PROTOCOL TEMPLATE: INTERVENTION STUDY (CLINICAL TRIALS)

Title:	**MyDiaText: Texting the Way to Better Diabetes Control**
Short Title	MyDiaText Intervention for Diabetic Adolescents
Sponsor:	The Children's Hospital of Philadelphia The National Institutes of Health (NIH)
eIRB Number	16-013222
NCT Number	02927639
Protocol Date:	October 6th, 2016
Version:	7.0, Last Revised April 22, 2019

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TABLE OF CONTENTS

ABBREVIATIONS AND DEFINITIONS OF TERMS

CHOP	Children's Hospital of Philadelphia
T1DM	Type 1 diabetes mellitus
HbA1c	Hemoglobin A1c
SCI	Self-Care Inventory

ABSTRACT

Context:

Type 1 diabetes mellitus is one of the most common chronic diseases in childhood in the United States and its incidence continues to rise. Glycemic control during adolescence can be extremely difficult to achieve due to various biological, social, behavioral, and psychological factors. Development of effective and sustainable interventions to improve diabetes control and diabetes self-management during adolescence is of utmost importance to prevent short- and long-term complications and improve the quality of life of adolescents with type 1 diabetes mellitus.

Objectives:

The primary objective of this study is to test a text messaging intervention using MyDiaText and to determine whether such an intervention will decrease HbA1c in children 12 to 18 years with type I diabetes mellitus.

The secondary objectives is to determine if a text messaging intervention using MyDiaText will improve diabetes self-management skills as measured by the Self-Care Inventory (SCI) in children 12 to 18 years.

Study Design:

Randomized trial

Setting/Subjects:

This study will take place at the Children's Hospital of Philadelphia.

It will include 200 adolescents aged 12-18 with T1DM.

Study Interventions and Measures:

This study will use MyDiaText text messaging program as an intervention.

The main outcome measure will be change HbA1c. The secondary outcome measure will be change in scores of the Self-Care Inventory questionnaire.

PROTOCOL SYNOPSIS

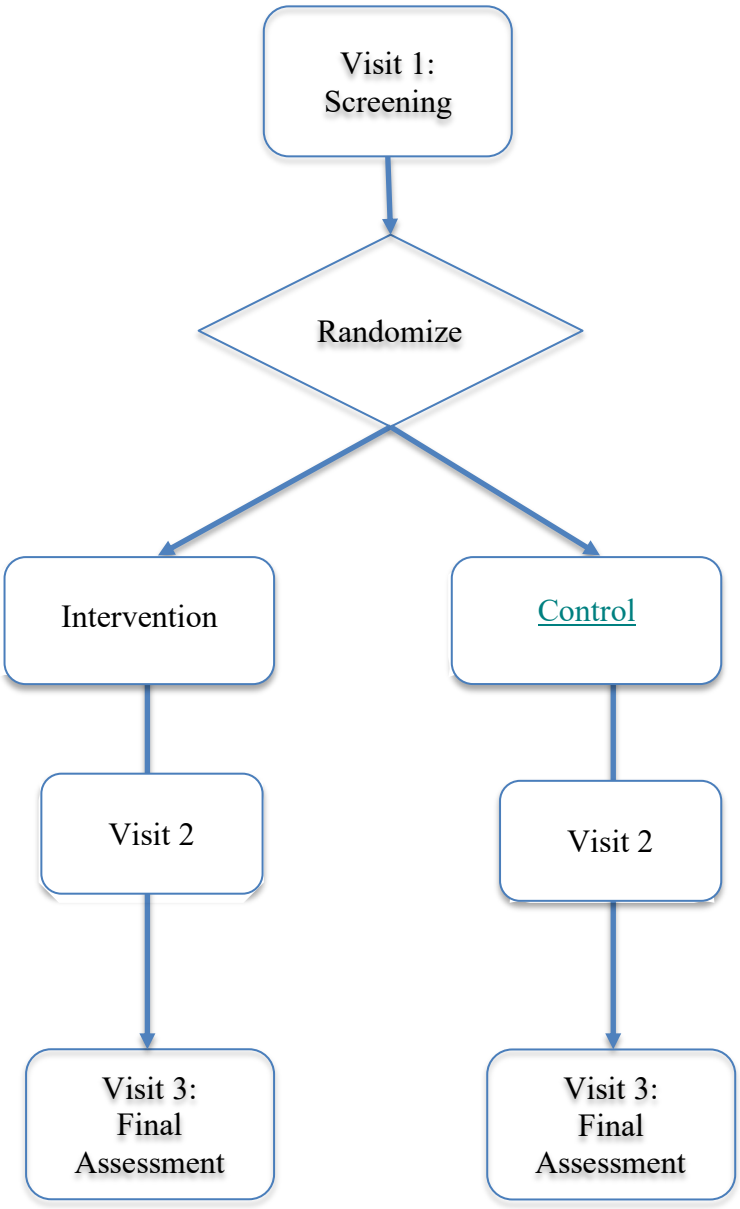
Study Title	MyDiaText: Texting the Way to Better Diabetes Control
Funder	NIH T32 Grant-Pediatric Endocrinology Division of CHOP
Clinical Phase	intervention
Study Rationale	Optimal control of type 1 diabetes may prevent, or at least decrease the risk of, diabetes complications. Adolescents with diabetes often have difficulty adhering to a diabetes management plan such a monitoring of blood glucose levels, administering insulin, and eating healthy. There is a need for an intervention that will resonate with youth and support adolescents with type 1 diabetes to improve their self-management practices in order to improve their glycemic control and prevent or reduce the risk of short- and long-term complications.
Study Objective(s)	**Primary** • To develop a text messaging intervention using MyDiaText and to determine whether such an intervention will decrease HbA1c in children 12 to 18 years **Secondary** • To determine if a text messaging intervention using MyDiaText will improve diabetes self-management skills as measured by the Self-Care Inventory (SCI) in children 12 to 18 years
Test Article(s)	The intervention will consist of daily text messages sent to the subject's personal mobile device. Previously developed text messages and quiz questions based on the ADA behavior goals will be used for this intervention.
Study Design	Randomized trial
Subject Population **key criteria for Inclusion and Exclusion:**	**Inclusion Criteria** 1. Subjects age 12 to 18 year of age. 2. Have a diagnosis of T1DM for more than 1 year. 3. HbA1c ≥ 8% but < 14%. 4. Have been seen in the diabetes clinic in the last 6 months. 5. Own a personal mobile device with unlimited text messaging plan. 6. Parental/guardian permission (informed consent) and, if appropriate, child assent. **Exclusion Criteria** 1. Non-English speaking. 2. Significant cognitive disability or major organ illness. 3. Hemolytic anemia.

	4. Ongoing oral steroid use
Number Of Subjects	200 subjects will be recruited from Diabetes Clinics affiliated with the Children's Hospital of Philadelphia
Study Duration	Each subject's participation will last for approximately 180 days
Study Phases **Screening** **Study Treatment** **Follow-Up**	(1) Pre-screening: focus groups to determine details of the intervention (2) Screening: screening for eligibility and obtaining consent, review medical record for HbA1C, obtain baseline Self-Care Inventory score (3) Intervention: review medical record for HbA1C, obtain Self-Care Inventory score (4) Follow-up: review medical record for HbA1C, obtain Self-Care Inventory score, complete satisfaction survey
Efficacy Evaluations	The primary efficacy endpoint will have two parts: the change in HbA1c between control and intervention groups between visit 1, 2 and 3.
Safety Evaluations	Adverse events are not anticipated in this study.
Statistical And Analytic Plan	Descriptive data analysis will include estimating means and standard deviations for continuous variables and counts and proportions of categorical variables for all aims. Two sample t-tests will be used to evaluate changes in HbA1c and SCI scores between the control and intervention groups and paired t-tests (or nonparametric methods if data is not normally distributed) will be used to compares the above changes within each group.
Data and Safety Monitoring Plan	The PI will monitor study progress, ensure the accuracy and security of the data, and ensure subject safety.

TABLE 1: SCHEDULE OF STUDY PROCEDURES

Study Phase	**Screening**	**Control**	**Intervention**	**Follow-Up**
Visit Number	1		**2**	**3**
Study Days		**90 (+/- 30 days)**	**90 (+/- 30 days)**	**1**
Informed Consent/Assent	X			
Review Inclusion/Exclusion Criteria	X			
Randomization	X			
Intake Questionnaire	X			
Height and Weight	X		X	X
HbA1c	X		X	X
SCI Questionnaire	X		X	X
Exit Questionnaire (Subjective Assessment of Intervention)				X

FIGURE 1: STUDY DIAGRAM



1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Type 1 diabetes mellitus (T1DM) is one of the most common chronic diseases in pediatrics in the United States with more than 18,000 children diagnosed every year. Management of T1DM in adolescence is challenging because pubertal hormonal changes result in insulin resistance and accelerated growth changes insulin requirements. Adolescence is also a time when diabetes care is being transferred from parent to child resulting in more diabetes self-management, which often leads to sporadic blood glucose monitoring and insulin administration resulting in poor diabetes control evidenced by elevated HbA1c. As a result, it is of utmost importance to develop effective interventions for adolescents that optimize their diabetes control. The use of technology has been shown to be a successful intervention in adolescents with chronic diseases and seems to be a promising intervention for adolescents with T1DM as well.

A recent review on the use of technology for adolescents with T1DM showed some improvements in HbA1c as high as a 1% decrease as well as improvement in diabetes self-management. These interventions included text messaging communication, phone and video communication, and smartphone applications. However, most studies have been small, interventions have been cumbersome, and most did not include a diverse sample of adolescents. A larger study using a feasible intervention in a diverse population is necessary to develop and evaluate an intervention that would be effective in improving diabetes control in adolescents.

1.2 Name and Description of Intervention

MyDiaText is an SMS texting program and website mydiatext.com developed by an interdisciplinary team of students, faculty, and clinicians from University of Pennsylvania School of Nursing and School of Engineering and Applied Sciences and the Children's Hospital of Philadelphia that follows the National Standards for Diabetes Self-Management Education established by the American Diabetes Association. It was developed to support behavior change in children aged 10-17 years with T1DM. A feasibility study was done with 20 adolescents (10 of whom identified as non-White) involving daily text messages for a 1 month period. This study showed the use of this application to be feasible and well received in this population.

1.3 Relevant Literature and Data

Each year, more than 18,000 children under the age of 20 are diagnosed with T1DM [1]. Management of T1DM is very demanding as it requires lifelong frequent blood sugar checks, frequent insulin administration, and many lifestyle changes or modifications to maintain good diabetes control. This is particularly challenging in adolescence for a number of reasons. Hormonal changes during puberty can result in insulin resistance necessitating increased insulin doses [2]. Adolescence is also a period of rapid growth which also increases the insulin requirement. Most importantly, parental involvement in the diabetes management generally decreases with increasing age of the child resulting in medical independence. This often occurs prematurely and leads to decreased blood glucose

monitoring and insulin administration, which results in poor diabetes control and can lead to significant morbidity and mortality.

Technology, in particular the use of text messaging, appears to be a good vehicle for interventions in adolescents because of its pervasive use in this population. About 3 in every 4 children aged 12-17 own a cell phone. Studies have shown that 75% of teenagers text, with 63% of them sending text messages on a daily basis [3]. This is also true in low income, urban, and minority adolescents. Some studies have shown high access to technology in this population with estimates of 94% sending text messages on a daily basis [4,5].

Interventions using text messages in adolescents with T1DM have been carried out previously with high levels of satisfaction, but variable improvements in diabetes control measured by HbA1c [6,7]. One intervention involved weekly text messages of encouragement based on self-identified barriers to diabetes self-management [8]. This intervention did not result in a change from baseline HbA1c after 3 months of intervention, but a matched historical control group had significant worsening of glycemic control. Another intervention involved automated text or email messages on blood glucose monitoring sent on a self-selected schedule [9]. This intervention showed a slight but not significant improvement in HbA1c after 3 months. Another intervention involved regular text messages based on diabetes goals compared to the same intervention in addition to an intensive insulin regimen [10]. This intervention lasted 12 months and at its conclusion there was a significant improvement in those adolescents receiving the intervention plus intensive insulin regimen, but no significant improvement in those receiving the intervention alone. All of these studies were rather small, with only 18-33 subjects per group. Of these interventions, only the third study reported race/ethnicity information and only included 4% non-White population.

While studies around text messages have been promising, they have not been conclusive. A systematic review of text messaging studies in T1D concluded that while text message interventions are likely a valuable behavioral change tool, that further research should be grounded in behavioral theory[14]. A study in the adolescent T1D population showed that financial incentives for adherence to blood glucose monitoring showed increased monitoring during the incentive period but not in follow up [15]. A study showing the effect of reward for engagement in diabetes education via text message does not exist.

1.4 Compliance Statement

This study will be conducted in full accordance with all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46, 21 CFR Parts 50, 54, 56, 312, 314 and 812. All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent, and will report unanticipated problems involving risks to subjects or others in accordance with The Children's Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be

accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

The purpose of the study is to determine if an intervention using MyDiaText for adolescents with T1DM will improve their glycemic control and self-management skills.

2.1 Primary Objective (or Aim)

The primary objective of this study is to develop a text messaging intervention using MyDiaText and to determine whether such an intervention will decrease HbA1c in children 12 to 18 years. This will be divided into 2 parts:

- To determine whether this intervention will decrease HbA1c in children 12 to 18 years after 3 months +/- 1 month.
- To determine whether the effect of the intervention persists after an additional 3 months +/- 1 month of intervention.

2.2 Secondary Objectives (or Aim)

The secondary objectives are to:

- Determine if a text messaging intervention using MyDiaText will improve diabetes self-management skills as measured by the Self-Care Inventory (SCI) in children 12 to 18 years.
- Analyze the response rate to educational text messages when a reward paradigm, in which children are intermittently rewarded for engaging in the application for multiple days in a row, is administered.

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

3.1.1 Focus Groups

Up to 5 focus groups of 10 adolescents with type 1 diabetes will be carried out to develop the text messaging intervention. Text messages previously developed for the feasibility study will be used for this intervention. These text messages will be presented to the focus group subjects to determine whether changes need to be made. The focus groups subjects will also have input on other details of the intervention such as frequency and timing of the text messages. Subjects for these focus groups will be recruited from the CHOP Endocrinology and Diabetes outpatient clinic. Focus groups will last about one hour. They will be held in a private location at a time that is convenient to the subjects. Focus groups will be digitally recorded and transcribed. Subjects of these focus groups will be excluded from participation in the intervention phase.

3.1.2 Inclusion Criteria for Focus Groups

1) Males or females age 12 to 18 years.

2) Have a diagnosis of T1DM for more than 1 year.

3) Own a personal mobile device.

4) Parental/guardian permission (informed consent) and, if appropriate, child assent.

3.1.3 Exclusion Criteria for Focus Groups

1) Subject is non-English speaking.

2) Subject has a significant cognitive disability.

3) Subject does not have insurance approval for point-of-care A1C measurement

3. 2 General Schema for Intervention Study

3.2.1 Screening Phase

Potential subjects will be recruited from the CHOP Endocrinology and Diabetes outpatient clinic. Clinic schedules will be reviewed for determination of potential subjects as per the inclusion criteria above. Some subjects will be pre-screened for interest only, without eliciting PHHI, by telephone prior to their clinic visit. Subjects will be approached during their clinic visit and informed about the current study. If the subject agrees to participate, informed consent (from caregiver if subject is < 18 y/o and from subject if he/she is >18 y/o) as well as assent if subject is < 18 y/o will be obtained. HbA1c and diabetes treatment plan will be collected from the medical record.

3.2.2 Phase 1

This phase will start enrollment. Subjects will be registered into the MyDiaText website by research staff. At registration, MyDiaText will randomize half of the subjects to the intervention group and the other half to the control group. At this time, SCI will be administered via a text message link to the MyDiaText website; this will serve also to ensure the phone number for the patient was entered correctly and that account is active for log-in. All subjects will get $5 upon completion of baseline self-care inventory. All subjects, control and intervention, will create a profile in the MyDiaText system. This profile will consist of his/her name, birthday, gender, ethnicity, phone number, and email. All subjects will be following their diabetes care plan as dictated by their primary diabetes provider. The subjects in the intervention group will start receiving the text messaging intervention as described in the intervention section (section 7). Subjects in the intervention group will be instructed to respond to each text as a proxy for having read it. Previously, a point system reflected scoring on quizzes and educational activities. To update the text messages based on current technology, all quizzes have been transitioned into text messages. To address gaps in research, a specific reward paradigm was created based on the concept of “streaks,” or reward for consecutive days of engagement in the application. Those with the longest “streak” will be placed in a drawing for an extra cash prize of $10 every two weeks.

3.2.3 Phase 2

This phase will start at their next visit with their diabetes provider, which usually occurs after 3 months +/- 1 month. During this phase, control group will continue to not receive text messages, and intervention group will continue to receive text messages. HbA1c and diabetes treatment plan will be collected from the medical record. SCI will be completed at this time. All subjects will get $10 for completing the second SCI. Invitation to fill out second SCI will be administered via text message. If second SCI is not filled out 7 days after this invitation, a reminder text message will be sent. If not filled out 7 days after reminder text message, a second reminder text message will be sent. No further reminders for that SCI will be sent.

3.2.4 Follow-up Phase

This phase will start and end at their next visit with their diabetes provider (second from randomization). This phase will only entail data collection on that day. HbA1c and diabetes treatment plan will be collected from the medical record. SCI will be completed at this time as well as a questionnaire assessing the intervention. Invitation to fill out third SCI and intervention assessment will be administered via text message. If third SCI and intervention assessment are not filled out 7 days after this invitation, a reminder text message will be sent. If not filled out 7 days after reminder text message, a second reminder text message will be sent. No further reminders for survey completion will be sent after this point. All subjects will get $15 for completing the third SCI and intervention assessment. This phase will conclude the study.

3.3 Allocation to Treatment Groups and Blinding

Half of the subjects will be randomized to the intervention and the other half will serve as controls. MyDiaText will randomly assign patients to treatment or control upon registration. Given the nature of the intervention, subjects will not be blinded. All study personnel and diabetes providers will not blinded to current subject phase during the study, since unblinding should not result in bias in this study and it would difficult to ensure that subjects do not tell their providers whether or not they are receiving text messages.

3.4 Study Duration, Enrollment and Number of Sites

3.4.1 Duration of Study Participation

The study duration per subject will be about 180 days, with up to 1 day for screening (which coincides with the first day of phase 1), about 90 days for Phase 1, about 90 days for Phase 2, and 1 day for follow-up (which coincides with the last day of phase 2).

3.4.2 Total Number of Study Sites/Total Number of Subjects Projected

The study will be conducted at up to 6 investigative sites in the United States, the main CHOP Diabetes and Endocrinology outpatient clinic at the Buerger Center in Philadelphia PA; CHOP Specialty Care in Princeton, NJ; CHOP Specialty Care & Surgery Center in Chalfont, PA; CHOP Specialty Care & Surgery Center in King of Prussia, PA; CHOP Specialty Care & Surgery Center in Voorhees, NJ; and CHOP Specialty Care in Lancaster, PA.

Recruitment for randomized controlled trial will stop when 200 subjects are enrolled. Recruitment for focus groups will stop when 50 subjects are enrolled.

3.5 Study Population

3.5.1 Inclusion Criteria

1) Males or females age 12 to 18 years.

2) Have a diagnosis of T1DM for more than 1 year.

3) HbA1c ≥ 8% but < 14%.

4) Have been in seen in the diabetes clinic in the last 6 months.

5) Own a personal mobile device with unlimited text messaging plan.

6) Parental/guardian permission (informed consent) and, if appropriate, child assent.

3.5.2 Exclusion Criteria

1) Subject is non-English speaking.

2) Subject has a significant cognitive disability or major organ illness.

3) Subject has hemolytic anemia.

4) Participation in the focus groups.

5) Ongoing steroid use

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

4 STUDY PROCEDURES

4.1 Pre-Intervention Phase: Focus Groups

Focus group will be recorded and transcribed. No identifying information will be collected.

4.2 Screening Visit (Visit 1)

Screening will take place just prior to Phase 1. It will consist of explaining the study and screening for eligibility. Subjects that qualify and are interested will move on to Phase 1

4.3 Study Treatment Phase

4.3.1 Visit 1

- Informed Consent and/or Subject Assent
- Medical Record Review
- Lab: hemoglobin A1c

- Registration on MyDiaText website by study staff
- SCI questionnaire

4.3.2 Visit 2

- Medical Record Review
- Lab: hemoglobin A1c
- SCI questionnaire

4.3.3 Visit 3

- Medical Record Review
- Lab: hemoglobin A1c
- SCI questionnaire
- Exit questionnaire

4.3.4 Assessment of adherence to program (Ongoing)

- Every two weeks, MyDiaText will report consecutive response to text message by subject number. If one subject has the longest streak, they will be rewarded with $10 placed on their bank card. If more than one subject has the longest streak, MyDiaText will pick one subject at random to receive this reward. They will be informed if they received this reward via text message.

4.4 Unscheduled Visits

Since study visits will coincide with visits with primary diabetes provider, no unscheduled visits will take place. If a subject is seen by their diabetes provider or care team less than 2 months from the previous visit, then the study team will not approach the subject at that time.

4.5 Subject Completion/Withdrawal

Subjects may withdraw from the study at any time without prejudice to their care. They may also be discontinued from the study at the discretion of the Investigator for lack of adherence to study treatment or visit schedules. The Investigator may also withdraw subjects who violate the study plan, or to protect the subject for reasons of safety or for administrative reasons. It will be documented whether or not each subject completes the clinical study.

4.5.1 Early Termination Study Visit

Subjects who withdraw from the study will have all procedures enumerated for Visit 3 as the early termination visit. Should they withdraw by sending a text message to the text message carrier "STOP," a one-time e-mail will be sent from study personnel to the address provided at registration with visit 3 procedures.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Focus Group Evaluation

Notes and transcripts from the focus groups will be read and analyzed by two different investigators. Common themes will be extracted and appropriate changes made to text message content and delivery.

5.2 Screening and Monitoring Evaluations and Measurements

5.2.1 Medical Record Review

- Weight
- Height
- BMI
- Most recent HbA1c value
- Current diabetes treatment plan
- Number of DKA admissions

5.2.2 Laboratory Evaluations

- Hemoglobin A1c

5.2.3 Other Evaluations, Measures

- Self-Care Inventory

5.3 Efficacy Evaluations

5.3.1 Diagnostic Tests, Scales, Measures, etc.

The efficacy of this intervention in improving glycemic control will be determined using HbA1c values. HbA1c is checked every 3 months as part of the diabetes treatment plan. These values will be collected as a research lab at each visit.

The efficacy of this intervention in improving diabetes self-management skills will be determined by the SCI questionnaire. This will be completed at each study visit.

5.4 Safety Evaluation

Given the nature of the intervention, no adverse events that will require intervention or monitoring will occur.

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

The primary endpoint will be the change in SCI score between Visit 1 and Visit 2 in control group as compared to intervention group

6.2 Secondary Endpoints

Secondary endpoints will include the following:

- The change in HbA1C score during the intervention phase.
- Measure the response rate to text messages in the context of the incentivized reward program
- Responses to the intervention assessment questionnaire.
- Durability analysis of adherence to text message intervention from visit 2 to 3.
- Mean SCI score and HbA1C changes from visit 1 to visit 3 and visit 2 to visit 3.

6.3 Statistical Methods

6.3.1 Baseline Data

Baseline and demographic characteristics will be summarized by standard descriptive summaries (e.g. means and standard deviations for continuous variables such as age and percentages for categorical variables such as gender).

6.3.2 Efficacy Analysis

The primary analysis will include all subjects randomized at Visit 1 who have gotten HbA1c measurements at visit 2. The primary efficacy endpoint will be the change in SCI Score.

The first analysis will be change in SCI score from visit 1 to visit 2 comparing treatment and control groups. For this analysis we will use paired t-tests to test the null hypothesis of no difference in change in SCI scores at the two-sided alpha = 0.05 level.

The secondary analysis will be the change in HbA1c between the intervention and control group from visit 1 to visit 2. For this analysis we will use two sample t-test to test the null hypothesis of no difference in the change in HbA1c at the two-sided alpha = 0.05 level.

An additional secondary analysis will be the durability of the text messaging intervention from visit 2 to 3. SCI score and HbA1C will continue to be tracked to compare visit 1 to visit 3 and visit 2 to visit 3 at study conclusions.

6.4 Sample Size and Power

The average HbA1c in adolescents at the CHOP Endocrinology and Diabetes clinic is 9.11% with a SD of 2.26%. Given this average HbA1c and its SD, a sample size of 164 subjects would be needed to observe a difference of 1% in mean HbA1c between groups at a

0.05 level of significance with 80% power in a cross-over study. We will aim to recruit up to 200 subjects out of over 1400 adolescents with T1DM seen at the CHOP Diabetes clinics for their routine care on a yearly basis.

7 STUDY INTERVENTION

7.1 Description

The intervention will consist of daily text messages sent to the subject's personal mobile device. Previously developed text messages based on the ADA behavior goals in addition to multiple-choice questions formerly used as quizzes on the MyDiaText website will be used for this intervention. These will be adapted with input from the focus groups that will be carried out with adolescents with T1DM. The details of the intervention, such as frequency and timing of text messages, will be determined from input obtained from the focus groups. The management of the website and SMS system is CHOP IT who will man the server as problems arise.

7.1.1 Treatment Compliance and Adherence

Compliance for the intervention arm will be measures on a bi-weekly basis. Once every two weeks, the MyDiaText website will create a report showing which subjects answered text messages for the most days in a row, and randomly pick one to win a cash prize. Subjects who do not answer any text messages will not be eligible for the bi-weekly cash prize, but will still be able to be reimbursed for completion of SCI.

8 SAFETY MANAGEMENT

8.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

8.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

9 STUDY ADMINISTRATION

9.1 Treatment Assignment Methods

9.1.1 Randomization

MyDiaText will randomize subjects to control or intervention arm. The number of subjects in each arm will be monitored to ensure they are equal.

9.1.2 Blinding

Given the nature of the intervention, subjects will not be blinded. All study personnel and diabetes providers will not blinded to current subject phase during the study.

9.1.3 Unblinding

No unblinding protocol needs to be established since no one is blinded in this study.

9.2 Data Collection and Management

Consistent with CHOP Policy A-3-6: Acceptable Use of Technology Resources that defines the requirements for encryption and security of computer systems. The MyDiaText application is hosted on a secure CHOP server. The application uses an external service, Twilio, to send and receive text messages through one secure port in the CHOP firewall. Databases are protected by CHOP's firewall.

Digital recordings from the focus group will be kept in a locked cabinet until they are uploaded to a private desktop computer. After the recordings are uploaded, the recordings will be deleted from the recording device. Recordings will be transcribed and transcriptions will be stored on a private desktop computer. Recordings and transcriptions will be retained for three years.

- PHHI and subject ID number will be stored in the MyDiaText Application. Only IRB-approved study personnel will have access to subject PHHI. Each subject will have access to their own PHHI.
- MyDiaText has the ability to export data without PHHI . For this reason, we will not require a separate master list to store PHHI. Data exports for analysis purposes will include subject number, age, and study data but not name, date of birth, phone number, address, or email.
- Profile history data will be purged within 6 months of study completion or when a subject opts to delete account.
- All consent forms will be kept in locked filing cabinets that only the study team has access to.
- The identifiers will be destroyed after publication. The other data will be retained for three years.

9.3 Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy and the Investigator and other study

personnel will not use such data and records for any purpose other than conducting the study. All data and records will be kept confidential by using password-protected files.

No identifiable data will be used for future study without first obtaining IRB approval. The investigator will obtain a data use agreement between the provider (the PI) of the data and any recipient researchers (including others at CHOP) before sharing a limited dataset (PHI limited to dates and zip codes).

9.4 Regulatory and Ethical Considerations

9.4.1 Data and Safety Monitoring Plan

The PI and lead investigator will monitor study progress, ensure the accuracy and security of the data, and ensure subject safety. The PI and lead investigator will also follow the adverse event reporting plan.

9.4.2 Risk Assessment

There is minimal risk of loss of confidentiality.

There is a potential risk of cost of text messaging incurred on the subject. However, this will be addressed by only recruiting subjects that own a mobile device with an unlimited texting plan.

There is a potential risk that subjects will use this platform for health questions or problems that should be handled by a healthcare professional. This will be addressed by installing a 'check' so that subjects are not under the impression that someone is reading their texts. If a subjects responds or sends an unprompted text, a reply will be sent saying "MyDiaText does not recognize that message. Please only respond when asked. If you have any medical questions or concerns contact your healthcare provider".

9.4.3 Potential Benefits of Trial Participation

Participation in this study can provide multiple benefits to the subjects. It could help improve the subjects' diabetes control. The subjects can also develop better self-management skills to treat his/her diabetes. This study can also provide indirect benefits to the subjects and other children with diabetes. Individuals can accrue the necessary skills to improve diabetes control that could prevent long-term complications of diabetes. If effective, this intervention could be implemented to improve the diabetes control of all children with diabetes.

9.4.4 Risk-Benefit Assessment

Since the risks are small and theoretical and the benefits are great in the short term and possibly in the long term, the benefits outweigh the risk.

9.5 Recruitment Strategy

Subjects for the focus groups will be recruited from the CHOP Diabetes and Endocrinology outpatient clinics. Clinic schedules of all diabetes providers will be screened for prospective subjects. These subjects will be approached in person by the research team.

Subjects for the intervention will be recruited from the main CHOP Diabetes and Endocrinology outpatient clinic. Occasionally, and for the intervention only, subjects may be screened for interest in the study by telephone prior to their clinic visit. PHHI will not be elicited to assess for eligibility during this conversation; only interest in learning more about the study will be assessed. Clinic schedules of all diabetes providers will be screened for prospective subjects based on the inclusion criteria mentioned above. These subjects will be approached in person by the research team.

9.6 Informed Consent/Assent and HIPAA Authorization

9.6.1 Focus Group

Upon recruitment for participation in the focus groups, subjects (if 18 years of age) or parents will be provided with written consent forms that must be signed for participation. Assent will also be obtained from the subject if he/she is < 18 years old. It will be made clear to subjects that all information will be kept confidential, their participation is entirely voluntary and they are allowed to leave or withdraw consent at any time.

9.6.2 Intervention

After a subject agrees to participate in this research study, written consent from the subject (if ≥ 18 years old) or parent (if subject is < 18 years old) as well as assent from the subject if he/she is < 18 years old will be obtained and documented by the study coordinator/study investigator. This will take place in a private patient room at the CHOP Diabetes and Endocrinology outpatient clinic. A description of the procedures involved in the study, as well as the risks/benefits will be provided verbally and written as part of this process. Additionally, it will be stressed that any questions are appropriate and that all aspects of the study are voluntary.

Consent documents will be maintained in the subject's study file and documented. The subject will receive a copy of the signed document(s). A combined consent-authorization document will be used.

9.7 Payment to Subjects/Families

9.7.1 Payments to subject for time, effort and inconvenience (i.e. compensation)

The payment for participation in the focus groups will be $10 per subject, which will be given in the form of a pre-paid bank card obtained from the CHOP Participant Research Card program).

The payment for participation in the intervention will be variable. All patients will get $5 to fill out the initial SCI, and $10 for the second SCI, and $15 for the third (total of $30/subject). Subjects in the intervention group will have additional opportunities for a $10 cash prize every other week. These will be given in the form of a pre-paid bank card obtained from the CHOP Participant Research Card program.

10 PUBLICATION

The results of this study may be submitted for consideration for presentations at national meetings and/or publication in academic journals. At no time will any PHI from this study be disclosed for any presentation(s) or journal article(s).

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