Diabetes Link Discord

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PROTOCOL TITLE:

Diabetes Link Discord

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IND/IDE NUMBER:

VERSION NUMBER/DATE:

Include the version number and date of this protocol.

REVISION HISTORY

This Revision History table is provided for the benefit of study team version control. If this table will not be useful please delete it.

Revision #	Version Date	Summary of Changes	Consent Change?

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STUDY INFORMATION

1.0 Study Summary*

Study Title	*An Investigation of the Diabetes Link Discord Platform*
Study Design	Single site, pilot, longitudinal
Primary Objective	To examine the feasibility and acceptability of the Diabetes Link's online social platform Discord among youth with diabetes as it relates to peer support, diabetes management, and usability.
Secondary Objective	To examine the efficacy/magnitude of the effect of the Discord group on treatment adherence among youth with diabetes.
Research Intervention(s)	Participants will join the Children's Mercy Discord group led by the nonprofit Diabetes Link. Participants will participate in live video gatherings, as well as posted chats/prompts, and will answer a few qualitative questions at the end of their participation. Discord user metrics--both quantitative and qualitative (deidentified transcripts/audio recordings)--and health record metrics will be analyzed in addition to the end survey.
IND/IDE #	N/A
Study Population	T1D patients in 11th and 12th grade (ages 16-19) who have access to a smartphone/laptop and speak English
Sample Size	Sample size for app use: 20 11th/12th graders
Study Duration for Individual Participants	Users will use Discord for 3 months.
Study Specific Abbreviations/Definitions	DL = Diabetes Link Nonprofit Organization T1D= type one diabetes T2D= type two diabetes Children's Mercy Hospital Kansas City (CMH) Mobile Application (app or apps) Children's Mercy- Kansas City (CMKC)

2.0 Objectives*

2.1 Purpose, specific aims or objectives:

Aim 1: To examine the feasibility and acceptability of the Diabetes Link's online social platform Discord among youth with diabetes as it relates to peer support, diabetes management, and usability.

Aim 2: To examine the efficacy/magnitude of the effect of the Happy Bob app on treatment adherence among youth with diabetes.

2.2 Hypothesis:

Aim 1, Hypothesis: The intervention will be considered feasible, and patients will be satisfied with the Discord peer group, as assessed with enrollment rate, retention and refusal rates, attrition rate, usage, as well as perceptions of the format, organization, and content of the app, perceived impact on disease/treatment management, and satisfaction with the app.

Aim 2, Hypothesis 1: Participants will demonstrate increased treatment engagement while participating in the Discord platform.

Aim 2, Hypothesis 2: Participants who increase treatment engagement as a result of this intervention will experience better diabetes-related health outcomes.

3.0 Background*

According to the CDC's National Diabetes Statistics Report, 2020, approximately 187,000 children and adolescents in the United States are living with type 1 diabetes (T1D). Managing T1D among youth can be challenging and time consuming. It requires adherence to routine blood glucose monitoring, insulin administration as well as close attention to balancing physical activity and diet. Effective management of T1D in youth is key to good glycemic control. Attaining good control early in the course of T1D is important for reducing the risk of T1D-related complications (e.g. metabolic memory; Chemtob et al., 2011; Ceriello, 2012; Giordano et al., 2011; Pop-Busi et al., 2010 Silverstein et al., 2005;). Some children and families excel when faced with the challenges of T1D, while others struggle with their disease, as evidenced by declining glycemic control (Helgeson et al., 2010; Kia-Keating et al., 2011; Rausch et al., 2012).

Improved engagement with treatment options (e.g. standard of care visits, **peer mentoring**, direct to consumer telehealth, digital therapeutics, etc.) will result in better glycemic control and will ultimately help reduce the risk of acute and chronic diabetes related complications. Furthermore, *a review by Oser and colleagues found that "diabetes online communities have grown" and "enabled communities of peers to both seek and receive support for living with diabetes, providing an important supplement to what is provided in healthcare settings " (2020). We would like to quantitatively and qualitatively evaluate the impact of these online communities.*

Our preliminary data—from focus groups, online events hosted by the Diabetes clinic, the clinic intake form, and ADA camp participation—highlights the desire among teens with T1 to connect with T1 peers.

A Canadian internet-based study found that 65% of youth aged 14 to 24 years with T1D reported stigma related to the disease. In response, a Virtual Peer Network (VPN) was built to provide a forum for peer

relatedness and social support. The VPN examined the proportions of different types of exchanges and delineated the topic of importance to members. The study's findings support the building of internet-based peer communities for T1D and other chronic conditions as they constitute a valuable resource for chronic disease management. (Wu et al. 2023)

The Canadian study found that "the ratio of comments, reactions, and views to posts were 3.6 to 1, 5.3 to 1, and 57 to 1, respectively," and that involvement increased with time. Comments were coded, and over 50% fit into social support categories (informational support, self-esteem support, etc). And 10 themes emerged: (1) intersections of T1D and life (school, work, travel, driving); (2) relationships between glucose levels and habits (alcohol, etc); (3) T1D and social relationships; (4) stories about diagnosis, milestones, and identity; (5) self-management; (6) meeting and interacting with others with T1D; (7) experience with healthcare providers/health system; (8) T1D and society (policy issues, insurance); (9) technology, supplies, and materials; (10) T1D and public sphere (advocacy). This study provides support for the online content and metrics we will incorporate into our study, and it also highlights an area in which we can add value. This Canadian study did not query participants about the value the social network provided them, and this is something we certainly intend to do. Social support/confidence/etc is a contributor to diabetes management, and thus diabetes outcomes, and so we want to examine the value that social support brings, and also the effect that that value then brings to management and outcomes.

4.0 Study Endpoints N/A

5.0 Study Design*

4.1 Study Design: *pilot, single site, longitudinal*

6.0 Study Interventions*

5.1 Description: *Describe the study intervention and/or experimental manipulation that is being evaluated.*

5.2 Behavioral Intervention*: If this study involves a behavioral intervention, describe the intervention in detail. Be sure to address whether the intervention is experimental or considered to be an accepted standard.*

The nonprofit organization Diabetes Link hosts an online Discord peer support server for young adults with Type 1 Diabetes. On the server, there are different channels for different topics (relationships, mental health, nutrition, etc). The Link has a library of resources called the Resource Hub (articles, worksheets, videos, etc) on various diabetes-related topics. The Diabetes Link has staff who monitor the server, host live online events, post conversation starters, and more to foster interaction among members. For this study, Diabetes Link will create a special server just for Children's Mercy study participants for at least 3 months. The organization's employees will not enroll Human Subjects or obtain the informed consent of any Human Subject for participation in the Research. A live video session will be held at the start to go over server etiquette, introductions, etc. Over the course of the 3 months, about 6 live video events will be held, hosted by Diabetes Link staff, allowing participants to interact. Events could be anything from watching a movie together, to informal chats, to question and answer sessions, etc. The DL staff will also make weekly posts for participants to respond to.

Employing the strategy of behavioral economics, up to 6 raffles will be held throughout the trial. Participants can earn a raffle entry for every 1 live event attended and/or for every 3 posts made. After 3 months of Discord use, participants will be asked a few survey questions about their experience.

PARTICIPANT MANAGEMENT

7.0 Inclusion and Exclusion Criteria*

6.1 Eligibility Criteria:

Inclusion Criteria

- T1D Diagnosis
- 16-19 years old
- 11th-12th graders
- Access to smartphone/laptop
- English-speaking (The Diabetes Link resources are only available in English)

6.2 Vulnerable Populations: *Check any vulnerable populations that are being targeted for enrollment into the study: (Members of the following populations may not be included as participants in the research unless selected here.)*

☐ Children/Minors (under 7 years of age)
☒ Children/Minors (7-17 years of age)
☐ Neonates (infants less than 30 days old)
☐ Neonates of Uncertain Viability (infants less than 30 days old)
☐ Non-Viable Neonates (infants less than 30 days old)
☐ Wards of the State
☐ Fetuses
☐ Pregnant Women
☐ Adults with impaired decision-making capacity
☐ CM Employees
☐ CM Students/Residents/ Fellows
☐ Economically or Educationally Disadvantaged Persons
☐ Prisoners

This study will include children (<18 Y.O.), who are a vulnerable population. We will collect data from the child's electronic health record and REDCap surveys. Many of the procedures required to collect these data are aspects of routine diabetes care for children and thus the risk for coercion/harm in participation is low. Parents will provide verbal permission for their child's participation.

8.0 Local Number of Participants

7.1 *Indicate the total number of participants or charts to be enrolled locally as well as the accrual goal. If the study includes multiple groups or cohorts, be sure to describe the number of participants required for each*

cohort. If one of the groups includes a chart review, each chart is considered a participant and needs to be reflected in the numbers below.

7.2

	Prescreening	TID: 17-19 years old	
Enrollment Goal: *Number of participants to be enrolled = the number of participants to be consented or to be screened for chart reviews.*	65	20	

9.0 Identification and Recruitment of Potential Participants*

8.1 Identification of Potential Participants:

How will participants be identified? (Check all that apply)

☒ Chart reviews

☒ By their treating physician who will then provide the study team's contact information to the potential participant/family

☒ By their treating physician who will obtain patient/family permission to share contact information with the study team

☒ Self-refer in response to IRB approved advertisements or websites

☒ Through Cerner or other CM sources (e.g. databases, billing records, pathology reports, admission logs, etc.) May involve access of records by individuals not involved in the patient's care.

☒ List of candidates provided through the Data Report Request Form

☒ Registry of individuals interested in research opportunities

☒ Past participant list

☐ Participants will roll-over from another research study: Study #

☐ Other:

8.2 Pre-Screening prior to HIPAA Authorization

Will any of the identification methods checked above involve access to Protected Health Information (PHI) prior to obtaining HIPAA Authorization?

☒ Yes

☐ No

- *If yes, a "Partial Waiver of HIPAA Authorization" is required. Be sure to make this selection in the "HIPAA & Confidentiality" section below and complete* ***Addendum E: Waiver/Alteration of HIPAA Authorization***

8.3 Recruitment of Potential Participants:

Patients will be prescreened to see if they meet enrollment criteria by a member of the research team. Patients who appear to meet criteria may be contacted by telephone or approached during a standard of care visit by a study team member and informed about this study. They may also learn of the study through the intake form, Find A Study page, or the study flyer. The flyer can be posted on the Diabetes Clinic intake form that families complete before appointments or in clinic spaces. The flyer and Study Information Sheet can be posted on the hospital's Find a Study page. Patients and their parent/legal guardian will be given information about the study and they will determine if they wish to participate. Once the potential participant has talked to a study coordinator about the study, the inclusion/exclusion survey will be shared with the participant via REDCap for completion.

If Recruitment takes place via telephone CM research policy will be followed.

Prescreening may involve either a review of clinic schedules or a report generated by IT that will involve a review of the electronic medical record (EMR) system to generate a list of potentially eligible participants.

Data will be stored in both REDCap and the CM Azure Cloud. All electronic survey data will be stored on a CMH shared drive folder and REDCap with access given only to the research personnel listed on this study.

31.0 Provisions to Monitor the Data to Ensure the Safety of Participants

See Data Management above. This study presents to more than minimal risk for participants.

STUDY MANAGEMENT

32.0 Setting & Locations* N/A

33.0 Multi-Site Research N/A

34.0 International Research N/A

Addendum A: Waiver of Documentation of Permission/Consent

Regulatory Criteria: *To qualify for a waiver of documentation of parental permission or adult consent, the study must fit into at least one of the three scenarios below. Indicate which scenario(s) applies.*

☐ **The only record linking the participant and the research would be the permission/consent form and the principal risk is potential harm resulting from a breach of confidentiality.** Each parent/LAR or adult participant will be asked whether they want documentation linking the participant with the research, and the parent/LAR's or adult participant's wishes will govern.

OR

☒ **The research presents no more than minimal risk of harm to participants and involves no procedures for which written parental permission or adult consent is normally required outside of the research context.**

OR

☐ **The parent(s)/LAR or adult participants are members of a distinct cultural group or community in which signing forms is not the norm**, the research presents no more than minimal risk of harm to participants and an appropriate alternative mechanism for documenting that informed parental/LAR permission or adult consent was obtained will be provided. Describe the alternative mechanism provided:

Addendum B: Waiver/Alteration of Permission/Assent/Consent

What's the difference between a "waiver" and an "alteration" of parental permission, child assent, or adult consent?

- A "waiver" of parental permission, child assent, or adult consent is when **all 9 required elements of permission/consent are waived.** If the IRB approves a waiver then the study team does not need to obtain the parental permission or adult consent in order to include a participant in the study.

- An "alteration" of parental permission, child assent, or adult consent is when **one or more of the 9 required elements are waived** because they are not relevant to the research activity. If the IRB approves an alteration, then the study team must still obtain parental permission or adult consent in order to include a participant in the study, but certain elements may not be required in the form/discussion.

NOTE: *If requesting a waiver of parental/LAR permission because parental permission is not a reasonable requirement to protect the participants [e.g. research on neglected or abused children], contact irb@cmh.edu to discuss additional regulatory requirements.*

Regulatory Criteria: *To qualify for a waiver or alteration of parental permission or adult consent,* ***ALL*** *of the following must apply. Explain how the study meets each of the regulatory criteria below.*

Criteria	Explain how the study meets the criteria
The research involves no more than minimal risk to the participants	
The research could not practicably be carried out without the requested waiver/alteration (i.e., explain why the study could not be done if permission/assent/consent were required)	
If the research involves using identifiable private information or identifiable	

biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format	
The waiver/alteration will not adversely affect the rights and welfare of the participants	
Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation	

Proposed Alteration (if applicable):

Select which required elements of permission are to be omitted.

☐ A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

☐ A description of any reasonably foreseeable risks or discomforts to the participant;

☐ A description of any benefits to the participant or to others that may reasonably be expected from the research;

☐ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;

☐ A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;

☐ For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

☐ An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant;

☐ A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled; and

☐ One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

☐ A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative, if this might be a possibility; or

☐ A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Provide the rationale for omitting the item(s) selected:

Addendum C: Non-English Speaking Participants

There are special considerations that must be made when obtaining permission/assent/consent from participants who prefer to communicate in a language other than English. To ensure that adequate processes are in place to obtain effective permission/assent/consent from these participants address each of the items below.

Indicate which language(s) other than English are understood by prospective participants or representatives.

☐ Spanish
☐ Arabic
☐ Burmese
☐ Somali
☐ Vietnamese
☐ Other:_____

Describe the plan for enrolling non-English speaking participants (e.g. fully translated consent forms, use of Qualified Bilingual Study Staff or interpreters):

If providing fully translated consent forms, explain if the ORI Translation Program for internally and/or federally funded studies will be used, or if translation services will be obtained through the study sponsor or some other service.
NOTE: If using ORI Translation Program services for an industry sponsored study, contact Research Business Operations staff to get this negotiated in the study agreement/contract.

Addendum D: Surrogate Decision Maker Consent

Assessment of Decision-Making Capacity:

- *Describe the process to determine whether an individual is capable of consent. See CM Research Policy 9.10 Incapacity, Temporary or Fluctuating Decision-Making Capacity for more information on the proper procedures for enrolling adults who are not able to consent for themselves.*

Identification of Surrogate Decision Maker

- *List the individuals from whom permission will be obtained in order of priority, e.g. durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.*
- *For research conducted in the states of Missouri and/or Kansas, review CM Research Policy 9.10 Incapacity, Temporary or Fluctuating Decision-Making Capacity to be aware of which individuals in the state meet the definition of "legally authorized representative."*
- *For research conducted outside of Missouri and/or Kansas, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective participant to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel review the protocol.*

Assent of Adult Participant

- *Describe the process for assent of the adult participants who are unable to consent for themselves. Indicate whether:*
    - *Assent will be required of all, some, or none of the participants. If some, indicate which participants will be required to assent and which will not.*
    - *If assent will not be obtained from some or all participants, an explanation of why not.*
    - *Describe whether assent of the participants will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents or require participants to sign assent documents.*
    - *Describe how participants will be closely monitored.*
    - *Describe whether participants will be withdrawn if they appear to be unduly distressed.*

Addendum E: Waiver/Alteration of HIPAA Authorization

What's the difference between a "waiver" and an "alteration" of HIPAA Authorization?

- A "waiver" of HIPAA Authorization is when **the requirement to obtain authorization is completely waived.** If the IRB approves a waiver then the study team does not need to obtain HIPAA Authorization in order to include a participant in the study.

- An "alteration" of HIPAA Authorization is when **one or more of the required elements of authorization are waived.** If the IRB approves an alteration then the study team must still obtain HIPAA Authorization in order to include a participant in the study, but certain elements may not be required in the form/discussion. The study team should still verify the identity of the participant as part of the process. For an online survey, for example, this could be accomplished by having the participant type in their name.

Regulatory Criteria: *To qualify for a waiver/alteration of HIPAA Authorization,* ***ALL*** *of the following must apply to a study. Explain how the study meets each of the regulatory criteria below.*

Criteria	*Explain how the study meets the criteria*
The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals based upon the following: a. Plan to protect PHI from improper use and disclosure: b. Plan to destroy PHI at the earliest opportunity, unless there is a health or research justification for retaining the PHI: c. Assurance that PHI will not be reused or disclosed to any other person or entity:	The study team will maintain a password protected recruitment log during the active portion of the study. Only members of the study team will have access. This will allow the study team to avoid approaching potentially eligible families more than once. PHI will be destroyed after publication. *PHI will not be reused or disclosed to any other person or identity.*

The research cannot practicably be conducted without the waiver/alteration, i.e. explain why a signature for HIPAA Authorization cannot be obtained.	Partial HIPAA Waiver for Screening: It would not be practical to obtain HIPAA authorization for every person screened as they will not know who meets the inclusion criteria until the records are accessed Alteration for HIPAA Authorization: The consent process will take place remotely. The study team will not have face to face interaction with participants for the study.
The research cannot practicably be conducted without access to and use of the PHI, i.e. explain why access to PHI is needed for this study.	Partial HIPAA Waiver for Screening: PHI must be accessed in order to determine eligible patients for recruitment. Alteration for HIPAA Authorization: All collected data is needed to meet the study aims.

Citations

Oser TK, Oser SM, Parascando JA, Hessler-Jones D, Sciamanna CN, Sparling K, Nease D Jr, Litchman ML. Social Media in the Diabetes Community: a Novel Way to Assess Psychosocial Needs in People with Diabetes and Their Caregivers. Curr Diab Rep. 2020 Feb 20;20(3):10. doi: 10.1007/s11892-020-1294-3. PMID: 32080765.

Wu N, Wang SJ, Brazeau AS, Chan D, Mussa J, Nakhla M, Elkeraby M, Ell M, Prevost M, Lepine L, Panagiotopoulos C, Mukerji G, Butalia S, Henderson M, Da Costa D, Rahme E, Dasgupta K. Supporting and Incentivizing Peer Leaders for an Internet-Based Private Peer Community for Youths With Type 1 Diabetes: Social Network and Directed Content Analysis. J Med Internet Res. 2023 Dec 12;25:e48267. doi: 10.2196/48267. PMID: 38085568; PMCID: PMC10751631.