

Can-Do-Tude: an Online Intervention Using Principles of Motivational Interviewing and Tailored Diabetes Self-Management Education for Adolescents with Type 1 Diabetes

by

Linda Louise Paul

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Graduate Supervisory Committee:

Pauline Kommenich, Chair
Melissa Spezia Faulkner
Gabriel Shaibi

ARIZONA STATE UNIVERSITY

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ABSTRACT

Type 1 diabetes (T1D) is one of the most common chronic diseases in youth and it has been shown that adolescents have the worst glycemic control of any age group. The objective of this study was to develop, test and evaluate the feasibility of an online intervention (*Can-Do-Tude*) that uses the principles of motivational interviewing (MI) to deliver tailored diabetes self-management education to adolescents with T1D. Bandura's efficacy belief system was used to guide the design of this study.

The study used a multi-phase, multi-method approach. The first phase (alpha) of this study was a qualitative descriptive design to examine the intervention's fidelity. Evaluation of performance was conducted by experts in the fields of MI, T1D, adolescence and/or online education. The second phase (beta) was a quantitative descriptive design conducted in order to evaluate feasibility by examining the acceptability (recruitment, retention and satisfaction) and implementation (diabetes self-management self-efficacy) to determine whether the intervention was appropriate for further testing.

First phase findings showed that the intervention passed all measures with the content experts ($n = 6$): it was functional, accurate, usable and secure. Improvements to the intervention were made based on reviewer recommendations. For the second phase 5 adolescents between 14 and 17 were enrolled. Three adolescents completed all 4 weeks of the intervention while 2 completed only 3 weeks. Participants ($n = 3$) rated satisfaction on a 5-point Likert-type scale ranging from "not at all" satisfied (1) to "very much" satisfied (5). There was a positive response to the intervention ($M = 4.28$, $SD = 0.55$). Implementation was measured by a pre- and post-test for diabetes self-

management self-efficacy. Participants ($n = 3$) demonstrated overall improvements in diabetes self-management self-efficacy ($Z = -2.952, p = .007$).

Implications for further Can-Do-Tude research are planned at a metropolitan diabetes center using updated technology including an application platform. Although the sample was small, findings indicate that the intervention can be conducted using a web-based format and there is initial evidence of improvement in self-efficacy for diabetes self-management.

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Chapter 1

Introduction

Overview

Adolescence is an unsettling time of life. It involves tremendous biological, cognitive and social transitions - changes that result from developments in the endocrine and central nervous systems. These changes help to ready the individual for adulthood and independence. Due to the various changes occurring in these systems, particular behaviors tend to emanate. Adolescence is characterized by risk-taking, impulsivity, questionable judgment and a predisposition for high excitement activities as well as preferences for peer as opposed to parental relationships (Lerner and Steinberg, 2009). Changes in these systems direct the drives and motivations of teens; consequently, these behaviors can potentially place the adolescent at a risk for harm. The normal developmental tasks of adolescence are themselves a challenge. Couple those with the rigorous responsibilities of managing a chronic illness such as type 1 diabetes (T1D) and the demands can become overwhelming.

Health behavior is a critical determinant of an adolescent's well-being. The health behaviors established during adolescence set the stage for one's health and well-being later in life (Centers for Disease Control and Prevention, 2004). T1D management involves the delicate balance of diet, exercise and insulin injections while closely monitoring blood sugars in order to keep glucose levels under control. This can be especially difficult in adolescence. The Diabetes Control and Complications Trial (DCCT) showed the importance of maintaining good glucose control to delay the onset and progression of diabetic complications (DCCT, 1993 and 1994). Although more

recent studies have shown a decline in diabetic complications with the use of intensive insulin therapy (Epidemiology of Diabetes Interventions and Complications [EDIC], 1999), adolescents and young adults are still developing the long-term complications of diabetes - neuropathy, nephropathy, retinopathy and cardiovascular disease (Nathan, 2014). As adolescents with T1D transition towards adulthood, metabolic control deteriorates until adulthood is reached (Bryden et al., 2001; Dabadghao, Vidmar and Cameron, 2001; Frey, Ellis, Naar-King and Greger, 2004 and Insabella, Grey, Knafl and Tamborlane, 2007). This deterioration has been linked to risky behaviors such as poor adherence to treatment regimes, insulin misuse and eating disorders (Court, Cameron, Berg-Kelly and Swift, 2009; Jaser, Yates, Dumser and Whittemore, 2011 and Wasserman, Anderson and Schwartz, 2017). Risk-taking in an adolescent's life involves a normal process of parental separation, individuation and testing limits, leading to the development and consolidation of one's identity; however, it can become self-destructive when the risks exceed healthy limits (Ponton, 1997). Taking risks with one's chronic illness may have devastating consequences, especially with a disease such as diabetes.

Research Problem

Diabetes is one of the most common chronic diseases in children and adolescents. The Centers for Disease Control and Prevention (CDC) estimate that about 208,000 Americans below the age of 20 years have either type 1 or 2 diabetes (CDC, 2014). In 2008-2009, an estimated 18,000 youth under the age of 20 years in the United States were newly diagnosed with T1D (CDC, 2014). For reasons that are unknown, T1D is rising around the globe at a rate of 3 to 5 percent each year (CDC, 2012). Preliminary findings from the CDC funded study SEARCH for Diabetes in Youth report that many

children and adolescents are already showing measurable signs of peripheral neuropathy and early indications of cardiovascular autonomic neuropathy which leads to cardiovascular disease (American Diabetes Association, 2012). Furthermore, findings from a large international study conducted by Sanofi and presented at the American Diabetes Association's 2014 Scientific Sessions suggest that 70% of young persons with T1D are not attaining their blood sugar targets measured by HbA1c and those with the worst control were between the ages of 13 and 18 years of age (PR Newswire - Paris, 2014). Adolescents, in general, need improved blood sugar control to avoid the complications of diabetes.

Given that a major cause of poor metabolic control in teenagers stems from poor decision making and lack of adherence to treatment regimens, adolescents need opportunities to develop intrinsic motivation to manage their diabetes. Motivational interviewing (MI) is a counseling technique that promotes goal setting, self-monitoring, and facilitates problem-solving. Miller and Rollnick (2002) define motivational interviewing as "a client-centered, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence" (Miller & Rollnick, 2002, pg 25). Motivational interviewing has become a topic of interest in the diabetes behavioral field because it helps patients to become interested in self-management and to develop plans for action that are clear and reasonable (Polonsky, 2007). A general goal of motivational interviewing is to support and enhance a person's self-efficacy by focusing on providing opportunities that help individuals assess for themselves what might be important or possible and how change might potentially be achieved (Welch, Rose & Ernst, 2006). In numerous studies, motivational interviewing has been demonstrated to be an effective

method for facilitating positive behavioral changes in adolescents with T1D (Channon et al., 2003, 2007; Knight et al., 2003; Viner et al., 2003, Nansel et al., 2007, 2009).

As Bandura (2006) has so eloquently pointed out, it is not enough for the adolescent to have self-management skills in order to manage the inconveniences of T1D; they must find worth in the work to manage this disease. They must have a sense of purpose and accomplishment or a sense of diabetes self-management self-efficacy. The greater the self-management self-efficacy, the greater will be their success in diabetes management.

Purpose

The purpose of this study was to develop, test the fidelity and evaluate the feasibility of a password protected online intervention that uses tailored diabetes self-management education and the principles of motivational interviewing. The intervention is entitled *Can-Do-Tude*. The guiding theoretical foundation used to conduct this intervention was Bandura's efficacy belief system which operates as a component within the broader conceptual framework of Social Cognitive Theory.

Theoretical Framework

Social cognitive theory is used as a basis for examining developmental changes across the life span in terms of involvement and exercise of human agency (Bandura, 2006). According to Bandura (2006), the most essential aspect of human agency is the perceived belief of personal efficacy. Self-efficacy is the foundation of human motivation, well-being and accomplishments.

Unless a person believes that they can succeed by their own actions, they have little incentive to continue trying. This is the case in health promotion. It is one thing to

encourage persons to engage in beneficial health habits and quite another to get them to adopt them. Maintenance of habit change relies heavily on self-regulatory capabilities and the functional value of the behavior (Bandura, 2006). Development of self-management requires building a “resilient sense of efficacy” as well as having the skills required to perform (Bandura, 2006). Experiences in exercising control over difficult situations serve as efficacy builders (Bandura, 1997; Marlatt, Baer & Quigley, 1995). There are four major components to an effective preventative program that builds generic self-management skills (Bandura, 2004):

1. Provide information.
2. Develop the social and self-management skills for translating informed concerns into effective practices.
3. Build a resilient sense of efficacy to support the exercise of control in the face of challenges that inevitably arise.
4. Enlist and create social supports for desired changes.

Virtually all people can identify goals they want to accomplish, things they would like to change and things they would like to achieve; however, most people also realize that putting these plans into action is not quite so simple. An individual’s self-efficacy plays a major role in how goals, tasks, and challenges are approached. Because diabetes self-management incorporates not only skills and knowledge but behavioral and personal factors into daily performance of diabetes tasks, the concept of self-efficacy is relevant for improving self-management and hence glycemia. The efficacy belief system which operates as a component within the broader conceptual framework of social cognitive theory will be the theoretical framework for this intervention. Self-efficacy is a key

element in the motivation to change and is a reliable predictor for effective treatment outcomes (Miller & Rollnick, 2002).

Intervention Model

The model that guided the intervention is provided in Figure 1. The model depicts social-cognitive theory for behavior change with intervention components that use tailored diabetes self-management education and the principles of motivational interviewing to promote diabetes self-efficacy; this should lead to increased self-management of diabetes and improved HbA1c values in adolescents with type 1 diabetes. This feasibility study was designed to test an intervention and evaluate the intermediate outcome (improved diabetes self-management self-efficacy), rather than the final outcome (improved or sustained HbA1c).

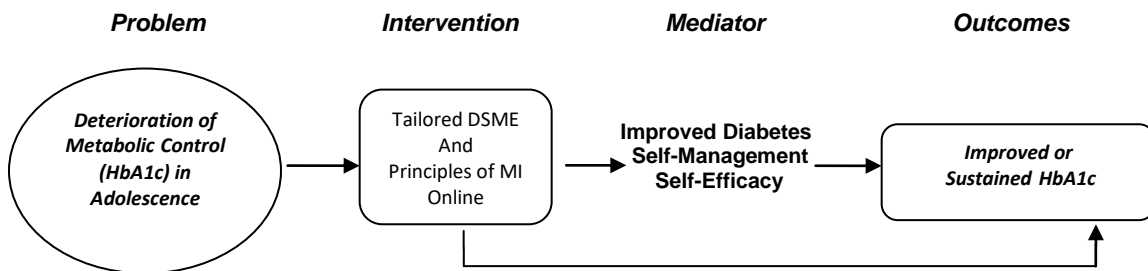


Figure 1. Intervention model.

Specific Aims

Specific Aim 1 (The Alpha Test). Develop a password protected online intervention (*Can-Do-Tude*) that uses tailored DSME and the principles of MI for adolescents with T1D and then have content experts evaluate its fidelity (functionality, accuracy, usability and security).

Specific Aim 2 (The Beta Test). Evaluate the feasibility of *Can-Do-Tude* by examining the acceptability (recruitment, retention and satisfaction of adolescents 13 - 17 years of age) and implementation (diabetes self-management self-efficacy).

Summary

It has been recognized that having T1D and progressing through adolescence are individually difficult processes that are tied together and may inevitably complicate each other. This can be seen when some adolescents assume self-management of their diabetes. Despite the potentially high cost of taking risks with one's diabetes management, some teens skip blood glucose checks and therefore insulin adjustments which in turn cause the poor metabolic control observed in adolescents (Weissberg-Benchell et al., 1995; Helgeson et al., 2009 and 2011; Rausch et al., 2012). Motivational interviewing empowers the adolescent to take responsibility and be an active participant in decisions about T1D self-management. It encourages behavioral autonomy (i.e. autonomy in decision making and the taking of responsibility for one's actions) which is important when working with adolescents who face the developmental quandary of exploring alternative behaviors (Naar-King, & Suarez, 2010).

Tailored DSME that uses the principles of MI online for adolescents with T1D should enhance self-efficacy (the belief that one is able to successfully deal with the challenges of life) to provide the staying power which Bandura (2006) refers to as necessary to override responses that might otherwise be elicited by adolescent stimuli and impulses. The risky and impulsive behavior to skip glucose monitoring that informs insulin adjustments contributes significantly to a lack of self-management of diabetes. Therefore, glycemia should improve if adolescents' intrinsic motivation and diabetes

self-efficacy is fostered. Developing an intervention that uses tailored DSME and the principles of MI online - a format that is very popular among adolescents - should be relevant and central to the behavioral patterns of this population.

Chapter 2

Background

The literature review in this chapter includes several topics as background for the study. Topics include the state-of-the-science for adolescents with type 1 diabetes regarding the challenges of diabetes management, diabetes self-management education (DSME), and behavioral interventions with a focus on problem solving, coping skills training and motivational interviewing (MI). Lastly, the basic tenets of MI are examined.

Type 1 diabetes in adolescence

Diabetes management involves uncompromising dietary maintenance, exercise and insulin injections to attain glucose control, especially for someone with T1D. The typical routine includes frequent blood sugar assessments with continual adjustments to the treatment plan, multiple insulin injections or control with an insulin pump, carbohydrate counting, routine medical visits, and constant evaluation of the effects of daily activities on blood sugar levels. These are just some of the obligations that an adolescent must fulfill to maintain normal glycemia and minimize the risk of complications. In childhood, these tasks are accomplished primarily by the parents, but as they transition to adulthood, the teen begins to take over the majority of the care. It is during adolescence that we see the poorest control. In addition to increasing the risk of developing diabetic complications, poor metabolic control in the adolescent is linked to eating disturbances, depression, poor peer relations, poor health perceptions and low scores on diabetes quality of life measures (Hoey et al. 2001; Helgeson et al., 2009).

Of all of the diabetes tasks that must be accomplished by the adolescent to maintain normal glycemia, self-monitoring of blood glucose (SMBG) is most critical for good

control. The frequency of SMBG is associated with improved HbA1c in adolescents with T1D (Rausch et al., 2012; Helgeson, Becker, Escobar & Siminerio, 2011; Haller, Stalvey & Silverstein, 2004; Plotnick, Clark, Brancati & Erlinger, 2003; Levine et al., 2001; Johnson et al., 1986; Wilson & Endres, 1986). Nonadherence to prescribed SMBG routines is linked to poor metabolic control (Helgeson, Becker, Escobar & Siminerio, 2011; Levine et al., 2001). Ultimately, it has been demonstrated that as children progress to adolescence (Rauch et al., 2012) and teens progress through adolescence (Johnson et al., 1986), SMBG decreases.

According to the American Diabetes Association (ADA) and the International Society for Pediatric and Adolescent Diabetes (ISPAD), the goal for metabolic control during adolescence is an HbA1c value $\leq 7.5\%$ (Silverstein et al., 2005; Rewers et al., 2009). To attain this goal it is recommended that SMBG be performed 4 – 6 times a day because frequency of SMBG correlates with glycemic control (Silverstein et al., 2005; Rewers et al., 2014). In an article written by Bjornstad et al. (2015), ADA/ISPAD goal achievement is associated with cardiorenal protection, yet most youth with T1D do not meet the ADA/ISPAD targets for HbA1c.

Adolescents face many obstacles to maintaining normal glycemia. Perhaps the most significant barrier to blood sugar control results from the greater emotional distancing from parents (Steinberg, 2007) contributing to the shift in responsibility for the management of diabetes from the parents to the teens. This can be a set-up for failure considering the adolescent is developmentally inclined toward risk taking, sensation seeking, and erratic, emotionally influenced decision-making. A big part of adolescence is learning how to assess the risk in an activity (Ponton, 1997) and perhaps the poor

glycemia seen in adolescence is a reflection of poor assessments of health risk-taking, such as missing blood sugar checks and ultimately skipping insulin adjustments (Arnett, 1992a and 1999, Weissberg-Benchell et al., 1995; Helgeson et al., 2009 and 2011; Rausch et al., 2012).

It is highly recommended that adolescents with T1D be treated with insulin pump therapy or multiple daily injections as well as frequent glucose monitoring (Silverstein et al., 2005; Danne et al., 2014). Adolescent development, with the need to attain more independent responsibility, should be a gradual transition from parental to eventual full self-management (Delamater, de Wit, McDarby, Malik and Acerini, 2014). The current recommendation from the ISPAD for the adherence to self-management of diabetes for adolescents is to provide ongoing DSME and behavioral interventions that enhance the ability of youth and families to control glycemia (Delamater, de Wit, McDarby, Malik and Acerini, 2014). Finally, socializing with peers is of the utmost importance to most adolescents and simply meeting other teens with the same condition and having the opportunity to exchange ideas may have important therapeutic value (Court, Cameron, Berg-Kelley and Swift, 2009).

Diabetes self-management education

Diabetes self-management education is a critical aspect of care for all people with diabetes and is necessary to improve outcomes (Funnel et al., 2010). DSME is the ongoing process of facilitating the knowledge, skill, and ability necessary for diabetes self-care (Funnel et al, 2010). This process incorporates the needs and goals of the person with diabetes and is guided by evidence-based practice standards (Funnel et al, 2010). There are five guiding principles of DSME: (a) diabetes education is effective for

improving clinical outcomes and quality of life; (b) DSME is theoretically based in empowerment models; (c) there is no one “best” education program or approach although programs that incorporate behavioral and psychosocial strategies and that are culturally and age appropriate have demonstrated improved outcomes; (d) ongoing support is critical; (e) behavioral goal-setting is an effective strategy to support self-management behaviors (Funnel et al, 2010).

There are nine content areas that are used when delivering DSME: (a) disease process and treatment options; (b) nutritional management; (c) physical activity; (d) medications; (e) monitoring of blood glucose and interpreting and using the results for decision making; (f) preventing, detecting and treating acute complications; (g) preventing, detecting and treating chronic complications; (h) developing personal strategies to address psychosocial issues and concerns; and (i) developing personal strategies to promote health and behavior change.

Behavioral interventions

Over the past decade, there have been many efforts to examine, understand, and refine interventions to help the adolescent negotiate diabetes self-management (Hood & Nansel, 2007). A variety of interventions have been devised to target psychosocial constructs, adherence/self-management and metabolic control in adolescents with T1D; in addition, many interventions are focused on both the family and the adolescent (Satin et al., 1989; Delamater et al., 1990; Forsander et al., 2000; Anderson et al., 1989, 1999; Laffel et al., 2003; Wysocki et al., 2000, 2001, 2006, 2007; Harris & Mertlich 2003, 2005; Svoren et al., 2003; Ellis et al., 2005; Nansel, Iannotti & Liu 2012; and Greco, Pendley, McDonnell & Reeves, 2001). Since this particular intervention is focused on

adolescent self-management, details of these interventions will not be discussed. Many of the remaining interventions fall under three categories: those that use either problem solving, coping skills training or motivational interviewing as the basis for the intervention.

Interventions to increase diabetes problem solving

Several interventions for adolescents with T1D focus on enhancing problem solving skills (Mendez & Belendez, 1997; Hains et al., 2000; Howells et al., 2002; Cook, Herold, Edidin & Briars, 2002; Olmsted et al., 2002 and Mulvaney et al., 2010). Mendez and Belendez (1997) investigated the potential benefits of a behavioral program that consisted of problem-solving strategies for adolescents with T1D specifically looking at treatment adherence and stress reduction. The intervention consisted of 10 weekly sessions incorporating education about diabetes self-care, blood glucose discrimination, relaxation exercises, self-instruction and problem-solving strategies. Significant improvements were made over time in the intervention group regarding measures of adherence barrier frequency, estimation of blood glucose levels and skill and frequency of blood sugar testing. There were also improvements in the severity of diabetes-related daily hassles and diabetes-related social skills. However, there were no significant changes in glycemic control.

Hains et al. (2000) provided training in the use of both cognitive-restructuring and problem-solving strategies in adolescents with poor diabetes control. The study was comprised of 15 youth who were randomized to either the experimental group or the control group. No differences were found between the experimental and control groups at post-test and follow-up.

Howells et al. (2002) evaluated changes in diabetes self-management self-efficacy in adolescents with T1D who participated in a ‘Negotiated Telephone Support’ intervention using the principles of problem-solving and social learning theory. After a year, and having received approximately 16 telephone calls, self-efficacy improved significantly in the intervention groups compared to standard care, but there was no difference in glycemic control.

Cook, Herold, Edidin & Briars (2002) conducted a pilot study with 53 adolescents 13 to 17 years of age who were randomly assigned to either a 6-week problem-solving diabetes education program or to a control group that consisted of diabetes care as usual. The experimental group showed significantly improved problem-solving test scores, more frequent blood sugar testing and improved HbA1c values from baseline to 6 months. There were no changes in the usual care group.

In a 6-session psycho-education program for adolescent girls with T1D and disturbed eating behaviors, Olmsted et al. (2002) demonstrated improvements in problem-solving diabetes care in the intervention group compared to treatment as usual. Although there were improvements in diabetes care problem-solving there were no improvements in HbA1c levels.

Lastly, Mulvaney et al. (2010) found non-statistical group differences in their *YourWay* internet-based intervention, although mean HbA1cs for the intervention group remained constant while the control group increased. Seventy-two adolescents, from ages 13-17 with T1D were randomized to the intervention involving internet support designed to enhance problem-solving barriers to self-management with diabetes care as usual or just diabetes care as usual. The intervention lasted 11 weeks and included six

multimedia stories depicting psychosocial barriers to self-management and approaches to coping and problem solving. There were other activities that included a personalized homepage, multimedia presentations on the steps of problem-solving and how to use the website, social networking via a peer forum, help from a problem-solving expert and weekly emails that encouraged participation.

Only one (Cook, Herold, Edidin & Briars, 2002) of the six problem-solving interventions (Hains et al., 2000; Howells et al., 2002; Mendez & Belendez, 1997; Olmsted et al., 2002 and Mulvaney et al., 2010) for adolescents had significant improvements on glycemia and it involved providing education on diabetes problem-solving skills. When a person has diabetes, achieving blood sugar control requires problem-solving skills to analyze and treat the acute complications of diabetes such as hyper/hypoglycemia, pump failure, etc. Diabetes self-management education supports problem-solving and informed decision-making (Funnell et al., 2010). In fact, recommendations from the ISPAD (2014) state that care for adolescents with T1D should aim to provide interventions that emphasize effective problem-solving and self-management skills with realistic expectations about glycemetic control (Delamater, de Wit, McDarby, Malik and Acerini, 2014). In general, the research demonstrates that problem-solving skills alone are not enough to improve glycemia.

Coping skills training

A considerable amount of work has been done over the past ten years with coping skills training (CST) for school-aged youth and adolescents with T1D. In these well controlled trials, CST has been used as an intervention to increase youths' sense of competence and mastery by retraining those who demonstrated poor coping styles (Grey

et al., 1998, 2000, 2013; and Whittlemore et al., 2012). The CST program teaches adolescents with T1D communication skills, social skills, social problem-solving, conflict resolution and cognitive behavior modification (a psychotherapeutic approach that focuses on dysfunctional behaviors with exercises to change those unwanted behaviors). In one of the first interventions to use CST, 65 youth ranging from 12 to 20 years old who were beginning a program of intensive insulin management were randomized to either CST with intensive insulin therapy or just intensive insulin therapy (Grey et al., 1998). Follow-up at 3 months indicated lower HbA1c levels and better diabetes self-efficacy in the intervention group. At 12 months, adolescents in the intervention group continued to have better HbA1c levels and better diabetes self-efficacy than the group that just received the intensive insulin therapy (Grey et al., 2000).

Grey et al.'s most recent study (2012, 2013) compared the effects of a 5-week internet-based CST program – *TEENCOPE* - with a 5-week internet-based education program that included problem-solving exercises and case studies for diabetes management. The study was conducted at four sites across the country and included 320 youth 11-14 years of age with T1D on intensive insulin therapy. In an effort to reach more youth and a more diverse population and to be more cost-efficient, the CST intervention was delivered via the internet (Grey, Whittlemore, Liberti, Delamater, Murphy & Faulkner, 2012). Outcomes after 6 months showed no significant between-group treatment effects post-intervention on primary outcomes (HbA1c and quality of life). Youth in the education group showed a significant increase in social competence compared to the *TEENCOPE* group (Whittlemore et al., 2012). At 12 months, follow-up results indicated, again, that there were no significant primary outcome differences

between those teens that received only *TEENCOPE* or diabetes management education (Grey et al., 2013). At 12 months, youth were invited to cross over to the other program (*TEENCOPE* or diabetes management education). Follow-up data were collected at 18 months. Youth who completed both programs had lower HbA1c levels, higher quality of life, social acceptance, and self-efficacy scores with lower perceived stress and diabetes family conflict compared with those who completed only one program (Grey et al., 2013). These results suggest that youth with diabetes may benefit from a combined approach using both a behavioral intervention and DSME. Despite the mixed results from these studies, the blended intervention approach shows promise).

Motivational interviewing

Motivational interviewing (MI) is another strategy that has been used to influence behavioral changes in adolescents with T1D. MI was first described as an approach to behavior change by William R. Miller in 1983 as a treatment tool for problem drinkers. It has become established as an evidence-based practice in the treatment of individuals with substance use disorders. MI is now being used as a modality for a variety of health conditions, including diabetes (Hettema, Steele & Miller, 2005; Rollnick, Miller & Butler, 2008).

Motivational interviewing is a method of communication that elicits the patients' goals and their desired approach to attaining their goals (Scarborough, Lewis and Kulkarni, 2010). Motivational interviewing encourages persons to identify aspects of their behavior that they would like to change and to also identify the benefits and difficulties in making such changes (Miller & Rollnick, 20023). It relies on reflective listening and positive affirmations (Miller and Rollnick, 2009). It uses a patient/family-

centered approach that addresses the ambivalence toward change by highlighting the discrepancies between a person's current values and behaviors and their future goals (Erickson, Gerstle & Feldstein, 2005). MI involves active listening that incorporates the individual's beliefs regarding health and illness, understanding of health risks of current behavior, readiness to change, and confidence in making the change (Gance-Cleveland and Oetzel, 2010). The counselor elicits goals, explores the discrepancy between current behavior and desired health goals. The process includes a) establishing rapport, b) assessing behavior and motivation for change, c) tailoring the approach to counseling based upon the readiness to change, d) facilitating the individual and family's ability to set goals, e) problem-solving and planning change and f) providing information when requested (Gance-Cleveland & Oetzel, 2010).

There are four broad guiding principles that underlie MI: express empathy, develop discrepancy, roll with resistance and support self-efficacy (Miller and Rollnick, 2002). Skillful reflective listening is fundamental to the expression of empathy; the attitude underlying this is acceptance and a desire to understand the adolescent. The client rather than the counselor should present the arguments for change; change is motivated by a perceived discrepancy between present behavior and important personal goals or values (Miller and Rollnick, 2002). In MI, resistance to change is not directly opposed. New perspectives are provided when invited but not imposed by the counselor. The client is a primary resource in finding answers and solutions and resistance to change by the client is a signal to respond differently to the client (Miller and Rollnick, 2002). Lastly, a person's belief in the possibility of change is an important motivator. The client, not the counselor, is responsible for choosing and carrying out change (Miller and Rollnick,

2002). These four principles of MI occur in two phases. During the first phase there is a building of intrinsic motivation to change, and during the second phase there is a strengthening of a commitment to change (Miller and Rollnick, 2002).

According to Miller & Rollnick (2002), the ‘spirit’ of MI involves collaboration between the client and the practitioner. Adolescents desire autonomy and want the respect and support of caregivers. MI with its goal setting and problem solving strategies encourages the adolescent to be in control which in turn enhance diabetes self-efficacy. MI has been used for young persons who express low motivation, hesitancy to engage in treatment, or difficulty in changing behavior (Naar-King & Suarez, 2010). Evidence is emerging to support the efficacy of MI for chronic illness management, especially in adolescents with T1D.

In a preliminary study looking at the impact of MI on glycemic control, well-being and self-care, Channon, Smith and Gregory (2003) conducted a pilot study in which participants were first assessed for readiness to change based on the Transtheoretical Model. Those teens in the “pre-contemplation” or “maintenance” stage were disqualified from the study. Only those teens in the “contemplation” stage were invited to participate in the intervention. The intervention took place over a 6-month period of time but could end when the participant desired. The participants chose the location and frequency of the intervention. The results of the study showed a significant reduction in HbA1c both during and after the study with a reduction in fear of hypoglycemia and living with diabetes but no changes in measures of wellbeing, diabetes self-care, family behaviors and process or diabetes knowledge. When assessed for readiness to change, 64% of participants indicated a movement towards action whereas 27% indicated a reduced

readiness to change. The results indicate inconsistencies between self-care and HbA1c improvements. In a follow-up randomized, controlled trial Channon et al. (2007) compared MI to support visits. At one year post intervention, the mean HbA1c of the MI group was significantly lower than the control group. The difference in HbA1c was maintained at 24 months. There were differences in psychosocial measures between the MI group and the control group at 1 year with improvements in well-being, quality of life and differences in their personal models of illness. Those differences were maintained at 24 months.

In a different study using small, group delivery format (5-6 in a group) and more than one group, Viner, Christie, Taylor and Hey (2003), enrolled 21 adolescents identified as being “ready to change” into an intervention that used motivational and solution-focused techniques. A group for parents was held prior to the start of the sessions for adolescents to facilitate parental support for change. The group that received the intervention had a 1.5% improvement in their HbA1c within 1-3 months and benefits of the intervention were partly maintained up to 7-12 months later. This was a non-randomized study in which the participants self-selected into either the intervention group or the control group.

Nansel et al. (2007, 2009) report positive long term outcomes at 1 and 2 years using a combination of MI with a “personal trainer” (PT). Eighty-one youth aged 11-16 – along with a parent – were randomized to the intervention or usual care by two categories, 11-13 or 14-16 years, and HbA1c, <8.0 or $\geq 8.0\%$, for a total of four groups. Each youth with parents received telephone calls and six in-person sessions. MI, applied behavior analysis (a psychotherapeutic approach to changing unwanted behaviors) and

problem-solving measures were implemented in the intervention. At both short term and 1 year follow-up, the trend showed an overall intervention effect on HbA1c and a significant intervention-by-age interaction indicating a greater effect among older than younger youth. At a two year follow-up (2009), an overall intervention effect on HbA1c with a significant intervention-by-age interaction for older youth continued indicating maintenance of intervention effects.

In a study conducted over a 9-month time frame, Wang et al. (2010) compared the effectiveness of MI-based education and structured diabetes education (SDE) in improving metabolic control and psychosocial outcomes in adolescents aged 12-18 years with poorly controlled T1D. Teens participated in two intervention sessions – one at enrollment and the second 3-4 months after enrollment. In addition, there was a phone follow-up at 1 and 2 months. Over the 6-month follow-up, the SDE group had a lower adjusted mean HbA1c over the MI group with no differences between the two groups for psychosocial measures. A limitation to this study is the intervention dose; two sessions separated by 3-4 months. The behavioral interventions that show success tend to have multiple sessions over several weeks.

Motivational interviewing involving more than two sessions has been shown to be an effective intervention for behavioral change and is a promising approach for improving glycemia in adolescents with T1D. As Skinner, Murphy and Huws-Thomas (2005) point out, the use of MI with adolescents makes sense as there is a natural fit with the principles surrounding the care of these youth and the tenets of MI: rapport building, directiveness and empathy (Skinner et al., 2005).

Literature summary

It is recommended that behavioral interventions that enhance the ability of youth to self-manage diabetes be incorporated into routine care (Silverstein et al., 2005). Several of the behavioral interventions discussed in this section enhance problem-solving, a necessary component of diabetes self-management; however, interventions working on problem-solving alone have not been shown to sufficiently improve glycemia. While many of the studies demonstrate effectiveness, coping skills training alone did not improve diabetes-related outcomes more than DSME or problem-solving intervention. It is when coping skills training and DSME are combined, outcomes improve, suggesting that youth need both a behavioral intervention and DSME.

Glasgow et al. (2006) described the challenges of evaluating diabetes self-management support interventions: “The areas of care least likely to be provided consistently are self-management support and patient-centered care...both involve understanding patient perspectives, setting collaborative goals, and tailoring interventions for patients. Added to these challenges are disparities in both care received and health outcomes (especially) for minority and underserved patients” (Glasgow et al., 2006, pg. 67). Many factors underlie an adolescent’s diabetes care which must be taken into consideration when developing interventions; therefore, it is crucial to look more closely at the person and target the intervention to the individual’s needs rather than to teens as a whole. The coping skills training interventions do not have an individualized focus. Not all adolescents need coping skills training nor do all adolescents have the same level of motivation to self-manage their diabetes. “MI differs from other approaches in that the focus is on the individual’s reasons for change instead of the pressure from external

forces” (Naar-King & Suarez, 2011, pg 22). Motivational interviewing can elicit self-determined goals and values for making behavior changes. Of all available behavioral interventions, MI has the greatest degree of respect for the adolescent’s autonomy and individuality. Although results for the use of MI are mixed, perhaps the combination of MI (with its problem-solving component) and DSME will produce better results than the use of MI alone.

Summary

There is a direct relationship between one’s actions and one’s blood glucose results which, in turn, influences beliefs about diabetes and how to manage it (Skinner, Murphy & Huws-Thomas, 2005). Self-efficacy is a key belief underlying an adolescent’s motivation to act intentionally. Self-efficacy beliefs are sensitive to variations in the conditions and outcomes of actual performance (Zimmerman & Cleary, 2006). If an adolescent is unable to regulate blood sugars effectively, diabetes control declines leading to a loss of self-efficacy relative to diabetes self-management. As self-efficacy diminishes, glycemia worsens (Johnston-Brooks, Lewis and Garg, 2002; Chih, Jan, Shu and Lue, 2010); hence, self-efficacy is an important factor influencing adolescent diabetes self-management behaviors. The development of diabetes self-management values during adolescence subsequently integrated into adulthood may prove very difficult to change later in life; therefore, education and psychosocial care early in an adolescent’s development are essential to achieving positive outcomes for adulthood (Skinner, Murphy & Huws-Thomas, 2005). The use of tailored DSME along with the principles of MI via the internet is a promising way to reach adolescents with T1D. Combining a behavioral intervention that focuses on the adolescent’s needs and goals and

that incorporates DSME with problem solving components has the potential to improve diabetes self-management self-efficacy and thus improve metabolic control.

Chapter 3

Methodology

Research Design

The purpose of this study was to develop, test the fidelity and evaluate the feasibility of *Can-Do-Tude*. Feasibility studies are relied on to produce a set of findings that help determine whether an intervention should be recommended for efficacy testing and are indicated when there are few previously published studies using a specific intervention technique (Bowen et al., 2009). Based upon a review of published literature, this is the first intervention to use the principles of MI online for adolescents with T1D. According to Bowen et al., (2009), in the initial phase of developing an intervention, “*Can it work?*” is usually the first and main question. Once it is determined that it might work, it is followed by the question “*Does it work?*” These are the questions used to address feasibility studies (Bowen et al., 2009).

This study used a multi-phase, multi-method approach to accomplish the aims. The study had two phases. The first, the alpha test of the intervention, was a qualitative descriptive study in which experiential experts that were familiar with either T1D and DSME, MI, or information technology/online education development evaluated intervention fidelity: functionality, accuracy, usability and security. The purpose of the phase 1 study design was to answer the question “*Can it work?*” The second phase of the study, the beta test, was a quantitative descriptive design to evaluate the recruitment, retention and satisfaction of adolescents between 13 and 17 years of age with T1D. They provided feedback via a satisfaction survey in regards to usability, purposefulness and recommended improvements. It also included a one-group, pre- and post-test to examine,

in a limited way, the intervention's intermediate outcome, diabetes self-management self-efficacy. Beta test design was meant to answer the question "*Does it work?*"

The purpose of this feasibility study is to determine if *Can-Do-Tude* has promise as an intervention that assists teens in improving diabetes management.

Bowen et al., (2009) proposes that feasibility research in the intervention-research process should be a mechanism to determine whether to accept or discard an intervention and that this is a key way to advance only those interventions that have a high probability of efficacy. Therefore, this feasibility study will determine whether *Can-Do-Tude* - as an online intervention using the principles of MI with DSME - is acceptable and worthy of advancing to further testing or whether the intervention should be rejected.

Sample and Setting

The alpha test. It was determined that for phase 1 of the intervention four content experts would be sufficient to assess the performance (functionality, accuracy, usability and security) of the online intervention. Participants were provided online access and also given hard copies to review the intervention. There was not a formalized setting for review.

The beta test. Adolescents 13 – 17 years of age with T1D were needed for the study and were recruited from four different settings: a) Children's Rehabilitative Services (CRS) at Flagstaff Medical Center (FMC) in Northern Arizona where an endocrinology clinic is run three days of the month; b) the American Diabetes Association's annual diabetes camp drop-off site at Phoenix Children's Hospital; c) Cardon Children's Medical Center at Banner hospital in Phoenix, Arizona where the Pediatric Diabetes Program Manager passed out recruitment flyers at her diabetes support

group; and in an effort to blanket Arizona with advertisements for subjects to participate in the study, d) recruitment flyers were posted on nine Craigslist sites throughout the state of Arizona (Flagstaff, Phoenix, Tucson, Yuma, Sierra Vista, Winslow, Lake Havasu, Kingman and Show Low).

The Intervention

The intervention consisted of diabetes self-management education and used the principles of motivational interviewing by way of an online platform to improve diabetes self-management self-efficacy in adolescents with type 1 diabetes. The intervention was conducted via a password protected site which was distributed through Qualtrics survey software. An internet URL link, as well as a password, was provided to participants. The link and password takes the participant directly to the intervention within Qualtrics. The intervention was accessible to only individuals who were invited to use the program by the principal investigator (PI). A detailed description of the online security is described under Human Rights Protection.

The online intervention consisted of MI messages that are tailored to the participant's response to readiness to change using an MI algorithm that assessed the participants' motivation (importance, readiness and confidence) to change their diabetes self-management behaviors. The language used in the tailored messages used the principles of MI. The intervention contained a script of MI tailored messages that address perceptions and beliefs around diabetes self-management such as benefits, barriers, perceived self-efficacy and perceived risks of not managing one's diabetes.

The intervention was a 4-week intervention involving 5 potential pathways based on a weekly assessment of readiness to change. Each week, the intervention began with

an assessment of how the adolescent felt about a particular diabetes behavior: (a) it is not important to change diabetes self-management behaviors and he/she doesn't want any information about self-management; (b) it is not important to change diabetes self-management behaviors that week but he/she will accept information on changing behaviors; (c) it is important to change current diabetes self-management behaviors but he/she is not confident in doing so; (d) it is important to change current diabetes self-management behaviors and he/she is confident that he/she can do it, but is not ready to change; and lastly, (e) it is important to change diabetes self-management behaviors and he/she is confident and ready to do so. If the adolescent was assessed to not believe it is important to change a behavior and did not want information, the intervention did not continue for the individual for that week. Otherwise, if the participant is assessed at any of the other levels of motivation the intervention addressed that particular level and that was the teen's module for the week. [See the MI algorithm (Appendix A)].

There was a specific DSME theme with objectives each week: monitoring blood sugars, physical activity, diet and blood sugar pattern recognition, respectively. Each of these 4 components then used appropriate MI techniques for the particular level of importance, readiness and/or confidence. The adolescent then completed 1 module a week for a total of 4 for the 4-week intervention. Each intervention took approximately 30 minutes. Assessing for the adolescent's importance, readiness and confidence about changing one's self-management behaviors each week and placing them in an appropriate module allowed the participant to have an individualized intervention. [See Intervention Objectives (Appendix B)].

The interventionist is a former certified diabetes educator who has received training in motivational interviewing through courses at Mid Atlantic Addiction Technology Transfer Center and Arizona State University. One of the content experts who evaluated the intervention has expertise in the use of MI and reviewed the intervention to ensure that MI principles were upheld by the interventionist.

Software Platform

Qualtrics is Web-based research survey software and was used to deliver the MI intervention. Surveys can be created by anyone with a license to use the product. The survey can be distributed to anyone invited to participate in the survey by the author. Qualtrics offers many advanced, but user-friendly features such as easy survey design, point-and-click editing and automatic choices. It also allows for a comprehensive list of question types including pick, group and rank, drill down, rank order, heat map and hot spots enabling an interactive design that will better engage an adolescent. The software enables users to do many kinds of online data collection and research analysis (Qualtrics, 2016).

Human Rights Protection

Adolescents as well as adults were used to provide feedback on the intervention and to test the intervention. The principal investigator (PI) was committed to protecting the rights of all participants. Study approval was granted from the Institutional Review Board (IRB) of Arizona State University in collaboration with the IRB of Northern Arizona Healthcare (for FMC) (Appendix C). Consents were obtained from the content reviewers for the alpha test. For the beta test, consents were obtained from a parent/legal

guardian and assents from the adolescent participants. Adolescents managed their diabetes as usual through their endocrinologist or primary care provider.

The study was developed to minimize participant burden by having the PI as the only facilitator of the online intervention with few instruments used. Participants could withdraw from the study at any time. All participant questions were answered and all information remained confidential. The PI was committed to following the guidelines of the Office for Protection of Human Subjects at Arizona State University and Northern Arizona Healthcare and followed all policies for the protection of research participants.

The PI was responsible for the protection of the study materials. Data from this study was derived from self-report questionnaires: an Adolescent Demographic Form (Appendix D) and Health Questionnaire (Appendix E). The self-report questionnaires were either collected in person during recruitment or sent to the PI through the mail from recruitment packets. Within the online intervention created with Qualtrics software, a Self-Efficacy for Diabetes Self-Management Instrument (Appendix F) and a Satisfaction Survey (Appendix G) were built into the intervention and the information obtained from those questionnaires is protected by Qualtrics. Qualtrics uses Transport Layer Security (TLS) encryption (also known as HTTPS) for all transmitted data. It protects surveys with passwords and HTTP referrer checking. Services are hosted by trusted data centers (such as universities) that are independently audited using the industry standard SSAE-16 method. HITECH (Health Information Technology for Economic and Clinical Health Act) updated the Health Insurance Portability and Accountability Act (HIPAA) rules to ensure that data are properly protected and best security practices are followed. Qualtrics

safeguards all customer data, and uses secure data centers to ensure the highest protection as per HITECH requirements (Qualtrics, 2016).

Alpha Test Recruitment

Inclusion criteria. To be included in this phase of the study, individuals had to have expertise in T1D, DSME, MI, or information technology/online education development as well as having a familiarity with adolescent behavior. Individuals needed expertise in at least one of these areas so that they could assess the performance of the online intervention as well as the developmental appropriateness of the intervention.

Besides having expertise in a particular area, each participant (who was not a member of the study committee) had to consent to participate in the study, have access to a computer and be willing to assess all 16 modules for performance.

Exclusion criteria. Exclusion criteria included persons that did not have strong computer skills and would not be able to navigate the website in order to give constructive feedback on the performance of the online intervention.

Participant recruitment. It was the research committee's desire to have at least four reviewers that have expertise in T1D and DSME, MI or information technology/online education development review the intervention.

Alpha test procedures. This was a performance test of the program. After the intervention was developed in Qualtrics and IRB approval for the intervention was obtained from Arizona State University, the PI provided each of the reviewers a packet. Within the packet there was an introductory cover letter, consent, directions for reviewing the intervention with a Guideline and Checklist for Website Testing (Appendix H) for

each week of the intervention, Intervention Objectives (Appendix B), the Intervention Algorithm (Appendix A) and a print-out of each week of the intervention. In addition, a username and password as well as the URL link to the intervention for the Qualtrics program were provided. Participants had 8 weeks to test every aspect of the intervention - all 16 modules - looking for such things as misspelled words, unclear directions or information, broken links, mis-synced audio and video clips and unacceptable download times. Participants assessed the overall performance (functionality, accuracy, usability and security) of the intervention. After eight weeks, the Web Testing Checklists with any comments were returned to the PI within a self-addressed stamped envelope provided in the packet. Some of the reviewers sent their assessments by email. Others sat with the PI or phoned the PI to provide feedback; detailed notes of conversations and recommendations were taken by the PI. Feedback from both the Web Testing Checklist and the participants were used to improve and further develop the intervention.

Beta Test Recruitment

Inclusion criteria. A purposive sampling technique was used. To be eligible for the study, a participant had to be 13 - 17 years of age with the diagnosis of T1D for at least one year. Tasks associated with the self-management of diabetes are being assumed by youth in early adolescence and this is a good time to begin instilling good self-management behaviors for later in life. There is a tremendous amount of education that is provided within the first several months of a new diagnosis of diabetes, as well as a steep self-management learning curve. It was desirable that all initial education for T1D be completed prior to the study and that the teen and their family have time to become

comfortable with the diabetes tasks. This was done in an effort to prevent potential influence on test results.

The participants had to be on intensive insulin therapy (i.e. multiple daily injections with a long acting insulin and rapid acting insulin or insulin pump therapy). It has been shown that this is the most optimal therapy for anyone with T1D. Although there will be treatment variability with either multiple daily injections or pump therapy themselves; these two treatments provide the best control (Silverstein et al., 2005; Rewers et al., 2014).

To participate in the intervention, subjects had to have access to a computer with high-speed internet. They had to also speak and write English since the intervention was in English only. And lastly, participants had to have a parental consent and an individual informed assent.

Exclusion. Subjects were excluded if they had any other significant health problems, an underlying psychiatric disorder or a learning disability reflected by being greater than two years behind in school. The rationale for these exclusions was that any one of these factors could greatly affect metabolic control and diabetes self-management.

Participant recruitment. Having received IRB approval first from Arizona State University and then Northern Arizona Healthcare, the PI met with the certified diabetes educators (CDEs) who are nurses at FMC where initial recruitment began through CRS. The PI was a former CDE at FMC and therefore had a positive relationship with the current CDEs. The intervention purpose and objectives were reviewed with the CDEs and the investigator demonstrated the on-line intervention. One particular CDE became the primary contact person for the study. That CDE was provided recruitment packets for

disbursement to eligible adolescents and their families. The recruitment packets contained a recruitment flyer (Appendix I), two Parent/Guardian Permission forms (Appendix J), two Adolescent Assent forms (Appendix K), a Contact Information form (Appendix L), an Adolescent Demographic form (Appendix D), a Health Questionnaire (Appendix E), a self-addressed envelope, the PI's contact information and a checklist with information on what needed to be returned to the PI. Extra recruitment flyers were also provided to the CDE. Information within the packets contained specifics about the program, the study's purpose and goals, participant rights, risks, benefits, privacy and confidentiality measures as well as options for withdrawal.

The CDE that works the clinic at CRS during the 3 endocrinology days (the primary contact) and the PI went through a registry of the youth that are treated at CRS. Fourteen adolescents were identified meeting the 13-17 year age range who had T1D for greater than one year. The CDE, with the approval of the attending endocrinologist, developed a letter that described CRS's full support of this research and encouraged the teens to participate in the study. The CDE then sent the letter on Northern Arizona Healthcare letterhead, signed by her, along with a recruitment flyer, to each of the 14 eligible teens.

Each month for 4 months, the PI attended the endocrinology clinic held at CRS. The CDE would give each of the 14 eligible teens, if they had an appointment during any of those 4 months, a recruitment packet. During the teen's clinic visit, if the family and teen were interested, the PI was invited to quickly discuss what the research involved and answer any questions the teen or family might have about participation in the intervention. Teens were further screened for inclusion criteria at this time.

Once it became apparent that the response to recruitment from the CRS endocrinology clinic was low, IRB approval was obtained from Arizona State University to recruit elsewhere. The American Diabetes Association gave approval for the PI to set up a vendor booth at the drop-off site for the annual diabetes camp. The drop-off site was held at an annex building associated with Phoenix Children's Hospital. Buses loaded with youth returning from camp were brought to the annex building to meet family. A table was provided to the PI to set-up a recruitment poster and to provide information and recruitment packets for interested parents and youth. Four sets of buses returned campers over a two-hour period of time. Prior to each set of buses, and while parents were waiting for the youth to arrive, the director of camp operations would announce to the parents that there was an opportunity to participate in a diabetes study for teens with T1D. When all families had left, representatives from Eli Lilly (sponsors of the event) took what was left of the recruitment flyers. They offered to take the rest of them to provide to Arizona endocrinology practices that they were planning to visit in the following week.

The program manager from the pediatric diabetes program at Cardon Children's Medical Center offered to pass out recruitment flyers at the diabetes support group meetings. Fifty flyers were provided to the manager.

In an effort to reach more youth with T1D in the state of Arizona, Craigslist was utilized to advertise the recruitment flyer. There are nine regions that have Craigslist sites. A recruitment flyer was posted on each of the sites and was posted under the city's name with internal links to community>volunteers>research study. The advertisements were reposted every week for 4 weeks in order to keep the advertisement active.

Retention and incentives. Adolescents earned five dollars for each week that they participated in the intervention with a total award of twenty dollars for completing all four weeks. Participants did not have to complete the four weeks to receive an incentive; it was given for each week they participated. The incentive was in the form of a cashier's check.

Beta test procedures. Once consents were obtained by the participant and parent or guardian, an email welcoming the adolescent to the intervention with the intervention link and password was sent. The participants were sent a link each week to access the following week's intervention. If a week went by without completing the intervention, a reminder was sent via e-mail. After four weeks, the adolescent was sent a thank you letter (Appendix M) along with a cashier's check and a follow-up Health Questionnaire (Appendix E) with a self-addressed envelope to return to the PI.

Alpha Test Measurements

Demographic variables. Demographic data for the alpha participants assessed educational level and experience with T1D and DSME, MI, IT and computer skills.

Intervention performance. To determine the performance of the internet intervention, a Web Testing Checklist was provided to the evaluators to assist them in the assessment of the website. Written and verbal communication was also utilized to provide feedback on the intervention. Performance was evaluated in regards to the online intervention's functionality (accuracy, usability and security) as well as the age appropriateness of the intervention.

Study measure. The alpha test used one study measure: the web testing checklist. The Web Testing Checklist (Appendix H) is a tool that was adapted from

various web application testing checklists and was provided to each of the reviewers as an optional instrument to be used to take notes and provide feedback and recommendations about the functionality of the online intervention.

Beta Test Measurements

Demographic variables. Demographic data for the beta testers was collected on the Adolescent Demographic form (Appendix D) and asked such information as date of birth, county of residence, race, ethnicity, gender, language, grade level, current grade point average and employment. Clinical information data for the adolescent was collected on the Health Questionnaire (Appendix E) which asked questions about characteristics of the adolescent's history of diabetes: initial diagnosis, last HbA1c, current diabetes self-management, number of hypoglycemic events, number of hospitalizations, diabetes related complications and any other conditions that the adolescent had been diagnosed with.

Evaluation of feasibility. Intervention feasibility was measured using two areas of focus: acceptability and implementation. Acceptability included an evaluation of the recruitment strategies, an evaluation of participant retention and participant satisfaction. Evaluation of the recruitment strategies included tracking the number of adolescents who expressed interest in participating in the online intervention and the number of adolescents and their parent who signed an informed assent/consent. Retention was measured by examining the number of participants who logged into the online intervention each week and completed it and the number of teens that finished all four weeks of the intervention. Lastly, acceptability of the online intervention was measured by participant satisfaction using a satisfaction survey. Feasibility of the intervention

focusing on implementation was measured by a pre- and post-test of diabetes self-management self-efficacy.

Study measures. The beta test included two study measures: the Satisfaction Survey and Diabetes Self-Management Self-Efficacy. Satisfaction was evaluated with a 6-item survey on how helpful, enjoyable, interesting, easy to use, worth the time spent and likelihood of changing behavior (Appendix G). Items were rated on a 5-point Likert-type scale with higher scores indicative of higher satisfaction (i.e., 1= not at all; 5=very much). The survey was created by the PI for this study and therefore has not undergone psychometric analysis.

The Self-Efficacy for Diabetes Self-Management (SEDM) is a 10-item questionnaire that covers major areas of diabetes self-management that tend to be challenging to good diabetes self-management (Appendix F). Psychometric properties of the SEDM show high internal reliability ($\alpha = 0.90$) and sound test-retest reliability ($r = 0.89$). In children 13 and older SEDM correlates with youth-reported diabetes self-management, parent reported diabetes self-management and glycemic control (Iannotti et al., 2006).

Data Collection

Data on demographics were collected during the consenting process and was provided as questionnaires (demographic form and health questionnaire) in the recruitment packet. The questionnaires were to be mailed back with the consents or filled out at time of consenting if this was done in person. A second health questionnaire was mailed with a thank you letter, cashier's check and self-addressed stamped envelope to be mailed back once the adolescent had either completed the intervention or had stopped it.

Recruitment data was collected during the consenting process. The remaining data - retention, satisfaction and diabetes self-management self-efficacy - was collected through the Qualtrics platform as part of the intervention.

Data Management

Confidentiality of all study data was maintained at all times by keeping hard-copy data locked in a file with no identifiers other than an identification number on the questionnaires. Data collected in Qualtrics has been secure and hidden behind passwords and access to Qualtrics and intervention responses has been restricted to all others other than the PI.

Data Analysis

Analysis for specific aim 1 (the alpha test). A detailed examination of the *Can-Do-Tude* intervention evaluating functionality (accuracy, usability and security) was used to analyze the results of the intervention's performance. To assist in the evaluation of its performance, a Web Testing Checklist (pg. 38 and Appendix H) was made available to reviewers. Feedback and suggestions from the Web Testing Checklist and any verbal and written communication to the PI were then used to revise and further develop the online intervention.

Analysis for specific aim 2 (the beta test). Feasibility, focusing on acceptability of the intervention, was evaluated by analysis of recruitment, retention and satisfaction. The recruitment strategies include the number of adolescents who expressed interest in taking part in the study and the number of adolescents and parent who assented/consented to participate. Retention was measured by the number of teens who logged into the intervention each week and the number who completed all four weeks of the intervention.

To indicate feasibility in regards to recruitment and retention, 75% of the adolescents that were recruited for the study would need to complete the 4 week intervention. Feasibility (acceptability) was also determined by participant satisfaction ratings. To indicate acceptability, 75% of the adolescent participants would need to rate their satisfaction as “mostly” to “very much” satisfied with *Can-Do-Tude*. Univariate descriptive statistics was run on all demographic and satisfaction survey variables.

Feasibility, focusing on implementation of the intervention, was also analyzed using a quantitative descriptive study design that included a pre- and post-test for diabetes self-management self-efficacy (The Self-Efficacy for Diabetes Self-Management Instrument). A Wilcoxon signed-rank test was conducted to compare scores prior to implementation of the intervention and again after its implementation. Criterion for statistical significance was set at .05.

This study was a requisite initial step in exploring a novel intervention. This study was not intended to test a hypothesis. The purpose of this study was to inform feasibility of an approach to diabetes care and identify modifications needed in the design of a larger, ensuing hypothesis testing study.

Chapter 4

RESULTS

The Alpha Test

Recruitment. It was desirable to have at least four individuals with expertise in either T1D and DSME, MI or information technology/online education development to review the intervention. Nine individuals were recruited to evaluate the intervention. Two individuals were recommended by the dissertation chair. They were faculty from the University of Colorado Denver who had expertise in both MI and technology/online education development. Another was faculty from the Ohio State University with a specialty in pediatrics and T1D. Three of the individuals were on the PI's dissertation committee. Two were college students familiar to the PI who had T1D and the last was an online course developer from Northern Arizona University. Of the nine individuals, all fit the inclusion criteria. Each consented to participate in the study.

The review took approximately 3 months. Of the 9 individuals recruited to review the intervention, 6 of the content experts gave full review of the 16 modules. The other 3 persons who had offered to review eventually backed out due to time constraints.

Demographics. Participant demographics (educational level and type of expertise are summarized in Table 1). Most participants were experts in more than one area.

Intervention performance (specific aim 1). Performance was evaluated in regards to the online intervention's functionality (accuracy, usability, security and age appropriateness). An internal test of the program was conducted prior to sending the intervention out for review. Thirty iterations or individual tests within the test survey

Table 1

Demographic Data for Intervention Reviewers (N = 6)

| Participant | Educational Level | Expertise |
|-------------|---------------------------------|-------------------------------------|
| 1 | Doctoral Degree | Adolescence, MI |
| 2 | Doctoral Degree | T1D in adolescents |
| 3 | Doctoral Degree | online education development |
| 4 | Doctoral Degree | online education development, MI |
| 5 | Doctoral Degree | Adolescence, T1D*, online education |
| 6 | 2 nd year in college | Adolescence, T1D* |

Note. * Denotes that the participant has T1D themselves.

feature of Qualtrics were completed for each of the four weeks. During the internal tests it was discovered that two of the weekly modules had a faulty link. Those links were fixed and subsequently the intervention was ready for content expert review.

Packets were sent to the reviewers containing the intervention link and password. The packets contained a hard-copy of the intervention as well as the Web Testing Checklist. The review of the intervention took approximately three months. Feedback on intervention performance was provided to the PI from comments via the Web Testing Checklist and verbal and/or e-mail communication. All links, forms and databases (i.e., the functionality) were found acceptable by the reviewers. The intervention content was deemed accurate, although several of the reviewers did find mistakes in spelling which were later corrected. The program was thought to be easy-to-use, requiring an appropriate amount of time to complete. Finally, there were no concerns about the security of the program.

In regards to age appropriateness of the program, the length of some of the information within the intervention was of the most concern to the reviewers. It was

suggested by 4 of the 6 content experts to cut information down to no more than a paragraph to keep adolescents engaged in the program. The PI therefore went through each week of the intervention and cut informational areas down to half their original content.

The intervention was designed to be interactive so as to keep the participant interested. Some of the reviewers suggested that forms within the intervention be more amusing than they were; therefore, different tools were utilized from Qualtrics to make those forms more attractive to adolescents.

The youngest participant to review the intervention was in early adulthood and himself a type 1 diabetic. That participant gave valuable feedback from the perspective of a young person dealing with T1D. The participant provided suggestions for changing the language so as to make it more appropriate for a young adolescent, especially one dealing with the challenges of T1D.

All of the suggestions from each of the reviewers were used to improve the intervention. After changes were made, 30 internal tests were conducted for each week of the intervention and no problems with functionality were identified.

At this point, the intervention was complete and ready for distribution for phase 2 testing (the beta test).

The Beta Test

Demographics. The sample for phase 2 of the study consisted of five adolescents. Three participants were male and two were female. All were Caucasian and of non-Hispanic/Latino ethnicity. All but one of the participants was in the 9th grade of school and the other was in the 11th grade. One participant was 14, three were 15 and one

was 17 years old. None of them were employed. Grade point averages for the teens ranged from 3.28 to 4.0. A summary of their clinical outcome data from the Health Questionnaire (Appendix E), pre- and post- intervention, is described in Table 2. The clinical outcome data were collected shortly before the adolescent began the intervention and then immediately after completing the intervention, four weeks after completing the first. As a result, much of the information is unchanged because of the short interval between the two questionnaires. Two of the participants never returned the Health Questionnaire post-intervention.

Table 2

Clinical Outcome Data Pre- and Post- Intervention (N =5)

| Clinical Outcome Study Number | 1 | 2 | Participants 3 | 4 | 5 |
|---|---------|------------------|-------------------|---------|---------|
| Glucose checks per day (pre/post) | 8/8 | 5-10/no results | 8-10/no results | 7/2 | 6/6-8 |
| Type of insulin therapy | pump | pump | pump | pump | pump |
| Last 2 HbA1c results | | | | | |
| 6 month pre intervention | 10.2 | 8.8 | 8.1 | 7.6 | 7.0 |
| 3 month pre intervention | 8.7 | 9.1 | 8.2 | 7.1 | 6.7 |
| Post intervention | 8.7 | no results | no results | 7.5 | 6.7 |
| Number of times below 50mg/dl in 3months (pre/post) | 10/5-10 | 9/no results | 9/no results | 24/3 | 2/3 |
| Diabetes related hospital visits in a year (pre/post) | 0/0 | 0/no results | 0/no results | 0/0 | 0/0 |
| Paramedic visits in a year (pre/post) | 0/0 | 0/no results | 0/no results | 0/0 | 0/0 |
| Highest blood sugar result within last month (pre/post) | 400/350 | > 400/no results | 349/no results | 430/450 | 335/312 |
| Lowest blood sugar result within last month (pre/post) | 43/55 | 47/no results | 43/no results | 53/40 | 54/48 |
| Diabetes related complications | none | none | none | none | none |
| Diabetes education in last 3 months | no | no | no | no | no |
| Attend diabetes support group | no | no | yes | no | no |
| Family or friend with T1D | Aunt | Father | no | no | Father |

Evaluation of feasibility (specific aim 2). Feasibility with a focus on acceptability and implementation of *Can-Do-Tude* was evaluated by (a) analysis of recruitment, retention and satisfaction and (b) diabetes self-management self-efficacy, respectively. Acceptability was determined by an analysis of recruitment, retention and satisfaction.

Recruitment for adolescent participants began as soon as IRB approval was obtained from Northern Arizona Healthcare. Recruitment was measured by the number of adolescents and family who were approached and consented. The first step of the recruitment process involved identifying those adolescents who were being seen through CRS for T1D and who were 13 – 17 years of age. The CDE identified fourteen potential participants and sent each of them a letter encouraging their participation in the study and a recruitment flyer (Appendix I). Of the fourteen potential participants, three of the adolescents and their parents emailed the PI expressing interest in participating. After six weeks, the CDE sent out a second mailing to the remaining eleven potential participants. No response was received from these eleven families. Of the three families that expressed interest, two provided assents/consents and were enrolled into the study. An assent/consent was not obtained for the third potential participant that expressed interest, even after two e-mail reminders.

The second step of the recruitment process involved recruitment when potential participants (the fourteen) had clinic visits with the endocrinologist. When the adolescent and their family were taken back to the clinic and the CDE met with them, the CDE would discuss the intervention and provide the family with a packet. If the family expressed interest, the CDE would ask the PI back to speak with the adolescent and their family to answer questions and clarify specifics about the study. The PI was present for 10 of the 14 potential participant visits: 2 were no-shows to their appointment and 2 were already participating in the intervention. Six adolescents or their families did not express a desire to ask the PI questions and therefore were provided information from the CDE only. Four adolescents or their family wanted further information. Two expressed

interest but were found not to have computer access to log into the study. And two other adolescents and their family expressed interest, asked questions and said they would consider participating but never contacted the PI to enroll in the study. Recruitment from CRS occurred over a 4-month period of time.

Recruitment from the ADA's diabetes camp drop-off site occurred on a Saturday morning in June. Four sets of buses returned campers over a two-hour period of time. Of the four buses, two had adolescent youth with both type 1 diabetes and type 2 diabetes. Three families waiting to pick up their teen spoke with the PI about the study. Before leaving for home, the three families had their son or daughter talked with the PI and all three teens expressed interest and took recruitment packets home with them. Eventually, all three teens and their parent assented/consented to participate in the study and test the intervention.

Flyers had been sent to the diabetes program manager at Cardon Children's Medical Center at Banner Health to be distributed at the diabetes support group for youth. One teen sent an email inquiry and asked for a recruitment packet. A packet was sent. After two weeks and no word from the teen, an email was sent offering to answer any questions. There was no reply. At the same time recruitment was occurring through the diabetes support group, advertisements for the study were posted on Craigslist sites throughout Arizona. Postings were refreshed each week for 2 months. After two months and no responses, the advertisements were taken off. A total of 5 teens were ultimately recruited to test the intervention.

Retention of the intervention was measured by the number of participants who logged into *Can-Do-Tude* each week and the number who completed all four weeks of

the intervention. Of the five participants, three completed all four weeks of the intervention and two completed 3 weeks of the intervention. One of the individuals who completed only 3 weeks of the study stopped the week that the winter holiday break began and the other stopped with the start of school after their summer break. An e-mail reminder had been sent to the two participants encouraging them to finish but neither responded nor logged in to continue. To indicate feasibility, it was desirable to have 75% of the teens complete all four weeks of the intervention. The completion rate for finishing the intervention was 60%; three of the five teens completed all four weeks. Between the 5 teens there were a total of 20 modules to complete. The participants logged into and completed 18 of the 20 modules, a 90% overall completion rate.

Feasibility in regards to the acceptability of the intervention was also measured using a Satisfaction Questionnaire (Appendix G). The survey was incorporated into the last module of the intervention, week 4. Because two of the participants did not complete week 4 of the intervention, there are only three completed satisfaction surveys. Results are shown in Table 3. Participants were asked to rate their responses on a 5-point Likert-type scale, ranging from “not at all” (1) to “very much” (5). The mean scores are reported for each question and a higher mean indicates a higher level of satisfaction. Results showed that the participants, overall, had a positive response to the intervention ($M = 4.28, SD = 0.55$). The teens reported that the intervention was helpful in managing diabetes ($M = 4.67, SD = 0.58$); enjoyable ($M = 4.0, SD = 1.0$); interesting ($M = 3.33, SD = 0.58$); easy to use ($M = 5.0, SD = 0$); that the time spent doing the intervention was worthwhile ($M = 4.33, SD = 0.58$); and that they were more likely to do something different in the management of their diabetes after completing the intervention

Table 3

Satisfaction (N=3)

| Question | Response* Mean (SD) | Comments (N=2) |
|---|---------------------------------|---|
| Has the intervention been helpful for you in managing your diabetes? | 4.67 (0.58) | |
| Was the intervention enjoyable to you? | 4.00 (1.00) | |
| Was the intervention interesting to you? | 3.33 (0.58) | |
| Was the program easy to use? | 5.00 (0.00) | |
| Do you feel that the time spent doing this intervention was worthwhile to you? | 4.33 (0.58) | |
| Are you more likely to do something Different in the management of diabetes after completing this intervention? | 4.33 (0.58) | |
| What improvements to the program would you recommend? | | “Nothing really.” “It was very easy to use!” |
| | Overall Response 4.28 (0.55) | |

Note. *Responses were on a 5-point Likert scale with 1 = Not at All; 2 = Not so Much; 3 = Sometimes; 4 = Mostly and 5 = Very Much.

($M = 4.33$, $SD = 0.58$). The one question that fell short of the desired “mostly” to “very much” satisfaction level asked the participants if the intervention was interesting to them. The participants had no recommendations for the improvement of the intervention *Can-Do-Tude*. One teen stated they saw no need for improvements and another said that it was easy to use.

Feasibility, focusing on implementation, was measured by a pre- and post-test using the Self-Efficacy for Diabetes Self-Management instrument (Appendix E). The

instrument was built into the first week's module and the last module, week 4. Again, since only 3 of the 5 teens completed week 4, only 3 of the instruments can be used for analysis. Analyses of the questions pre- and post-intervention are summarized in Table 4. Participants were asked to rate their responses on a 5-point Likert-type scale, ranging from "not sure at all" (1) to "completely sure" (5). The mean scores are reported for each question and a higher mean indicates a higher level of diabetes self-management self-efficacy. Of the 10 questions, 8 of the items showed improvement in diabetes self-management self-efficacy after completion of the intervention ($n = 3$). Participants reported improvements in the ability to adjust insulin correctly when eating ($M = 4.33$, $SD = 0.58$), to choose healthful foods when going out to eat ($M = 4.0$, $SD = 1.0$), to exercise even when they didn't really feel like it ($M = 3.67$, $SD = 1.15$) and to adjust insulin or food accurately based on exercise ($M = 4.33$, $SD = 0.58$). They reported improvements in the ability to talk to their doctor or nurse about any problems with diabetes management ($M = 5$, $SD = 0$). When asked about managing diabetes the way the health care team wanted them to, the participants responded favorably ($M = 3.67$, $SD = 1.15$). The responses indicated improvements in finding ways to deal with feelings of frustration about diabetes ($M = 3.0$, $SD = 1.73$) as well as identifying things that could get in the way of managing diabetes ($M = 4.0$, $SD = 0$). There was no change between pre- and post-test scores that asked if they would check blood sugars even when they were really busy ($M = 2.67$, $SD = 1.15$). One item had a small decrease in score; it asked whether they were able to manage their diabetes even when they felt overwhelmed ($M = 3.33$, $SD = 1.15$). A Wilcoxon signed-rank test indicated that the post-test scores were statistically significantly higher than pre-test scores ($Z = -2.952$, $p = .007$).

Table 4

Self-Efficacy for Diabetes Self-Management Pre- and Post-Intervention Analysis of Questions

| How Sure Are You That You Can Do Each of the Following, Almost All of the Time?* | Pre Intervention (N=3) | | | Post Intervention (N=3) | | |
|---|------------------------|-----|-----|-------------------------|-----|-----|
| | Mean (SD) | Min | Max | Mean (SD) | Min | Max |
| 1. Adjust your insulin correctly when you eat | 4.0 (1.0) | 3 | 5 | 4.33(0.58) | 4 | 5 |
| 2. Choose healthful foods when you go out to eat. | 3.0 (1.73) | 2 | 5 | 4.0 (1.0) | 3 | 5 |
| 3. Exercise even when you don't really feel like it. | 3.0 (1.73) | 2 | 4 | 3.67 (1.15) | 3 | 5 |
| 4. Adjust your insulin or food accurately based on how much exercise you get. | 3.33 (.94) | 2 | 4 | 4.33 (0.58) | 4 | 5 |
| 5. Talk to your doctor or nurse about any problems you're having with taking care of your diabetes. | 3.67 (1.53) | 2 | 5 | 5.0 (0) | 5 | 5 |
| 6. Do your blood sugar checks even when you are really busy. | 2.67 (2.08) | 1 | 5 | 2.67(1.15) | 2 | 4 |
| 7. Manage your diabetes the way the health care team wants you to. | 3.0 (1.0) | 2 | 4 | 3.67 (1.15) | 3 | 5 |
| 8. Manage your diabetes even when you feel overwhelmed. | 3.34 (2.08) | 1 | 5 | 3.33**(1.15) | 2 | 4 |
| 9. Find ways to deal with feeling frustrated about your diabetes. | 2.33 (2.31) | 1 | 5 | 3.0 (1.73) | 2 | 5 |
| 10. Identify things that could get in the way of managing your diabetes. | 3.67 (1.53) | 2 | 5 | 4.0 (0) | 4 | 4 |

Note. *Responses to the questions were valued on a 5-point Likert scale with 1 = Not Sure at All; 2 = Sometimes Sure; 3 = Half of the time Sure; 4 = Most of the time Sure; and 5 = Completely Sure.

**Indicates a drop in diabetes self-management self-efficacy.

Chapter 5

DISCUSSION

The purpose of this feasibility study was to develop, test and then evaluate *Can-Do-Tude*, a password protected online intervention that uses tailored diabetes self-management education and the principles of motivational interviewing for adolescents with type 1 diabetes. Feasibility studies are conducted in order to produce a set of findings that help determine whether an intervention should be recommended for efficacy testing (Bowen et al., 2010). The purpose of this study was two-fold: first, to determine if *Can-Do-Tude* could work (the alpha test), and second, to determine if *Can-Do-Tude* does work (the beta test) as an intervention for youth with T1D. To test “Can it work?” the study examined acceptability (recruitment, retention and satisfaction). To test “Does it work?”, implementation of the intervention was evaluated. Both acceptability and implementation were used to determine the feasibility of the *Can-Do-Tude* intervention. This chapter provides interpretations of the findings from the *Can-Do-Tude* intervention testing and examines the strengths and limitations of the study. Additionally, implications for future research will be examined.

Summary of Findings

After the four week online intervention was developed using Qualtrics software, content experts with expertise in T1D, DSME, MI or information technology/online education development evaluated the performance of the intervention. Changes were made to the intervention based on feedback and recommendations. *Can-Do-Tude* was then launched and tested by 5 adolescents 13 -17 years old with T1D who had been recruited throughout Arizona.

The alpha test (specific aim 1, intervention performance). Six content experts reviewed all 16 modules of the four week intervention and found the intervention to be functional, correct, usable, and secure but they had some concerns about the developmental appropriateness of the intervention. It was recommended by the majority of those that reviewed *Can-Do-Tude* to cut down on the material in the intervention to make it to a suitable length for an adolescent. It was also suggested to make some of the items in the intervention more interactive to engage the teen. The suggestions and recommendations were incorporated. The intervention was then ready for beta testing.

The beta test (specific aim 2, evaluation of feasibility). To evaluate feasibility, acceptability (recruitment, retention and satisfaction) and implementation (diabetes self-management self-efficacy) were examined.

Due to the very small sample size, feasibility cannot be demonstrated by recruitment and retention strategies. Only five teens were recruited for the study. Of those five adolescents, three of the five (60% completion rate) finished the 4-week intervention. However, there was a 90% completion rate (18 of 20) of all modules for the 4-week intervention between the five participants. Overall satisfaction for *Can-Do-Tude* was demonstrated, yet the sample size was very small and therefore feasibility cannot be assumed.

Limited efficacy was demonstrated in this small sample when it comes to diabetes self-management self-efficacy and may indicate *Can-Do-Tude*'s feasibility; several measures had moderate to large effects, but again, the sample was so small, feasibility is difficult to determine.

In looking at the health data from the Health Questionnaire, it was noted that all but one of the participants showed a declining trend in HbA1c values 6 months to 3 months out from the start of the intervention. Furthermore, all five participants had overall grade point averages in the A and B range. This may suggest that these teens were already at a high level of motivation.

The most significant road block to the success of this study was the inability to recruit more adolescents to test *Can-Do-Tude*. Five is a very small sample size. If this intervention was to be tested on a larger scale, there would need to be improvements in recruitment strategies in order to recruit more youth. This was a study that examined an intervention to build intrinsic motivation to self-manage diabetes in a population that has been shown to have poor glycemic control. The five recruited for this intervention appear to have motivation for self-care already and may not necessarily represent the typical teen with T1D. A larger sample size with a less homogenous sampling is needed for any future testing.

Five adolescents were recruited to participate in the beta test. Two of the five did not complete the last week of the intervention which meant they did not complete the Satisfaction Questionnaire or the Self-Efficacy for Diabetes Self-Management Instrument, limiting the results of this study. Recruitment occurred during major school breaks. One of the participants was recruited at the end of November with the last module of the intervention falling into winter break. Another teen was recruited during summer break and was lost when the last module of the intervention occurred at the onset of the new school year. Email reminders did not help to have these two participants finish the intervention. One valuable lesson learned from this study is that timing of

recruitment, considering the length of the intervention and the time needed to focus on it, is essential. In the future, the recruitment time frame will not occur during major holidays or other important events that would interfere with a participant's ability to complete the intervention.

The *Can-Do-Tude* intervention was well received by those who completed the satisfaction survey. All but one of the items surveyed reported high satisfaction. The item surveying whether participants found the intervention 'interesting', reported that they thought it was interesting "sometimes". Although the intervention was developed to engage the teen as much as possible, it is apparent future edits to the intervention need to be made to make the intervention more pleasing for teens.

All surveyed felt that the intervention was easy to use. Most felt that the intervention was helpful in managing their diabetes. Additionally, most felt that the time spent doing the intervention was worthwhile and that they would do something different about managing their diabetes. The fact that participants rated these items positively is indeed encouraging; and if only for this reason, this innovative study warrants further testing.

Improvements in diabetes self-management self-efficacy were exhibited in 8 of the 10 items on the Self-Efficacy for Diabetes Self-Management tool as well as overall for the three participants. Two items, one showing no change in results and the other a very slight decrease in results, reflect areas to improve upon in the intervention: checking blood sugars when really busy and finding ways to deal with diabetes when feeling overwhelmed, respectively. Although the sample size was small, diabetes self-

management self-efficacy results are very encouraging and demonstrate a need to further test *Can-Do-Tude*.

Summary

Strengths. The strengths of the study are as follows: (1) the designed intervention performs (i.e., content experts found the intervention to be functional, correct, usable and secure as well as being appropriate for adolescents); (2) the intervention is acceptable to those teens who participated in the study as demonstrated in the satisfaction survey; and (3) successful implementation was demonstrated in several items from the SEDM instrument.

Can-Do-Tude was developed as an online intervention incorporating principles of motivational interviewing and tailored diabetes self-management education. Each week the participant is assessed for their readiness to change particular behaviors--testing blood sugars, diet, exercise and pattern management, respectively. There are 5 potential paths that a participant can be directed to, based on their assessed level of motivation which accounts for the individualization of this particular intervention. It is a 4-week intervention that takes approximately 20-30 minutes a week to complete, an appropriate amount of time for an adolescent. *Can-Do-Tude* is easy to use and interactive since it utilizes activities, videos and topics that are meant to engage a teen.

The teens that tested *Can-Do-Tude* found it to be acceptable. In general, they had no recommendations for improvement. Most important, they found the intervention to be helpful in managing their diabetes and they were more likely to do something different to improve the management of their diabetes. *Can-Do-Tude* demonstrated improvements in diabetes self-efficacy in 2 of the 3. These are promising findings considering this was the

initial implementation of a new intervention to improve glycemia in adolescents with T1D. A sense of self-efficacy, or feelings of confidence in one's self-management behaviors, is fundamental to successful self-management (Beckerle & Lavin, 2013).

Limitations. Feasibility was not supported by the recruitment strategies for this study. It was speculated by the CDE, the endocrinologist and the PI that there would have been a much larger population of adolescents with T1D between the ages of 13 and 17 years that met inclusion criteria through CRS. With a pool of only fourteen adolescents to recruit from, determining feasibility based on recruitment and retention was impossible. Furthermore, recruiting during diabetes camp drop-off was chaotic and not conducive to attracting youth and families to participate in an intervention when they were anxious to return home (many had lengthy drives home). And lastly, advertising on Craigslist was not an effective recruitment strategy. Perhaps that is because the recruitment flyers were posted in the research study area of Craigslist. It is likely that most teens are not going to voluntarily look in that area of Craigslist.

Feasibility was not demonstrated with regards to retention when examining intervention completion. It could, though, be demonstrated if the total number of modules completed is taken into account. Participants completed 18 of the 20 modules, representing a 90% completion of material, as opposed to 3 of the 5 teens finishing the intervention.

Retention might have been more successful if recruitment did not happen prior to the beginning of the winter holiday break or the end of the summer break. Participants should be recruited during times of the year when they are less likely to have significant and/or lengthy distractions.

Another limitation to the study was the distribution of the Health Questionnaire. The Health Questionnaire was given to the participants prior to the start of the intervention and directly after the completion of the 4 week intervention. Changes in a participant's HbA1c could not be determined using self-report so soon after the intervention since the HbA1c test is collected at 3 month intervals during routine clinic visits. In addition, the Health Questionnaire was composed of self-reported data. In the future, clinical outcome data will need to be obtained from clinical records and not self-reports.

Lastly, the satisfaction survey used for this study was developed by the PI and not psychometrically tested. It is unclear how valid the questions are on the survey. For example, what is measured by the question "Was the intervention interesting to you?" Questions on the satisfaction survey need to be more specific. Words like "interesting" are vague and subjective and have too many frames of reference.

Conclusion and Implications for Future Research

Despite the limitations of the study, the improvements demonstrated by this handful of adolescents are encouraging. This is the first online intervention that has used the principles of motivational interviewing and tailored diabetes self-management education for adolescents with T1D. Although recruitment was not successful and retention had limited feasibility, the promising results garnered from the small participant pool suggest that *Can-Do-Tude* has potential. Ideally, future research should be conducted through a large diabetes center where recruitment can be better facilitated. Also, participants should not be recruited prior to long holiday breaks or at the end of a

break and the number of teens recruited not only need to be much larger but more diverse as well.

In future studies, the Health Questionnaire not only needs to be obtained prior to the start of the intervention but also at 3-month and 6-month intervals post-intervention to determine any lasting effects on an adolescent's HbA1c. The clinical outcome data will be obtained from the participant's clinical records as opposed to self-reports.

Furthermore, the satisfaction survey needs to be modified to be more specific in what it is asking so that results can be better measured. In the future, it will be helpful to add additional measures to the study such as quality of life and assessments of adherence. Future studies will target teens with very poor control such as those who have repeat occurrences of diabetic ketoacidosis and (in a different study) pre-adolescent youth with T1D transitioning into adolescence. Lastly, future studies need to separate out the ages so that results describe the younger adolescents separately than the older adolescents.

Since the development of the *Can-Do-Tude* intervention, Miller and Rollnick have published a third edition to their book, *Motivational Interviewing*, (Miller & Rollnick, 2013) that takes into account the thousands of research articles that have been published since their last edition, some of which have been cited in this study. They have taken best practice and evidence and instead of proposing phases and principles of MI, as they did in their last edition, they describe four broad processes - engaging, focusing, evoking and planning – and present new methodologies associated with these processes in the practice of MI. In addition, there have been substantial additions to technology since the development of this intervention. Currently the intervention is delivered online. With such widespread smart phone use by adolescents the intervention should be adapted

to be delivered by a phone app that the teen can access via their smart phone. Future research will need to take into account these new MI methodologies as well as a more teen favorable platform for the *Can-Do-Tude* intervention.

This study is the first step in a program of research to explore a unique and innovative intervention to improve diabetes self-management in adolescents with type 1 diabetes. Beta testing was limited and cannot fully answer the question “Does it work?” but preliminary testing indicates that it may. *Can-Do-Tude* is a novel - and timely intervention - that warrants further research.

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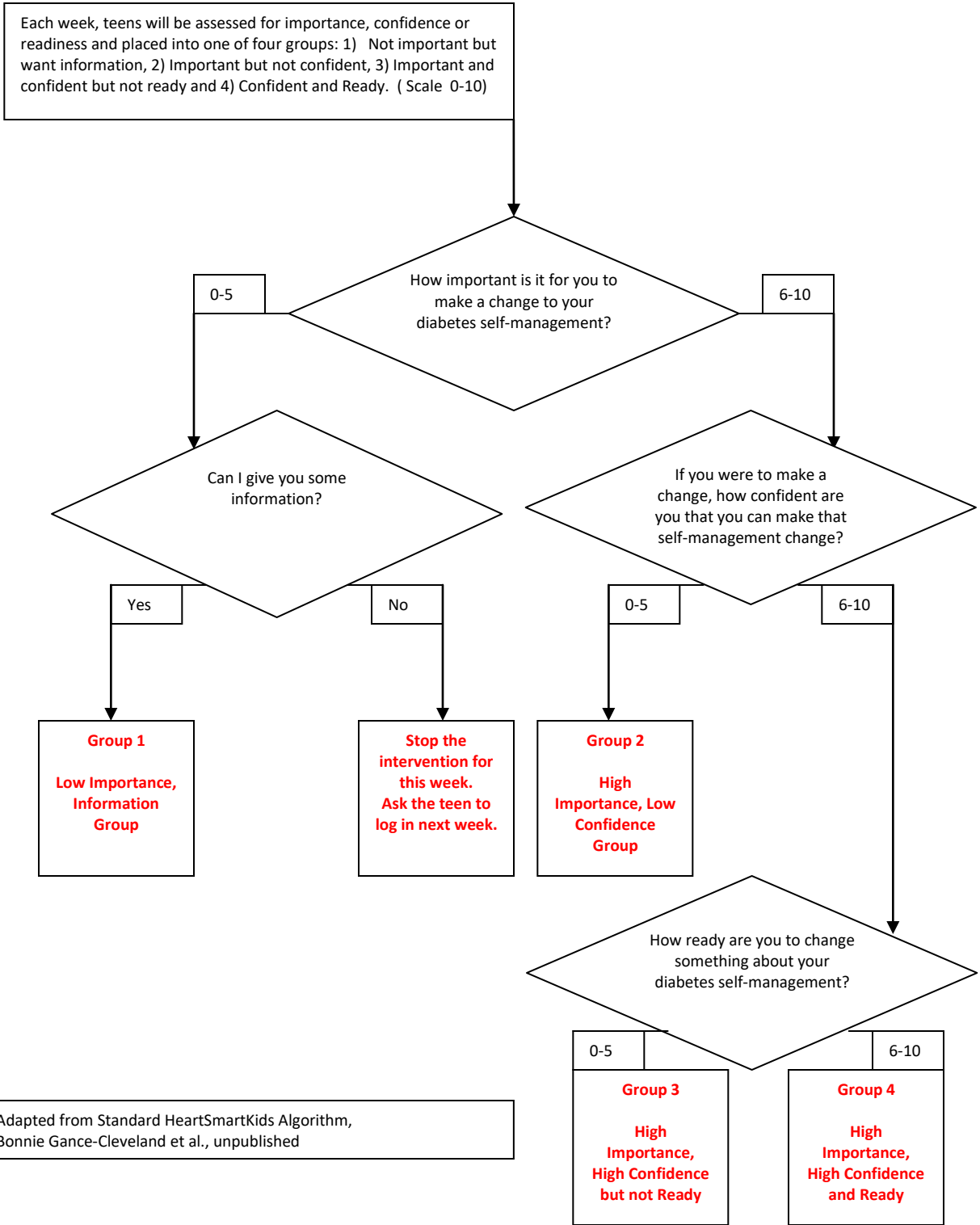
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APPENDIX A

MOTIVATIONAL INTERVIEWING ALGORITHM

Motivational Interviewing Algorithm



APPENDIX B
INTERVENTION OBJECTIVES

INTERVENTION OBJECTIVES

Overall Intervention Objective

Using the language and philosophy of motivational interviewing, elicit from the adolescent the motivation to improve self-management of their diabetes.

Overall Module Objectives

Each week the adolescent's baseline level of motivation (importance, confidence and readiness) to change diabetes self-management behaviors will be measured. Based on whether they deem change not important, important but not confident that they can change, important and confident that they can change but not ready to do so or important, confident and ready to change, the adolescent will be directed to a tailored intervention. Each intervention will use the four guiding principles of MI: resisting the righting reflex, exploring the adolescent's own motivations, being empathetic, and empowering the adolescent by encouraging hope and optimism.

Change is Not Important Group – Information Exchange

- Determine if the adolescent wants information or not.
- If the adolescent does not want information, the session ends.

Changing is Important but they are Not Confident that they can Change

- Explore ambivalence by using MI strategies to raise awareness and doubt and to increase the teen's perceptions with risks and problems of current behavior.
- Explore health threatening behaviors, prior attempts to change behaviors, and options that the teen has considered for changing behaviors.

Changing is Important, they are Confident that they can change but they are not Ready to Change

- Move the conversation to the possibility of change.
- Elicit change talk by asking the adolescent to consider life with and without change and by building discrepancy between the adolescent's current actions and his or her broader life goals and values

Changing is Important, they are Confident that they can change and they are Ready to Change

- Make decisions about change.
- Help teen identify a goal, build an action plan, anticipate barrier, agree on a plan for monitoring and elicit commitments.

APPENDIX C
INSTITUTIONAL REVIEW BOARD APPROVALS

APPROVAL: EXPEDITED REVIEW

Pauline Komnenich CONHI - PhD 602/496-0861 paulina@asu.edu

Dear Pauline Komnenich:

On 1/6/2014 the ASU IRB reviewed the following protocol:

| | |
|---------------------|---|
| Type of Review: | Initial Study |
| Title: | Tailored Web-Based Diabetes Self-Management Education Using the Principles of Motivational Interviewing for Adolescents with Poorly Controlled Type 1 |
| Investigator: | Pauline Komnenich |
| IRB ID: | STUDY00000199 |
| Category of review: | (7)(b) Social science methods, (7)(a) Behavioral research |
| Funding: | None |
| Grant Title: | None |
| Grant ID: | None |
| Documents Reviewed: | <ul style="list-style-type: none"> • Parent/Guardian Permission Form, Category: Consent Form; • Alpha Tester's Consent Form, Category: Consent Form; • Adolescent Assent Form, Category: Consent Form; • Komnenich/Paul Social Behavioral Protocol, Category: IRB Protocol; • Demographic Form - Adolescent, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Demographic Form - Parent/Guardian, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); |

| | |
|--|--|
| | <p>Instrument, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);</p> <ul style="list-style-type: none"> • Satisfaction Survey, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Permission to Use Self-Efficacy Instrument, Category: Off-site authorizations (school permission, other IRB approvals, Tribal permission etc); • The Intervention, Category: Other (to reflect anything not captured above); • Guideline and Checklist for Website Testing, Category: Participant materials (specific directions for them); • ASU CONHI Study Recruitment Flyer, Category: Recruitment Materials; • Log for Contact Information, ID and Intervention Password, Category: Resource list; • Health Questionnaire.pdf, Category: Screening forms; |
|--|--|

The IRB approved the protocol from 1/6/2014 to 1/5/2015 inclusive. Three weeks before 1/5/2015 you are to submit a completed “FORM: Continuing Review (HRP-212)” and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 1/5/2015 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the “Documents” tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator
cc: Linda Paul



APPROVAL:CONTINUATION

Pauline Komnenich CONHI - PhD 602/496-0861 paulina@asu.edu

Dear Pauline Komnenich:

On 12/30/2014 the ASU IRB reviewed the following protocol:

| | |
|---------------------|--|
| Type of Review: | Continuing Review |
| Title: | Tailored Web-Based Diabetes Self-Management Education Using the Principles of Motivational Interviewing for Adolescents with Poorly Controlled Type 1 |
| Investigator: | Pauline Komnenich |
| IRB ID: | STUDY00000199 |
| Category of review: | (7)(b) Social science methods, (7)(a) Behavioral research |
| Funding: | None |
| Grant Title: | None |
| Grant ID: | None |
| Documents Reviewed: | <ul style="list-style-type: none"> • Parent/Guardian Permission Form, Category: Consent Form; • Alpha Tester's Consent Form, Category: Consent Form; • Adolescent Assent Form, Category: Consent Form; • ASU CONHI Study Recruitment Flyer, Category: Recruitment Materials; |

The IRB approved the protocol from 12/30/2014 to 1/4/2016 inclusive. Three weeks before 1/4/2016 you are to submit a completed "FORM: Continuing Review (HRP-212)" and required attachments to request continuing approval or closure.



Page 1 of 2

If continuing review approval is not granted before the expiration date of 1/4/2016 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the “Documents” tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc:

86001 928-779-3366 <http://www.nahealth.com/>

TO: Linda Paul, PhDc

STUDY/ACTIVITY TITLE: [649256-1] Tailored Web-Based Diabetes Self-Management Education Using the Principles of Motivational Interviewing for Adolescents with Poorly Controlled Type 1 Diabetes

SUBMISSION TYPE: **New Project Expedited Review**
REVIEW TYPE:

ACTION: **APPROVED**

APPROVAL DATE: **September 29, 2014**

NEXT REVIEW DUE: **September 29, 2015**

SPONSOR: None

RECUSALS:

Thank you for your submission. Your activity/study proposal has been APPROVED by the Northern Arizona Healthcare Institutional Review Board (NAH IRB) under the category of Expedited Review based on applicable regulations. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research and/or activities must be conducted in accordance with this approved submission.

This study/activity has been determined to be a Minimal Risk project. It requires continuing review by NAH IRB on an annual basis unless otherwise noted in your review date. Please use the appropriate forms for this procedure.

Also, please be advised of the following stipulations of continuing approval for all NAH IRB studies/ activities, as applicable:

Review/Continuation of Study/Activity: Must be submitted to the IRB three (3) weeks prior to the study/activity review date and you will receive a courtesy reminder notice in advance of the deadline for submission (Next Review date is noted above, if applicable). Note that late submissions may result in studies/activities being temporarily suspended and/or closed to accrual of new subjects, or permanent closure;

Amendments or Changes (Protocol or Consent Form): Unless done to eliminate immediate hazard to the subject/patient, any and all changes in the study/activity must be promptly submitted to the IRB and approved by the IRB prior to their implementation (i.e., Protocol revisions, Investigator/ Treating Physician changes, consent form revisions, etc.);

Risks and Information: Unanticipated risks and new relevant information that may impact the risk/ benefit ratio of the test article for the subject must be submitted to the IRB within five (5) working days;

Adverse Events: Prompt reporting is required for events that are (a) unanticipated (i.e., not identified as reasonably foreseeable in the protocol and/or consent form and (b) of sufficient seriousness to affect the relative risks and benefits of participating in the study/activity as contemplated by the approved protocol and/or consent form). "Prompt" is defined to mean as soon as the seriousness of the issue reasonably demands. Serious adverse events should be reported to the IRB within one (1) week of Investigator/Treating Physician becoming aware of the event; any other unanticipated problem should be reported to the IRB within two (2) weeks;

Life Threatening/Death Events: Any life-threatening event or study-related death must be submitted to the IRB within twenty-four (24) hours;

Emergency Use: Emergency use of an Investigational Drug in a life-threatening situation, which must be documented and certified by an uninvolved Hospital physician, i.e., that the emergency existed which required use of the investigational article, must be submitted to the IRB within five (5) working days; and

Informed consent: If applicable, please remember that informed consent is a process beginning with a description of the project and assurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require that each participant receives a copy of the consent document.

Please note that all research records must be retained for a **minimum** of three years after the completion of the project.

The IRB maintains the authority to terminate or suspend approval of research that is not being conducted in accordance with stated IRB requirements or that has been associated with unexpected serious harm to subjects. The IRB operates in compliance with 21 Code of Federal Regulations ("CFR") Part 56 and 45 CFR Part 46.

If you have any questions, please contact Paula McAllister at 928-214-3616 or paula.mcallister@nahealth.com. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Northern Arizona Healthcare Institutional Review Board's records.

Generated on IRBNet

APPENDIX D
ADOLESCENT DEMOGRAPHIC FORM

Adolescent Demographic Form Online Intervention for T1DM Study

ID #: _____ will be assigned for study confidentiality.

Telephone Number: _____ E-
mail: _____

Date of Birth: _____

County of Residence: _____

Race

- Black/African American
- American Indian/Alaska Native
- Asian
- Native Hawaiian/Pacific Islander
- White
- Other: _____
- Don't Know

Ethnicity

- Hispanic/Latino
- Non-Hispanic/Latino

Gender

- Male
- Female

Preferred Language

- English
- Spanish
- Other: _____

Current Grade Level

- 5th Grade
- 6th Grade
- 7th Grade
- 8th Grade
- 9th Grade
- 10th Grade
- 11th Grade
- 12th Grade
- Other

Current GPA: _____

Are you currently employed? yes no

APPENDIX E
HEALTH QUESTIONNAIRE

Health Questionnaire
(Clinical Outcome Data)

ID #: _____ Date: _____

| | |
|--|--|
| Tell us about you: | |
| Date of Birth | |
| When were you diagnosed with Diabetes (year) | |
| How do you manage your diabetes: | |
| Current Number of Blood Glucose Tests/ Day | |
| Type of Insulin Therapy (Circle One) | Insulin Pump Injections Other |
| Number of Insulin Injections /Day (if applicable) | |
| Last 2 A1C Lab Results | A1C Result: Date: A1C Result: Date: |
| Tell us about your diabetes: | |
| Number of times that you have been below 50 mg/dl within the past 3 months (estimate)? | |
| Number of diabetes-related hospital visits within the last year (please explain) | |
| Number of paramedic visits within the last year | |
| Highest and lowest blood glucose levels within the last month | |
| Diabetes related complications (please list): | |
| Have you had diabetes education in the last 3 months? (please explain) | |
| Do you belong to a diabetes support group? (Circle One) | Yes No |
| Do you know of anyone else with Type 1 diabetes? (please explain) | |
| Have you been diagnosed with any other conditions? (please list) | |

APPENDIX F

SELF-EFFICACY FOR DIABETES SELF-MANAGEMENT

RE: Permission to use the Self-Efficacy for Diabetes Self-Management instrument

Linda Louise Paul

To:

[Nansel, Tonja \(NIH/NICHD\) \[E\] \[nanselt@mail.nih.gov\]](mailto:nanselt@mail.nih.gov)

Monday, September 23, 2013 5:17 PM

Thank you. Linda

From: Nansel, Tonja (NIH/NICHD) [E] [nanselt@mail.nih.gov]

Sent: Monday, September 23, 2013 2:50 PM

To: Linda Louise Paul

Subject: RE: Permission to use the Self-Efficacy for Diabetes Self-Management instrument

Dr. Paul,

Dr. Iannotti recently moved to a new position. However, you do not need formal permission to use the instrument – you are welcome to do so. Best of luck in your research!

Tonja

From: Linda Louise Paul [mailto:Linda.Paul@nau.edu]

Sent: Sunday, September 22, 2013 2:53 PM

To: Nansel, Tonja (NIH/NICHD) [E]

Subject: Permission to use the Self-Efficacy for Diabetes Self-Management instrument

Dear Dr. Nansel. I am a PhD student at Arizona State University in the College of Nursing and Healthcare Innovation. I am conducting a study that will evaluate a password protected online intervention that I have created that uses tailored diabetes self-management education and the principles of motivational interviewing for adolescents with poorly controlled type 1 diabetes. The guiding theoretical framework that is guiding this intervention is Bandura's efficacy belief system. I would like permission to use the Self-Efficacy for Diabetes Self-Management instrument that you and your colleagues developed to test the effect of my intervention on diabetes self-efficacy. I have tried to contact Dr. Iannotti but do not think I have his current e-mail. Would it be OK to use your instrument for my research purpose? Thank you very much for your consideration.

Yours truly, Linda Paul, RN, PhDc

Self-Efficacy for Diabetes Self-Management
Please circle the best response for each item.

How Sure Are You That You Can Do Each of the Following, Almost All the Time?

1. Adjust your insulin correctly when you eat more or less than usual.

| | | | | |
|-----------------|----------------|-----------------------|-----------------------|-----------------|
| Not Sure at All | Sometimes Sure | Half of the Time Sure | Most of the Time Sure | Completely Sure |
| 1 | 2 | 3 | 4 | 5 |

2. Choose healthful foods when you go out to eat.

| | | | | |
|-----------------|----------------|-----------------------|-----------------------|-----------------|
| Not Sure at All | Sometimes Sure | Half of the Time Sure | Most of the Time Sure | Completely Sure |
| 1 | 2 | 3 | 4 | 5 |

3. Exercise even when you don't really feel like it.

| | | | | |
|-----------------|----------------|-----------------------|-----------------------|-----------------|
| Not Sure at All | Sometimes Sure | Half of the Time Sure | Most of the Time Sure | Completely Sure |
| 1 | 2 | 3 | 4 | 5 |

4. Adjust your insulin or food accurately based on how much exercise you get.

| | | | | |
|-----------------|----------------|-----------------------|-----------------------|-----------------|
| Not Sure at All | Sometimes Sure | Half of the Time Sure | Most of the Time Sure | Completely Sure |
| 1 | 2 | 3 | 4 | 5 |

5. Talk to your doctor or nurse about any problems you're having with taking care of your diabetes.

| | | | | |
|-----------------|----------------|-----------------------|-----------------------|-----------------|
| Not Sure at All | Sometimes Sure | Half of the Time Sure | Most of the Time Sure | Completely Sure |
| 1 | 2 | 3 | 4 | 5 |

6. Do your blood sugar checks even when you are really busy.

| | | | | |
|-----------------|----------------|-----------------------|-----------------------|-----------------|
| Not Sure at All | Sometimes Sure | Half of the Time Sure | Most of the Time Sure | Completely Sure |
| 1 | 2 | 3 | 4 | 5 |

7. Manage your diabetes the way your health care team wants you to.

| | | | | |
|-----------------|----------------|-----------------------|-----------------------|-----------------|
| Not Sure at All | Sometimes Sure | Half of the Time Sure | Most of the Time Sure | Completely Sure |
| 1 | 2 | 3 | 4 | 5 |

8. Manage your diabetes even when you feel overwhelmed.

| | | | | |
|-----------------|----------------|-----------------------|-----------------------|-----------------|
| Not Sure at All | Sometimes Sure | Half of the Time Sure | Most of the Time Sure | Completely Sure |
| 1 | 2 | 3 | 4 | 5 |

9. Find ways to deal with feeling frustrated about your diabetes.

| | | | | |
|-----------------|----------------|-----------------------|-----------------------|-----------------|
| Not Sure at All | Sometimes Sure | Half of the Time Sure | Most of the Time Sure | Completely Sure |
| 1 | 2 | 3 | 4 | 5 |

10. Identify things that could get in the way of managing your diabetes.

| | | | | |
|-----------------|----------------|-----------------------|-----------------------|-----------------|
| Not Sure at All | Sometimes Sure | Half of the Time Sure | Most of the Time Sure | Completely Sure |
| 1 | 2 | 3 | 4 | 5 |

APPENDIX G
SATISFACTION SURVEY

Code Number: _____

Date: _____

Satisfaction Survey – MI INTERVENTION

We want to know how you feel about your experience with the diabetes program.

Please put an X through the item that best answers the questions.

| | 1 ☹ | 2 | 3 ☺ | 4 | 5 ☺ |
|---|------------|-------------|-----------|--------|-----------|
| Has the intervention been helpful for you in managing diabetes? | Not at All | Not so Much | Sometimes | Mostly | Very Much |
| Was the intervention enjoyable to you? | Not at All | Not so Much | Sometimes | Mostly | Very Much |
| Was the intervention interesting to you? | Not at All | Not so Much | Sometimes | Mostly | Very Much |
| Was the program easy to use? | Not at All | Not so Much | Sometimes | Mostly | Very Much |
| Do you feel that the time spent doing this intervention was worthwhile to you? | Not at All | Not so Much | Sometimes | Mostly | Very Much |
| Are you more likely to do something different in the management of diabetes after completing this intervention? | Not at All | Not so Much | Sometimes | Mostly | Very Much |

What improvements to the program would you recommend?

Thank you for your participation.

APPENDIX H
WEBTESTING GUIDELINE AND CHECKLIST

Guideline and Checklist for Website Testing (Adapted from QATutorial.com)

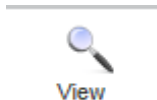
Directions for Use of Guideline and Checklist

This document is to be used as a guide to check the functionality, usability, performance and security of the **Can-Do-Tude** intervention. Please use one checklist for each separate week of the intervention. The guideline is to direct you to test various aspects of the intervention. Please use the checklist to note the question number (found on the printed version of the intervention) that you have a concern or suggestion for improvement about and please provide comments on what that concern or suggestion is. You may also provide comments on the printed version of the intervention.

When completed, please use the self-addressed envelope to mail the four checklists and printed versions of the intervention back to Linda Paul.

Previewing the **Can-Do-Tude** Intervention

Access the intervention at <https://www.qualtrics.com/login/> and login using the username and password that you have been provided. **View** is a way to view and take the intervention, just as the intended audience (adolescents with type 1 diabetes) would see it. In this way, you will be able to make sure that the intervention is looking and working as it should.



- a. From the **My Surveys** tab, select the desired week.
 - b. Click the **View** button located on the right of the desired week.
 - c. A new window will open, and the survey will appear in *Preview* mode.
2. Go through the intervention, answering questions as though you were a respondent. Make sure that all of the flow, links and output is working. Please keep an eye out for typos, appropriate language for adolescents and appropriate content.

Guideline for Website Testing

1. Functionality:

1.1 Links

Objective is to check for all the links in the website.

- 1.2 All Internal Links
- 1.3 All External Links
- 1.4 Check for Broken Links

1.5 Forms

Test for the integrity of submission of all forms.

- 1.6 All Field Level Checks
- 1.7 All Field Level Validations.
- 1.8 Optional versus Mandatory fields.

1.9 Database

Two types of errors that may occur in Web applications:

a. Data Integrity:

Missing or wrong data.

b. Output Error:

Errors in writing, editing or reading data operations.

Qualtrics will run a series of random completions of this survey to verify that data is being collected in the manner that is desired and anticipated. The results of the random tests will then be deleted. *You will not be able to assess this.*

2. Usability:

2.1 Navigation

Navigation describes the way users navigate within a page, between different user interface controls (buttons, boxes, lists, windows etc.), or between pages via e.g. links.

- 2.2 Application navigation is proper through Mouse
- 2.3 Navigation through Tab
- 2.4 Content

Correctness is whether the information is truthful or contains misinformation. The accuracy of the information is whether it is without grammatical or spelling errors. Remove irrelevant information from your site. This may otherwise cause misunderstandings or confusion.

- 2.5 Spellings and Grammars
- 2.6 Appropriate content
- 2.7 Appropriate language for developmental level (adolescence)
- 2.8 Interactive and engaging for developmental level (adolescence)

- 2.9 General Appearance
 - 2.10 Page appearance
 - 2.11 Color, font and size
 - 2.12 Frames
 - 2.13 Consistent design

3. Server Side Interfaces:

- 3.1 Server Interface
- 3.2 Qualtrics link, login

4. Client Side Compatibility:

- 4.1 Platform

Check for the compatibility of

- a. Windows
- b. Macintosh
- c. Any other platform

- 4.2 Browsers

Check that Qualtrics works with:

- Internet Explorer
- Chrome
- Firefox
- Any other Browser setting

- 4.3 Imaging

Loading of images, graphics, etc., works.

- Graphics
- Videos

- 4.4 Printing

Printing of goals and action plans will be important for participants to reference. Verify that pages are either printable or that the Print Screen shot is working.

5. Performance:

5.1 Connection speed

- a. Website speed
- b. Page speed
- c. Image speed
- d. Video speed

5.2 Load

Check/Measure the following:

- a. Usage: How did the system react during various times of the day?
- b. Peak load: Can the site a large amount of users requesting a certain page?
- c. Large amount of data from users: Can the site handle a large amount of data from users?

5.3 Stress

- a. System Crash – should not happen.

5.4 Continuous use

- a. Is the application available continuously 24 hours a day 7 days a week?
- b. Did you encounter any downtime?

6. Security:

- 6.1 Valid and Invalid Login
- 6.2 Can it be bypassed by typing URL to a page inside directly in the browser?

Checklist for Website Testing

Please circle for which week this checklist is for: One Two Three Four

** Enter "Not Applicable" for whichever test not carried out.

| Test Carried Out | Expected | Yes | No | Question Number of Concern | Comments/ Suggestions |
|--------------------------------|--|-----|----|----------------------------|-----------------------|
| 1. Functionality | | | | | |
| 1.1 Links | | | | | |
| Internal Links | Should flow according to schematic diagram | | | | |
| External Links | Should connect to appropriate outside website | | | | |
| Broken links | Should not be present | | | | |
| 1.2 Forms | | | | | |
| Field Level checks | Checkboxes, radio buttons and text fields work and text fields have enough room for typing responses | | | | |
| Field Level validation | Responses carry over to next question when appropriate and needed | | | | |
| Optional and mandatory fields. | Mandatory field should not be left blank. | | | | |

| | Optional should allow the user to skip the field. | | | | |
|---------------------------|--|------------|-----------|--|------------------------------|
| Test Carried Out | Expected | Yes | No | Question Number of Concern | Comments/ Suggestions |
| 1.3 Database | | | | | |
| Data Integrity- skip this | Should not be any missing or wrong data in the database | | | Qualtrics will run a series of random completions of this survey to verify that data is being collected in the manner that is desired and anticipated. The results of the random tests will then be deleted. | |
| Output Errors-skip this | Errors in writing, reading or editing operations should not be present | | | You will not be able to perform this assessment. | |
| 2. Usability | | | | | |
| 2.1 Navigation | | | | | |
| Navigation through Mouse | Works | | | | |
| Navigation through Tab | Works | | | | |
| Touch screen | Works | | | | |
| 2.2 Content | | | | | |

| | | | | | |
|--|--|------------|-----------|-----------------------------------|------------------------------|
| Spelling and Grammar | Is proper | | | | |
| Test Carried Out | Expected | Yes | No | Question Number of Concern | Comments/ Suggestions |
| Appropriate content | Is proper | | | | |
| Appropriate language for developmental level (adolescence) | Is proper | | | | |
| Interactive and engaging for developmental level (adolescence) | Is proper | | | | |
| 2.3 General Appearance | | | | | |
| Page Appearance | Not too busy or too much information on a page | | | | |
| Color, font and size | Is proper | | | | |
| Frames | All frames appear | | | | |
| Consistent Design | Everywhere in the website consistent layout and design should be carried out | | | | |
| 3. Server Side Interface | | | | | |
| 3.1 Server Interface | | | | | |
| Qualtrics link, login | Should be working | | | | |
| 4. Client side Compatibility | | | | | |

| | | | | | |
|--|---|------------|-----------|-----------------------------------|------------------------------|
| 4.1 Platform | | | | | |
| Windows (XP, Vista, 7, 8, 8.1) | Should be working | | | | |
| Macintosh | Should be working | | | | |
| Test Carried Out | Expected | Yes | No | Question Number of Concern | Comments/ Suggestions |
| Other | | | | | |
| 4.2 Browsers | | | | | |
| Internet Explorer | Should work | | | | |
| Chrome | Should work | | | | |
| Firefox | Should work | | | | |
| Other | | | | | |
| 4.3 Imaging | | | | | |
| Graphics | Load of images, graphics should be proper | | | | |
| Videos | Load and display of videos should be proper | | | | |
| 4.4 Printing | | | | | |
| Can print screen or obtain screen shot | Should work | | | | |
| 5. Performance | | | | | |
| 5.1 Connection speed | | | | | |

| | | | | | |
|--|---|--|--|--|--|
| Website speed | The website loads fast enough | | | | |
| Page speed | Pages within the website load fast enough | | | | |
| Image speed | Images within a page appear instantly | | | | |
| | | | | | |
| Video speed | Videos load fast enough | | | | |
| 5.2 Load | | | | | |
| Usage | Works at any time of the day regardless of number of users accessing site | | | | |
| Peak load | Should withstand | | | | |
| Large amount of data from users | Should accept | | | | |
| 5.3 Stress | | | | | |
| System Crash | Should not be present | | | | |
| 5.4 Continuous use | | | | | |
| Estimate whether available for 24 Hrs, 7 days a week | Try with various timings | | | | |
| Downtime | Measure any downtime | | | | |
| 6. Security | | | | | |
| 6.1 Valid and Invalid | Should not enter with Invalid login | | | | |
| Enter url directly without logging in. | Should not display information | | | | |

APPENDIX I
RECRUITMENT FLYER

Can-Do-Tude



I am recruiting teens with type 1 diabetes that would be willing to participate in an online intervention to improve diabetes self-management. **Can-Do-Tude** is a 4 week intervention. Your participation should take no longer than 30 minutes each week – two hours total time. You will be provided \$5 for each week that you participate for a total of \$20.

Can-Do-Tude can be done on any computer. You will be given the link and a password to the intervention if you choose to participate. You will have access to each week's program at any time of the day for seven days before one week closes and the other one opens.

To be included in this study you must:

- be 13 – 15 years of age with the diagnosis of T1D
- be on intensive therapy (i.e. multiple daily injections or pump therapy)
- have access to a computer with high-speed Internet access
- able to speak and write English
- and have a parental consent and an individual informed assent

Your participation in this study is voluntary. Your participation and evaluation of the intervention will help to determine if this is a useful tool that should be used by others.

If you have any questions concerning the research study, please call me, Linda Paul, at (928) 864-6679 or e-mail me at Linda.Paul@nau.edu. This research has received Internal Review Board approval from both Northern Arizona Healthcare and Arizona State University.

Study Title: *Tailored Web-Based Diabetes Self-Management Education Using the Principles of Motivational Interviewing for Adolescents with Poorly Controlled Type 1 Diabetes*

Consent Version Date: 09/29/14

Approved by the Northern Arizona Healthcare IRB: 09/29/14

APPENDIX J

PARENT/GAURDIAN PERMISSION



Institutional Review Board

Parent/Guardian Permission Form

Tailored Web-Based Diabetes Self Management Education Using the Principles of Motivational Interviewing for Adolescents with Poorly Controlled Type I Diabetes

INTRODUCTION

The purposes of this form are to provide you (the parent/guardian) information that may affect your decision as to whether or not it is all right for your child to participate in this research and to record the permission of those who agree to allow their children to be involved in the study.

RESEARCHERS

Linda Paul RN, who is pursuing a PhD from Arizona State University's College of Nursing and Health Innovation, is inviting your participation in a research study.

STUDY PURPOSE

The purpose of the research is to test and evaluate a password protected online intervention that uses tailored diabetes self-management education and the principles of motivational interviewing to improve diabetes self-management and eventually blood sugar control in adolescents with poorly controlled type 1 diabetes.

DESCRIPTION OF RESEARCH STUDY

If you decide to grant permission for your child to participate, then your child will join a study involving research of an online intervention that consists of diabetes education and uses the principles of motivational interviewing (MI), a counseling style, with the purpose of improving their self-management of diabetes. The intervention will be conducted via a password protected site which is distributed through Qualtrics survey software. Qualtrics is a web-based program used at Arizona State University. Qualtrics is used by faculty and students to collect data for research. Qualtrics data security has SAS 70 Certification and meets the rigorous privacy standards imposed on health care records by Health Insurance Portability and Accountability Act (HIPAA). An Internet URL link and password will be provided to participants that will take them to the intervention within Qualtrics. The intervention is accessible to only individuals who are invited to use the program. The intervention is a 4 week intervention that has 4 components (or modules) per week. Each module should take approximately one half of an hour per week to complete.

If you say YES, then your child's participation will last for a little over 4 weeks if they choose to complete the entire study. Your child will be asked at the beginning and then at the end of the 4 weeks to fill out some questionnaires on what has been going on with their diabetes and another questionnaire asking them about how confident they are that they can take care of their diabetes. They will also be asked at the end of the 4 weeks to fill out a satisfaction survey.

The goal is to recruit 30 teens in the state of Arizona to participate in this study. Results of the study will be provided to you and your child at its completion.

RISKS

Although the risk is small, there may be a breach of confidentiality since the intervention is administered via the Internet.

BENEFITS

While no benefits can be guaranteed, your child's participation in the research may help to evaluate whether a

tailored online intervention that uses diabetes education and a form of communication called motivational interviewing is worthwhile and potentially an effective means to help adolescents better manage their diabetes and perhaps even improve glucose control.

CONFIDENTIALITY

All information obtained in this study is strictly confidential. The results of this research study may be used in reports, presentations, and publications, but the researchers will not identify your child. In order to maintain confidentiality of your child’s personal information and responses to the intervention, Linda Paul will first provide questionnaires with a code so that names will not be necessary on any questionnaires collected. Coded questionnaires will be saved in a file on Linda Paul’s locked computer that will be deleted after the completion of the study. Information gathered on the online intervention are protected by Qualtrics and a password and only Linda Paul and the participant will be able to see it and have access to it.

WITHDRAWAL PRIVILEGE

Participation in this study is completely voluntary. It is ok for your child to say no. Even if they say yes now, they are free to say no later, and withdraw from the study at any time.

Your decision will not affect your relationship with Northern Arizona Healthcare or otherwise cause a loss of benefits to you or your child which you might otherwise be entitled.

COSTS AND PAYMENTS

The researchers want your decision and that of your child’s about participating in the study to be absolutely voluntary, yet they recognize that your child’s participation may pose some inconvenience. In order to compensate for your child’s time, your child will receive \$5 for each week that he or she participates, or a total of \$20 for 4 weeks of participation. Payments will be provided in one lump sum at the end of the study in the form of a cashier’s check.

VOLUNTARY CONSENT

Any questions you have concerning the research study or your child’s participation in the study, before or after you provide permission, will be answered by (Linda Paul, 411 Cattle Drive Trail, Flagstaff, Arizona, 86005 and 928-864-6679.)

If you have questions about your child’s rights as a subject/participant in this research, or if you feel you have been placed at risk; you can contact the Chair of the Northern Arizona Healthcare Human Subjects Institutional Review Board at 928-773-2346.

This form explains the nature, demands, benefits and any risk of the project. By signing this form you are providing permission for your child to participate in the research. Remember, your child’s participation is voluntary. They can choose not to participate or to withdraw and discontinue participation at any time without penalty or loss of benefit. In signing this permission form, you are not waiving any legal claims, rights, or remedies. A copy of this permission form as well as your child’s signed assent form will be given (offered) to you.

Your signature below indicates that you are giving permission for your child to participate in the above study.

Parent or Guardian

Printed Name

Date

Your Child’s Name

INVESTIGATOR’S STATEMENT

I certify that I have explained to the above individual the nature and purpose, the potential benefits and possible risks associated with their child’s participation in this research study, have answered any questions that have been raised, and have witnessed the above signature.

Signature of Investigator _____ Date _____

Study Title: *Tailored Web-Based Diabetes Self-Management Education Using the Principles of Motivational Interviewing for Adolescents with Poorly Controlled Type I Diabetes*

Consent Version Date: 9/29/14

Approved by the IRB: 9/29/14

APPENDIX K
ADOLESCENT ASSENT

Tailored Web-Based Diabetes Self-Management Education Using the Principles of Motivational Interviewing for Adolescents with Poorly Controlled Type 1 Diabetes

My name is Linda Paul. I am a student at Arizona State University.

I am asking you to take part in a research study because I am trying to learn more about improving blood sugars in teens. I want to see if an online program that uses a special type of interviewing along with diabetes education could assist you in improving your blood sugar control. Your parent(s) have given you permission to participate in this study.

If you agree, you will be asked to fill out two forms: one that asks a few questions about yourself (what grade you are in, if you work, etc.) and one that asks a few questions about your diabetes (how often you check blood sugars, if you use a pump or not, etc.). The online program involves questions that have you look at what is important or not about taking care of your diabetes and what you do well or would like to do better with your diabetes. It may involve setting goals and making a plan to improve your management. The program also provides information about diabetes that is pertinent to being a teenager. Your participation should take no longer than 30 minutes per week and will last up to four weeks. At the end of the program you will be asked to fill out a satisfaction survey. Your name will not be on any of the questionnaires. You do not have to answer any questions that make you uncomfortable. I will not be able to see anyone's responses until the study closes. Once it closes, I will see everyone's responses but I will not know who wrote what. The information you provide will be anonymous.

You will be provided \$5 each week that you participate. If you complete all four weeks you will be paid \$20.

You do not have to be in this study. No one will be mad at you if you decide not to do this study. Even if you start the study, you can stop later if you want. You may ask questions about the study at any time. You can contact me, Linda Paul at Linda.Paul@nau.edu or at 928-864-6679.

Signing here means that you have read this form or have had it read to you and that you are willing to be in this study.

Signature of subject _____

Subject's printed name _____

Signature of investigator _____

Date _____

Study Title: *Tailored Web-Based Diabetes Self-Management Education Using the Principles of Motivational Interviewing for Adolescents with Poorly Controlled Type I Diabetes*

Consent Version Date: 9/29/14

Approved by the NAH IRB: 9/29/14

APPENDIX L
CONTACT INFORMATION

Contact Info to Send Intervention Links To

Participant Name: _____

ID#: _____

Telephone Number: _____

E-mail: _____

Parent/Guardian Name: _____

Telephone Number: _____

E-mail: _____

APPENDIX M
THANK YOU LETTER



Can-Do-Tude

December 15, 2014

Dear *****,

I want to thank you for participating in the Can-Do-Tude intervention. When I get enough participants and I close the intervention, I will gather information about the project and mail the results of it out to everyone that went through it.

I have enclosed your stipend and another Health Questionnaire. Please fill it out and mail it back to me in the self-addressed envelope.

Again, thank you for your participation. Have a great upcoming year!

Sincerely,

Linda Paul, RN, PhDc