling costs, training of employees, difficulties integrating ontologies in the enterprise technology stack and inability for ontologies to transport tested changes from the test environment to the production environment [76] which is the typical configuration used in enterprises. After weighing both rule methods, Drools was selected to implement the decision logic for the iheart application. Defining rules in Drools was less cryptic and easier to use than SWRL, not to mention it better positioned the application for enterprise use. Further, the decision tables stored in spreadsheet format were easily loaded and used by Drools.

3.5. Application Testing

Shared decision making performed through an online chat system represents a novel approach to healthcare. Thus, several rounds of testing were applied to objectively prepare the system for evaluation. First, two medical doctors and two hypertensive patients critically reviewed the first-cut of the iheart prototype. Patient engagement in research, including its planning and execution, can potentially lead to improvement in the credibility of results [77]. Adjustments followed in response to this initial, informal feedback. The formal application testing involved both white box and black box testing. An inward look at the application (white box) focused on unit and integration testing of internal components such as the chat feature. An outward look at the application (black box) tested its external and user facing features. For example, the black box portion validated the seamless use of the Big Life Sodium Calculator web service within iheart. The testing template is provided in Appendix D. During both types of testing, modifications were made in iterations followed by regression testing of the application to ensure its readiness for the ensuing assessment study.

3.6. Application Assessment

The assessment of iheart was completed through a pilot study approved by the research ethics board of Dalhousie University, Canada (REB# 2014-3219). Pilot studies are a necessary first step in exploring novel interventions and novel applications of interventions – whether in a new patient population or with a novel delivery system (Leon, Davis and Kraemer, 2011) [78]. The use of behavioural and decision theory within a technology intervention that promotes shared decision making is certainly a novel approach to healthcare. As such, a pilot study to assess the technical feasibility and usability of iheart was an appropriate first step in its lifecycle. A summary of the study design is presented in table 3.4.

STUDY DESIGN	
Study Type	Technical Feasibility and Usability pilot study
Target Population	Hypertensive persons: • blood pressure above 140/90 mmHg for non-diabetic • blood pressure above 130/80 mmHg for diabetic
Sample Size	Target recruitment of 8-10 participants
Materials Used	Two devices (laptop and iPad); wireless internet
Methods	Each participant completes two goal-based scenarios within a 2 hour study session. Participants are asked to think out loud with their feedback while being audio and video recorded with screen capture.
Evaluation	Mixed methods - both quantitative & qualitative data analyzed

Table 3.4 – Study Design Summary

3.6.2. Study Sample

The sample size for a pilot study is based on the pragmatics of recruitment and the necessities for examining feasibility. According to Vizri, only 4 to 5 subjects are needed to identify 80% of the usability problems with a system [79]. The iheart study recruited 9 hypertensive participants from the local area for this purpose, approximately twice the recommended number. The study population was adults with hypertension living in Halifax capable of using a computer. According to Hypertension Canada and the Public Health Agency of Canada, hypertension refers to blood pressure above 140/90 mmHg for non-diabetic persons and 130/80 mmHg for diabetics, with measurements taken in a clinical setting [80, 81]. Participants self-identified they were hypertensive. Participants wishing to participate in the study but unclear about being hypertensive were given the option of taking a blood pressure measurement. An Omron 7-series home blood pressure monitoring system for the upper arm was used to confirm if the participant met the study inclusion criteria. Participants had to voluntarily agree to have their blood pressure measured when unclear about their hypertension status. A person with blood pressure of 135/85 mmHg or higher is considered to have hypertension when measured with a home monitoring system [80].

Persons under treatment for high blood pressure (i.e. using antihypertensive medications) or those on an existing exercise, smoking cessation or salt reduction plan were still able to participate in the study. The study used goal-based scenarios in which the participant entered hypothetical data. Thus, the study posed no health risk to participants during the 2 hour usability assessment of iheart. Recruitment occurred by circulating a recruitment notice electronically and manually posting within the Dalhousie medical faculty, local hospital, primary care offices and other local facilities and public venues within the Halifax-Regional-Municipality (HRM) (i.e., recreational/sports facilities, churches, drugstore/clinic bulletin boards, etc.) and through the use of social networking (i.e., facebook).

The recruitment notices posted in a variety of different locations and venues attracted a random group of individuals that met the inclusion criteria for the evaluation study. The research ethics board did not approve solicitation of personal identifiers (i.e. age) from potential recruits. Hence, the researcher made a best-guess at the individuals' identifiers to ensure randomness and eliminate the possibility of any confounding factors impacting the evaluation. Four people were recruited that appeared to match the [19-34] age group, three people in the [35-54] age group and two people in the [> 54] age group. Of these people, three were females and six were males. The visually perceived ethnicities of the sample were: three Caucasians, three Asians, two persons of Middle Eastern descent and one Oriental. Thus a random group of HRM residents interested in hypertension reduction were recruited consisting of varying age groups, genders and ethnicities.

Scenario-based, usability testing is an important methodology that characterizes how human-software interaction contributes to success or failure in clinical system implementations [82]. Three goal-based scenarios were devised to assess the technical feasibility and usability of iheart. The Canadian clinical practice guideline for hypertension [24] was the evidence-based framework used to guide development of the goal-based scenarios. The scenarios were validated by a medical doctor with an interest in lifestyle medicine and appropriate adjustments made collaboratively. For example, the medical doctor pointed out for scenario B in Appendix E, the cut-off for managing hypertension in diabetics is less than 140/80 mm HG for diabetics and less than 130/80 mm HG for diabetics with complications as opposed to 140/90 mm HG for the general population. The medical doctor was given a copy of the Canadian hypertension CPG and American Medical Association's (AMA) description of shared decision making tools [83] as reference for critiquing and improving the goal-based scenarios. AMA endorses that "formal shared decision-making tools are intended to help increase patient engagement in medical decisions when there are several clinically appropriate options from which to choose." [83] This definition provided the medical doctor and researcher with a common understanding of SDM within a technology intervention when designing the goal-based scenarios.

The cases provide the study participants with information to enter data and make shared decisions representing actual use of the system. The three scenarios ensure that all features of iheart are assessed for completeness. Each scenario presents decisional conflict for the participant. For instance, in shared decision 1 (selecting the health improvement), multiple lifestyle changes could benefit the participant's health. In each scenario, at least two potential lifestyle changes could apply from the three health improvement choices: 1) increasing exercise 2) decreasing smoking and 3) decreasing sodium intake. The sample goal-based scenarios are provided in Appendix E.

Each participant completed two of the three scenarios during a 2 hour period in order to sufficiently assess and rate the iheart application. Thirty minutes of the study session was used for administrative tasks such as study consent and authorization, training and question and answers. Each scenario was used six times by the pool of nine participants. This ensured uniformity and consistency in the assessment of the application. The patient and the researcher representing the provider were in separate rooms during the study to simulate a geographic disconnection during patient-provider chats (i.e., simulating patient is at home and provider is in their clinical office).

3.6.3. Data Collection

A single online data collection method was used during the study. The iheart application collected study consent, demographic information, health improvement choice, behavioural states, main barrier to change, personal goal, health measurements and post-study questionnaire responses through a single online interface. The study captured both quantitative and qualitative data for analyses.

The **quantitative data** was collected using a post-study questionnaire that solicited the participant's assessment scores using a 5-point Likert scale. The data was stored in the MySQL database shown in figure 3.13. The questionnaire contained sections on the usability, content, choice architecture, shared decision making and overall functionality of iheart. Input screen P12 in Appendix B shows a sample section of the post-study questionnaire.

The study captured **qualitative data** primarily using the "think aloud protocol" [20]. This protocol captures participant feedback spoken out loud while using iheart to achieve the goal-based scenarios. The software, Active Presenter [84] captured the participant's audio and video feedback including screen captures. Participants also responded to three open ended questions in the post-study questionnaire which was included in the qualitative data capture.

CHAPTER 4: EVALUATION

The study captured both quantitative and qualitative data to objectively evaluate the iheart application. Using mixed methods produced rich information for comparative analysis. The quantitative data gave a general perception of the iheart application's technical feasibility and usability. The qualitative data allowed deeper investigation into areas for improvement of iheart. A combined analysis affirmed if the datasets produced consistent results, especially in terms of usability.

4.1. Quantitative Analysis

A post-study questionnaire solicited the participant's assessment scores using a 5-point Likert scale, combined with open ended questions for capturing experience and thus allowing qualitative analyses (see next section). The questionnaire contained sections on the usability, content, choice architecture, shared decision making and overall functionality of iheart. Following is the Likert Scale used: 1=Strongly Agree, 2=Moderately Agree, 3=Neither Agree nor Disagree, 4=Moderately Disagree and 5=Strongly Disagree. A score of 1 or 2 favoured iheart whereas scores of 4 or 5 indicated discontentment.

The questionnaire contained forty-one Likert scale questions. Statistical software calculated the mean, median and mode scores within each section of the post-study survey (table 4.1). Further analysis transpired at the individual participant level (table 4.2).

Section	Mean	Median	Mode	Cronbach's Alpha
Usability	2.07	1.5	1	0.97
Content	2.35	2.0	1	0.94
Choice	1.98	1.0	1	0.85

Section	Mean	Median	Mode	Cronbach's Alpha
SDM	2.09	1.0	1	0.95
Overall	2.13	1.0	1	0.97

Table 4.1 – Section Level Data

The within survey sections in table 4.1 showed participant satisfaction across the board demonstrated by a mean overall satisfaction score of 2.13. Cronbach's alpha validated response consistency within the survey sections giving both section level and overall scores credibility. Acceptable values of Cronbach's alpha are reported to be 0.75 to 0.95 [85]. A value of Cronbach's alpha that is too high indicates there was redundancy in some of the questions [85].

Participant	Mean	Median	Mode
p1	1.44	1.0	1
p2	1.34	1.0	1
p3	1.80	1.9	1
p4	1.05	1.0	1
p5	1.61	1.0	1
p6	3.49	4.0	4
p7	4.24	4.0	5
p8	2.95	3.0	2
p9	1.24	1.0	1

Table 4.2 – Participant Level Data

The participant level results in table 4.2 demonstrated that six participants (two-thirds) favoured the iheart application while participant 8 appeared neutral, participant 6 leaned towards dissatisfaction and participant 7 was dissatisfied. This quantitative data, when collated with the qualitative information, identified specific areas of dissatisfaction and determined appropriate improvements to iheart.

The chat sessions also provided rich feedback for the study. The average number of chat exchanges was nine across all participants for accomplishing the three shared decisions. There was certainly variability in the number of chat exchanges, ranging from a low of 3 to a high of 17. Note that there were nine participants in the study that completed two goal-based scenarios each, thus producing a total of 18 sessions. However, two participants lost their internet connection during the study sessions and as a result; their chat data was not stored in the database. Therefore, only 16 sessions could be reported upon.

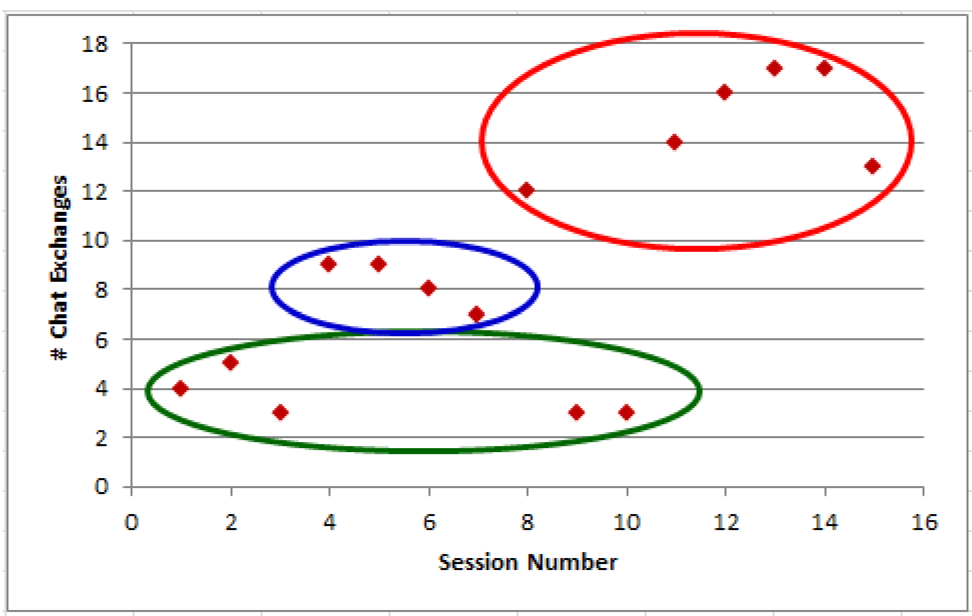

Figure 4.1 – Scatter Plot of Chat Exchanges

Analysis of the scatter plot in figure 4.1 shows three distinct groupings. Group 1 (green ellipse) shows participants made their shared decisions with only a few, succinct chat exchanges. Group 2 (blue ellipse) shows participants that needed between 6-10 chat exchanges. Group 3 (red ellipse) shows participants that required a larger number of chat exchanges to achieve the three shared decisions. Examining the chat dialogues shows that Group 3 is more verbose and "chatty" in nature. A sample chat dialogue for participant p4 is provided in figure 4.2 below. The participant chat exchanges are shown in blue text and the healthcare provider chat exchanges are shown in red text.

Patient Login	Shared Decision	Selection	Chat Dialogue
p4	Intervention	Reduce Sodium	My sodium level is 4,700 mg, what should I do to reduce it? That's very high. I would start off by cutting out a few salty snacks each day So, I should eat less chips and fries, and that would reduce my sodium? Yes, that is a very good way to do it. Thank you. I'll choose reduce sodium. Great How much salt per day should I have? The recommended amount is no more than 2300 mg per day Wow, that is a lot less than I eat now. I don't think I can reduce my salt by half. No, but cut it gradually. Perhaps try reducing 200 mg per day for a week Ok, I can try that. Thank you. Great
	Barrier	Loves or Craves Salt	I really love to have fries for lunch. How many times a week would be ok to have them? You can have fries a couple if times a week but hold the salt At McDonald's you can ask for fries without salt I did not know that! I can try that next time I go. Yes, give it a try
	Goal	20 mg	I think I can reduce my salt by 20 mg per day That is a very reasonable goal K, that's what I'll do then

Figure 4.2 – Sample Chat Dialogue

The length of the chat sessions is relevant from two perspectives, that of providing the best healthcare and from an efficiency perspective. From the perspective of patient-centred care, the quality of the chat session is the determining factor and not its length. A longer chat session may imply the patient was able to engage with the healthcare provider, ask relevant questions and receive detailed enough answers. It could also imply there was confusion or miscommunications requiring more exchanges. Unless the chat histories are examined in detail it is difficult to assess the chat quality for shared decision making. From the perspective of efficiency, using fewer chat exchanges to achieve the three shared decisions is more desirable. It releases the healthcare provider to chat with more patients simultaneously (reducing chat wait time) or perform other duties (multi-task).

There was also variation in the amount of time it took to complete the three shared decisions. The study participants completed two goal-based scenarios each. A total of 18 sessions transpired but two were discarded due to internet disconnection. The duration for shared decision making was measured from the time the patient started entering their demographic information (screen P2) to completion of shared decision 3 (screen P8). The average time to complete all three shared decisions was 14.3 minutes with a range of [5.1, 35.0] minutes. A scatter plot of the various completion times is shown in Figure 4.3 below. The graph clearly shows that the data points are more prominent below the 15 minute mark.

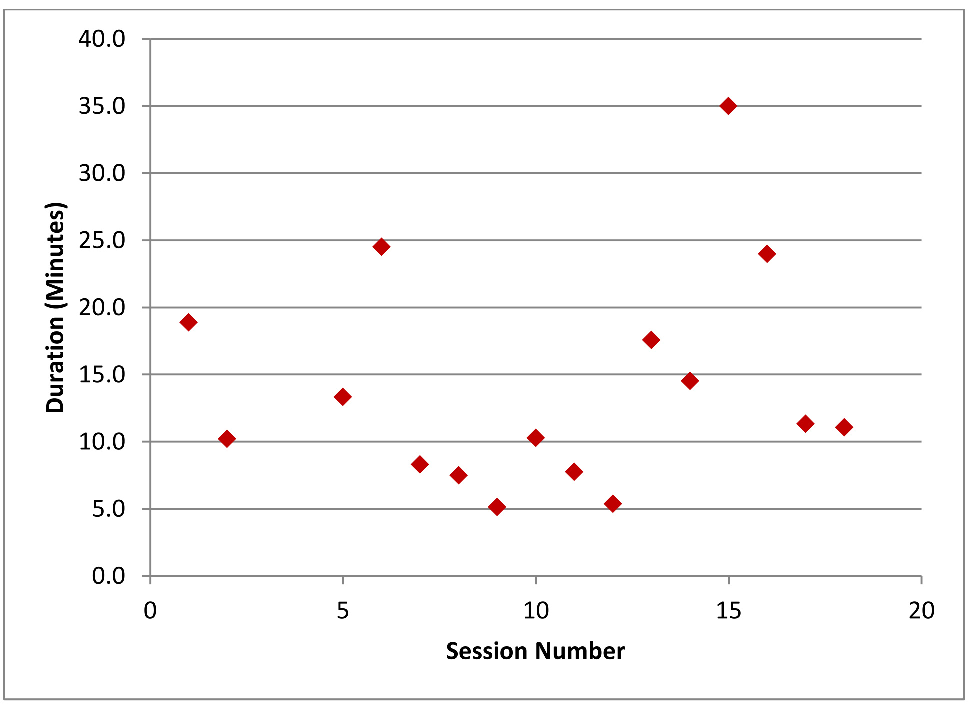

Figure 4.3 – Scatter Plot of Shared Decision Making Durations

4.2. Qualitative Analysis

The study captured qualitative data primarily using the "think aloud protocol" [20]. This protocol captures participant feedback spoken out loud while using iheart to achieve the goal-based scenarios. The software, Active Presenter [84] captured the audio and video feedback including screen captures. Participants also responded to three open ended questions in the post-study questionnaire.

The qualitative data was imported and analyzed using the qualitative analysis tool, ATLAS.Ti [86]. Inductive thematic coding [87] within the software occurred in two stages: 1) open coding and 2) axial coding [88]. First, a comprehensive code list was built incrementally as each piece of qualitative data was openly coded. Open coding involves reading through the data several times, and labelling chunks of data. Afterwards, the frequency or "groundedness" of each code (Figure 4.4) was reviewed to identify the most common feedback, either positive or negative (prefixed with a plus and minus sign, respectively).

Name	Grounded
+ Flexible and Mobile access to HCP online from anywhere	7
+ Real Time Exchange	6
+ Shared Decision Making	6
- Font Too Small	5
- Salt Calculator Issues / Validation Error	5
- No Indication Provider Actively Sending Chat	5
- Salt Calculator Accuracy Questioned / Excessively High Value	4
- Forcing Salt Calculator Undesirable (Free Entry Preferred)	4
+ Chat Feature	4
- No Links to Other Useful Resources as Supports	4
+ Anchor Messages Useful	3
- Too Many Questions / Prompts	3
- More Detail Desired by Participant	3
- No Spell Check or AutoCorrect	3
+ Patient Empowered	3
+ Simplicity of App	3
- Not Intuitive / Training Needed	3

Figure 4.4 – Participant Feedback by Frequency

Axial coding was then applied to draw categories from the open code list. Axial coding consists of identifying commonalities or relationships amongst the open codes. The "family manager" in the ATLAS.Ti software was used to manage these categories or themes. The derived themes and their frequencies were: communication (10), usability (8), content (8), user interface (9), features (7), chat (6), salt calculator (3) and a miscellaneous (3) category. The themes included both positive and negative feedback, meaning each theme represents areas for improvement. Sorting by theme gives a detailed account of the specific improvements needed.

In evaluating the study data, the quantitative analysis was positive and consistent across the board which makes iheart appear ready for use. However, there was great value derived from the qualitative analysis which provided rich, detailed feedback and themes for improvement. A mixed methods study provided a more in depth evaluation than using a strictly quantitative approach and is described in further detail in the next section.

4.3. Combined Analysis

A mixed methods research design concurrently collected quantitative and qualitative data. The datasets were analyzed individually with results presented in Sections 4.1 and 4.2, then merged for combined analysis. The diagram in Figure 4.5 depicts the mixed methods research design. Study subjects completed a post-study questionnaire that contained Likert-scale questions (quantitative) and open-ended questions (qualitative). Think aloud feedback was video/audio captured as the primary source of qualitative data, supplemented by the open-ended questions from the post-study questionnaire.

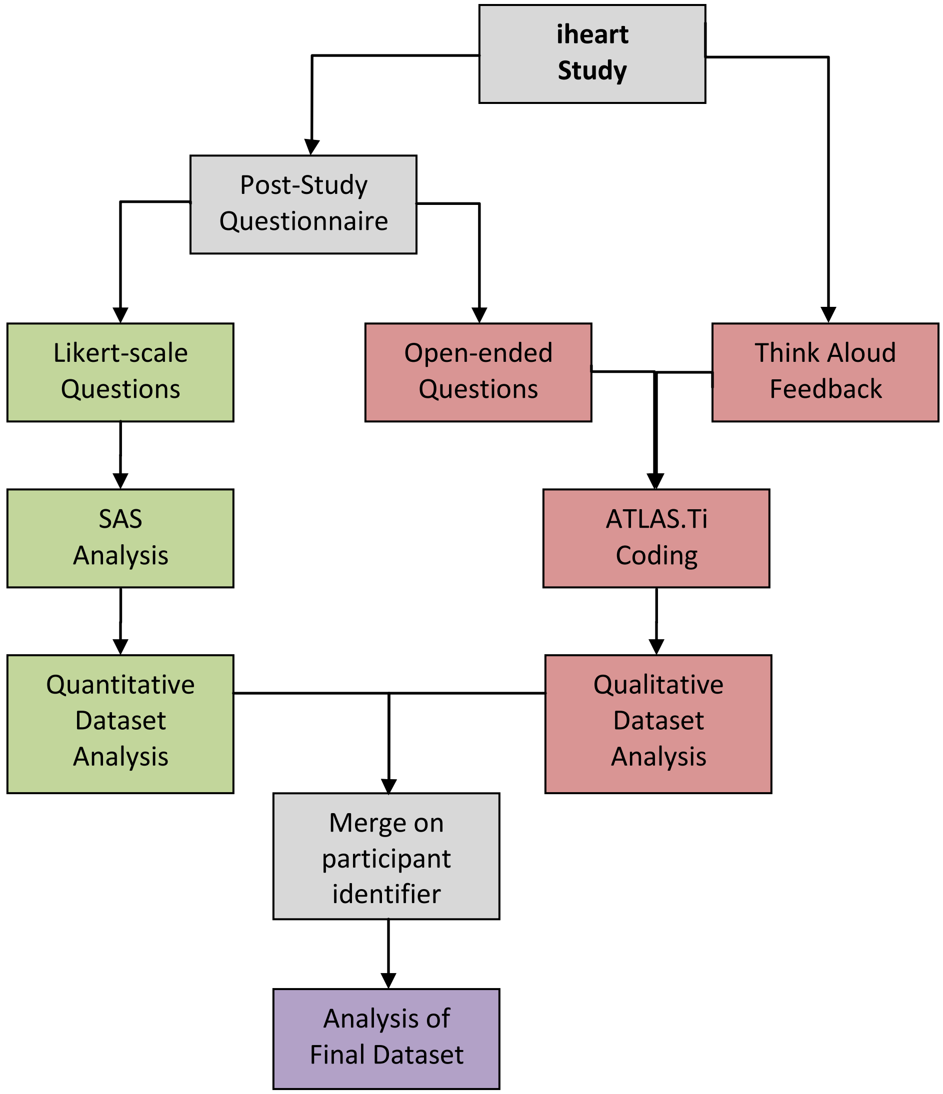

Figure 4.5 – iheart Mixed Methods Study Design

The mixed method approach used in this study "quanticized" [89] the qualitative data and merged it with the existing quantitative data by linking the datasets using the participant ID. Quanticizing is a strategy that counts the frequency of a qualitative code to produce quantitative data. In this study, any code with a frequency of less than three was excluded as being insignificant. The frequencies of the remaining codes were then reported at the aggregated family level (i.e., Chat, Communication, Content, etc.). The comprehensive dataset after merging has been split into two tables: table 4.3 and 4.4 for easier readability.

ID	Median	Mean	Mode	Chat Exchanges	POSITIVE FEEDBACK				
					Chat	Comm	Content	Usability	User Interface
1	1.44	1.0	1	Med	✓	✓✓✓✓✓✓✓	✓✓✓	✓✓	✓
2	1.34	1.0	1	Low					
3	1.80	1.9	1	High					
4	1.05	1.0	1	Med	✓✓	✓✓		✓✓✓✓	
5	1.61	1.0	1	High					
6	3.49	4.0	4	Med					✓✓
7	4.25	4.0	5	High		✓		✓	
8	2.95	3.0	2	Low		✓		✓✓✓	

Table 4.3 – Combined Data for Positive Feedback

ID	Median	Mean	Mode	Chat Exchanges	NEGATIVE FEEDBACK				
					Comm	Content	Features	Salt Calc	User Interface
1	1.44	1.0	1	Med	XX	X	XX	XXXX	XXXXX
2	1.34	1.0	1	Low					
3	1.80	1.9	1	High			X		
4	1.05	1.0	1	Med		XX		X	X
5	1.61	1.0	1	High	X				X
6	3.49	4.0	4	Med	X			XXXXX	
7	4.25	4.0	5	High		X		XXXX	X
8	2.95	3.0	2	Low					
9	1.24	1.0	1	Low		XXX			

Table 4.4 – Combined Data for Negative Feedback

Columns that don't appear in the Positive Feedback (i.e., Features, Salt Calculator) or Negative Feedback (i.e., Chat, Usability) had less than three remarks, thus did not meet the frequency quota for inclusion. Reviewing the data in table 4.3 demonstrates that participants positively rated the communication and usability of iheart. Usability was an explicit, pre-defined section in the post-study questionnaire and also a theme that naturally surfaced in the qualitative data. Consistency in the datasets is observed when comparing the mean value of 2.07 for usability in table 4.1 with the frequency for usability in table 4.3. Participants found iheart to be useful, practical and empowering when drilling into the specific qualitative codes that emerged for usability. Content, produced a mean of 2.35 in Table 4.1 indicating it falls between being neutral and moderately liked by participants. We see in tables 4.3 and 4.4 that participants actually had more critiques of the content than positive remarks. Drilling into the qualitative codes show participants felt the content was not detailed enough and hyperlinks to other resources would have improved iheart. For instance, suggesting participants walk 30 minutes a day to increase exercise should have been supplemented with website links to locations in the local area where there are walking paths.

Analysis of table 4.4 demonstrates that participants disliked aspects of the communication, content, salt calculator and user interface. Participant 1 had the most feedback both positive and negative but favoured the application according to the post-study questionnaire. Participants 6 and 7 who had the highest mean values in the quantitative data in table 4.2 demonstrate low positive feedback in table 4.3 and are the more critical, except for participant 1, in table 4.4. Again, we see consistency in the original quantitative data (post-study questionnaire) and the quanticized data (qualitative coding of think aloud feedback converted to frequency counts).

The chat exchanges were averaged for each participant as they all completed two goal-based scenarios. The participant averages were than categorized as low (between 0-9), medium (between 6-10) or high (greater than 10). Except for the low category, a correlation did not exist between chat exchanges and feedback received. The participants in the low category did have a tendency to also give less feedback. Neither their chat style nor think aloud feedback was verbose in nature.

4.4. Technical Feasibility

For the purpose of this study, technical feasibility was defined as the practical, effective and robust use of the application. It includes the caveat that all recommended enhancements can be reasonably implemented in the next revision of iheart. When analyzing the quantitative data, there were no practicality or robustness issues. This is demonstrated by the section level and overall means from the post-study questionnaire. It is further confirmed by the themes and frequency graphs of the qualitative data. It is noted that participant 6 and 7 were dissatisfied with aspects of iheart and in terms of effectiveness, participants across the board contributed to areas for improvement through their written and audio feedback. The video screen captures also identified a few areas where participants experienced some minor difficulty effectively using iheart. Figure 4.6 shows a list of the areas for improvement, denoted by the negation prefix:

Name	Grounded
- No Indication Provider Actively Sending Chat	5
- Salt Calculator Issues / Validation Error	5
- Font Too Small	5
- Salt Calculator Accuracy Questioned / Excessively High Value	4
- No Links to Other Useful Resources as Supports	4
- Forcing Salt Calculator Undesirable (Free Entry Preferred)	4
- Not Intuitive / Training Needed	3
- No Spell Check or AutoCorrect	3
- More Detail Desired by Participant	3
- Too Many Questions / Prompts	3
- Lost Internet Connection in Kellog building	2
- No Help Feature for tasks or fields	2
- Questions Should be More Prominent (Font Size, Bold, etc.)	2
- Difficult to Explain a Medical Condition Online	2
- Chat Feature could be Improved	2
- Loss of Face-to-Face Expressions and Visual Cues	2
- No Option to Select Multiple Barriers	2
- Participant Confused on Barrier Screen	2
- Not Graphical and Interactive	2
- Disliked Text Oriented Interface	1
- App not Usable by Every Age Group	1
- Patient may feel misunderstood by HCP	1
- Disliked Interacting with Provider	1
- Not Sure Where to Type Chat Message	1
- Not Clear on Progress Hearts (incentive)	1
- Not Aware of BACK Button to Revisit Previously Entered Info	1
- Previous Chat (decision point) should be erased from screen	1
- Poor Message Display on Chat Box	1
- Mis-enters Daily Salt amount (Progress)	1
- Unfamiliar with Medical Terms (Systolic/Diastolic)	1

Figure 4.6 – Areas for Improvement based on Participant Feedback

Analyzing instances where three or more participants reported the same feedback returns the more prominent areas for improvement. However, in reviewing the entire list, all items can either be corrected in the next revision of iheart through enhancements, training or addition of third party software or plug-ins. For instance, "Loss of Face-to-Face Expressions and Visual Cues" can be remedied by adding a video and text chat feature as opposed to the current text-only chat. The concerns with the salt calculator accounts for a high proportion of the improvement needed. Participant p1 expressed out loud, *"I think you should give the patient the chance to enter the salt amount. Especially when the salt amount has been determined already with a doctor. The text box for salt amount should appear before forcing the salt calculator."* This can be remedied by making the salt calculator an optional rather than mandatory feature. Hypertensive patients tend to already know their sodium intake and felt the salt calculator was better as an optional tool.

This valuable feedback will lead to an improved version of iheart. Furthermore, accuracy and error validation concerns with the salt calculator will be reviewed with its external creators. However, adjusting the salt calculator is outside the scope of this research study. The salt calculator is a third party product and there also exist other web-based, salt calculators that could be plugged in if more appropriate for hypertensive patients. Overall, there was no feedback solicited during the study that would render iheart technically infeasible. All desired improvements are achievable, including functional (e.g., no indication a chat is being sent back), informational (e.g., links to other resources desired) or cosmetic in nature (e.g., font size too small).

4.5. Usability

Usability according to the ISO 9241 standard was previously defined in section 3. Measuring the "extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use" translates for the iheart study as:

- **specified users** were hypertensive patients
- **specified goals** were achieved through the goal-based scenarios
- **effectiveness** was measured using the first four sections of the post-study questionnaire that assessed the usability, content, choice process and shared decision making
- **efficiency** was measured using the number of chat exchanges and durations needed to make the three shared decisions
- **satisfaction** was measured using the section mean score for "overall satisfaction" within the post-study questionnaire and feedback from the audio/video recordings
- **specified context of use** refers to a patient and healthcare provider being in two separate locations making shared health decisions using the iheart application (simulated during the study by being in separate locations within the same building)

Examining the effectiveness of iheart, we see in table 4.2 that six participants (two-thirds) favoured the iheart application while one participant was neutral and two participants, participant 6 and participant 7, were on the dissatisfaction end of the spectrum. Drilling further into the qualitative data shed light on the specific areas of dissatisfaction. Participant 8 commented that, "I dislike so many questions". This was reiterated by participant 3 who commented that, "Users may not like filling in so many forms". Patients should never be over-burdened with data entry or questionnaires when interacting with a healthcare application. The salt calculator alone asks 23 questions. Participant 7 who demonstrated the highest dissatisfaction commented that, "I don't agree with the salt calculator – it was very frustrating. It doesn't seem accurate." Making the salt calculator optional or an independent task to complete in advance would reduce the cognitive and data entry load on the patient, thereby improving the usability of iheart. The salt calculator as a stand-alone tool is not necessarily overburdening but when embedded within an application with other questionnaires, it adds significantly to the patient load. May, Montori and Mair suggest "minimally disruptive medicine" [90] to reduce the burden of treatment. It is a particular concern for the chronically ill who may have diminished capacity and/or comorbidities requiring different treatment including different interventions. Care is needed to ensure that health interventions do not incrementally add to the already difficult load of being sick.

The shared decision making efficiency of iheart is demonstrated in figure 4.1 (number of chat exchanges) and figure 4.3 (SDM duration). Five participants were able to make shared decisions with very short chat exchanges. On the other end of the spectrum, six participants had lengthy chat exchanges. The mean duration for chat exchanges was 14.3 minutes with a range of [5.1, 35.0]. There was a definite correlation between the number of chat exchanges and the duration of making the shared decisions. The more verbose the patient during their chats, the longer it tended to take to complete their shared decisions (goal-based scenarios). However, all participants were able to complete two goal-based scenarios well within the study allotment, indicating overall efficiency in use of the application. Similarly a review of the audio/video feedback did not identify any glaring efficiency concerns. However, it was noted that if a participant forgot to enter their age (mandatory field) in the salt calculator, they spent a considerable amount of time trying to uncover which part of the salt calculator generated the generic message, "please review the form and ensure that everything is filled in correctly". Efficiency was an important consideration when designing the application. For example, iheart allows a provider to engage in multiple chats at once by simply toggling the patient chat sessions listed as active in their queue. This allows for efficient multi-tasking during chats as the healthcare provider can respond to patients awaiting a response while other patients are typing a new response.

Satisfaction of iheart is demonstrated by a mean score of 2.13 in the "overall satisfaction" section of the post-study questionnaire. This was also reflected in the open-ended questions and audio feedback. Some excerpts follow:

Participant 1: *I liked making decisions together with my doctor. The chat box was really effective and made it easy for me to exchange opinions and ideas about what I should do or not do.*

Participant 4: *I like that I don't have to wait days or weeks to see the doctor, I can do it from home without having to make arrangements or deal with bad weather.*

Participant 8: *Having this web app accessible on smart phones would definitely be a win.*

Participant 9: *I like being able to chat with a health care professional. It's easier to be open sometimes to an online presence over someone you are in a room with. I like that the decision making on iheart isn't extreme.*

The ATLAS.Ti qualitative analysis tool allowed different views of the participant feedback. Figure 4.7 shows a "cloud view" where the participant's positive feedback is presented in alphabetical order. The more prominent the text string in the cloud, the more grounded the feedback (higher frequency of occurrence). Feedback shown in a very small font pitch had a grounded value of one.

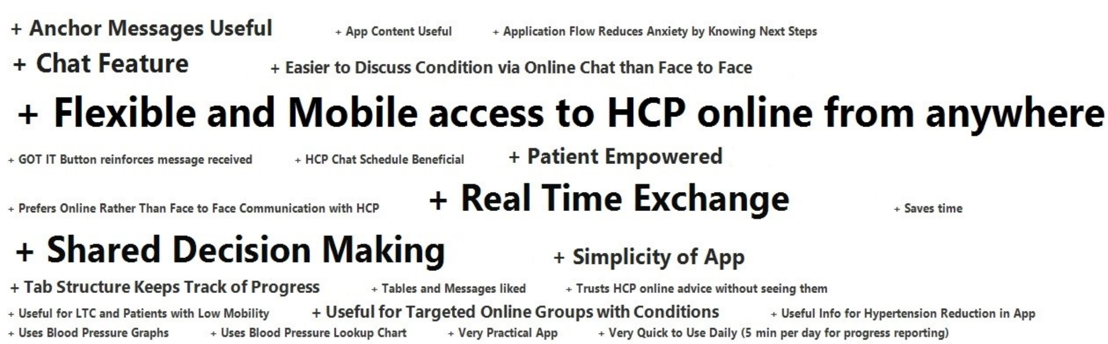

Figure 4.7 – Positive Feedback Shown in Cloud View

An interesting observation is the differing opinions by patients on whether they preferred online interaction with a healthcare provider. The open coding revealed that three distinct patients expressed concerns that there was a loss of face-to-face expressions and visual cues, difficulty explaining a medical condition online and that they may feel misunderstood. However, at the same time the study revealed three distinct patients that embraced online shared decision making. They indicated it's easier to discuss their condition through an online chat rather than face-to-face, valued the real time exchange and trusted the healthcare provider without seeing them. This mixed view towards online shared decision making suggests that different patient segments exist based on communication style. Nonetheless, evaluation of the effectiveness, efficiency and satisfaction of iheart demonstrated that the application was usable.

CHAPTER 5: DISCUSSION

The work presented in this thesis demonstrates that combining multiple theories within a technology intervention for shared decision making can engage patients to make a lifestyle change to manage a non-critical chronic illness. Previous work has studied behavioural theory, decision theory and technology interventions independently or a combination of two methods, but in this novel study, we combined all three approaches within one solution. Using a patient-centred design and integrating the theories within a single ontology model is an innovative approach to computerizing shared decision making between patients and providers. This study explores the frontier of online medicine by affirming that patients are receptive to theory-based, shared decision making. In fact, we found that some participants became very engaged with the iheart solution. These patients became interested to the degree they wanted to expand and add additional features (i.e., links to other useful tips or sites) to iheart.

Although it received primarily positive reviews, our mixed methods study also provided rich feedback on possible refinements for the iheart web application. In particular, the qualitative data presented a wealth of information on the benefits and challenges of the intervention that was not apparent in the quantitative data. For instance, the usability section of the post-study questionnaire had a mean score of 2.07, meaning the participants rated the application as usable. This quantitative score indicates there is room for improvement which can be explored in the qualitative data. Six minor items were identified in the think aloud feedback, screen captures and open-ended questions to improve the user interface and four items to improve the chat feature. Importantly, both the user interface and chat feature contribute to the application's usability making the refinements desirable. It emphasizes that a mixed methods study produced much more valuable information than a quantitative-only approach of simply gathering feedback through a post-study questionnaire.

Additionally, the qualitative feedback identified practical situations where iheart could be applied to manage chronic illness. In particular, participants felt that iheart would be very useful in long term care where a physician is not always present onsite. They also saw value in situations where patient mobility is limited (e.g., cannot leave home). Sands and Wald point out that the availability of more powerful and cheaper information and communication technology has raised the capacity to gather and process information, communicate more effectively, and monitor the quality of care processes [91]. Thus, the iheart application should be further explored in various contexts, such as long term care, to see if the patient feedback has merit.

5.1. Vision

A notable feature of iheart is its scalability. The application was designed with expansion in mind. The ontology knowledge model accommodates decision-making with more than one health provider and patient. Thus, it can accommodate multi-disciplinary teams of medical professionals making decisions together with the patient. Due to its reusable components, the web application can be customized for other chronic illnesses as well, thus expanding its use to other medical domains.

The study data demonstrates that participants most appreciated the flexibility, mobility, shared decisions and real time chat exchanges with a remote healthcare provider. This suggests a paradigm shift within the practice of traditional medicine. It means medical providers, endorsing a tool such as iheart, would have to accommodate scheduled “chat time” in their daily or weekly schedule to interact online in a real-time fashion with patients. Or, similar to an online call centre, the configuration could include recruitment of a pool of qualified medical professionals to provide real-time interaction with patients. It is the next frontier in online medicine. Patients are increasingly seeking timely and informative medical answers online. Currently, they seek it in the form of static information (e.g., webMD knowledge bases). Based on our study, it seems that online, human interactive exchange is another appealing knowledge medium for patients.

5.2. Limitations

A limiting element of iheart was found to be the loss of face-to-face communication currently used in traditional medicine. Some participants expressed that without facial expressions, body language and visual cues, they found it difficult to read the healthcare provider and also describe their medical situation adequately. Seeing how patients appreciated the flexibility and mobility of the real-time text-based chats, this challenge could be addressed through the use of a video chat option. Patients could alternatively have a combined video and text chat (much like a Snapchat session) during decision points with a health care provider to reduce the communication void from a text-only session.

There are also limits to what can be extrapolated from the iheart pilot study. The evaluation for iheart focused on the technical feasibility, usability, benefits, challenges and value of the online shared decision making intervention. The pilot study cannot determine long term adherence to behaviour change. A subsequent, longer study would have to assess adherence. What is known at this point is that hypertensive patients are open and desire online shared decision making tools that can empower them towards health behaviour change.

Another limiting factor was the research ethics restrictions. The study was not approved to collect the participants' actual identifiers or personal health information to protect their privacy and confidentiality. Rather, the study was approved for use with hypothetical, goal-based scenarios. Therefore, in the post-study analysis, the findings could not be correlated to personal factors linked to the actual participants. For example, perhaps individuals that engage in longer chat sessions have similar ethnicities (some ethnic groups are culturally more verbose or lengthy in communication exchanges). This cannot not be determined without approved data collection.

CHAPTER 6: FUTURE WORK

The iheart application should be revised based on the study feedback. Moreover, a logical next step would be performing an efficacy study, to assess adherence to the application's daily use for managing chronic illness such as hypertension. To empower the patient towards adherence, behaviour change choices available during shared decision making could be accompanied by evidence-based metrics. Knowing and understanding the best available evidence is a key element of shared decision making [92], especially in the context of chronic illness. A health informatics approach could capture each participant's intervention choice and their adherence to the particular behaviour. After a fixed number of participants (e.g., 100) have used iheart, the cumulative data could be used to indicate success rates for each behaviour choice by reporting on people with similar demographics as the current patient.

In terms of the practical application of iheart, the system is best piloted in the primary care setting. This requires some further adjustments to ensure the shared decisions, chat history and blood pressure measurements can be transferred to the patient's medical record. The ability to print the information in iheart or upload to an integrated electronic health record system would be very beneficial. Two medical doctors reviewed iheart and provided feedback during the testing phase. However, detailed evaluation and feedback from a healthcare provider's perspective would further refine iheart for practical use. Ideally, iheart could be incorporated in an EHR or patient portal if desired by healthcare providers and clinics.

CHAPTER 7: CONCLUSION

This study uniquely developed and assessed the iheart application that incorporates shared decision making supported by the I-Change behavioural theory and choice architecture. The findings demonstrate that technology founded on the appropriate behavioural theories and choice methods could be a valuable tool in today's information age for empowering patients in their health journey. Our research accomplished three unique health informatics innovations: 1) it used an ontology knowledge model to combine theories to engage patients in online SDM; 2) it computerized the encounter for a non-critical chronic illness; and 3) it used real-time chats between patients and provider to share health decisions. Virtual healthcare is an underestimated and underutilized avenue for sharing health decisions. The iheart study is leading edge and demonstrates that patients are receptive and open to creative and innovative methods of engaging them in shared health conversations with their providers. As noted by Sands and Wald, "adapting health care systems to serve current and future needs requires new streams of data to enable better self-management, improve shared decision making, and provide more virtual care." [91]

In particular, vulnerable populations such as the elderly, immigrants and those without the social skills or capacity to meet face-to-face with a healthcare provider stand to benefit from engaging in online shared decision making [93]. The revelation by the iheart study that some patients preferred face-to-face encounters over online interaction while others felt the opposite, demonstrates that a patient's communication style is relevant to the delivery of their care. Clearly, there is a group of patients that prefer remote, online access to their provider even when residing in close proximity with their provider. They view non-critical visits as inconvenient or inefficient. As participant 4 noted, "it reduces driving, waiting, and appointment time for a simple BP reading if I can take home blood pressure measurements, then converse and chat with my provider online."

As Canada's population is set to enter a period of relatively rapid aging [93], we need to pursue innovative means of delivering care. The Canadian trend for elderly patients with chronic illness or low mobility is to seek care in their homes [94]. Health care delivery systems need to be more effective in the management of chronic conditions as the population ages and experiences escalating chronic illness that threatens to consume more health care resources than available. As indicated by our test subjects, a system like iheart could be a good fit for residential and long term care of non-critical chronic illness. We recommend the revised version of iheart be pilot tested in a variety of settings including where patients have low mobility or challenges reaching their healthcare provider.

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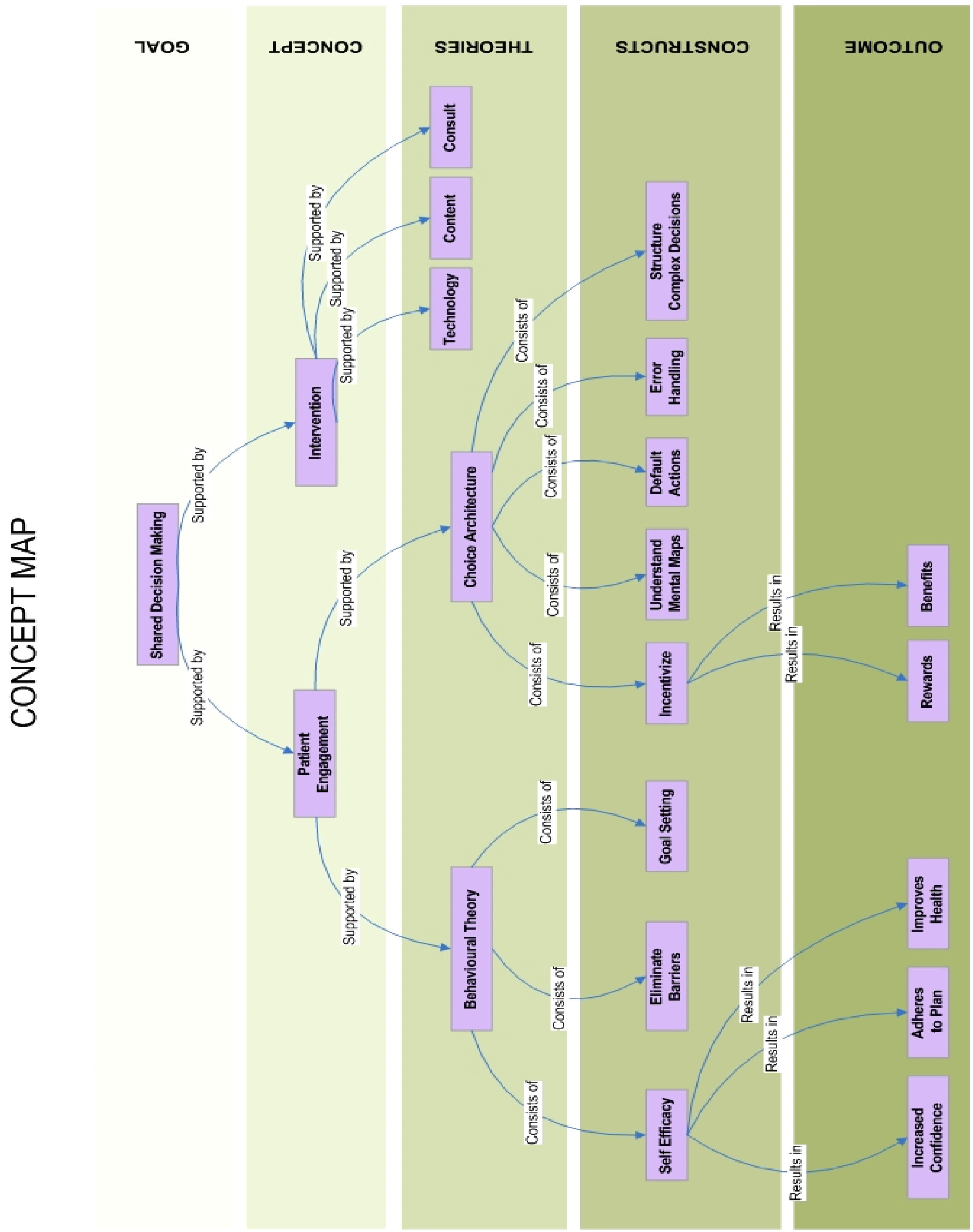
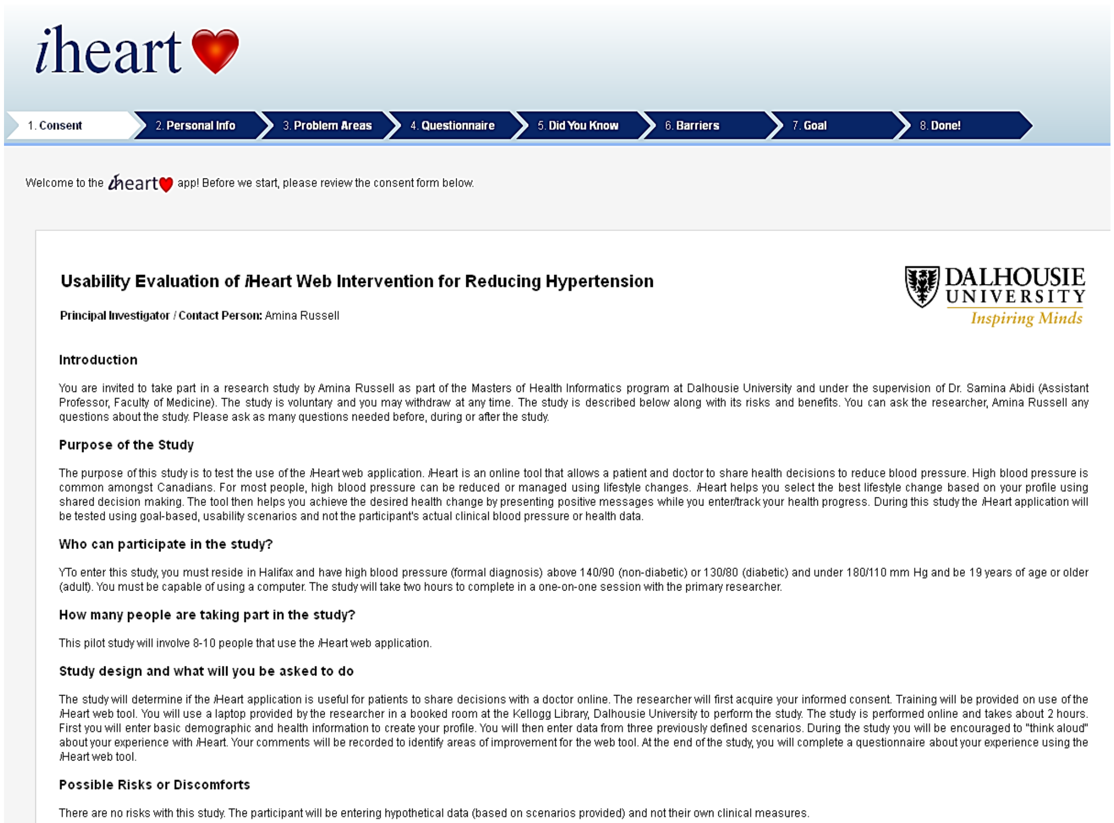
APPENDIX A: CONCEPT MAP



APPENDIX B: PATIENT ENTRY SCREENS



Usability Evaluation of *i*Heart Web Intervention for Reducing Hypertension

Principal Investigator / Contact Person: Amina Russell

Introduction

You are invited to take part in a research study by Amina Russell as part of the Masters of Health Informatics program at Dalhousie University and under the supervision of Dr. Samina Abidi (Assistant Professor, Faculty of Medicine). The study is voluntary and you may withdraw at any time. The study is described below along with its risks and benefits. You can ask the researcher, Amina Russell any questions about the study. Please ask as many questions needed before, during or after the study.

Purpose of the Study

The purpose of this study is to test the use of the *i*Heart web application. *i*Heart is an online tool that allows a patient and doctor to share health decisions to reduce blood pressure. High blood pressure is common amongst Canadians. For most people, high blood pressure can be reduced or managed using lifestyle changes. *i*Heart helps you select the best lifestyle change based on your profile using shared decision making. The tool then helps you achieve the desired health change by presenting positive messages while you enter/track your health progress. During this study the *i*Heart application will be tested using goal-based, usability scenarios and not the participant's actual clinical blood pressure or health data.

Who can participate in the study?

YTo enter this study, you must reside in Halifax and have high blood pressure (formal diagnosis) above 140/90 (non-diabetic) or 130/80 (diabetic) and under 180/110 mm Hg and be 19 years of age or older (adult). You must be capable of using a computer. The study will take two hours to complete in a one-on-one session with the primary researcher.

How many people are taking part in the study?

This pilot study will involve 8-10 people that use the *i*Heart web application.

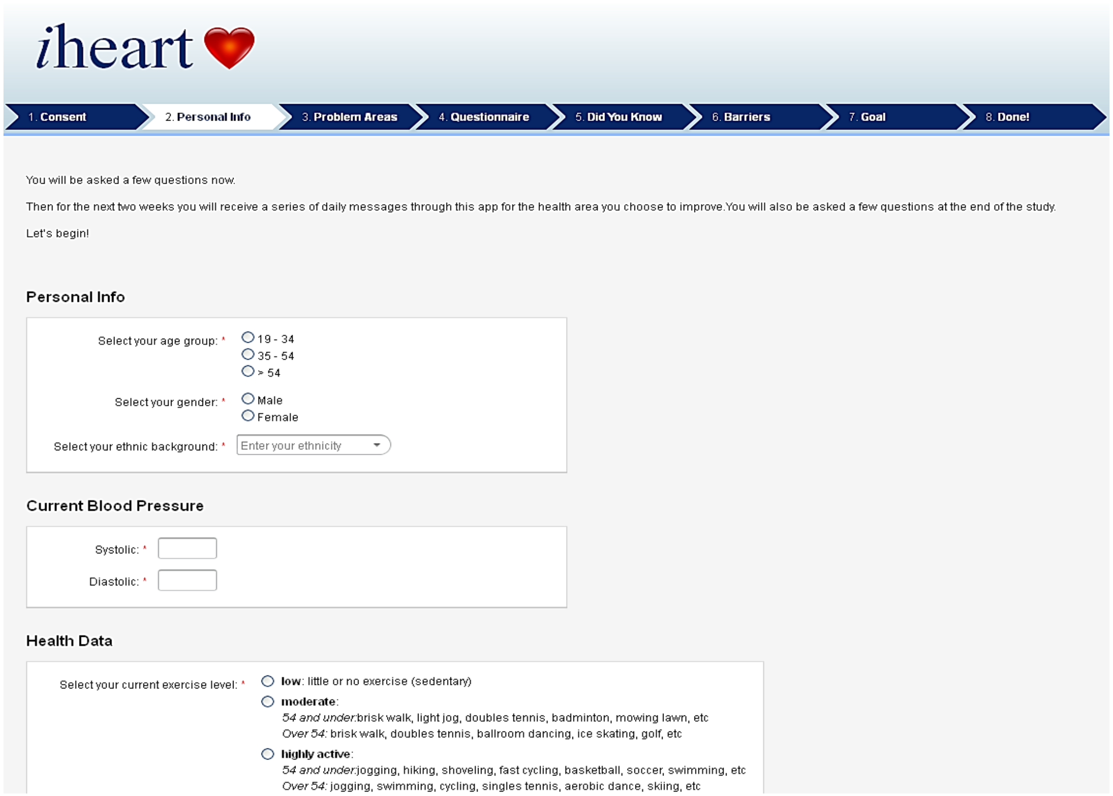
Study design and what will you be asked to do

The study will determine if the *i*Heart application is useful for patients to share decisions with a doctor online. The researcher will first acquire your informed consent. Training will be provided on use of the *i*Heart web tool. You will use a laptop provided by the researcher in a booked room at the Kellogg Library, Dalhousie University to perform the study. The study is performed online and takes about 2 hours. First you will enter basic demographic and health information to create your profile. You will then enter data from three previously defined scenarios. During the study you will be encouraged to "think aloud" about your experience with *i*Heart. Your comments will be recorded to identify areas of improvement for the web tool. At the end of the study, you will complete a questionnaire about your experience using the *i*Heart web tool.

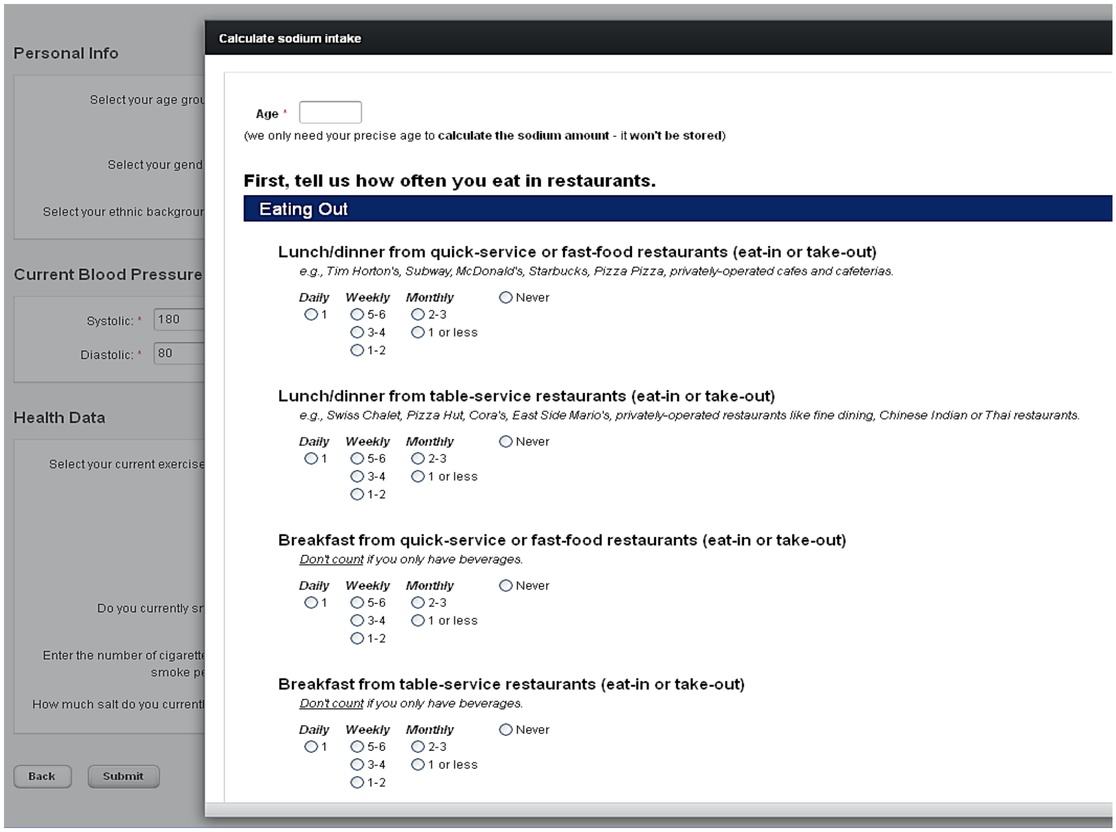
Possible Risks or Discomforts

There are no risks with this study. The participant will be entering hypothetical data (based on scenarios provided) and not their own clinical measures.

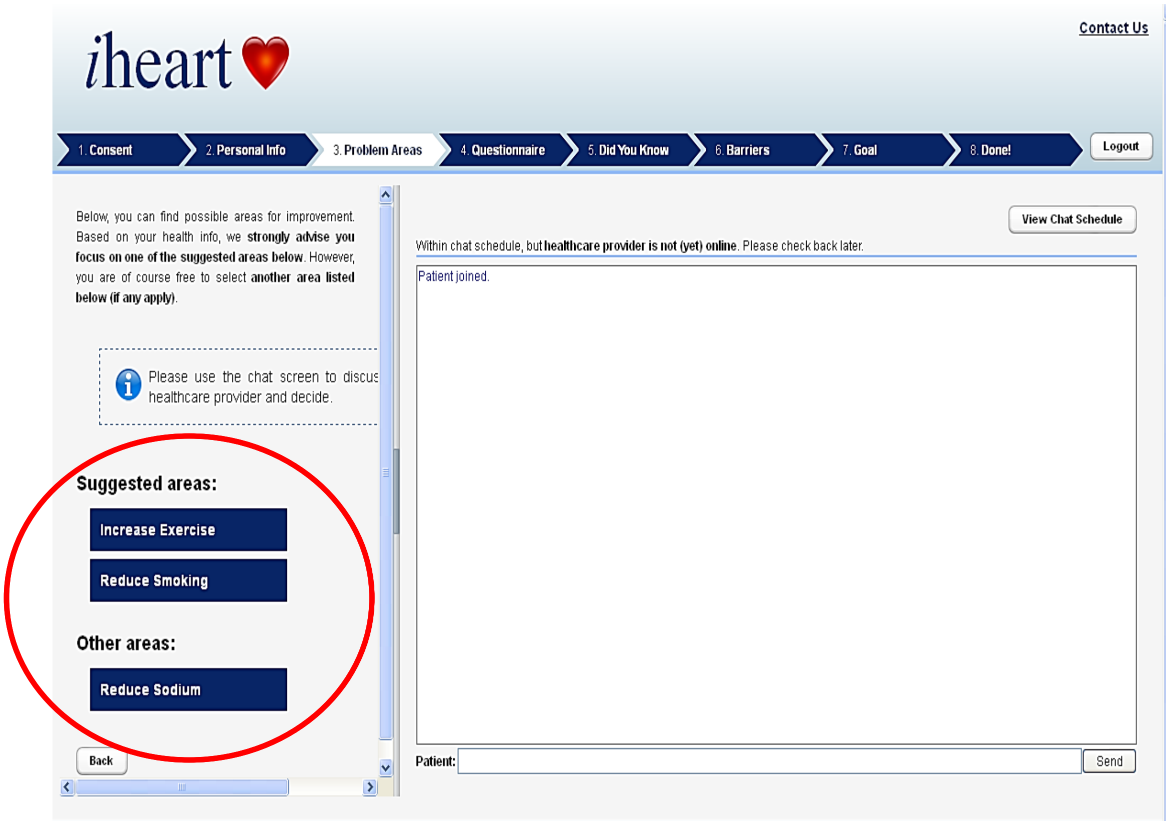
Screen P1: Study Consent (excerpt shown)



Screen P2: Patient Profile (excerpt shown)

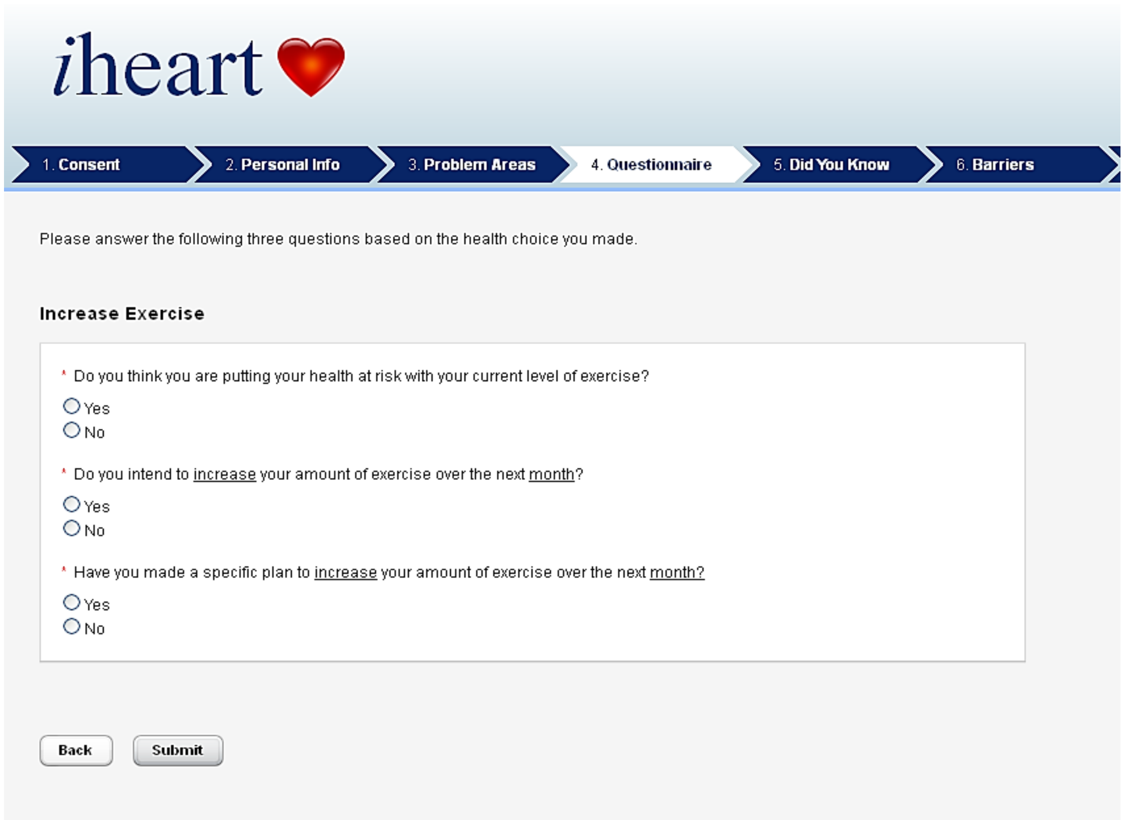


Screen P3: Salt Calculator (excerpt shown)



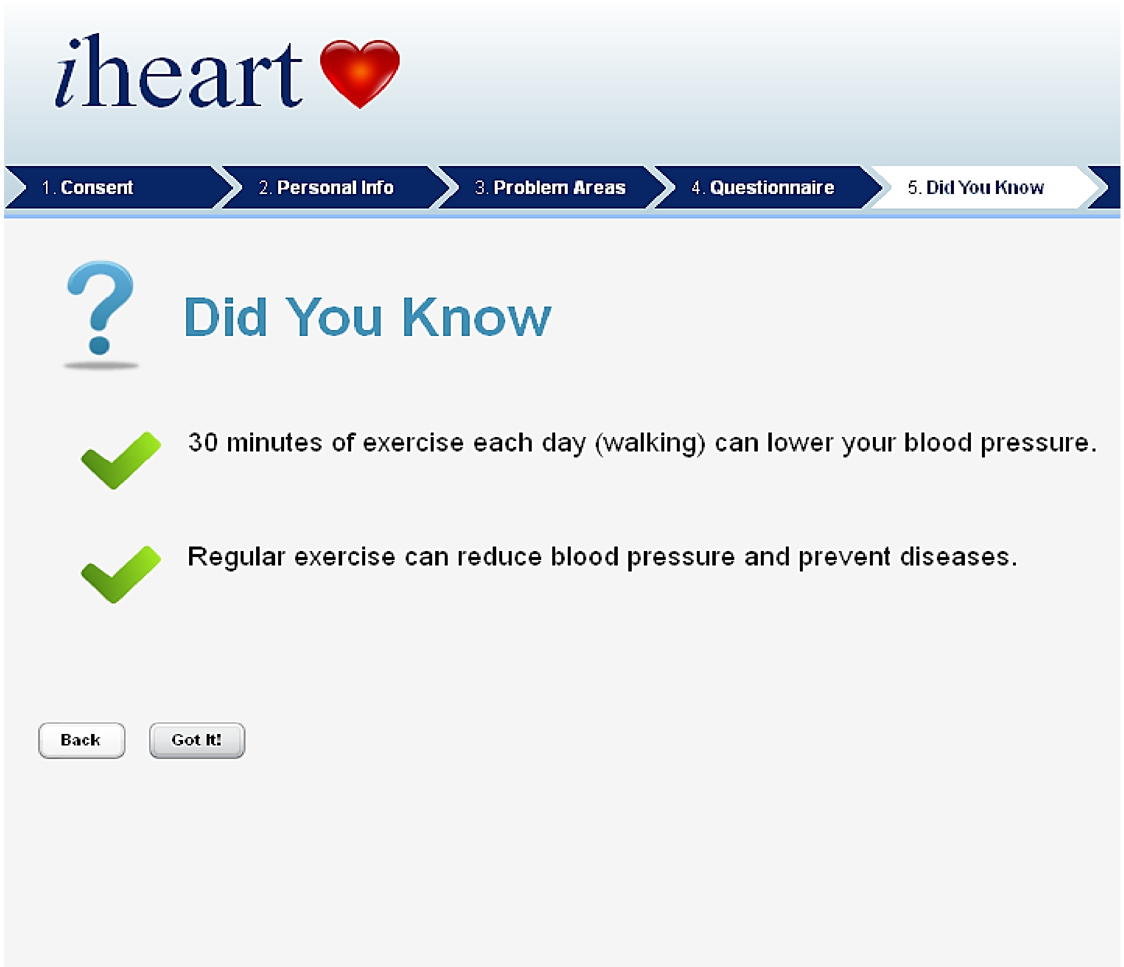
Screen P4: Share Decision 1 (Health Behaviour Change Selection) and Chat

Shows CA feature of default options

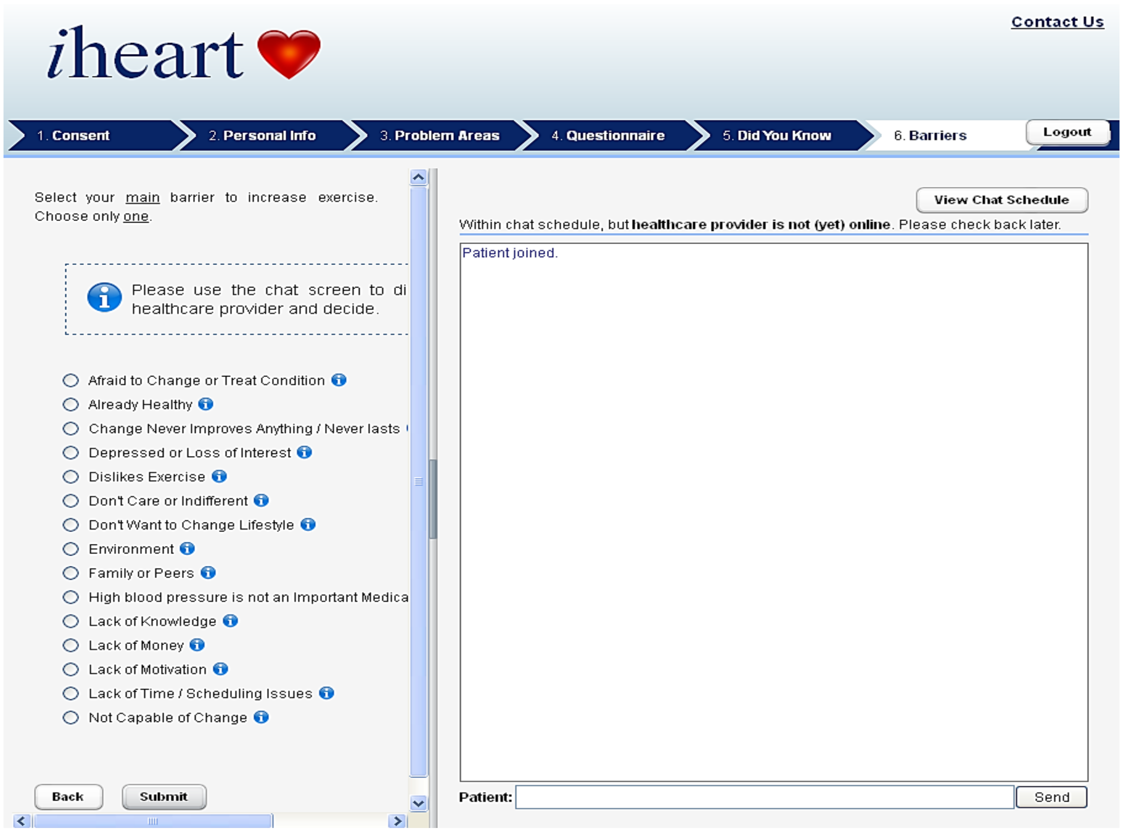


Screen P5: I-Change Behavioural Questionnaire

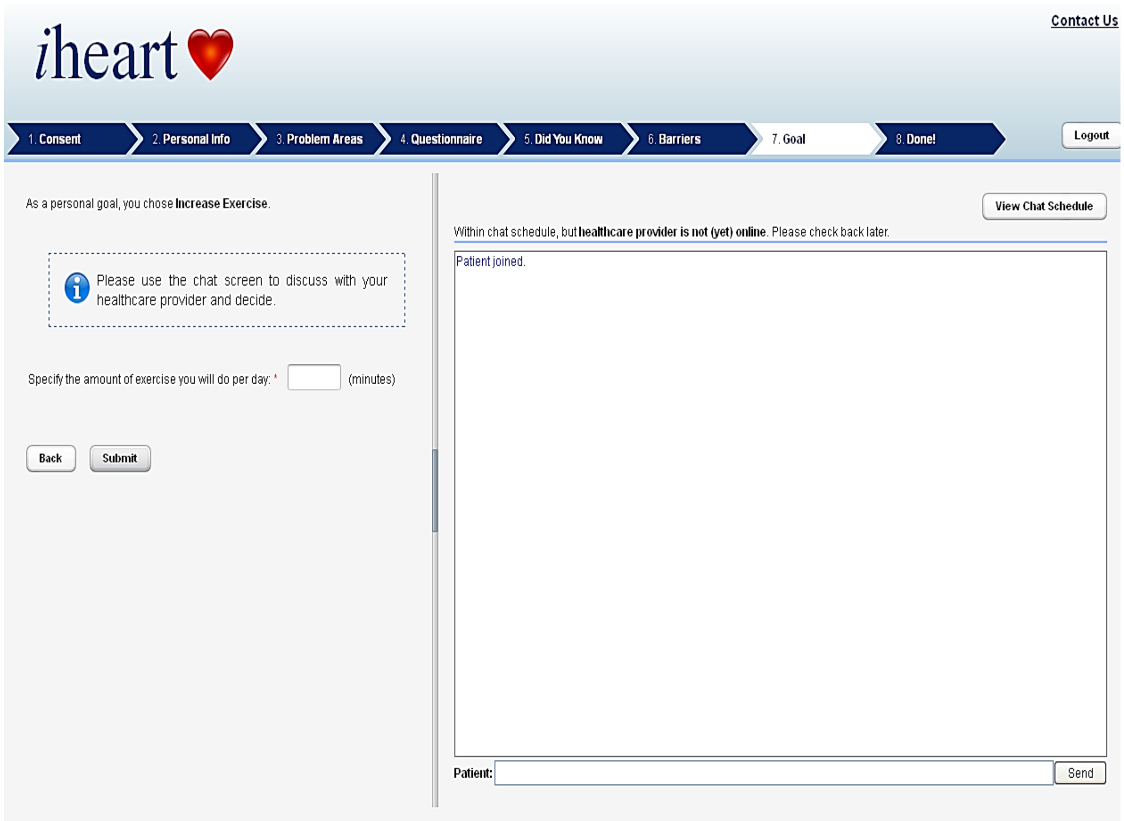
Scored by the application logic described in Section 3.2.2



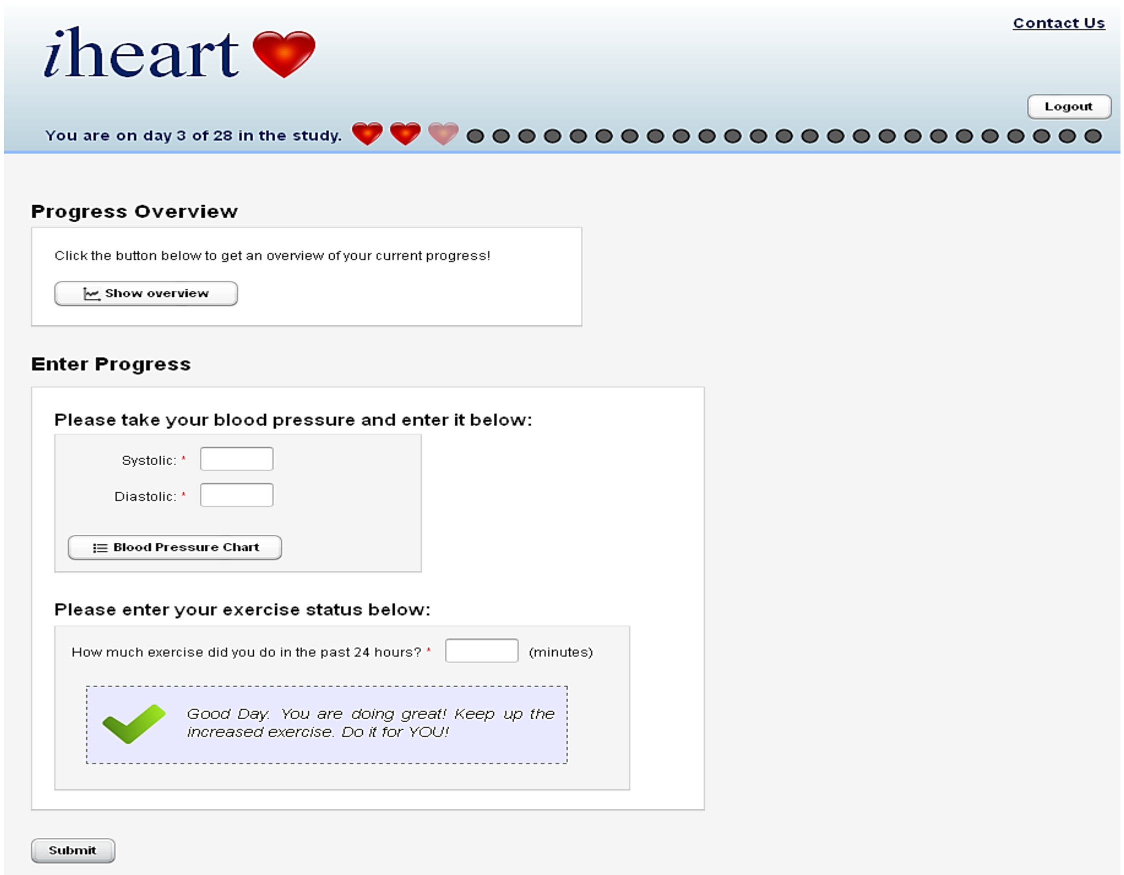
Screen P6: CA Anchor Messages



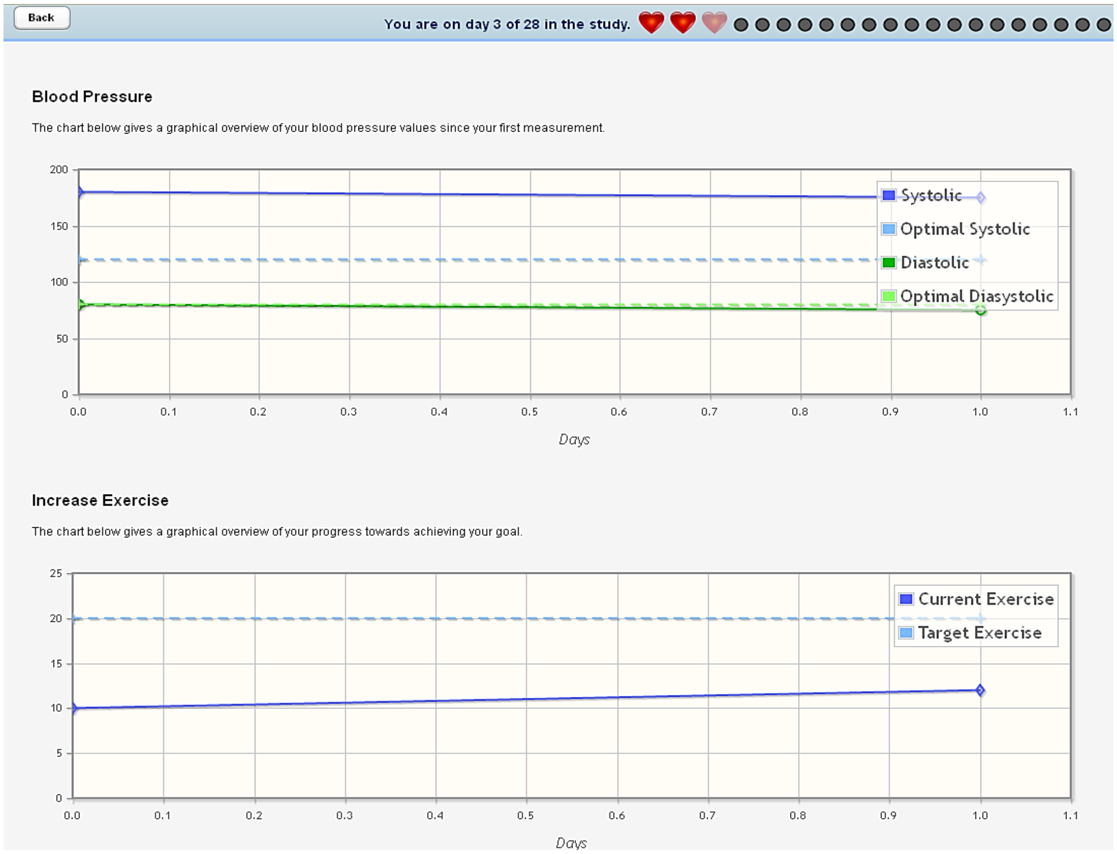
Screen P7: Share Decision 2 (Main Barrier Selection) and Chat



Screen P8: Share Decision 3 (Goal Setting) and Chat



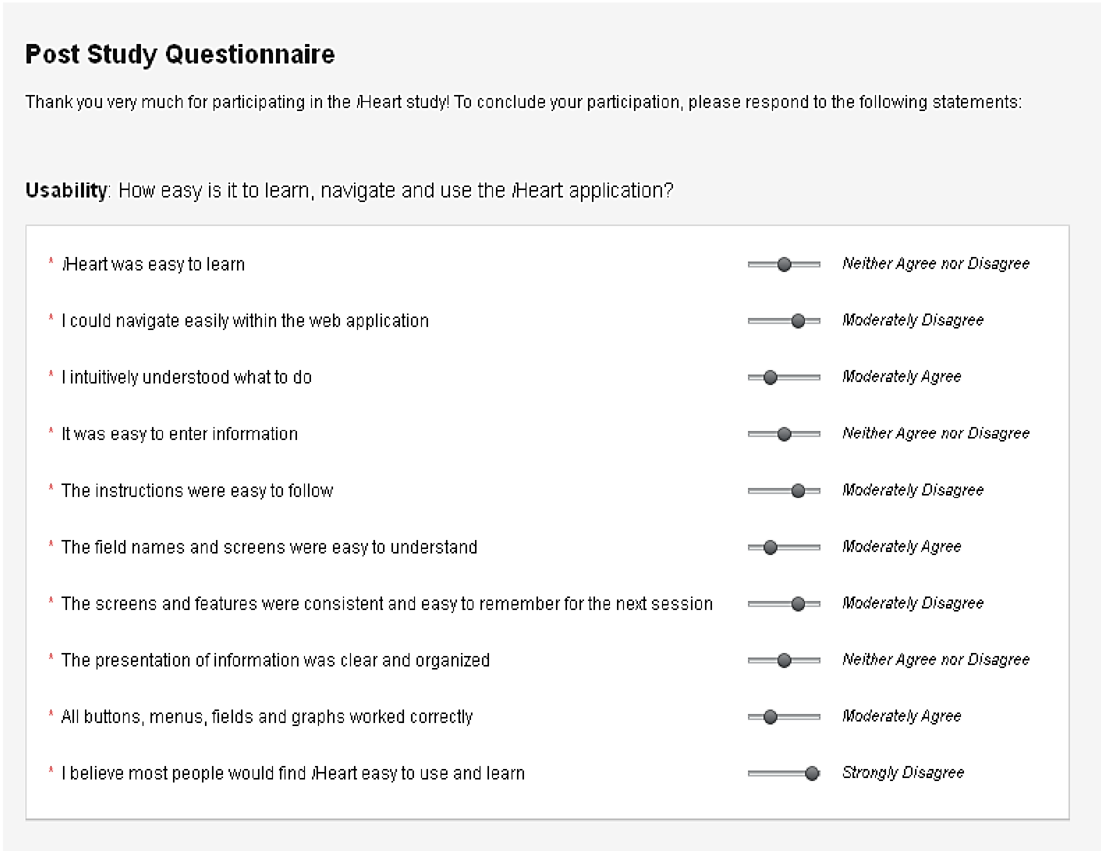
Screen P9: Progress Entry



Screen P10: Progress Graphs (appears when “Show Overview” button selected on screen P9)

Blood Pressure Category	Systolic		Diastolic
Normal	less than 120	and	less than 80
Pre-Hypertension	120 - 139	or	80 - 89
High Blood Pressure (Hypertension Stage 1)	140 - 159	or	90 - 99
High Blood Pressure (Hypertension Stage 2)	160 or higher	or	100 or higher
Hypertensive Crisis (Emergency Care Needed)	higher than 180	or	higher than 110

Screen P11: appears when “Blood Pressure Chart” button selected on screen P9



Post Study Questionnaire

Thank you very much for participating in the *i*Heart study! To conclude your participation, please respond to the following statements:

Usability: How easy is it to learn, navigate and use the *i*Heart application?

* *i*Heart was easy to learn	*Neither Agree nor Disagree*
* I could navigate easily within the web application	*Moderately Disagree*
* I intuitively understood what to do	*Moderately Agree*
* It was easy to enter information	*Neither Agree nor Disagree*
* The instructions were easy to follow	*Moderately Disagree*
* The field names and screens were easy to understand	*Moderately Agree*
* The screens and features were consistent and easy to remember for the next session	*Moderately Disagree*
* The presentation of information was clear and organized	*Neither Agree nor Disagree*
* All buttons, menus, fields and graphs worked correctly	*Moderately Agree*
* I believe most people would find *i*Heart easy to use and learn	*Strongly Disagree*

Screen P12: Excerpt of Post-Study Questionnaire (Usability Section)

APPENDIX C: EMBEDDED SALT CALCULATOR

Age *

(we only need your precise age to **calculate the sodium amount** - it **won't be stored**)

First, tell us how often you eat in restaurants.

Eating Out

Lunch/dinner from quick-service or fast-food restaurants (eat-in or take-out)

e.g., Tim Horton's, Subway, McDonald's, Starbucks, Pizza Pizza, privately-operated cafes and cafeterias.

Daily	*Weekly*	*Monthly*	Never
1	5-6	2-3	
	3-4	1 or less	
	1-2		

Lunch/dinner from table-service restaurants (eat-in or take-out)

e.g., Swiss Chalet, Pizza Hut, Cora's, East Side Mario's, privately-operated restaurants like fine dining, Chinese Indian or Thai restaurants.

Daily	*Weekly*	*Monthly*	Never
1	5-6	2-3	
	3-4	1 or less	
	1-2		

Breakfast from quick-service or fast-food restaurants (eat-in or take-out)

Don't count if you only have beverages.

Daily	*Weekly*	*Monthly*	Never
1	5-6	2-3	
	3-4	1 or less	
	1-2		

Breakfast from table-service restaurants (eat-in or take-out)

Don't count if you only have beverages.

Daily	*Weekly*	*Monthly*	Never
1	5-6	2-3	
	3-4	1 or less	
	1-2		

Now, tell us how often you eat these foods, either prepared or eaten at home.

Bakery Products & Cereals

Bread products

e.g., bread, bagels, English muffins, buns, croissants, flatbreads, croutons.

Daily	*Weekly*	*Monthly*	◯ Never
◯ 6+	◯ 5-6	◯ 2-3	
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Baked goods

e.g., cookies, muffins, scones, doughnuts, cakes, brownies, pie, danishes, Pop Tarts.

Daily	*Weekly*	*Monthly*	◯ Never
◯ 6+	◯ 5-6	◯ 2-3	
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Breakfast cereal & hot instant cereal

Don't count shredded cereals (e.g., Shredded Wheat) or hot cereal made from scratch.

Daily	*Weekly*	*Monthly*	◯ Never
◯ 6+	◯ 5-6	◯ 2-3	
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Processed Meat, Fish & Poultry

Processed meat products

e.g., luncheon meats, cured meats, sausages, hot dogs, jerky, bacon, baked ham.

Daily	*Weekly*	*Monthly*	◯ Never
◯ 6+	◯ 5-6	◯ 2-3	
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Frozen or pre-seasoned meat, poultry & fish

e.g., frozen burgers, meatballs, frozen breaded fish, smoked salmon, chicken burgers, nuggets, wings.

Daily	*Weekly*	*Monthly*	◯ Never
◯ 6+	◯ 5-6	◯ 2-3	
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Canned tuna and salmon & smoked fish

Include sardines, herring, and imitation seafood.

Daily	*Weekly*	*Monthly*	◯ Never
◯ 6+	◯ 5-6	◯ 2-3	
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Cheese & Dairy

Cheese eaten alone or with other food

Include cheese on sandwiches and with other meals, like lasagna or hamburgers.

Daily	*Weekly*	*Monthly*	◯ Never
◯ 6+	◯ 5-6	◯ 2-3	
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Milk as a hot or cold drink & milk in cereal

Include milk alternatives like soy or almond milk, and café latte, cappuccino and hot chocolate from home or a restaurant.

Daily	*Weekly*	*Monthly*	◯ Never
◯ 6+	◯ 5-6	◯ 2-3	
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Canned Vegetables

Canned vegetables, legumes, pickles & olives

e.g., chick peas, kidney beans, lentils, refried beans. Don't count canned baked beans with sauce.

Daily	*Weekly*	*Monthly*	◯ Never
◯ 6+	◯ 5-6	◯ 2-3	
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Added Salt

Add a dash or shake of salt to food

Include salt added at the table at each meal, and salt that was added during cooking.

Daily	*Weekly*	*Monthly*	◯ Never
◯ 6+	◯ 5-6	◯ 2-3	
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Spreads, Condiments, Dips & Sauces

Condiments & dips

e.g., salad dressing, mayonnaise, ketchup, relish, BBQ sauce, soy sauce, hummus, dips for chips or veggies, plum sauce, salsa.

Daily	*Weekly*	*Monthly*	◯ Never
◯ 6+	◯ 5-6	◯ 2-3	
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Prepared sauces & marinades

e.g., pasta sauce, gravy, curry paste, seasoning mixes.

Daily	*Weekly*	*Monthly*	◯ Never
◯ 6+	◯ 5-6	◯ 2-3	
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Prepared Meals, Sides & Soups

Pasta and rice dishes with sauce/seasonings, and packaged mashed/scalloped potatoes and stuffing dishes

e.g. macaroni and cheese, pasta side dishes, seasoned instant rice dishes.

Daily	*Weekly*	*Monthly*	◯ Never
◯ 6+	◯ 5-6	◯ 2-3	
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Frozen appetizers & side dishes

e.g., Frozen french fries, spring rolls, sausage rolls, cheese sticks, perogies. Don't count chicken wings or frozen vegetables.

Daily	*Weekly*	*Monthly*	◯ Never
◯ 6+	◯ 5-6	◯ 2-3	
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Frozen entrees & meals

e.g., pasta dishes like lasagna, stuffed meat and poultry, a "TV dinner".

Daily	*Weekly*	*Monthly*	
◯ 6+	◯ 5-6	◯ 2-3	◯ Never
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Canned chili, stew & pasta or baked beans with sauce

Daily	*Weekly*	*Monthly*	
◯ 6+	◯ 5-6	◯ 2-3	◯ Never
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Pizza or pizza snacks

Include packaged and made-from scratch pizza. Don't count pizza from a restaurant.

Daily	*Weekly*	*Monthly*	
◯ 6+	◯ 5-6	◯ 2-3	◯ Never
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Soup, broth, oriental noodles & bouillon

Include soups and bouillon added to recipes. Don't count soups with broth made from scratch.

Daily	*Weekly*	*Monthly*	
◯ 6+	◯ 5-6	◯ 2-3	◯ Never
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Salty Snacks

Salty snack foods

e.g., potato chips, pretzels, popcorn, peanuts, other nuts.

Daily	*Weekly*	*Monthly*	
◯ 6+	◯ 5-6	◯ 2-3	◯ Never
◯ 4-5	◯ 3-4	◯ 1 or less	
◯ 2-3	◯ 1-2		
◯ 1			

Calculate

APPENDIX D: TESTING SUMMARY

WHITE BOX TESTING: Testing of Internal Code Structures

INTERNAL FEATURE	**RESULT**	**STATUS**
Security in place: password protection, login ID, no blanks	✓	Completed
API Testing		Completed
• Salt Calculator functions within App	✓	Completed
• Chat Feature functions within App	✓	Completed
• Phys Queue functions within App	✓	Completed
Study Consent Functions (logic)	✓	Completed
I-Change Questionnaire shows correct questions for health choice and scores correctly	✓	Completed
All drop down lists correct/completed	✓	Completed
All enterable fields correct	✓	Completed
All mandatory fields correct	✓	Completed
All ontology classes represented	✓	Completed
All design rules implemented	✓	Completed
All SDM options exist: Health choices, barriers, open-ended goal	✓	Completed
All messages correct	✓	Completed
Rotates through check-in messages for each health choice	✓	Completed
Uses Grade 8 language (recommended for patient screens)	✓	Completed
Fault Injection: all error handling works as expected	✓	Completed
BP measure cannot be negative	✓	Completed
BP Chart presents	✓	Completed
Progress graphs present	✓	Completed
Navigation is intuitive, functions correctly	✓	Completed
Cannot navigate backwards (to any tab) – after entering personal goal	✓	Completed
Works in all browsers (Firefox, IE, Chrome) **IE can be very slow**	✓	Completed
Works on computer, iPad and laptop devices	✓	Completed
Review stored data to ensure it will give me evaluation I need	✓	Completed
Post Study Likert Questionnaire Functions	✓	Completed
Study ends gracefully when expected	✓	Completed
Ad hoc testing – handles random, unexpected situations	✓	Completed
Exploratory testing – try things / explore	✓	Completed

BLACK BOX TESTING: Testing of External Application / User Facing Components

EXTERNAL FEATURE	RESULT	STATUS
Accessible from any location: home, QEII, DAL, etc.	✓	Completed
Robustness	✓	Completed
Performance – login, data entry/commits, navigation, graphs, etc.	✓	Completed
Every expected screen / prompt / questionnaire displays	✓	Completed
Salt calculator accessible and functions correctly	✓	Completed
Every expected anchor message displays	✓	Completed
Every expected check-in message displays	✓	Completed
Patient can chat functionally	✓	Completed
Physician can chat functionally	✓	Completed
Physician responses appear to patient – immediate, busy, etc.	✓	Completed

APPENDIX E: SAMPLE GOAL-BASED SCENARIOS

SCENARIO A: [Stage 2 Hypertension]

[Possible lifestyle choices = reduce smoking; increase exercise]

A married Hispanic; middle aged man has smoked 1 pack of cigarettes per day for the past 20 years. He works in a white collar job and has a sedentary lifestyle. He has no complaints about his health except that he becomes short of breath when going up a short flight of stairs. His blood pressure is presently 165/85 mmHg. He's here today to try the iheart application because he understands his lifestyle of smoking combined with a sedentary lifestyle is affecting his general health. However, having smoked for 20 years, cigarettes are a big part of his life and identity and he doesn't know how he can possibly quit. He's afraid to quit cold turkey and would like to explore the option of cutting down the number of cigarettes he smokes by 40% over the next four weeks. He wishes to start by making one lifestyle change today to reduce his hypertension.

Sample values for blood pressure progress:

Systolic:	165	164	162	161
Diastolic:	85	85	82	82

<u>SCENARIO B:</u> [Diabetic with Stage 2 Hypertension]

[Possible lifestyle choices = reduce smoking; reduce salt intake]

An older woman of East Indian descent in her 50's has been struggling with her weight for quite some time. Her BMI is 29.2 (overweight category) and she is also a stage I diabetic. It has been a real struggle for her to stay away from sweets and her salt intake is borderline (2400 mg salt). She stopped working after having her second child almost 15 years ago and only does some light administrative work for her husband's home business now. She smokes a pack of cigarettes a day. Her family is very social and involved in their community. At least 2-3 times a week they are at someone's house for a big meal (usually 3 courses and dessert) and smokes socially. She also likes to snack and lately has been trying to substitute sweet treats with fruits or veggies. Her blood pressure is 159/98 mm Hg and her family doctor has recommended both hypertension medications and trying one lifestyle change at a time to improve her health. She is technology savvy and would like to use an online tool to help her make a lifestyle change and track her progress.

Sample values for blood pressure progress:

Systolic:	159	158	158	157
Diastolic:	98	97	95	94

SCENARIO C: [Stage 1 Hypertension]

[Possible lifestyle choices = increase exercise; reduce salt intake]

A single, African-Canadian male in his early thirties has been diagnosed by his family doctor as having hypertension. Hypertension and cardiac disease run in his family. His family doctor measured his blood pressure at his last visit to be 145/92 mm Hg. He never finished high school and his literacy level is grade 7. He used to smoke when he was younger but has not done so for over a decade. His diet is not great as he does not understand or read food labels, doesn't have time to cook and works a blue collar job with long shifts so he eats out a lot. He is very frustrated because his physician has advised that he may need hypertension medications if he doesn't change his lifestyle. He does not have much time to do anything outside of his long work hours and doesn't know where to get help to lower his blood pressure (hypertension). He hears mixed information from people in the African-Canadian community on what to do to take charge of his health. His doctor told him that moderate exercise and salt intake below 2400 mg per day is ideal. Use of an online tool was suggested for making a lifestyle change to improve hypertension.

Sample values for blood pressure progress:

Systolic:	145	145	144	143
Diastolic:	92	92	91	90

APPENDIX F: BIG LIFE SODIUM CALCULATOR SERVICE AGREEMENT

SERVICE AGREEMENT

THIS AGREEMENT made this 26th of June 2014

BETWEEN:

Amina Russell

(hereinafter referred to as ("Researcher")

-AND-

Ottawa Hospital Research Institute

(hereinafter called "OHRI")

-and-

Dr. Douglas Manuel

(hereinafter called "OHRI Researcher")

(Hereinafter OHRI and Researcher shall collectively be referred to as "Institution").

1. PURPOSE OF THE AGREEMENT

1.1. The purpose of this Agreement is to set out the terms and conditions governing the provision of technical infrastructure that will be provided by Institution to the Researcher for sodium calculations.

2. INFORMATION TO BE PROVIDED

2.1. The Researcher has requested, and the Institution has agreed to provide to the Researcher access to sodium calculations for individual users from the existing Project Big Life Sodium Calculator (the Application) at the Researcher site. The parties agree that no personally identifiable information or personal health information will be exchanged hereunder.

3. USE OF THE INFORMATION

3.1. The Researcher shall use the Application only as necessary for the following purposes:

3.1.1. To produce individual sodium consumption estimates, including sodium levels from specific food groups (the "Project").

3.2. The Researcher will not in any way modify, translate, reverse engineer, decompile, attempt to derive the source code of, disassemble (except to the extent that this restriction is expressly prohibited by law), modify or create derivative works based upon the Application.

3.3. The Researcher will provide the Institution with an outline of the analysis for which the Application will be used upon signature of this Agreement. The Researcher will not undertake any other project involving the use of the Application without the written consent of the Institution.

3.4. The Researcher will provide the Institution with copies of all final reports produced using the Application.

4. MECHANISMS FOR TRANSMISSION

4.1. The parties shall mutually determine the method, medium, frequency and timetable to be used with respect to the provision of the Application under this Agreement.

5. CONFIDENTIALITY

5.1. Researcher and Institution may disclose confidential information one to the other to facilitate work under this Agreement. Such information clearly marked as "Confidential" or "Not for Publication" at the time of disclosure shall be safeguarded and not disclosed to anyone without a "need to know" within the Researcher and the Institution. The confidential nature of verbal disclosures shall be identified as such at the time of disclosure and confirmed in writing within 15 days of the disclosure. Each party shall also strictly protect such information from disclosure to third parties. The obligation to keep confidential shall however not apply to information which:

5.1.1. Is already known to the party to which it is disclosed;

5.1.2. Becomes part of the public domain without breach of this Agreement

5.1.3. Is obtained from third parties which have no obligations to keep confidential to the contracting parties

5.1.4. The disclosure is made in order to comply with the requirements of applicable law or governmental regulation, provided the receiving party gives prior written notice of such disclosure and takes reasonable actions to avoid such disclosure or minimize its extent

5.1.5. Is independently developed by the receiving party, provided that the person or persons developing same have not had access to, either directly or indirectly, the

Confidential Information received and provided such independent development is documented

5.2. Personal Health Information Protection Act, 2004

5.2.1. The Institution shall not use or further disclose "personal health information" (PHI) except as may be permitted or required by this Agreement, or as may be otherwise permitted or required by law.

5.2.2. The Institution shall use appropriate safeguards to prevent use or disclosure of PHI, other than as specifically provided by this Agreement

5.2.3. The OHRI Researcher shall immediately report to Institution any loss or, theft or use or disclosure of PHI not provided for by this Agreement of which he may become aware.

5.2.4. The Institution shall ensure that Institution employees, agents or sub-contractors, if any, to which PHI may be disclosed agree to the same restrictions and conditions to which Institution are subject.

5.2.5. The Researcher shall make available all information required to provide an accounting of any disclosures of PHI relating to this Agreement by the Institution that are made pursuant to applicable law.

5.2.6. Upon the termination or expiry of this Agreement, the Institution shall return or destroy all PHI that the Institution received from the Researcher, and the Researcher shall not retain any copies of PHI received, except as allowed or required by applicable laws and regulations.

6. FINANCIAL ARRANGEMENTS

6.1. Each party shall bear its own cost of implementing this Agreement.

7. INTELLECTUAL PROPERTY

7.1. Any intellectual property belonging to a party to the start of the Project or developed and owned by a party independently of the Project and this Agreement shall remain the property of that party. The Institution will be providing calculation services to the Researcher. This Service Agreement does not involve generation of new intellectual property.

8. AMENDMENTS

8.1. This Agreement may be amended if the parties agree to such amendments in writing.

9. TERMS, COMMENCEMENT AND TERMINATION OF AGREEMENT

9.1. This Agreement shall take effect on the date set out on page 1.

9.2. This Agreement shall continue in effect for as long as the Institution provides the Application identified in this Agreement, unless there is an amendment or termination, subject to Article 10.1.

9.3. The Institution may cease disclosing any one or more Application elements, without cause, by giving the Researcher notice in accordance with Article 11.

9.4. Despite Article 9.3, the Researcher may continue to use such data for a specific project that it has already notified the Institution that it has begun, if it has written authorisation from the Institution to do so.

9.5. If the Institution ceases disclosing the Application under Article 9.3, the entire Agreement is not terminated but continues with respect to the remaining Application elements which the Institution is willing to continue to disclose.

9.6. This Agreement may be terminated by either party without cause on at least thirty (30) days written notice or immediately by written notice on breach by any party.

9.7. This Agreement may be amended or terminated on mutual agreement by the parties.

9.8. On termination the Institution shall cease disclosing the Application and the Researcher shall cease using the Application for ongoing projects.

10. SURVIVAL OF OBLIGATIONS

10.1 Terms and conditions relating to (a) use and destruction of the Application, (b) confidentiality; and (c) indemnification shall survive the termination of this Agreement.

11. NOTICE

11.1. Unless otherwise specified in this Agreement, any notice required to be given hereunder shall be in writing and may be delivered personally or be sent by registered mail to:

If to INSTITUTION:
Douglas G. Manuel
Senior Scientist, Ottawa Hospital Research Institute

Marisa Akow
Director, Research Administration
Ottawa Hospital Research Institute

If to RESEARCHER:

Amina Russell

11.2. Any notice sent by registered mail shall be deemed to have been received by the party to whom it is addressed on the third (3^{rd}) business day following such mailing.

12. INDEMNIFICATION

12.1. The Researcher hereby indemnifies and holds harmless the Institution, including its directors, officers, employees, students, servants and agents from all claims, demands, losses, damages and expenses of any kind (including but not limited to legal fees and disbursements on a solicitor-and-client basis) that result from: (a) the Researcher's negligent acts or omissions in the performance of its obligations under this Agreement of those of its directors, officers, employees and agents or any other person for whom the Researcher is in law responsible; and, (b) the use by the Researcher, or by any party acting on behalf of or under authorization from the Researcher of the results of the Project or from any use, sale or disposition by the Researcher, or by any party acting on behalf of or under authorization from the Researcher, of products or services made or provided using the result of the Project.

12.2. The Institution hereby indemnifies the Researcher, including its directors, officers, employees, servants or agents against all claims, losses, damages or expenses of any kind arising from the negligence, willful neglect or malfeasance of the Institution (or those for whom in law it is responsible) with respect to the Project

12.3. Notwithstanding any other provisions of this Agreement, no party hereto shall be responsible for any lost profits, lost opportunities, or other indirect or consequential damages suffered by another party hereto as a result of the conduct of the Project or the performance of this Agreement.

13. GENERAL

13.1.a This Agreement shall be construed and interpreted in accordance with the laws of the Province of Ontario and the federal laws of Canada applicable therein.

b. Any disputes arising from the implementation of, or in connection with, this Agreement shall be settled through good faith negotiations by the parties using their reasonable efforts.

c. In case no settlement can be reached through negotiation as set out in subsection b. either party may provide notice to the other that if the dispute is not settled by negotiation within thirty (30) days of delivery of the notice, the dispute shall be finally settled by a single arbitrator appointed in accordance with the *Arbitration Act* of Ontario. The arbitration shall take place in Ottawa, Ontario.

d. The decision of the arbitrator shall be final and binding upon both parties and may be enforced in any court to which any party is or may be subject by suit on the award (a certified or exemplified copy of such award shall be deemed conclusive evidence thereof and of the amount of the liability of such party) or by any other means provided by law. The arbitration expenses shall be borne by the losing party unless otherwise awarded by the arbitrator.

e. In the course of arbitration, this Agreement shall continuously be implemented by both parties except for the part that is under arbitration.

13.2 This Agreement must be signed on behalf of each party by someone with the authority under institution policies to enter into contracts on behalf of that party. This Agreement may be signed in counterparts, and each counterpart may be delivered by facsimile or signed PDF by email. Each counterpart shall constitute an original, and when taken together, shall constitute one and the same instrument.