Improving Diabetes Management in Emerging Adulthood: An Intervention Development Study Using the Multiphase Optimization Strategy

April Idalski Carcone, PhD, MSW; Deborah A Ellis, PhD; Susan Eggly, PhD; Karen E MacDonell, PhD; Samiran Ghosh, PhD; Colleen Buggs-Saxton, PhD; Steven J Ondersma, PhD

1Department of Family Medicine and Public Health Sciences, School of Medicine, Wayne State University, Detroit, MI, United States
2Population Studies and Disparities Research Program, Karmanos Cancer Institute, Wayne State University, Detroit, MI, United States
3Department of Pediatrics, School of Medicine, Wayne State University, Detroit, MI, United States
4Division of Public Health, Department of Obstetrics, Gynecology, and Reproductive Biology, Michigan State University, East Lansing, MI, United States

Corresponding Author:
April Idalski Carcone, PhD, MSW
Department of Family Medicine and Public Health Sciences
School of Medicine
Wayne State University
6135 Woodward
Integrated Biosciences Bldg
Detroit, MI, 48202
United States
Phone: 1 3135771057
Email: acarcone@med.wayne.edu

Abstract

Background: Poor diabetes self-management in emerging adulthood (age 18-25 years) is associated with poorer diabetes health and diabetes complications. Emerging adults' focus on individuation and independence underlies their poor diabetes outcomes, offering a lever for behavior change. Self-determination theory (SDT) suggests that interventions leveraging emerging adults' innate developmental need for autonomy may offer a route to improving diabetes outcomes by increasing feelings of responsibility for and control over diabetes self-management activities.

Objective: This research project will use the multiphase optimization strategy to test the efficacy of three autonomy-supportive intervention components to elicit a clinically significant improvement in metabolic control, assessed by a 0.5% improvement in hemoglobin A1c (HbA1c), among older adolescents and emerging adults (16-25 years) with poorly controlled type 1 diabetes (T1D; HbA1c ≥9.0%).

Methods: A question prompt list (QPL) is a tool to empower patients to assume a more active role during medical visits by asking questions and stating concerns. The motivation enhancement system (MES) is a brief counseling intervention that uses motivational interviewing communication strategies to build intrinsic motivation and self-efficacy for self-management. Text message reminders to complete diabetes care tasks may increase self-efficacy for diabetes self-management. After refining these intervention components for emerging adults, we will conduct a component selection experiment using an eight-arm full factorial design: 2 (QPL yes or no) × 2 (MES yes or no) × 2 (Text yes or no). Participants will complete 3 study visits: baseline, treatment end at 2 months, and a follow-up at 6 months. The primary outcome is metabolic control, which will be measured via HbA1c. Secondary outcomes include diabetes management and diabetes clinic attendance. SDT constructs of intrinsic motivation, self-efficacy, and the quality of the patient-provider relationship (ie, relatedness) are hypothesized mediators. Depression symptoms and emerging adults’ gender are hypothesized moderators. We will use the mixed-effects linear model for the analysis of variance of a factorial design to analyze continuous longitudinal experimental data; the generalized linear model will be used with categorical outcomes (eg, treatment attendance). The experiment was powered to detect the main effects of the intervention on the primary outcome.

http://www.researchprotocols.org/2020/10/e20191/
Results: A total of 20 participants have enrolled and completed a qualitative interview after reviewing one or more intervention components. Analysis of interview data are underway, with a report of these results anticipated in the fall of 2020. The clinical trial will be launched in the fall 2020, with participants enrolled through May 2023 and data collection continuing through November 2023.

Conclusions: At the end of this experiment, we will have empirical evidence to support a large-scale, multisite effectiveness trial of an intervention package that has been optimized for older adolescents and emerging adults with poorly controlled T1D.

Trial Registration: ClinicalTrials.gov NCT04066959; https://clinicaltrials.gov/ct2/show/NCT04066959

International Registered Report Identifier (IRRID): DERR1-10.2196/20191

(JMIR Res Protoc 2020;9(10):e20191) doi: 10.2196/20191

KEYWORDS
emerging adults; type 1 diabetes; self-determination theory; motivational interviewing

Introduction

Background

Diabetes management involves a regimen of daily blood glucose monitoring, insulin administration, and carbohydrate monitoring [1], a complex and demanding care routine that is primarily under the control of the patient [2]. Once considered a transient time of poor type 1 diabetes (T1D) management, the persistence of suboptimal diabetes management from adolescence into emerging adulthood (the unique developmental period between adolescence and adulthood, age 18-25 years [3]) is increasingly evident [4,5]. Studies of emerging adults suggest that rates of self-reported diabetes management are no different than those of adolescents [6]. Emerging adults complete fewer blood glucose checks per day and are more likely to miss insulin doses than older adults, a pattern of diabetes management associated with elevated hemoglobin A\textsubscript{1c} (HbA\textsubscript{1c}) levels, the standard measure of glycemic control, and diabetes disease control [7]. Poor diabetes management in emerging adulthood has been attributed to factors such as a continuation of the decline in parental involvement in diabetes care that begins in adolescence [6] and the characteristic developmental focus of this age group on identity exploration, increasing independence, developing social networks, including increased peer and romantic relationships, new opportunities and choices, and becoming less reliant on parental support and oversight [3].

Entering adulthood with inadequate diabetes management increases the risk for gaps in health care [8] and overreliance on the emergency department for primary health care needs [9,10]. Consequently, the HbA\textsubscript{1c} levels of emerging adults are similar to those of adolescents, with mean levels in the range of 8.4%-9.3% (SD 1.2-2.4) [6,11] and an estimated 83% of emerging adults failing to meet glycemic control recommendations [11]. Further, poor metabolic control is not the only consequence of inadequate diabetes management [12,13]; it is also associated with short- and long-term diabetes complications, which can appear as early as 5 years post diagnosis [14]. Thus, emerging adulthood and the period immediately preceding it are critical times for intervention. Despite this, no intervention study specifically targeting older adolescents’ and emerging adults’ T1D self-management has demonstrated improvement in diabetes management or health outcomes [15].

The developmental need for autonomy is particularly salient during late adolescence and early adulthood [3,5], making this an optimal time for interventions focused on improving capacity for independent self-management. The proposed study will test a new intervention designed to align with emerging adults’ developmental need for autonomy based on self-determination theory (SDT), an empirically derived theory of human motivation. SDT posits that autonomous (ie, self-initiated, driven by intrinsic vs extrinsic motivation [16]) behavior depends upon the fulfillment of 3 innate psychological needs: autonomy, or the perception that one’s behavior is self-directed; competence, or self-efficacy; and relatedness, or the existence of caring relationships supportive of the behavior [17,18]. Interventions grounded in SDT have been empirically linked to enhanced feelings of autonomy [19-21] and competence [21] as well as improvements in glycemic control [20-22] and related health outcomes [19] among adults with diabetes. Among adolescents and emerging adults with diabetes, interventions to improve self-management and glycemic control have been few. Husted et al [23] found that guided self-determination delivered by diabetes clinicians in a clinic setting increased adolescents’ perceptions of autonomy and decreased amotivation for diabetes self-management but did not improve metabolic control. Autonomy-supportive T1D camps increased adolescents’ sense of relatedness but did not change autonomy and competence; glycemic control was not examined [24]. Neither study examined the effect of autonomy-supportive interventions on diabetes self-management behavior. Most interventions targeting older adolescents and emerging adults have focused on strengthening family and peer support for diabetes management or on addressing psychological barriers (eg, mood) [25]. Few have targeted older adolescents’ and emerging adults’ own sense of responsibility for and control of their own health.

Aims

In this paper, we present the protocol for a research project (NIH R01DK116901; Multimedia Appendix 1). The goal of this project is to develop an optimized, guided eHealth autonomy-supportive intervention to improve metabolic control through improved diabetes self-management among older adolescents and emerging adults (16-25 years) with poorly controlled (HbA\textsubscript{1c}≥9.0%) T1D. We have developed three self-management intervention components with theoretical and empirical links to SDT; each of which can function
The primary aim of this study is to test the efficacy of the QPL, MES, and text intervention components to improve older adolescents’ and emerging adults’ metabolic control (primary outcome) and diabetes management behavior (secondary outcome). We hypothesize that at the end of treatment (2 months) and at follow-up (6 months), older adolescents and emerging adults with poorly controlled T1D who receive one or more of the intervention components will demonstrate a clinically significant improvement in metabolic control (improvement in HbA1c \( \geq 0.5\% \)) and a statistically significant improvement in self-reported and objectively measured (frequency of blood glucose monitoring) diabetes management behavior. Secondary aims include examining whether changes in SDT constructs (self-reported autonomy, self-efficacy, and patient-provider relationship) mediate intervention effects on primary outcomes at the end of treatment (2 months) and at follow-up (6 months). We also aim to explore whether treatment participation improves diabetes clinic visit attendance and whether gender and depressed mood moderate intervention effects.

**Methods**

**Design**

This study will use a factorial trial model following the multiphase optimization strategy (MOST) [48,49]. The MOST design is an efficient approach to develop a multicomponent intervention in which the final intervention components are tested against an a priori defined optimization criteria. The MOST design involves 3 phases: preparation, optimization, and evaluation (Figure 2 [49]). In the preparation phase, a theoretical model for intervention is derived, intervention components are selected, the optimization criteria for intervention component selection are identified, and preclinical pilot and/or feasibility studies may be undertaken. In this study, we will invite members of the target population (ie, emerging adults with T1D) to review and provide feedback on three
existing intervention components and then refine the components based on their feedback. In the optimization phase, we will conduct a component selection experiment using a randomized factorial research design to build an autonomy support intervention that has been optimized for efficacy. We will use a clinically significant improvement in metabolic control (decrease in HbA1c, HbA1c ≥ 0.5%) as the optimization criterion for determining which intervention components should be retained in the multicomponent intervention. We chose efficacy as the optimization criterion because the eHealth intervention components, once developed, are relatively low cost (a common optimization criterion) to implement and sustain making a clinically significant reduction in HbA1c the most persuasive optimization criterion for clinicians and potential payers. The MOST approach offers distinct advantages over the traditional multiple pilot randomized clinical trial approach. Including all participants in the analysis will enable an efficient, simultaneous investigation of the efficacy of each intervention component as well as synergies resulting from combinations of intervention components. Thus, this component selection experiment is analogous to conducting multiple pilot randomized clinical trials to evaluate the efficacy of each of the three intervention components and the combination of intervention components using only a fraction of the sample size and resources. At the end of this study, we will have empirical evidence supporting the efficacy of each intervention component and estimates of the efficacy of the intervention package as a whole to improve metabolic control, diabetes self-management, and diabetes clinic attendance. Empirical evidence from this study will inform the design of a large-scale, multisite effectiveness trial of the optimized intervention package.

**Figure 2.** The multiphase optimization strategy study design.

As shown in **Figure 3**, the component selection experiment will use an eight-arm full factorial design: 2 (QPL yes or no) × 2 (MES yes or no) × 2 (text yes or no). In arms 1-3, participating youth will receive one of the three intervention components, in arms 4-6 two components; arm 7 will include all three components, and arm 8 will be the standard care control. This design will allow us to evaluate the main effect of each intervention component and explore whether combinations of components have synergy (interaction effects). The experiment, powered on the main effects, will require 320 (296 after attrition) older adolescent and young adult participants (16-25 years) with poorly controlled T1D (HbA1c ≥ 9.0%). Participants will complete 3 study visits: baseline and 2 and 6 months. The intervention period is 30 days with MES session 1, and text message reminders initiated 1 week after the baseline visit. MES session 2 occurs 30 days later with the text intervention occurring between the two MES sessions. The QPL is delivered 2 weeks before the participant’s next diabetes clinic visit; hence, participants will be enrolled approximately 1 month before an upcoming diabetes clinic visit to ensure that the QPL occurs during the intervention period. The participant timeline is shown in **Figure 4**.
Setting and Participants

Participants will be recruited from two Wayne State University School of Medicine sites, both located in Detroit, Michigan. We will invite eligible youth from the pediatric diabetes clinics at the Children’s Hospital of Michigan (CHM) and the adult comprehensive diabetes clinics at the Detroit Medical Center’s (DMC) University Health Center (UHC). We will target older adolescent and emerging adult patients aged 16 to 25 years, inclusive, who have been diagnosed with T1D for at least 6 months and have an elevated HbA\textsubscript{1c} (HbA\textsubscript{1c} ≥ 9.0% currently and averaged over the previous 6 months). We select this age range based on expert recommendations for when autonomous diabetes management is appropriate [14]. We will not exclude youth based on comorbid mental health problems (e.g., depression) with the exception of conditions (i.e., thought disorders, psychosis, autism, developmental delay, and suicidality) or problems of a severity that compromise data integrity, intervention participation, or youths’ ability to assume autonomous diabetes care. Nor will we exclude based on the presence of comorbid physical health problems unless the diagnosis of diabetes is secondary to another chronic medical illness (e.g., cystic fibrosis) or results in atypical diabetes management. Due to the minority of non-English speaking youth at CHM and UHC, the ability to speak and read English will be required. Finally, youth will also be required to have access to a mobile device with texting capability on which they can receive the intervention components.

Procedures

Recruitment and Retention

Following procedures approved by the institutional review board, we will mail a letter, cosigned by our clinician collaborators, introducing the research study to all potentially eligible youth and the caregivers of minor youth. This strategy will ensure that all eligible youth are informed of the study with adequate time to enroll. It will also permit disinterested youth the opportunity to opt out of being contacted regarding the study. Research assistants (RAs) will follow-up with potentially eligible youth and the caregivers of eligible minors by telephone to present the details of the study and assess their interest in participating. If the recruitment letter is returned undeliverable or RAs are unable to establish contact by phone, clinicians will introduce the study at a diabetes clinic visit and obtain a release of information and updated contact information for follow-up. RAs will obtain informed consent or, in the case of participants <18 years old, parental consent and youth assent before data collection. We will use multiple techniques to minimize follow-up attrition, including collecting detailed contact information (including three contact persons), advanced scheduling, and multiple reminder mailings and phone calls.
**Data Collection**

Given this population’s known propensity to miss clinic visits, we will conduct all study visits in youths’ homes. One month before an upcoming diabetes clinic visit, participants will have their first study visit at which the RA will obtain informed consent, baseline measurements, and download the intervention software app to the participant’s preferred device (eg, phone or tablet). The postintervention study visit will occur 2 months after baseline and is timed to occur immediately after the completion of the interventions. A second follow-up study visit will occur 6 months after baseline to assess the sustainability of intervention effects. RAs will collect self-report data using REDCap, a Health Insurance Portability and Accountability Act -compliant electronic data capture system. RAs will manually download glucose meters and extract medical chart data obtained as part of the routine medical care encounter onto paper-based forms for direct data entry. The results of HbA1c tests will be similarly entered from laboratory test result forms. RAs will offer participants US $50 for completing each of the three data collections (US $150 total).

**Randomization**

Participants will be randomly assigned to one of the eight intervention conditions following their first study visit. We will stratify randomization by HbA1c (high: >11.5% vs low: ≤11.5% based on the median HbA1c in our prior T1D intervention studies with emerging adults). As HbA1c is strongly associated with age [14], race [50], and insulin treatment [14], we effectively control for these other variables via this strategy. We will use a permuted block algorithm with blocks of eight within each HbA1c stratum. Permuted blocks have the advantage of ensuring balance between treatment arms for important prognostic variables without unmasking the next treatment allocation [51]. To keep data collection staff blind to the youth’s treatment status, one RA will have exclusive data collection responsibilities. A data analyst, under our biostatistician’s supervision, will develop the randomization schedule and convey treatment assignments to the intervention coordinator who will deliver treatment assignments and initiate and monitor treatment protocols.

**Interventions**

During the first study visit, the RA will ensure that the participant can access the intervention via their preferred device (either as a mobile web app for Android devices or as a hybrid app on iOS devices) and will explain the different intervention components via text message–delivered hyperlinks. The intervention coordinator will monitor youths’ treatment completion rates, providing support and technical assistance as needed. Conversations between the intervention coordinator and youth will be audio recorded. These audio recordings will be randomly selected on a biweekly basis for the assessment of protocol fidelity. Drift from the delivery protocol will be addressed with retraining.

All three intervention components will be delivered using communication strategies derived from MI, a method of talking with people about their behavior in a way that is simultaneously client-centered and directive [34,52]. The MI framework is an autonomy-supportive intervention with strong empirical support for eliciting behavior change through intrinsic motivation. MI is consistent with SDT [53,54], as the goal of MI is to increase intrinsic motivation and self-efficacy for engaging in health-promoting behaviors [55]. In addition, emphasis on patients’ decision-making autonomy is a critical element of MI spirit, the relational component of MI [32-34]. The technical component of MI, that is, the use of communication techniques consistent with the MI framework [56], leads to behavior change through the elicitation of patients’ statements of intrinsic motivation (ie, change talk, statements about patients’ own desire, ability, reasons, and need for behavior change, and commitment language, patients’ statements about their intentions and plans for change). The empirical link between change talk, commitment language, and behavior change is well established [57], and evidence is growing to support the role of providers’ use of MI-consistent communication strategies in eliciting patient motivational statements [58-66]. We have previously demonstrated that clinician use of autonomy-supportive statements has been empirically linked to patient statements of intrinsic motivation [67,68]. This knowledge is integrated into the three intervention components for this study by including statements that explicitly emphasize decision-making autonomy.

**Computerized Intervention Authoring Software**

All three interventions will be developed and delivered via the Computerized Intervention Authoring Software (CIAS), version 2.0 (Interva, Inc) CIAS 2.0 is an e-intervention authoring tool that generates HTML5 mobile web apps with a responsive design capable of being deployed on any web browser and accessed via any device (eg, Apple or Android) of any size (ie, automatically reformats for optimal viewing on any size screen). As interventions built using CIAS 2.0 feature an animated narrator and a voice that reads content out loud for each screen and as iOS devices specifically disallow automatic triggering of sound files, participants with iOS devices access content via a hybrid app approach. The current mobile version of CIAS has an enhanced feature set including improved voice quality for narrated content and an updated appearance. Although mobile web and hybrid apps require internet access, 96% of Americans aged 18-29 years report consistent internet access [69]. Furthermore, technology-based interventions are ideal for youth who already have technology (cell phones and computers) integrated into their natural ecology [70-72]. Mobile web apps offer several advantages over native apps in that they do not require separate programming for different platforms, are less expensive to build and maintain, updates are centralized and automatic, they are more easily accessible and shared, and require negligible device storage space. Thus, mobile web apps exclude only a minority of youth and are consistent with trends toward ubiquitous device ownership and ready access to the internet.

**Diabetes QPL**

A QPL is a simple, inexpensive communication tool composed of questions related to the physical and psychosocial aspects of
illness and treatment that patients may want to ask their physicians during a clinic visit [26,27]. QPLs are grounded in social cognitive theory, which posits that behavioral performance is largely a function of confidence in one’s ability to perform the behavior (self-efficacy) and the expectation that the behavior will result in the desired outcome [73]. Patients prepared with a QPL are more likely to ask questions and state their concerns, enabling shared decision-making and bolstering self-efficacy.

The diabetes QPL content development will be guided by the American Diabetes Association’s guidelines for diabetes treatment [14] and the empirical literature on factors that influence diabetes management during emerging adulthood. The diabetes QPL will focus on common questions about the management of T1D, various treatment options, complications, psychosocial adjustment, and transitioning to adult medical care. A diabetologist and a certified diabetes nurse educator will review the diabetes QPL for clinical relevance. Ten members of the target population will provide feedback on its relevance and acceptability via a semistructured interview. The QPL will be further refined based on this feedback.

Within 1 week of the first study visit, the intervention coordinator (an unblinded research assistant) will contact the youth randomized to the QPL by phone to explain the QPL. Approximately 2 weeks before their diabetes clinic visit, the youth will receive a text message containing a link to complete the QPL. The youth will receive reminders to complete the QPL every 3 days, escalating to daily reminders for the 3 days before the clinic visit. Upon completion, the personalized QPL will be emailed to the youth with a message reminding them to bring their QPL to their upcoming diabetes clinic visit. Additional reminders to bring the QPL to the diabetes clinic visit will be sent 1 week before and the day before the scheduled clinic visit.

**MES**

MES is a brief, computer-delivered intervention to enhance intrinsic motivation for behavior change. MES is grounded in the MI framework [32-34] and the information-motivation-behavioral skills (IMB) model of health behavior change [74]. The IMB model posits that behavior change results from the joint function of 3 critical components: accurate information about risk behaviors (eg, risks of poor diabetes self-management) or replacement health behaviors (eg, benefits of effective diabetes self-management), motivation to change behavior, and having the behavioral skills necessary to perform the behavior (eg, self-efficacy) [75]. The MES system delivers therapeutic content with high fidelity to MI principles. An animated character (avatar) guides patients through the intervention, reflecting back their responses with affirmations to boost self-efficacy and making statements emphasizing personal choice. The avatar speaks, moves/points, and displays emotional responses such as surprise, sadness, or thoughtfulness, as appropriate. The inclusion of a lifelike, synchronously interactive avatar (ethopoeia) is related to better treatment outcomes [76].

The 3Ms MES is a brief (>15 min), two-session mobile health intervention originally developed to improve preadolescents’ motivation for diabetes management behavior, that is, monitoring blood glucose, medication/insulin adherence, and meal/carbohydrate counting [41]. Session 1 begins with psychoeducation describing optimal diabetes self-management (ie, information). Youth’s motivation (operationalized as the importance of diabetes self-management) and self-efficacy (operationalized as confidence for diabetes self-management) are assessed, followed by exercises designed to increase or reinforce his/her current motivational state (eg, decisional balance) and build self-efficacy (eg, building on strengths and past success). Session 1 concludes with goal setting to promote autonomous diabetes self-management and provides the participant with optional strategies for improving diabetes management. Session 2 begins with an assessment of progress toward the behavioral goal and proceeds to build motivation and self-efficacy with exercises consistent with the youth’s current motivational state. Session 2 concludes with goal setting to promote autonomous diabetes self-management. The content of the 3Ms MES will be refined to be more consistent with the needs of older adolescents and emerging adults with T1D. Specifically, we will edit the avatar’s language to more strongly emphasize youths’ autonomy as it relates to diabetes self-management and edit the interactive components (ie, reasons to engage in self-management activities, potential past successes, and personal strengths/weaknesses) to be developmentally consistent with emerging adulthood. A diabetologist will review the MES for clinical relevance, and 10 members of the target population will provide feedback on its relevance and acceptability via a semistructured interview. The MES will be further refined based on this feedback.

Within 1 week of the baseline data collection, the intervention coordinator will contact youth randomized to MES by phone to explain the intervention and initiate session 1 via a link sent by text message. Thirty days after the initial session, youth will receive a link to complete session 2. Youth will receive weekly reminders to complete the sessions until they complete the session or the intervention period has elapsed.

**Text Message Reminders**

Text message reminders (one-way) are a behavioral support strategy with theoretical support from social cognitive theory. Text message reminders promote adherence by increasing the likelihood that health-related tasks are completed, which leads to perceptions of control over health behavior and supports goal attainment [77]. We will refine a one-way text messaging protocol previously developed and evaluated with young adults with moderate to severe persistent asthma [39]. Youth will receive 30 days of one-way text message reminders. Messages will be tailored according to the youths’ preferred behavioral target derived from the 3Ms MES intervention, that is, youth may choose to receive text messages to monitor their blood glucose, take their insulin, count carbohydrates, or all 3 behaviors. They will be given the ability to opt out of text message reminders (none did in the asthma study [39]). Youth that do not opt out will receive daily text messages but will choose at what time(s) of day to receive their reminders. A diabetologist will review the text message reminders for clinical relevance, and 10 members of the target population will provide feedback on its relevance and acceptability via a semistructured

---

http://www.researchprotocols.org/2020/10/e20191/
Within 1 week of the baseline data collection, the intervention coordinator will contact youth randomized to text by phone to explain the intervention. The intervention coordinator will solicit a target behavior (ie, monitoring, medicine, meals, or all 3) using standardized language. The intervention coordinator will also finalize the reminder schedule and other logistics. Youth will then receive 30 days of one-way text message reminders consistent with their diabetes management goals and delivery preferences.

**Standard Medical Care**

All participants will continue to receive standard medical care at 1 of the 2 DMC clinical sites: CHM or the UHC comprehensive diabetes clinic. DMC’s clinical practices are consistent with the standards of T1D care recommended by the American Diabetes Association. Established patients with T1D visit a DMC diabetes clinic every 3-4 months for routine diabetes medical care provided by an endocrinologist and/or nurse practitioner.

**Measures**

All measures have previously been used with adolescent populations; however, we will assess their psychometric performance before analysis.

Metabolic control is the primary outcome and will be measured using $\text{HbA}_1\text{c}$. $\text{HbA}_1\text{c}$ is an indirect and retrospective measure of average blood glucose levels over the previous 2-3 months. The Accubase $\text{A}_1\text{c}$ test kit manufactured by DTI Laboratories will be used to measure $\text{HbA}_1\text{c}$. This kit is United States Food and Drug Administration approved and uses a capillary tube blood collection method instead of venipuncture, making it suitable for home-based data collection by nonphlebotomists. DTI uses high-performance liquid chromatography to analyze the blood sample; the reagent solution contains 1 ml of ethylenediaminetetraacetic acid and 0.025 mmol/l potassium cyanide, a blood preservative. A custom lot of test kits will be ordered to minimize variability across test kits. The Accubase test kit is comparable with $\text{HbA}_1\text{c}$ obtained from venous whole blood ($r^2=0.987$) [78].

Diabetes management is a secondary outcome and will be assessed via self-report and objective measures. The diabetes management scale (DMS) [79] is a self-report measure of daily diabetes care that assesses a broad range of management behaviors, including insulin management, dietary management, blood glucose monitoring, and symptom response. Questions ask “What percent of the time do you [eg, take all your insulin doses every day]?” with a 0%-100% response scale. The DMS has been adapted for intensive insulin regimens with good internal consistency ($\alpha=.74$ to .84) [80]. RAs will download glucose monitors to obtain objective data on the frequency of blood glucose monitoring. Data for participants using a blood glucose meter will be reported as the mean daily frequency of blood glucose testing during the 14 days before assessment. Continuous glucose monitoring data will be reported as the proportion of days the monitor was worn out of 14.

SDT constructs are mediators and will be assessed via self-report. The treatment self-regulation questionnaire (TSRQ) assesses the extent to which youth perceive their behavior as intrinsically (autonomous) or extrinsically (controlled externally) motivated [81]. The diabetes version of the TSRQ is valid and reliable ($\alpha=.80$ to .86) [20]. Items (N=19, 7-point Likert) form 2 subscales, autonomous and controlled regulation, and an overall scale, the relative autonomy index [82]. Two versions of Rollnick’s readiness ruler [83] will be used to assess adolescents’ motivation to change their diabetes self-management routines. The importance ruler assesses individuals’ perceptions of the importance of changing their blood glucose testing frequency, taking prescribed doses of insulin, and adhering to dietary recommendations. The confidence ruler assesses an individual’s confidence (self-efficacy) in their ability to implement changes in self-management [33]. Both rulers use a 1 (not ready to change) to 10 (already trying to change) rating scale. Items are summed to obtain the total motivation for change score. Behavior-specific rulers have been widely used and are related to adolescent medication adherence [84], treatment dose [85], and treatment outcomes [86]. Cronbach $\alpha=.71$ in previous research with the study population [87]. Self-efficacy for diabetes self-management will also be assessed using the diabetes empowerment scale (DES) [88] and the perceived health competence scale (PHCS) [89]. DES has 28 items assessing 3 domains of diabetes self-efficacy: managing the psychosocial aspects of diabetes, assessing dissatisfaction and readiness to change, and setting and achieving diabetes goals. DES is a widely used measure with demonstrated reliability ($\alpha=.96$), validity [88], and sensitivity to change with improvements in $\text{HbA}_1\text{c}$ [90]. PHCS (8 items, 5-point Likert) will be modified to assess perceptions of diabetes (vs health) competence. PHCS is reliable ($\alpha=.82$ to .90) and valid (associated with health intentions and behavior) [89]. The patient-provider relationship will be assessed with the health care climate questionnaire (HCCQ) [91]. Participants use a 7-point Likert scale to rate 18 items in 2 domains: communicative support and practical support. The HCCQ is reliable ($\alpha=.87$) and valid. The patient activation scale (PAS) was derived from the observation scale of the same name developed by Street et al [92]. The PAS consists of 19 items rated on a 5-point Likert scale comprising 2 scales, patient-centered communication and patient active participation.

Due to the comorbidity of depression and diabetes [93,94] and the moderating role of depression on self-efficacy in chronic illness self-management [95], symptoms of depression will be measured with the Center for Epidemiologic Studies Depression Scale (CES-D) [96]. The CES-D is a widely used, 20-item self-report scale that has been validated for use with adolescents [97].

The investigator-developed family information form will be used to collect demographic information, such as age, gender, race/ethnicity, family structure, and income level. Clinical data, including type of diabetes regimen (ie, traditional injections, intensive injections, and insulin pump), duration of diabetes, and other relevant clinical variables, will be extracted from the participants’ medical records. Diabetes clinic attendance will
also be extracted for the 6-month periods before and after study initiation.

The client evaluation of treatment (CET), an investigator-developed measure to assess participants’ perceptions of the usability, comprehensibility, comfort with, and usefulness of the intervention components, will be completed at the first follow-up data collection visits. Sample questions include “Do you feel this question list/computer session/text messaging program will be useful for you?” and “How easy was it for you to use the question list/computer session/text messaging program?”, with a 4-point Likert response scale.

Data Analysis Plan

The data analysis plan is twofold. Qualitative interview data collected during the intervention refinement phase will be analyzed using thematic analysis. Quantitative experimental data will be analyzed using the mixed-effects linear model for the analysis of variance (ANOVA) of a factorial design to identify the intervention components that significantly contribute to a clinically significant improvement in HbA\(_{1c}\) (ie, a ≥0.5% decrease from baseline).

Framework matrix analysis (FMA) is an efficient, systematic approach to conducting thematic analysis [98]. An FMA analysis begins with the construction of a matrix in which the rows are based on content areas derived from the interview guide and the columns represent respondents. Two coders will first familiarize themselves with the data by reviewing the interview data. They then independently code the interviews by charting a summary of participant feedback into the matrix. Coders will meet after every interview to review and compare their matrices. Discrepancies will be resolved through a review of the audio and discussion, resulting in the construction of a final consensus-coded matrix. Together, the coders will identify emergent themes summarizing youths’ feedback. Data analysis will be ongoing during the data collection process. We will solicit feedback from up to 10 youth, stopping interviews if there is evidence of data saturation [99], that is, interviews are no longer generating new feedback.

Analysis of experimental data will begin with descriptive statistical analyses. The biostatistician will first characterize data heterogeneity and document the distributions of HbA\(_{1c}\), the primary outcome, and all secondary and exploratory outcomes (ie, diabetes management and clinic attendance). The data will be examined for out-of-range values, outliers, and abnormal values using graphical methods (eg, boxplots and histograms) and descriptive statistics. Unexpected findings will prompt the checking of raw data for accuracy of data entry and recording. The effect of the intervention components on the longitudinal measures of HbA\(_{1c}\) will be examined using the mixed-effects linear model for the ANOVA of a factorial design. This model will include a fixed effects indicator for each intervention component (QPL, MES, and text), time, and all interactions with time. Random intercepts will be used to account for the longitudinal nature of the data. Each model will include a random intercept and slope and fixed effects for treatment combinations (=2\(^3\)) and time as well as the stratification variable (eg, high/low HbA\(_{1c}\)). Before evaluating which components contribute to a potential reduction in HbA\(_{1c}\), models comparing the treatment with all three components and the control treatment will be examined to determine whether the complete intervention was efficacious. If this statistical test is significant, components resulting in a significant reduction in HbA\(_{1c}\) will be identified by examining the interactions between the main effects and time using the strategy advocated by Collins et al [100], which begins with the simplest effects and only adding higher-order interactions if needed. Significance thresholds will be set at \(\alpha=0.05\) for the test of total effect (difference between the treatment with all three components and the control treatment) and \(\alpha=1\) to identify which components contribute to the total effect. A higher alpha value will be used for the component selection test because it reduces the likelihood of not selecting a component that contributes to the total effect. Secondary and exploratory outcomes (diabetes management and treatment attendance) will be analyzed using a similar approach but are not powered. As treatment attendance is not a continuous outcome, a generalized linear model will be employed.

The power analyses examined the sample size required to detect clinically meaningful group differences using a mixed effect model. The proposed experiment quantifies the effects of the three experimental treatment components. Factorial trials are most often powered to detect the main effects of interventions, as adequate power to detect plausible interactions requires a greatly increased sample size [101]. As two primary hypotheses have been proposed, the Hochberg alpha adjustment will be used in hypothesis testing. The smaller of those sequential alpha levels of .025 was used in our estimates of the multiplicity-adjusted sample sizes [102]. On the basis of the simulation, the protocol proposes recruitment of 296 participants (37/condition) for a standardized medium effect size (Cohen \(d\)=0.47). After adjusting for 10% attrition, our final projected sample size is 320 (40/condition), which is sufficient to preserve >80% power. The power analysis was completed in SAS (SAS Institute Inc) 9.3 software using the mixed linear model procedure. Strong preliminary support for each intervention component’s efficacy suggests that each intervention component will uniquely contribute to the overall intervention’s efficacy. Thus, the study has sufficient power to determine whether any combination of the intervention components is efficacious in improving older adolescents’ and emerging adults’ metabolic control (HbA\(_{1c}\), H1) or self-reported diabetes management behaviors (H2).

The role of sex and baseline depression status (high vs low) as moderators will be explored. These results will not be used for treatment decision-making but instead could guide the design of subsequent confirmatory trials (eg, inclusion/exclusion criteria). The focus will be on the magnitude of the effect, as recommended by Kraemer et al [103], not on significance. Fixed effects linear regression models will be used for the exploratory analyses of moderators. The dependent variable (HbA\(_{1c}\)) will be expressed as a change from baseline to treatment endpoint. Independent variables include treatment and one hypothesized moderating effect per model. To demonstrate evidence of the
effect of each hypothesized moderator, there must be a treatment by moderator interaction with $R^2 \geq 0.05$. Treatment effect sizes will be estimated for each level of the moderator.

The hypothesis that SDT constructs (autonomy, self-efficacy, and the patient-provider relationship) will mediate intervention effects on primary outcomes at the end of treatment (2 months) and at follow-up (6 months) will also be assessed using fixed effects linear regression models. The dependent variable will be change in the primary outcome from baseline to months 2 and 6. In the main effects model, the hypothesized mediator effect (specified as change from baseline to months 2 and 6). Initially, the main effects will be tested with subsequent models examining the incremental contribution of the treatment by mediator interaction. Either a main effect of the mediator or treatment by mediator interaction would provide evidence of a mediator effect [103].

Attrition introduces bias and reduces power, precision, and generalizability [104]. To offset these threats and in keeping with the intention-to-treat principle, intervention termination and study termination will be distinguished, and all efforts to continue study assessments for the entire course of the study, even among those who do not continue with randomized treatment, will be undertaken [105]. The proposed mixed-effects models will incorporate all available data, even from subjects who do not complete the trial. Mixed-effects models yield valid inferences assuming ignorable attrition [106]. Two approaches will be used to examine the sensitivity of the assumption of ignorable attrition. First, we will use a pattern mixture model [107] to examine response to treatment among participants with various dropout patterns and implemented using a longitudinal strategy [108]. Second, we will ask subjects at each assessment session to rate their intent-to-attend the next assessment session on a Likert scale and, at baseline, to rate their intent to complete the study [109]. This variable will be used in sensitivity analyses as a baseline covariate. Estimates of the treatment effect from the models described above will be compared with models that also include the main effects of either dropout pattern or intent-to-attend.

Results

At the writing of this report, intervention refinement activities are underway. As of July 2020, 20 participants have been enrolled and have completed a qualitative interview after reviewing one or more intervention components. The interventions are being further refined in response to this feedback. Analysis of interview data are underway, with a report of these results anticipated in the fall of 2020. The clinical trial phase is contingent on the intervention refinement activities and, thus, will be launched in the fall 2020. Participant enrollment is scheduled through May 2023, with intervention delivery wrapping up about 1 month later, in June 2023. Data collection activities will continue through November 2023, at which point study activities will focus on data analysis, dissemination, and preparing the next phase of the research, for example, developing an effectiveness trial proposal.

Discussion

This research addresses the problem of poor diabetes management among adolescents that persists into early adulthood. We leverage the developmental needs of older adolescents/emerging adults for independence and autonomy in the construction of a multicomponent intervention that translates a basic social science theory, SDT, into three autonomy-supportive intervention components with demonstrated efficacy in similar populations and/or problems: a QPL, a MES (an eHealth intervention), and text message reminders. These intervention components will be vetted by the target population of emerging adults and then efficacy tested using the MOST, an efficient method of intervention development resulting in a potent, efficacious multicomponent intervention.

Acknowledgments

This research project was funded by the National Institute of Diabetes, Digestive, and Kidney Diseases, grant #R01DK116901.

Conflicts of Interest

SO is a part owner of Interva, Inc. All other authors have no conflicts of interest to report.

Multimedia Appendix 1

National Institute of Diabetes, Digestive, and Kidney Diseases peer reviews.

References

1. American Diabetes Association. Standards of medical care in diabetes-2014. Diabetes Care 2014 Jan;37 Suppl 1:S14-S80. [doi: 10.2337/dc14-5014] [Medline: 24357209]
2. Gonder-Frederick LA, Cox DJ, Ritterband LM. Diabetes and behavioral medicine: the second decade. J Consult Clin Psychol 2002 Jun;70(3):611-625. [doi: 10.1037/0022-006x.70.3.611] [Medline: 12090372]
3. Arnett JJ. Emerging adulthood: a theory of development from the late teens through the twenties. Am Psychol 2000 May;55(5):469-480. [doi: 10.1037//0022-006x.55.5.469] [Medline: 10842426]
4. Wiebe DJ, Helgeson V, Berg CA. The social context of managing diabetes across the life span. Am Psychol 2016 Oct;71(7):526-538 [FREE Full text] [doi: 10.1037/a0040355] [Medline: 27690482]
5. Weissberg-Benchell J, Wolpert H, Anderson BJ. Transitioning from pediatric to adult care: a new approach to the post-adolescent young person with type 1 diabetes. Diabetes Care 2007 Oct;30(10):2441-2446. [doi: 10.2337/dc07-1249] [Medline: 17666466]

6. Keough L, Sullivan-Bolyai S, Crawford S, Schilling L, Dixon J. Self-management of type 1 diabetes across adolescence. Diabetes Educ 2011;37(4):486-500. [doi: 10.1177/0145721711406140] [Medline: 21602489]

7. McCarthy MM, Grey M. Type 1 diabetes self-management from emerging adulthood through older adulthood. Diabetes Care 2018 Aug;41(8):1608-1614. [doi: 10.2337/dc17-2597] [Medline: 29802144]

8. van Walleghem N, Macdonald CA, Dean HJ. Evaluation of a systems navigator model for transition from pediatric to adult care for young adults with type 1 diabetes. Diabetes Care 2008 Aug;31(8):1529-1530 [FREE Full text] [doi: 10.2337/dc07-2247] [Medline: 18458141]

9. Callahan ST, Cooper WO. Changes in ambulatory health care use during the transition to young adulthood. J Adolesc Health 2010 May;46(5):407-413. [doi: 10.1016/j.jadohealth.2009.09.010] [Medline: 20413075]

10. Fortuna RJ, Robbins BW, Mani N, Halterman JS. Dependence on emergency care among young adults in the United States. J Gen Intern Med 2010 Jul;25(7):663-669 [FREE Full text] [doi: 10.1007/s11606-010-1313-1] [Medline: 20306149]

11. Bryden KS, Dunger DB, Mayou RA, Peveler RC, W Neil HA. Poor prognosis of young adults with type 1 diabetes: a longitudinal study. Diabetes Care 2003 Apr;26(4):1052-1057. [doi: 10.2337/diabetes.26.4.1052] [Medline: 12663572]

12. Helgeson VS, Siminerio LS, Escobar O, Becker D. Predictors of metabolic control among adolescents with diabetes: a 4-year longitudinal study. J Pediatr Psychol 2009 Apr;34(3):254-270 [FREE Full text] [doi: 10.1093/jpepsy/jsn079] [Medline: 18667479]

13. Haller MJ, Stalvey MS, Silverstein JH. Predictors of control of diabetes: monitoring may be the key. J Pediatr 2004 May;144(5):660-661. [doi: 10.1067/j.ipeds.2003.12.042] [Medline: 15127007]

14. Silverstein J, Klingensmith G, Copeland K, Plotnick L, Kaufman F, Laffel L. American Diabetes Association. Care of children and adolescents with type 1 diabetes: a statement of the american diabetes association. Diabetes Care 2005 Jan;28(1):186-212. [doi: 10.2337/diabetes.28.1.186] [Medline: 15616254]

15. Hilliard ME, Powell PW, Anderson BJ. Evidence-based behavioral interventions to promote diabetes management in children, adolescents, and families. Am Psychol 2016 Oct;71(7):590-601 [FREE Full text] [doi: 10.1037/a0040359] [Medline: 27690487]

16. Williams GC, Deci EL, Ryan RM. Building healthcare partnerships by supporting autonomy: promoting maintained behavior change and positive health outcomes. In: Suchman AL, Botelho RJ, Hinton-Walker P, editors. Partnerships in Healthcare: Transforming Relational Process. Rochester, NY: University of Rochester Press; 1998:67-87.

17. Deci EL, Ryan RM. Intrinsic Motivation and Self-Determination in Human Behavior. New York, USA: Springer US; 1985:372.

18. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. Am Psychol 2000 Jan;55(1):68-78. [doi: 10.1037/0003-066X.55.1.68] [Medline: 11392867]

19. Williams GC, Lynch M, Glasgow RE. Computer-assisted intervention improves patient-centered diabetes care by increasing autonomy support. Health Psychol 2007 Nov;26(6):728-734. [doi: 10.1037/0278-6133.26.6.728] [Medline: 18020845]

20. Williams GC, Freedman ZR, Deci EL. Supporting autonomy to motivate patients with diabetes for glucose control. Diabetes Care 1998 Oct;21(10):1644-1651. [doi: 10.2337/diabetes.21.10.1644] [Medline: 97737274]

21. Williams GC, McGregor HA, Zeldman A, Freedman ZR, Deci EL. Testing a self-determination theory process model for promoting glycemic control through diabetes self-management. Health Psychol 2004 Jan;23(1):58-66. [doi: 10.1037/0278-6133.23.1.58] [Medline: 14756604]

22. Williams GC, McGregor H, Zeldman A, Freedman ZR, Deci EL, Elder D. Promoting glycemic control through diabetes self-management: evaluating a patient activation intervention. Patient Educ Couns 2005 Jan;56(1):28-34. [doi: 10.1016/j.pec.2003.11.008] [Medline: 15590220]

23. Husted GR, Thorstenson B, Esbensen BA, Gluud C, Winkel P, Hommel E, et al. Effect of guided self-determination youth intervention integrated into outpatient visits versus treatment as usual on glycemic control and life skills: a randomized controlled trial in adolescents with type 1 diabetes. Trials 2014 Aug 12;14(1):321 [FREE Full text] [doi: 10.1186/1745-6215-14-321] [Medline: 25118146]

24. Hill E, Sibthorp J. Autonomy support at diabetes camp: a self determination theory approach to therapeutic recreation. Ther Recreation J 2006;40(2):107-125 [FREE Full text]

25. Dayte KA, Moore DJ, Russell WE, Jaser SS. A review of adolescent adherence in type 1 diabetes and the untapped potential of diabetes providers to improve outcomes. Curr Diab Rep 2015 Aug;15(8):51 [FREE Full text] [doi: 10.1007/s11892-015-0621-6] [Medline: 26084580]

26. Sansoni JE, Grootemaat P, Duncan C. Question prompt lists in health consultations: a review. Patient Educ Couns 2015 Jun 03 ePub ahead of print. [doi: 10.1016/j.pec.2015.05.015] [Medline: 26104993]

27. Brandes K, Linn AJ, Butow PN, van Weert JC. The characteristics and effectiveness of question prompt list interventions in oncology: a systematic review of the literature. Psychooncology 2015 Mar;24(3):245-252. [doi: 10.1002/po.3637] [Medline: 25082386]
28. Brandes K, Butow PN, Tattersall MH, Clayton JM, Davidson PM, Young J, et al. Advanced cancer patients' and caregivers' use of a question prompt list. Patient Educ Couns 2014 Oct;97(1):30-37. [doi: 10.1016/j.pec.2014.06.010] [Medline: 25023487]

29. Rodenbach RA, Brandes K, Fisceka K, Kravitz RL, Butow PN, Walczak A, et al. Promoting end-of-life discussions in advanced cancer: effects of patient coaching and question prompt lists. J Clin Oncol 2017 Mar 10;35(8):842-851 [FREE Full text] [doi: 10.1200/JCO.2016.68.5651] [Medline: 28255883]

30. Dimoska A, Butow PN, Lynch J, Hovey E, Agar M, Beale P, et al. Implementing patient question-prompt lists into routine cancer care. Patient Educ Couns 2012 Feb;86(2):252-258. [doi: 10.1016/j.pec.2011.04.020] [Medline: 21741195]

31. Sleath B, Carpenter DM, Davis SA, Watson CH, Lee C, Loughlin CE, et al. Acceptance of a pre-visit intervention to engage teens in pediatric asthma visits. Patient Educ Couns 2017 Nov;100(1):2005-2011 [FREE Full text] [doi: 10.1016/j.pec.2017.05.013] [Medline: 28550963]

32. Rollnick S, Miller WR. Motivational Interviewing: Preparing People to Change Addictive Behavior. New York, USA: The Guilford Press; 1992.

33. Miller W, Rollnick S. Motivational Interviewing: Preparing People for Change. Second Edition. New York, USA: The Guilford Press; 2012.

34. Kolmodin MacDonell K, Naar S, Gibson-Scipio W, Lam P, Secord E. The Detroit Young Adult Asthma Project: Pilot of a Technology-Based Medication Adherence Intervention for African-American Emerging Adults. J Adolesc Health 2016 Oct;59(4):465-471 [FREE Full text] [doi: 10.1016/j.jadohealth.2016.05.016] [Medline: 27475032]

35. Outlaw AY, Naar-King S, Tanney M, Belzer ME, Aagenes A, Parsons JT, Adolescent Medicine Trials Network for HIV/AIDS Interventions. The initial feasibility of a computer-based motivational intervention for adherence for youth newly recommended to start antiretroviral treatment. AIDS Care 2014 Jan;26(1):130-135 [FREE Full text] [doi: 10.1080/09540121.2013.813624] [Medline: 23869650]

36. Ellis DA, Carcone AI, Ondersma SJ, Naar-King S, Dekelbab B, Moltz K. Brief computer-delivered prevention intervention for youth initiating antiretroviral treatment. J Pediatr Psychol 2013 Jul;38(6):638-648 [FREE Full text] [doi: 10.1093/pepsy/jss132] [Medline: 23359664]

37. Ellis DA, Carcone AI, Ondersma SJ, Naar-King S, Dekelbab B, Moltz K. Adolescent Medicine Network for HIV/AIDS Interventions. Motivational enhancement system for adherence (MESA): pilot randomized trial of a brief computer-delivered prevention intervention for youth initiating antiretroviral treatment. J Pediatr Psychol 2013 Jul;38(6):638-648 [FREE Full text] [doi: 10.1093/pepsy/jss132] [Medline: 23359664]

38. Kolmodin MacDonell K, Naar S, Gibson-Scipio W, Lam P, Secord E. The Detroit Young Adult Asthma Project: Pilot of a Technology-Based Medication Adherence Intervention for African-American Emerging Adults. J Adolesc Health 2016 Oct;59(4):465-471 [FREE Full text] [doi: 10.1016/j.jadohealth.2016.05.016] [Medline: 27475032]

39. Outlaw AY, Naar-King S, Tanney M, Belzer ME, Aagenes A, Parsons JT, Adolescent Medicine Trials Network for HIV/AIDS Interventions. The initial feasibility of a computer-based motivational intervention for adherence for youth newly recommended to start antiretroviral treatment. AIDS Care 2014 Jan;26(1):130-135 [FREE Full text] [doi: 10.1080/09540121.2013.813624] [Medline: 23869650]

40. Ellis DA, Carcone AI, Ondersma SJ, Naar-King S, Dekelbab B, Moltz K. Brief computer-delivered intervention to increase motivation for diabetes self-management in adolescents with type 1 diabetes. Health Psychol Behav Med 2015;3(1):236-250 [FREE Full text] [doi: 10.1080/09540121.2013.813624] [Medline: 23869650]

41. Outlaw AY, Naar-King S, Tanney M, Belzer ME, Aagenes A, Parsons JT, Adolescent Medicine Trials Network for HIV/AIDS Interventions. The initial feasibility of a computer-based motivational intervention for adherence for youth newly recommended to start antiretroviral treatment. AIDS Care 2014 Jan;26(1):130-135 [FREE Full text] [doi: 10.1080/09540121.2013.813624] [Medline: 23869650]

42. Arora S, Peters AL, Agy C, Menchine M. A mobile health intervention for inner city patients with poorly controlled diabetes: proof-of-concept of the TExT-MED program. Diabetes Technol Ther 2012 Jun;14(6):492-496. [doi: 10.1089/dia.2011.0252] [Medline: 22524591]

43. Dick JJ, Nundy S, Solomon MC, Bishop KN, Chin MH, Peek ME. Feasibility and usability of a text message-based program for diabetes self-management in an urban African-American population. J Diabetes Sci Technol 2011 Sep 1;5(5):1246-1254 [FREE Full text] [doi: 10.1177/193229681100500534] [Medline: 22027326]

44. Nundy S, Dick JJ, Solomon MC, Peek ME. Developing a behavioral model for mobile phone-based diabetes interventions. Patient Educ Couns 2013 Jan;90(1):125-132 [FREE Full text] [doi: 10.1016/j.pec.2012.09.008] [Medline: 23063349]

45. Nundy S, Mishra A, Hogan P, Lee SM, Solomon MC, Peek ME. How do mobile phone diabetes programs drive behavior change? evidence from a mixed methods observational cohort study. Diabetes Educ 2014;40(6):806-819 [FREE Full text] [doi: 10.1177/0145721714551992] [Medline: 25278512]

46. Franklin VL, Waller A, Pagliari C, Greene SA. A randomized controlled trial of sweet talk, a text-messaging system to support young people with diabetes. Diabet Med 2006 Dec;23(12):1332-1338. [doi: 10.1111/j.1464-5491.2006.01989.x] [Medline: 17116184]

47. Fischher HH, Moore SL, Ginosar D, Davidson AJ, Rice-Peterson CM, Durfee MJ, et al. Care by cell phone: text messaging for chronic disease management. Am J Manag Care 2012 Feb 1;18(2):e42-e47 [FREE Full text] [Medline: 22435883]

48. Collins L, Murphy S, Nair V, Strecher V. A strategy for optimizing and evaluating behavioral interventions. Ann Behav Med 2005 Aug;30(1):65-73. [doi: 10.1207/s15324796abm3001_8] [Medline: 16097907]
49. Collins LM, Kugler KC, Gwadz MV. Optimization of multicomponent behavioral and biobehavioral interventions for the prevention and treatment of HIV/AIDS. AIDS Behav 2016 Jan;20 Suppl 1:S197-S214 [FREE Full text] [doi: 10.1007/s10461-015-1145-4] [Medline: 26238037]

50. Auslander WF, Thompson S, Dreitzer D, White NH, Santiago JV. Disparity in glycemic control and adherence between African-American and caucasian youths with diabetes. Family and community contexts. Diabetes Care 1997 Oct;20(10):1569-1575. [doi: 10.2337/diacare.20.10.1569] [Medline: 9314637]

51. Matts JP, Lachin JM. Properties of permuted-block randomization in clinical trials. Control Clin Trials 1988 Dec;9(4):327-344. [doi: 10.1016/0197-2456(88)90047-5] [Medline: 3203524]

52. Rollnick S, Miller WR, Butler CC. Motivational Interviewing in Health Care: Helping Patients Change Behavior. New York, USA: Guilford Press; 2007.

53. Markland D, Ryan R, Tobin V, Rollnick S. Motivational Interviewing and Self–Determination Theory. Journal of Social and Clinical Psychology 2005 Sep;24(6):811-831 [FREE Full text] [doi: 10.1521/jscp.2005.24.6.811]

54. Ryan RM, Lynch MF, Vansteenkiste M, Deci EL. Motivation and Autonomy in Counseling, Psychotherapy, and Behavior Change: A Look at Theory and Practice 1η7. The Counseling Psychologist 2010 Feb;39(2):193-260. [doi: 10.1177/0001074309359313]

55. Miller WR, Rollnick S. Ten things that motivational interviewing is not. Behav Cogn Psychother 2009 Mar;37(2):129-140. [doi: 10.1080/1352465890905128] [Medline: 19364414]

56. Miller WR, Rose GS. Toward a theory of motivational interviewing. Am Psychol 2009 Sep;64(6):527-537 [FREE Full text] [doi: 10.1037/a0016830] [Medline: 19739882]

57. Apodaca TR, Longabaugh R. Mechanisms of change in motivational interviewing: a review and preliminary evaluation of the evidence. Addiction 2009 May;104(5):705-715 [FREE Full text] [doi: 10.1111/j.1360-0443.2009.02527.x] [Medline: 19413785]

58. Moyers TB, Martin T. Therapist influence on client language during motivational interviewing sessions. J Subst Abuse Treat 2006 Apr;30(3):245-251. [doi: 10.1016/j.jsat.2005.12.003] [Medline: 16616169]

59. Moyers TB, Martin T, Christopher PJ, Houck JM, Tonigan JS, Amrhein PC. Client language as a mediator of motivational interviewing efficacy: where is the evidence? Alcohol Clin Exp Res 2007 Oct;31(10 Suppl):40s-47s. [doi: 10.1111/j.1530-0277.2007.00492.x] [Medline: 17880345]

60. Moyers TB, Martin T, Houck JM, Christopher PJ, Tonigan JS. From in-session behaviors to drinking outcomes: a causal chain for motivational interviewing. J Consult Clin Psychol 2009 Dec;77(6):1113-1124 [FREE Full text] [doi: 10.1037/a0017189] [Medline: 19968387]

61. Gaume J, Bertholet N, Faouzi M, Gmel G, Daepenne J. Counselor motivational interviewing skills and young adult change talk articulation during brief motivational interventions. J Subst Abuse Treat 2010 Oct;39(3):272-281. [doi: 10.1016/j.jsat.2010.06.010] [Medline: 20708900]

62. Gaume J, Gmel G, Faouzi M, Daepenne J. Counsellor behaviours and patient language during brief motivational interventions: a sequential analysis of speech. Addiction 2008 Nov;103(11):1793-1800. [doi: 10.1111/j.1360-0443.2008.02373.x] [Medline: 19032529]

63. Glynn LH, Moyers TB. Chasing change talk: the clinician’s role in evoking client language about change. J Subst Abuse Treat 2010 Jul;39(1):65-70. [doi: 10.1016/j.jsat.2010.03.012] [Medline: 20418049]

64. McCambridge J, Day M, Thomas BA, Strang J. Fidelity to Motivational Interviewing and subsequent cannabis cessation among adolescents. Addict Behav 2011 Jul;36(7):749-754. [doi: 10.1016/j.addbeh.2011.03.002] [Medline: 21440994]

65. Glynn L, Houck J, Moyers T, Bryan A, Montanaro E. Are Change Talk and Sustain Talk Contagious in Groups? Sequential Probabilities and Safer-Sex Outcomes in Alcohol-and Marijuana-Using Adolescents. Alcoholism-Clinical and Experimental Research 2014: Wiley-Blackwell. Alcoholism: Clinical and Experimental Research 2014;38(s1).

66. Gaume J, Bertholet N, Faouzi M, Gmel G, Daeppen J. Counselor motivational interviewing skills and young adult change talk articulation during brief motivational interventions. J Subst Abuse Treat 2010 Oct;39(3):272-281. [doi: 10.1016/j.jsat.2010.06.010] [Medline: 20708900]

67. Carbone AI, Naar-King S, Brogan KE, Albrecht T, Barton E, Foster T, et al. Provider communication behaviors that predict motivation to change in black adolescents with obesity. J Dev Behav Pediatr 2013 Oct;34(8):599-608 [FREE Full text] [doi: 10.1097/DBP.0b013e3182a67daf] [Medline: 24131883]

68. Jacques-Tiuara AJ, Carcone AI, Naar S, Brogan Hartlieb K, Albrecht TL, Barton E. Building motivation in african american caregivers of adolescents with obesity: application of sequential analysis. J Pediatr Psychol 2017 Mar;1;42(1):131-141 [FREE Full text] [doi: 10.1093/jpepsy/jsx044] [Medline: 27246865]

69. Perrin A, Duggan M. Americans' internet access 2000-2015. Pew Research Center. 2015. URL: https://www.pewresearch.org/internet/2015/06/26/americans-internet-access-2000-2015/ [accessed 2020-09-30]

70. Aoki K, Downes EJ. An analysis of young people’s use of and attitudes toward cell phones. Telematics and Informatics 2003 Nov;20(4):349-364. [doi: 10.1016/s0736-5853(03)00018-2]

71. Auter PJ. Portable social groups: willingness to communicate, interpersonal communication gratifications, and cell phone use among young adults. JIMC 2007;5(2):139. [doi: 10.1504/jimc.2007.011813]
72. Fotheringham MJ, Wonnacott RL, Owen N. Computer use and physical inactivity in young adults: public health perils and potentials of new information technologies. Ann Behav Med 2000;22(4):269-275. [doi: 10.1007/BF02895662] [Medline: 11253437]

73. Street RL, Sleeman, Kalaoukalani DK, Dean DE, Tancredi DJ, Kravitz RL. Improving physician-patient communication about cancer pain with a tailored education-coaching intervention. Patient Educ Couns 2010 Jul;80(1):42-47 [FREE Full text] [doi: 10.1016/j.pec.2009.10.009] [Medline: 19962845]

74. Fisher JD, Fisher WA. Changing AIDS-risk behavior. Psychol Bull 1992 May;111(3):455-474. [doi: 10.1037/0033-2909.111.3.455] [Medline: 1594721]

75. Herbert L, Owen V, Pascarella L, Streisand R. Text message interventions for children and adolescents with type 1 diabetes: a systematic review. Diabetes Technol Ther 2013 May;15(5):362-370. [doi: 10.1089/dia.2012.0291] [Medline: 23550554]

76. Levesque CS, Williams GC, Elliot D, Pickering MA, Bodenhamer B, Finley PJ. Validating the theoretical structure of the treatment self-regulation questionnaire (TSRQ) across three different health behaviors. Health Educ Res 2007 Oct;22(5):691-702. [doi: 10.1093/her/cyl148] [Medline: 17138613]

77. Grolnick WS, Ryan RM. Parent styles associated with children's self-regulation and competence in school. Journal of Educational Psychology 1989;81(2):143-154. [doi: 10.1037/0022-0663.81.2.143]

78. Stott N, Rollnick S, Rees M, Pill R. Innovation in clinical method: diabetes care and negotiating skills. Fam Pract 1995 Dec;12(4):413-418. [doi: 10.1093/fampra/12.4.413] [Medline: 8826057]

79. MacDonell KE, Naar-King S, Murphy DA, Parsons JT, Harper GW. Predictors of Medication Adherence in High Risk Youth of Color Living with HIV. Journal of Pediatric Psychology 2009 Sep 15;35(6):593-601. [doi: 10.1093/jpepsy/jsp080] [Medline: 19755495]

80. MacDonell K, Ellis DA, Naar-King S, Cunningham P. Predictors of Home-Based Obesity Treatment Efficacy for African American Youth. Children's Health Care 2010 Jan 21;39(1):1-14. [doi: 10.1080/0723610903455087]

81. Gunnarsdottir T, Njardvik U, Olafsdottir AS, Craighead LW, Bjarnason R. The Role of Parental Motivation in Family-Based Treatment for Childhood Obesity. Diabetes Care 2003 May;26(5):1641-1642. [doi: 10.2337/diacare.26.5.1641-a] [Medline: 12716841]

82. Ellis DA, Naar-King S, Chen X, Moltz K, Cunningham PB, Idalski-Carcone A. Multisystemic therapy compared to telephone support for youth with poorly controlled diabetes: findings from a randomized controlled trial. Ann Behav Med 2012 Oct;44(2):207-215 [FREE Full text] [doi: 10.1007/s12160-012-9378-1] [Medline: 22644587]

83. Anderson RM, Funnell MM, Fitzgerald JT, Marrero DG. The Diabetes Empowerment Scale: a measure of psychosocial self-efficacy. Diabetes Care 2000 Jun 01;23(6):739-743. [doi: 10.2337/diacare.23.6.739]

84. Smith MS, Wallston KA, Smith CA. The development and validation of the perceived health competence scale. Health Educ Res 1995 Mar;10(1):51-64. [doi: 10.1093/her/10.1.51] [Medline: 10150421]

85. Anderson RM, Fitzgerald JT, Grupen LD, Funnell MM, Oh MS. The diabetes empowerment scale-short form (DES-SF). Diabetes Care 2003 May;26(5):1641-1642. [doi: 10.2337/diacare.26.5.1641-a] [Medline: 12716841]

86. Ellis DA, Naar-King S, Chen X, Moltz K, Cunningham PB, Idalski-Carcone A. Multisystemic therapy compared to telephone support for youth with poorly controlled diabetes: findings from a randomized controlled trial. Ann Behav Med 2012 Oct;44(2):207-215 [FREE Full text] [doi: 10.1007/s12160-012-9378-1] [Medline: 22644587]

87. Anderson RM, Funnell MM, Fitzgerald JT, Marrero DG. The Diabetes Empowerment Scale: a measure of psychosocial self-efficacy. Diabetes Care 2000 Jun 01;23(6):739-743. [doi: 10.2337/diacare.23.6.739]

88. Smith MS, Wallston KA, Smith CA. The development and validation of the perceived health competence scale. Health Educ Res 1995 Mar;10(1):51-64. [doi: 10.1093/her/10.1.51] [Medline: 10150421]

89. Anderson RM, Funnell MM, Fitzgerald JT, Marrero DG. The Diabetes Empowerment Scale: a measure of psychosocial self-efficacy. Diabetes Care 2000 Jun 01;23(6):739-743. [doi: 10.2337/diacare.23.6.739]

90. Smith MS, Wallston KA, Smith CA. The development and validation of the perceived health competence scale. Health Educ Res 1995 Mar;10(1):51-64. [doi: 10.1093/her/10.1.51] [Medline: 10150421]

91. Gensichen J, von Korff M, Rutter CM, Seelig MD, Ludman EJ, Lin EH, et al. Physician support for diabetes patients and clinical outcomes. BMC Public Health 2009 Sep 29;9:367 [FREE Full text] [doi: 10.1186/1471-2458-9-367] [Medline: 19788726]

92. ‘tten A, Krämer NC, Gratch J. Does Humanity Matter? Analyzing the Importance of Social Cues and Perceived Agency of a Computer System for the Emergence of Social Reactions during Human-Computer Interaction. Advances in Human-Computer Interaction 2012:2012:1-10. [doi: 10.1155/2012/324694]

93. Herbert L, Owen V, Pascarella L, Streisand R. Text message interventions for children and adolescents with type 1 diabetes: a systematic review. Diabetes Technol Ther 2013 May;15(5):362-370. [doi: 10.1089/dia.2012.0291] [Medline: 23550554]

94. A1c Home Test Kit. DTI Laboratories Inc. 2004. URL: https://www.dtilaboratories.com/accubase-a1c-test-kit.html [accessed 2020-09-30]

95. Anderson RJ, Freedland KE, Clouse RE, Lustman PJ. The prevalence of comorbid depression in adults with diabetes: a meta-analysis. Diabetes Care 2001 Jun;24(6):1069-1078. [doi: 10.2337/diacare.24.6.1069] [Medline: 11375373]

96. Grey M, Whittemore R, Tamborlane W. Depression in type 1 diabetes in children: natural history and correlates. J Psychosom Res 2002 Oct;53(4):907-911. [doi: 10.1016/s0022-3999(02)00312-4] [Medline: 12377302]

97. Jerant A, Kravitz R, Moore-Hill M, Franks P. Depressive symptoms moderated the effect of chronic illness self-management training on self-efficacy. Med Care 2008 May;46(5):523-531. [doi: 10.1097/MRL.0b013e31815f53a4] [Medline: 18438201]
96. Radloff LS. The CES-D scale: A self-report depression scale for research in the general population. Applied Psychological Measurement 1977;1(3):385-401 [FREE Full text]

97. Radloff LS. The use of the center for epidemiologic studies depression scale in adolescents and young adults. J Youth Adolesc 1991 Apr;20(2):149-166. [doi: 10.1007/BF01537606] [Medline: 24265004]

98. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med Res Methodol 2013 Sep 18;13:117 [FREE Full text] [doi: 10.1186/1471-2288-13-117] [Medline: 24047204]

99. Francis JJ, Johnston M, Robertson C, Glidewell L, Entwistle V, Eccles MP, et al. What is an adequate sample size? operationalising data saturation for theory-based interview studies. Psychol Health 2010 Dec;25(10):1229-1245. [doi: 10.1080/08870440903194013] [Medline: 20204937]

100. Collins LM, Trail JB, Kugler KC, Baker TB, Piper ME, Mermelstein RJ. Evaluating individual intervention components: making decisions based on the results of a factorial screening experiment. Transl Behav Med 2014 Sep;4(3):238-251 [FREE Full text] [doi: 10.1007/s13142-013-0239-7] [Medline: 25264464]

101. Chakraborty B, Collins LM, Streecher VJ, Murphy SA. Developing multicomponent interventions using fractional factorial designs. Stat Med 2009 Sep 20;28(21):2687-2708 [FREE Full text] [doi: 10.1002/sim.3643] [Medline: 19575485]

102. Leon AC. Multiplicity-adjusted sample size requirements: a strategy to maintain statistical power with bonferroni adjustments. J Clin Psychiatry 2004 Nov;65(11):1511-1514. [Medline: 15554764]

103. Kraemer HC, Mintz J, Noda A, Tinklenberg J, Yesavage JA. Caution regarding the use of pilot studies to guide power calculations for study proposals. Arch Gen Psychiatry 2006 May;63(5):484-489. [doi: 10.1001/archpsyc.63.5.484] [Medline: 16651505]

104. Leon AC, Mallinckrodt CH, Chuang-Stein C, Archibald DG, Archer GE, Chartier K. Attrition in randomized controlled clinical trials: methodological issues in psychopharmacology. Biol Psychiatry 2006 Jun 1;59(11):1001-1005. [doi: 10.1016/j.biopsych.2005.10.020] [Medline: 16503329]

105. Lavoir PW. Clinical trials in psychiatry: should protocol deviation censor patient data? Neuropsychopharmacology 1992 Jan;6(1):39-48; discussion 49. [Medline: 15716046]

106. Laird NM. Missing data in longitudinal studies. Stat Med 1988;7(1-2):305-315. [doi: 10.1002/sim.4780070131] [Medline: 3353609]

107. Little RJ, Wang Y. Pattern-mixture models for multivariate incomplete data with covariates. Biometrics 1996 Mar;52(1):98-111. [Medline: 8934857]

108. Hedeker D, Gibbons R. Application of random-effects pattern-mixture models for missing data in longitudinal studies. Psychological Methods 1997;2(1):64-78. [doi: 10.1037/1082-989X.2.1.64]

109. Leon AC, Demirtas H, Hedeker D. Bias reduction with an adjustment for participants' intent to dropout of a randomized controlled clinical trial. Clin Trials 2007;4(5):540-547. [doi: 10.1177/1740774507083871] [Medline: 17942469]

Abbreviations

ANOVA: analysis of variance
CES-D: Center for Epidemiologic Studies Depression Scale
CHIM: Children's Hospital of Michigan
CIAS: Computerized Intervention Authoring Software
DES: diabetes empowerment scale
DMC: Detroit Medical Center
DMS: diabetes management scale
FMA: framework matrix analysis
HbA1c: hemoglobin A1c
HCCQ: health care climate questionnaire
HPLC: high-performance liquid chromatography
IMB: information-motivation-behavioral skills
MES: motivation enhancement system
MI: motivational interviewing
MOST: multiphase optimization strategy
PAS: patient activation scale
PHCS: perceived health competence scale
QPL: question prompt list
RA: research assistant
SDT: self-determination theory
TID: type 1 diabetes
TSRQ: treatment self-regulation questionnaire
UHC: University Health Center
Improving Diabetes Management in Emerging Adulthood: An Intervention Development Study Using the Multiphase Optimization Strategy

Idalski Carcone A, Ellis DA, Eggly S, MacDonell KE, Ghosh S, Buggs-Saxton C, Ondersma SJ

Please cite as:
Idalski Carcone A, Ellis DA, Eggly S, MacDonell KE, Ghosh S, Buggs-Saxton C, Ondersma SJ
Improving Diabetes Management in Emerging Adulthood: An Intervention Development Study Using the Multiphase Optimization Strategy
JMIR Res Protoc 2020;9(10):e20191
URL: http://www.researchprotocols.org/2020/10/e20191/
doi: 10.2196/20191
PMID: