THE DESIGN AND EVALUATION OF A SIMULATION-BASED BEHAVIOR CHANGE INTERVENTION FOR INDIVIDUALS WITH TYPE 2 DIABETES

by

Bryan Smith Gibson

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STATEMENT OF DISSERTATION APPROVAL

The dissertation of **Bryan Smith Gibson**

has been approved by the following supervisory committee members:

Charlene Weir	, Chair	**12/16/11** Date Approved
Jason Jones	, Member	**1/24/12** Date Approved
Robin Marcus	, Member	**12/16/11** Date Approved
Nancy Staggers	, Member	**12/16/11** Date Approved
Matthew Samore	, Member	**2/6/12** Date Approved

and by **Joyce Mitchell** , Chair of

the Department of **Biomedical Informatics**

and by Charles A. Wight, Dean of The Graduate School.

ABSTRACT

This dissertation describes a line of research that addresses translational research questions related to the use of computerized simulation to affect the knowledge, beliefs, motivation and self-management behaviors of individuals with chronic disease. The specific research projects focus on type 2 diabetes (T2DM) and physical activity as exemplars of a prevalent chronic disease and an underutilized self-management behavior, respectively.

We first describe a conceptual framework for the design of Consumer Health Informatics (CHI) applications. The design of an envisioned diabetes self-management application is described as an example of the application of design principles derived from this framework. Subsequent chapters describe tests of research questions related to this envisioned intervention.

The second chapter describes the development and preliminary evaluation of the interface for the intervention described above. The estimation of simulated glucose curves for individuals with T2DM is described. Next, the formative evaluation of a paper-based prototype based on those curves and a novel method to measure individuals' outcome expectations are described.

The third chapter describes a randomized experiment of a narrated simulation based on simulated glucose curves. This trial tested the question: can computerized simulations affect the beliefs and behaviors of individuals with T2DM? In this experiment participants' beliefs changed in accordance with the discrepancy between the presented evidence, and their prior beliefs, and in combination with the completion of a planning intervention, which resulted in significantly greater increase in physical activity

The fourth chapter describes a test of the question: can predictive models of the acute physiologic effects of behavior be individualized? In this study we compared different predictive modeling techniques and found that a mixed effects modeling approach improves in accuracy as the individual contributes more data. This result is foundational to the development of the next generation of our simulation-based intervention, and has implications for CHI as a field; these are discussed.

The dissertation concludes with a review of the strengths and limitations of the work described, a discussion of the implications of this work for consumer health informatics and a brief discussion of the next steps in this line of research.

This thesis is dedicated to the memory of

Kyle Gibson

and is the product of the influence of many great teachers, particularly:

Barbara and Darcy Gibson

James Yedowitz

Eduard Gappmeier, PT, PhD

Robin Marcus, PT, PhD

Charlene Weir, RN, PhD

and my wife and editor

Pamela

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CHAPTER 1

A CONCEPTUAL FRAMEWORK FOR CONSUMER HEALTH INFORMATICS

1.1 Introduction

The promise of consumer health informatics (CHI) systems to impact health related behavior change remains largely untapped. CHI intervention studies have either found no effects or small effect-sizes. For an information system to reliably and effectively change users' behavior, the system's design must be based on an understanding of the mechanisms by which interactions with each component of the system will affect users' knowledge, beliefs, motivation and behavior. This dissertation describes work that attempts to address this important issue in the field of consumer health informatics, particularly the issue of the self-management of exercise for patients with diabetes.

In this dissertation we begin with a conceptual framework for the design of consumer health informatics behavior change interventions. The purpose of this framework is to translate evidence from the psychology literature into a set of design principles for consumer health informatics systems in order to improve the predictability and efficacy of IT interventions. The resultant design principles for CHI systems are based on established evidence of efficacy but which have seen only limited translation into the design of CHI systems. Related to these design principles is a group of hypotheses that are particularly amenable to testing in CHI research. The remaining three chapters of this dissertation describe research that applies some of the design principles and tests hypotheses derived from the conceptual framework. The context of this research is the design and development of an application that is intended to promote physical activity as a self-management behavior in individuals with Type 2 Diabetes

This introductory chapter begins with a brief overview of the epidemiology and health effects associated with Type 2 Diabetes (T2DM), followed by a definition of diabetes self-management and a review of the role of physical activity in T2DM self-management. A conceptual framework for CHI applications is then described. Studies of computer-based interventions to promote physical activity in individuals with diabetes are then specifically reviewed in terms of the conceptual framework. Evidence of the importance of the constructs included in the conceptual framework in the broader domain of consumer health informatics is then summarized. A series of design principles and related hypotheses for CHI systems that are based on the conceptual framework are then proposed. Next the design of a diabetes self-management application that is intended to instantiate some of the design principles is described. The specific research questions tested in the three main chapters of this dissertation are then discussed.

1.2 Specific Aims

The specific aims of the research described in this dissertation are:

1. To test the usability of an interface for the proposed diabetes self-management application.

2. To test the efficacy of a computerized simulation in changing the knowledge, intentions, beliefs, and short–term behavior of individuals with Type 2 Diabetes

3. To develop and test a method to individualize the outcomes presented in the simulation.

1.3 Type 2 Diabetes Epidemiology and Health Effects

Type 2 Diabetes Mellitus Type (T2DM) is a chronic, progressive endocrine disease which affects approximately 22 million Americans.[1] Type 2 Diabetes is associated with older age, obesity, family history of diabetes, history of gestational diabetes, impaired glucose metabolism, physical inactivity, and race/ethnicity. T2DM is a significant cause of morbidity and mortality, and is the leading cause of adult-onset blindness, nontraumatic amputations, and kidney failure among adults in the US and is the seventh leading cause of death. [2]

The prevalence of T2DM has been rising dramatically in the last 20 years: from 1990 to 2009 the age-adjusted incidence of diabetes increased 131% from 3.8 to 8.8 per 1000 population. [3] This increase in disease incidence is paralleled by the increase in obesity in the US population, which, according to NHANES data, increased from a prevalence of 22.7% in 1988-1994 to 33.9 % in 2005-2008. [4]

1.4 Self-Management of Diabetes and the Role of Physical Activity

The American Association of Diabetes Educators (AADE) has identified seven behaviors as the components of diabetes self-management. These are: healthy eating, being active, monitoring, taking medication, problem solving, reducing risks and healthy coping. [5] In 2007 the society commissioned and published systematic reviews of the efficacy of each of these behaviors and of the efficacy of interventions intended to facilitate each behavior.

Included in the AADE's systematic review of physical activity was the observation that although being physically active is among the most efficacious of the self-management behaviors,[6] it is also the self-management behavior least often performed by individuals with T2DM.[7] We will briefly summarize evidence for this important point.

In individuals with T2DM, physical activity has been shown to positively affect insulin resistance,[8] pancreatic beta cell function,[9] acute glycemic control,[10] hemoglobin A1c,[11] visceral adiposity,[12] blood pressure,[13] lipids [14] and cardiorespiratory fitness. [15] The potential for improvement in fitness with regular physical activity is particularly important. A recent retrospective review of 2,867 veterans with T2DM found that regardless of age, cardiorespiratory fitness was significantly associated with risk of mortality during the 7-year follow-up: for each 1 MET increase in exercise capacity, risk of mortality decreased by 18% (95%CI=0.79-0.86). [16] Since physical activity is the only known mechanism by which to increase an individual's cardiorespiratory fitness, this suggests that increased physical activity reduces risk by at least one unique mechanism (e.g., fitness) as well as affecting several intermediate outcomes which are shared with other self-management behaviors (e.g., glucose, blood pressure, lipids). As stated above, most individuals with T2DM are insufficiently active. A recent U.S. population-based survey including 3,897 individual with T2DM found that < 30% of individuals with T2DM performed the recommended 15O minutes/week of moderate intensity physical activity. [17]

In this dissertation we describe research that is focused on the promotion of physical activity as a self-management behavior in individuals with T2DM. We have focused on this behavior precisely because it is efficacious and the majority of individuals with T2DM do not perform it.

1.5 A Conceptual Framework for the Design of Consumer Health Informatics Applications

While the AADE's conception of self-management described above identifies self-management behaviors that are efficacious, it does not identify specific mechanisms by which these behaviors can be facilitated in individuals who are not performing them. In this section we propose a conceptual framework that addresses the mechanisms by which self-management behaviors can be facilitated via the use of specific software functions.

The focus of our conceptual framework is on the design of informatics solutions to affect users' behavior. As a result of this focus, the framework integrates constructs across several psychological theories. Our premise is that the self-regulatory processes (goal oriented thoughts and behaviors) needed for effective diabetes self-management can be facilitated through interaction with information systems. In other words, the use of self-management systems can directly impact a user's behaviors. The foundational concepts of self-regulation, mental simulation and dual process models are presented first because they are central to our framework. The conceptual framework, which includes two groups of targets and five groups of self-regulatory processes, is then described.

1.5.1 Self-regulation

Self-regulation refers to the process by which people control, direct and correct their own actions as they move toward or away from their goals. Self-regulation is often conceptualized as a feedback loop between *goals*, *monitoring* and *action.*[18] Diabetes self-management provides an example: an individual may have the *goal* to keep their blood glucose within a target range and use a glucometer to *monitor* their blood glucose.

If there is a discrepancy between the goal state and their current state, they might take *action* such as altering their medication regimen to bring their current state nearer to the goal state. Self-regulation is not a single concept but rather an overarching idea that has informed the design of many health related behavior change interventions. A central tenet of our conceptual framework is that self-regulatory processes are the antecedent psychological processes underlying self-management behaviors and should be the target of information system design.

The classic model of self-regulation is reactive: individuals modify their behavior in response to feedback. In many cases this is not ideal: an individual with insulin dependent diabetes who monitors their glucose after a meal notes that it is too high and reacts with extra insulin has already been exposed to a period of hyperglycemia. Newer perspectives on self-regulation involve a more anticipatory component. [19] It would be preferable if, in the previous example, the person had *anticipated* that the meal would result in high blood glucose and acted in accordance with the anticipated outcome (e.g., reduced the carbohydrates in the meal). This is called *Anticipatory Self-Regulation* and when successfully employed, may prevent the onset of acute problems. The next logical step: a person acting well in advance of a potential stressor to avoid its onset (e.g., a healthy person with a family history of Type 2 Diabetes loses weight to prevent the onset of disease) is termed *Proactive Coping.* The latter two forms of self-regulation (anticipatory and proactive) rely on mental simulation.

1.5.2 Mental Simulation

Mental simulations have been defined as "the imitative representation of some event or series of events" [20] and have been found to be a common mode of thought. [21] Mental simulations serve self-regulation in several ways; we will use the example of the insulin dependent person with diabetes who has been offered a dessert. A mental simulation might be used to anticipate potential problems (" if I eat this cake my blood sugar will be high in an hour"). A second mental simulation might serve to make projections about the impact of potential behaviors on the anticipated problem ("how much insulin do I need to take now to keep my glucose in range later?"). A third simulation might be used to plan the concrete steps needed for goal-directed action ("my insulin and glucometer are in the car, I need to get my keys from my jacket, get the stuff from the car, test my sugar, calculate the right amount of insulin and then inject it"). From these examples it should be clear that mental simulations are not simply "pictures in the mind's eye" but are complex structures, which stimulate emotional, cognitive, motivational, and behavioral domains within the simulator. In this framework we propose that external computerized simulations could augment individuals' abilities to recognize potential problems and to understand the effects of potential behaviors. We also present evidence that guided mental simulations in combination with the creation of specific behavioral plans strongly facilitate subsequent action.

1.5.3 Dual Process Theories

Dual process theories are those that explain differences in how individuals think and behave under various circumstances as a function of one of two cognitive systems. On the one hand, well-learned and well instantiated memory structures result in thinking that is associative, effortless, rapid, and usually unconscious (e.g., automatic stereotyping). In contrast, some thinking is slower, effortful, deliberative and usually conscious (e.g., solving a novel math problem). [22] In the past 25 years a growing body of evidence has demonstrated that processes previously assumed to be wholly conscious and deliberative (e.g., goal oriented thinking and behavior) can and do occur automatically (without conscious intent).[23, 24] This framework should therefore be described as a dual process framework since it addresses both conscious and unconscious paths towards changing behavior.

1.5.4 The Conceptual Framework

Our conceptual framework draws on concepts from several self-regulatory models of human thought and action. These include Social Cognitive Theory,[25] Proactive Coping Theory,[19] and Action Phases Theory.[26] This framework is not intended to be a new psychological theory; its purpose is to facilitate the translation of evidence from psychology into informatics research and practice.

Figure 1.1 is a graphical depiction of the conceptual framework. The two groups of targets of interventions are represented by rectangles. The psychological targets include knowledge and social cognitive determinants of behavior (e.g., self-efficacy beliefs, outcome expectancies). The behavioral targets are the specific targeted behaviors (e.g., increased physical activity).

There are five groups of self-regulatory processes (represented by rounded rectangles in Figure 1.1). *Monitoring* refers to the continuous perceptual attention individuals give to their current state. The *Comparative Thinking* group refers to mental processes the individual uses to compare current states and behaviors to goals, to past states and behaviors, to the states and behaviors of other people and to things that "might have been." The *Simulation* group includes mental processes the individual uses to evaluate the past and consider possible futures. The *Goal Setting* group includes the processes individuals use to form effective goals (reference standards) in relation to

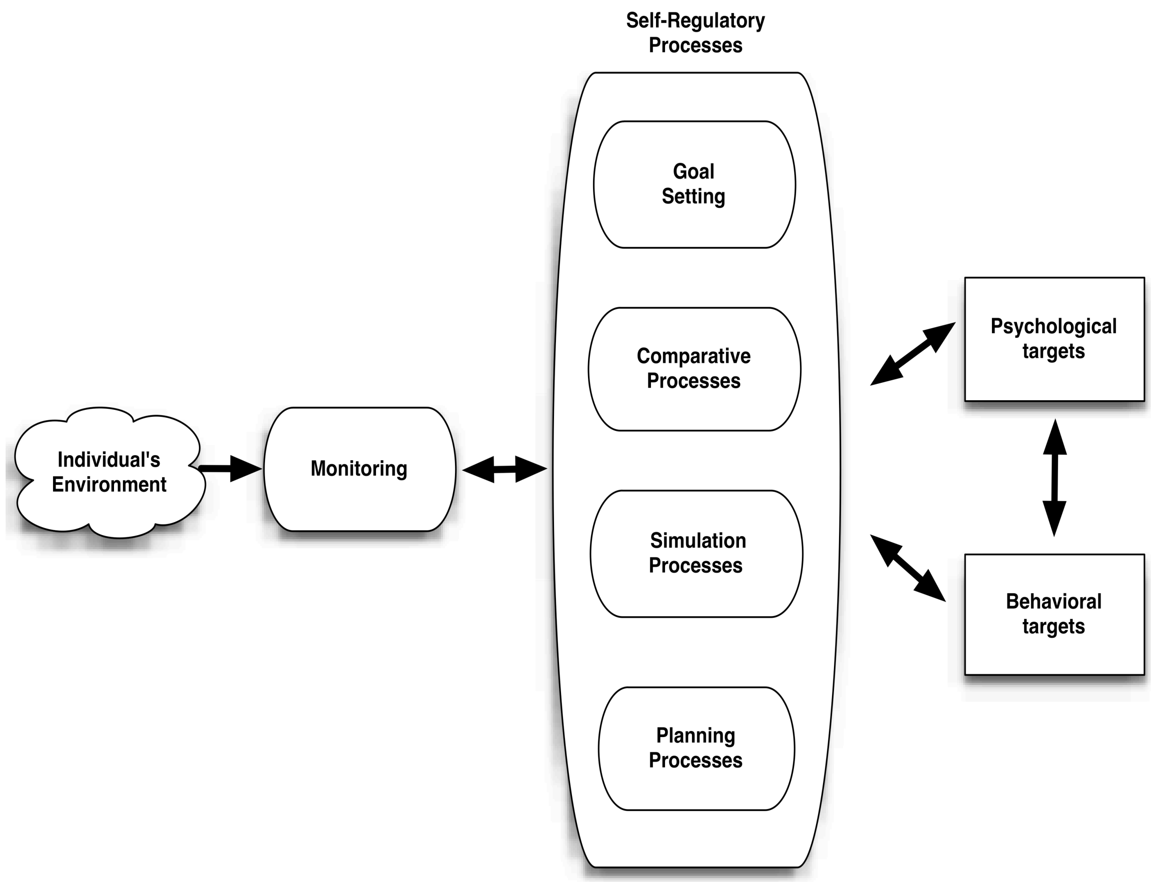

Figure1.1 The Conceptual Framework

specific behaviors. *Planning* refers to the explicit linking of intentions, goals and actions. The arrows represent bidirectional relationships between constructs (for the sake of clarity not all relationships are depicted).

1.5.5 Behavioral Targets

The previously mentioned AADE 7 behaviors (healthy eating, being active, monitoring, taking medication, problem solving, reducing risks and healthy coping) [5] form an evidence-based list of relevant behaviors for which there is evidence that increasing adherence to these behaviors results in improvements in both clinical outcomes and quality of life .

1.5.6 Psychological Targets

While knowledge is a prerequisite to behavior, the evidence suggests that knowledge by itself does not influence behavior. [28, 29] Knowledge consists of the mental representations that individuals have of the world. Knowledge has been categorized as: declarative knowledge (knowledge of facts and concepts) and procedural knowledge (knowledge of how to do something). [30] A third type of knowledge, structural knowledge, represents the functional relationships between pieces of declarative or procedural knowledge. This type of knowledge represents an individual's mental model of a domain. According to Jonassen: "Mental models are the conceptions of a system that develop in the mind. Mental models possess representations of objects or events in systems and the structural relationships between those objects and events." [31] An implication of this definition is that *accurate* mental models, which represent an accurate and functional integration of the three forms of knowledge should be the goal of patient education.

Beliefs are mental representations that have as their content relationships between concepts. Research based on Social Cognitive Theory (SCT) has developed an extensive body of evidence demonstrating the relationship between individuals' beliefs and their actions. Several beliefs are central to SCT and our framework; these include perceived self-efficacy, outcome expectations and outcome evaluation. [32] *Perceived Self-Efficacy* refers to the individual's belief that he or she can perform a given activity. *Outcome expectations* refer to the individual's belief about the likely outcome of a behavior. *Outcome Evaluations* refer to the value the individual places on the expected outcome of a behavior. These constructs are predictive of both the initiation [33] and maintenance [34] of health related behaviors.

Self-efficacy and outcome expectations are beliefs about particular behaviors in a given context and they change in response to the individual's interactions with the environment. [35] According to Bandura, there are four information sources by which an individual determines their self-efficacy (SE) beliefs: 1) enactive mastery (e.g., the individual performs the target behavior and is successful and SE increases), 2) vicarious experience (e.g., the individual observes other individuals failing at the target behavior and SE decreases), 3) verbal persuasion (another person convinces the individual that they are capable of the target behavior, SE increases) and 4) physiologic states (e.g., sweaty palms and a racing heart beat suggest to the individual that they are not confident). Although Bandura has focused his research on perceived self-efficacy, other authors have suggested that the mechanisms of enactive mastery, vicarious experience and verbal persuasion also determine individuals' outcome expectations.[36, 37]

1.5.7 Self-Regulatory Processes

Monitoring refers to gathering of information about one's states or behaviors. This may occur unconsciously. It is important to emphasize that this process is only the collection of information. Subsequent processes are involved with the interpretation and evaluation of that information. For the purpose of the paper we will distinguish between *monitoring* in which the users is actively involved in gathering information (the user is the mechanism to "pull" information) and *feedback* in which the user is the recipient of information which has been "pushed" to them.

Goals are integrated mental representations of desired states and behaviors that include values, expectations and associated behaviors. Some goal states are chronic (as in personality attributes) and others are acutely activated as in hunger states. Several descriptors of goals are important to our framework. First, *temporality:* goals can be elaborated and construed from the proximal and concrete ("I want to lose two pounds in the next week") to the more distal and abstract ("I don't want to die at 52 like my father").[38] Second, *Difficulty and Specificity*: meta-analyses of studies that compare the formation of difficult and specific goals (compared to easy, "do your best" goals) have consistently found positive medium-sized effects on subsequent action. [39] Finally *goal ownership:* goals that are self-determined, which the individual makes for himself, are more likely to be achieved than goals that are imposed externally. [40]

The group of comparative processes includes the mental processes individuals use to compare external referents to their beliefs about themselves, to that of other people, to their current state and behaviors and to their past states and behaviors. *Social Comparison* refers to comparing oneself to other people. It has been known for some time that if an individual compares themself to a worse-off other (*downward comparison*), their motivation for related behavior decreases. [41] Conversely, comparing oneself to a better-off other (*upward comparison*) increases motivation. *Goal comparison* refers to comparing an individual's current state or behavior to a goal state or behavior. This form of feedback is known to positively affect subsequent behavior. [39] *Temporal Comparison* refers to comparing oneself in the present to oneself in the past, and along with social comparison has recently been shown to facilitate increased self-efficacy. [42] These comparisons are continuously being activated as a function of the environment and can be either conscious or unconscious.

The simulation processes are mental processes the individual uses to evaluate and learn from past events and to recognize and evaluate possible future events. In contrast to the comparative processes, in which the referent is an actual person or piece of information, all of these processes involve mental simulation of potential situations. As described earlier mental simulations serve self-regulation in several ways: they allow individuals to anticipate potential problems (e.g.,"if I eat this cake my blood sugar will be high in an hour") this is referred to this as *recognition and appraisal of a potential stressor*. They are also used to estimate the impact of potential behaviors on the anticipated problem (e.g.,"how much insulin do I need to take now to keep my glucose in range later?") This is called *initial coping.* They also may consist of *reality checks* on specific planned actions (e.g., "I should take some more insulin but since I left it at home, I will need to do something else.")

Counterfactual thinking (CFT) is a particular type of simulation process in which the person thinks about how things "might have been." As with comparative thinking CFT can be classified by its direction: *upward* CFT refers to thinking that things could be better, *downward* CFT refers to thinking that things could have been worse. For example, a person with T2DM who eats a piece of cake for dessert and then notes that their blood glucose is too high may engage in upward CFT: "my blood sugar would have been better if I hadn't eaten that cake." Upward counterfactual thinking has been shown to increase motivation for future behaviors both in the laboratory [43] and in health related behaviors. [44, 45]

Planning refers to the deliberate linking of goals to actions. *Action planning* relates to desired mental or physical behaviors. An example of an action plan would be a specific plan that included the details of where, when, with whom, and any preparatory actions needed for a specific behavior. A significant body of evidence supports the effectiveness of action plans, particularly in the initiation of new behaviors. [46] *Coping Planning* is concerned with addressing the barriers to action. These barriers may be external states or events (e.g., limited sidewalks to walk on in a neighborhood) or internal states (e.g., moods, recurrent negative thoughts). Recent evidence suggests that coping plans increase in importance as the individual shifts from the initiation of behavior change to maintenance of the behavior.[47]

Implementation Intentions (IMPs) are a specific form of planning which facilitate the translation of intentions into action outside of conscious awareness.[48] IMPs take the form of "if situation X is encountered then I will perform behavior Y." IMPs appear to work by strengthening the mental link between the environmental cue and the target behavior. IMPs have been studied as a mechanism for many forms of behavior change and a meta-analysis reported a strong effect size (d= 0.59) on health related behaviors.[49] The impact of intentions on behavior is enhanced when IMPs are in place: the stronger the individual's intentions the more effective the plan is in translating that intention into action. [50]

1.5.8 The Role of Constructs in the Framework in Facilitating Behavioral Maintenance

Earlier in this chapter we suggested that this conceptual framework addresses behavioral initiation and maintenance and addresses both conscious and unconscious determinants of behavior. These two ideas are related. One barrier to behavioral maintenance is the cognitive effort required for ongoing self-regulatory behavior: individuals must continually expend mental effort thinking about and planning the desired behavior in order to "keep it up." *Ego Depletion* refers to the idea that the energy for conscious self-regulation is limited and when depleted from prior self-regulatory efforts, individuals are more likely to fail at subsequent self-regulatory tasks.[51] A hypothesis that naturally arises from this literature is that the maintenance of behavioral change is facilitated as control of behavior shifts from the conscious to unconscious mind. In other words, the more automated and habitual the behavior becomes, the more resistant it is to decay.

There are two well-studied mechanisms in the psychology literature by which to facilitate the automatization of behavior (facilitate behavior outside of conscious awareness). The first technique is to have participants form implementation intentions; there is laboratory evidence that after forming IMPs, individuals perform the target behavior without even being aware of the environmental cue. [52] The second technique that is known to facilitate automatized behavior is goal priming. According to Bargh, "priming refers to the passive, subtle, and unobtrusive activation of relevant mental representations by external environmental stimuli such that people are not and do not become aware of the influence of that stimuli." When individuals are primed with goals they act in accordance with those goals; this occurs even though the individual is unaware of "having" the goal. [53,54] In experimental studies goal priming is manipulated via two types of conditions: either the presence of subtle environmental cues such as a briefcase on a table (to suggest the goal of acting assertively), or by having subjects perform lexical tasks (e.g., individuals perform a word search and the words they find are semantically associated with the goal). It should be evident that these methods of priming goals could easily be integrated into informatics systems: the presence of specific cues in the user's information environment would serve as goal primes. These cues would not need to be brought to the conscious attention of the user.

Several intervention studies using implementation intentions (IMPs) have found significant effects on the maintenance of behavior change. [55, 56, 57, 58] In addition a "booster" intervention appears to provide additional benefits. [59] We suggest that by virtue of their potential to be ubiquitously available, CHI based interventions are ideally suited to determine the optimal frequency and intensity of application of these planning techniques to real world behavior.

1.5.9 The Interdependence of the Self-Regulatory Processes Described in the Framework in Diabetes Self-Management

Diabetes self-management will now be discussed as an example that illustrates the interdependence of the self-regulatory processes described in our framework. First, the individual must test their blood glucose (monitoring). To assess this information they must compare the reading to their knowledge of their state related goal (e.g., high and low glucose values for fasting vs. postprandial reading). If the individual determines that they are not "at goal" they must choose an action. To do so, they must understand the expected effect of each of the means at their disposal to affect their glucose (e.g., diet, physical activity, medications, stress reduction) in the given situation. This requires either comparative thinking (drawing on past experiences or the experiences of others to determine the expected effects of each behavior) or in the absence of personal experience, simulation processes (using available information to generate a mental simulation of expected effects). After choosing an action the individual must plan its execution. If the action is not immediate this process draws on the individual's knowledge and requires simulation ("where will I be at that time, what do I need to do to prepare?"). From this discussion it should be clear that the process of diabetes self-management requires each of the types of mental processes discussed in the conceptual framework and that each is insufficient to affect behavior on its own. With this in mind we suggest that interventions that intend to facilitate health related behaviors in individuals with chronic disease should address all of the areas of monitoring, goal setting, comparative processes, simulation processes, and planning.

1.6 A Review of Prior Informatics Research Intended to Facilitate Physical Activity in Individuals with Diabetes

In this section we will review prior work of internet-based or computer centered interventions that have addressed the specific behavior of physical activity in individuals with diabetes. This literature will be reviewed in terms of four themes which have been reported in reviews of consumer health informatics interventions: the efficacy of the interventions in promoting initiation and maintenance of behavior change, usage of systems over time, experimental isolation of the technology, and testing of the proposed mechanisms by which the interventions may change users' behaviors. We will summarize this review with a discussion of this literature in terms of the conceptual framework described above.

Several studies have demonstrated that internet-based interventions can positively affect physical activity behaviors in individuals with T2DM. However most have also reported diminished use of the system over time. This finding that use of web-based interventions decreases over time was also reported in a review of website delivered physical activity interventions by Vandelanotte who reported an average attrition of use over the course of 15 studies of 27% with a range of 7-69%. [60] Similar findings have been found reported in the specific are of promotion of physical activity in diabetes. For example, McKay et al. reported on an 8-week study that randomized individuals with T2DM to either a control condition of web-based information and graphic feedback on self-monitored glucose or the "active lives" intervention. The intervention included a guided process to complete the "5 steps to action": identifying the benefits of activity, setting a goal for moderate intensity activity, selection of a specific activity, scheduling times to be active and then identifying barriers to being more active. They reported that both groups reported very small increases in moderate physical activity (an increase of only 8 minutes/week) with no significant difference between groups. This is likely due to the markedly decreased use of the system over the 8 weeks of the study: only 46% of recruited participants visited the website with 77% of those hits recorded in the first 2 weeks of the intervention. [61] Similarly Liebrich et al. reported that use of the intervention version of their website was associated with a mean increase of 47 minutes/ week of moderate and vigorous exercise compared to the control group. However they also reported that login frequency decreased in 60% of the participants over the 12-week study. Finally Richardson et al. reported on a randomized pilot study which compared the use of structured physical activity goals (to be more active in specific bouts of increased walking) vs. lifestyle physical activity goals (to be more active by increasing walking spread through the day) while using pedometers which uploaded data to a website. These authors reported that both groups increased total walking by an average of 1,938 steps, with no significant difference between them but that adherence to the recommended walking and use of the system was lower in the structured goals group. [62]

To our knowledge the Richardson study is the only study that has related intervention components (lifestyle vs. structured goals) to engagement with the intervention. From the perspective of our conceptual framework this finding makes sense: individuals who could choose the means (time/place) by which to increase their walking would be assumed to experience greater *goal/plan ownership* than individuals who were assigned a specific means to address their goal, *and* therefore should be more engaged.

A second theme which has been reported in the broader consumer health informatics literature is that many studies have not isolated the effect of the informatics component of an intervention; in a review of 49 eHealth interventions which addressed physical activity and/or dietary behaviors in the general population, Norman et al. reported that less than half of these studies isolated the effect of the eHealth component of the intervention. [63] This theme is echoed in the literature regarding PA and diabetes: studies that have tested websites intended to affect physical activity behaviors in individuals with T2DM have not experimentally isolated the effect of the technology on users' behaviors. Several studies have included repeated direct interaction with a nurse or health coach [64, 65] as a component of the intervention. Others have employed the use of email between participants and a health coach. [66, 67] This factor makes it impossible to attribute the effects found to the informatics component of the intervention. In other words, the differences in the effects found in these studies could be attributed to variations in the abilities of the person with whom participants interacted.

Finally, few studies have tested the mechanism by which their interventions might change user's behaviors. For example Liebrich et al. randomized 49 individuals to use either an intervention website or a control website. The authors suggested that the intervention website was designed around social cognitive theory and measured 10 different constructs derived from social cognitive theory. However the only construct that was significantly changed in either group was an increase in behavioral capacity among intervention participants (self-reported ability to perform physical activity) and as discussed above found positive effects on physical activity. Therefore although these authors reported a significant effect on physical activity, their findings cannot account for how this change occurred. Only two studies have found that their web-based physical activity interventions directed at adults have influenced the proposed theoretical variables around which the intervention was designed. [68, 69] This consideration is extremely important. Without some knowledge of how an intervention affects outcomes, there is no basis on which to generalize the intervention's components to other settings or domains.

Due to limited descriptions of interventions in these papers, characterization of these studies in terms of the conceptual framework described above is only possible on an abstract level. Most of the studies incorporated monitoring, either glucose monitoring, [66] or behavioral monitoring. [61] Two studies addressed the setting of goals and employed goal feedback but descriptions of the constructs of goal specificity, and difficulty are missing. Two articles included the creation of plans for physical activity [64, 66] although details are lacking regarding the structure and content of these plans.

In summary, in the area of physical activity promotion for individuals with Type 2 Diabetes, prior work has been limited, and of insufficient quality to provide generalizable evidence. Based on the above review we conclude that there are fundamental gaps in the current literature related to the use of information-system or web-based interventions to promote physical activity in individuals with Type 2 Diabetes. First, studies are needed which isolate technological components of the intervention from interpersonal components. Second, studies that test the efficacy of specific intervention components in changing the determinants of behavior are needed before complex interventions multicomponent interventions can be tested for effectiveness. Finally, we conclude that the components of our conceptual framework—monitoring, comparative processes, simulation processes, goal setting, and planning—have been tested in this population to some degree but due to poor specification of intervention components in the published literature, it is nearly impossible to assess how and to what degree they have been tested.

1.7 Evidence of Efficacy of Constructs in the Conceptual Framework in Consumer Health Informatics

While evidence of tests of components of our conceptual framework in promoting physical activity in individuals with T2DM is minimal, there is evidence that web-based interventions that have implemented components of our framework (to at least some level of specificity) are associated with efficacy in promoting behavior change. In 2010 Webb et al. reported a meta-analysis of 85 studies of web-based behavior change interventions. Overall they found that interventions had a small but significant effect (d_+= 0.16), that increased use of theory in intervention design and evaluation was associated with greater efficacy, and that increased use of evidence based behavior change techniques leads to great efficacy.

In order to compare the use of specific behavior change techniques across studies these authors used a list of behavior change techniques and associated definitions to determine if a specific technique was employed in a particular study. The list of behavior change techniques used by Webb et al. was an expansion of prior work. In 2008, Michie et al., recognizing the need for standardization in the description of psychological interventions, reported on the development of a list of 26 behavior change techniques that according to expert consensus were believed to be efficacious. [70] The list was intended to provide standardized definitions of behavior change techniques which the expert panel believed were effective, thus allowing for the comparison of behavioral interventions across studies. In their 2010 meta-analysis of internet-based behavior change interventions, Webb et al. used an expanded 40-item version of the list of behavior change techniques developed by Michie to compare studies.

Table 1.1 relates the groups of mental processes in our framework to these behavior change techniques. The 13 behavior change techniques in Table 1.1 are those that were found to be efficacious in the meta-analysis by Webb et al. and that relate directly to the mental processes in the conceptual framework. These include 13 of the 15 most effective behavior change techniques identified in Webb's meta-analysis. The rightmost column of Table 1.1 represents the weighted average of the separate effect sizes of the studies that employed that behavior change technique. Webb at al. used Hedges *g* as the primary estimate of effect size for each intervention. Hedges *g* is the difference between the two means (for experimental and control conditions, respectively) divided by the pooled standard deviation.

Based on Table 1.1 it is apparent that many of the constructs included in the conceptual framework have been instantiated and tested in consumer facing behavior change interventions and they have demonstrated efficacy. However, a comparison of the definitions of specific behavior change techniques used by Webb et al. to the descriptions of the self-regulatory processes provided in our conceptual framework highlights important differences. For example in the definitions of behavior change techniques used by Webb the technique of *facilitate social comparisons* is defined as: "explicitly drawing attention to others' performance to elicit comparisons," the direction of comparison is not included in the definition. This is in contrast to the evidence presented earlier when discussing our conceptual framework: social comparison should increase

Table 1.1 Relation of groups of self-regulatory processes in conceptual framework to behavior change techniques identified in a meta-analysis of consumer facing informatics behavior change interventions by Webb et al. [71]

Group	Behavior change technique	Related Psychological Theory	Number of Articles	Effect size (d_+)
Knowledge	Provide instruction	SCT	25	0.2 (0.13-0.28)
Monitoring	Prompt self -monitoring of behavior	SCT	28	0.16 (0.07-0.24)
	Prompt self -monitoring of behavioral outcome	SCT/SRT	13	0.12 (0.03-0.26)
Comparative Processes	Facilitate social comparison	REM	4	0.29 (0.04-0.55)
	Provide normative information about other's behaviors	REM	16	0.18 (0.07-0.28)
Simulation Processes	Model/demonstrate the behavior	SCT	5	0.35 (0.01-0.70)
	Provide info on consequences	SCT	29	0.14 (0.06-0.21)
	Provide info on consequences for individual	SCT	12	0.14 (0.04-0.24)
Goal Processes	Goal setting	SCT	25	0.27 (0.16-0.38)
	Goal comparison - provide feedback on performance	SCT	19	0.22 (0.09-0.34)
Planning	Relapse prevention coping planning	Proactive coping	14	0.32 (0.17-0.47
	Action planning	Action phase	18	0.25 (0.13-0.37)
	Plan social support	Proactive coping	15	0.18 (0.10-0.27)

motivation *if* the individual is comparing themselves to someone who is better off (*upward social comparison*) while downward social comparison should decrease motivation.

Other definitions employed by Webb et al. do not account for the quality or specificity of how the behavior change technique was instantiated. For example, Webb defined outcome related goal setting, as “the person is encouraged to set a general goal that can be achieved by behavioral means." This definition does not address the components of goal difficulty, specificity, temporality or ownership included in our conceptual framework. Based on this discussion, we suggest that the small effect sizes evident for consumer facing informatics interventions found by Webb may be improved by increasing the quality and specificity of intervention components based on the evidence discussed in our conceptual framework.

1.8 Design Principles for Consumer Health Informatics Systems

The following design principles for consumer health informatics interventions are intended to provide actionable guidance regarding the implementation of our conceptual framework in consumer health informatics.

1.8.1 Systems Should Facilitate Monitoring

There are several mechanisms that CHI systems can employ to address this recommendation. First, when possible, systems can be designed to perform the function of monitoring automatically (e.g., a mobile phone based accelerometer can measure physical activity with no interaction required of the individual). This eliminates the need for the individual to remember to monitor and to spend the time and energy to do so.

Automatic monitoring may reduce individuals' response burden so that they have the time and energy to provide the types of data that require their actively involvement (e.g., self–report of pain). Active monitoring can be facilitated by systems that schedule and remind users of the need to monitor, by systems that allow for data capture from mobile systems and by storage of data that allows for the usage of captured data across platforms and applications. The first two considerations center on making monitoring easy to remember and convenient to perform; the second addresses the value that users derive from providing data, the assumption being that users will derive greater value from data that they enter once and use many times. It should be noted that monitoring in and of itself should be expected to have little effect on motivation and behavior. It is only when the other self-regulatory processes are applied to the collected data, either by internal mental processes or by external facilitation via software functions, that motivation and behavior will change.

1.8.2 Systems Should Facilitate Goal Setting

Systems should be designed to guide users through the process of goal setting. This process should facilitate the setting of specific, measurable, attainable, realistic, time based and difficult goals that the user considers personally relevant.

1.8.3 Systems Should Facilitate Goal Awareness and Negotiation

Since health related behaviors are often associated with goals generated by the patient and sometimes different or conflicting goals created by providers, systems should first facilitate shared awareness of goals: providers should be made aware of patients' goals and vice versa. Goal awareness for patients can be as simple as providing the discrepancy between a monitored value and the relevant goal (e.g., “your glucose is 183 mg/dl, Dr. Jones has set a goal of < 150 mg/dl for glucose 2 hours after eating.”)

In the cases of goal conflict, systems should highlight this discrepancy and provide the negotiation of goals between patients and their healthcare providers. It should be evident that this principle and other principles described in this paper are best instantiated in a system that allows for secure and efficient data transfer and communication between patients and providers and the longitudinal storage of all resultant information. Currently the only systems which provide these important functions are tethered personal health records.

1.8.4 Systems Should Provide Users with Comparative Functions

As described above, individuals compare their states and behaviors to the past (e.g., “How am I doing compared to how I was?”), they compare their states and behaviors to other people's (“How am I doing compared to others?”) and they compare their current states to counterfactual scenarios (“What might have been if I had done X?”) in order to understand their health in context. To facilitate this sort of thinking, systems should provide functions that allow for these types of comparisons. For temporal comparisons this requires a longitudinal data store in order to present relevant data. For social comparisons, this might require either the ability to compare oneself to aggregated data of others, or deidentified individuals. For comparison to counterfactual scenarios the comparison could be to similar cases or, via the integration of a predictive model, an estimate of the likely outcome of a possible past action.

1.8.5 System Should Increase User's Motivation through Framing of Comparative Information

Since upward comparisons are known to generally increase motivation, for the promotion of desired behaviors, feedback to users should be framed as upward comparisons. This includes the presentation of social comparisons, temporal and counterfactual comparisons. This design consideration for motivational interventions is employed in the design of the intervention tested in Chapter 2 of this dissertation.

1.8.6 Systems Should Help Users to Detect Potential Problems

In current CHI systems risk engines are the only components that make individuals aware of potential problems. These systems generally highlight outcomes that are temporally distant (e.g., 10-year risk of heart attack). We hypothesize that systems that incorporate predictive models to warn users of potential proximal problems could facilitate anticipatory self-regulation. Such models might predict a range of potential problems that vary in their immediacy from the next few hours to the next few months. For example a system that notes that the user is exercising and based on recent data predicts a high risk of exercise-induced hypoglycemia could provide an anticipatory warning and advice (e.g., "your last blood sugar was 98 mg/dl and you have not eaten, you should eat 10 gms of carbohydrate before exercising”).

1.8.7 Systems Should Help Users Understand Potential Outcome of Behaviors

Since individuals’ intentions to perform a behavior are partially determined by their outcome expectancies, systems should help individuals to develop accurate outcome expectancies. This could be facilitated by providing external referents that demonstrate the likely outcomes of potential behaviors. The form of these referents may vary depending on the outcome of interest. For example, if the outcome is an individual's functional capacity this may be best imparted as brief narrative (e.g. "before knee replacement she couldn't walk to the mail box, now she walks to the grocery store every day"). Alternatively if the outcome can be described numerically this may be presented graphically. We test the effect of a graphical simulation on individuals' outcome expectancies in Chapter 3 of this dissertation.

A hypothesis related to this principle is that the time frame of the presented outcome may be related to its effects on motivation: changing individuals' outcome expectancies for acute outcomes (e.g., change in blood glucose with exercise today) may facilitate greater intention for behavior change than one which changes outcome expectancies for distal outcomes. We hypothesize this effect based on the idea that thinking about the outcome of a proximal behavior (if the outcome is desirable) may more naturally lead to a concrete mental simulation of where, when and how the person might perform the behavior. This is akin to the spontaneous formation of an implementation intention. In contrast thinking about potential distal outcomes may not facilitate this spontaneous planning function. To the best of our knowledge this "temporal congruence" hypothesis has not yet been tested.

1.8.8 Systems Should Help Users' to Increase Their Self-Efficacy for Desired Behaviors

Since individuals' intentions to perform a behavior are partially determined by their self-efficacy, systems should help to increase user efficacy for desired behaviors. As described above self-efficacy can be facilitated via the use of verbal persuasion as well as via the facilitation of self-experimentation with graded tasks (e.g., "Go for a 10 minute walk today and add 1 minute every day until you reach a time that you feel confident that you can maintain"). Finally, self-efficacy can be enhanced via the use of modeling, (e.g., interactive simulations, photos, video, stories, etc.).

1.8.9 Systems Should Guide Users Through the Formation of Plans

Systems should facilitate users creating action plans and coping plans and should facilitate the formation of implementation intentions to enact these plans. Action plans should be emphasized for behavioral initiation. The use of coping plans should be facilitated as a mechanism to deal with barriers to behavior, and may increase in importance after the behavior has been initiated. Systems should guide users to mentally simulate their plans in order to make sure the relevant environmental cues are accessible and to ensure that the plans are realistic for the individual. We employed this design principle in the design of the narrated simulation tested in Chapter 3 of this dissertation.

1.8.10 Computerized Simulation as a Mechanism to Address Knowledge and Beliefs

In the next section we will describe an intervention that is intended to instantiate many of the design principles discussed above. We have centered this intervention on a computerized simulation because we believe they are ideally suited to changing users' beliefs and knowledge. First, by allowing individuals to play with relevant variables, simulation based learning promotes the construction of structural knowledge. [72] Second simulations can be used to compress time so that users can experience both the acute and chronic outcomes of their current and potential behaviors offering the potential to change user's outcome expectancies. We test this hypothesis in Chapter 3 of this dissertation. Third simulations can be used to model target behaviors and thereby change users' self-efficacy for that behavior. Finally computerized simulations can be informed by data, thus allowing for the personalization of the simulation. We test the potential to personalize our simulation in Chapter 4 of this dissertation.

Although a growing body of evidence supports the use of simulation in the education and training of healthcare workers,[73] little work has evaluated the use of simulation tools to motivate patients or change their health related beliefs. In the case of diabetes, computerized simulators of blood glucose variation in response to insulin and meals in Type 1 Diabetes have been developed. [74, 75-77] However, the two published evaluations of these systems, while encouraging (decrease in hypoglycemia, decreases in A1c), have been flawed by lack of a control group [75] small sample sizes, [78] and a failure to isolate the effect of the simulation from an in-person intervention. Importantly none of these studies addressed the critical question of whether these simulations could be used to change individuals' beliefs.

1.9 Description of a CHI System that Instantiates the Design Principles

In this section a proposed application to promote physical activity in individuals with diabetes is described. The application serves as an example of the instantiation of the principles of behavior change described in our conceptual framework. This includes application functions that support the mental processes of monitoring, goal setting, comparative processes, simulation processes and planning.

The application is centered on simulated glucose curves. These are employed as the interface for our intervention because they provide contextual information that typical self-monitored glucose values do not. When users first engage with the system they are oriented to the simulated glucose curves and the system by video: users view 1-2 minute videos that explain key concepts necessary to effective use of the system (e.g.," What is the glucose curve ?", "How do I use the simulator?", "How do I make my own glucose curve?"). The video library includes other short videos that explain key diabetes related concepts (e.g., "What is the dawn phenomenon?"); users can view these videos at any time.

The simulation has three modes that reflect different time frames of the effect of physical activity on the glucose curve. In the "What would have happened?" mode, users manipulate sliders for walking duration, walking intensity, and the time of day to walk. They then click a button labeled "what would have happened?" After the button click a short flash presentation plays showing a person testing their blood glucose, tying their shoes, walking (with a clock icon showing the duration), and then sitting down and retesting their blood sugar (this flash presentation is intended to model the desired behavior and therefore increase the user's self-efficacy). The user is then shown the expected change in the glucose curve due to walking. This presentation of the potential outcome as an upward counterfactual (how things would have been better if you had walked yesterday) is intended to increase the users' motivation to perform the behavior.

In the "What would happen in three months?" mode, users can manipulate the same sliders as above, as well as an activity frequency (days/week) slider to see the effect of a given exercise regimen on hemoglobin A1c. A similar flash presentation is played between choosing the exercise parameters and displaying the expected outcome. Again the flash presentation is intended to model the behavior. The presentation of the change in A1c is intended to augment the simulation process of determining the likely distal outcome of a proximal behavior.

In the "How will things change over years?" mode, users can manipulate a vertical slider to see the projected change In the glucose curve over years. They can also use the previously described sliders describing the walking parameters (duration, intensity, time of day and frequency to see how different exercise regimens will affect the curve at different points in the disease process. The presentation of the change in the glucose curve as A1c changes is intended to facilitate the simulation process of determining the likely distal outcome of a proximal behavior in this case inactivity.

After choosing a specific exercise routine users are guided to a calendar type interface to create a plan of where, when, for how long and with whom they will perform that activity in the next week. After creating the plan, users are instructed, via both text and audio, to mentally simulate their plan. This component of the application is intended to facilitate the formation of mentally accessible action plans.

Users are then prompted for their confidence in completing the plan as a percentage. If the users feel less than 70% confident they will complete the plan, the system advises the user to adapt the plan to one in which they are more confident. In addition to planning actions, users are prompted to identify potential barriers to implementing the planned activity (e.g.," I might feel tired") and to form planned responses to those barriers (e.g., "if I feel tired, I will remind myself that walking actually increases my energy"). This component of the application is intended to facilitate the formation of coping plans.

To facilitate follow-through on planned actions, users can have email or test reminders sent to them. Using the calendar interface they can choose the frequency, time, method and content of reminders sent to them. Reminders can be text based or email reminders. Email reminders can include short (2-4 seconds) video segments showing the expected change in the curve, the previously described flash segment (a person testing their glucose, walking and testing again) or user-provided images (e.g., pictures of the user's typical walking route). These reminders are hypothesized to facilitate action by serving as the environmental cue in an implementation intention or as a priming stimulus to prime the goal of being more active.

Users can place their current states and behaviors in context in the "How am I doing?" section. Users can view graphs of their current states (A1c, fasting glucose, postprandial glucose) and behaviors (minutes walking/week) in relation to their goal states and behaviors, in relation to their past states and behaviors and in relation to the states and behaviors of other individuals like them. These functions are intended to facilitate comparative thinking in the user, the content of these comparisons will be tailored to the individual user so that they serve as upward comparisons and therefore increase the user's motivation to be more active.

In the description of the simulation above, the user is shown the mean glucose curve for individuals with their A1c and the population effect of physical activity on the glucose curve. A novel component of this intervention is the capacity to personalize the curve and the simulated outcomes. Users can create their own glucose curve via seven-point glucose monitoring (premeal, 90 minutes postmeal, prebed). If the user provides their exercise related data (pre-and postwalking glucose, time since meal, duration, intensity) the underlying predictive model can be personalized so that the change in the curve is indicative of the likely outcome for that individual. By making the intervention content personally relevant this is hypothesized to facilitate engagement in the intervention. The possibility of personalizing the predictive model underlying this simulation is discussed in Chapter 4 of this dissertation.

In order to maximize the potential impact of this intervention, it should be deployed within a tethered PHR. This will allow for integration of the system with other

PHR functionalities, and facilitate patient-provider communication. The system should integrate with the PHR to access the user's data (e.g., self-monitored and fasting glucose and hemoglobin A1c), these data will be used to provide the comparisons shown in the "How am I doing?" tab. These data will also be used to inform the underlying predictive models if the person's opts-in to personalize the predicted changes in the curve. The system will integrate with the PHR's secure messaging to facilitate patient-provider shared goal setting, and shared understanding: patients can share summaries of their goals, behaviors and self-monitored values (e.g., glucose values presented as a curve) with their provider via secure messages. For convenience these summaries can be automatically sent to the user's healthcare provider immediately prior to clinic appointments. We hope that integration of the system with the personal health record will facilitate healthcare providers giving positive reinforcement for their patient's behavior changes and decrease the attrition of use commonly found in web-based behavior change interventions. To maximize the usefulness of this software we will also deploy a mobile phone application. The phone application will interface with the user's glucometer to upload self-monitored glucose data and present it to the patient in real-time as simulated glucose curves.

1.10 Overview of Subsequent Chapters

In this chapter we have described the epidemiology and health effects associated with Type 2 Diabetes (T2DM), defined diabetes self-management and described the role of physical activity in T2DM self-management. We then described a conceptual framework for Consumer Health Informatics applications and reviewed evidence of the importance of its constructs in both the specific domain of physical activity promotion in Type 2 Diabetes and in the domain of consumer health informatics. Finally we have proposed the design of a diabetes self -management application as an example of an instantiation of our conceptual framework.

We will now discuss the specific research questions that are addressed in the remainder of this dissertation. These research questions were tested using the development of the proposed physical activity promotion application as a specific platform but they generalize to the field of consumer health informatics.

In the second chapter of this dissertation we describe the development and preliminary evaluation of the interface for our intervention. First, we describe the derivation of simulated glucose curves. Next we describe the formative evaluation of a paper-based prototype based on those curves. Our goal in this pilot research was to determine if simulated glucose curves could effectively display complex diabetes related concepts and to test the feasibility of measuring individuals' beliefs using these curves.

In the third chapter we describe a randomized experiment in which participants watched a short narrated simulation that demonstrated both the acute and intermediate changes in the glucose curve with exercise. We were interested in determining if the discrepancy between individuals' outcome expectancies and the presented outcomes would affect subsequent outcome expectancies so that individuals' beliefs would change to be more in line with the presented evidence. The design of the intervention in this trial implemented several components of our conceptual framework. This included the presentation of potential outcomes to change outcome expectancies, the presentation of that information as an upward counterfactual to increase behavioral intentions in all subjects, and the writing of action plans with simultaneous mental simulation to facilitate subsequent behavior change.

Chapter 4 describes a test of a question that is central to our envisioned intervention: can predictive models be individualized so that as the individual contributes more data the accuracy of the model improves? In this study we used data aggregated from eight prior exercise trials to test different modeling techniques and found that a mixed effects modeling approach does in fact improve as repeated measures data are added by the individual. We discuss the implications of this for personalized consumer health informatics interventions.

In the conclusion of this dissertation we discuss the strengths and limitations of the work presented. We also discuss the implications of the presented work for the field of consumer health informatics and the next planned steps in this line of research.

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CHAPTER 2

DEVELOPMENT AND EVALUATION OF A SIMULATION-BASED DIABETES EDUCATION MODEL

2.1 Introduction

Type 2 Diabetes (T2DM) is a chronic, progressive endocrine disease affecting approximately 21 million Americans. [1] The primary abnormality is insulin resistance resulting in hyperglycemia. If hyperglycemia is persistent (particularly along with other risk factors such as elevated blood pressure or cholesterol) the disease is associated with significant morbidity and early mortality. [1]

In order to achieve glycemic control, individuals with diabetes need to manage their daily behaviors. Components of self-management include medication adherence, dietary regulation, physical activity regulation, psychosocial stress control and self-monitoring of blood glucose to assess glycemic control in real time and react appropriately. In order to make sense of a given blood sugar reading in the context of all these factors, individuals with diabetes need to develop functional mental models of the disease and the relationships between behavior and glycemia.

Prior studies have used the naturalistic decision making framework to analyze semistructured interviews with individuals with T2DM.[2, 3, 4] They have found that the rules-based education provided in many diabetes education settings is confusing to patients and too rigid to be applied by patients to their individual situation. As a result many of their subjects had faulty mental models of the disease.[2] These authors have offered the concept of "everyday expertise": individuals with diabetes need not be subject matter experts but they need cognitive skills which allow them to appropriately self-manage. In particular they need to develop skills in problem detection, understanding functional relationships and to develop problem-solving strategies. These authors have proposed simulation-based education as a potential method to improve patient cognition in these three areas.

By allowing the users to "play" with variables, simulation based education supports active and constructive learning. [5] These types of learning are hypothesized to result in deeper understanding of the domain. [6] In the context of promoting behavior change in individuals with chronic disease we hypothesize an additional benefit. We believe that by demonstrating divergent possible futures (e.g., "your glucose curve after breakfast with and without exercise") simulation can be used to induce *implementation intention planning*. Implementation intentions are specific intentions regarding the behavior that take the form of “if-then” logic. For example, having intentions such as "if my blood sugar is high after breakfast then I will go for a walk." This type of cognition has been shown to be a powerful mechanism for behavior change. [7]

We have developed a simulation-based module that is intended to help users learn to recognize problems, understand functional relationships and develop problem-solving skills related to diabetes. The purpose of this paper is to present early assessments of users understanding of the variables they will be manipulating, and determine if they have a sufficient understanding of the functional relationships between variables to develop appropriate hypotheses and understand the outcomes that are the feedback. Deficits in any of these areas will likely limit the effectiveness of the simulation in improving understanding and behavior.

In order to address these prerequisites to effective use of the simulator we have developed an introductory module. The introductory module is intended to serve three roles. It orients users to the novel interface: simulated continuous glucose monitoring (CGM) curves. The introductory module also explains variables which are poorly understood by many individuals with diabetes such as Hemoglobin A1c. [8] Finally it graphically demonstrates important functional relationships.

Our purpose in performing this pilot study was to:

1) test the feasibility of generating simulated CGM curves.

2) evaluate the understandability of a paper version of the introductory module.

3) pilot test methods to assess the mental models of users.

4) collect qualitative feedback on the interface for the purposes of improving its understandability and effectiveness.

2.2 Methods

2.2.1 Development of Simulated CGM Curves

The intervention is based on simulated Continuous Glucose Monitoring (CGM) curves. CGM is a method to estimate serum blood glucose using interstitial glucose values. Typically measurements are done at 5-minute intervals for 72 hours resulting in a curve representing diurnal variation in glucose. Our first step in creating our dataset of simulated CGM curves was to replicate the mean CGM curves for groups with a given A1c presented by Monnier et al. [9] (Table 2.1). These authors studied 130 individuals with DMII and stable A1c to determine the change in shape of the daily CGM curve with increasing A1c.

Table 2.1 Groups used by Monnier et al. to create glucose curves

Number of subjects in group	A1c	Duration of Diabetes (Yrs)
30	5.9 +/- 0.1	.7 +/-.3
17	6.8+/- 0.0	4.4 +/-2.3
32	7.4+/- 0.1	8.4 +/- 1.4
25	8.4+/- 0.2	10.0 +/-2.2
26	10.1+/- 0.1	11.5 +/-1.7

Our goal was to replicate these mean curves as closely as possible while eliminating some of the measurement error associated with CGM. Therefore we estimated the values at the start, end and at each change in direction of the curve. Between these points, the intervening values were derived: if the value did not appear to vary by more than 25 mmol/L (~4.5 mg/dl) the variation in values was assumed to represent measurement error in CGM and we assigned an identical value to each point on this section of our curve. If there was a difference of > .25 mmol/L between two points we used linear interpolation to derive the values in between our estimated values. In order to assess the accuracy of our estimation method we compared the means of our simulated curves to those published in Table 2 of Monnier in which they describe the means (and SE) for each of the five groups for 3 periods of the day (12-7 am, 7-10 am, and 10 am-midnight). For all 5 curves and all periods of the day the mean error in our curves was 3.3 mg/dl with a range of .42-11 mg/dl. We deemed this error acceptable for our current purposes of development and testing of the intervention. Next we interpolated curves for each 0.1% change in Hemoglobin A1c between the mean curves. As a result we have a dataset describing 41 curves, one for each .1% increment in A1c from 5.9% to 10.1%. The data were smoothed using a spline function to eliminate noise prior to plotting with the goal of making them more illustrative.

Our purpose in developing these simulated CGM curves is to support individualized education customized to the user by presenting them with a curve that is the best approximation of the truth for their A1c. Within the simulator these curves are integrated with predictive models describing the change in glucose (or A1c) with specific behaviors. This feedback is as accurate as possible for the individual's situation and is very congruent with the goals of personalized health.

The curves for this study were plotted without numeric values on the y-axis. Time of day was printed on the x-axis (Figure 2.1). The rationale for presenting the graph without numbers is based on recent literature suggesting that low numeracy has recently been implicated in poor understanding of diabetes self-management. [10] We have designed our intervention to limit this issue by avoiding the use of numbers. We are using the graphs to convey a conceptual understanding of key concepts in diabetes self-management.

Figure 2.1 illustrates an example simulated CGM graph. Graphs were plotted in R [11] using the simulated CGM data described previously. The graphs were modified by adding icons that are freely available on the Internet .[12] Sizing of icons and the addition of arrows to point out features of interest were done using Omnigraffle. [13]

For this pilot work we used a sample of 12 graduate students in Biomedical Informatics at the University of Utah (6 male, 6 female ages 23-52, median age 36). Per our inclusion criteria none of the subjects were health care providers, had diabetes, had first degrees relatives with diabetes or had lived with anyone with diabetes. Our intention in using this population was to recruit subjects who would be naive to many of the concepts in diabetes self-management.

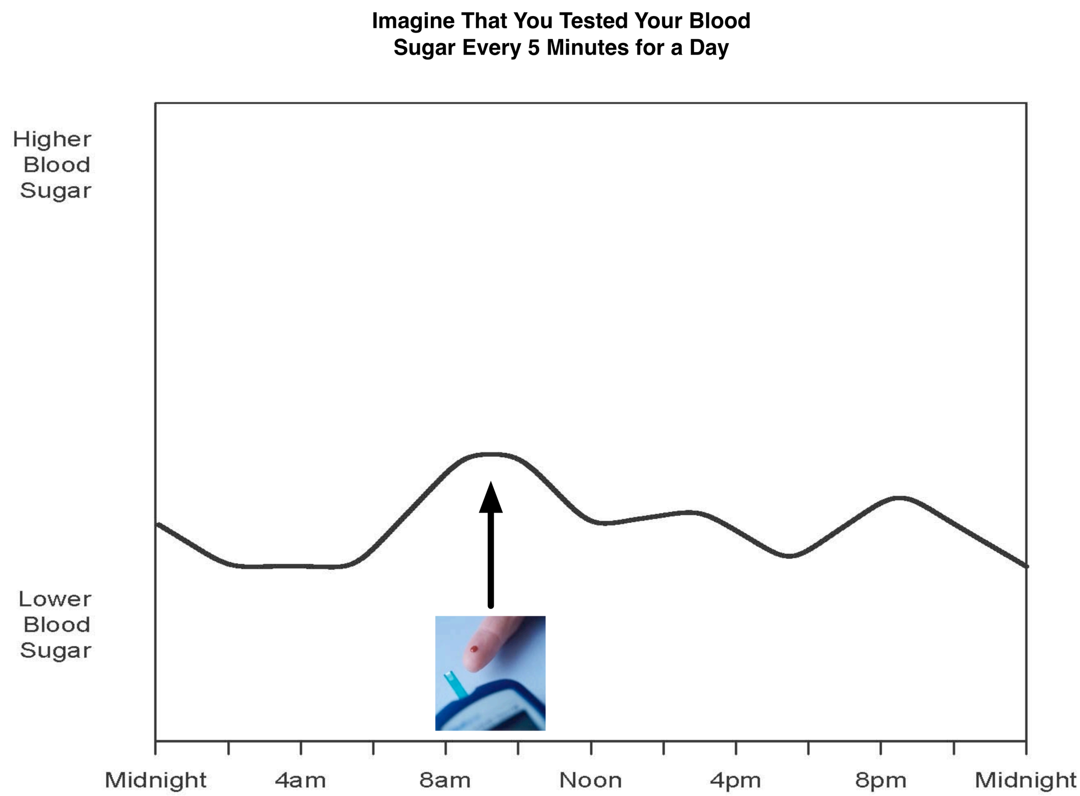

Figure 2.1 Sample Graph

Prior to the intervention written informed consent was obtained for all participants.

2.2.2 Intervention

The draft module was presented on paper and included nine graphs based on simulated CGM with accompanying text and icons. Each graph was accompanied by preparatory text and 1-5 questions testing the participants understanding of the graph itself and associated icons. Following each graph subjects were provided with an explanation of the concepts in the previous graph (Table 2.2). After viewing all of the graphs and answering the questions related to understandability, subjects were asked for their qualitative feedback on each graph, the accompanying text and icons.

Table 2.2 Concepts presented in the paper prototype

1. Blood glucose varies through the day
2. What is A1c?
3. What causes blood sugar to rise?
4. How do blood sugar and A1c change over years?
5. What are the risks of prolonged high blood sugars?
Drawing tasks **-** Between graphs 5 and 6 subjects were given two graphs depicting the CGM curve of a person with an A1c of 7.0 %. On the first graph they were asked to draw the curve of what they thought: "would happen if this person went for a 30 minute walk at 10am today." On the second graph they were asked to draw a curve of what they thought "will happen to the curve after 3 months of this person walking 30 minutes a day."
6. How does exercise effect blood sugar acutely? (Two graphs)
7. How does exercise affect A1c over 3 months? (Two graphs)

Approximately one day after completing the above survey, subjects were emailed a follow-up survey. The survey was comprised of 22 questions in three categories. The first group of questions related to concepts which were either incorrectly answered in the initial survey or were mentioned in the qualitative survey as being confusing.

The second section of questions were intended to more directly test the first stage of an effective simulation hypothesis, that is if participants understood the fluctuation in diurnal blood glucose well enough to answer questions which had not been explicitly explained in the intervention.

The next group of questions required the integration of concepts taught in the intervention but applied to a new problem. This is a cognitive activity at a higher level then recognizing variables, and/or understanding relationships. This was intended to assess the effectiveness of the intervention on the subject's ability to apply problem-solving and forecasting strategies. Finally, after each of the sections, participants were asked if they had visualized the graphs to answer each question. We hypothesized that subjects naive to the concept would refer to the graphs mentally to problem solve.

2.2.3 Analysis

For all questions in both the initial and follow-up survey we calculated the percentage of participants who answered correctly for each question.

2.3 Results

2.3.1 Understandability

Most of the intervention components had good understandability: 25/32 questions related to understandability were answered correctly by at least 83% of the participants. We examined the remaining 7 questions as areas of poor understandability. The 7 questions that were answered incorrectly by >/=25% of participants were related to two graphs. The first graph depicted the progression of A1c over a 10-year period and used two curves to represent two different people. The second graph used two curves to represent the curve for one person in two possible situations: a day on which they exercised for 30 minutes and a day during which they were sedentary.

2.3.2 Pictographs

Our icon for the kidney was only correctly identified by 75% of participants (2 participants thought it might be a lung); all other icons were correctly identified by 100% of participants.

2.3.3 Mental Models

For the drawing task there was a pattern of underestimation of the magnitude of blood glucose changes with acute exercise. Seventy-five percent of the participants underestimated the magnitude of the change and 16% overestimated the magnitude of the change. Conversely 75% of participants overestimated the duration of the deviation, while most (91%) participants drew the correct direction.

When drawing the expected change in A1c after 3 months of regular exercise the pattern was essentially reversed: Seventy-Five percent overestimated the magnitude in the change in A1c after 3 months of regular exercise while most (83%) got the direction correct.

When asked questions regarding the integration of more than one concept to solve a new problem the results varied. For a problem in which the user was asked to suggest the ideal time of day to exercise 91% answered correctly. Results were similar for the ideal time of day to inject short-acting insulin (83% correct), when asked to offer potential solutions to ameliorate hypoglycemia at 3 am only 50% of subjects offered a realistic solution.

When asked to recall the graphs to answer factual questions not specifically addressed in the intervention users did poorly: only 8% were able to correctly answer the question" blood sugar rises before eating breakfast" and only 33% were able to recall whether "blood glucose returns to fasting levels between meals."

When asked whether the concepts were new to them all but three concepts were previously known by all participants. Surprisingly for over half (58%) of participants the idea that diabetes is progressive was new. For the same proportion the concept that A1c is an estimate of the average blood glucose over a 2-3 month period was new. Twenty-five percent of participants were not previously aware that diabetes is associated with kidney disease.

Finally subjects were asked for their opinions as to what was clear in the graph icons and text. Recurrent themes were: suggestions for a legend for each graph, larger icons, the impression that the meal icons reflected specific foods rather than the concept of the meal (e.g., cereal instead of the idea of breakfast) and for two individuals confusion over whether higher blood glucose was "good or bad."

2.4 Discussion

In this paper we have described the development and formative evaluation of an introductory module for a simulation-based diabetes education module. From the results of our understandability test it is clear that our graphs representing two divergent situations simultaneously are confusing and do not serve our educational purpose. Our solution is to toggle between the two possibilities in our introductory module and to allow the user to do so in the simulation user interface. We hypothesize that it is important for users to see the two alternatives juxtaposed as this may induce implementation intention planning.[7]

Since we used freely available icons to depict concepts such as "healthy heart" we were surprised to see that with the exception of the kidney icon, most were well understood by our subjects. This may be due to our users' previous understanding of the disease and not the inherent understandability of the icons. Since our target population is older and less educated than the subjects in this study, we are concerned that our current icons may not be well understood by them. For our current purposes we plan to accompany the icons with text and audio to insure clarity of their meaning. Since several researchers are actively working to develop pictograph dictionaries and grammars, we expect in the future to replace our current icons with ones that are more thoroughly developed and tested for their inherent understandability.

Simulation requires three levels of mental models, understanding the meaning of information presented, forecasting from the information given and integrating information effectively to create an "if-then" intention. In our assessment of the mental models of these subjects two findings seem particularly important. First, our subjects consistently *underestimated* the magnitude of exercise on acute blood glucose. If this finding is replicated in our target population it could be useful in promoting behavior change. By pointing out that the effect is larger than the user expected we might facilitate the user actually performing the behavior.

Second, most subjects *overestimated* the magnitude of change in A1c with regular exercise over 3 months. In order to avoid our target user's discounting the benefits of behavior change we will redesign the interface for this feedback. In this study the values of the y-axis of the graph ranged from A1c 5.9-10.1. In order to present the change in A1c in a more motivational light while maintaining the truth of the relative change, we will change the presentation of A1c by reducing the range of the y-axis so that it is specific to the user's current state (e.g., your current A1c +/- 1.5%).

2.4.1 Implications

We believe that this approach should generalize to web-based patient education in general. By incorporating testing of our user's mental models into the design process we hope to maximize the educational and motivational effectiveness of our intervention.

2.4.2 Limitations

Limitations of this study include the use of graduate students to assess the understandability of an intervention for which the target population is a low literacy, low numeracy group. A second limitation is that this study only addressed one component of usability (the effectiveness of the interface in conveying information). Future work will need to address the efficiency of use our system and user satisfaction with it. A third limitation of this study is that the testing was done in a single block instead of as an iterative process of design-test-redesign -retest. After using the findings from this pilot study to inform a redesign we will test the module in our target population. The three components of simulation were somewhat inadequate in this study that likely hampered the formation of effective "if-then" intentions.

Future work will involve providing subjects with diabetes the opportunity to “play” (imagine sliders for variables such as pre-exercise glucose, exercise duration and intensity which users can move to see the effect on the curve) with the simulation and examine the effect of this intervention on the accuracy of user's mental models and behavioral intentions.

2.4.3 Postscript

After this study was published we performed additional usability testing of the user interface. This was done with 6 veterans at the Salt Lake City Veterans Administration Hospital. These participants had all been diagnosed with T2DM, were aged 53-67 and were taking oral antidiabetic agents. For the first 3 participants the methods were identical to the study described above. For this second iteration of usability testing the icons were redesigned. With these redesigned icons, all graphs were understood by all participants. The next 3 participants provided both written and verbal feedback on the narrative simulation described in the next chapter. Some redesign of the simulation interface was also done between testing with the last 3 subjects. These redesigned features include the addition of high and low control bars to indicate hyperglycemia and hypoglycemia, respectively, and the removal of the arrows on the left side of the graph (which provided redundant information).

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CHAPTER 3

EFFICACY OF A COMPUTERIZED SIMULATION IN PROMOTING WALKING IN INDIVIDUALS WITH TYPE 2 DIABETES

3.1 Introduction

Type 2 Diabetes (T2DM) affects approximately 24 million people in the United States, and is associated with significant morbidity and early mortality. [1] Regular physical activity has been shown to improve glycemic control,[2,3] reduce blood pressure, [4] reduce lipids [4] and improve cardiorespiratory fitness in individuals with T2DM.[5] These intermediate outcomes have been associated with diabetes-related morbidity and mortality.[6] Although physical activity is considered one of the three pillars of diabetes self-management, [7] most people with T2DM do not perform sufficient amounts. [8]

There are many reasons why individuals with T2DM may fail to perform an appropriate self-management behavior such as being active. In this study we used a brief, narrated simulation to address two factors that we believe are amenable to an informatics intervention: inaccurate mental models of the effects of behavior on the disease [9-11] and difficulties in translating good intentions into action. [12]

3.1.1 Glucose Curves

The intervention in this study was based on simulated glucose curves. Glucose curves represent an individual's variation in plasma glucose through a day. Prior work suggests that glucose curves may be useful as an interface for educational and motivational interventions. Small trials of participants with Type 1 Diabetes have shown that classroom education using simulated glucose curves positively affects knowledge, [13] the frequency of hypoglycemic events, [14] and hemoglobin A1c. [14] In T2DM, interviews with individuals before and after viewing their own glucose curves suggest that viewing the curves appears to provide individuals with a greater understanding of the daily variation in glucose (particularly postprandial peaks) and may result in greater intention to perform self-care activities, including being more physically active. [15] We believe glucose curves offer value because they provide contextual information that individual self-monitored glucose values do not provide.

3.1.2 Theory of Planned Behavior

According to the Theory of Planned Behavior (TPB), an individual's intention to perform a behavior is a function of their beliefs. In this study we focused on a particular type of belief: *Outcome expectancies*. Outcome expectancies are an individual's belief regarding the likely outcome of a given behavior. The intervention version of our simulation demonstrates the expected change in the glucose curve with both a single walk as well as regular walking over time.

Prior work has shown that outcome expectancies are related to self-care behaviors in individuals with T2DM [16-19] and that individuals with T2DM generally have low outcome expectancies regarding the effect of exercise on blood glucose. [19] We are not aware of studies that have attempted to *change* outcome expectancies in this population. In general, interventions targeted at outcome expectancies related to physical activity have shown limited efficacy in most populations. [20]

3.1.3 Implementation Intentions

While the beliefs included in the Theory of Planned Behavior have been shown to be predictive of the intentions of individuals' with T2DM to be physically active, [16] changes in behavioral intention are only moderately predictive of actual changes in behavior. [21] *Implementation intentions* (IMPs) are if-then plans linking specific cues in the environment to a desired behavior. IMPs have been found to be strongly effective in translating intentions into action. [12] Recent evidence suggests that individuals who mentally simulate the behavior as they create the implementation intention are even more successful in acting on their intentions. [23, 24]

The intervention version of our simulation guided participants through writing an action plan for walking while concurrently mentally simulating the planned behavior. In this plan participants indicated where, when, with whom, and for how long they would walk for each day in the next week.

Our hypotheses in this trial were: 1) individuals viewing the intervention version of the narrated simulation would report more walking in the subsequent week than control subjects; 2) Changes in outcome expectancies for intervention participants would vary as a function of the discrepancy between the effect presented in the simulation and the individual's prior beliefs. Finally, we hypothesized that overall both groups would increase in behavioral intentions to walk in the subsequent week, and in diabetes related knowledge.

3.2 Methods

3.2.1 Participants

Participants were recruited between March 2010 and August 2011 at the George E. Whalen Salt Lake City VA Medical Center (SLCVA) in primary care clinics, diabetes education and weight management classes, at a biweekly diabetes exercise group at the University of Utah, at a community diabetes health fair and via an email to a diabetes related list serve.

Our inclusion criteria were that participants be between 30 and 70 years of age, have a diagnosis of Type 2 Diabetes and the ability to speak English fluently. Participants with a diagnosis of dementia or severe mental disease, using insulin, or microvascular or macrovascular complications of diabetes were excluded. The rationale for these last two criteria was twofold: first the content of the narrated simulation is geared towards individuals on oral medications and second to minimize the risk of walking-induced hypoglycemia, foot ulceration or cardiac event. Initial recruitment efforts were exclusively among veterans at the Salt Lake City Veterans Administration Healthcare System (SLCVA) aged 40-60 years old; however, due to slow recruitment, in June 2010 recruitment was expanded to the larger community and the age range was expanded.

3.2.2 Settings

The study was conducted in a location convenient to the participant. These locations included the Salt Lake City VA library, a room adjacent to the exercise room at the diabetes exercise group, a table at a diabetes health fair, a meeting room at a public library and a private office. All meetings were between the principal investigator (BG) and individual participants.

3.2.3 Description of the Simulation

The narrated simulation is based on simulated glucose curves. [26] Concepts are presented using the curves without numbers, supplemented by simple icons. A voiceover and music soundtrack accompany the narrated simulation. Table 3.1 lists the concepts addressed in the narrated simulation and the time used to explain each concept.

Participants were shown one of two versions of the simulation. The intervention version and the control version were identical through the first 7 minutes and 45 seconds (Figure 3.1).

3.2.4 Drawing Tasks

At this point in the narrated simulation, participants were shown a glucose curve of an individual "who has had diabetes for a few years" and the voiceover asked them to imagine that the curve was their glucose curve from yesterday. Using a paper copy of the curve on the screen (Figure 3.2), participants were asked to draw what they think the curve would have looked like if they had gone for a "30-minute walk yesterday an hour after breakfast." As a second drawing task participants were shown the same curve of an individual "who has had diabetes for a few years," asked to imagine that it was their curve from yesterday and asked to draw what they think the curve would have looked

Table 3.1 Concepts included in the narrated simulation and timing

Concept	Timing
What is the glucose curve?	1:40
When is blood sugar highest and when is it lowest?	: 20
How do meals affect the glucose curve?	: 30
What is the dawn phenomenon?	: 30
What is the safe range of blood sugar?	: 40
What is Hemoglobin A1c?	: 15
How does the blood sugar curve change (over years) as A1c increases?	1:40
Why is high blood sugar bad for you? (Includes photographs of individuals with microvascular complications)	1:40
How are changes in A1c associated with complications?	: 20
What can you do today to control your blood sugar?	: 35

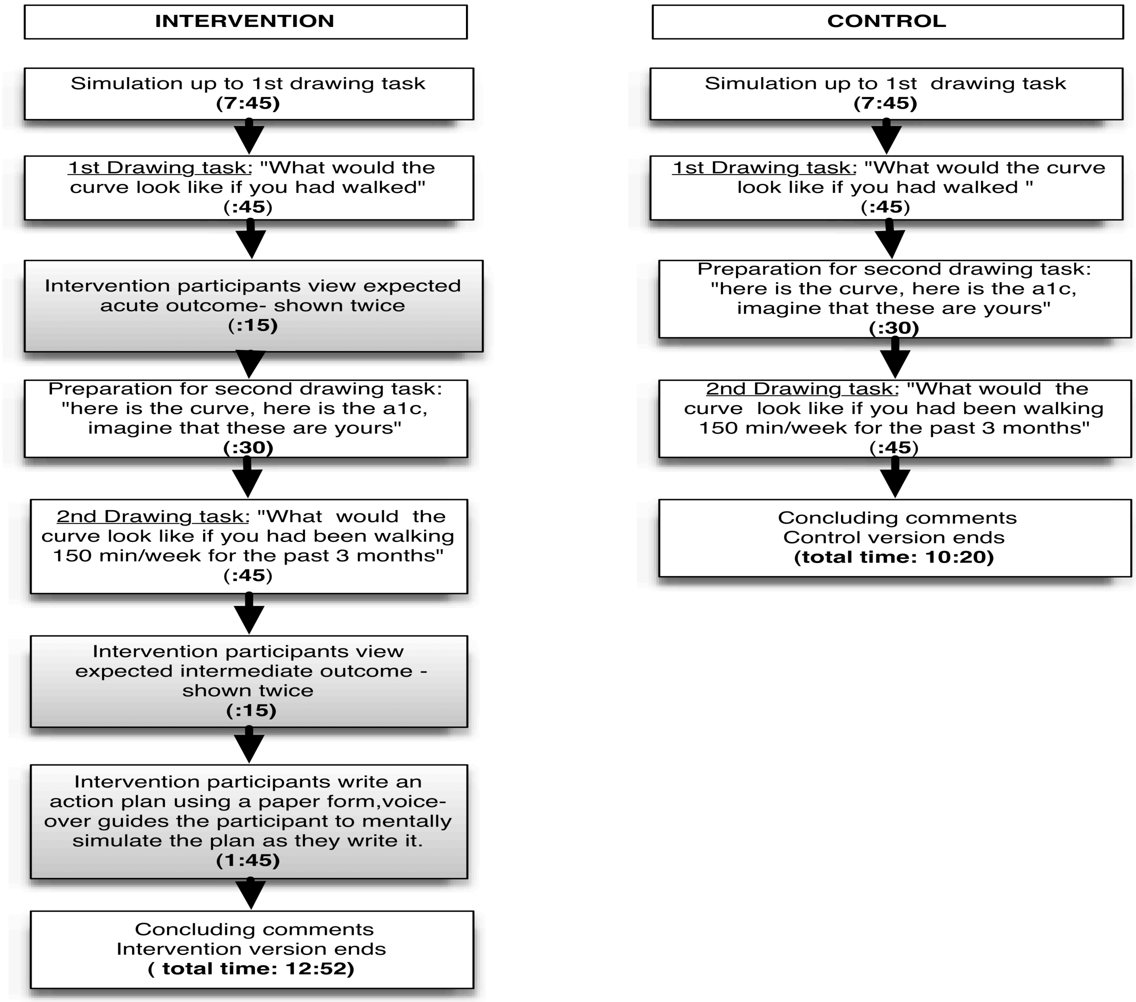

Figure 3.1 Simulation Procedures

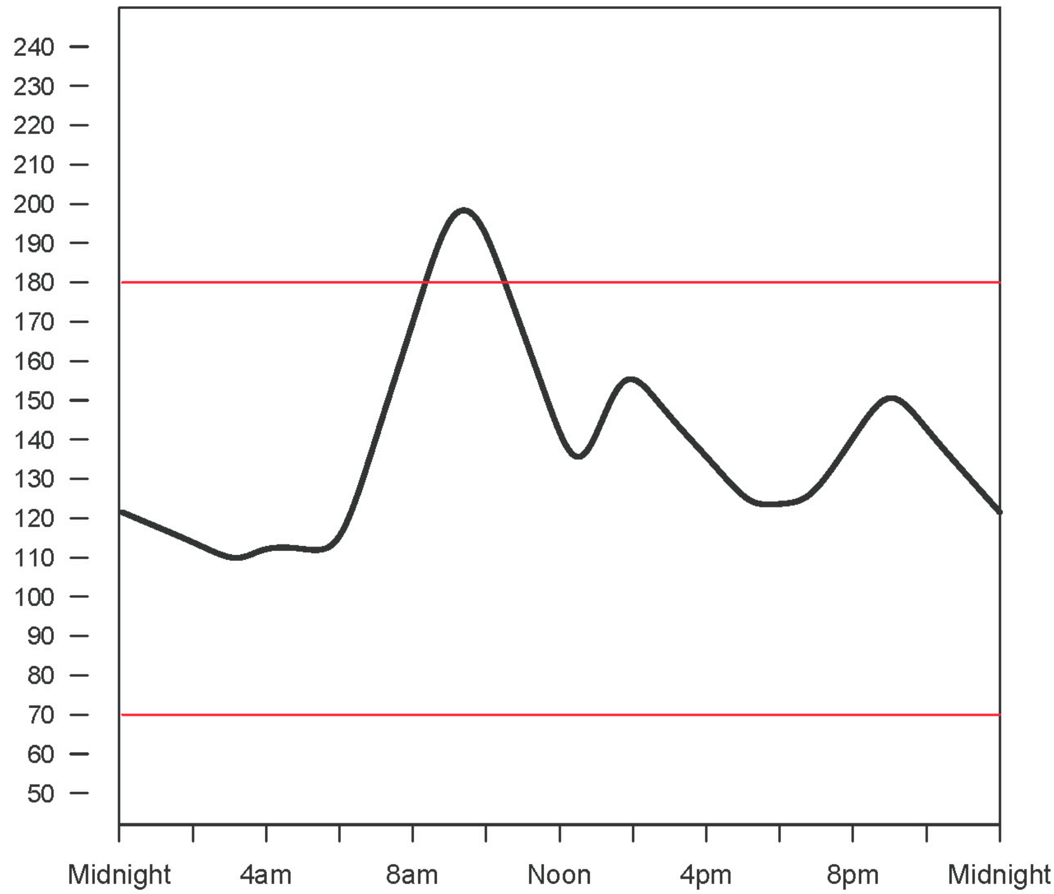

Figure 3.2 Glucose Curve Used in Drawing Tasks

like if they had been walking 5 days a week for 30 minutes each for the past 3 months. The purpose of these two drawing tasks was to capture the individual's outcome expectancy regarding the change in glucose with a single walk and the change in A1c with regular walking. The advantage of this method is that it allowed us to measure the individuals' outcome expectancy across three dimensions: the magnitude, direction and duration of the change in the curve.

3.2.5 Difference Between Control and Intervention Conditions

The control version of the narrated simulation ended after the two drawing tasks. In the intervention version of the narrated simulation, after completing each drawing task, viewers were shown the expected change in the curve. They were then guided by the voiceover to complete a paper plan of their walking over the next week: how many days they will walk, which days they will walk, how long each walk will be, in what location they will walk, at what time of day, with whom, and any preparatory actions they will take to facilitate the plan (e.g., put walking shoes in car) (Figure 3.3). As participants completed the paper plan, the voice over guided them to mentally simulate the plan. These procedures were specifically designed to facilitate the formation of implementation intentions (IMPs) in the minds of the participants.

3.2.6 Motivational Components of Both Versions of the Simulation

We hypothesized two components of the simulation might increase behavioral intentions for both groups. First, in the elicitation of individuals' outcome expectancies via the drawing task, the potential outcome of exercise is framed as an upward counterfactual (how could things have been better? "what *would have* happened if you had exercised?"). This was done based on theory [27] and evidence indicating that upward counterfactual thinking facilitates behavioral intentions. [28] Second, the narrated simulation presents the long-term outcomes of being sedentary to both groups ("here is how the glucose curve changes over years if you don't eat right and exercise regularly.") We included this component based on Williams' suggestion that the construct of outcome expectancy in physical activity research should incorporate both the positive effects of increased activity and the negative effects of being sedentary. [20] We included these components because we wanted to maximize intentions in the intervention group

Make a Plan for Your Walks over the Next Week

How many days in the next week do you plan to walk ?______________________________

	Sunday	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**
Where will you walk? (ex: In the park)							
At what time of day will you walk? (ex: 5:00 pm)							
For how long will you walk? (ex: 30 minutes)							
With whom will you walk? (ex: With my friend)							
How will you prepare for the walk? (ex: Put my walking shoes in the car)							

Figure 3.3 Walking Plan Completed by Intervention Participants

prior to their writing the action plan for walking in the next week; this was based on prior evidence that implementation intentions are most effective when intentions are strong. [25] We did not manipulate these constructs across conditions in this study because our goal was to experimentally determine the effect of the combination of presenting potential outcomes and action planning on behavior.

3.3 Procedures

After completing informed consent, we collected the following measures: 1) demographic information 2) a 10-item version of the diabetes numeracy test, [29] 3) a 14-item questionnaire that measures constructs from the theory of planned behavior (TPB); this was developed in pilot testing using procedures described by Azjen, [30] 4) the short telephone version of the International Physical activity Questionnaire (IPAQ), a validated self-reported measure of physical activity over the last 7 days, [31] and 5) the 14-item Diabetes knowledge test [32] and the 5-item ABC test ,[33] both tests of diabetes-specific knowledge.

Participants then watched the narrated simulation on a laptop computer while wearing headphones. During the narrated simulation, all participants completed the two drawing tasks described above. To minimize demand effects the investigator left the room while participants watched the animation; most questionnaires were administered by paper. However, since the IPAQ was going to be readministered by phone a week later, this questionnaire was administered orally by the investigator during the in-person meeting.

After participants watched the narrated simulation, the 14-item TPB related questionnaire and both diabetes related knowledge tests were repeated. In addition, to measuring the degree to which participants felt that the information in the animation was personally relevant, participants answered two 7- point Likert-type questions: "I think the glucose curves in the movie were related to *my diabetes*" and "I think the complications shown in the movie *could happen to me."*

To conclude the in-person meeting, we asked participants about their qualitative impressions of the narrated simulation: what they liked and did not like, if there were parts of the simulation they found confusing and if there were concepts they would like to see presented in this manner that were not included in the narrated simulation. These questions were administered orally.

One week later, participants were contacted by phone. The IPAQ self-report measure of physical activity over the last 7 days [31] was readministered. This was followed by a questionnaire asking if the participant thought about the glucose curves in the week since watching the narrated simulation, and if so, did they think about them before, during or after eating, exercising, or testing their glucose. The purpose behind these last questions was exploratory for future work with this intervention.

3.3.1 Analysis

All analyses were performed using R, freely available statistical computing software. [34] We excluded 2 individuals from this analysis: 1 control participant who reported walking 35 hours/week at baseline and 1 intervention participant who reported walking 18 hours/week; these individuals' baseline walking was >= 2.5 standard deviations above the mean. In addition, including these individuals would have overestimated the effect of the intervention in our main hypotheses.

To test our primary hypothesis (the intervention version of the narrated simulation would more positively impact individual's walking), we used a linear model with intervention status and preintervention walking (minutes/week) as the covariates. We adjusted for significant between group differences in age and a near significant difference in baseline behavioral intent.

To test our second hypothesis (among intervention subjects change in outcome expectancies (beliefs) would be a function of the discrepancy between prior beliefs and those presented in the narrated simulation), we first needed to calculate the change in outcome expectancy and then calculate a score reflecting the discrepancy between the presented outcome and the individuals' expected outcome. Once these scores were calculated we used a linear model with an interaction between the discrepancy score and intervention status as a covariate after adjusting for age and base

Outcome expectancies were measured using the following questions on the TPB questionnaire: "Walking for at least 30 minutes will lower my blood sugar," and "Walking for at least 30 minutes/day, 5 days a week *over the next 3 months* will lower my Hemoglobin A1c." Participants agreed or disagreed on a 7 point Likert scale (see Multimedia Appendix 3). As suggested by Azjen, for each of the pre- and post-TPB measures the individuals' score for these two questions was averaged to reflect the overall construct of outcome expectancy.

A change score was calculated by subtracting the preintervention measure of line intent outcome expectancy from the postintervention measure.

We calculated the outcome expectancy discrepancy score by measuring the difference between the presented change in the glucose curve and the individual's outcome expectancy elicited in the drawing task. We scored each dimension of the individual's outcome expectancy (direction, duration and magnitude) according to whether the individual's outcome expectation was negative, neutral or positive. For example, if the decrease in the individual's drawn curve was greater in magnitude than the decrease in the presented curve (positive expectancy), this dimension was scored a

1. If the magnitude of their expectation was the same as the presented curve they were scored a 0 (accurate understanding). If their drawn magnitude was less than the presented curve they were given a -1 (negative expectancy). Since the direction of the change in the curve could only increase or decrease, individuals were scored 1 if their drawing reflected a decrease (a positive expectancy and accurate understanding) and -1 if their drawing reflected an increase in blood glucose post-exercise (negative expectancy). The discrepancy score used in the regression is the sum of all the dimension scores for both drawing tasks with possible range of -6 to 6. Figure 3.4 is a histogram of the distribution of discrepancy scores.

To test our secondary hypotheses (overall both versions of the narrated simulation would positively impact behavioral intentions and knowledge), we used paired t-tests to compare presimulation and postsimulation measures.

Finally, we conducted an exploratory analysis to inform future work by examining participants' responses to the qualitative questions of what they liked and did not like in the narrated simulation, what they found confusing and what they would like to see in future versions for recurrent themes. We also examined the proportion of individuals who reported thinking about the glucose curves in the next week and the context in which they reported thinking about them.

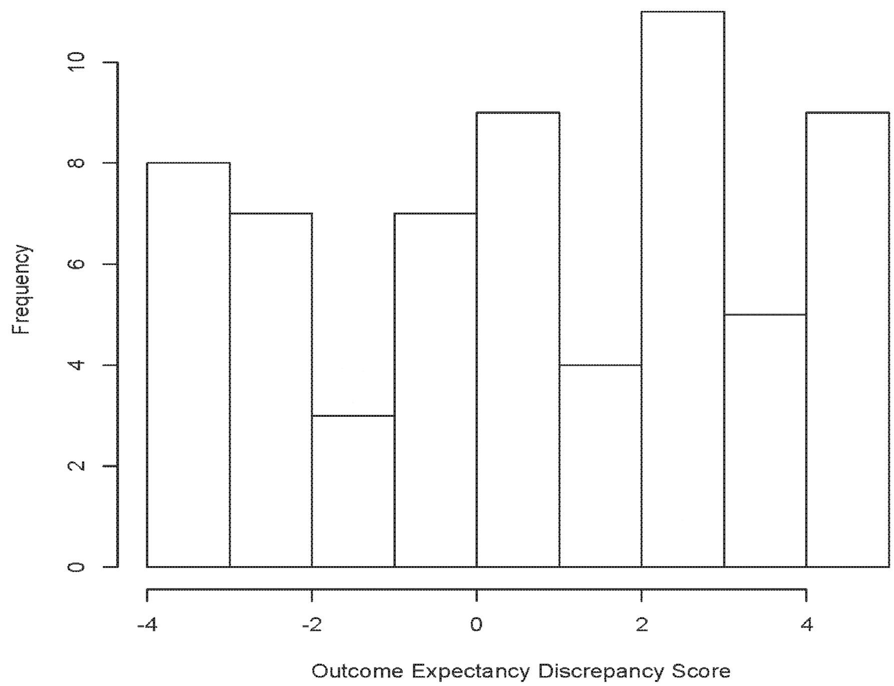

Figure 3.4 Histogram of Outcome Expectancy Discrepancy Scores

3.4 Results

3.4.1 Description of the Sample

Table 3.2 presents the baseline characteristics of the intervention and control groups. The randomization resulted in equal groups on all measures with the exception of age; the average age of the control group was slightly higher than the intervention group; in addition, a near significant difference existed in baseline intentions regarding walking in the intervention group.

3.4.2 Hypothesis 1

Our first and most clinically significant hypothesis was supported: Intervention subjects increased walking time more than control subjects. After taking into account baseline walking and adjusting for age and baseline behavioral intent, the effect of the intervention was an increase of 61.0 minutes (se= 30.5, t= 1.9, p= .05). Neither age (est.=-1.2, se= 1.9,t= -0.6, p= 0.5) nor baseline behavior intent (est.= 3.6, se= 9.5, t=0.3, p= 0.7) were significant predictors of the change in walking. Figure 3.5 presents the change in walking by intervention status.

3.4.3 Hypothesis 2

Our second hypothesis was supported: Among intervention participants, the discrepancy between the individuals' prior beliefs and the presented outcomes and was associated with individuals' change in outcome expectancy. The coefficient for the interaction between intervention status and discrepancy score was -.25 (se= 0.07, t=-3.2, p<. 01), indicating that the more negative the individual's baseline outcome expectancy the greater the improvement in their outcome expectancy.

Table 3.2 Baseline Characteristics of Participants

	Intervention Group	**Control Group**	**P-Value**
Sex [1]	20 M, 13 F	21 M, 11 F	0.87
Veterans [1]	10/33	12/32	0.72
Age [3](yrs)	56 (34-70)	61 (36-70)	0.015*
Years since Diagnosis [3]	7 (.02-20)	8.5 (.12-19)	0.96
Hemoglobin A1c [3]	7.0 (5.6-11.8)	6.9 (6.1-10.3)	0.63
Diabetes Numeracy[3] (scale=0-10)	8 (1-10)	8 (2-10)	0.34
Frequency of Self monitoring [3] (x/week)	5 (.1-21)	2.75 (0-21)	0.13
Have Email? [1]	29/33	29/32	0.96
Frequency of Non-Job Email Use [3](x/week)	14 (0-14)	14 (0-14)	0.65
Have PHR? [1]	12/21	11/21	0.93
Non- Walking Physical Activity [3] (MET*minutes/week)	960 (0-8820)	512 (0-8640)	0.12
Walking [3] (minutes/week)	90 (0-1080)	145 (0-2100)	0.27
Knowledge [3] (dkt, scale= 0-14)	12 (5-14)	12 (6-14)	0.55
Behavioral Intention [3] (scale=1-7)	5 (1-7)	6 (1-7)	0.08

1-Chi-Squared test, 2-unpaired t-test; values are mean (range), 3- Kruskal- Wallis test; values are median (range)

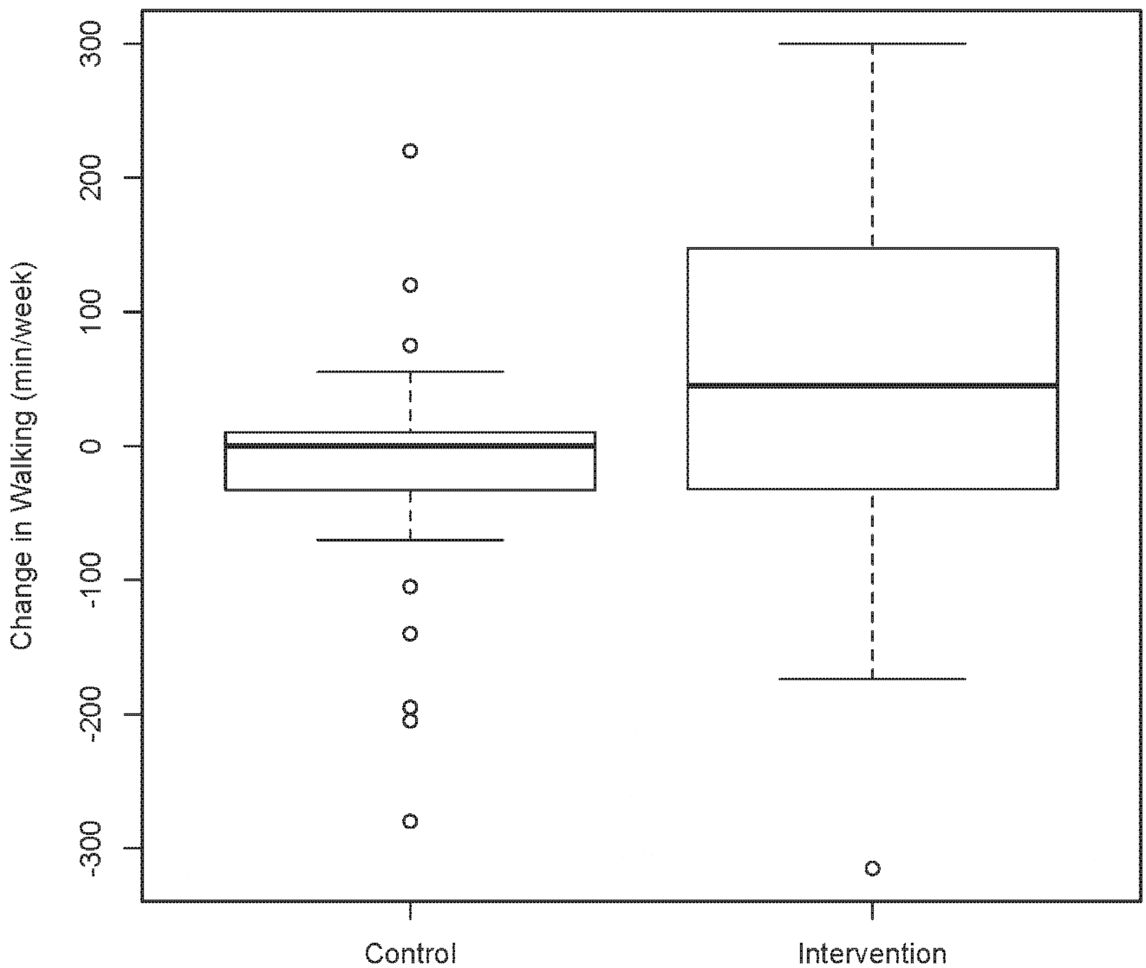

Figure 3.5 Change in Walking by Intervention Status

3.4.4 Hypotheses 3 and 4

Our secondary hypotheses were also supported; both groups increased in behavioral intentions; mean difference= 0.66 on a scale of 7 ($t = 4.5$, $df = 62$, p-value<0.001), and knowledge; mean difference= 0.38 on a scale of 14 ($t = 2.4$, $df = 62$, p-value = .02). Table 3.3 presents a summary of the hypotheses tested and their results. Table 3.4 presents the means and standard deviations for all outcome measures.

3.4.5 Qualitative Themes

Responses to qualitative questions were coded into general themes and the proportion of each theme was determined. When asked, "What were the things that you liked about the simulation?" 47.6 % of subjects' responses were coded as "informative": these included comments such as "I thought the simulation was very clear," and "I think it was better than what I got in diabetes education." Other themes that emerged were "Surprise": 11/65 subjects commented that they were surprised at the effect of walking on the glucose curve. A third theme was "Complications"- 7/65 of subjects reported liking the inclusion of pictures of individuals with complications, as 1 participant said she felt that this was "important for people to see what might happen to them." Finally, 5 participants reported that they had not seen or thought of glucose as a curve before and 4 participants reported that they were previously unaware of the dawn phenomenon.

Table 3.3 Summary of hypotheses and results

Hypothesis	**Model**	**Estimate**	**Standard Error**	**T Value**	**P-Value**
Walking will increase more in intervention subjects	Linear model regressing post -intervention walking on intervention status, pre -intervention walking adjusted for age and pre-intervention intent	61.0	30.5	1.9	0.05
Among intervention participants, change in outcome expectancy will be a function of the discrepancy between prior beliefs and the presented outcome	Linear model regressing the change in outcome expectancy on an interaction term between intervention status and discrepancy score, adjusted for age and pre-intervention intent	-0.25	0.07	-3.213	<0.01
Both group will increase in behavioral intention	Paired t- test comparing post intervention to pre intervention measure	0.66	NA	4.5	<0.001
Both groups will increase in diabetes related knowledge	Paired t- test comparing post intervention to pre intervention measure	0.38	NA	2.4	0.02

Table 3.4 Means (SD) for all outcome measures pre- and postintervention

Outcome Measure	Intervention Status	Preintervention	Postintervention
Walking	Intervention	182.9 minutes (245)	230.3 minutes (262)
	Control	203.5 minutes (203)	185.6 minutes (193)
Outcome Expectancy	Intervention	6.07 (1.1)	6.56 (0.82)
	Control	6.37 (.89)	6.69(0.55)
Behavioral Intent	Intervention	4.79 (1.62)	5.62 (1.80)
	Control	5.53 (1.60)	6.03 (1.24)
Knowledge	Intervention	11.15 (2.3)	11.71 (2.14)
	Control	11.29 (1.95)	11.48 (2.18)

When asked, "Were there things you did not like about the simulation?" Most participants (70%) answered, "No." Of those who provided specific negative feedback (13/65), 4 reported that the simulation contained "nothing new" or was "not interesting." Two participants, both of whom worked nights and slept during the day, reported feeling that the content of the simulation was not relevant to them. Three reported not liking the music or voiceover, 1 reported not liking the glucose curves, 1 reported not liking the drawing task, 1 reported not liking the numeracy test and 1 thought the simulation was too slow in the beginning.

When asked, "Were there parts of the simulation you found confusing or that brought up questions in your mind," most participants(90.7% or 59/65) answered "No." Of those who provided specific feedback, 3 reported finding the drawing task confusing and 2 participants reported not understanding the meaning of the curves.

When asked, "Are there things that were not in the simulation that you would like to see in a simulation like this?" 9 participants commented they would like to see the effect of different foods on the glucose curve, 5 participants wanted more information about how the disease progresses over time and whether it was reversible, 4 participants commented that they would like to see numbers on the curves, 3 participants commented that they would like to see more answers to the test questions addressed in the narrated simulation (not all the questions on the knowledge tests were addressed in the simulation), 2 commented that they would like to see the effect of insulin, and 2 control participants wanted to see the effect of exercise on the curve.

Although there was a small difference in the proportion of individuals who reported thinking about the glucose curves in the week following the simulation by condition (81.8% (27/33) intervention subjects, 68.8% (22/32) controls), this difference was not significant (chi-squared = .88, df=1, p=. 35). When asked whether they thought about the glucose curves in the context of specific self-management behaviors, the proportions for all subjects were as follows: when exercising (38/65), eating (35/65), testing their blood sugar (30/65). There was no difference between groups in the incidence of thinking about the glucose curves in these contexts.

3.5 Discussion

This study had two main findings. First, intervention participants who completed an action plan for walking in the next week reported significantly more walking in the subsequent week than control subjects. This finding is congruent with a large number of both laboratory and clinical studies that have found a positive impact of implementation intentions and action plans. [12] Our use of an action plan with simultaneous mental simulation of the plan is not novel. However, prior studies used a healthy university student population. [23, 24] This study used an older diabetic population.

Our second main finding was that intervention participants' beliefs changed in accordance with the discrepancy between their prior beliefs and the outcomes presented in the simulation. The idea that computerized simulations could change outcome expectancies was suggested by Bandura in 1999 [35] and is in line with his earlier work demonstrating that individuals' beliefs change as a result of their observations of the effects of their own and others' behaviors. [36] We are unaware of any studies that have translated these ideas into a patient-facing intervention. We believe this finding suggests that computerized simulations could be used much more broadly to change individuals' health related beliefs.

We are aware of only one other study involving glucose curves to promote physical activity among individuals with T2DM. Allen et al. randomized 52 individuals to one-on-one educational sessions. [37] The intervention session incorporated glucose curves to demonstrate the effect of physical activity on glucose. The session also included discussing the benefits of increased activity, assessing the individual's barriers to physical activity and self-efficacy for exercise, and providing an appropriate exercise prescription. The control session mentioned but did not stress physical activity as a self-management behavior for T2DM. At the 8-week follow-up, individuals in the intervention group had significantly greater improvements in self-efficacy for physical activity, accelerometer measured physical activity, hemoglobin A1c and BMI. Both our study and Allen's used glucose curves to promote physical activity in individuals with T2DM, but there are important differences. First, the proposed mechanisms are different: the Allen intervention was intended to increase physical activity by increasing participants' self-efficacy while our intervention was intended to increase physical activity by changing outcome expectancies and implementing an action plan. Second, the degree of experimental control is different: our study was a comparison between two computerized simulations that differed only in the inclusion of two components, but Allen's study compared in-person interventions that differed in many respects. Taken together, we believe the two studies provide evidence that the outcome expectancies, and self-efficacy of individuals with T2DM can be positively affected by modeling using glucose curves.

3.5.1 Implications for Translation

The results of this study highlight the potential for the translation of specific evidence from the psychology literature into the design of informatics-based behavioral interventions. We used an action planning intervention to facilitate subsequent action in intervention participants. This technique holds great promise to facilitate health-related behaviors, particularly in mobile phone-based interventions. In fact, recent evidence has shown that sending text message reminders of planned actions further facilitates the desired action. [38] We also presented potential outcomes as upward counterfactuals (how things might have been better) to maximize participants' behavioral intentions. This framing of information might be more widely used in consumer health informatics to increase user motivation; however, since we did not experimentally test this component of our intervention, further work is needed to test this idea.

3.5.2 Strengths

This study has several strengths. First, we employed prior findings in the psychological literature to design a brief, self-contained intervention and conducted a hypothesis driven test of the efficacy of components of the intervention. Second our use of glucose curves for both the presentation and elicitation of outcomes allowed for the measurement of individual's outcome expectancies across three dimensions: the magnitude, duration and direction of the effect. We believe this method is superior to the more common Likert scale measures of belief, and that a computer-based version of this drawing task could further improve upon the discrepancy score used in this study. A limitation of the discrepancy score used in this study is that it does not account for differences in the magnitude and duration of the individual's expectation (a larger discrepancy reflects a more inaccurate belief than a smaller discrepancy). A better measure of the discrepancy would be the difference in the area under the curve between the individual's curve and the presented outcome. This was not feasible using the complex curves drawn on paper in this study, but a computer-based version of the drawing task could easily calculate this difference.

3.5.3 Limitations

This study has limitations. First, our primary outcome measure, physical activity, was measured by self-report. Since all participants used the same measure, we do not believe this undermines the results; however, the true magnitude of the effect of our intervention on subsequent physical activity needs to be determined with objective measures in future work. Additionally, some of our participants did not represent the target population for this intervention: some subjects possessed adequate diabetes related numeracy, had positive outcome expectancies and intentions for exercise, were knowledgeable about their disease, and were already physically active. We plan to address this issue in the future by integrating the intervention into diabetes education classes in target populations, particularly newly diagnosed and low numeracy groups. The third limitation of this study was that the tests used to measure knowledge were not well aligned with the simulation's presentation of content. We developed the simulation around gists we considered important based on theory, [44] our clinical experience, and pilot work. Currently available measures of diabetes related knowledge, including those used in this study, measure an individual's knowledge of facts. Instruments measuring conceptual understanding of diabetes self-management are not available. In future work simple simulations such as those used in this study could serve as a method to both teach and test understanding of diabetes-related concepts. A final limitation of this study is that while we attempted to minimize the interaction between the investigator and the participant, some interaction was necessary (e.g., the administration of the IPAQ questionnaire). Further work is needed to determine if an entirely computer-based version of the intervention will demonstrate similar efficacy.

3.5.4 Future Research

The next generation of this intervention will test the effectiveness of personalizing the feedback provided in an interactive phone based intervention. A phone-based intervention may facilitate the integration of the simulation into the user's daily life, may be easier to access than traditional diabetes education [42] and might be less costly than an in-person intervention. [43] Recently, Polonsky et al. reported on an in-person intervention called the Structured Test Protocol (STeP). The core of this intervention was the estimation of the individual's glucose curves using seven-point glucose monitoring for 3 days. In their study, estimated curves facilitated shared decision making between patient and provider resulting in a greater improvement in HbA1c, diabetes self-efficacy, autonomous motivation for diabetes care, and a more positive attitude toward self-monitoring of glucose than usual care. [45] This protocol concentrates the timing of self-monitoring but does not require a net increase in the volume of glucose monitoring, [46] and therefore may be a cost-neutral and minimally invasive method to tailor the curves presented in the simulation. We hypothesize that the personalization of the presented curves, in combination with the personalization of the predicted effect of exercise (a subject of current research), may result in greater effectiveness of the intervention.

3.6 Conclusion

In this study we tested a simple form of a computer-based simulation. Participants outcome expectancies changed in accordance with the discrepancy between their prior beliefs and the presented outcomes and, in combination with action planning, the simulation positively affected short-term behavior.

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CHAPTER 4

A METHOD TO DEVELOP INDIVIDUALIZED PREDICTIVE MODELS OF THE ACUTE EFFECT OF EXERCISE ON GLUCOSE

4.1 Introduction

Exercise has been widely recognized to ameliorate hyperglycemia and insulin resistance in Type 2 Diabetes (T2DM). [1, 2] Studies that have examined the acute effects of moderate exercise on blood glucose in T2DM have generally demonstrated an immediate, positive effect .[3-7]

To date only one study has attempted to develop a predictive model of the effect of acute exercise on blood glucose in individuals with Type 2 Diabetes. With 37 subjects, Jeng and colleagues examined the effects of pre-exercise blood glucose, exercise duration, exercise heart rate and gender on blood glucose changes. [8] In this study pre-exercise blood glucose, exercise duration, and exercise heart rate were significant predictors of glucose change with exercise. Their linear model accounted for 37% of the variance in glucose change with exercise.

Our ultimate goal is to develop and validate an individualized predictive model that is accurate to within 1.1 mmol/L (20 mg/dL) and that can predict exercise-induced hypoglycemia. The development of such a model requires at least three phases: 1) choosing an appropriate statistical modeling approach; 2) the identification of significant predictors of acute blood glucose response to exercise; and 3) validation of the resulting model. This paper compares the predictive accuracy of potential modeling approaches and discusses considerations for the identification of significant predictors in future work.

Our specific aim in this study was to use repeated measures data to compare the predictive accuracy of a model that accounts for individual differences (a "mixed effects" model) to one which does not (an ordinary linear model). We believe this is an important comparison because acute blood glucose responses to exercise appear to vary significantly both within and across persons.

4.2 Research Design and Methods

We aggregated data from eight diabetes and exercise studies conducted at sites around the world.[4, 7, 9-14] The resulting dataset represents 177 individuals performing 4,468 exercise sessions. However, data were missing for some proposed predictors, and individuals varied in the number of exercise sessions for which data were collected. Accordingly, a subset of the dataset was used for this study, which included 52 individuals completing 628 exercise sessions who met the following criteria:

1) Individuals had an A1c ≥6.0%. We chose this criterion to allow for the possibility that an individual may not have met the diagnostic criteria for T2DM based on A1c (≥ 6.5%) (15), but could still have met other criteria (e.g., impaired fasting glucose or impaired glucose tolerance, data that were not available for our analyses).

2) Individuals were taking an oral diabetes medication. In the larger dataset, there were a few subjects who were either diet controlled (n=6) or taking insulin (n=14), who met our other inclusion criteria; however, given that the acute blood glucose response to exercise is known to be different in such groups (15), we restricted the development of this model to individuals taking an oral medication only.

3) Individuals had complete data for our outcome variable, post-exercise blood glucose (measured within 5 minutes of exercise termination), and the following eight predictors: age, sex, race, A1c prior to the study, exercise type (aerobic, resistance or combined), exercise session number, pre-exercise blood glucose (measured no more than 5 minutes prior to the start of exercise), and exercise duration.

4) All individuals had completed at least three exercise sessions. We required this because our analysis plan was to select the variables using only data from the first exercise session and then determine the model's predictive validity in future sessions.

4.2.1 Development of the Model

For variable selection, we used a bootstrap variable selection procedure. To do so, 2,000 bootstrap samples were taken from the data for the first exercise session of the 52 subjects. Variables were selected in a forward stepwise procedure based on improvements in the adjusted R-squared achieved in the out-of-bag bootstrap sample.

For our predictive models we compared a mixed effects model with random intercepts to an ordinary linear model. A mixed effects model produces estimates for two model components: the fixed components, which are the same for all groups (in this case the coefficients for each covariate); and the random components, which are values drawn randomly from a population that *may* be specific to each group (in this case, the intercepts for each subject).

To create training and testing datasets we created a function that iteratively partitioned the data. For each subject and exercise session, a training set was created that consisted of all data for all other subjects and only those data available prior to the specific exercise session of interest for the individual in question. The model was constructed using this training set. The predicted post-exercise glucose was calculated using the test set, which were the data for the subject and session of interest. This approach allowed the use of all of the data without creating a biased estimate of predictive performance.

The terms “adaptive” and “static” refer to the individual-specific data the model uses for training. We used the term adaptive to indicate that as an individual contributed more data to the training set, the model might better adapt to the individual’s pattern of blood glucose response to exercise. The static training set consisted of data from the first exercise session for that subject, along with all data from all other subjects; in this case the individual did *not* contribute more data to the training set with each iteration. The adaptive training set consists of the data for that subject up to, but not including, the session in the test set along with all data from all other subjects. For example, when the test set was session number two for subject [S], the adaptive training set only included data for the first session from that person. However, when the test set was session 15 for subject [S], the adaptive training set included data for sessions 1 to 14 for subject [S].

We compared the performance of three models (static mixed, adaptive mixed, adaptive linear) graphically using the proportion of predictions within 1.1 mmol/L (Figure 4.1) and compared the two best models statistically with a paired t-test. We then compared the absolute error of the adaptive mixed effects model with and without a random slope for pre-exercise glucose (the most significant predictor of post-exercise glucose in prior work (8) using a paired t test, along with model error across individuals graphically. Finally, we created a mixed effects logistic regression model (which accounts for the clustering of model errors within individuals) to determine if individual level variables, exercise session level variables, or the primary data source was associated with model error.

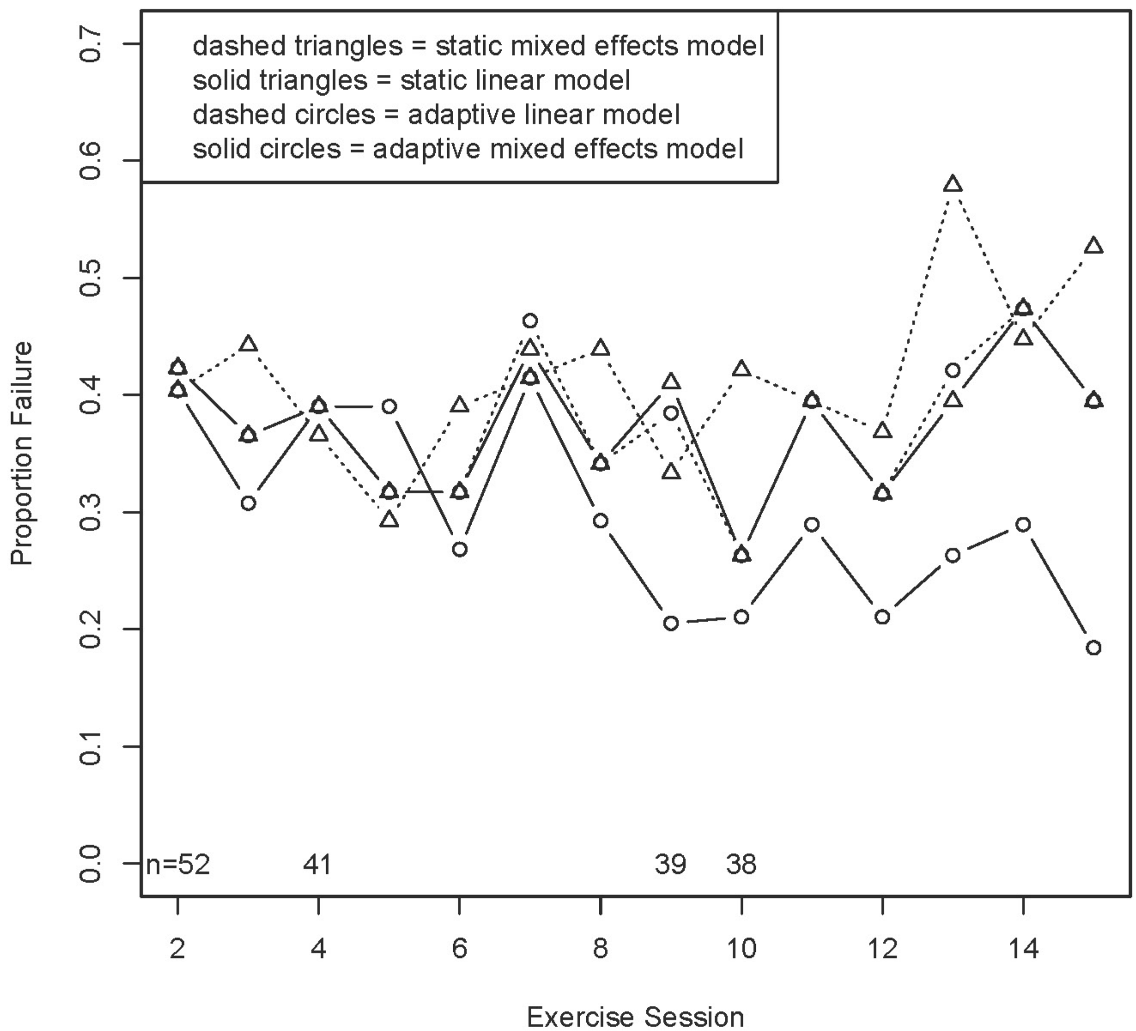

Figure 4.1: Proportion failure for adaptive and static models by session

All analyses were performing using R statistical computing software. [16] For the mixed effects predictive models we used the nlme package. [17] For the mixed effects logistic regression we used the Zelig package. [18]

4.3 Results

Table 4.1 presents descriptive statistics of the individuals included in this analysis. The median values of each descriptor might be considered "typical" values of individuals with T2DM treated with oral medications, and the ranges are indicative of their heterogeneity.

4.3.1 Variable Selection

After the bootstrap procedure, only two variables remained in the model: pre-exercise blood glucose and A1c prior to starting the exercise study. Table 4.2 presents the bootstrap estimates of proportion of variance in post-exercise glucose explained by these two predictors. The "in the bag" (ITB) estimate refers to the model's R^2 in data used to estimate parameters for that sample. The "out of the bag" (OOB) estimate refers to the model's R ^2 in data not used to estimate parameters for that sample and can be thought of as a test of the external validity of parameter estimates. The difference between ITB estimates and OOB estimates represents the degree to which the model is "overfit" to training data.

In addition to the variables selected by this procedure, we forced two variables that we expected to be important and that could not have been selected into the model using the first exercise session data. We included a lag variable for change in glucose with the previous exercise session to account for the correlation in outcomes between

Table 4.1. Descriptive statistics of individuals used in model development

Variable	Median and Range in Dataset used for Model (n= 52)
Age	56 yrs (37- 81 yrs)
Sex	31 males, 21 females
Years since diagnosis**	5.5 yrs (<1yr-14yrs)
Hemoglobin A1c	7.9 % (6.1-13.1 %)
Pre-exercise glucose	10.5 mmol/L (3.4-25.0 mmol/L)
Post-exercise glucose	7.9 mmol/L (2.7-20.4 mmol/L)

**Data on years since diagnosis was missing for 42% of subjects

Table 4.2. Bootstrap estimates of model performance using first exercise session data

Predictors	Median R^2	Lower bound of 95% CI of R^2	Upper bound of 95% CI of R^2
"In the bag"	.852	.768	.914
"Out of the bag"	.789	.561	.896

exercise sessions and included exercise session number to account for a change in acute blood glucose response to exercise over time. All modeling was performed with these four predictors: pre-exercise glucose, A1c at start of study, exercise session number, and lag glucose change.

It should be noted that in this dataset, some potentially important predictors were excluded from analysis due to unavailability (such as heart rate during exercise). In addition we had limited variability in some predictors within individuals (e.g., 32/52 subjects had only one unique value for exercise duration). These factors likely limited our ability to identify significant predictors.

4.3.2 Comparison of the Models

All models contained the same four predictors: pre-exercise glucose, A1c at the start of the study, exercise session number, and the change in glucose during the prior exercise session. We compared the performance of an adaptive mixed effects model, an adaptive linear model, and a static mixed effects model. Figure 4.1 depicts each model's performance across exercise sessions with model failure defined as an absolute error of >1.1 mmol/L. The adaptive mixed effects model performed best, with a difference in model performance evident at about exercise sessions > 8 (Figure 4.1). A comparison of the absolute errors of the adaptive mixed effect model and the adaptive linear model confirmed that the difference was significant ($t = -6.9315$, $df = 575$, p-value<0.0001).

4.3.3 Additional Model Improvement with Random Slopes

In our comparison of models above, all coefficients for the predictors in the model were fixed effects (the same for all subjects), and only intercepts were random effects (allowed to vary between individuals). One additional mechanism by which we can further individualize the mixed effects model is by allowing for random slopes. Conceptually, this means that the effect of a given predictor would be different across individuals. We chose to model pre-exercise glucose as a random effect since this was the most significant predictor of post-exercise glucose in prior work (8). Overall, model performance improved from 70.2% of predictions within 1.1 mmol/L for the model without random slope to 74.7% for the model with random slope. This reduction in model error was significant (t =3.7495, df=575, p-value<0.0001).

4.3.4 The Accuracy of Individualized Models across Subjects

Figure 4.2 represents a box plot of the absolute error of the predictive model (including random slopes for pre-exercise glucose) by subject. Each box represents the distribution of the absolute value of model error for an individual. When examining the left side of the plot, it is evident that for a few individuals the model performed quite well: for 13 individuals all predictions were within 1.1 mmol/L (20 mg/dl), and for 23 individuals all were within 1.7 mmol/L (30 mg/dl). The right side of the plot, however, shows the 7 individuals for whom the model failed in at least 50% of exercise sessions.

4.3.5 Predictors of Model Error

To determine if individual-level variables, exercise session-level variables or the primary data sources were associated with model error, we created a mixed effect logistic regression model with random intercepts by individual. Model error (absolute error $\geq$ 1.1 mmol/L) was the dichotomous outcome and all individual level variables, exercise session level variables and primary data sources were included as predictors.

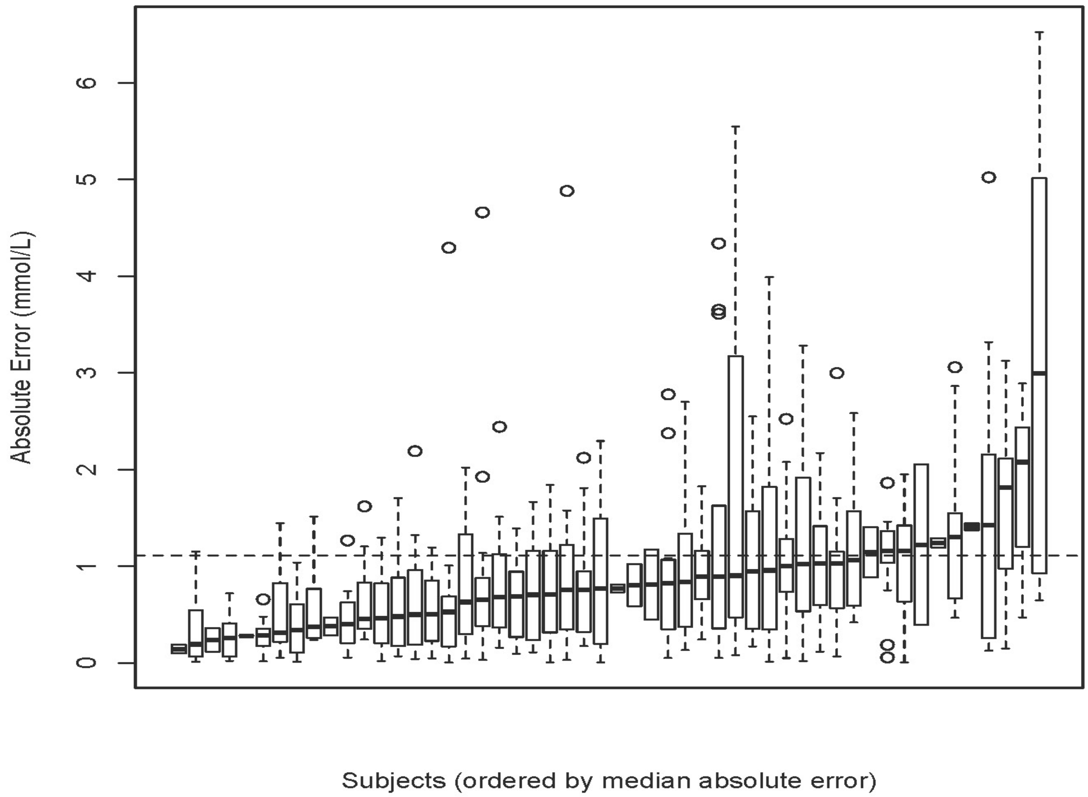

Figure 4.2: Absolute error of adaptive mixed effects model by subject with random slopes for preexercise glucose

In addition we created two individual level variables to determine if individuals' glucose variability was associated with model error: these were the standard deviation of the individuals' pre- or post-exercise glucose values up to, but not including, the session used in the test set. None of the primary data sources were associated with model error. The standard deviation of the individuals' post-exercise glucose values was the only individual level variable associated with model error (OR 1.019, 95% CI 1.007-1.032), indicating that the model was very slightly more likely to fail for individuals with greater variability in their post-exercise glucose. Exercise session number was the only exercise session level variable associated with model error and this was negatively associated with model error (OR .87, 95% CI .87-97), indicating that as individuals contribute more data to the model, its accuracy improved.

4.3.6 Prediction of Exercise Induced Hypoglycemia

In the analyzed sample, 9 individuals performing 21 exercise sessions had a post-exercise glucose ≤3.9 mmol/L. Model error was >1.1 mmol/L for 13 of these sessions; however, in 2 cases subjects were taking a sulfonylurea and their pre-exercise glucose was ≤ 5.6 mmol/L. The recent ADA/American College of Sports Medicine (ACSM)/American Diabetes Association (ADA) position statement on exercise and diabetes in T2DM suggests that these individuals should consume some carbohydrate prior to exercise. [21] If individuals had followed these guidelines, they would have had a different pre-exercise glucose, making these cases training data for the model rather than errors. Removing those individuals left a group of 7 individuals performing 11 exercise sessions with a post-exercise glucose ≤ 3.9 mmol/L (lowest value: 3.1 mmol/L) and a model error >1.1 mmol/L, which did not meet the precautions by the ACSM/ADA. Six out of these 7 subjects were taking a sulfonylurea. In all 11 cases, the model predicted higher glucose than the true outcome.

4.4 Discussion

In this study, we have presented a method to develop individualized predictive models of the effect of exercise on glucose in individuals with T2DM taking oral diabetes medications. The method proved to be superior to an ordinary linear model. We have identified A1c as a predictor of acute blood glucose responses to exercise and confirmed previous evidence that pre-exercise glucose is a determinant of glucose response to activity. In our sample, exercise duration was not a significant predictor, as reported by Jeng and colleagues. [8] However, this outcome is likely due to limited variability in this predictor in our data.

Our main finding that the mixed effects model improved in accuracy as individuals contributed more data replicates findings reported by Olofsen et al. [19] These investigators used simulated data to show that the random component of a mixed effects model converges toward its true value as the individual contributes more data to the model. Our combined use of repeated measures data with a mixed effects model to develop predictive models is not without precedence: Dongen et al. reported an application of this method to predict cognitive impairment due to sleep deprivation. [20] However this application of mixed models differs from the more common usage that treats interindividual variation (the random effects) as a "nuisance" variable in order to improve the estimate of population effects. [21]

This study has two main strengths. First, we used rigorous methods to develop and validate our model: the bootstrap variable selection procedure and the prospective validation of the models tested. Second, we used a geographically diverse sample that minimizes the likelihood that these findings are anomalous. Considering these points, the finding that the adaptive mixed effects model was superior and has further capacity for individualization (as was demonstrated with the addition of a random slope component for pre-exercise glucose) is encouraging.

The primary limitation of this study is that the models tested did not include some predictors known to be important to acute glucose response to exercise in T2DM. In order to approach our goal of a model that is accurate to within 1.1 mmol/L, future work will need to include known predictors as well as determine novel predictors of acute blood glucose to exercise. These data should be captured prospectively and include both individual level and exercise session level variables. Individual level predictors that have been previously been reported to affect acute glucose response to exercise include specific medication classes. [22, 23] In this study we found that A1c was a significant predictor. We propose that other individual level variables, which are associated with diabetes onset and progression (such as age, ethnicity, bodyweight, and body mass index) should be tested for their importance in predicting acute glucose response to exercise. Exercise session level variables that have previously been reported to be predictive of acute glucose response include exercise heart rate, [8] exercise duration [8] and postprandial state. [4,14] We suggest that other exercise session level variables that should be investigated include time elapsed since medication ingestion and exercise type (aerobic, resistance or combined). By identifying an appropriate statistical modeling approach, the present study represents an important first step towards our goal of developing practically useful predictive models. However, work remains to be done to determine the significant predictors of acute blood glucose response to exercise in T2DM.

The eventual clinical application of this work will enable a prospective, personalized approach to glucose management in persons with T2DM. We plan to use a mobile phone based system to facilitate the prospective repeated measures data capture needed to develop individualized models of the effect of exercise on glucose. We will then provide the output of these models to participants in the form of simulated glucose curves [24] in an interactive simulation. This intervention will provide users with the opportunity to "play" with different exercise routines, observe the predicted effects on glycemic control, and plan their own activity. Users will begin by seeing the population effect of physical activity on the glucose curves. As they contribute their exercise related data, the presented outcomes will be personalized. We describe this project in order to highlight the potential of incorporating the methods described in this paper in a personalized healthcare intervention.

We have presented a method used to develop individualized predictive models of acute blood glucose response to exercise. Both the method and approach are promising for further work in the area of personalized healthcare.

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CHAPTER 5

CONCLUSION

In the introduction to this dissertation three issues in the design and evaluation of CHI applications for self-management activities were described, specifically focusing on diabetes. First, some studies have deployed complex multicomponent interventions without a theoretical specification of how the intervention might impact users' thoughts and behaviors. Second, some studies have failed to separate interpersonal components of the behavior change intervention from the technological components, making it impossible to determine the efficacy of the technological component of the intervention. Finally, few studies have tested the efficacy of specific application components in affecting individuals' behavior or determinants of behavior, providing little generalizable evidence of the mechanisms by which these systems may affect users' behaviors. The work presented in this dissertation represents an attempt to address these issues in the specific the case of the design and development of a diabetes self-management application.

To address the problem of limited use of theory in the design and evaluation of CHI applications, a conceptual framework that translates evidence from the psychological sciences was described. Nine recommendations for the design of a CHI intervention and several related hypotheses were also presented and described. The remainder of the dissertation described three research studies addressing different aspects of the problem. The first two studies served as primary tests of the usability (effectiveness and user satisfaction with the system) of our envisioned self-management application. The second study also tested the incremental effectiveness of specific components of the intervention. Finally, the conceptual framework described in the introduction and the latter two studies addressed questions that have broad implications to the field of consumer health informatics.

The first study tested the efficacy of an application interface (simulated glucose curves and icons) in conveying information and tested the feasibility of using that interface to measure individuals' beliefs. First, simulated glucose curves were estimated for each 0.1 increment in hemoglobin A1c from 5.9 % to 10.1 %. These simulated curves were combined with icons representing concepts related to diabetes. Participants' understanding of the concepts presented in these paper graphs was tested. The primary outcome of this study was users' understanding of these curves and icons. The results were positive: > 83% of the presented information was understood. The information that was poorly understood in this paper based prototype study were the change in A1c over years, and the change in the glucose curve with exercise. These results suggested a dynamic interface should be tested in the next phase. A novel method to measure the outcome expectancies of individuals was also pilot-tested: individuals drew the change in the glucose curve they expected with acute exercise and with habitual exercise. This method allowed the measurement of outcome expectancies across three dimensions: the direction, magnitude and duration of the expected change. Strengths of this study were the isolation of the testing of the effectiveness of the interface in conveying specific concepts (without verbal explanation) and the novel drawing task to elicit individual's beliefs. Limitations of this study were the use of students for this formative evaluation (rather than users from the target population) and the use of a single round of testing rather than an iterative process of usability testing. These limitations were partially addressed by unpublished pilot work with veterans described in the chapter's postscript.

The second study used a narrated simulation based on the simulated curves and refined versions of the icons developed in the first study to test two hypotheses in a randomized trial. First, we hypothesized that individuals' beliefs (outcome expectancies) would change in accordance with the discrepancy between the simulated outcome and their prior beliefs (measured by the drawing task from the first study). Second we hypothesized that the completion of an action plan with a concurrent mental simulation by intervention participants would result in greater behavior change (walking) in the following week. Both of these hypotheses were confirmed. Strengths of this study were the design of intervention components based on evidence from psychology and the experimental isolation of two of these components. This intervention was novel in that it combined the use of a computerized simulation to change beliefs, the presentation of that simulation as an upward counterfactual to increase motivation, and an action planning/ mental simulation component as a mechanism to translate the increased motivation into action. The design of the experiment allowed us to determine the incremental effect of the combination of presentation of potential outcomes and completion of an action plan on participant’s beliefs and behaviors. Limitations of this study were the use of self-report to measure physical activity, the use of fact based measures of knowledge rather than concept-based measures of knowledge and imperfect representation of the target population among study participants.

The purpose of the third study was to determine if, in future implementations, the presented acute outcomes in our simulation could be individualized. In this study we used aggregated data from eight prior trials of exercise and diabetes to compare the predictive accuracy of different statistical modeling techniques. The outcome of interest was the acute effect of physical activity on glucose in individuals with T2DM. The results of the study were that a mixed effects model improved in accuracy as repeated measures data were added for the individual, whereas other models did not. Strengths of this study are that this use of mixed effects modeling is relatively novel; mixed effects models typically treat intraindividual variation as a 'nuisance' variable. Our use of these models takes advantage of the fact that as the user contributes more data the random component of the model converges towards a true value. A second strength of this study is that we used a geographically distributed sample to reduce the likelihood that our results were anomalous. The two limitations of this study were that data was missing for some predictors that are known to be significant. Similarly data were missing for some predictors that we hypothesized might be important. We were therefore unable to test the importance of these predictors.

5.1 Implications for Consumer Health Informatics

There are three main implications of the work described in this dissertation for the field of Consumer Health Informatics. The first implication is that the nine design principles for CHI applications described in the introduction of this dissertation should be applied and tested in future CHI applications. These design principles are (for the details of these principles see the introduction):

1. Systems should facilitate monitoring
2. Systems should facilitate goal setting
3. Systems should facilitate goal awareness and negotiation
4. Systems should provide users with comparative functions

5. Systems should increase user's motivation through framing of comparative information

6. Systems should help users to detect potential problems

7. Systems should help users to understand potential outcome of behaviors-

8. Systems should help users to increase their self-efficacy for desired behaviors

9. Systems should guide users through the formation of plans.

The second implication of the work presented in this dissertation is that simulation could be used much more widely to change patients' knowledge and beliefs in CHI interventions. The results of the study described in Chapter 3 provide initial evidence that computerized simulations have promise as vehicles with which to change the beliefs of individuals with chronic disease. We believe these results warrant further investigation particularly with simulations that are personalized to the user, and in individuals of different levels of literacy and numeracy .

The third implication of the work presented in this dissertation is based on the finding from Chapter 4 that individualizing predictive models of acute outcomes improves their accuracy over time. Assuming that we are able to produce acceptably accurate predictive models of the acute outcomes in future work, these models could serve to detect potential proximal problems or could serve to provide individuals with accurate outcome expectancies of possible actions and may have additional benefits. For example, in the case of predicting the acute effect of exercise on glucose we will integrate such a model into our diabetes related application. In the application, variables describing a physical activity session (duration, time of day, etc.) will be presented as sliders that the user can play with to see the acute effect of different physical activity regimens on the glucose curve. We hypothesize that the individualization of this feedback will result in increased user engagement. A similar model could be used to predict the potential problem of exercise-induced hypoglycemia in order to facilitate anticipatory self-regulation.

5.2 Future Work

In future work we plan to complete the development and evaluation of the planned mobile phone based diabetes self-management application described in the introduction to this dissertation. In the process we hope to address several related scientific questions.

First, we will test our hypothesis that the temporal congruency between the presentation of acute outcomes via simulation and the planning of acute behaviors may facilitate greater behavior change than a system that presents distal outcomes but facilitates planning of acute behaviors.

Next we plan to test the efficacy of mobile phone based goal priming and planning interventions on behavioral initiation. We will then compare the efficacy of repeated "booster" interventions of varying frequency on behavioral maintenance

Finally, we will develop and refine the next generation of the predictive model of the acute effect of exercise on glucose, and develop and validate a predictive model of change in hemoglobin A1c with exercise and another model to predict exercise induced hypoglycemia If these models are acceptably accurate they will be integrated into the simulation software. If not, we will use either population means or the individual's historical outcomes to inform the simulation.

5.3 Conclusion

In summary in this dissertation we have presented a conceptual framework for the design of Consumer Health Informatics self-management applications and three related research studies. The overarching goal of this work is improve patients' ability to manage their disease by translating evidence from the psychological sciences into the design of information technology solutions for self-management. Our central thesis is that applications which address the self-regulatory processes of monitoring, goal setting, planning, simulation and comparison will have the greatest influence on subsequent user behavior.