RCT OF ASSISTIVE-READING TECHNOLOGY FOR POST-VISIT TYPE 2 DIABETES PATIENT EDUCATION

Protocol Number: 1

National Clinical Trial (NCT) Identified Number: NCT05337306

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Sponsor: GogyUp Inc

Grant Title: Increasing Health Equity Through In-The-Moment Reading Assistance for Adults with Diabetes Served at Community Health Centers

Grant Number*: 1R43NR020340

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2022 – 12-26

1 STATEMENT OF COMPLIANCE

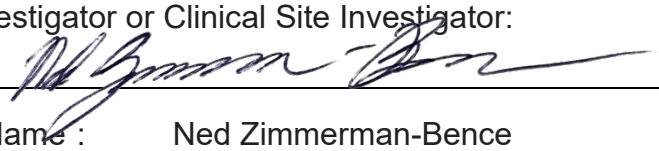
The study will be conducted in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP), applicable United States (US) Code of Federal Regulations (CFR), and the **National Institute of Nursing Research** Terms and Conditions of Award. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the funding agency and documented approval from the Institutional Review Board (IRB), and the Investigational New Drug (IND) or Investigational Device Exemption (IDE) sponsor, if applicable, except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

1 INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

Principal Investigator or Clinical Site Investigator:

Signed:  Date: 01/06/2023

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2 PROTOCOL SUMMARY

2.1 SYNOPSIS

Title:	Increasing Health Equity Through In-The-Moment Reading Assistance for Adults with Diabetes Served at Community Health Centers
Grant Number:	1R43NR020340
Study Description:	This protocol describes a pilot randomized controlled trial to test the primary hypothesis that a mobile application, GogyUp Reader, will result in higher health literacy in understanding print diabetes patient education materials than print patient education and care plan materials alone.
Objectives*:	The **primary objective** of this study is to conduct a pilot trial of the effect of the GogyUp Reader app on health literacy. The **secondary objectives** are to assess the effect of GogyUp Reader on perceived diabetes self-management.
Endpoints*:	**Primary Endpoint**: three-month (follow-up) scores on two subscales of the Health Literacy Questionnaire: Subscale 9: Understanding health information well enough to know what to do ("Understanding health information"); Subscale 2: Having sufficient information to manage my health ("Having sufficient information"). **Secondary Endpoints**: three-month (follow-up) score on the Perceived Diabetes Self-Management Scale (PDSMS)
Study Population:	The maximum sample size is up to 200 individuals, with expectation of potential non-contact by patients after a recruitment mailing, screening failures and refusal bringing likely sample size down to approximately 120-160. The target population are individuals aged 18-85 diagnosed with type 2 diabetes mellitus seen at clinics serving large proportions of low-income patients (e.g., safety net clinics). We will attempt to sample up to 200 individuals from the MHealth Fairview health system in the seven-county Twin Cities Metropolitan area.
Phase* or Stage:	Although the proposed trial is not of a pharmaceutical or other therapeutic treatment, it most resembles a phase 2 trial in that we have early preliminary data of use and feasibility and are testing initial efficacy.
Facilities Enrolling Participants:	Study activities will not take place in any clinical sites; participants will be identified based on having been seen for a clinic visit to a primary care clinic within the partnering health system and will receive a mailing from the health system providing contact

	information for the researchers; patients will themselves contact the research team if they choose. The study will not include sites outside of the United States.
Description of Study Intervention / Experimental Manipulation:	The study intervention is the GogyUp Reader app for three months (up to study follow up). The app is self-led; users will choose when (and if) to use it. Delivery will be at the individual level.
Study Duration*:	The study is expected to take up to 12 months, but if recruitment exceeds expectation, may take less time.
Participant Duration:	Individual participant duration is expected to be three months, with the possibility of one additional month if follow-up measures take unexpectedly long to obtain/complete.

2.2 SCHEMA

Total maximum n: 200; Total likely n: 120-160

Initial recruitment mailer (interested participants will contact the research team)

Pre-Screening
<Day -20>

Pre-screen potential participants by inclusion and exclusion criteria
Conduct informed consent process.

Visit 1
<Time Point, e.g., Day 1>

Enroll; Randomize; Conduct baseline assessments

Arm 1
N = 60

Arm 2
N = 60

Visit 2
<Day 90+/- 15>

Final Assessments
Compare follow-up levels of functional, communicative, and overall health literacy between arms.

2.3 SCHEDULE OF ACTIVITIES

	Pre-consent: Health system sends mailing based on eligibility	Consent (by research coordinators)	Visit 1 Day 1	Visit 2 Day 90 +/- 15 days	Unscheduled Visit
EMR Review Eligibility	X				
Informed Consent		X			
Demographics			X		
Outcome Evaluation					
Randomization			X		
Control & Experimental Interventions – GogyUp Reader app.			X	X	
Outcomes assessments			X	X	
Adverse Events Reporting			X	X	X

3 INTRODUCTION

3.1 STUDY RATIONALE

Type 2 Diabetes Mellitus (T2DM) affects over 30 million Americans and requires patients to competently manage their conditions at home. However, the majority of diabetes self-management education (DSME) and aftercare print materials remain overly complicated, with excessively high reading difficulty and fall short in supporting readiness for self-management at home, especially for the 18% of U.S. adults unable to read beyond a second-grade level. [1 – 2, 4 - 6]

The research team will determine whether the GogyUp Reader app facilitates patient understanding for managing T2DM when compared to the established standard for after-visit care (print materials alone). Specifically, the project will investigate GogyUp's potential to:

1. expand patient capacity to understand DSME materials,
2. increase T2DM self-management adherence.
3. reduce, at a scale, disparate outcomes in a chronic disease.

The study's aim is to conduct a pilot trial of GogyUp's embedded, in the moment, assistive-reading technology for improving health literacy. We will assess GogyUp's potential effectiveness to increase patient knowledge and the feasibility of conducting a larger, multicenter trial by conducting a pilot randomized trial with a randomized, pre-post design.

Primary outcomes will include two aspects of health literacy measured by two validated subscales of the Health Literacy Questionnaire, Subscale 9: understanding health information well enough to know what to do ("Understanding health information") and Subscale 2: Having sufficient information to manage my health ("Having sufficient information").[52] The secondary outcome will be the Perceived Diabetes Self-Management Scale (PDSMS) . Participants in the intervention arm will also be asked to provide user experience feedback but only after they complete the follow-up assessments.

End-user data from individual app users and adult education pilots indicate broad uptake among 1,600+ all-volunteer user base in several use cases. A focused, randomized trial is needed to assess the technology's potential impact on health literacy specifically and its applicability for reducing health disparities.

This real-world application and assessment of the GogyUp Reader app for T2DM will inform system improvements and provide initial data for a Phase II project as a fully powered, multi-year randomized controlled trial to evaluate GogyUp's assistive reading technology on patient health literacy.[53]

3.2 BACKGROUND

Type two diabetes mellitus (T2DM) affects over 30 million Americans and requires patients to competently manage their condition at home. [1] However, health care supports for patients fall short in supporting functional readiness for day-to-day T2DM self-

management. [16] Despite decades of research, supportive or educational print materials for patients remain overly complicated, with excessively high reading difficulty. Efforts to improve this have been project-limited rather than systemic, and adaptive measures such as teach-back techniques have diminishing, short-term effects.[17–20]

Compounding the difficulty of print materials are endemic barriers that further impede patients' capacity for health literacy (ability to process health information to make decisions), including low print literacy, and limited English proficiency. [4-5] For instance, nearly 1 in 5 (19%) of adults in the United States are unable to read at the most basic level, including medicine labels or identify information from written directions, and upwards of 53% of U.S. adults have low health literacy, but less than 5% of the adult population with low print literacy has access to literacy instruction.[6-7, 22, 24]

Because print materials for patients remain overly complicated, and systems to increase patients' literacy remain out of reach, this proposal aims to test an alternative paradigm: to provide in-the-moment support via assistive technology. Integrated adult literacy is a proven strategy that provides comprehensive approaches to ensuring delivery and understanding of information. [12-15]

In our proposed model, and implemented in the technology we propose to test, patients can have immediate, in-the-moment access to assistive-reading technology, designed specifically for adults with limited literacy or English proficiency, that they carry with them to support and improve their capacity to understand information and follow self-management care protocols.

While many mobile and online applications for diabetes exist, we are not aware of any that apply in-the-moment, assistive-reading technologies to immediately convert existing education materials into interactive teaching aids. The GogyUp Reader app incorporates these technologies to amplify the patients' capacity to read and understand difficult written materials required to understand how to successfully adhere to T2DM self-care management. The lack of low-cost, highly responsive, and flexible assistive-reading technologies represents a gap in serving a large percentage of patients' needs and presents an opportunity to understand the potential benefits of assistive-reading technology on patient understanding.

GogyUp Inc developed the GogyUp Reader app with immigrant and native-born adults possessing limited print literacy, English proficiency, and digital skills. The app's in-the-moment reading assistance makes GogyUp Reader an "in-pocket tutor" that converts previously inaccessible material into interactive, autonomous, and personalized training, including vocabulary instruction and no-fail comprehension questions. For users not yet proficient in English, GogyUp's reading assistance includes word-by-word multimedia translations (currently in fifteen languages prevalent in the Midwest) and pronunciation instruction optimized for the user's preferred language.

GogyUp's "content agnostic" approach provides for broad application across multiple patient education use cases with instant context-specific assistance, whenever and wherever it's needed. Three years of internal app data from over a thousand users and multiple use cases have validated the system's engagement value and suggest efficacy. A sister app developed by GogyUp, Snap Reader, employs similar technologies used in

GogyUp Reader that, at the time of this submission, is used by over 3,500 weekly, recurring end-users. The proposed study will build on those data to examine the feasibility for implementing GogyUp with T2DM after-visit educational materials and its potential effectiveness for health literacy.

This real-world implementation and assessment of the GogyUp Reader for a prevalent health problem (T2DM) will provide the evidence to develop a fully powered randomized controlled trial across a larger, regional network of Federally Qualified Health Centers in rural, suburban, and urban settings, to test the app in a Phase II SBIR grant. Potential outcomes include widespread adoption of a highly scalable and low-cost technology with potential to improve patient capacity and reduce health disparities through improved understanding.

3.3 Risk/Benefit Assessment

3.3.1 Known Potential Risks

- *Immediate risks.* We do not anticipate any immediate risks other than risks to confidentiality in the event of a data security breach prior to assigning study numbers (rather than identifiable information) for individuals. As such, our data security plan includes research training for use of secure, HIPAA compliant data storage, and access to identifiable data limited within the study team.
- *Long-term risks*. We do not anticipate any long-term risks other than risks to confidentiality in the event of a data security breach prior to assigning study numbers (rather than identifiable information) for individuals. As such, our data security plan includes the use of secure, HIPAA compliant data storage and access to identifiable data limited within the study team.

3.3.2 Known Potential Benefits

- *Immediate potential benefits.* The study intervention (a literacy-focused mobile software application that provides immediate reading assistance) is designed to support and increase users' functional print literacy, which in turn is intended to support engagement with print self-care and educational materials. As such, there is a potential, though speculative, that literacy, health literacy, or diabetes self-care mastery may have modest improvements. We do not identify any other direct potential benefits.
- *Long-term potential benefits.* Long-term benefits are also speculative as well, pertaining mainly to the potential for the intervention to modestly or moderately improve functional print literacy, health literacy, and/or self-care mastery. Benefits beyond those, such as actual control of diabetes (measured via improved

hemoglobin A1C levels), are further removed, and so we will not claim any other long-term or downstream benefits at this time.

3.3.3 Assessment of Potential Risks and Benefits

- We found this study justifiable given the balance between potential, if speculative, improvements in print literacy, health literacy, and diabetes self-care mastery and measures taken to prevent against the primary risk of data confidentiality.
- Given that the primary risk to participants is confidentiality, data security including a summary of the ways that risks to participants were minimized in the study design
- The information gathered as part of this study could point to the beginning of a paradigm shift away from existing efforts (e.g., in-clinic patient education, online training) that require primarily knowledge retention to support health literacy toward in-the-moment support through assistive technology to do the same. Because we are able to take steps to limit risks to confidentiality (the primary risk here), we felt the value of such information to inform patient self-management support was worthwhile for this study.

4 OBJECTIVES AND ENDPOINTS

	OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS	PUTATIVE MECHANISMS OF ACTION
Primary	The primary objective of this study is to conduct a pilot trial of the effect of the GogyUp Reader app on health literacy.	The primary endpoint are the three-month (follow up) values of two validated subscales of the Health Literacy Questionnaire: Understanding health information well enough to know what to do ("Understanding health information"); and having sufficient information to manage my health ("Having sufficient information")..	This study's main objective is to study the effect of GogyUp on aspects of health literacy that relate the ability to understand and use written health information as the most proximal effect of in-the-moment support. As such, these two subscales are the most direct measures; the three-month time frame reflects (a) a brief follow-up as part of a pilot trial; and (b) is reasonable because of the use of this proximal outcome based on putative mechanisms.	The mechanism of action is a chain whereby improved in-the-moment capacity to interact with print patient education materials and care instructions improves the ability to use and understand written health information.
Secondary	The secondary objectives are to assess the effect of GogyUp Reader on participants' ability to self-manage their diabetes.	The secondary endpoint is the three-month (follow up) value of the Perceived Diabetes Self-Management Scale (PDSMS). .	The PDSMS and self-management generally are less proximal to the intervention but reflect a more pragmatic outcome further along the causal chain toward actually affecting health outcomes.	Health literacy (primary outcomes) is a foundational hurdle to understanding self-management needs and expectations. While our focus is that most proximal outcome focused on ability to use/understand written materials (primary endpoints), this secondary endpoint will indicate whether GogyUp Reader has effects that are closer to actually impacting outcomes (i.e., health literacy and understanding may or may not lead to improved self-management activities to better control diabetes).

5 STUDY DESIGN

5.1 OVERALL DESIGN

Hypotheses:

H1: GogyUp Reader app use with written patient education materials or self-care instructions will result in better health literacy in understanding health information compared with print patient education or care plan materials alone.

H2: GogyUp Reader app use with written patient education materials or self-care instructions will result in better health literacy in reporting having enough information compared with print patient education or care plan materials alone.

H3: GogyUp Reader app use with written patient education materials or self-care instructions will result in better diabetes self-management compared with print patient education or care plan materials alone.

5.1.1 PHASE OF STUDY/TRIAL:

This study examines a non-medical intervention (self-directed software application). However, while a pilot trial, it occurs within normal clinical practice, is not limited to healthy volunteers, and is supported by early data on use and feasibility of the app. It therefore has aspects of phase II and phase III trials. However, because we are testing initial efficacy, it likely fits best within a phase II trial study.

5.1.2 STUDY INTERVENTION:

The study intervention is the use of the GogyUp Reader app. The GogyUp Reader is a software app that can be used on mobile phones, tablets, and on PC's with any widely available, Chromium-based web browser (e.g., Google Chrome, Microsoft Edge, etc.). It is designed to provide both in-the-moment support for interacting with written materials, combined with activities designed to address overall functional adult literacy. This is intended to address personal capacity to deal with complex written patient education or care plan materials on an as-needed, low-cost/free and low-burden basis.

5.1.3 TYPE/DESIGN OF TRIAL:

This is a randomized, pre-post superiority trial with two arms: GogyUp Reader app for use with patient education or care plan materials (or other written health information) compared with the same written materials alone. We are using a randomized study design because our overall goal for this study is to ascertain efficacy estimates in a clinical population with diabetes and randomization (with sufficient sample size and other study procedures in place) is the best way for us to address potential confounding.

Individual study duration (baseline to follow up) is planned to be three months, although up to one additional month may be needed if follow-up measures take too long to obtain.

Due to rolling recruitment, the full study is expected to take up to 12 months, although if recruitment is faster than expected, the overall study may take less time.

Randomization is detailed below. In brief, we will randomize participants 1:1 at the individual level at enrollment using pre-generated trial allocation sequence from the National Cancer Institute's Clinical Trial Randomization Tool service (https://ctrandomization.cancer.gov/tool/) at recruitment Study staff not involved in analysis will refer to an externally generated allocation sequence for intervention or comparison allocation. To avoid or limit randomization errors, the crosswalk file and the binary indicator for allocation arm will be known /available to study staff but not investigators involved in analysis or interpretation (until analyses are complete).

This study will include multiple primary care clinic sites in the sense that recruitment will occur at a health-system level in collaboration with Fairview research/trial support and therefore eligible patients can come from many clinics. However, recruitment, consent, pre-screening, data collection, and trial intervention itself are all remote– they do not occur in a clinical site.

Our planned analyses, also discussed in section 9, include an interim analysis approximately five to six months after the beginning of recruitment and data collection to provide preliminary data and feasibility/design information for a later Phase II SBIR application to NIH. This analysis will include all planned endpoints.

5.2 Scientific Rationale for Study Design

Existing written patient education and care plan materials for patients with type 2 diabetes mellitus are typically overly complex. Most existing interventions to address this either (a) rely on in-clinic coaching or education (which can erode or lose effectiveness over time due to recall issues, etc.), (b) rely on other materials or technology which themselves require good functional reading literacy and good health literacy, or (c) require heavy burdens in patient coaching and management over the phone or through mobile technology. These incur high costs, patient and health system burden, and typically do not offer support when it is most needed, and overall show mixed or eroded effectiveness in supporting patients' health literacy. Given that GogyUp Reader is intentionally designed to provide both in-the-moment support with written materials (beyond its literacy-building activities), our approach in using this low-risk intervention is akin to the use of assistive technology for functional problems– the intervention provides support exactly when it is needed. To the degree that this assistive technology approach can improve health literacy—specifically, the ability to understand health information and having all the information needed to manage one's condition –it could provide an as-needed support for patients' capacity in the same way assistive technology helps to offset many other functional capacity limitations or difficult tasks. This is a paradigm shift in the approach to health literacy in that we have not seen an in-the-moment capacity support or assistive technology approach to health literacy in diabetes in the same way in previous literature.

Three years of initial feasibility and app usage data for GogyUp Reader (submitted/under review) indicates that users can find, install and use GogyUp Reader on their own and without training. We have also applied it to other use cases, including citizenship class participants and have had good app usage numbers.

5.3 JUSTIFICATION FOR INTERVENTION

Intervention delivery via mobile software app is precisely central to the potential benefit of the intervention: in-the-moment support for patients' capacity to interact with complex written patient materials. We will only have two actual study contacts beyond recruitment and pre-screen/consenting: baseline and follow-up at three months, which will only include obtaining outcome measurement administration necessary to analyze data to meet our study objectives. We will have app usage data (internal to GogyUp) that can provide any indication as to whether lack of differences between arms in an intent-to-treat analysis is simply due to low app usage (this would provide a finding, and inform future study design, rather than being a failure).

5.4 END-OF-STUDY DEFINITION

Participants will be considered to have completed the study if they have completed the baseline and three-month follow-up assessments.

The end of the study is defined as completion of the 3-month follow-up assessment shown in the Schedule of Activities (SoA), **Section 2.3**.]

6 STUDY POPULATION

6.1 INCLUSION CRITERIA

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Provision of signed and dated informed consent form
2. Males and females; Aged 18-85 years
3. Documented diagnosis of type II diabetes mellitus
4. Has had a visit to an MHealth Fairview clinic in the past year (November 2021-November 2022); can include a telehealth visit

6.2 EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Currently enrolled in another treatment or intervention study (at pre-screen)
2. Pregnancy (because pregnancy becomes the primary condition of interest in treatment)
3. Blind

Note: Although it is assumed that most participants placed in the GogyUp Reader group will have access to necessary resources for participating in a technology-based intervention (i.e., computer, smartphone, internet access) such access will NOT be a criterion - GogyUp will make a limited supply of hardware and data plans available to participants without consistent, reliable internet access.

6.3 LIFESTYLE CONSIDERATIONS

During this study, participants are not asked to maintain any additional lifestyle alterations or considerations.

6.4 SCREEN FAILURES

Screen failures are defined as participants who consent to participate in this study but are not subsequently assigned to the study intervention or entered in the study. Individuals who do not meet the criteria for participation in this trial (screen failure) because of meeting one or more exclusion criteria will not be rescreened.

6.5 STRATEGIES FOR RECRUITMENT AND RETENTION

We plan on asking our clinical partner, MHealth Fairview, to sample 2,000 individuals, with the understanding that some may fail pre-screening, to reach our needed sample size (our maximum sample size with no screening failures would be 200). Given that our sampling frame is patients in a health system serving communities within the Twin Cities metro region, with a focus on clinics serving relatively high proportions of low-income/publicly insured patients, and given some non-response and pre-screen failures

might occur, we anticipate an enrollment sample size of 160 individuals, evenly divided by gender, with most participants 45 years old or older (possibly a median age of 55, with a possible range of the full 18-85 age range); with approximately 50 to 60 percent of our sample being White and non-Hispanic/Latino, 20 to 30 percent Black non-Hispanic, 10-15 percent Hispanic/Latino, and another 10-15 percent of other groups. We do plan to prioritize diversity of racial and ethnic groups in our sample in collaboration with our research/trial support partner at the point of sample identification and recruitment (prioritizing sample identification and recruitment contact to oversample Black, Indigenous, Hispanic/Latino, Asian and Pacific Islander, and multiracial ethno-racial categories.

Due to the ongoing COVID-19 pandemic, potential future waves of infection, and limited clinic capacity to accommodate studies, a clinic site-based recruiting approach is both inefficient and less likely to succeed within the study timeframe, would require additional considerations for participants' privacy and safety, and potentially limit the diversity of the available patient pool.

For recruitment, we have contracted with a local health system, M Health Fairview, to send out a letter mailer to patients meeting the inclusion and exclusion criteria noted in Section 5.1 and 5.2. The letter invites these patients to the study and to contact our research coordinators by call, email, or text or by visiting a website with a contact form. Upon initial contact by interested patients, GogyUp's research coordinators will perform the remote consent / enrollment / placement workflow.

Candidates who enroll and are placed in the intervention group will be asked to use their personal devices. If a participant placed in the intervention group does not have regular, consistent access to an Internet-connected device will be provided a cellular-enabled tablet with an active SIM card for the duration of their participation. Participants who use their own intent-connected devices will be sent a $25 gift card at baseline to offset network expenses.

All participants, whether they are in the control group or are in the intervention group, will receive a $25 gift card in compensation at the end of the study period. These measures will assist both with ensuring that the intervention is not hindered by technological or network access barriers and also provide both an incentive to stay enrolled, helping to ensure retention. We will also obtain multiple forms of contact information from consented participants to ensure we can contact them at follow-up. We believe our proximal outcome and short follow-up will further ensure retention and completion.

7 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

7.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

7.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

The study intervention is the use of the GogyUp Reader app. The GogyUp Reader is a software app that can be used on mobile phones, tablets, and PCs. and is designed to

provide both in-the-moment support for interacting with written materials, combined with activities designed to address overall functional adult print literacy. This is intended to address personal capacity to deal with complex written patient education or care plan materials on an as-needed, low-cost/free and low-burden basis. This mechanism (in-the-moment support with written materials) is supported theoretically by Co-PI Shippee's theoretical model of patient complexity, the Cumulative Complexity Model, which posits that problems with patient access to care and self-care or adherence arise from an interaction between the work that patients are asked to do (in life and in caring for their conditions) and the capacity they have to do it. This model has been supported all or in part in both systematic reviews and intervention designs. In brief, complex patient written materials add burden to the workload of being a patient with diabetes– and without sufficient capacity, patients are not in a position to use those patient education or care plan materials in the way they need to– the definition of functional health literacy. While other interventions are designed to increase patients' capacity through either in-clinic sessions, additional materials or differently designed materials, or time-and resource-intensive coaching, the mechanism of action with GogyUp Reader as an intervention is that the support for capacity is available exactly when patients need it, allowing them to understand materials and successfully enact self-care. The control condition will consist of the written materials (and other clinical guidance) that patients normally receive (essentially a usual care arm), without GogyUp Reader.

7.1.2 Administration and/or Dosing

Given that this study involves assistive-reading technologies, administration and dosing are problematic concepts. However, to specify: participants will install GogyUp Reader app onto their devices (or devices supplied by GogyUp upon request) at baseline. A brief tutorial will be given by GogyUp staff trained in the protocol. The analog to "dosing" here is the degree to which participants might be expected to use the app or, if in the control group, review the paper documents. We are not requiring any particular level of app usage; our preliminary app usage data (GogyUp internal app data) have indicated consistent levels of self-directed app usage data in past applications and, to the degree intervention participants did not use the app, GogyUp would be able to see that in the app's activity data (or lack thereof). Of course for the control group, activity data is not measurable.

7.2 Fidelity

7.2.1 Interventionist Training and Tracking

The protocol objectives for this study do not depend on consistent administration of the study intervention beyond the baseline visit. To date, the GogyUp Reader app has been used for multiple sessions, and in some cases over months and years, by over 1,500 adult learners with minimal digital literacy and a wide range of print literacy and English proficiency. The majority of these adults installed the app on their own while a minority need brief training while enrolled an adult basic education setting. To ensure consistent onboarding and app usage, a standard script for downloading the app onto devices will

be used during a brief tutorial at the baseline visit to ensure standard initial introduction of the GogyUp Reader (study intervention). Technical support will also be provided by trained GogyUp personnel through email and a dedicated phone number capable of receiving voice calls and text messages.

7.3 Measures to Minimize Bias: Randomization and Blinding

We will use a random allocation sequence from the National Cancer Institute's Clinical Trial Randomization Tool (https://ctrandomization.cancer.gov/tool/). Study staff will refer to the allocation sequence to determine allocation arm for each newly recruited participant.. As such, study staff not involved in analysis will not be blinded because they will provide initial access to the GogyUp Reader app. Lastly, using an encrypted Microsoft Excel file for which only study staff not involved in analysis will have the password, study staff will create and enter the study id and trial arm into two crosswalk files: the first, a crosswalk identifying study id number with study arm (for unblinding following blinded analysis), and a crosswalk file linking intervention-arm study identification numbers to a separate id number from GogyUp internal data (for assessments of adherence; see above). Study staff will then enter name, contact information, study id and baseline variables into REDCap. Investigators (Drs. Shippee, Rogers, and Peterson and Mr. Zimmerman-Bence) will be blinded to participants' status, only have access to the REDCap file prior to analysis, and indeed will not have contact with participants. To support interim analysis, all procedures above will be followed, but for participants recruited during the first three months, an additional study id variable (interim study id) and REDCap trial arm indicator (interim indicator) will be used– these will ensure that the interim analysis (see above) does not effectively unblind the full analysis. After *interim* analysis, study staff will use the encrypted file to inform the investigators which random study arm number indicated which study arm. After *final* analyses, study staff will provide the password for the encrypted crosswalk files to the investigators for unblinding. The criterion for unblinding will be that all participants have had a final follow-up visit and (masked/blinded) comparative analyses are complete. In the unlikely event of an *unplanned* unblinding/breaking of randomization indicators, because investigators have no contact with participants and this protocol will be registered publicly, instigators will simply report the unplanned breaking and reasons for it in all subsequent publications for transparency.

As noted above, study staff cannot be blinded but staff and investigators will have no other contact with participants other than staff administration of follow-up questionnaires. Staff enrolling and administering baseline and follow-up assessments will not have a role in analysis and investigators will not have access to blinded materials until after analysis nor have contact with participants.

7.4 Study Intervention/Experimental Manipulation Adherence

Adherence in this study is easy to assess in that GogyUp has internal data indicating users' interactions with the Reader app across its functionalities, including timestamps, functionality or activity used, and whether a user conducted a reading activity

successfully. We will assign study numbers so that adherence data can be linked to other study data later (while maintaining participant confidentiality). We will be able to assess the degree to which intervention adherence (regular or continued use of the GogyUp Reader app) has occurred and whether this may explain differences found or not found between the intervention and control arms.

7.5 Concomitant Therapy

As noted above regarding exclusions, we do not have any exclusions for concomitant therapy– only for the exclusions listed above and for being part of any treatment or intervention study.

7.5.1 Rescue Therapy

N/A

8 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

8.1 Discontinuation of Study Intervention/Experimental Manipulation

Other than participant withdrawal (self-decided for any reason), we do not have any specific circumstances that would lead us to discontinue participants from the study. Because the intervention is a mobile app that participants will use on a self-directed, as-needed basis, it will be available to participants regardless of moves, or other changes in circumstance. In the case of adverse events, we would not revoke a participants' access to the app, but it could mean issues with loss to follow up, which we will address below.

8.2 Participant Discontinuation/Withdrawal from the Study

Participants are free to withdraw from participation in the study at any time upon request. As noted above, we have no explicit reasons, as the research team/investigators, to withdraw participants. We may of course have issues if people are highly non-adherent or we are not able to follow up with them, but we will address these as either empirical questions (see intervention adherence above) or analytically (see lost to follow-up below).

The reason for participant discontinuation or withdrawal from the study will be recorded in an electronic Case Report Form (CRF). Subjects who sign the informed consent form and are randomized but do not receive the study intervention may be replaced.

Subjects who sign the informed consent form, and are randomized and receive the study intervention, and subsequently withdraw, or are discontinued from the study, will not be replaced and lost to follow-up will be addressed analytically.

8.3 Lost to Follow-Up

A participant will be considered lost to follow-up if contact fails for the three-month follow-up assessment and study staff are unable to contact the participant after at least 3 attempts using a mixture of voice calls and SMS texts, spaced over several days.

The following actions must be taken if a participant fails to attend or answer a follow-up research visit or call:

- Before a participant is deemed lost to follow-up, the research coordinator or study staff will make every effort to regain contact with the participant (where possible a mix of 3 telephone calls and text messages and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts will be documented in a study file.
- Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of "lost to follow-up."

9 STUDY ASSESSMENTS AND PROCEDURES

9.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Assessments for this study will include eligibility assessment and initial contact for pre-screening, as well as baseline and follow-up measures. We will also extract internal app data for the study period to assess adherence in the intervention arm (and to ensure no contamination in the control arm).

To ensure a focus on equitable representation and on a sample reflective of our interest in low income (publicly or non-insured) patients, the study team and health system research support staff determined that initial contact with recruiting materials (see above) will be prioritized to individuals seen at primary care clinics in the health system that see the largest proportions of publicly insured or non-insured patients. Iterative mailings will continue to prioritize patients from these clinics as well as patients in historically excluded and underrepresented groups (e.g., Black or Indigenous patients) among those fitting initial eligibility criteria (see above). Health system staff will conduct pre-screening procedures including identifying a potential sample and sending recruitment mailings (see Recruitment Collateral below). To ensure candidates are fully opted-in, GogyUp and study staff will not have access to any potential participants until participants contact GogyUp by filling out an online intake form or calling, texting, or emailing the GogyUp Research Coordinator through a study-designated phone number and email address listed on the recruitment letter.

Once eligible participants are consented by the GogyUp Research Coordinator, enrollment and baseline assessments will take place within an expected two-week (maximum) timeframe. Baseline assessments will include study staff administration (remotely via phone or video call) of the validated Health Literacy Questionnaire subscales 9 and 2, "Understanding health information" and "Having sufficient information," as well as the secondary outcome of the PDSMS. At three months post-baseline, study staff will conduct follow-up administration of the same outcomes. Based on our theoretical mechanism of action (see above), health literacy is the primary set of

outcomes, with diabetes self-management as the secondary outcome. Although we will conduct standard training and include standard scripts for study staff for the baseline and three-month follow-up appointments, study staff administering these assessments will not have specific training or degree requirements. They will use a time stamp of “time 0” for the baseline survey date.

9.2 Safety Assessments

N/A

9.3 Adverse Events and Serious Adverse Events

As noted in 3.3.1, the primary risks to participants are a breach of data prior to assigning study numbers (rather than identifiable information) for individuals. Should a data breach occur, the research staff will respond according to GogyUp’s Privacy Policy and University of Minnesota procedures. These include notification of the data breach in accordance with the United States Department of Health and Human Services HIPAA Breach Notification Rule, 45 CFR §§ 164.400-414, section 13407 of the HITECH Act and the information previously reviewed in the Study Disclosure Document and Informed Consent Form.

Upon discovery of a breach, GogyUp technical staff will immediately evaluate data systems to identify the source of the leak and determine whether the vulnerability can be removed. If the vulnerability is determined to be a continued risk, then study enrollment and/or activity will be halted - dependent on which systems were impacted by the vulnerability, whether the vulnerability has been verified to have been removed and patches to the GogyUp’s data systems have been successfully implemented and tested, and if continuing the study would be in accordance with the Univeristy of Minnesota policies.

9.4 Unanticipated Problems

9.4.1 Definition of Unanticipated Problems

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent form; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research (“possibly related” means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.]

9.4.2 Unanticipated Problems Reporting

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB) and to the lead research co-principal investigator (Co-PI Shippee). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number
- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB and to the funding agency within 24 hours of the investigator becoming aware of the event
- Any other UP will be reported to the IRB and to the funding agency within 36 hours of the investigator becoming aware of the problem
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and the Office for Human Research Protections (OHRP) within 7 days of the IRB's receipt of the report of the problem from the investigator

9.4.3 Reporting Unanticipated Problems to Participants

N/A

10 STATISTICAL CONSIDERATIONS

We will publicly register this protocol with ClinicalTrials.gov prior to study recruitment; it contains all details regarding statistical analysis and so there will be no separate statistical analysis plan.

10.1 Statistical Hypotheses

10.1.1 Primary Endpoint:

We hypothesize that GogyUp Reader app use with written patient education materials or self-care instructions will result in better health literacy compared with print patient

education or care plan materials alone. Alternatively, our null hypothesis is that there will be no difference in health literacy.

10.1.2 Secondary Endpoints:

We hypothesize that GogyUp Reader app use with written patient education materials or self-care instructions will result in better patient self-management of diabetes compared with print patient education or care plan materials alone. Alternatively, our null hypothesis is that there will be no differences in secondary endpoints.

10.2 Sample Size Determination

Due to lack of literature on meaningful effect size for our primary effectiveness outcome , our power calculation is based on a general effect size, the standardized mean difference (SMD). SMD consists of the mean difference in the outcome between arms, divided by the standard deviation of the outcome in the control arm, with moderate effect size being SMD=0.5 and large effect size being SMD=0.7. Based on information in the original validation paper, mean Understanding subscale summary score was 3.85, standard deviation 0.74. With 60 subjects per arm (a low estimate), we will have 78% power to detect a moderate effect size (a between-group difference of .37 on the scale, SMD=0.5) and 97% power to detect a large effect size (SMD=0.7, difference of .52) based on performing a two-sample t-test comparing the treatment arms. With differences in post means of 0.3 and 0.5, power will be 60% and 96%, respectively. However, we want to help insure against difficult recruitment as well as, in particular, a potentially smaller effect size, which can have a large impact on sufficient power. Therefore, our targeted enrollment is 80 per arm (n=160), which would support 73% power for a .3 difference in post means (modest of SMD of .405), with attempted recruitment of up to 200 (given a possible 20 percent recruitment/screening failure rate). Individuals who withdraw or otherwise lost to follow-up will be included in the analysis (see below re: attrition). Regarding our other primary endpoint, for the having sufficient information subscale, (mean 2.98, standard deviation .54), 80 participants per arm would provide 72% power to detect a modest SMD of .40 and 60 participants would provide 78% power to detect a SMD of .5. For our secondary outcome, the perceived diabetes self-management scale (mean 2.585, standard deviation .455), 80 participants per arm would provide 72% power to detect SMD=.4, and 60 participants would likewise provide .78 power to detect SMD=.5.

10.3 Populations for Analyses

Study population will include only intention-to-treat (as randomized).

10.4 Statistical Analyses

10.4.1 General Approach

For descriptive statistics, we will present percentages for binary variables, and medians and means (with standard deviations and overall ranges) for continuous variables. For

inferential tests, marginal p-value and confidence intervals for statistical significance (using two-tailed tests) will be p<.05 and 95% confidence, respectively. We will specify covariate and other design information below.

10.4.2 Analysis of the Primary Endpoint(s)

We will specify the primary outcome as three-month follow-up level of the Health Literacy Questionnaire subscales 9 and 2 (understanding written information and having enough in enough information) as single endpoints (not repeated measures)..

We will compare the mean outcomes at follow-up between the treatment arms using analysis of covariance (ANCOVA), which compares follow-up outcome values between study arms while controlling for the baseline levels to gain power to detect an effect. The primary analysis will be an intent-to-treat (ITT); for non-monotonic missing (e.g., missing a baseline value), we will use multiple imputation with pattern mixture model adjustments in sensitivity analyses allowing for plausible differences among the missing–the justification for this is that pattern mixture models allow for a Missing Not At Random assumption, which is plausible in this case because we will not have measures for all likely variables associated with missingness. Pattern mixture models allow for us to set plausible values for missingness at both high or low levels to obtain a range of outcome estimates allowing for plausible missing data scenarios. For any monotonic missing– i.e., attrition (withdrawal or other lost to follow-up), we will use last observation carried forward but will also conduct sensitivity analyses using pattern mixture models under plausible assumptions of missing data patterns. We will present results using adjusted (least-squares) means with standard errors, p-values, and 95% confidence intervals. Baseline levels of endpoint outcomes will be included as a covariate to gain power to detect an effect, a standard use of ANCOVA.

10.4.3 Analysis of the Secondary Endpoint(s)

The secondary endpoint will be analyzed and presented in the same manner as the primary endpoint, with the same model assumptions and the same approach to missing data. The analysis will not depend on findings or analysis of the primary endpoint.

The secondary endpoint, like the primary endpoints, is a continuous score.

10.4.4 Safety Analyses

N/A

10.4.5 Baseline Descriptive Statistics

We will compare study arms descriptively across baseline levels of endpoints, age, gender, and race without inferential analysis.

10.4.6 Planned Interim Analyses

We will conduct an interim analysis of the primary endpoints to provide data for a SBIR Phase II application, likely six months into the study period. The analysis, while lower-powered, will be the same analysis as described in 2.4.2 above. The interim analysis will not prompt study discontinuation or participant withdrawal by the investigators. Type I error will be addressed in the final analysis as described in 2.4.2.

10.4.7 Sub-Group Analyses

We do not plan any sub-group analyses; the study is not powered for stratified analyses.

10.4.8 Tabulation of Individual Participant Data

We will not tabulate individual participant data.

10.4.9 Exploratory Analyses

We will conduct an exploratory analysis of association between study adherence (level of use, by number of sessions, cumulative length of time of use of GogyUp Reader) and primary endpoint.

11 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

11.1 Regulatory, Ethical, and Study Oversight Considerations

11.1.1 Informed Consent Process

The COVID-19 pandemic presents unique challenges to patient and staff safety. Diabetic patients in particular are more susceptible to infection. Potential partner clinics have expressed concern of hosting additional personnel during the recruitment, consent, and enrollment phases. The team has therefore decided to conduct consent through the e-consent procedures described below. A benefit to this approach is the opportunity to leverage assistive technology and communication tools to tailor the recruitment / consent / enrollment process to different candidate preferences and needs for reviewing information and interacting with the research coordinator.

11.1.2 Consent/assent and Other Informational Documents Provided to participants

To ensure each candidate is fully informed about the study expectations and risks, candidates may select from a menu of options that provide various modes of communication to accommodate individual candidate's preferences and allow the greatest amount of access to consent information, support for understanding and opportunities to demonstrate their understanding – at scale.

Prior to enrollment, each candidate will meet with the research coordinator through either a teleconference or a video conference to confirm each candidate is fully informed about

the purpose, risk, and expectations for involvement in the study. At multiple stages, a comprehensive study disclosure document detailing the study intervention, study procedures, and risks will be available to the participant. Signed informed consent will be completed prior to starting the study intervention.

To accommodate individual candidate preference, English proficiency, as well as varying technology literacy and print literacy skillsets, candidates will be able to choose from several options to receive disclosure information, engage with the study's research coordinators, and proceed through the recruitment / consent / enrollment process.

Regardless of the candidate's chosen option, the process will progress through these steps:

1) Outreach Letter via postal mail. (Recruitment)
2) Provide Contact Information via HIPAA compliant intake form.
3) Review Disclosure Information
4) Confirm Consent
5) Enrollment & Assignment
6) Baseline Assessment
7) Participant Provisioning
8) Follow-Up Assessment
9) Thank You

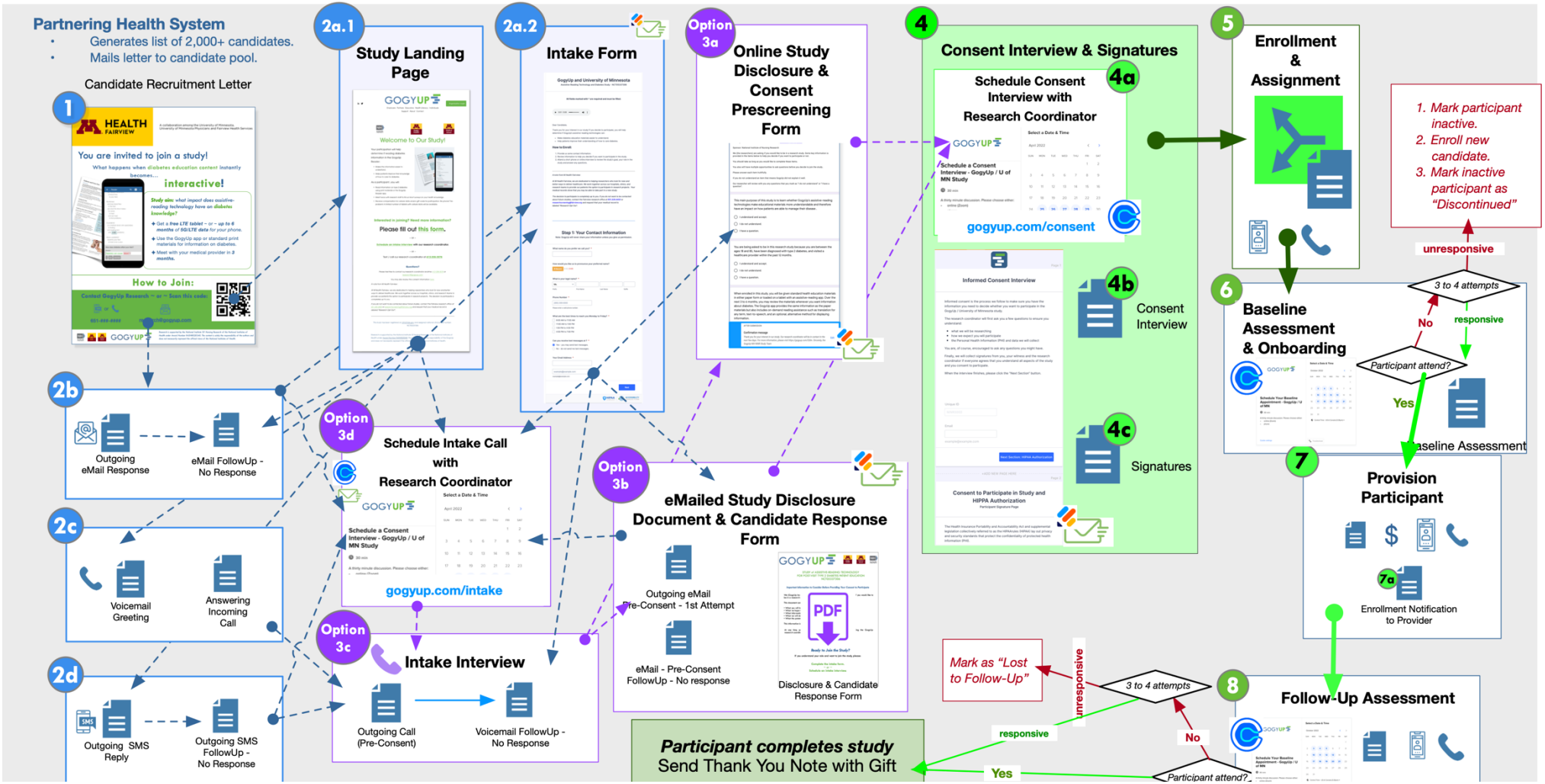
All recruitment and consent materials are submitted with this protocol under section 15 and are presented through one or more systems listed in the table below.

11.1.3 HIPAA Compliant Systems Employed for Informed Consent and Enrollment Process

System	Function	HIPAA Compliance
JotForm	Candidate Intake Disclosure Information Signature: Informed Consent Baseline Assessment Follow-Up Assessment Candidate / Participant Database Appointment Scheduling	https://www.jotform.com/hipaa/
Google Workspace Business	HIPAA compliant e-mail HIPAA compliant telephone and SMS (Google Voice) Device management (for tablets requested by participants without intent access or computing device).	HIPAA Business Associate Agreement Covered Services
Zoom	Video Conferencing for interviews and any ad hoc information requests candidates / participants might have.	HIPAA Business Associate Agreement

Figure 1, Study Participant Workflow, illustrates how the candidate's engagement options and study disclosure and consent materials are interconnected and presented to potential study participants.

11.1.4 Recruitment / Consent / Enrollment / Placement & Follow Up Workflow and Documentation



Step	Description	Documents & Scripts
1	**Recruitment Letter** Research staff at M Health Fairview, the health system we are partnering with for recruitment, will pre-screen and develop a list of 2,000+ qualified study candidates based on the inclusion and exclusion criteria described previously. M Health Fairview mails the Candidate Recruitment Letter to those candidates. The letter contains top level information about the study and presents several ways to learn about the study and contact GogyUp's research coordinator through SMS text, voice call, email, or scanning a QR code to visit the landing page for the study on gogyup.com (step 2a.1).	Candidate Recruitment Letter
2a.1	**Candidate Recruitment Landing Page: gogyup.com/study** To prevent individuals not in the candidate pool from engaging with the study, the study's recruitment landing page is only accessible through the QR code on the Recruitment Letter, the URL listed in the recruitment letter, or if individually provided to candidates / participants through scripted communications. The page is also hidden from search engines, the gogyup.com homepage and gogyup.com site index.	Study Landing Page: gogyup.com/study
2a.2	Candidates may access disclosure information about the study and GogyUp Reader prior to choosing to contact the research coordinator through email, phone, or SMS texting or opting to continue on to Step 2a.2 - the intake form. The Candidate Intake form captures basic contact information and provides three options to review disclosure information, described further below in these sections: • Online review of disclosure information online and pre-screen their level of understanding for each section (Option 3a). • Receive the disclosure information as a PDF attachment via e-mail (Option 3b). • Request that the research coordinator initiate a phone call with the candidate (Option 3c). • Schedule an intake call via a Zoom videoconference or phone conference with the research coordinator (Option 3d).	Candidate Intake Form Online Disclosure Information & Candidate Pre-Screen Form

Step	Description	Documents & Scripts
2b to **2d**	**Initial Candidate Contact** If candidates choose to contact the research coordinator directly, these scripts serve to standardize the conversation and ensure equitable and equal access to information: ● Inbound SMS text response and Outbound follow-up response if no reply ● Inbound voice call script ● Outbound voice call to candidate and follow-up script ○ Outbound voicemail message (no answer / no reply follow-up) ● Inbound eMail response script (automated) ● Outbound eMail response follow-up if no reply (automated) ○ both email messages will contain links to the Online Disclosure Document and Consent Form All communication with an individual candidate and participant is captured in a HIPAA-compliant JotForm database record for that individual.	Study Landing Page: gogyup.com/study Scripts: ● *SMS Response* ● *SMS Follow-Up* ● *Incoming Call* ● *Voicemail Greeting* ● *Outbound Follow-Up* ● *Voicemail Follow-Up – 1st Message* ● *Voicemail Follow-Up – 2nd Message / No Response* ● *Outbound eMail Response (automated)* ● *Outbound eMail – No Response (automated)*

Step	Description	Documents & Scripts
3a	**Study Disclosure Document and Pre-Screening Form** The Study Disclosure Document and Pre-Screening Form is modeled off of Pearl Pathways' consent documentation: the All-in-One Consent Form and the Federally Required Elements for Consent. Disclosure information is arranged thematically. To ensure equitable access to information, each content section contains a verbatim audio recording of the text content. Following each section is a screening question that asks the candidate to indicate whether they understand the information covered in each disclosure document section or if the candidate needs additional information: Prompt: Do you understand [topic]? A) Yes. B) I have a question. C) I want this explained to me We will assume that candidates answering with choice C may be indicating they do not understand the information and the research coordinator should be prepared to explain the topic during the consent interview. Each section also lists the contact information for the research coordinator (text messaging / phone / email) should the candidate want to stop and ask questions directly. ***Please note:*** the screening questions are not designed to exclude candidates from the study. Rather, their purpose is to provide the research coordinator with advance knowledge of each candidate's depth of understanding in order to facilitate an efficient and productive consent interview (step 4).	Online Study Disclosure Document & Pre-Screening Form
3b	**Review Consent via Email** The Study Disclosure Document and Screening Form will be sent as a password-protected, PDF attachment to the candidate's email address in 2a – d. Each attachment will have a unique identifier and will be pre-filled with the candidate's contact information. If candidate chooses to respond to prompts within the PDF, the candidate's study database record will be updated with the candidate's responses. eMail text contains: • contact information for research coordinator • option to schedule an intake call for 1:1 consent review • option to complete consent review online Password to access the document will be texted or shared in a follow-up call with the candidate.	Study Disclosure Document (PDF) Script: • *eMail – Outgoing eMail – Disclosure Review*

Step	Description	Documents & Scripts
3c	**Research Coordinator Calls Candidate** Candidate chooses this option by indicating their preference on the intake form accessed through gogyup.com/study. Research Coordinator (RC) is notified via automation from JotForm and schedules the call, when possible, according to preferred time windows the candidate indicated on the intake form. During the call, the RC will review and complete the Online Disclosure Document and Prescreening Form (Option 3a) with the Candidate. The candidate will receive a copy of the disclosure document and form responses via email which will also be automatically added to the candidate's database record. If the candidate chooses to proceed, the call may continue to Step 4, 5, 6, and 7 with the option to switch to an online video session through Zoom.	Online Study Disclosure Document & Prescreening Form Script: ● *Step 3c: Intake Interview Script*
3d	**Schedule Intake Call with Research Coordinator** Candidate chooses this option by selecting the Intake Call option on the intake form, choosing an open timeslot in the JotForm form and whether the call should be a tele- or videoconference. As with Step 3c, the research coordinator will review the Online Disclosure Document and Pre-Screening Form with the Candidate in real time and the candidate will receive a copy of the form via email to review prior to the Consent Confirmation step. If the candidate chooses to proceed, the call may continue to Step 4, 5, 6, and 7 with the option to switch to an online video session through Zoom.	Online Study Disclosure Document & Pre-Screening Form Jotform Intake page Scripts: eMail opt-in confirmation eMail opt-in
4	**Consent Interview & Signatures** After the candidate has had the option to review the study disclosure information, this step is to provide consent authorization. This step is broken into three sub-steps: 4a: Schedule Interview 4b: Consent Interview 4c: Consent Signature Depending on their choices through the workflow, candidates may not experience all three.	Online Consent Form
4a	**Schedule Interview** Ideally, this step is needed only if the candidate does not have the time (10 to 15 minutes) to review the study disclosure information with the researcher coordinator. This option is designed to efficiently schedule a follow-up session with the candidate.	JotForm Consent Interview page Scripts: eMail: opt-in confirmation eMail: opt-in reminder email

Step	Description	Documents & Scripts
4b	**Consent Interview** This interview is a scheduled online / over-the-phone session between the research coordinator, the candidate. Once the candidate joins the phone or online conference, the coordinator: 1. Reviews with the candidate's unanswered questions noted on the online disclousre document and consent form. 2. Asks open-ended questions to assess the depth of the candidate's comprehension of the study and the activity the candidate is consenting to. If the coordinator confirms the candidate has demonstrated understanding, the candidate is invited to sign the consent form (step 4c). Note: the script outlines two sub-procedures if the candidate does not demonstrate sufficient depth of comprehension: 1 If the candidate states they are unable to read the information in the Online Disclosure Document or responses indicates their level of literacy or English proficiency would prevent understanding, a witness will be added. 2 To ensure the most inclusive study population, candidates have the option to reschedule if they need more time and interaction with the coordinator to understand the research and the risks and benefits involved.	Online Study Disclosure Information and Prescreening Form Script: *Step 4b - Consent Confirmation Interview*
4c	**Consent Signature** To gather the candidate's consent signature, the research coordinator launches a video conference in ZOOM, an accessible and HIPAA-compliant video / audio conferencing and screen sharing program and shares the conference link as well as a link to the online JotForm form to be signed.	Script: *Step4c – Consent Signature* Online Consent Form
5	**Enrollment & Assignment** The research coordinator verifies the participant's contact information and mailing address where the participant may securely receive packages. The research coordinator then refers to the allocation sequence to determine intervention or comparison arm for the newly recruited participant. Depending on the result, the participant in placed in the control or GogyUp Reader group. If the participant is out of time, the RC schedules a baseline assessment with the participant prior to officially enrolling the participant.	Script: *Step 5 - Enrollment & Assignment* Randomization Allocation Sequence

<table>
<tr><th>Step</th><th>Description</th><th>Documents & Scripts</th></tr>
<tr><td>6</td><td>Baseline Assessment & Onboarding

Research coordinator (RC) conducts the baseline assessment (remotely and preferably through Zoom video conference) of the Health Literacy Questionnaire (HLQ) with additional demographic questions for patient age in years, gender, self-identified race and ethnicity, and duration of diabetes diagnosis.

Before the participant signs-off, the RC will schedule and/or confirm the Follow-Up assessment, ideally scheduled close to any follow-up appointment the participant has scheduled with their provider.

The script for this step includes procedures for if the participant misses the appointment. After 3 attempts (or 4 attempts if we are towards the end of the recruitment phase), the RC will mark the participant as inactive and then mark the participant as “discontinued” if a new candidate is enrolled in the previous participant’s place.

If there is enough time and the participant has a mobile device, the RC will walk the participant through how to download GogyUp and create an account on their device or access GogyUp’s webapp.</td><td>Scripts:

● Baseline Assessment (Phone or Online Meeting)
● SMS Script – 1 Day Reminder
● Voicemail – Missed Appointment
● SMS Script – Missed Appointment

Online Health Literacy Questionnaire (HLQ)

Online Demographic Questionnaire</td></tr>
<tr><td>7</td><td>Provisioning

RC will enroll the participant in the assigned group.

An administrative assistant will send out:

<table><tr><th>Intervention</th><th>Control</th></tr><tr><td>● Directions for downloading the mobile app or accessing the webapp.
● Directions for creating a GogyUp account and signing into the study’s walled library.
● Enrollment Notice to Provider</td><td>● Packet of reading materials sent weekly
● Enrollment Notice to Provider</td></tr></table>
RC will be provided daily activity reports by the administrative assistant. If a participant’s account as no activity at the start of the study period, the RC will contact the participant to ensure they have access to GogyUp and are able to log in.</td><td>Scripts:

● Shipment Notification SMS / eMail

.

● Enrollment Notice to Provider</td></tr>
</table>

Step	Description	Documents & Scripts
8	**Follow-Up Assessment** RC conducts the follow-up assessment (remotely via phone or video call) of the HLQ. The script for this step includes procedures for if the participant misses the appointment. After 3 attempts (or 4 attempts towards the end of the recruitment phase), the RC will mark the participant as "lost to follow up". If the participant was supplied with a GogyUp tablet supplied, the RC will ask if the participant would prefer to hold on to the tablet instead of a gift card. .	Scripts: • *Follow-Up Assessment (Phone or Online Meeting)* • *SMS Script – 1 Day Reminder* • *Voicemail – Missed Appointment* • *SMS Script – Missed Appointment* Health Literacy Questionaire (HLQ)
9	**Thank You Procedure and Notices** The RC will send participants who completed the Follow-Up Assessment and Follow-Up Appointment thank you note that either contains a $25 gift card to reimburse network expenses / thank you for participating (if control group) or a notice that the tablet is now unlocked as may be used by the participant for their personal use.	Scripts: • *Thank You Note*

11.1.5 Study Discontinuation and Closure

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, funding agency, and regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and sponsor/funding agency and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Insufficient compliance of study staff to the protocol (i.e., significant protocol violations)
- Data that are not sufficiently complete and/or evaluable

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, sponsor, IRB, or other relevant regulatory or oversight bodies (OHRP, DSMB).

11.1.6 Confidentiality and Privacy

Participant confidentiality and privacy is strictly held in trust by the participating investigators, staff, and the funding agency. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally identifiable information from the study will be released to any unauthorized third party without prior written approval of the funding agency. All research activities will be conducted in as private a setting as possible.

Authorized representatives of the funding agency, or representatives of the Institutional Review Board (IRB) may inspect all documents and records required to be maintained by the investigator

The study participant's contact information will be securely stored for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor/funding agency requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored in a secure server maintained by the University of Minnesota Academic Health Center Information Exchange or by University of Minnesota Information Technology office; the storage and access space for the data will be HIPAA compliant and include Includes encryption, activity logging, Duo Two-Factor Authentication, and access controls such as view-only access..\ This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at the Data Repository for the University of Minnesota (DRUM).

Measures Taken to Ensure Confidentiality of Data Shared per the NIH Data Sharing Policies

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see *https://grants.nih.gov/policy/sharing.htm*). The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be traceable to a specific study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate.

11.1.6.1 Certificate of Confidentiality

To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers

engaged in biomedical, behavioral, clinical or other human subjects research funded wholly or in part by the federal government. Recipients of NIH funding for human subjects research are required to protect identifiable research information from forced disclosure per the terms of the NIH Policy (see *https://humansubjects.nih.gov/coc/index*). As set forth in 45 CFR Part 75.303(a) and NIHGPS Chapter 8.3, recipients conducting NIH-supported research covered by this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award. It is the NIH policy that investigators and others who have access to research records will not disclose identifying information except when the participant consents or in certain instances when federal, state, or local law or regulation requires disclosure. NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

11.1.7 Future Use of Stored Specimens and Data

Data collected for this study will be analyzed and stored in a secure server maintained by the University of Minnesota Academic Health Center Information Exchange or by University of Minnesota Information Technology office; the storage and access space for the data will be HIPAA compliant and include encryption, activity logging, Duo Two-Factor Authentication, and access controls such as view-only access. After the study is completed, the de-identified, archived data will be transmitted to and stored at the Data Repository for the University of Minnesota (DRUM), for use by other researchers including those outside of the study. Permission to transmit data to the DRUM will be included in the informed consent. Access to study data will be provided through the DRUM.

11.1.8 Key Roles and Study Governance

Principal Investigator	**Principal Investigator**	**Independent Safety Monitor: Data Safety and Monitoring Board (DSMB)**
Nathan Shippee, PhD, Associate Professor	Ned Zimmerman-Bence, CEO / Co-Founder	TBD; see DSMB in **11.1.9.**
University of Minnesota	GogyUp Inc	
D375 Mayo Building MMC 729 University of Minnesota 420 Delaware Stree SE Minneapolis, MN 55455	825 Washington Ave SE Suite 220 Minneapolis, MN 55414	
612-624-3579	612-460-5358	

nshippee@umn.edu	ned.zb@gogyup.com	

11.1.9 Safety Oversight - DSMB

Safety oversight will be under the direction of a Data and Safety Monitoring Board (DSMB) composed of individuals with the appropriate expertise, including trial conduct and research data storage and use. Members of the SMC will be independent from the study conduct and free of conflict of interest. The SMC will meet at least semiannually to assess safety and efficacy data from each arm of the study. The SMC will operate under the rules of an approved charter that will be written and reviewed at the organizational meeting of the DSMB. At this time, each data element that the SMC needs to assess will be clearly defined. The DSMB will provide its input to National Institutes of Health staff.

11.1.10 Clinical Monitoring

Despite being a randomized controlled trial, this study will take place outside of the clinical environment and examines an intervention that is used outside of any clinical site. The research team also does not have access to clinical information for monitoring and the research team has no specific clinical role or clinical access with the possible exception of Dr. Rogers in general terms as a practicing clinician-researcher.

11.1.11 Quality Assurance and Quality Control

The investigator team will perform internal quality management of study conduct, data collection, documentation and completion.

Quality control (QC) procedures will be implemented as follows:

Informed consent --- Study staff will review both the documentation of the consenting process as well as a percentage of the completed consent. This review will evaluate compliance with GCP, accuracy, and completeness.

Source documents and the electronic data --- Data will be initially captured on source documents (see **Section 11.2, Data Handling and Record Keeping**) and will ultimately be entered into the study database. To ensure accuracy, study staff will compare a random sample of source data documents against the database, targeting key data points in that review.

Intervention Fidelity — Consistent delivery of the study interventions will be monitored throughout the intervention phase of the study. Procedures for ensuring fidelity of intervention delivery are described in **Section 7.2.1, Interventionist Training and Tracking**.

Protocol Deviations – The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

Should independent monitoring become necessary, the PI will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor/funding agency, and inspection by local and regulatory authorities.

11.2 Data Handling and Record Keeping

11.2.1 Data Collection and Management Responsibilities

Data collection will be the responsibility of the study staff under the supervision of the principal investigators. The investigators will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents will be completed electronically with timestamped activity. End-user data generated in GogyUp Reader will be stored internally by GogyUp by study id and merged with other participant data for exploratory analysis of “adherence” and literacy. Data recorded in the electronic case report form (eCRF) derived from source documents will be consistent with the data recorded on the source documents.

Source document data will be exported from JotForm HIPAA compliant webforms via CSV and be entered into REDCap, a 21 CFR Part 11-compliant data capture system available to the study team through the University of Minnesota’s Clinical and Translational Sciences Institute. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data will be entered directly from the source documents.

11.2.1.1 Study Records Retention

Any source document records containing HIPAA PHI will be maintained for a minimum of 6 years after the end of the study in REDCap (follow-up assessments complete or lost to follow up met for all participants) AND Federal Financial Report (FFR) submission. Other records will be maintained for a minimum of 3 years.

11.2.2 Protocol Deviations

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, International Council on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- Section 4.5 Compliance with Protocol, subsections 4.5.1, 4.5.2, and 4.5.3
- Section 5.1 Quality Assurance and Quality Control, subsection 5.1.1
- Section 5.20 Noncompliance, subsections 5.20.1, and 5.20.2.

It will be the responsibility of the investigators to use continuous vigilance to identify and report deviations within three working days of identification of the protocol deviation. All deviations will be addressed in study source documents, reported to NINR Program Officer and sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator will be responsible for knowing and adhering to the reviewing IRB requirements.

11.2.3 Publication and Data Sharing Policy

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers 5 years after the completion of the study period by contacting Co-PI Shippee. Considerations for ensuring confidentiality of these shared data are described in Section 10.1.3.

11.2.4 Conflict of Interest Policy

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with the NINR has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

12 Additional Considerations

N/A

13 Abbreviations and Special Terms

A1c	A1C is a blood test for type 2 diabetes and prediabetes.
AE	Adverse Event
ANCOVA	Analysis of Covariance

CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
CMP	Clinical Monitoring Plan
COC	Certificate of Confidentiality
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
DRUM	Data Repository for the University of Minnesota
DSMB	Data Safety Monitoring Board
DRE	Disease-Related Event
EC	Ethics Committee
eCRF	Electronic Case Report Forms
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FFR	Federal Financial Report
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GWAS	Genome-Wide Association Studies
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICH	International Council on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IDE	Investigational Device Exemption
IND	Investigational New Drug Application
IRB	Institutional Review Board
ISM	Independent Safety Monitor
ITT	Intention-To-Treat
LSMEANS	Least-squares Means
MedDRA	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
NCT	National Clinical Trial
NIH	National Institutes of Health
NIH IC	NIH Institute or Center

NINR	National Institute for Nursing Research
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
RC	Research Coordinator
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMC	Safety Monitoring Committee
SOA	Schedule of Activities
SOC	System Organ Class
SOP	Standard Operating Procedure
TBD	To be determined
UP	Unanticipated Problem
US	United States

14 Protocol Amendment History

The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A **Summary of Changes** table for the current amendment is located in the **Protocol Title Page**.

Version	Date	Description of Change	Brief Rationale
1.1	11/06/2023	Removed collection of A1c Switched health literacy measure to Health Literacy Questionairre	Collecting A1c was determined to be unnecessary for measuring outcomes. Health Literacy Questionairre provides broader measure of participant health literacy.
1.2	12/26/2023	Revised allocation	Revisions better accommodate remote enrollment.
1.3	01/06/23	Revised assent procedure.	Alignment with University of Minnesota's standard practice.
1.4	02/10/2023	Revised ICF to include language required by UofMN IRB	Alignment with University of Minnesota Institutional Review Board

15 Subject-Facing Materials and Scripts

15.1 Step 1: Recruitment Letter

Our recruitment partner, M Health Fairview, will develop a list of 2,000 or more candidates based on the inclusion and exclusion criteria (Sections 6.1 and 6.2) and then mail the letter displayed on the next page to that candidate pool. GogyUp will not have access to the information contained in the list of candidates and will only be able to communicate with candidates who opt to contact GogyUp through any of these methods:

- Phone
- SMS Text
- E-Mail
- Visiting the study's landing page gogyup.com/study.
    - Please note – gogyup.com/study is hidden from search engine indexing and gogyup.com's site map. Only candidates who received a letter from M Health Fairview or contact the research coordinator will have the URL address.

HEALTH FAIRVIEW

GOGYUP NIH NINR

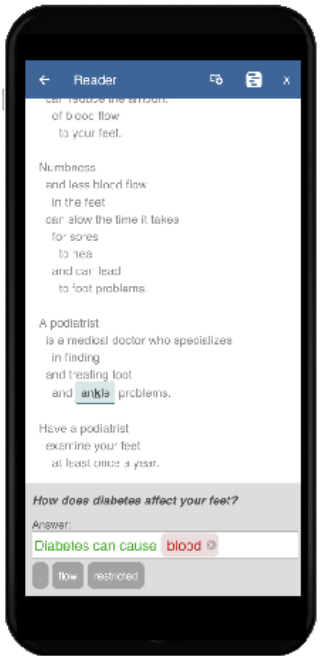
Study Invitation

NCT# 05337306

Your medical records show that you may be able to take part in a study to improve diabetes education. The study will be conducted by GogyUp, an external sponsor. The decision to participate is completely up to you. If you do not want to be contacted about future studies, please contact the Fairview research office at 651.326.4450 or researchscreening@fairview.org and request that your medical record shows as "Research Opt Out."

What if the diabetes information was..

interactive?



***Study Question**: does the GogyUp Reader app increase patient understanding compared to standard print materials?*

If you participate, you will:

- Use the GogyUp Reader app or read print materials to learn about diabetes.
- Meet with research staff to fill out short surveys on your health knowledge.
- Receive reimbursement for your network connection and participation.
- No phone or network connection? A limited number of tablets with cellular data are available for you to use at no cost.

To Join or Learn More:

SMS or 612-208-3078

www.

research@gogyup.com

gogyup.com/study

Research is supported by the National Institute Of Nursing Research of the National Institutes of Health under Award Number R43NR020340. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

15.2 STEP 2: CANDIDATE OPT-IN

The candidate opt-in process begins with the candidate selecting how to respond to the recruitment letter:

A. Scan the QR code or use the URL www.gogyup.com/study, both listed on the recruitment letter, to access the study's landing page. The **Landing Page** provides an abbreviated study summary and provides choices for how the candidate may proceed:
    1. Complete an online intake form.
    2. Set up an appointment to speak with the research coordinator (3d).
    3. Contact the research coordinator directly through email, phone, or text.
B. Email the research coordinator (2b)
C. Call the research coordinator (2c).
D. Text the research coordinator (2d).

15.2.1 STEP 2A.1: RECRUITMENT LANDING PAGE AT GOGYUP.COM

Candidates who scan the recruitment letter's QR code or enter the URL gogyup.com/study into a browser will land on the landing page, responsive to phone, tablet, and PC screens (full text is listed in section 15.2.1.1 below).

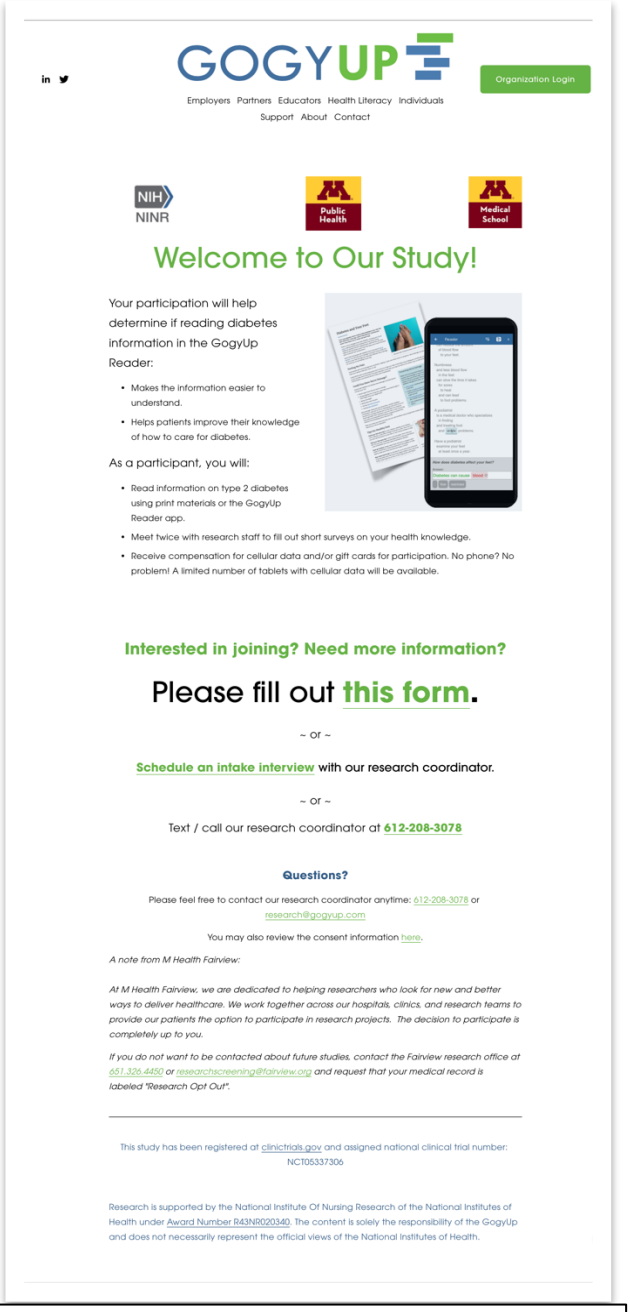


*Figure SEQ Figure * ARABIC2: Recruitment Landing Page -*

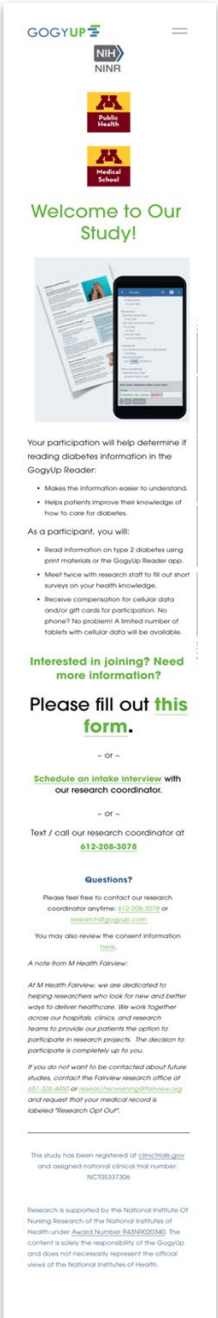


Figure 3: Recruitment Webpage - Mobile Client View

15.2.1.1 Landing Page Text

The following landing page text is the same for both desktop and mobile views and uses the same language as a candidate would have encountered in the candidate recruitment letter:

Welcome to Our Study!

Your participation will help determine if reading diabetes information in the GogyUp Reader:

- Makes the information easier to understand.
- Helps patients improve their knowledge of how to care for diabetes.

As a participant, you will:

- Read information on type 2 diabetes using print materials or the GogyUp Reader app.
- Meet twice with research staff to fill out short surveys on your health knowledge.
- Receive compensation for cellular data and/or gift cards for participation. No phone? No problem! A limited number of tablets with cellular data will be available.

Interested in joining? Need more information?

Please fill out this form.

~ or ~

chedule an intake interview **with our research coordinato**

~ or ~

Text / call our research coordinator at **612-208-3078**

Direct link to JotForm schedule page.

Direct link to the intake form.

Google Voice (HIPAA compliant) number to receive text and voice calls.

Questions?

Please feel free to contact our research coordinator anytime: 612-208-3078 or research@gogyup.com

You may also review the consent information here.

A note from M Health Fairview:

At M Health Fairview, we are dedicated to helping researchers who look for new and better ways to deliver healthcare. We work together across our hospitals, clinics, and research teams to provide our patients the option to participate in research projects. The decision to participate is completely up to you.

If you do not want to be contacted about future studies, contact the Fairview research office at 651.326.4450 or researchscreening@fairview.org and request that your medical record is labeled "Research Opt Out".

This study has been registered at clinictrials.gov and assigned NCT05337306

Direct link to study on clincialtrials.gov

Research is supported by the National Institute Of Nursing Research of the National Institutes of Health under Award Number R43NR020340. The content is solely the responsibility of the GogyUp and does not necessarily represent the official views of the National Institutes of Health.

15.2.2 STEP 2A.2: ONLINE INTAKE FORM

The online intake form is developed within the HIPAA compliant JotForm system (as indicated in *Figure 3 Intake Form Screenshot* – see bottom right had corner). Both sections of the form have audio playback available should a candidate prefer to have the information read to them.

The intake form's full text is posted below.

A critical step occurs is the form's step 2: the candidate is prompted to choose how to review the study disclosure information:

A. Review the Study Disclosure Document and answer preliminary screening questions to indicate their understanding of the disclosure information – step Option 3a below.

   Please note: Asking the candidate to indicate their level of understanding is not intended to be the only indicator of understanding or to screen out candidates. Rather, it is to streamline the process and flag any potential issues for the research coordinator to cover during the consent interview.

B. Have the Study Disclosure Document sent via email as a PDF. The candidate will be given the opportunity to follow a link to an online version with audio descriptions for each section.

C. Request the research coordinator call the candidate to review the disclosure information together.

D. Schedule an intake interview to review the disclosure information together.

If the candidate choses to contact the research coordinator directly through email, text, or by phone, the research coordinator will use the intake form to capture the candidate's contact information and provide the candidate with the same options for reviewing the study disclosure information.

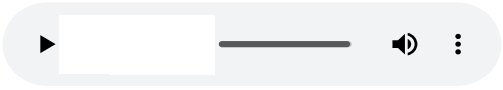
*Figure SEQ Figure * ARABIC 3 Intake Form*

15.2.2.1 ONLINE INTAKE FORM TEXT

GogyUp and University of Minnesota

Assistive-Reading Technology and Diabetes Study

Dear Candidate,

Thank you for your interest in  our study! If you decide to participate, you will help determine if GogyUp's assistive-reading technologies can:

- Make diabetes education materials easier to understand.
- Help patients improve their understanding of how to care diabetes.

Next Steps:

1. Provide us some contact information.
2. Review information to help you decide if you want to participate in the study.
3. Attend a short phone or online interview to review the study's goal, your role in the study and answer any questions.

A note from M Health Fairview:

At M Health Fairview, we are dedicated to helping researchers who look for new and better ways to deliver healthcare. We work together across our hospitals, clinics, and research teams to provide our patients the option to participate in research projects. Your medical records show that you may be able to take part in a new study.

The decision to participate is completely up to you. If you do not want to be contacted about future studies, contact the Fairview research office at 651.326.4450 or researchscreening@fairview.org and request that your medical record is labeled "Research Opt Out".

Step 1: Your Contact Information

Note: GogyUp will never share your information unless you give us permission.

What name do you prefer we call you? *

How would you like us to pronounce your preferred name?

Record 0:00 / 0:05

What is your legal name? *

Prefix First Name Last Name Suffix

Phone Number *

Please enter a valid phone number.

What are the best times to reach you Monday to Friday? *

- c 8:00 AM to 11:00 AM
- c 11:00 AM to 1:00 PM
- c 1:00 PM to 4:00 PM
- c 4:00 PM to 7:00 PM

Can you receive text messages at {phoneNumber}? *

- o Yes - you may send text messages.
- o No - do not send me text messages.

Your Email Address *

Step 2: Disclosure and Informed Consent

Thank you, {preferredName}!

We (GogyUp Inc and the University of Minnesota researchers) are asking if you would like to be in a research study.

It is therefore our job to provide you (to disclose) with as much information as possible to help you decide if you want to participate in our study.

Informed consent is the process to make sure you have the information you need to decide if you want to participate.

Before you decide to provide your consent to participate, there is specific information you will need to learn about the study.

How do you want to review the information about the study? *

- o Review online.
- o Download and review on my own.
- o Have the research coordinator call me.
- o Meet with the research coordinator over the phone or online.

15.2.2.2 EMAILED CONFIRMATION OF INTAKE INFORMATION

Once the candidate submits their information on the intake form, they will receive the following email confirmation - sent to the address the candidate provided.

Figure 4: Email Notification to Candidate - Summary Intake & Next Steps

15.2.3 STEP 2B: EMAIL CONTACT SCRIPTS

If the candidate chooses to contact the research coordinator by email, the following scripts will be used to respond.

15.2.3.1 Outgoing eMail Response to Interest

SUBJECT: GogyUp / U of MN Research

Hello,

I am [your name], the GogyUp Research Coordinator, responding to your interest in our study.

I want to be sure I answer any questions you might have about the study.

Can we schedule a time to meet online or over the phone or online in Zoom?

If you decide to join study after we talk, I can help you with our enrollment process.

Please let me know:

1) A time and day to meet for 10 to 15 minutes.
2) If you prefer a phone call or to meet online.

You can also schedule a time here: gogyup.com/intake

I have attached a document that has the information we will cover in our meeting. You are not expected to read it before we meet.

Thank you, [INSERT PARTICIPANT NAME]. I look forward to meeting with you soon!

Sincerely,

[YOUR NAME HERE]

GogyUp Research Coordinator

Phone / Text: 612-208-3078

NOTE TO RESEARCH COORDINATOR: Record contact attempt in JotForm database.

The following email is sent if the research coordinator has not received a response from the candidate after a 3 to 5 business days.

15.2.3.2 Outgoing eMail – Follow Up for No Response

Hello, this is [YOUR NAME], the GogyUp Research Coordinator.

Thank you so much for you contacting us earlier about our study! Are you still interested?

If you are, lease either:

- schedule a time for 10 – 15 minute intake interview here: gogyup.com/intake
- respond to this message with a few days and times that is convenient for you.

I re-attached the consent information document. You are not expected to read it before we meet.

If you are not interested, no problem! Please let me know so that I stop trying to contact you.

Thank you, [INSERT PARTICIPANT NAME].

I hope to meet with you soon!

Sincerely,

[YOUR NAME HERE]

GogyUp Research Coordinator

Phone / Text: 612-460-5358

NOTE TO RESEARCH COORDINATOR: Record contact attempt in JotForm database.

15.2.4 Step 2c: Voice Contact

If the candidate chooses to contact the research coordinator by phone, the following scripts will be used to respond.

15.2.4.1 Answering Incoming Call

Hello, this is [your name] – GogyUp Research Coordinator.

How may I help?

If a candidate indicates they are interested in participating in the study:

1. Capture their information using the online Intake form – Step 2a.2.
2. Review the Online Disclosure Document and Candidate Response Form with them – Step Option 3a – preferably through a Zoom video sharing session.
3. Reference the Online Disclosure Document when answering questions about study.
4. If appropriate and the candidate has the time, move onto Step 4 – Consent Interview

15.2.4.2 Voicemail Greeting

Hello, this is [your name] – GogyUp Research Coordinator.

I am sorry I am not able to answer your call right now.

If you are interested in participating in or have questions about our type 2 diabetes study, please leave your name, number, and a few times that would be convenient for me to return your call.

You may also find answers and complete an intake form at gogyup.com slash study. That's g o g y u p dot com slash s t u d y.

Thank you!

If caller left contact information:

1) Review JotForm database to check if candidate already filled out an intake form.
    a. Add any additional info caller has left.
    b. If no record has been created for the candidate, add information.
    c. Return candidate's call according to any suggested window.
2) Forward any non-candidate voice messages to Ned Zimmerman-Bence: ned.zb@gogyup.com

15.2.4.3 VOICEMAIL FOLLOW UP – 1ST MESSAGE

Hello, this is [your name], the GogyUp Research Coordinator responding to a message you left about our study.

I am sorry I missed you. When you have a moment, please try calling me again or you may also text me at 612-208-3078.

You may also find answers and complete an intake form at gogyup.com slash study. That's g o g y u p dot com slash s t u d y.

Thank you!

NOTE TO RESEARCH COORDINATOR: Record contact attempt in JotForm database.

15.2.4.4 VOICEMAIL SCRIPT FOLLOW-UP – 2ND MESSAGE / NO RESPONSE

Hello, this is [your name], the GogyUp Research Coordinator. If you are interested in our study, I'm available to answer any questions. Please try calling me again or you may also text me at 612-208-3078.

You may also find answers and complete an intake form at gogyup.com slash study. That's g o g y u p dot com slash s t u d y.

Thank you!

NOTE TO RESEARCH COORDINATOR: Record contact attempt in JotForm database.

15.2.5 STEP 2D: SMS CONTACT

If the candidate chooses to contact the research coordinator by text messaging, the following scripts will be used to respond.

15.2.5.1 SMS RESPONSE SCRIPT

Hello, this is [your name] – GogyUp Research Coordinator.

Are you interested in the GogyUp / U of MN study?

If individual expresses interest in the study, ask how they heard about it.

Great! How did you hear about the study?

Proceed only if they state they heard about it through a letter mailed to them.

Do you have any questions I can answer?

Reference the Online Disclosure Document (in JotForm) when answering questions about study.

If individual expresses interest in enrolling, ask for their first name, last name and explain the next steps:

Excellent. The next step is to review some information about the study before you provide consent to participate. Do you have 10 to 15 minutes now to meet online or by phone?

If the individual can't meet at the moment, send them the gogyup.com/intake link to establish a time to meet online.

If individual can meet now, determine whether they prefer to meet over the phone or online. Send the link to the Zoom meeting environment or use Google Voice to call the candidate.

Follow the script for Step 3c – Outgoing Call.

NOTE TO RESEARCH COORDINATOR: Capture text record and add it to candidate's record in the JotForm database.

15.2.5.2 SMS Follow Up – No Response

Hello, this is [your name] – GogyUp Research Coordinator.

We received a text from this number. Are you were interested in the GogyUp / U of MN study?

Do you have a question about the study?

If individual responds, follow the SMS Response Script (see above) from here.

15.3 Step 3: Disclosure of Information and Consent Information Prescreening

Process Overview: The research coordinator will use these steps for orienting a candidate to the research and help each candidate decide whether they will participate. The main objective is to fully explain the study to the candidate, providing all pertinent information (purpose, procedures, risks, benefits, alternatives to participation), and allow the candidate ample opportunity to ask questions.

NOTE: "Sufficient time" can range from minutes to days, depending on how long it reasonably takes to evaluate the procedures, risks, potential benefits, and alternative treatments. If it is clear that the participant may need longer than a scheduled phone or online conversation, arrange for a follow up call or to take questions via email and text messaging, depending on candidate preference.

Candidates are given four options for reviewing the disclosure document prior to providing consent:

- **Option 3A**: The candidate continues on to review the online Study Disclosure Document and completes the Prescreening Form independently, confirming whether they understand or do not understand a section through a multiple-choice question before continuing on to the next session.

  Each section in the document has a verbatim recording (in English) to ensure the candidate understands each of the section of the disclosure document.

  The candidate's answers will be recorded in JotForm and available to the Research Coordinator to review prior to calling the candidate and proceeding to Step 4: Consent Interview and Signatures.

  At the end of the form, the candidate will schedule a Consent Confirmation Interview (Step 4) with the Research Coordinator.

- **Option 3B:** A PDF containing a copy of the online Study Disclosure Document and Prescreening Form will be emailed to the candidate for the candidate to review offline. The email will also contain a link for the candidate to review the Study Disclosure Document and complete the Prescreening Form online and a second link to schedule the Consent Confirmation Interview.
- **Option 3C:** The research coordinator will call the candidate directly to review the Informed Consent Form together. If the candidate declares themselves ready to provide consent, this step then moves to the Consent Interview (Step 4b – see section 15.4.2 below).

- **Option 3D:** The candidate schedules a meeting with the research coordinator through the to walk through the Informed Consent Form (see section 15.4.3) together.

For options 3C and 3D, attendance via Zoom should be encouraged to review the disclosure information with the candidate to ensure the candidate is reviewing the correct information.

15.3.1 Step 3a: Study Disclosure Document and Prescreening Form

The Study Disclosure Document and Prescreening Form content is an exact duplicate of the content in the Informed Consent Form. Both are accessible on any mobile device or PC with a browser and intent connection and are hosted on the HIPAA compliant JotForm system.

The live form may be reviewed online here:
https://hipaa.jotform.com/221136037340140.

The Study Disclosure Document and Prescreen Form will be used if the candidate chooses to review on their own.

Should the candidate prefer to review 1:1 with the research coordinator, the Informed Consent Form will be used.

A screenshot of the Study Disclosure Document and Prescreening Form's first page is posted below along with the document and form's full text. The information is divided into 5 topical sections. Each section contains discrete pieces of content or questions. Each content section has a verbatim audio recording in English to assist with comprehension.

Following each content section, a question will ask candidates to indicate whether they understand the content with three choices:

- Yes.
- I have a question.
- I want this explained to me.

These responses will be recorded in JotForm and available to the research coordinator to review prior to conducting the Consent Interview (see 15.4.2 below). Responses other than a "yes" will be flagged in an individual report for each candidate so that they may be addressed during the Consent Interview.

Note: Asking the candidate to indicate their level of understanding is not intended to be the only indicator of understanding or to screen out candidates. Rather, it is to streamline the process and flag any potential issues for the research coordinator to cover during the consent interview.

15.3.1.1 Directions for Research Coordinator

If the candidate chooses to review the Study Disclosure Document and Prescreening Form independently, they will indicate understanding through the "Yes / I have a question / I need more information" multiple-choice questions:

The candidate's responses will be captured in the candidate's JotForm database record. Prior to contacting the candidate for the Consent Interview, review the candidate's responses to prepare answers to questions marked as "have a question" or "don't understand".

As noted earlier, each section of the Study Disclosure Document and Prescreening Form will have a verbatim audio recording in case the candidate prefers to have each section read aloud.

15.3.1.2 Study Disclosure Document and Prescreening Form

Key Information

You are invited to take part in a research study.

GogyUp Inc is sponsoring the research study.

Please review this document carefully.

Reviewing this form and talking to the study's research coordinator may help you decide whether to take part or not.

Take your time and ask the research coordinator as many questions as you would like. The research coordinator can explain words or information that you do not understand.

You may click a " ► " button to have the text read to you.

Background and Purpose

You are invited to participate in the study because you are receiving care for diabetes.

The study's purpose is to research if the GogyUp Reader app improves how patients understand diabetes information.

*Do you understand the study's key information, background and purpose? **

- o Yes.
- o I have a question.
- o I want this explained to me.

What Will Happen in This Study?

The study will last between three and four months.

In order to participate, you will be asked to read, sign, and date this consent form.

If you decide to take part in this study, you will:

1. Meet with the research coordinator to complete a baseline assessment and provide some demographic information.
2. Each week, read about diabetes in the GogyUp Reader app or from standard print documents.
3. After three months, meet with the research coordinator again to complete another assessment and, if you are placed in the GogyUp Reader group, a questionnaire about the app.

About 200 subjects will participate in this study. The participants will be equally divided into two groups. Both groups will have access to the same information.

You will be randomly assigned by chance (like the flip of a coin) to either group. You will have a 50% (1 in 2) chance of being placed in the group using the GogyUp Reader and a 50% (1 in 2) chance of using the print materials.

The group assigned to the GogyUp Reader will have access to on-demand reading assistance technologies such as text-to-speech, translation for any term, optional comprehension quizzes, and an alternative method for displaying information.

We assume GogyUp Reader participants will use their own mobile device or PC to download the GogyUp Reader. If you do not have Internet access, GogyUp has a limited number of tablets with Internet access you can borrow for the study.

Each week you will receive new materials about diabetes produced by the United States Centers for Disease Control and Prevention.

IMPORTANT: the diabetes information in this study is only meant to supplement your regular care. If you have specific questions about diabetes during the study, you should consult with your primary health care provider.

Do you understand what will happen in the study, how long the study will take, and how you will be assigned to a study group? *

o Yes.

o I have a question.

o I want this explained to me.

Expectations for Participation

You will be expected to complete three activities:

1. **Assessment.** At the beginning of the study, you will take an assessment given by the research coordinator.
2. **Review Care Information:** You will use the GogyUp Reader app or printed patient materials to read information about diabetes.
3. **Follow-Up Assessment:** At the end of the study period, you will take another assessment given by the research coordinator.

If you are assigned to the GogyUp Reader group, you will be expected to follow GogyUp Reader's Terms of Service while using the GogyUp Reader.

The Terms of Service may be reviewed here: https://www.gogyup.com/serviceterms

*Do you understand the expectations for participating in the study? **

o Yes.

o I have a question.

o I want this explained to me.

Risks, Side Effects, and/or Discomforts

There are no expected side effects or discomforts.

You participation will have very little risk. The risk is similar to reading a newspaper or using a mobile device to look at information.

*Do you understand the study's risk for harm, potential side effects and/or discomforts? **

o Yes.

o I have a question.

o I want this explained to me.

Alternatives to Participation

This research study is for just for research. The only alternative is to not participate in this study.

*Do you understand the alternatives to taking part in the study? **

o Yes.

o I have a question.

o I want this explained to me.

New Findings

We will notify you if new important information is discovered during the study that might change whether you want to continue to participate.

*Do you understand if new information will be shared with you? **

o Yes.

o I have a question.

o I want this explained to me.

Benefits

You may benefit from participating in the study. But there is no guarantee that you will benefit. Information learned from the research may help other people in the future.

*Do you understand the potential benefits to participating in the study? **

o Yes.

o I have a question.

o I want this explained to me.

Compensation for Participation

You will receive a $25.00 gift card if you complete all three study activities.

If you have any questions about the compensation, please contact the study research coordinator: 612-208-3078 or research@gogyup.com.

If you are placed in the GogyUp group, you will receive an additional $25.00 at the end of the study for the use of your network access. To receive the network reimbursement, your activity data should show you used and accessed the GogyUp for at least one session each week.

*Do you understand how you will be compensated for your participation? **

o Yes.

o I have a question.

o I want this explained to me.

Confidentiality and Your Data

Key Points:

- The researchers have a duty to protect your data.
- The researchers will store all data collected about you in secure systems and locations.
- The researchers will only share data that can identify you if required by law.

If you sign this form, you will permit us to use and share your data with other research if it cannot identify you.

Detailed Information:

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the National Institutes of Health (NIH) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your study records including confidential information about you collected during the study will be kept at a secure location and on a 21 CFR Part 11-compliant data capture system.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

By signing and dating this informed consent form, you consent to the collection, access, use and disclosure of your information as described above.

*Do you understand who how your data will be kept confidential and protected? **

o Yes.
o I have a question.
o I want this explained to me.

Is this research covered by a Certificate of Confidentiality (CoC)?

Key Points:

- Your information can be released only if you agree.
- If you do not agree, the researchers cannot release your information.
- Researchers must release your information if they are required by law to do so.

Detailed Information:

This research is covered by a CoC from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you have agreed. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know regarding the CoC.

The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.

The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.

The Certificate DOES NOT stop disclosures required by the federal FDA.

The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you if you provide them permission to do so. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research.

The CoC does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Do you understand what it means that the research is covered by a Certificate of Confidentiality? *

- o Yes.
- o I have a question.
- o I want this explained to me.

What data are will be collected and who will have access to your data?

Your consent allows the researchers to collect this personal health information (PHI) about you:

- Your first and last name,
- Your age
- Your diabetes diagnosis

Only research staff assigned to work on the study will have access to your PHI.

Data that is not PHI may be collected while using the GogyUp Reader as described in GogyUp's Terms of Use and Privacy Policy.

- Terms of Use: gogyup.com/serviceterms
- Privacy Policy: gogyup.com/privacy

*Do you understand who will have access to your data? **

o Yes.
o I have a question.
o I want this explained to me.

Will my data be used for profit?

Data from the GogyUp Reader will help improve and design products that could result in a profit. Study participants will not share in profits earned from products improved by this study.

Do you understand data from your participation will not entitle you to a share in profits resulting from this research? *

o Yes.
o I have a question.
o I want this explained to me.

What if I change my mind about participating or sharing my data?

Key Points:

- Participation is completely voluntary.
- You have the right to not sign this form.
- There is no penalty if you do not sign this form.
- You cannot participate in the study if you do not sign this form.
- You can choose to leave the study at any time.
- You will not lose any benefits if you stop participating.
- You will not be penalized if you stop participating.
- All data collected before you changed your mind may still be used by the researchers.

Detailed Information:

You may change your mind and revoke (take back) this authorization at any time by withdrawing from the study.

To withdraw, please write to:

Ned Zimmerman-Bence, Co-PI

825 Washington Ave SE Suite 220

Minneapolis, MN 55414

ned.zb@gogyup.com

PHI collected before you withdraw your authorization will still be used and reported to the extent that those noted above have taken action in reliance of this authorization, including as necessary to maintain the integrity of the research or to conduct investigations or to report adverse events (bad effects).

If you revoke this authorization, you may no longer be allowed to participate in the research.

Participation is voluntary in the study is completely voluntary and refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

You have a right to not to sign this form. You will not be penalized if you do not sign the form. Your health care treatment and your health care benefits ***will not be affected***.

However, you will not be able to participate in the research if you do not sign the consent form.

*Do you understand what to do and what will happen if you want to leave the study or stop sharing your PHI or other data? **

o Yes.

o I have a question.

o I want this explained to me.

Access to Information.

Organizations that may inspect and copy your information include the University of Minnesota Institutional Review Board (IRB) which is a committee that provides ethical and regulatory oversight of research, and other representatives of the University of Minnesota, including those that have responsibilities for monitoring or ensuring compliance, such as the Quality Assurance Program of the Human Research Protection Program (HRPP).

The study doctor and study staff may share your information with representatives of the University of Minnesota and M Health. These people may use your information to provide oversight and administrative support for the research, conduct evaluations and reviews, and perform other activities related to the conduct of the research.

*Do you understand who will have access to your information? **

- o Yes.
- o I have a question.
- o I want this explained to me.

Costs

There is no cost to participate in the study.

The GogyUp Reader app, and all study activities will be provided at no charge to you. Your primary health care provider and your insurance company will not be billed.

If you are placed in the GogyUp Reader group, you will receive a $25.00 gift card for network access after you complete the baseline assessment. If you do not have access to the Internet, you may be able to borrow a tablet with internet service from GogyUp. Please contact the research coordinator for details.

Do you understand that there is no charge to participate and how internet access will be compensated? *

- o Yes.
- o I have a question.

o I want this explained to me.

Future Research Studies

Your consent allows GogyUp to use or share study data for future research studies. Any data used or shared for future studies will be anonymized and will not identify you.

*Do you understand how your information may be shared with other researchers or in future studies? **

o Yes.

o I have a question.

o I want this explained to me.

Are there any conflicts of interest reported for this study?

Key Points:

- Mr. Zimmerman-Bence owns part of GogyUp. He is a researcher in the study.
- Mr. Zimmerman-Bence's role in the study will not affect the research.
- Pearl Pathways IRB does not find Mr. Zimmerman-Bence's role to create a conflict of interest.

Detailed Information:

Mr. Zimmerman-Bence is a Co-Founder and part owner of GogyUp and is serving as Co-PI on the study.

GogyUp, the study's sponsor, is receiving funding from the National Institute of Nursing Research. The outcome of this research study could be of interest to GogyUp and help develop products that may generate a profit in the future. This investigator does not and will not participate in the recruitment, obtaining of informed consent, enrollment, or assignment for this research.

The IRB oversees the conflict-of-interest policies. In accordance with these policies, the IRB has determined that Mr. Zimmerman-Bence's interests create no significant risk to the welfare of participants in this study or to the integrity of the research. If you would like more information about this, please contact Pearl Pathways IRB at (317) 899-9341 or support@pearlirb.com.

*Do you understand the potential conflicts of interest reported for this study?**

o Yes.
o I have a question.
o I want this explained to me.

What if something changes?

Any significant, new information that may affect you will be explained to you in a timely manner. Such information may help you decide if you want to stay in the study.

*Do you understand how you will be notified if there are changes? **

o Yes.
o I have a question.
o I want this explained to me.

Who do I contact if I have questions about this study?

Contact the research coordinators for general questions about the study: research@gogyup.com or 612-208-3078.

The study's Primary Investigators are:

- Ned Zimmerman-Bence, GogyUp: 612-460-5358 or ned.zb@gogyup.com
- Dr. Nathan Shippee, University of Minnesota: nshippee@umn.edu

Contact either Primary Investigator if you have a concern about the study or a question about:

- Your compensation.
- Your study responsibilities.
- How you can participate.

Pearl Pathways is the institutional review board (IRB) responsible for protecting your rights as a research subject. Please contact them if you have questions about your rights as a research subject:

(Monday through Friday 9-5 EST/EDT):

- By mail:

  Pearl IRB

  29 East McCarty Street

  Suite 100

  Indianapolis, IN 46225

  https://www.pearlirb.com/
- or call: 317-899-9341 (main)
- or fax: 317-602-6554 (fax)
- or by email: support@pearlirb.com

Contact your primary care provider for questions about your medical care.

*Do you understand who to contact if you have concerns or questions about the study? **

o Yes.
o I have a question.
o I want this explained to me.

Research Participant Advocate Line.

To share feedback privately with the University of Minnesota Human Research Protection Program (HRPP) about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

● Your questions, concerns, or complaints are not being answered by the research team.

● You cannot reach the research team.

● You want to talk to someone besides the research team.

● You have questions about your rights as a research participant.

● You want to get information or provide input about this research.

The University of Minnesota HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous. If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the University of Minnesota HRPP.

*Do you understand you may contact the University of Minnesota's Research Participant Advocate Line and that the HRPP may ask you to complete a survey? **

o Yes.
o I have a question.
o I want this explained to me.

Voluntary Participation / Withdrawal

Your participation is voluntary.

You may choose to leave the study for any reason and without any penalty.

Any information collected before you leave the study cannot be removed from the study.

A Primary Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If you do not follow directions for participating in the study.
- You do not meet the study requirements.

- If the study is canceled.
- For administrative reasons.

*Do you understand that your decision to participate is voluntary, that you may withdrawal without penalty, and that the investigator can stop your participation? **

o Yes.

o I have a question.

o I want this explained to me.

15.3.1.3 Email Confirmation of Prescreening Responses

The following two screenshots depict the email that candidates will receive once they complete the online disclosure review form. Information in the curly brackets will be populated with the candidate's responses.

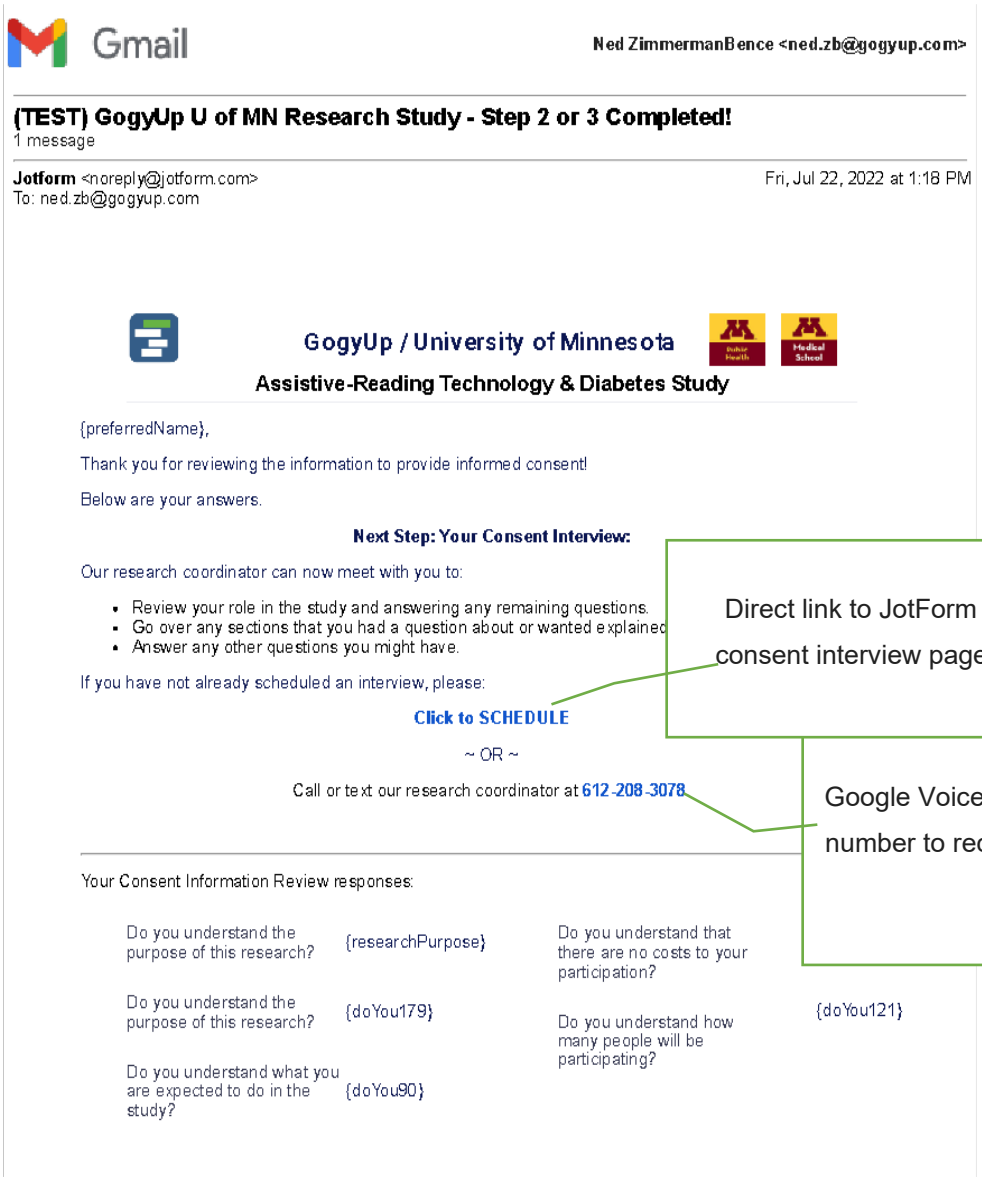


Figure 5: Email Confirmation of Answers Submitted for Consent Prescreening

Do you understand what you may receive for being in the research?	{doYou148}
Do you understand how your participation will help?	{doYou227}
Do you understand what will happen in the study?	{doYou86}
Do you understand the requirement that you agree to the GogyUp Reader's Terms of Use and how to find them?	{doYou118}
Do you understand what health information we would like your provider to share with us?	{doYou93}
Do you understand the information you are authorizing to share and how it will may shared?	{doYou130}
Do you understand who will have access to your data?	{doYou}
Do you understand the information you are authorizing to be shared and how it will may shared?	{doYou205}
Do you understand your participation will not entitle you to a share in any commercial profit that results from this research?	{doYou224}
Do you understand what to do and what will happen if you want to revoke your HIPAA authorization?	{doYou133}
Do you understand what information will be available to you and the public about the study and study results?	{doYou112}
Do you understand the study's risk potential for harm?	{doYou103}
Do you understand the potential benefits to participating in the study?	{doYou106}
Do you understand the alternatives to taking part in the study?	{doYou115}
Do you understand the reasons why your participation could end early?	{doYou142}
Do you understand who to contact if you have concerns or questions about the study?	{doYou124}
Do you understand what it means that the research is covered by a CoC?	{doYou136}
Do you understand the potential conflicts of interest reported for this study?	{doYou127}
Do you understand how you will be notified if there are changes?	{doYou145}

Figure 6: Email Confirmation of Answers Submitted for Consent Prescreening (cont)

15.3.2 STEP 3B: CANDIDATE REVIEWS DISCLOSURE DOCUMENT AND CONSENT FAQS AS PDF

PREP:

- Automated eMails (below) are sent to the candidate with Online Disclosure Document and Consent FAQs attached as a PDF.
- Candidate may schedule a call or just call the research coordinator to continue to Step 4: Consent Interview
- If candidate does not contact the RC after a 2nd email is sent, the database will flag the candidate for you to follow up via phone or email.

15.3.2.1 Outgoing eMail – Disclosure Review

SUBJECT: GogyUp / U of M Study Please Review This Disclosure Document

Hello,

Thank you for your interest in participating in our study!

Attached is the study disclosure information for you to review. At any time, please feel free to call or text me with any questions: 612-208-3078.

For the next step, please either

- Schedule an interview to review the information with me: gogyup.com/consent.
- Simply reply to this email.
- Call me at 612-208-3078.

Thank you, [INSERT CANDIDATE NAME]. I look forward to meeting with you soon!

Sincerely,

[YOUR NAME HERE]

GogyUp Research Coordinator

Phone / Text: 612-208-3078

Contact attempt recorded in the candidate's database record.

15.3.2.2 2ND ATTEMPT EMAIL

If there is no response from the first email in 4 business days after being sent, this email is sent. Contact attempt recorded in the candidate's database record.

SUBJECT: GogyUp / U of MN Research

Hello,

I'm checking in whether you are still interested in participating in our study. I've re-attached the disclosure information for you to review. Please feel free to call me with any questions.

If you are no longer interested, that's fine! Just reply to this email so I can take you off our list.

If you decide to join our study, please:

- Schedule an interview to review the information with me: gogyup.com/consent.
- Contact me by replying to this email.
- Call me at 612-208-3078 to set up an intake interview.

Thank you, [INSERT PARTICIPANT NAME].

Sincerely,

[YOUR NAME HERE]

GogyUp Research Coordinator

Phone / Text: 612-208-3078

15.3.3 STEP 3C: INTAKE INTERVIEW SCRIPT

Prep:

- If the candidate previously filled out Online Disclosure Document, have the responses available prior to calling and the candidate's database record ready to add any notes / log questions that were not answerable.
- If candidate does not answer or is not available, refer to the Voicemail Follow Up script below.

Hello. This is [name] with GogyUp. Is [name] available?

Wait for confirmation that you at speaking with the candidate.

I am calling about your interest in the GogyUp / University of Minnesota Type 2 Diabetes study. Are there any questions that I can answer for you?

If candidate has questions, refer to the Online Disclosure Document and answer any before moving on.

If you believe the candidate's questions were fully addressed and the candidate indicates interest, ask if they would like to consider providing consent to enroll and participate at this moment.

Does participating in the study sound interesting to you?

If yes, then ask:

May we begin the consent and enrollment processes with you now? It might take anywhere between 10 and 15 minutes. Of course, we can take as much time as we need to answer any questions you may have as we go thought the process.

Wait for confirmation that candidate has the time. If the candidate wants to proceed now, skip

If they do not have time now, use the online schedule intake form [gogup.com/intake] to schedule a follow up time.

If no, then say:

That is, of course, fine. Would you like me to put you on our "do not contact" list or would you just a like a little more time to consider joining the study?

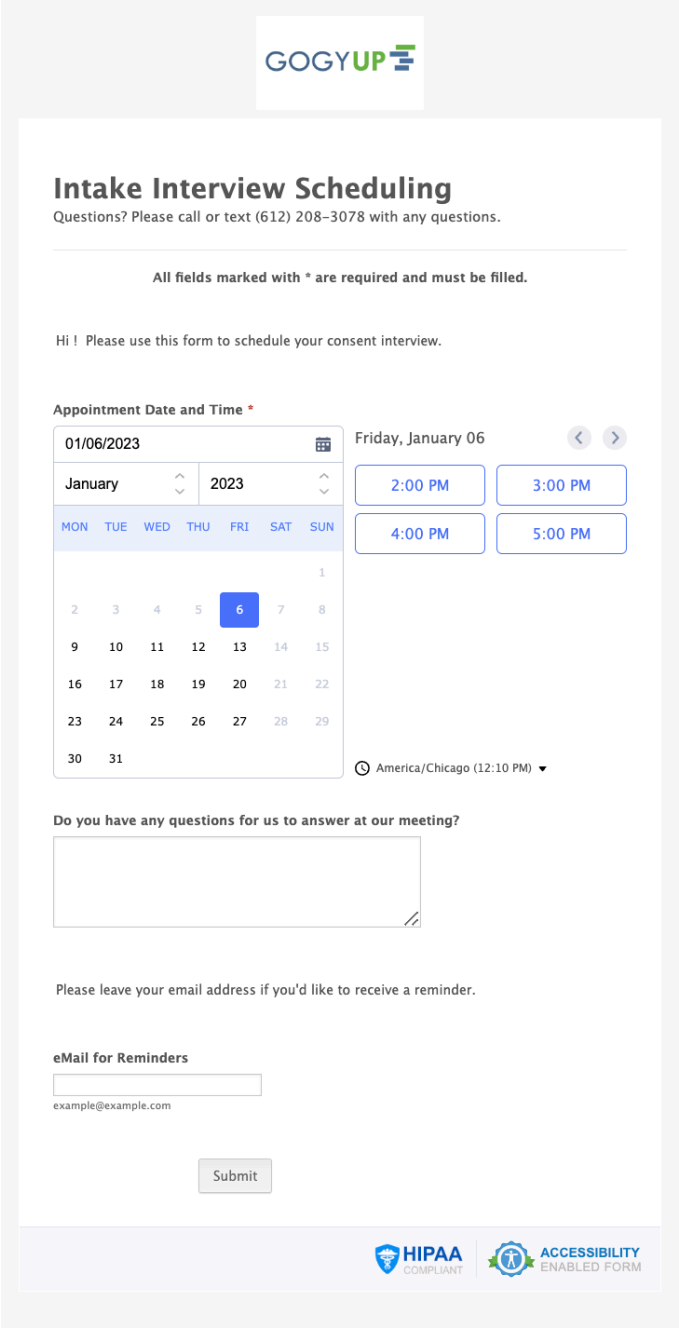
Note the candidate's choice in the JotForm record. Depending on the answer, thank them for their time and (if appropriate) mention you will contact them in a week to check in.

15.3.4 Step 3d: Schedule Intake Interview

Candidates who choose to schedule an intake interview via the study's landing page or from within an email or text correspondence with the research coordinator will be brought to this page to choose from available slots in the research coordinator's calendar.

A field is provided for questions or notes the participant would like to cover during the intake interview.

The intake interview will be automatically scheduled on the Research Coordinator's calendar. If the candidate opts-in, reminder emails (see below) will be sent to the candidate 48 hours and 2 hours before the scheduled meeting.



15.3.4.1 Automated eMail / SMS: Scheduled Interview Confirmation

SUBJECT: GogyUp Study Interview: [DATE AND TIME of INTERVIEW]

Hi [Firstname]! I'm looking forward to meeting with you on [DATE AND TIME of INTERVIEW].

If you need to change your appointment, please reply to this message or reschedule here: [LINK to RESCHEDULE].

Sincerely,

[YOUR NAME] - GogyUp Research Coordinator

15.3.4.2 Automated eMail Scheduled Interview Reminder

SUBJECT: Reminder: GogyUp Study Interview – [TIME] Tomorrow!

Hi [Firstname]! I'm looking forward to meeting with you tomorrow at [TIME].

If you need to change the time, please reply to this message or reschedule here: [LINK to RESCHEDULE].

Sincerely,

[YOUR NAME]

GogyUp Research Coordinator

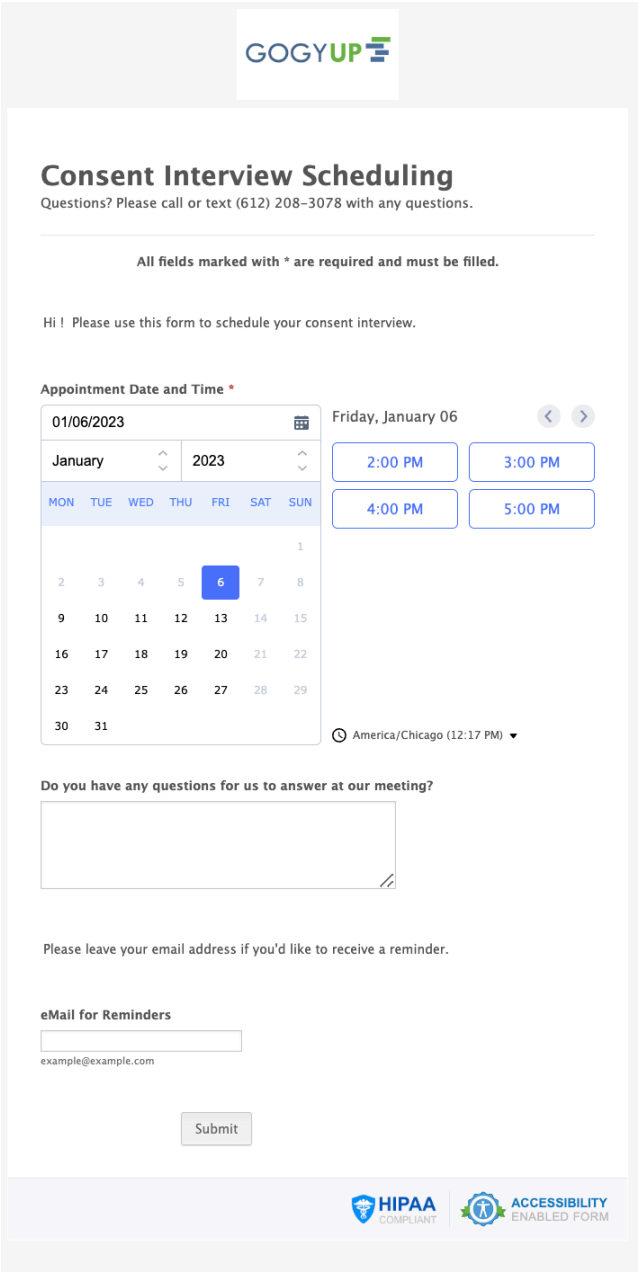
15.4 STEP 4: CONSENT INTERVIEW AND SIGNATURES

The Consent Interview provides the final verification whether the candidate has reviewed and fully understands the study's purpose and the information disclosed in the Online Disclosure Document – which the candidate might have reviewed on their own online or with a PDF version or in a synchronous phone or video conversation with the research coordinator.

15.4.1 STEP 4A: SCHEDULE CONSENT INTERVIEW

Depending on the candidate's "path" to move through the steps for intake (2) and disclosure (3), the candidate may need to schedule a consent interview to review the disclosure information with research coordinator prior to providing consent and PHI authorization.

Consent Interview scheduling is handled through JotForm with a page similar to the Intake interview. Again, the candidate may opt-in to receive email reminders and leave specific questions to be answered.



15.4.1.1 AUTOMATED EMAIL SCHEDULED INTERVIEW CONFIRMATION

SUBJECT: GogyUp Study Interview: [DATE AND TIME of INTERVIEW]

Hi [Firstname]! I'm looking forward to meeting with you on [DATE AND TIME of INTERVIEW].

If you need to change your appointment, please reply to this message or reschedule here: [LINK to RESCHEDULE].

Sincerely,

[YOUR NAME]

GogyUp Research Coordinator

15.4.1.2 AUTOMATED 24-HOUR EMAIL SCHEDULED INTERVIEW REMINDER

SUBJECT: Reminder: GogyUp Study Interview – [TIME] Tomorrow!

Hi [Firstname]! I'm looking forward to meeting with you tomorrow at [TIME].

If you need to change the time, please reply to this message or reschedule here: [LINK to RESCHEDULE].

Sincerely,

15.4.2 Step 4b: Consent Interview - Assessing Comprehension

The research coordinator (not the candidate / participant) has the responsibility for ensuring that a candidate understands the research and the risks and benefits involved. The coordinator should use these steps to assess participant understanding:

Answer questions but also ask questions to further the discussion and elicit questions from the candidate. The coordinator's questions should be open ended to prompt the candidate to think more carefully about the study.

Open-ended questions are those that begin with "who," "what," "when," "where," "why," and "how often," or "please describe."

Do not use close-ended questions that are answerable with a "yes" or "no" answers.

PREP:

- Access record in JotForm database.
- If the candidate submitted the Prescreening form, review it to note any items the candidate marked as "I do not understand" or "I have a question." Find appropriate section in the Informed Consent Form to go over with candidate.
- Check that participant's contact information is recorded in database record.
- Launch ZOOM for screensharing.
- Copy ZOOM link to online meeting to share with candidate.
- Load consent JotForm Step 3 document and form for screensharing.
- Prep assessment (see section 14.3.5a – Enrollment)

15.4.2.1 Outgoing Voice Call to Candidate

Hello. This is [name] with GogyUp. Is [name] available?

Wait for confirmation that you at speaking with the candidate.

I am calling to thank you for your interest in the GogyUp / University of Minnesota Type 2 Diabetes study and to confirm if you are still interested in participating.

Wait for confirmation that candidate is still interested.

Should we begin enrolling you? It can take anywhere between 5 and 10 minutes. Of course, I can take as much time as we need to answer any questions.

Wait for confirmation that candidate has the time. If not, schedule a follow up time now.

If candidate has questions, refer to the Online Disclosure Document before moving on.

Informed consent is the process for telling our potential research participants the key aim, the information we will collect, and what your participation will involve. This process is required to ensure you are being treated ethically and in accordance with Federal law. The consent process includes providing a written disclosure document and consent form that contains required information and then reviewing that information with you.

15.4.2.2 Add Witness to Call (If Applicable)

Note to Research Coordinator: *If the candidate states they are unable to read the information in the Online Disclosure Document or responses indicates their level of literacy or English proficiency would prevent understanding, explain that a witness will be needed.*

As part of the consent process, we often need to have a witness available to confirm your understanding and consent. Is there someone over the age of 18 who could join the call – either physically by you or reachable by phone?

If a witness is not available, propose using another GogyUp team member not affiliated with the study as a witness.

We do need a witness to make sure you have understood everything we are about to go over. Would it be alright if I included a colleague to join our call?

If candidate prefers their own witness, establish another time to call and review the form and mark the candidate as “Waiting on Witness” in the study database.

Ask for the witness contact number to call or text.

With the candidate still in the meeting, contact the witness and ask that they join the meeting in progress:

Hi, [NAME OF WITNESS]. This is [YOUR NAME], the research coordinator at GogyUp.

[NAME OF CANDIDATE] asked me to contact to you. [NAME OF CANDIDATE] is considering joining a study we are conducting and would like you to act as a witness and confirm that [NAME OF CANDIDATE] understands what will happen during the study.

Your role will be just to listen in on the meeting and, if you agree that [NAME OF CANDIDATE] understands the study requirements, provide your verbal agreement that [NAME OF CANDIDATE] understands.

Are you available for 5 to 10 minutes to listen in on my call with [NAME OF CANDIDATE]?

Send screenshare link to participant and witness (if in a different location). Coach candidate and witness through accessing the screenshare.

Confirm candidate and witness can see screenshare.

15.4.2.3 Explain Informed Consent

Informed consent is the process for telling our potential research participants the key aim, the information we will collect, and what your participation will involve. This process is

required to ensure you are being treated ethically and in accordance with Federal law. The consent process includes providing a written disclosure document and consent form that contains required information and then reviewing that information with you.

15.4.2.4 Review Informed Consent Form

Display the Informed Consent Form in 15.4.3 below.

Review the form with candidate, pausing for any question, up until Section 3 – Participant Signature.

15.4.2.5 Comprehension Confirmation Interview

To be sure you understand what it means to participate in the study, I need to ask you a few questions.

Open-ended questions to use:

1. "Describe in your own words the purpose of the study."
2. "How would you explain to others what you will have to do in the study?"
3. "What is the possible benefit to you if you participate in this study? What are the possible risks?"
4. "How long does your participation in this study last?"
5. "Who do you contact if you have questions?"

Based upon the candidate's responses, decide whether the candidate adequately understands the study.

15.4.2.6 Procedure For When Comprehension Issues Are Detected

If you believe the candidate does not understand the study disclosure information enough to provide informed consent, offer to review the information again – touching on the areas that you believe the candidate doesn't understand.

Thank you so much for your time. At this point, I think there are a few points we still need to review before it is safe to proceed. Would you like to review the material again or schedule another time to meet?

If candidate prefers to schedule another meeting, establish the time and day with the candidate. Update candidate's JotForm record to "Waiting On – Consent 2nd Try".

Review the appropriate sections of disclosure information.

Mark the candidate as "Not Ready" in the candidate's JotForm record.

15.4.3 STEP 4C: INFORMED CONSENT SIGNATURE

The live form may be reviewed online here:
https://hipaa.jotform.com/221085579452158

The form is divided into sections:

1) About Informed Consent
2) Study Disclosure Information
3) Candidate Signature Page.
4) Witness Signature Page (if applicable)
5) Investigator Verification Page

As with the Study Disclosure Document and Prescreening Form, the form also has verbatim audio should the candidate prefer to review to each section spoken at their preferred pace.

The form is also available for download as a PDF and a physical copy may be mailed to the candidate's address for the candidate to review and sign a time convenient for them.

Confirm that candidate can still see your screen.

Explain the final step in enrolling the candidate:

1) Signing the consent form.
2) Collecting contact information.

I'm so glad you're able to join the study! The last step is for you to sign the consent form so we have documentation that we've answered your questions.

Display the Informed Consent Form.

Confirm that the candidate is able to see the form.

Briefly review sections 1 and 2, pausing for any questions.

Provide computer control via ZOOM to candidate. Explain to the candidate how to navigate to the signature section and provide their signature.

Prompt the candidate to sign the consent form.

Follow Up Tasks after Consent Interview is finished:

1) JotForm will email the participant an enrollment confirmation with a link to the signed form.
2) Print and mail the participant's practioner notification if participant consents to the notification on the form.
3) Notify GogyUP's admin assistant to mail participant a hardcopy of the signed form.

NOTE: both the print copy and emailed notification will contain:

1) A link to a version of the Study Disclosure Document (without prescreening questions) so the participant may refer to the verbatim audio for additional help in referring back to the information.
2) Contact information for the research coordinator.

15.4.3.1 Informed Consent Form - Section 1

GogyUp / U of MN Study

Assistive-Reading Technology and Type 2 Diabetes Study - NCT05337306

Step 3 - Consent Interview and Consent Forms

Informed consent is the process we follow to make sure you have the information you need to decide whether you want to participate in the GogyUp / University of Minnesota study.

The research coordinator will first ask you a few questions to ensure you understand:

- what we will be researching
- how we expect you will participate
- the Personal Health Information (PHI) and data we will collect

You are, of course, encouraged to ask any questions you might have.

Finally, we will collect signatures from you, your witness and the research coordinator if everyone agrees that all aspects of the study are understood and you consent to particpate.

Please wait for the research coordinator to indicate when to click the "Next Section" button.

Next Section: HIPAA Authorization

HIPAA COMPLIANT ACCESSIBILITY ENABLED FORM

15.4.3.2 Informed Consent Form – Section 2

Note: each content section will have an audio narration available for the candidate to listen to at their own pace.

Key Information

You are invited to take part in a research study.

GogyUp Inc is sponsoring the research study.

Please review this document carefully.

Reviewing this form and talking to the study's research coordinator may help you decide whether to take part or not.

Take your time and ask the research coordinator as many questions as you would like. The research coordinator can explain words or information that you do not understand.

To participate in this study, you must sign your name to provide consent to participate in the study in the next section.

If you choose to sign this form, a physical copy will be sent to your street address.

Background And Purpose

You are invited to participate in the study because you are receiving care for diabetes.

The study's purpose is to research if the GogyUp Reader app improves how patients understand diabetes information.

What Will Happen During the Study?

The study will last between three and four months.

In order to participate, you will be asked to read, sign, and date this consent form.

If you decide to take part in this study, you will:

1. Meet with the research coordinator to complete a baseline assessment and provide some demographic information.
2. Each week, read about diabetes in the GogyUp Reader app or from standard print documents.
3. After three months, meet with the research coordinator again to complete another assessment and, if you are placed in the GogyUp Reader group, a questionnaire about the app.

About 200 subjects will participate in this study. The participants will be equally divided into two groups. Both groups will have access to the same information.

You will be randomly assigned by chance (like the flip of a coin) to either group. You will have a 50% (1 in 2) chance of being placed in the group using the GogyUp Reader and a 50% (1 in 2) chance of using the print materials.

The group assigned to the GogyUp Reader will have access to on-demand reading assistance technologies such as text-to-speech, translation for any term, optional comprehension quizzes, and an alternative method for displaying information.

We assume GogyUp Reader participants will use their own mobile device or PC to download the GogyUp Reader. If you do not have Internet access, GogyUp has a limited number of tablets with Internet access you can borrow for the study.

Each week you will receive new materials about diabetes produced by the United States Centers for Disease Control and Prevention.

IMPORTANT: the diabetes information in this study is only meant to supplement your regular care. If you have specific questions about diabetes during the study, you should consult with your primary health care provider.

Expectations for Participation

You will be expected to complete three activities:

1. **Assessment.** At the beginning of the study, you will take an assessment given by the research coordinator.
2. **Review Care Information:** You will use the GogyUp Reader app or printed patient materials to read information about diabetes.
3. **Follow-Up Assessment:** At the end of the study period, you will take another assessment given by the research coordinator.

If you are assigned to the GogyUp Reader group, you will be expected to follow GogyUp Reader's Terms of Service while using the GogyUp Reader.

The Terms of Service may be reviewed here: https://www.gogyup.com/serviceterms

Risks, Side Effects, and/or Discomforts

There are no expected side effects or discomforts.

You participation will have very little risk. The risk is similar to reading a newspaper or using a mobile device to look at information.

Alternatives to Participation

This research study is for just for research. The only alternative is to not participate in this study.

New Findings

We will notify you if new important information is discovered during the study that might change whether you want to continue to participate.

Benefits

You may benefit from participating in the study. But there is no guarantee that you will benefit. Information learned from the research may help other people in the future.

Compensation for Participation

You will receive a $25.00 gift card if you complete all three study activities.

If you have any questions about the compensation, please contact the study research coordinator: 612-208-3078 or research@gogyup.com.

If you are placed in the GogyUp group, you will receive an additional $25.00 at the end of the study for the use of your network access. To receive the network reimbursement, your activity data should show you used and accessed the GogyUp for at least one session each week.

Confidentiality and your Data

Key Points:

- The researchers have a duty to protect your data.
- The researchers will store all data collected about you in secure systems and locations.
- The researchers will only share data that can identify you if required by law.

If you sign this form, you will permit us to use and share your data with other research if it cannot identify you.

Detailed Information:

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the National Institutes of Health (NIH) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At

most, the Web site will include a summary of the results. You can search this Web site at any time.

Your study records including confidential information about you collected during the study will be kept at a secure location and on a 21 CFR Part 11-compliant data capture system.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

By signing and dating this informed consent form, you consent to the collection, access, use and disclosure of your information as described above.

Is this research covered by a Certificate of Confidentiality (CoC)?

Key Points:

- Your information can be released only if you agree.
- If you do not agree, the researchers cannot release your information.
- Researchers must release your information if they are required by law to do so.

Detailed Information:

This research is covered by a CoC from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you have agreed. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know regarding the CoC.

The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.

The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.

The Certificate DOES NOT stop disclosures required by the federal FDA.

The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you if you provide them permission to do so. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research.

The CoC does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

What data are will be collected and who will have access to your data?

Your consent allows the researchers to collect this personal health information (PHI) about you:

- Your first and last name,
- Your age
- Your diabetes diagnosis

Only research staff assigned to work on the study will have access to your PHI.

Data that is not PHI may be collected while using the GogyUp Reader as described in GogyUp's Terms of Use and Privacy Policy.

- Terms of Use: gogyup.com/serviceterms
- Privacy Policy: gogyup.com/privacy

Will my data be used for profit?

Data from the GogyUp Reader will help improve and design products that could result in a profit. Study participants will not share in profits earned from products improved by this study.

What if I change my mind about participating or sharing my data?

Key Points:

- Participation is completely voluntary.
- You have the right to not sign this form.
- There is no penalty if you do not sign this form.
- You cannot participate in the study if you do not sign this form.
- You can choose to leave the study at any time.
- You will not lose any benefits if you stop participating.
- You will not be penalized if you stop participating.
- All data collected before you changed your mind may still be used by the researchers.

Detailed Information:

You may change your mind and revoke (take back) this authorization at any time by withdrawing from the study.

To withdraw, please write to:

Ned Zimmerman-Bence, Co-PI

825 Washington Ave SE Suite 220
Minneapolis, MN 55414
ned.zb@gogyup.com

PHI collected before you withdraw your authorization will still be used and reported to the extent that those noted above have taken action in reliance of this authorization, including as necessary to maintain the integrity of the research or to conduct investigations or to report adverse events (bad effects).

If you revoke this authorization, you may no longer be allowed to participate in the research.

Participation is voluntary in the study is completely voluntary and refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

You have a right to not to sign this form. You will not be penalized if you do not sign the form. Your health care treatment and your health care benefits ***will not be affected***.

However, you will not be able to participate in the research if you do not sign the consent form.

Access to Information.

Organizations that may inspect and copy your information include the University of Minnesota Institutional Review Board (IRB) which is a committee that provides ethical and regulatory oversight of research, and other representatives of the University of Minnesota, including those that have responsibilities for monitoring or ensuring compliance, such as the Quality Assurance Program of the Human Research Protection Program (HRPP).

The study doctor and study staff may share your information with representatives of the University of Minnesota and M Health. These people may use your information to provide oversight and administrative support for the research, conduct evaluations and reviews, and perform other activities related to the conduct of the research.

Costs

There is no cost to participate in the study.

The GogyUp Reader app, and all study activities will be provided at no charge to you. Your primary health care provider and your insurance company will not be billed.

If you are placed in the GogyUp Reader group, you will receive a $25.00 gift card for network access after you complete the baseline assessment. If you do not have access to the Internet, you may be able to borrow a tablet with internet service from GogyUp. Please contact the research coordinator for details.

Future Research Studies

Your consent allows GogyUp to use or share study data for future research studies. Any data used or shared for future studies will be anonymized and will not identify you.

Are there any conflicts of interest reported for this study?

Key Points:

- Mr. Zimmerman-Bence owns part of GogyUp. He is a researcher in the study.
- Mr. Zimmerman-Bence's role in the study will not affect the research.
- Pearl Pathways IRB does not find Mr. Zimmerman-Bence's role to create a conflict of interest.

Detailed Information:

Mr. Zimmerman-Bence is a Co-Founder and part owner of GogyUp and is serving as Co-PI on the study.

GogyUp, the study's sponsor, is receiving funding from the National Institute of Nursing Research. The outcome of this research study could be of interest to GogyUp and help develop products that may generate a profit in the future. This investigator does not and will not participate in the recruitment, obtaining of informed consent, enrollment, or assignment for this research.

The IRB oversees the conflict-of-interest policies. In accordance with these policies, the IRB has determined that Mr. Zimmerman-Bence's interests create no significant risk to the welfare of participants in this study or to the integrity of the research. If you would like more information about this, please contact Pearl Pathways IRB at (317) 899-9341 or support@pearlirb.com.

What if something changes?

Any significant, new information that may affect you will be explained to you in a timely manner. Such information may help you decide if you want to stay in the study.

Who do I contact if I have questions about this study?

Contact the research coordinators for general questions about the study: research@gogyup.com or 612-208-3078.

The study's Primary Investigators are:

- Ned Zimmerman-Bence, GogyUp: 612-460-5358 or ned.zb@gogyup.com
- Dr. Nathan Shippee, University of Minnesota: nshippee@umn.edu

Contact either Primary Investigator if you have a concern about the study or a question about:

- Your compensation.
- Your study responsibilities.
- How you can participate.

Pearl Pathways is the institutional review board (IRB) responsible for protecting your rights as a research subject. Please contact them if you have questions about your rights as a research subject:

(Monday through Friday 9-5 EST/EDT):

- By mail:
  Pearl IRB
  29 East McCarty Street
  Suite 100
  Indianapolis, IN 46225
  https://www.pearlirb.com/
- or call: 317-899-9341 (main)
- or fax: 317-602-6554 (fax)
- or by email: support@pearlirb.com

Contact your primary care provider for questions about your medical care.

Research Participant Advocate Line.

To share feedback privately with the University of Minnesota Human Research Protection Program (HRPP) about your research experience, call the Research Participants'

Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contactthe HRPP if:

● Your questions, concerns, or complaints are not being answered by the research team.

● You cannot reach the research team.

● You want to talk to someone besides the research team.

● You have questions about your rights as a research participant.

● You want to get information or provide input about this research.

The University of Minnesota HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous. If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the University of Minnesota HRPP.

Voluntary Participation / Withdrawal

Your participation is voluntary.

You may choose to leave the study for any reason and without any penalty.

Any information collected before you leave the study cannot be removed from the study.

A Primary Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If you do not follow directions for participating in the study.
- You do not meet the study requirements.
- If the study is canceled.
- For administrative reasons.

15.4.3.3 Informed Consent Form – Section 3 - Participant Signature

Participant Signature

To be completed by individual consenting to participate in the study.

May the researchers contact you after your participation is over to invite you to participate in other research studies? Your answer does not impact your eligibility to participate in this study.*

- Yes
- No

I have read and understand the information in this informed consent document.*

- Agree
- Disagree

I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction.*

- Agree
- Disagree

I voluntarily agree to participate in this study until I decide otherwise.*

- Agree
- Disagree

I understand that I do not give up any of my legal rights by signing and dating this consent document.*

- Agree
- Disagree

I understand that will receive a copy of this signed and dated consent document.*

- Agree
- Disagree

I consent to having my primary health care provider notified by the study team of my participation in this study (please check yes or no).*

- Yes
- No

Provider Name

Clinic Address (if known)

Street Address

Street Address Line 2

City

State / Province

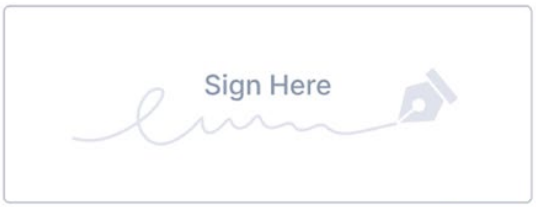
Postal / Zip Code

Adult Participant: Please confirm your full legal name.

First Name

Last Name

Adult Participant Signature *



Clear

15.4.3.4 Informed Consent Form – Section 4 – Witness Signature (when applicable)

Witness Signature

To be completed by individual witnessing informed consent when participant is unable to read or sign consent because of the following reason:

- ○ Participant was unable to read the information.
- ○ Participant was unable to respond in English.
- ○ Other (please specify below).

Reason covered under "other":

Select all applicable statements:

- ☐ Check for remote consent (conference call or video conference).
- ☐ Check to confirm participant agreed to participate in the study and signed the informed consent form(s) and all questions were answered.
- ☐ Check if participant could not sign the consent form but signaled consent to participate and describe method of consent in next question (i.e., gave thumbs up).

Did the participant indicate consent through a means other than signature?

Type here...

If participant was not able to sign, please describe how participant indicated consent.

Witness: Please type your full legal name.

First Name Last Name

Witness Relationship:

- ○ Impartial witness - not affiliated with GogyUp or the University of Minnesota.
- ○ Witness - may be affiliated with GogyUp or the University of Minnesota.

Witness Signature

Sign Here

Powered by Jotform Sign Clear

Back Next: Investigator Signature

HIPAA COMPLIANT

15.4.3.5 Informed Consent Form – Section 5 - Investigator Verification Page

Investigator Verification

Investigator's Full Name

First Name

Last Name

Investigator's Role

Research Coordinator

☐ By adding your signature, the investigator agrees: *

In addition to advising the person authorizing the research about any appropriate alternatives to research participation, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be, associated with this research, and to answer any further questions.

Check the conditions that apply: *

- ☐ Check to confirm participant consents to participate in the study.
- ☐ Check to confirm participant signed the informed consent forms.
- ☐ Check to confirm participant authorized the release of PHI.
- ☐ Check to confirm all questions were answered.
- ☐ Check if remote conference call (audio only)
- ☐ Check if remote conference call (video).
- ☐ Check if participant was asked to mail, fax, or e-mail a copy of consent form to team.
- ☐ Check if the informed consent document was not retained, due to contamination of the document by infectious material.

Back Submit

15.4.3.6 Enrollment Confirmation eMail to Participant

Once the signature pages are complete, the participant will receive the following email with the signed forms attached. A physical copy will also be sent to the address the participant provided on the intake form.

The letter also provides a link to a version of the Study Disclosure Document (without the prescreening questions) that has a verbatim audio recording for each section.

{preferredName},

Welcome aboard and thank you for joining our study!

We will mail your signed consent form to this address:

{physicalAddress}

If you need it sent to a different location, please contact us:

- Call or text our research coordinator at 612-460-5358.
- eMail us: research@gogyup.com

Next:

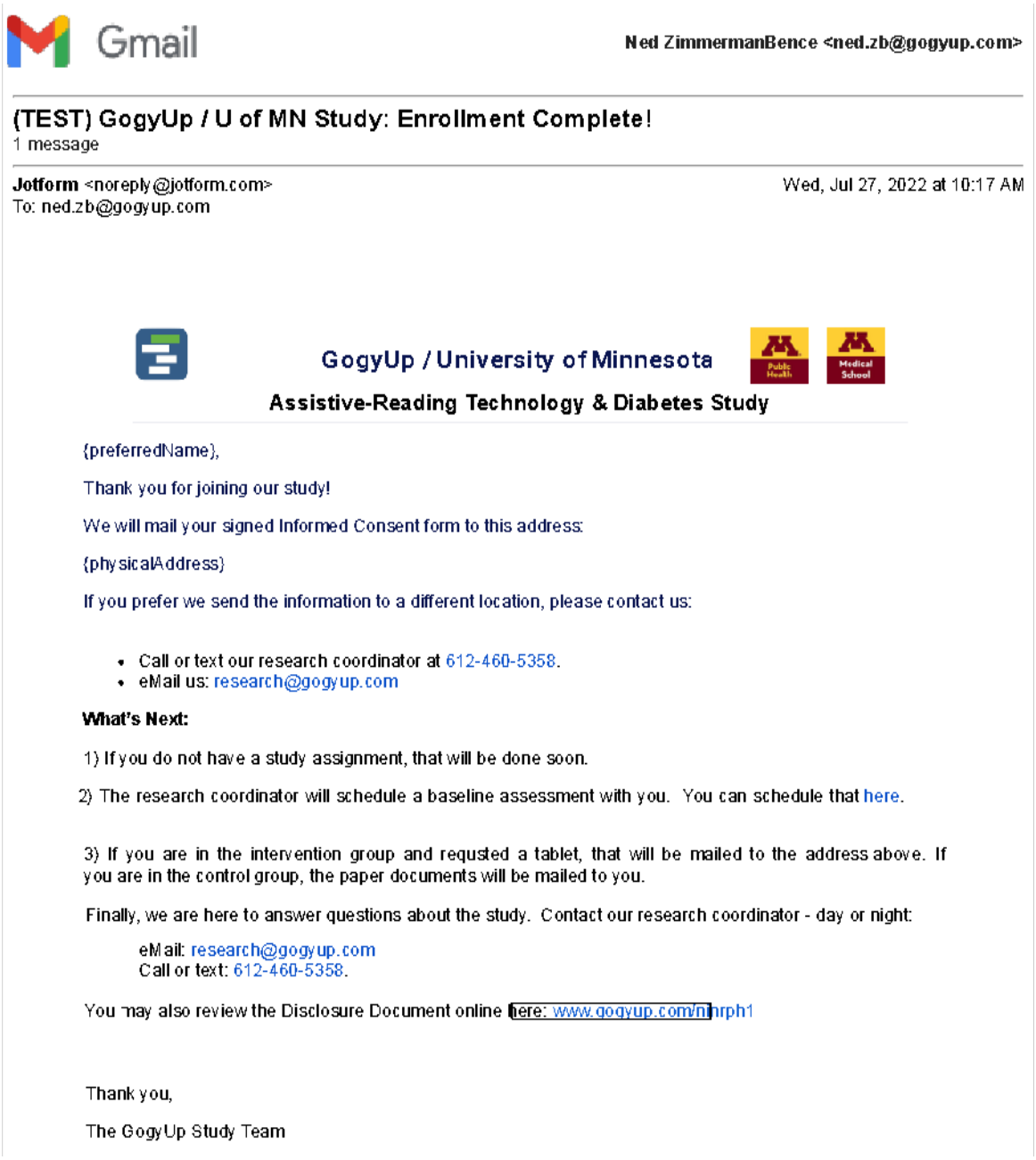
1) Your baseline assessment is scheduled for {BaselineAssessmentDate}. If you need change the date, please contact the research coordinator. schedule that **here.**

2) If you are in the group using GogyUp Reader, we will send a gift card to reimburse network costs and instructions for getting and using the app.

3) Important! Please be sure you continue to contact your health provider if you have questions about diabetes or your health..

Thank you,

The GogyUp Study Team



Gmail

Ned ZimmermanBence <ned.zb@gogyup.com>

(TEST) GogyUp / U of MN Study: Enrollment Complete!
1 message

Jotform <noreply@jotform.com>
To: ned.zb@gogyup.com

Wed, Jul 27, 2022 at 10:17 AM

GogyUp / University of Minnesota

Assistive-Reading Technology & Diabetes Study

{preferredName},

Thank you for joining our study!

We will mail your signed Informed Consent form to this address:

{physicalAddress}

If you prefer we send the information to a different location, please contact us:

- Call or text our research coordinator at 612-460-5358.
- eMail us: research@gogyup.com

What's Next:

1) If you do not have a study assignment, that will be done soon.

2) The research coordinator will schedule a baseline assessment with you. You can schedule that here.

3) If you are in the intervention group and requsted a tablet, that will be mailed to the address above. If you are in the control group, the paper documents will be mailed to you.

Finally, we are here to answer questions about the study. Contact our research coordinator - day or night:

eMail: research@gogyup.com
Call or text: 612-460-5358.

You may also review the Disclosure Document online here: www.gogyup.com/nihrph1

Thank you,

The GogyUp Study Team

15.5 STEP 5: ENROLLMENT & ASSIGNMENT

Review contact information with participant and double check participant information is correctly entered in JotForm database:

- First name
- Last name
- Contact phone number
- eMail address

And if the participant consented to provider notification:

- Primary provider's name
- Primary provider's street address
- Primary provider's phone number

Revise as necessary the contact information in the candidate's JotForm record.

Mark the participant as "enrolled" in the JotForm database.

15.5.1.1 STEP 5A: ASSIGNMENT & NEXT STEPS

Thank the participant for enrolling in the study and explain the assignment process.

Review procedure detailed in section 6.3 of the study protocol to assign participant to a study arm: intervention or control.

I am going to unseal this envelop that contains your assignment.

Unseal the envelope and show the card to the camera so that the participant may view the assignment.

15.5.1.2 STEP 5A-1: CONTROL GROUP ASSIGNMENT

If participant is assigned to the control group (content only), state:

Oh, great! You are assigned to what we're calling "the control group" – this is the group that will use standard, printed diabetes education materials. I will send them to you in the postal mail and they should arrive in 2 – 3 days.

Note assignment in candidate's JotForm record and send materials in the postal mail.

15.5.1.3 STEP 5A-2: INTERVENTION GROUP ASSIGNMENT

If participant is assigned to the intervention group (GogyUp Reader App), state:

Ok – you've been assigned to the GogyUp Reader app group.

Do you have a device – either a mobile phone, tablet, or computer, that you can access regularly? Does this device have regular intent access?

If so, we will send you a $25 gift card to help cover the cost of your network access during the study after you've completed a baseline assessment. Once you complete a follow-up assessment at the end of the three months, we will send you another $25 gift card to thank you for your participation..

If participant mentions that they do not have internet cell service or access to a computer or mobile device, explain that we can provision a internet-connected tablet while they are enrolled in the study.

15.5.1.4 STEP 5B: SCHEDULE FOLLOW-UP APPOINTMENT AND BASELINE ASSESSMENT

The very last items we need to do is to set up an appointment to take a survey together to help establish some base line information.

If there is enough time and the participant is willing, conduct the baseline assessment now. Otherwise, set up baseline and follow-up assessment appointments.

Note for Intervention Group Participants:

- If participant is in Intervention group, explain that the data plan compensation or tablet will be sent once the baseline assessment has occurred.

Ok – great! Next, we need to set up a time to meet for 10 – 15 minutes to take a survey together. If you have the time, we could do that now. Otherwise, what days and times would work with your schedule?

Again, thank you so much for joining the study. Over the next few months, always free to contact me if you have any questions about the study, how to access GogyUp Reader, etc..

IMPORTANT: Assign the participant a study number and note the assignment in the candidate's record in the JotForm database and whether to follow up.

You will need the participant's study number for the GogyUp training.

15.6 STEP 6: BASELINE ASSESSMENT AND PROCEDURES

Notes:

- A participant's ability to follow through and keep the baseline assessment appointment may indicate whether the participant will remain active or become inactive.
- For participants in the control group, education materials should be mailed once the baseline assessment is confirmed. Ideally, the follow-up appointment should be confirmed as well.
- For participants in either group who miss their baseline assessment appointment, at least three attempts (which can be a mix of voice call / voicemail and SMS messages) should be made to contact and reschedule.
- For participants in the intervention (GogyUp Reader) group, data plan reimbursement should be made available only after the baseline assessment has been completed and a follow-up appointment has been confirmed.
    - If a participant mentions they do not have internet access or an internet-enabled device, notify GogyUp's administrative assistant to provision a tablet for the participant.
- After the baseline assessment is complete, follow the script for onboarding participants in the intervention group.

15.6.1 1 Day Baseline Assessment – SMS Appointment Reminder

Hi, this is [your name] – the GogyUp Research Coordinator.

I'm looking forward to taking the survey together on [APPOINTMENT DATE AND TIME]. *We're planning to meet* [Online / Over the phone].

If the participant signed up for an online meeting, text the link. Otherwise confirm you'll call them at this phone number.

Here is the link for us to meet: [ZOOM LINK].

Record each contact attempt must in the participant's database record.

15.6.2 Script for Baseline Assessment - Phone or Online Meeting

If the baseline assessment appointment is schedule as a phone meeting:

Hello. This is [YOUR NAME] FROM GogyUp. Is [NAME OF PARTICIPANT] available?

Wait for confirmation that you at speaking with the participant.

I am calling to take our GogyUp / University of Minnesota Type 2 Diabetes survey with you. Is this still a good time?

Wait for confirmation that participant is ready, then explain why we're administering the assessment.

Great! Ok – the reason why we're taking this questionnaire now is to establish every participant's current understanding of health and diabetes.

Before we begin, do you have any questions for me about the survey or the study?

Answer any questions that the participant has, referring to the Study Disclosure Document as necessary.

Questions that cannot be addressed by the Study Disclosure Document should be forwarded to the Primary Investigators.

If you're meeting via Zoom, display the JotForm Baseline Assessment form and administer the Health Literacy Questionnaire (HLQ) and Baseline Demographic Questions according to the directions in the JotForm form. Record participant score in the JotForm form. Add any other notable questions asked to the comments area in the participant's database area.

15.6.3 Both Groups – Confirm Follow-Up Appointment and Schedule Follow-Up Assessment

Make every effort to schedule and confirm their follow-up assessment appointment. Display the scheduling page to provide 3 to 4 options for the participant to choose from.

We have scheduled our follow-up call for [TIME and DATE of APPOINTMENT]. Is that still convenient?

15.6.4 For Intervention Group (GogyUp Reader) Participants

If participant is in the GogyUp Reader group, explain the first gift card to reimburse network access will be mailed in the next day or so. Confirm the mailing address.

If the participant requested to use a tablet, explain that it should arrive in a few days and confirm that the mailing address can securely receive packages.

Lastly, I want to make sure we have the best address to send the [TABLET / DATA PLAN REIMBURSEMENT / DIABETES HEALTH MATERIALS] to you. I have [PROVIDE THE PARTICIPANT'S ADDRESS] – is that the correct location to send it?

Thank the participant for their time. Note interactions, questions, and appointments in the participant's database record.

15.6.5 For Control Group (Paper Documents) Participants

If participant is in the control group, confirm the mailing address to receive the packet of materials.

Lastly, I want to make sure we have the best address to send the DIABETES HEALTH MATERIALS to you. I have [PROVIDE THE PARTICIPANT'S ADDRESS] – is that the correct location to send it?

Thank the participant for their time. Note interactions, questions, and appointments in the participant's database record.

15.6.6 Missed Base Appointment Scripts and Procedure

If a participant misses a baseline appointment and is unresponsive to three contact attempts (mix of voice mail and SMS messages) sent in intervals of 2 days between messages, then mark the participant as "inactive" and move to enroll another candidate.

If another candidate is identified and attends the baseline appointment, then mark the inactive candidate as "replaced" in the participant database.

15.6.6.1 VOICEMAIL SCRIPT: MISSED BASELINE APPOINTMENT

Hi, this is [YOUR NAME] from GogyUp. I'm calling to leave a message for [NAME OF PARTICIPANT].

*[NAME OF PARTICIPANT], please call or text me when you have a moment at [**612-208-3078***

]. That's 6 … 1 … 2 …2 …ZERO…8….3…ZERO….7….8

Record each contact attempt and outcome in the comments area of the participant's database record.

15.6.6.2 SMS SCRIPT: MISSED BASELINE APPOINTMENT

Hi [NAME OF PARTICIPANT]! This is [YOUR NAME] from GogyUp. We were going to meet [TIME AND DAY OF MEETING]. When would be a good day and time to reschedule?

Record each contact attempt and outcome in the comments area of the participant's database record.

15.6.7 Intervention Group – Onboarding for GogyUP Reader

After the baseline assessment is completed, display the quick start guide (see section 15.7.2) and ask if the participant is ready to try GogyUp Reader.

If the participant does not have the time or access to an internet-connected device, explain that they will receive a quick start guide with their network access reimbursement. If they would like help with accessing the app, they are always welcomed to contact the research coordinators.

If the participant is ready and available, walk through these steps.

1) Point to step 1 in the Quick Start Guide and point out that the GogyUp Reader can be used on any Android or iOS device – or on a PC with a Chrome or Edge web browser.
2) Ask the participant which device they plan to use and verify they are able to find the GogyUp Reader on their device's app store (or through their browser).
3) Point to step 2 and state that the next step is to fill out a GogyUp profile. This information is used to sync progress so that if they want to use GogyUp on another device, they can.
    a. Note that they don't have to use their real name.
    b. For the **UserName** they should use their assigned **Study Number.**
4) Point to step 3 in the Guide and note that if the participant has a preferred language other than english, they may select from the options to have an individual word translated into that preferred language.
5) Point to step 4 and emphasize that the participant should put in "**ninr1"** in the invite code box – this is needed so that the participant has access to the content library for the study.
6) Guide the participant to tap "Save profile" and then point out the different features in the app:
    a. **Points A&B** in the Guide's Features section: Touch any word to launch the "word menu"
        i. Request that the word be spoken, defined, or translated.
        ii. Point out the "hear sentence" button if the participant wants the entire sentence spoken.
        iii. Note that some words will have a "practice" button – this is a quick, optional spelling activity and isn't related to the study.
    b. **Point C:** Demonstrate how the EZText button can instantly re-format the text so that it fits better on smaller screens and enables individuals to focus on individual words and phrases. Point out how the participant can increase the font size.
7) Point out how to close the "x" in the upper right to go back out to the page where the participant can access the help menu and get technical support.

15.7 STEP 7: PROVISION PARTICIPANT

Following completion of the baseline assessment, provisioning participants will be dependent on the group each is enrolled in.

Depending on the participant's assignment, send one of the following via postal mail:

- **Control Group**: the set of education materials and welcome letter.
- **Intervention Group - Network Access:** the $25 gift card to cover their network expense and instructions for downloading and signing-in to the GogyUp Reader app.
- **Intervention Group - Tablet:** If the participant requested a tablet, instructions for powering on the tablet and accessing the materials in the GogyUp Reader app. Accessing GogyUp on the tablet will be a "one click" experience – the GogyUp app and GogyUp account required to access the materials will be pre-provisioned with the end-user's information.

Depending on IRB guidance, each participant's provider will also be sent an enrollment notification via postal mail.

15.7.1 INTERVENTION GROUP – WELCOME LETTER

GOGYUP
Removing barriers to understanding.

Medical School | Public Health | NIH NINR

Street Address 1
Street Address 2
City, State Zip

[DATE]

Welcome to the study!

In this envelope, please find:

- the $25 gift card to help cover network costs
- "How to Use GogyUp Reader" quick start guide.

Please remember to use GogyUp Reader a few days each week to review information about diabetes.

If you need help with GogyUp Reader or have questions about the study, contact our research coordinator:

- Phone / Text: 612-208-3078
- eMail: research@gogyup.com

You can also review study information here: gogyup.com/study

Your follow-up assessment is scheduled for **{followupAssessmentDate}** at **{followupAssessmentTime}**. If you need to change it, please call the research coordinator: 612-208-3078

Remember, the information in GogyUp Reader does not replace the information you receive from your doctor or clinic. ***If you have questions about diabetes or your health, contact your doctor or clinic.***

Sincerely,
The GogyUp Study Team

encl.

15.7.2 Intervention Group – GogyUp Reader Quick Start Sheet

This information sheet will be included with the welcome letter sent to study participants enrolled in the intervention (GogyUp Reader) group. This is meant as a supplement to the brief training provided by the research coordinator.

15.7.3 Intervention Group - Tablet

If the participant requests to use a GogyUp-provided tablet, follow this procedure:

1. Connect with GogyUp Admin Assistant for tablet to be drop-shipped to participant.
2. Note tablet shipped date and serial number in participant's Study Database record.
3. Share estimated arrival date with participant via text and/or email:

15.7.3.1 Shipment Notification SMS / eMail

Hi, this is [your name] – GogyUp's Research Coordinator.

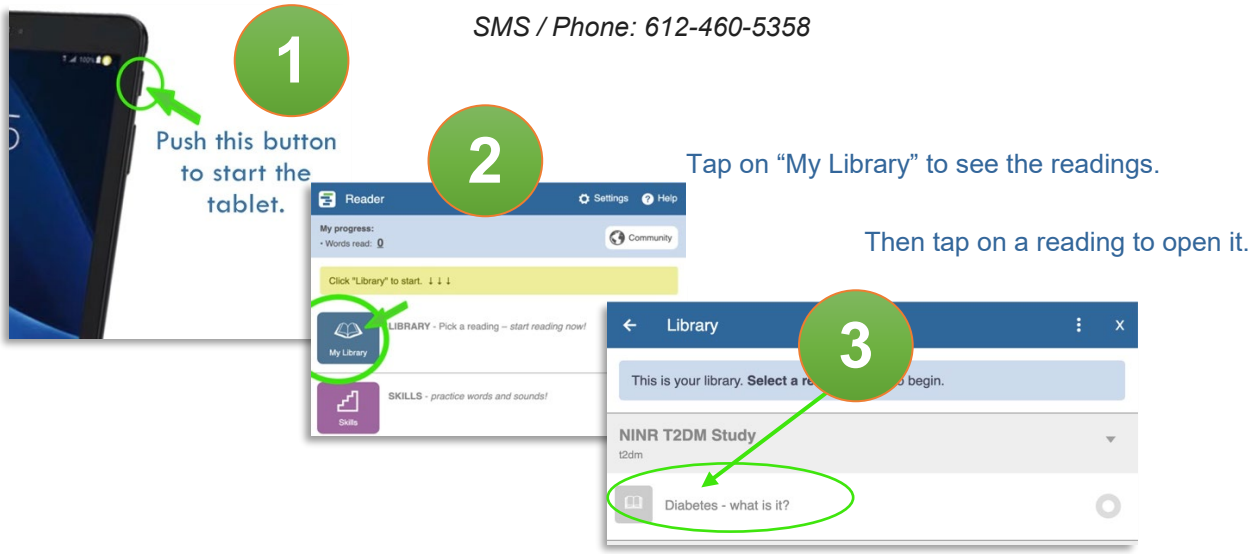
The tablet should arrive on [ARRIVAL DATE AND TIME].

Please text / call / or email me when you receive it and have turned it on.

The tablet will be already configured to launch GogyUp – all you should need to do is turn it on! Of course, please contact me or contact me or GogyUp's technical support if you need help:

eMail: support@gogyup.com

SMS / Phone: 612-460-5358



15.7.4 CONTROL GROUP – WELCOME LETTER

Use the following letter template to mail the hardcopy reading materials to study participants in the control group.

GOGYUP
Removing barriers to understanding.

Medical School | Public Health | NIH NINR

Street Address 1
Street Address 2
City, State Zip

[DATE]

Welcome to the study!

Here are your diabetes reading materials! Please feel free to review them over the next 12 weeks.

If you have questions about the study, contact our research coordinator:

- Phone / Text: 612-208-3078
- eMail: research@gogyup.com.

You can also review study information here: gogyup.com/study

Your follow-up assessment is scheduled for **{followupAssessmentDate}** at **{followupAssessmentTime}**. If you need to change it, please call the research coordinator: 612-208-3078

Remember, the information in GogyUp Reader does not replace the information you receive from your doctor or clinic. ***If you have questions about diabetes or your health, contact your doctor or clinic.***

Sincerely,
The GogyUp Study Team

encl.

15.7.5 Enrollment Notification to Provider

Should either Institutional Review Board require it, the following notice will be sent to the participant's provider indicated on the intake form.

GOGYUP
Removing barriers to understanding.

Medical School | Public Health | NIH NINR

Dr. #### #####
c/o Clinic
Street Address 1
Street Address 2
City, State Zip

[DATE]

RE: Enrollment in Clinical Trial NCT05337306

Dear [NAME OF CLINICIAN],

I am writing to notify you that your patient, [PARTICPANT NAME], has enrolled in a clinical trial managed by GogyUp Inc, the University of Minnesota School of Public Health and the School of Medicine.

Enclosed is the consent form [PARTICPANT NAME] completed. Please place this letter and consent form in the patient's medical file.

If you would like to learn more about the study, please visit gogyup.com/study or contact me directly: ned.zb@gogyup.com

Sincerely,

Ned Zimmerman-Bence
Project Principal Investigator
CEO, GogyUp
612-460-5358
ned.zb@gogyup.com

encl.

15.8 Step 8: Follow-Up Assessment

Notes:

- If a participant misses a follow-up assessment appointment, make at least three attempts (which can be a mix of voice call / voicemail and SMS messages) to contact and reschedule.
- Participants in the control (non-intervention) group will complete both the HLQ and the Perceived Diabetes Self-Management Scale (PDSMS).
- Participants in the intervention (GogyUp Reader) group will complete the HLQ, PDSMS, and User Experience Questions.

15.8.1 1 Day SMS Appointment Reminder - Follow-Up Assessment

Hi, this is [your name] – the GogyUp Research Coordinator.

I'm looking forward to taking the survey together on [APPOINTMENT DATE AND TIME]. *We're planning to meet* [Online / Over the phone].

If the participant signed up for an online meeting, text the link. Otherwise confirm you'll call them at this phone number.

Here is the link for us to meet: [ZOOM LINK].

Record each contact attempt must in the participant's database record.

15.8.2 Script for Follow-Up Assessment - Phone or Online Meeting

If the follow-up assessment appointment is schedule as a phone meeting:

Hello. This is [YOUR NAME] FROM GogyUp. Is [NAME OF PARTICIPANT] available?

Wait for confirmation that you at speaking with the participant.

I am calling to take our GogyUp / University of Minnesota Type 2 Diabetes survey with you. Is this still a good time?

Wait for confirmation that participant is ready, then explain why we're administering the assessment.

Great! Before we begin, do you have any questions for me about the survey or the study?

Answer questions that the participant has, referring to the Online Disclosure Document as necessary.

Display the JotForm assessment.

Administer the HLQ and PDSMS according to directions posted on the JotForm site.

For participants in the intervention group, administer the User Experience Questions after the HLQ and PDSMS. Record participant scores using the online form. If the participant asks additional questions or provides additional feedback, record in the comments area of the participant's database record.

15.8.3 Missed Follow-Up Appointment Scripts and Procedure

If a participant misses a follow-up appointment and is unresponsive to three contact attempts (mix of voice mail and SMS messages) sent in intervals of 2 days between messages, then mark the participant as "inactive" and move to enroll another candidate.

If another candidate is identified and attends the follow-up appointment, then mark the inactive candidate as "replaced" in the participant database.

15.8.3.1.1.1 Voicemail Script: Missed FOLLOW-UP Appointment

Hi, this is [YOUR NAME] from GogyUp. I'm calling to leave a message for [NAME OF PARTICIPANT].

*[NAME OF PARTICIPANT], please call or text me when you have a moment at [**612-208-3078***

]. That's 6 … 1 … 2 …2 …ZERO…8….3…ZERO….7….8

Record each contact attempt and outcome in the comments area of the participant's database record.

15.8.4 SMS Script: Missed FOLLOW-UP Appointment

Hi [NAME OF PARTICIPANT]! This is [YOUR NAME] from GogyUp. We were going to meet [TIME AND DAY OF MEETING]. When would be a good day and time to reschedule?

Record each contact attempt and outcome in the comments area of the participant's database record.

15.9 Baseline and Follow-Up Assessments

The majority of the Baseline and Follow-Up Assessments is the 44 question Health Literacy Questionnaire (HLQ) divided into 2 sections. Each assessment will begin with a landing page (sample below) to help orient the participant. Following the landing page, the participant will be presented with each section of the HLQ. The research coordinator will read each HLQ question and record the participant's response.

The Baseline Assessment also has a demographic that serves a few purposes:

1) Capture important information that may have dissuaded candidates from initially enrolling (e.g., gender, age, preferred language, etc.) but would allow the team to compare any intervention effect across different sub-groups.
2) Pilot a question concerning whether GogyUp impacts a participant's confidence in using a smartphone or tablet to learn new health information.
3) In addition to the HLQ, the Follow-Up Assessment includes the Perceived Diabetes Self-Management Scale (PSDMS) and 14 questions to capture end-user Gather information about the user experience for GogyUp's development team (administered to the GogyUp Reader group only).

15.9.1 Assessment Landing Page

Both the Baseline and Follow-Up Assessment pages will be as follows:

Figure 8: Baseline Assessment Landing Page

15.9.2 HLQ Text – Part One

Part 1 of the questionnaire starts here

Please indicate how strongly you **disagree** or **agree** with each of the following statements. Remember to check only **one** box for each statement.

Check a box by crossing it like this: ☒

		Strongly disagree	Disagree	Agree	Strongly agree
1	I feel I have good information about health	☐	☐	☐	☐
2	I have at least one healthcare provider who knows me well	☐	☐	☐	☐
3	I can get access to several people who understand and support me	☐	☐	☐	☐
4	I compare health information from different sources	☐	☐	☐	☐
5	When I feel ill, the people around me really understand what I am going through	☐	☐	☐	☐
6	I spend quite a lot of time actively managing my health	☐	☐	☐	☐
7	When I see new information about health, I check up on whether it is true or not	☐	☐	☐	☐

Part 1 continued
Please indicate how strongly you disagree or agree with each of the following statements. Remember to check only **one** box for each statement.

		Strongly disagree	Disagree	Agree	Strongly agree
8	I have at least one healthcare provider I can discuss my health problems with	☐	☐	☐	☐
9	I make plans for what I need to do to be healthy	☐	☐	☐	☐
10	I have enough information to help me deal with my health problems	☐	☐	☐	☐
11	If I need help, I have plenty of people I can rely on	☐	☐	☐	☐
12	I always compare health information from different sources and decide what is best for me	☐	☐	☐	☐
13	Despite other things in my life, I make time to be healthy	☐	☐	☐	☐
14	I am sure I have all the information I need to manage my health effectively	☐	☐	☐	☐
15	I have at least one person who can come to medical appointments with me	☐	☐	☐	☐
16	I know how to find out if the health information I receive is right or not	☐	☐	☐	☐
17	I have the healthcare providers I need to help me work out what I need to do	☐	☐	☐	☐
18	I set my own goals about health and fitness	☐	☐	☐	☐
19	I have strong support from family or friends	☐	☐	☐	☐
20	I ask healthcare providers about the quality of the health information I find	☐	☐	☐	☐
21	There are things that I do regularly to make myself more healthy	☐	☐	☐	☐
22	I can rely on at least one healthcare provider	☐	☐	☐	☐
23	I have all the information I need to look after my health	☐	☐	☐	☐

15.9.3 HLQ TEXT – PART TWO

Part 2 of the questionnaire starts here
Please indicate how difficult or easy the following tasks are for you now. Remember to check only one box for each statement.

Check a box by crossing it like this: ☒

		Cannot do or always difficult	Usually difficult	Sometimes difficult	Usually easy	Always easy
1	Find the right health care	☐	☐	☐	☐	☐
2	Make sure that healthcare providers understand your problems properly	☐	☐	☐	☐	☐
3	Find information about health problems	☐	☐	☐	☐	☐
4	Feel able to discuss your health concerns with a healthcare provider	☐	☐	☐	☐	☐
5	Confidently fill medical forms in the correct way	☐	☐	☐	☐	☐
6	Find health information from several different places	☐	☐	☐	☐	☐
7	Have good discussions about your health with doctors	☐	☐	☐	☐	☐
8	Get to see the healthcare providers you need to	☐	☐	☐	☐	☐
9	Accurately follow instructions from healthcare providers	☐	☐	☐	☐	☐
10	Get information about health so you are up to date with the best information	☐	☐	☐	☐	☐
11	Decide which healthcare provider you need to see	☐	☐	☐	☐	☐
12	Read and understand written health information	☐	☐	☐	☐	☐
13	Make sure you find the right place to get the health care you need	☐	☐	☐	☐	☐

Part 2 continued
Please indicate how **difficult** or **easy** the following tasks are for you now. Remember to check only **one** box for each statement.

		Cannot do or always difficult	Usually difficult	Sometimes difficult	Usually easy	Always easy
14	Get health information in words you understand	☐	☐	☐	☐	☐
15	Discuss things with healthcare providers until you understand all you need to	☐	☐	☐	☐	☐
16	Find out which healthcare services you are entitled to	☐	☐	☐	☐	☐
17	Read and understand all the information on medication labels	☐	☐	☐	☐	☐
18	Get health information by yourself	☐	☐	☐	☐	☐
19	Work out what the best care is for you	☐	☐	☐	☐	☐
20	Ask healthcare providers questions to get the health information you need	☐	☐	☐	☐	☐
21	Understand what healthcare providers are asking you to do	☐	☐	☐	☐	☐

15.9.4 BASELINE: DEMOGRAPHIC QUESTIONS

1) Birth month and year: ___/___/ _____

2) Which gender do you identify with?

□ Female □ Male
□ Non-binary
□ Prefer to self-describe:
□ Prefer to not answer.

3) In which country were you born?
_____

4) What is your current zip code?
_____

5) Which language do you most often use at home?

c English
c Spanish
c Somali
c Hmong
c Vietnamese
c Arabic
c Other (Please specify)

6) How do you most often access the internet?

c Smartphone with a cellular network.
c Smartphone with Wi-Fi
c Tablet with Wi-Fi
c Laptop or desktop with Wi-Fi
c Laptop or desktop and a dial-up telephone line
c Other: (Please specify)
c I don't have access to the internet

7) How confident are you using a smartphone or tablet to learn new information?

c Very confident
c Fairly confident
c Somewhat confident
c Slightly confident
c Not at all confident

8) Please indicate your highest level of education. (Check only **one** box):

c Less than 8 years
c 8 through 11 years
c High school diploma
c GED / Adult Diploma
c 2-year technical degree
c 4-year college degree
c Postgraduate degree (Masters or PhD)

15.9.5 Follow-Up: Perceived Diabetes Self-Management Scale (PSDMS)

INSTRUCTIONS: This is a questionnaire designed to determine how well you, yourself, feel you manage your diabetes. Each item is a belief statement with which you may agree or disagree. Next to each statement is a scale which ranges from strongly disagree to strongly agree. Please respond to each of the following items by choosing one number for each statement. Try to respond to each statement separately in your mind from each other statement. Choose your responses thoughtfully and make them as true FOR YOU as you can. Please respond to every statement.

1. It is difficult for me to find effective solutions for problems that occur with managing my diabetes.
   - c Strongly disagree
   - c Disagree
   - c Neutral
   - c Agree
   - c Strongly agree

2. It is difficult for me to find effective solutions for problems that occur with managing my diabetes.
   - c Strongly disagree
   - c Disagree
   - c Neutral
   - c Agree
   - c Strongly agree

3. I handle myself well with respect to my diabetes.
   - c Strongly disagree
   - c Disagree
   - c Neutral
   - c Agree
   - c Strongly agree

4. I am able to manage things related to my diabetes as well as most other people.
   - c Strongly disagree
   - c Disagree
   - c Neutral
   - c Agree
   - c Strongly agree

5. I succeed in the projects I undertake to manage my diabetes.
   - c Strongly disagree
   - c Disagree
   - c Neutral
   - c Agree
   - c Strongly agree

6. Typically, my plans for managing my diabetes don’t work out well.
   - c Strongly disagree
   - c Disagree
   - c Neutral
   - c Agree
   - c Strongly agree

7. No matter how hard I try, managing my diabetes doesn't turn out the way I would like.
   - c Strongly disagree
   - c Disagree
   - c Neutral
   - c Agree
   - c Strongly agree

8. I'm generally able to accomplish my goals with respect to managing my diabetes.
   - c Strongly disagree
   - c Disagree
   - c Neutral
   - c Agree
   - c Strongly agree

15.9.6 Follow-Up: User Experience Questions (Intervention Group Only): Likert

1) I am confident using a smartphone or tablet to learn new information.
   - c Strongly disagree
   - c Disagree
   - c Neutral
   - c Agree
   - c Strongly Agree

2) The app is easy to use.
   - c Strongly disagree
   - c Disagree
   - c Neutral
   - c Agree
   - c Strongly agree

3) It is easy to navigate within the app.
   - c Strongly disagree
   - c Disagree
   - c Neutral
   - c Agree
   - c Strongly agree

4) The information on the app is credible.
   - c Strongly disagree
   - c Disagree
   - c Neutral
   - c Agree
   - c Strongly agree

5) The information on the app is trustworthy.
   - c Strongly disagree
   - c Disagree
   - c Neutral
   - c Agree
   - c Strongly agree

6) How likely are you to recommend this app to a friend or family member?
   - c Strongly disagree
   - c Disagree
   - c Neutral
   - c Agree
   - c Strongly agree

7) I will likely use the app in the future.
   - c Strongly disagree
   - c Disagree
   - c Neutral
   - c Agree
   - c Strongly agree

8) I find the app to be attractive.
   - c Strongly disagree
   - c Disagree
   - c Neutral
   - c Agree
   - c Strongly agree

9) The app has a clean and simple presentation.
   - c Strongly disagree
   - c Disagree
   - c Neutral
   - c Agree
   - c Strongly agree

15.9.7 Follow-Up: User Experience Questions (Intervention Group Only): Open Ended

1) Describe what you like most about the app and why.

2) Describe what you found frustrating and why.

3) Describe what your primary motivation might be for downloading the app.

4) What features did you frequently use on the app?

5) Under what circumstances would you continue to the app?

15.10 Diabetes Education Materials

All diabetes materials will be sources from the Center for Disease Control's Fact Sheets, English editions, available at:
https://www.cdc.gov/diabetes/library/factsheets.html#managing

The materials will include:

About Diabetes/General Information

- At A Glance 2018
- Diabetes and Prediabetes Fact Sheet

Complications

- Take Charge of Your Diabetes: Your Medicines
- What You Need to Know About Diabetes and Adult Vaccines
- Take Charge of Your Diabetes: Healthy Eyes
- Take Charge of Your Diabetes: Healthy Feet
- Take Charge of Your Diabetes: Healthy Teeth
- Take Charge of Your Diabetes: Healthy Ears
- Diabetes and Hepatitis B Vaccination
- Smoking and Diabetes
- Take Care of Your Kidneys and They will Take Care of You

Lifestyle

- Choosing Healthy Foods on Holidays and Special Occasions
- Tips for Eating Healthy with Diabetes
- Tips for Being Active with Diabetes

Managing Diabetes

- Steps to Help You Stay Healthy With Diabetes
- 5 Questions to Ask Your Health Care Team

- Managing Diabetes: Medicare Coverage and Resources

4. REFERENCES

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