Study Protocol

Project PEACH^2 (Promoting Engagement and COVID-19 Testing for Health)

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PROTOCOL TITLE: Project PEACH^2 (Promoting Engagement and COVID-19 Testing for Health)

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REVISION HISTORY

Revision #	Version Date	Summary of Changes
V1.1	8/14/2023	Information about Data Transfer Agreement with DCRI included. Data Transfer agreement is pending.
V1.1	8/14/2023	Page 1: Clarifies that external collaborators' (MSM & GIT) respective IRBs will be also review the study.
V1.1	8/14/2023	Section 12; Page 10: Vulnerable Populations. A statement including pregnant women in the study has been added.
V1.1	8/14/2023	Section 14; Page 11: Information about recruitment materials and eligibility screening has been added to Section 14.
V1.1	8/14/2023	Section 18; Page 12: Compensation to Participants has been clarified.
V1.1	8/14/2023	Section 19; page 14: Reviewed participantId and left it as-is as it refers to a unique participant identifier that will be created in the nudge database and is defined in the description. "phoneNumber"and "firstName" have been updated to "phone number" and "first name" for readability.
V1.1	8/14/2023	Section 23; Page 15: Informed Consent: Section clarified to read that potential participants may opt to be contacted about participating in an interview and/or to contribute their social media data.
V1.1	8/14/2023	Section 24; Page 15: Non-English-speaking participants: Clarified to include why non-English speaking participants will not be included.
V1.1	8/14/2023	Section 24; Page 16: Waiver of documentation of consent required.
V1.1	8/14/2023	Section 26: Multi-site description
V1.2	10/3/2023	Modification of eligibility screening process to take place before informed consent.

V1.3	10/11/2023	Removed Institution "institution's IRB will review" for MSM and GT Partners
V1.3	10/11/2023	Updated Section 26 to clarify partner/site activities.
V1.3	10/11/2023	Updated sections 6, 18, 19, 20 to clarify social media study participant engagement, data upload, analysis and anonymization processes, storage and protections.
V1.4	1/19/2023	Section 14, Recruitment Methods has been updated to describe new screening of potential participants to limit fraudulent enrollment.
V1.5	3/25/2024	Section 26 has been updated to clarify that Grady Health System / Grady Diabetes Clinic is a location for study promotion via flyers and palm cards.
V1.5	3/25/2024	Section 14, #3 has been updated to include addition of a text message check (receive and respond) during the eligibility interview to ensure a valid text message.
V1.6	4/26/2024	Section 14, Recruitment, has been updated to include the use of lists of participants from other RADxUP studies who agreed to be contacted about other studies they might be interested in.

Table of Contents

1. Study Summary

Study Title	PEACH [2]: Promoting Engagement and COVID-19 Testing for Health
Study Design	A mixed methods community-based, adaptive intervention trial with quantitative and qualitative evaluation components.
Primary Objective	Understand the feasibility, acceptability and sustainability of COVID-19 home testing for high-risk individuals affected by or at risk for diabetes and their household contacts.
Secondary Objective(s)	Test the applicability of a text-based COVID-19 test result reporting system and targeted behavioral nudges for disease prevention in a pandemic situation
Research Intervention(s)/Interactions	Qualitative in-depth interviews; survey questionnaires; text-based test result submission; testing of behavioral nudges via text messages; modeling of news and social media posts
Study Population	Underserved populations in urban and rural Georgia affected by or at-risk for diabetes
Sample Size	N=600
Study Duration for individual participants	12 months
Study Specific Abbreviations/ Definitions	Application Programming Interface (API) Database (DB) Emory Global Diabetes Research Center (EGDRC) Emory University (EU) Federally Qualified Health Center (FQHC) Georgia Center for Diabetes Translation Research (GCDTR) Georgia Institute of Technology (GT) Morehouse School of Medicine (MSM) Prevention Research Center (PRC) Promoting Engagement and COVID-19 Testing for Health (PEACH) Protected Health Information (PHI)

	Rollins School of Public Health (RSPH)
Funding Source (if any)	NIDDK

2. Objectives

The objectives and specific aims are:

Objective 1: Understand the feasibility, acceptability, and sustainability of at-home testing as well as the perceived advantages and disadvantages of home-based testing compared to clinic-based testing among the high-risk population of individuals affected by or at risk for diabetes.

Objective 2: Test the application of behavioral nudges to change behaviors around disease prevention in a pandemic situation. The study team will design and evaluate in a community-based, adaptive intervention study among individuals affected by diabetes (with diabetes, at risk for diabetes, or caring for someone with diabetes), a home-based COVID-19 testing program with behavioral nudges delivered via mobile phone texts to increase uptake of COVID-19 testing and prevention behaviors (vaccination, social distancing, masking, etc.)

Aim 1: Using mixed methods (continued analysis of the Project PEACH study population, qualitative interviews, modeling of news and social media posts, social media data analytics), we will describe the current climate around home testing for COVID-19 including current usage, views, interest, acceptability, and barriers and facilitators to adoption.

Aim 2a: Evaluate uptake, usage, and views of a home testing nudge platform (encouraging home testing, protective health behaviors, and targeted behavioral nudges delivered via text messages) in a community-based, adaptive intervention trial (N=600) targeting individuals affected by diabetes through collaborations with community partner sites (faith- and community-based organizations, Grady Diabetes Clinic, and COVID-19 community testing and vaccine distribution sites).

Aim 2b: Evaluate changes in vaccine uptake and hesitancy among study participants and family members after implementation of the home-based testing nudge platform.

3. Background

This study leverages data collected during Project PEACH 1 (Promoting Engagement and COVID-19 Testing for Health), a RADx-UP funded study to understand barriers to effective and equitable COVID-19 testing in high-risk and minority populations in Georgia that are affected by diabetes. PEACH 1 applied mixed-methods (quantitative, qualitative, geographic and spatial analysis) to gather evidence to describe COVID-19 epidemiology, locate regions and populations with low testing and vaccine uptake, and targeting key informant interviewing and monitoring social and news media, to identify barriers, motivators, and perceptions around COVID-19 as well as related behaviors among different populations and regions.

Analysis of Project PEACH (PEACH 1) data collected from key informants and community partners indicated gaps in capacity for and commitment to community testing when vaccines became available, and sites were pivoting to prioritize vaccinations even as they continued to provide COVID-19 testing. However, COVID-19 testing can be a key tool to address the pandemic, particularly in areas with low vaccination rates[1] and high diabetes rates[2-4] such as Georgia. People with diabetes, prediabetes, and obesity have elevated risk for COVID-19 infection and are 3.5 times, 2.6 times, and 3 times more likely to suffer in-hospital complications, respectively.[5-7] Further, Diabetes is 2.4 times more common in socioeconomically vulnerable and minority populations. Throughout the pandemic, counties with predominantly Black communities had a 6-fold COVID-19 death rate compared to those that are predominantly White.[8] For these reasons, finding sustainable, easy to disseminate, and acceptable ways to increase and sustain COVID-19 testing is needed. Further, understanding the relationship between attitudes toward testing in situations of continued vaccine hesitancy and resistance and developing insights in how to address them in a dynamic pandemic situation will be fundamental to future pandemic response.

Home-based testing may help people overcome barriers to testing (identifying where to get tested, scheduling and attending appointments, stigma).[9] However, in order for it to be successful we need to understand the feasibility, acceptability, and sustainability of at-home testing as well as the perceived advantages and disadvantages of home-based testing compared to clinic-based testing among the high-risk population of individuals affected by or at risk for diabetes. This information can be used to create targeted behavioral "nudges".[10] Nudges are indirect suggestions and positive reinforcements designed to encourage certain choices. They may be a useful means of promoting acceptability and usage of home-based testing as well as increasing an understanding of and acceptability of other key preventive behaviors like COVID-19 vaccination. These targeted messages, sent via text messages, would be designed based on findings from PEACH 1 and the Georgia CEAL Study (1OT2HL156812-01/16-312-0217571-66105L). Behavioral nudges have been shown to have a noticeable effect on health behaviors and study recruitment,[11,12] however, research testing the application of behavioral nudges relating to behavior change around disease prevention in a pandemic situation is needed.

4. Study Endpoints

Aim 1 Endpoint: Development of a suite of behavioral nudges text message designed to inform (Knowledge) and encourage (Persuade) study participants to perform COVID-19 testing at home or at other locations (primary behavior change focus) and other COVID-19 prevention activities (masking when needed, vaccination/boosters, etc.). Persuasive messaging will address perceived characteristics of COVID-19 testing and home-based testing (relative advantage, compatibility, complexity, trialability, observability) and be adapted to subgroups such as vaccination status and demographic data provided in the baseline survey.

Aim 2a Endpoint: Evaluation of uptake, usage, and perception of a community-based, adaptive intervention trial targeting individuals affected by diabetes through collaborations with community partner sites. The intervention entails reporting of COVID-19 testing via a text-based reporting system and targeted behavioral nudges delivered via text messages.

Aim 2b: Evaluation of changes in vaccine uptake and hesitancy among study participants and family members post-implementation of the home-based testing platform as well as acceptability of nudges to affect behavior change.

5. Study Intervention/Design

PEACH ^{2} is a community-based, mixed methods, randomized, adaptive intervention trial, targeting individuals affected by diabetes. Study participants will be randomized into the PEACH^2 Intervention Arm or the Control Arm (*See Figure 1 below*). Participants may also opt to participate in an in-depth interview at the end of the intervention and/or to contribute social media data (see descriptions below).

All participants will be asked to complete surveys at baseline and again post intervention at Months 4 and end of follow-up at month 12. T The intervention period will last 16 weeks. Baseline surveys will capture demographic data, history of COVID-19, diabetes and diabetes risk factors, views about COVID-19 risk factors and preventive behaviors, and experiences with COVID-19 testing; follow-up surveys at 4 and 12 months will collect information on intervention acceptability, COVID-19 testing, prevention, and vaccine behaviors and views from all participants.

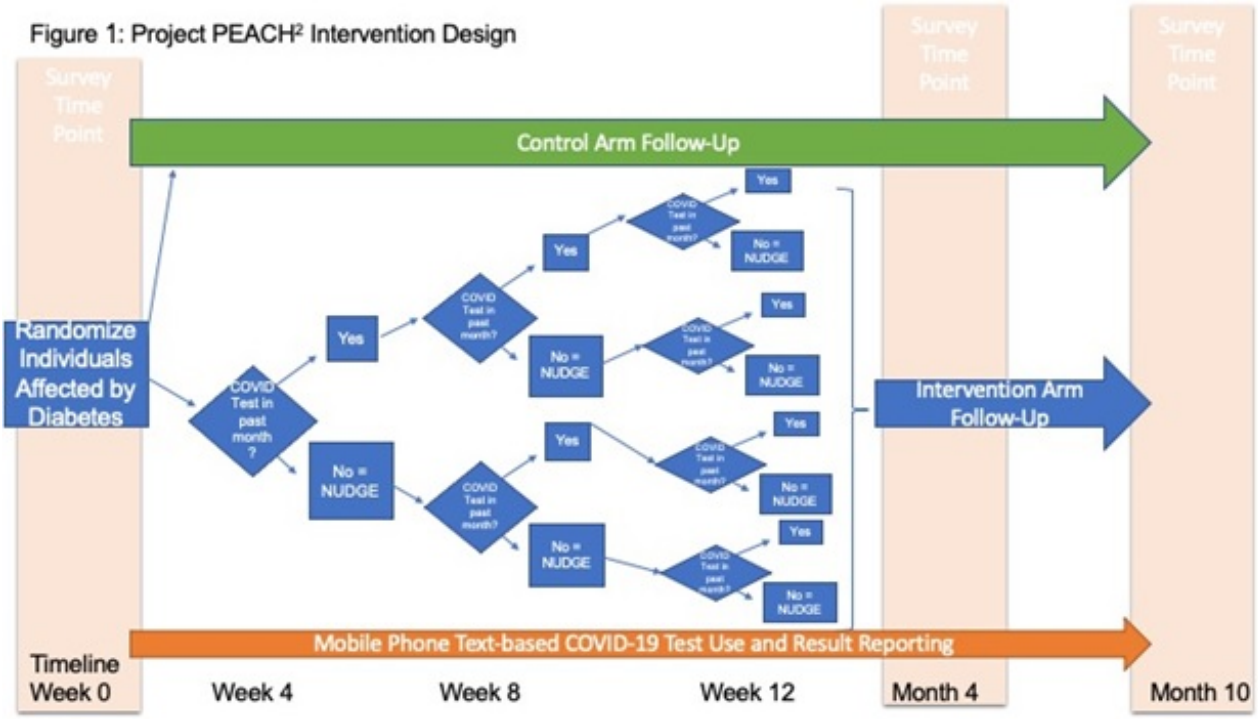
PEACH ^{2} Intervention Participants: Intervention arm and control arm participants will be sent weekly text messages throughout the intervention period. Control arm participants will receive messages with general diabetes prevention/management information including messages on COVID-19 prevention, but these messages will not be tailored to the participant.

Intervention arm participants will receive weekly text messages with behavioral nudges targeted to their demographic and vaccination group targeting COVID-19 prevention behaviors. Results of qualitative interviews, social media reporting, and feedback from community partners from Project PEACH will be analyzed and used to draft group specific nudges for testing and other prevention behaviors. In weeks 4, 8, and 12, participants will be sent a series of text messages to determine if:

1. They had any COVID-19 symptoms in the past 4 weeks; and, if so:
2. They did a COVID test.

Following the adaptive intervention design (Figure 1), at weeks 4, 8 and 12 participants who report COVID-19 symptoms but no COVID-19 testing will receive targeted behavioral nudges via mobile phone text message that will encourage adherence to COVID-19 testing recommendations. Behavioral nudges targeting other COVID-19 preventive behaviors such as

staying home when sick, wearing a mask, etc. will be sent to all PEACH^2 Intervention participants in weeks 1-3, 5-7 and 9-11.



In-depth Interviews

From among all study participants, a sub-sample of 30 information-rich participants (10 control, 20 intervention) will be invited to participate in in-depth interviews to understand participant perceptions of the intervention and text messages as well as topics important for future testing or dissemination efforts (e.g., suggestions for other ways to deliver these health messages).

Social Media Analytics

As a stream of data analysis to inform the nudge intervention, the Georgia Tech team plans to conduct social media analytics. We will use two forms of social media data: data collected from publicly accessible posts and data collected from participants. This data will be stored on the Georgia Tech server (described below in Section 18).

Publicly Accessible Social Media Data

We will be downloading publicly accessible posts from X (formerly Twitter), Facebook, and Instagram using the respective platforms' APIs. Publicly accessible posts containing COVID testing-related keywords, along with the posts' publicly accessible metadata including timestamp and engagement metrics, will be downloaded for a curated set of accounts on each platform. These accounts, in addition to having technically publicly accessible content, are also generally "public" facing accounts, such as those of government agencies, community-based organizations, media and other companies, prominent influencers, and public online groups. Data will be downloaded prior to the intervention, dating back to May 2021 to match the

beginning of survey data being used to inform this study; data collection will be continued throughout the period of the intervention. Analyses will include natural language processing techniques such as topic modeling and sentiment analysis and analyzing trends in engagement data. Reporting will involve sharing aggregate statistics, as well as example individual posts.

Participant Social Media Data Contribution
Participants will have the option to contribute additionally to the study by sharing their own social media data with the study. We will focus on the following data from participants' Facebook, Instagram, and X (Twitter) accounts: the accounts, pages, and groups they follow; other accounts' content that they have engaged with; and their own posted content related to COVID-19 and health. Social media data collected from participants will be used to inform our collection and analysis of publicly available social media data (described above) as well as additional analysis of participants' social media engagement and posted content. This will allow us to better curate our data collection to include accounts followed and engaged with by our participants as well as analyze what kinds of social media accounts and content different demographics of participants follow and engage with. For participant social media content (i.e., their own posts on social media), we will use state-of-the-art natural language processing techniques, such as sentiment analysis and word embeddings, and other metadata like post length to reduce such data to key pieces of metadata for analysis.

6. Procedures Involved

Study participants in PEACH [2] will be asked to complete baseline surveys as well as follow-up surveys at completion of the intervention period (Month 4) and again at Month 12, about their experiences and perceptions of COVID-19 testing and vaccination. Survey data will be captured using REDCap. Selected participants that agree to be contacted on their informed consent form may also be invited to participate in semi-structured interviews. These will be conducted over a secure Zoom account. Semi-structured in-depth interviews will explore acceptability and experiences with the text messaging program.

Participants will also be asked if they are willing to contribute data from their social media posts (detailed methods below). Those that are willing will receive an automated link from REDCap with additional information about participation in the social media part of the study as well as an informed consent form specific to that part of the study. Participants will be given the option to share or not share data from the different platforms they use; their consent for this social media data collection will have no implications for their participation in the rest of the study.

Participant social media data contribution
Data we collect about study participants' social media accounts and activity will be retrospective and limited. Data would be collected at two time points: once towards the start of the intervention period and once after the end.

Social media data to be collected includes:

1. *Other accounts that they follow:*

- Facebook: "Pages" and "Groups" which the participant follows. (This does NOT include the participant's Facebook "Friends.")
- Instagram: Accounts which the participant follows.
- X (Twitter): Accounts which the participant follows.

2. *Their engagement with content from other accounts:*
   - Facebook: "Reactions" to others' posts (including "likes"), comments by the participant's account on others' posts
   - Instagram: "Likes" of others' posts and stories, comments by the participant's account on others' posts
   - X (Twitter): "Likes" of others' tweets

3. *Content that they themselves posted related to COVID-19 and health:*
   - Facebook: Posts
   - Instagram: Posts and stories (text captions only)
   - X (Twitter): Tweets and retweets
   - These will be filtered to content that contains any COVID-19 and health related keywords:
     - COVID-related keywords: covid, coronavirus, corona, rona, omicron, vaccine, vacunas, vax, vaccinated, vxxed, unvxxed, pandemic, pandemia, masks, n95, quarantine, booster, pcr, antigen, binax, binaxnow.
     - Health-related keywords: We will use the "body" and "health" category keywords in LIWC (Linguistic Inquiry and Word Count) 2015, a labeled set of words which is popularly used for textual analysis. These two categories contain a total of 509 words.

To remove possible personally identifying information in any of the above social media data that includes text content, such as posts and comments, we will use a named entity recognition algorithm to remove and auto-delete mentions of any usernames (which appears as "@username"), and mentions of people's names.

The following data will be removed, auto-deleted and will NOT be stored or analyzed for this study: social media account username, multimedia (photos, videos) from participants' own social media content, device identifiers, geotag of posts, login and logout or any other platform access and time use metadata, and private messages (i.e., Facebook/Instagram Messenger or X (formerly Twitter) direct messages).

7. Data Specimen Banking

No specimens will be banked.

8. Sharing of Results with Participants

Results of the nudging trial will be shared with collaborating partners through in-person meetings, feedback sessions and presentations, and with participants through an end-of-study newsletter.

9. Study Timelines

The duration of time an individual will be asked to participate in the study will be approximately 12 months, from completion of baseline survey through enrollment and randomization, participation in the nudge intervention trial and follow-up surveys and interviews.

10. Inclusion and Exclusion Criteria

Inclusion criteria: English speaking adults, at or over the age of 18, living in Georgia, with access to a cellphone, not currently pregnant, and at-risk for diabetes, have diabetes, or are a family caregiver of someone living with diabetes. Participants must agree to receive text messages and be randomized to the intervention or control arm of the study.

Exclusion Criteria: Individuals that do not meet the inclusion criteria or are unwilling to receive text messages or be randomized will not be eligible.

11. Population

The study population for Project PEACH^2 will be recruited in both urban and rural areas of Georgia to capture inherent diversity in geographic and population characteristic backgrounds which may affect differences in response to COVID-19 risk, attitude, barriers, and testing strategies in the area.

12. Vulnerable Populations

Participants must be able to use a cellphone to receive nudge messages. Therefore, prisoners, adults unable to consent, and children under the age of 18 will not be included in the study. Pregnant women with or at risk for diabetes need different and specific advice and therefore would require specific health messaging that is targeted to pregnant women, and is out of the scope of this study. Pregnant women will not be included.

13. Local Number of Participants

Six hundred (n=600) participants will be recruited to participate in the study, and randomly assigned to participate in the intervention and control groups. Randomization will be done using a random allocation table created in SAS. Study participants that indicate they would be willing to participate in an interview will comprise the qualitative interview sampling frame. From total study sample, up to thirty in-depth interviews will be conducted with information rich individuals from the Control (N=10) and PEACH^2 Intervention (N=30) arms. Interview participants will be purposively selected based on data collected in the baseline survey. Demographics, vaccination status, prior experience with COVID-19 and testing, and testing reporting will be considered when compiling the contact list for interview.

The sample size of 600 was estimated using the following assumptions: (a) 80% power; (b) Alpha of 0.05; and (c) the percentage of participants receiving a COVID-19 test in the past month in the control arm would be equal to the percentage of the Georgia population getting a PCR test for COVID-19 in the month of June: 3.44 (standard deviation [SD] 0.49). Using these assumptions, a sample size of 520 (260 per study arm) will be powered to see a 4.5% increase in the percentage of individuals receiving COVID-19 test in the intervention arm compared to controls. We plan to randomize 600 individuals to allow for attrition.

Social media analysis enrollment

Given the complexity of the data download and upload process for participants to complete, we anticipate a significant amount of attrition. Thus, we will conduct individual phone call follow-ups with a selected subset of participants who had consented to being contacted about sharing their social media data for the study, but have not at that time completed the social media data contribution process. As we are conducting this data collection as a proof-of-concept, participants chosen for individual follow-up would be sampled (out of those who indicated use of a social media platform of interest) to cover different demographic groups and other characteristics that are represented by the broader participant pool, and from both the control and intervention arms. We aim to conduct individual follow-up with up to 50 participants.

14. Recruitment Methods

Emory, MSM and GT will leverage their existing relationships with community organizations and partners. Specific partner organizations include faith-based organizations (Big Miller Grove Baptist Church, Elizabeth Baptist Church), a community-based organization (Rx MTM), and a diabetes clinic (Grady Diabetes Center), and other Emory RADxUP studies. These partners have experience conducting COVID-19 testing activities and/or will be of assistance in recruitment. Informational materials such as palm cards, flyers and posters with eligibility information and a QR code that links to the study website will be disseminated through study partners. Participants will be recruited at in-person events, and via the Project PEACH studies website (www.projectpeach.org).

Due to several attempts of fraud when data collection began, the study team has added layers of authentication screening that intend to help to identify fraudulent attempts by incentive miners utilizing bots and AI. These include hidden questions in REDCap that capture timestamps and location, and qualitative questions that are visible to bots but hidden from a person. These include:

1. Completion of a short consent to be contacted form that asks for first and last name, cellphone number and email address in REDCap.

    a. This form will capture the timestamps of the machine that opens the survey and the Emory server for comparison, as well as the latitude and longitude, if allowed.

b. The potential participant's information will be searched in the Project PEACH database to identify any overlap in participants or reuse of information.

c. The participants information will be searched for online. Any information pertaining to someone with the same name or phone number, will be noted and used to compare to what the individual says to the interviewer.

2. Those determined most likely to be genuine potential participants and eligible to participate will be emailed a link to complete the eligibility screener.

3. An eligibility interview over Zoom will be scheduled with participants that complete the form. The team member will review key points of the study (timeframe; what is involved), informed consent, discuss what is involved, and ask questions relating to the information found on their identity. This will be used to help determine if the individual is eligible to participate prior to officially initiating the study. The individual will also be asked to verbally provide a cell-phone number, we will text them and ask them to respond. This will be done to ensure that a) we have a valid cellphone number for them, and 2) the number we have is correct.

4. If determined to be eligible, the individual will be emailed a link to complete the informed consent in REDCap; if they agree to participate, they will receive the link to take the baseline survey and officially enroll in the study.

Data on those deemed not eligible will be captured and used in the authenticity screening (Step 1.b above) of future participants.

Participants may request to be contacted by a study team member who can conduct the informed consent, answer any additional questions and ensure that the potential participant is both eligible and understands what the study entails.

For each part of the study (text message nudge study/surveys; social media, in-depth interview), all potential participants that would like to join the study and participate will be asked to indicate their agreement to participate in the study by entering their name and contact information at the bottom of the informed consent survey form. They will be advised that checking "yes" to statements about being contacted by a study team member for information about the survey, and that they agree to participate indicates that they choose to participate.

We will also contact individuals that self-report being at risk for diabetes and have participated in other RADxUP studies, and agreed in their informed consent form to be contacted about other studies they might be interested in. Study team members will contact them via email or text message according to their indicated preference advising them about the study and directing them to the website for more information and to complete the contact form if they are interested.

Withdrawal of Participants

A participant may withdraw at any time by contacting the study team at the phone number or email address provided on the consent form. Any data collected up to the point of withdrawal will be retained and the individual will not be contacted again unless they agreed on the original consent form to be contacted about future research opportunities.

15. Risk to Participants

Risks to participants include the possibility someone could gain access to study participant survey, social media and/or interview data. Survey and interview data will be carefully controlled and maintained on a secure HIPAA compliant, EU OneDrive account or RSPH IT server folder. Limited participant data to be used for the text message nudges and participant social media data will be housed on the Georgia Tech server. Only team members designated by the study or site PI, that have completed the necessary ethics trainings (CITI certification), and are included on the EU and/or partner IRB will be given access to the survey data. Survey data and informed consent will be collected from participants and stored using REDCap.

Qualitative data: Similar to survey data, qualitative interview data will be carefully controlled and maintained on a secure, HIPAA compliant, One Drive account and as above, only study team members designated by the PI and involved in data collection, management or analysis will have access to the folders. Interviews will be conducted and recorded using a secure EU Zoom account.

Text messages: Participants will be advised that there is a risk that someone that has access to their phone might learn of their participation via SMS messages to their device. Participants will be asked to help protect their data and ensure the integrity of the data by not sharing the text messages we send them with others and not allowing others to view the messages.

Social media data sharing: Risks to participants include the possibility someone could gain access to participant social media data, which may include identifying information or private content. To mitigate these risks, as described (in Section 18), we are collecting and keeping participant social media data in a secure environment, and conducting further social media data sub-selection and anonymization to minimize the potential sensitivity of the data we go on to analyze. Furthermore, by having the participants download their social media account data themselves from the social media platforms before sharing it with us, we hope the data sharing process and content of the data shared will be more transparent to participants.

16. Potential Benefits to Participants

While there is no direct benefit to subjects who participate in the study, information gained from their participation in the study may be used to develop resources that could support them in the event of a future pandemic. Further, data shared with the community partners might be used to improve COVID-19 education and testing at their respective sites.

17. Compensation to Participants

Study participants will receive e-gift cards via email for their time and participation. Survey participants will receive $25 after they complete the baseline survey, $35 after they complete the 4-month survey, and $40 after they complete the 12-month survey. Those that participate in an interview will receive a $25 gift card for their participation after the interview. Participants contributing their data to the social media component will receive a $40 gift card after the upload has been completed.

18. Data Analysis, Management and Confidentiality

Informed consent and survey data will be collected using and stored in REDCap. REDCap will assign a unique project ID number to participants when they complete informed consent. In-depth interview and survey questionnaire data will be collected from participants. In-depth interview data collection will be conducted in-person, over Zoom or phone (according to the participant's preferences) and stored on EU's OneDrive. Any personally identifiable information will be removed from data sets and interview transcripts prior to sharing with the study team for analysis. To enable follow-up, a file linking the name and project ID of participants will be available only to the project PI, study team members involved in data collection and management, and key co-investigators. To ensure data quality and participant eligibility, a respondent authentication protocol will be implemented for individuals not taking the survey with a study team member present. Only team members designated by the study PI, that have completed the necessary ethics trainings (CITI certification), and are included on the EU and/or partner IRB will be given access to the survey data.

Nudge Dashboard and Nudge Platform development

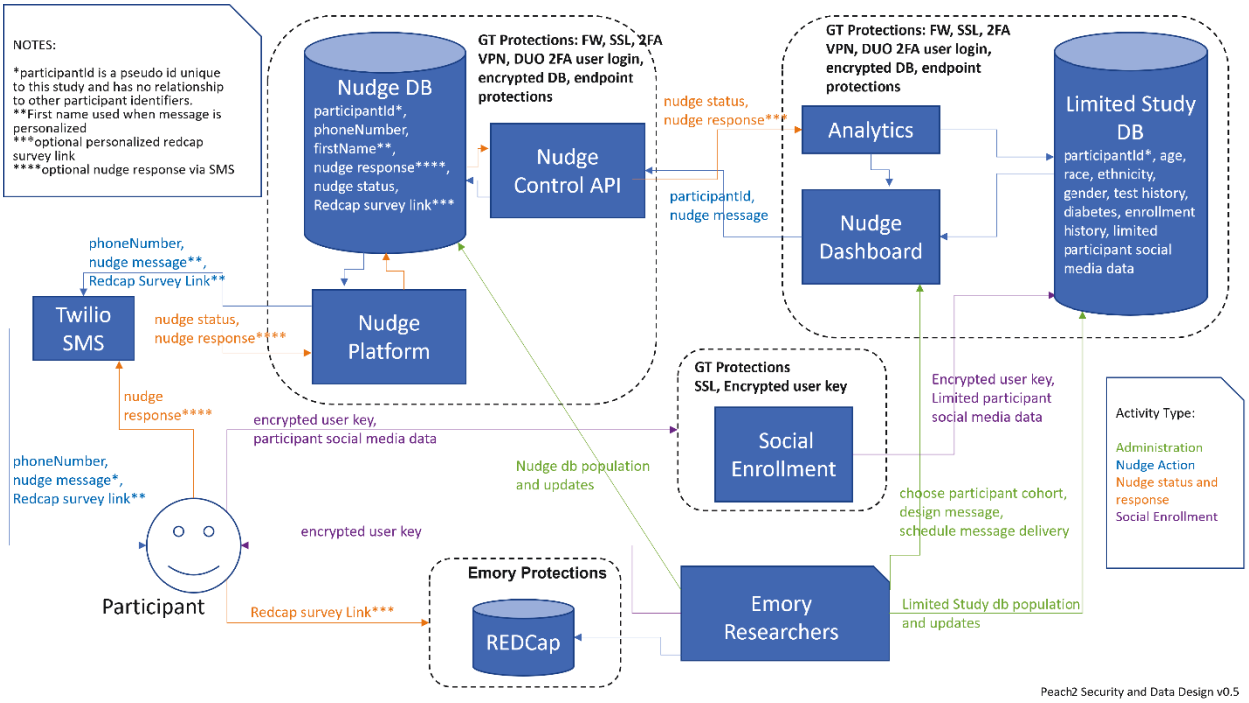


Figure 2. Security and data design for technical applications supporting the project

Participant survey data storage and handling

Georgia Tech is developing several technical applications for sending nudge messages, and will house limited participant data (described below) and de-identified, participant social media data in a Limited Study Database. This database will be maintained separately from the Nudge Database and the social media collection and analytics platform. The Georgia Tech Team is developing the Nudge Dashboard. The dashboard will be available for users among the study team to select nudges to send to study participants and also view (aggregated) analysis results. This Nudge Dashboard will then send these participant-nudge message assignments to the Nudge Platform via the Nudge Control API, which will handle sending these as SMS messages to the participants (*See Figure 2 above*).

Participant survey data will be exported by a member of the study team with access to REDCap and uploaded via HTTPS via 2-Factor VPN to one of two databases which support the Dashboard and the Nudge Platform. This export will include a "participantId", which is a pseudo ID unique to this study and has no relationship to other participant identifiers.

The Limited Study Database (DB) will be maintained separately from both the social media data collection and analytics platform, and from the Nudge Database (DB) to minimize risks and control access. The Limited Study DB used by the Dashboard will contain the participantId, age in years, race, ethnicity, gender, testing history, vaccine status, diabetes status, study enrollment status and history; if provided, participant social media account and activity data will be maintained in the Limited Study Database following collection and anonymization. The Nudge DB will contain the participantId, cell phone number, first name, nudge response, nudge status, and an optional REDCap survey link.

The Nudge Platform will only be accessible via the Dashboard. The Dashboard will implement role-based access controls to limit who is able to send nudge messages to approved study staff. Operators of the Dashboard will have access to nudge responses and the status of a nudge message, but no operator will have direct access to the participant phone numbers, first name, or personalized survey link (if used). Nudges will be delivered to users via the Twilio SMS text messaging platform using secure communications. Nudge responses will be delivered via secure callbacks to the Nudge Platform via Twilio.

Should the study include social media data collection from participants, this will be collected via a secure website using a non-reversible encrypted user key which can only be mapped to the participantId (or other information) in the Limited Study DB. Both the Nudge Dashboard and Platform will be developed and maintained by the Georgia Tech study team. Access will be restricted to select members of the study team. All access to the Dashboard by EU, MSM or GT will require a Georgia Tech account or guest account, sponsored by the GT sub-award Co-PI. Access will require the use of 2-Factor authentication to a VPN and 2-Factor authentication to the web Dashboard. No public access will be possible. The Nudge Platform will only support access via the Dashboard. Certificate-based authentication for all transactions with the Nudge

Platform by the study team and participants will be required and logged. This includes authorized Dashboard users. All data will be encrypted "at rest" and "in flight" (over the network). Georgia Tech endpoint security protections will be used for hosts used for the Nudge Dashboard and Nudge Platform. Endpoint protections include a secure Linux-based host (patched monthly), a network firewall restricting access to the GT 2-FA VPN, Antivirus and intrusion detection tools installed locally, Georgia Tech authentication restricted to appropriate personnel, regular backups, and host firewalls with "deny by default" polices enabled.

Participant social media data storage and handling

The participant social media data portal website will be hosted on a Georgia Tech server, the uploaded file will be encrypted by the upload process. The encrypted file will be moved inside Georgia Tech's dedicated protected health data infrastructure (PHDI) environment, where the decryption and any processing of the files participants upload through the portal website will be handled prior to sending processed, limited participant social media data to the limited study database. All communication between the external facing portion of the portal (i.e., what the participants will directly access via the internet) and the server will be over secure protocols.

The social media account data that participants will receive from their social media platforms are in the format of a .zip file, with multiple sub-files containing different types of social media account data. Upon the participant uploading a file on the social media portal website, the portal will first automatically check that participants have uploaded a correct file format (i.e., a .zip file that has a structure that matches what we would expect for a Facebook, Instagram, or X/Twitter account data file). If the file uploaded by the participant is not of the correct format, we will immediately automatically delete the file, and notify the participant through the social media data portal website that their file was not the correct format and has been deleted. If the file is the correct format, we will then automatically delete any sub-files that do not contain data of interest to us (including data like private direct messages, account profile information, photo and video media associated with posts, device information, login timestamps, etc.). Then, we will automatically do further processing and deletion of irrelevant data, namely to delete participants' posts that are not related to COVID-19 or health, and remove username and persons' names mentions.

The resulting participant social media data will be stored in the Limited Study Database, which will be carefully controlled and maintained on a secure HIPAA compliant environment, on the Georgia Tech server. Team members designated by the study PI, that have completed the necessary ethics trainings (CITI certification), and are included on the EU and/or partner IRB will be given access to the survey data only. Social media data contribution survey data and informed consent will be collected from participants and stored using REDCap.

Social Media Data analysis and usage

Participants' social media data will be used to inform our collection and analysis of publicly available social media data (described elsewhere in the protocol), as well as additional analysis of participants' social media engagement and posted content. For our analysis of publicly available social media data, we will be able to better curate our data collection to include accounts followed and engaged with by our participants, as well as analyze what kinds of social media accounts and content different demographics of participants follow and engage with. For participant social media content (i.e., their own posts on social media), we will use state-of-the-art natural language processing techniques, such as sentiment analysis and word embeddings, and other metadata like post length to reduce such data to key pieces of metadata for analysis. This will inform us about how our participants post and share online about health-related topics, for example what kind of health-related topics they engage with the most and the language they use online when doing so, which can in turn inform how we choose to write nudge messages for the study.

There are no international sites.

19. Provisions to Monitor the Data to Ensure the Safety of Participants

This study poses minimal risk to participants.

20. Provisions to Protect the Privacy Interest of Participants

Participants will have the option to participate in the study or not as they choose. They will have the option of opting to be contacted to participate in other studies if they are interested. During the informed consent process, potential participants will be made aware of possible discomforts, who is able to access their information, and what kind of information they can access, how we plan to maintain their confidentiality, and the measures in place to protect their data. Potential study participants will have the opportunity to ask questions before they agree to participate in the study as well as other interactions (interviews, sharing social media data).

Personal identifiable data will be maintained on EU's REDCap account, in a dedicated, password protected OneDrive account, or as detailed above, limited personal identifiable information will be stored on the Georgia Tech server.

Social media data contribution

Those agreeing to contribute their social media data will be asked to provide their downloaded social media data to the study team as described above in Sections 14 and 18. For those that consent to participate provide their social media data, a unique identifier will be created when data is shared with the study team (See #19, Figure 2: Security and data design for technical applications supporting the project).

Data will be preserved through the end of the project, or until the period of time stipulated by the funding agency. No data will be maintained in medical records.

21. Economic Burden to Participants

There are not costs to participants related to their participation in the study.

22. Informed Consent

Individuals expressing interest in the study will be directed to the study site to complete an e-consent form. When conducting onsite recruitment, a study team member that is trained in conducting informed consent and is registered on the study IRB may be available to read through the informed consent form with the potential participant. In this case, the consent process will be performed in a private location, and any questions the participant has will addressed.

Optional additional participation: Participants will be asked in the informed consent in-take questionnaire, if they would be willing to participate in an interview as a part of the study as well as to contribute their social media data. Participants are not required to be interviewed or contribute their social media data to participate in the study. During the informed consent, they will have the option to agree to be contacted about participating in an interview and/or to be contacted about contributing their social media data.

Before each interview, a trained interviewer will review the consent document with the participant and obtain verbal consent for both the interview and recording of the discussion.

Participant social media consent and contact

During the baseline survey, participants will be asked whether they consent to being contacted about sharing their social media data for the study. Those who indicated that they are willing, and also indicated on the baseline survey that they use at least one of Facebook, Instagram, or X (Twitter), will receive an automated email and link from REDCap with additional information about participation in the social media part of the study as well as an informed consent form specific to that part of the study if they decide to contribute their social media data. Participants' consent for this social media data contribution would have no implications for their participation in the rest of the study.

Non-English-Speaking Participants

Non-English-speaking participants will not be included in the study due to funding limitations.

Cognitively Impaired Adults

No cognitively impaired adults will be eligible for inclusion in the study.

Adults Unable to Consent

Participants that cannot provide consent will not be eligible for inclusion in the study.

Waiver or Alteration of Consent Process

A waiver of alteration of the consent process will be required. In lieu of a signed informed consent form, at the end of the Informed Consent form, the following information will be included:

e-Consent

By checking "yes" in the boxes at the end of this form, you consent to take part in those parts of the study. If you have any questions about anything in this document, please contact the study team by sending an email to radxup@emory.edu or calling 470-289-6178. You may also contact Dr. Mary Beth Weber or the Emory IRB Review Board at the contact numbers above.

First and last name _____

Email address _____

Mobile phone number _____

1) Do you agree to take part in the study?	☐Yes	☐No
2) Are you willing to be contacted about other studies that might be of interest to you?	☐Yes	☐No
3) Are you willing to be contacted to participate in an interview about the study?	☐Yes	☐No
4) Are you willing to be contacted about sharing your social media data with the study team?	☐Yes	☐No
5) Do you agree to let the Duke Clinical Research Institute (DCRI) collect information that can identify you, such as your name, address, contact information?	☐Yes	☐No
6) Do you agree to let the DCRI collect only your zip code and no other identifiable information?	☐Yes	☐No

Informed consent will be obtained, required information will not be disclosed and research does not involve deception. An encrypted copy of the form will be emailed to participants.

23. HIPAA

This study will not record identifiers from medical records of living or non-living subjects. A unique study identifier will be created when the participant completes the informed consent and enrolls in the study. PHI collected is self-reported data and will be used to assign the participant to a nudge group based on how they are affected by or at risk for diabetes. Identifiable study data will be maintained in the study's secure REDCap project database, which is password protected and HIPAA compliant and in Georgia Tech's Nudge Platform. Only authenticated study team members that have assigned user privileges will have access to PHI.

24. Setting

Potential participants will be recruited through existing EU, MSM and GT partnerships with community based (RX MTM) and faith-based organizations (Big Miller Grove Baptist Church, Elizabeth Baptist Church), Diabetes clinics (Grady Diabetes Center) and FQHCs that serve communities at risk across Georgia. Partners will promote the study at their sites via in-person presentations, flyers and distribution of palm cards, or to their patients (clients), and direct them to the study website to complete the e-informed consent and online eligibility and study enrollment forms. Those that enroll will agree and consent to utilize their own cellular devices

to receive behavioral nudge text messages and submit responses about whether they had COVID symptoms in the past 30 days (Y/N) and if they took a COVID-19 test (Y/N).

The study will continue the community advisory board (CAB) started during Project PEACH, which is comprised of members of the partner organizations, community investigators, and local stakeholders. Parter organizations involved in Project PEACH, but not PEACH2, will be informed that they can choose to continue in an advisory role or leave the group as they wish. Any new community organizations that join the study team will have a member seated on the CAB. Members of partner organizations will not be involved in recruitment beyond the distribution of promotional information. Their participant-related contact will be limited to assisting participants to access the e-informed consent form.

25. Resources Available

Facilities: Emory University (EU), Georgia Institute of Technology (GT) and Morehouse School of Medicine (MSM) all house institutes and centers that engage with or include the other partner institutions. The PEACH ^{2} study PIs and team members are members of the **Georgia Center for Diabetes Translation Research (GCDTR)** with PIs (EU: Weber, Narayan MSM: Quarrels; GT: Best) also serving on or leading the GCDTR Cores (Design and Evaluation; Engagement and Behavior Change; Disparities; Enrichment Program). GCDTR Cores afford access to subject area expertise relevant to the study, including diabetes and related risk factor epidemiology, biostatistics, engineering, and demography. Other EU, GT, MSM collaborations and centers provide a rich pool of subject matter expertise and community partners that can be leveraged for this project. The Georgia Institute of Technology team members are also members of the **GT Institute for People and Technology** and **GT Center for Health and Humanitarian Systems**. The MSM team members are PIs and key investigators of the **Georgia CEAL**, the **GCTSA Community Engagement (CE) Program** and the **MSM Prevention Research Center (PRC)**. Further, each institution is involved in other RADx projects, such as The Atlanta Center for Microsystems Engineered Point-of-Care Technologies (ACME POCT)'s Rapid Acceleration of Diagnostics (RADx) Validation Core (U54 EB027690-02S1) at EU, Children's Healthcare of Atlanta. GT assesses user needs for novel COVID-19 devices and evaluates point of care devices for performance (EU/GT).

Study Team: PEACH2 PIs and study team members began collaborating during Project PEACH and will utilize lessons learned and gaps identified through Project PEACH as well as leverage community partnerships and infrastructure for this study.

Sample Size: The sample size of 600 was estimated using the following assumptions: (a) 80% power; (b) Alpha of 0.05; and (c) the percentage of participants receiving a COVID-19 test in the past month in the control arm would be equal to the percentage of the Georgia population getting a PCR test for COVID-19 in the month of June: 3.44 (standard deviation [SD] 0.49). Using these assumptions, a sample size of 520 (260 per study arm) will be powered to see an 4.5%

increase in the percentage of individuals receiving COVID-19 in the intervention arm compared to controls. We plan to randomize 600 individuals to allow for attrition. In addition, given the rapidly changing status of COVID testing, we will employ a two-stage adaptive approach to recalculate sample size using first stage study data, as recommended by Brown and others for adaptive intervention studies.[13]

Medical or psychological resources: It is unlikely that study participants will require mental health support following participation in the study. Regardless, the study team will have a list of resources gathered from community partners to provide participants requesting help finding resources. There are no funds available to cover these services.

Research Team Preparation: The protocol and research procedures will be presented to study team members at partner institutions and organizations as they join the study team. SOPs that detail each activity (participant enrollment; survey data collection; qualitative data collection) will be reviewed with and available for the study team to follow. The study team will be organized into functional teams with scopes of work detailing functions for each role. Project coordinators will be responsible for ensuring team members on their teams are trained and understand the process, and for monitoring their work.

26. Multi-Site Research When Emory is the Lead Site

The total number of participants that will be recruited across the study is 600.

Study-wide Recruitment Methods/Participant Recruitment

Study partners (EU, GT, MSM) will utilize the same study recruitment methods as described in Section 14. All study partners will have access to copies of the most recent version of the protocol and study documents in SharePoint. Informed consent documents are available both in SharePoint and in REDCap at Emory. Relevant study team members (i.e., internal study team members; External Study Team List members whose roles include data collection) that will assist participants or conduct informed consent will have access to the most current documents in REDCap. All study team members involved in participant recruitment, performing informed consent, survey data collection and management, will undergo training.

Emory, MSM and GT will leverage their existing relationships with community organizations and partners for participant recruitment. Partner organizations include faith-based organizations (Big Miller Grove Baptist Church, Elizabeth Baptist Church), a community-based organization (Rx MTM), a diabetes clinic (Grady Diabetes Center) and Emory School of Medicine. These partners have experience conducting COVID-19 testing activities and/or diabetes care, treatment and/or prevention, and will help to disseminate the study among their communities to promote the study.

Grady Diabetes Clinic and Emory School of Medicine's involvement is limited to study promotion and will be limited to display of promotional materials (palm cards and flyers) in allowable patient areas and mention of the study to clients (patients) by providers. Individuals interested in participating will complete the online request for information form via the study website. No in-person study recruitment will take place.

Informational materials (palm cards, flyers, posters and promotional letters to community organizations with an interest in diabetes prevention and care) that contain study participation and eligibility information and a QR code that links to the study website will be disseminated through study partners. These have been co-developed by EU, MSM and GT study team members, with input from Community Investigators and Partners. These provide information about the study, what the study entails (complete 3 surveys at start, after 4 months, after 12 months; receive and respond to weekly text messages (16), participation in an optional interview, participation in an optional

Additionally, the Project PEACH study website (www.projectpeach.org) will be updated and refreshed to include detailed study information and eligibility criteria for PEACH2, with links to an eligibility screener. Participants will complete the online screener in REDCap; those eligible will continue to go on to complete the informed consent for the study online. Data on those not eligible will not be captured. Participants may also opt to be contacted by a study team member who can conduct the informed consent, answer any questions and ensure that the potential participant is both eligible and understands what the study entails.

No recruitment methods are not under control of the Lead site (EU).

Emory University's Activities:

Emory University is responsible for the overall coordination of the study, including weekly study team meetings, overseeing training of EU/MSM and GT study team members involved in study promotion and recruitment, and survey data and interview data collection. This includes consenting participants at in-person events and in-depth interviewing. Study survey data will be housed in an Emory REDCap Project; interview study data (audio-recordings, transcripts) will be collected by EU and MSM study team members and housed on Emory's server in a secure SharePoint Folder with restricted access to team members as described above in Section 18. Access to interview data will be controlled by the Emory study PI and Project Coordinators. Emory research staff will schedule and send weekly behavioral text message "nudges" via the Nudge Dashboard developed by and housed at GT. Together with PIs and study staff from GT and MSM, the EU team will develop, test and refine the survey questionnaires and interview guides. EU, MSM and GT team members will collaborate on data analysis, write up and dissemination of results. Emory staff and research assistants will provide support to study participants and cover the Google phone account and check the study's email box.

Georgia Institute of Technology's Activities

Georgia Tech is responsible for developing and maintaining the text message nudge platform and dashboard. GT will receive and upload limited participant and demographic data to the

platform. They will upload, process and store participate social media data. The GT team will conduct data analysis of publicly accessible data on social media platforms that provide health information, and participant social media data relating to diabetes, health, and COVID-19 and testing, which will contribute to an understanding of the kinds of information that people have access to and that they consume, and to inform the development of text message nudges. GT staff and research assistants will provide support to study participants interested in contributing their social media data to the study, and may provide additional support to the study team, including in-person recruitment at events, conducting qualitative interviews, covering the Google phone account and check the study's email box. EU, MSM and GT team members will collaborate on data analysis, write up and dissemination of results.

Morehouse School of Medicine's Activities

Morehouse School of Medicine's study team will be responsible for community partner engagement. This includes involving community investigators in the process of refining the survey questionnaire to ensure questions are relevant to the community as well as to ensure that questions are readable and easy to understand, the promotional materials are meaningful and relevant, and to promote the study. The MSM team will be engaged in study promotion, and recruitment, and survey data and interview data collection. This may include consenting participants at in-person events, assisting them to complete the baseline survey, and in-depth interviewing. EU, MSM and GT team members will collaborate on data analysis, write up and dissemination of results. MSM staff and research assistants will provide support to study participants and cover the Google phone account and check the study's email box.

Figure 3: Study Partner Activities	Emory University	Georgia Institute of Technology	Morehouse School of Medicine
Overall Study Coordination	X		
Study Enrollment/ Informed Consent/Data collection (EU lead)	X	X	X
Community Partner Engagement (MSM lead)	X	X	X
Interview Data Collection (EU lead)	X	X	X
Nudge Platform Development		X	
Upload of Limited Participant Data to Portal		X	
Nudge assignment, scheduling and push	X		
Social media data collection/Informed Consent		X	
Social media data analysis		X	
Upload of participant social media to database		X	
Monitoring of Google phone / E-mail box (EU lead)	X	X	X
Participant support	X	X	X
Data Management	X	X	
Data analysis, write-up, dissemination	X	X	X

Resolution of Disputes

The study team (Emory, Morehouse, Georgia Tech) meets bi-weekly to discuss progress and issues. All questions and/or issues are discussed and resolved as a group. If a reportable event were to occur, the event would be documented and reported as soon as identified. Study team members are expected to maintain participant confidentiality and adhere to the responsible conduct of research. The study team has cross-institutional functional teams. These teams have members from each institution, and are responsible for conducting the work of the study. These teams include study promotion and data collection, qualitative interviews, social media, and nudge development.

27. References

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28. Protocol Checklist

Please note that protocol sections with an asterisk (*) should always be included in the protocol; if the section does not have an asterisk, and you have not included the section in the protocol, the IRB will consider it your attestation that the section does not apply to your study.

Protocol Section	Added to the protocol ?
External Collaborators- if applicable, add each external collaborator information and indicate whether that institution's IRB will review (or has already reviewed) that individual's engagement in human participants research activities)	☒ **Yes**
Funding Source*: Include the information for the funding entity for this study. Please explain if this study is covered by a sub-award or other pertinent information. Say "department" if you do not have any other funding.	☒ **Yes**
Objectives*: Describe the purpose, specific aims, or objectives and state the hypotheses to be tested	☒ **Yes**
Background*: Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data. Provide the scientific or scholarly background for, the rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. Describe any relevant preliminary data or knowledge to be built upon in this study. Examples of issues to address are cultural expectations, political conditions, economic conditions, disease prevalence/incidence, environmental factors. Provide the scientific or scholarly background for, the rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. Include any other non-research rationale for the work, if this study is a mix of non-research and research	☒ **Yes**
Study Endpoints: Sample: provide some information about the data set that the research team will be analyzing.	☒ **Yes**
Study Intervention/Design*: Describe the study intervention that is being evaluated, and/or the nature of interactions proposed.	☒ **Yes**
Procedures involved*: Describe and explain the study design in more detail. Describe all research procedures being performed and when they are performed, including procedures being performed to monitor participants for safety or minimize risks. Procedures performed to lessen the probability or magnitude of risks.	☒ **Yes**
Procedures-Source Records*: The source records that will be used to collect data about participants. (Attach all surveys, scripts, and data collection forms in the smartform on the	☒ **Yes**

"Study-Related Documents" page under "Other Attachments." If unable to attach data collection instruments due to copyright requirements, include a description of the instrument in the protocol document	
Procedures-Data collection*: What data, specifically, will be collected during the study, and how that data will be obtained. If audio/video-recordings will be generated, describe processes for transcribing audio/video recordings. Will audio-recordings be destroyed after transcription? If so, how long after transcription? If not, how will they be kept secure? If video-recordings will be used beyond the current research procedures for educational/presentation purposes.	☒ **Yes**
Procedures- Long Term Follow Up*: If there are plans for long-term follow-up (once all research-related procedures are complete), what data will be collected during this period.	☒ **Yes**
Procedures-Deception: Does the research design require subjects to be deceived? Describe and justify the need for deception. Describe the plan to debrief participants after study participation is completed. Will the subjects be exposed to any stress? Describe and justify the need for stress.	☒ **Yes**
Data and Specimen Banking: If data or specimens will be banked for future use, describe where the data or specimens will be stored, how long they will be stored, how the data or specimens will be accessed, and who will have access to the data or specimens. List the data to be stored or associated with each specimen. Describe the procedures to release data or specimens, including the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.	☐ **Yes**
Sharing of Results with Participants*: Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with participants or others (e.g., the subject's primary care physicians) and if so, describe how the results will be shared.	☒ **Yes**
Study timelines*: Describe the duration of an individual subject's participation in the study, the duration anticipated to enroll all study participants, and the approximate total duration of the overall study	☒ **Yes**
Population and Inclusion/Exclusion Criteria*: Describe how individuals will be screened for eligibility; the criteria that define who will be included or excluded in your final study sample; and indicate specifically whether you will include or exclude each of the following special populations: • Adults unable to consent	☒ **Yes**

• Individuals who are not yet adults (infants, children, teenagers) • Pregnant women • Prisoners Note: you cannot exclude people with limited English proficiency unless you can demonstrate the scientific need for such exclusion. Community Participation: For studies aimed at addressing issues that affect a certain community or group: How, if at all, will this study involve people from the target community in the design of the study? Conduct of the study? How will the results of the research be shared with the participants and/or the target community/ies?	
Research with pregnant women, fetuses, or neonates: review this checklist to verify you have provided enough information to ensure the safety and well-being of this population.	☐ **Yes**
Research with neonates of uncertain viability: review this checklist to verify you have provided enough information to ensure the safety and well-being of this population.	☐ **Yes**
Research involving prisoners: review this checklist to verify you have provided enough information to ensure the safety and well-being of this population.	☐ **Yes**
Research involving children: review this checklist to verify you have provided enough information to ensure the safety and well-being of this population.	☐ **Yes**
Research involving cognitively impaired adults: review this checklist to verify you have provided enough information to ensure the safety and well-being of this population.	☐ **Yes**
Research involving economically or educationally disadvantaged persons: describe the additional safeguards that have been included in the study to protect the rights and welfare of these subjects	☐ **Yes**
Local Number of Participants*: Indicate the total number of participants to be accrued locally. If applicable, distinguish between the number of participants who are expected to be enrolled and screened, and the number of participants needed to complete the research procedures (i.e., numbers of participants excluding screen failures.) Provide your projected enrolling goals, including the percentage of participants according to sex and race.	☒ **Yes**
Recruitment Methods*: Describe when, where, and how potential participants will be recruited, who will make initial contact and how, and if physicians or staff refer participants. Describe the source of participants. Describe the methods that will be used to identify	☒ **Yes**

potential participants. Describe materials that will be used to recruit participants. (Attach copies of these documents in Smartform on the "Study-Related Documents" page under "Recruitment material templates." with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/videotape. You may submit the wording of the advertisement before taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/videotape.) How will eligibility be determined? Provide a detailed description of any eligibility screening done before enrolling the subject (including whether any identifiers will be recorded – note that IP address is an identifier). If recruiting online, describe how potential participants would be directed to your recruitment information and study description. If using contests or raffles as an incentive, you must offer entry to all potential participants, not just those who enroll in the study/complete study-related procedures, per Georgia State Law. If recruiting online, describe how potential participants would be directed to your recruitment information and study description. All research recruitment through social media needs to follow this guidance, which does not allow the use of personal social media accounts for some recruitment activities	
Withdrawal of Participants*: Describe anticipated circumstances under which participants will be withdrawn from the research without their consent. Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.	☒ **Yes**
Risk to Participants*: List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related to the participant's participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. Include risks of loss of privacy or breach of confidentiality. If applicable, indicate which procedures may have risks to the participants that are currently unforeseeable. If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant. If applicable, describe risks to others who are not participants. Do not state that there are no risks.	☒ **Yes**
Potential Benefits to Participants*: Describe the potential benefits that individual participants may experience Indicate if there is no direct benefit. Do not include benefits to society or others. Describe areas of knowledge that would be strengthened. Compensation should NOT be stated as a benefit.	☒ **Yes**

Compensation to Participants*: Describe if/how subjects will be compensated for participation in this study. Indicate what method compensation will be delivered (e.g. cash, gift card, school credit). Describe the amount and timing of any payments to participants. How much? What kind? Is tax information required? (if so, must be reflected in the informed consent form). Will payments be pro-rated if a participant withdraws early?	☒ **Yes**
Data Analysis, Management and Confidentiality*: Describe the data analysis plan, including any statistical procedures or power analysis. Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission. Describe any procedures that will be used for the quality control of collected data.	☒ **Yes**
Describe how data or specimens will be handled study-wide*: What information will be included in that data or associated with the specimens? • Where and how data or specimens will be stored? • How long the data or specimens will be stored? • Who will have access to the data or specimens? • Who is responsible for receipt or transmission of the data or specimens? • How data or specimens will be transported?	☒ **Yes**
Data Monitoring and Participants Safety ***(if this study is no more than minimal risk, this section is not required)*** • Ensure that you review our Data and Safety Monitoring plan guidance for specific details about this section, and examples of what the IRB will be requiring according to the level of risk. • If a DSMB is needed, please describe the composition of the board (if not already detailed in the protocol). Review this guidance for more information. If the sponsor protocol does not contain all required information, please in this section. • Describe the plan to periodically monitor the data at the site level, and if you have international sites. • Description of the plan for notifying the IRB of reportable events; whether the sponsor requires reporting above and beyond the Emory IRB reporting requirements, and if so, a description of the requirements and plan for meeting them. • Please address the specific details below. If deemed not applicable, please provide rationale: • Subject safety:	☒ **Yes**

○ Specific subject safety parameters ○ Frequency of subject safety observations ○ Individual responsible for safety monitoring ○ Subject stopping rules – under what conditions will a subject be removed from study participation and who will make the decision? ○ ○ Study stopping rules - under what conditions will the study be modified or stopped and who will make the decision? ○ Reporting mechanisms (i.e. Deviations, adverse events, UPs) • Data Integrity: ○ Specific data elements to be reviewed ○ Frequency of monitoring data, points in time, or after a specific number of participants ○ Individual responsible for data monitoring	
Provisions to Protect the Privacy Interests of Participants*: • Describe the steps that will be taken to protect participants' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact with or whom they provide personal information. • Describe what steps you will take to make the participants feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a participant might experience in response to questions, examinations, and procedures. • Indicate how the research team is permitted to access any sources of information about the participants.	☒ **Yes**
Economic Burden to Participants*: Describe any costs that participants may be responsible for because of participation in the research.	☒ **Yes**
Informed Consent*: Describe where the consent process will take place, any waiting period available between informing the prospective subject and obtaining the consent; and the process to ensure ongoing consent. Describe the role of the individuals listed in the application as being involved in the consent process; the time that will be devoted to the consent discussion; steps that will be taken to minimize the possibility of coercion or undue influence; and steps that will be taken to ensure the participants' understanding.	☒ **Yes**

Note: If you are planning to obtain consent via electronic signature, please review this document. Additional guidance on consent documentation and process can be found on our website, under the consent toolkit.	
Consent Process-Non-English-Speaking Participants*: Indicate what language(s) other than English are understood by prospective participants or representatives. If participants who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent. If you checked N/A, please provide reasoning of why subjects with limited English proficiency are excluded. **Note**: if you stated that subjects with LEP will be enrolled, you are approved for the use of the Emory IRB short forms. Please read the guidance about the use of short forms here.	☐ **Yes**
Consent Process-Children: After determining if the subject is a child per GA law (or if enrolled outside GA, per state/country law), please describe whether parental permission will be obtained from:	☐ **Yes**
• Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. • One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.	
Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.	
When assent of children is obtained describe whether and how it will be documented per Emory Policies and Procedures	
Consent Process-Cognitively Impaired Adults: describe the process to determine whether an individual is capable of consent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require children to sign assent documents.	☐ **Yes**
Consent Process-Adults Unable to Consent: List the individuals from whom permission will be obtained in the order of priority. (E.g., durable power of attorney for health care, a court-appointed guardian for health care decisions, spouse, and adult child.)	☐ **Yes**

For research conducted in the state, review "46 LEGALLY AUTHORIZED REPRESENTATIVES AND SURROGATE CONSENT" to be aware of which individuals in the state meet the definition of "legally authorized representative." For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. Describe the process for the assent of the participants. Indicate whether: • Assent will be required of all, some, or none of the participants. If some, indicated, which participants will be required to assent and which will not. • If assent will not be obtained from some or all participants, an explanation of why not. Describe whether the assent of the participants will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require participants to sign assent documents	
Waiver or Alteration of Consent and HIPAA authorization (consent will not be obtained, required information will not be disclosed, or the research involves deception) Review the Emory IRB waiver document to ensure you have provided sufficient information for the IRB to make these determinations. If the research involves a waiver of the consent process for planned emergency research, please review the Emory P&Ps, Chapter 48, WAIVERS OF, AND EXCEPTIONS FROM, INFORMED CONSENT FOR PLANNED EMERGENCY RESEARCH to ensure you have provided sufficient information for the IRB to make these determinations.	☒ **Yes**
Setting*: Describe the sites or locations where your research team will conduct the research including where the subject will be identified and recruited, where the research procedures will be performed, and if you will involve a community advisory board. For research conducted outside the organization and its affiliates describe the site-specific regulations or customs affecting the research outside the organization and the local scientific and ethical review structure outside the organization.	☒ **Yes**
Resources Available*: Describe the resources available to conduct the research such us the feasibility of recruiting the required number of suitable participants within the agreed recruitment period; describe the time that you will devote to conducting and completing the research; describe the availability of medical or psychological resources that participants might need as a result of an anticipated consequences of the human research; describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.	☒ **Yes**

Multi-Site Research when Emory is the Lead Site Study -Wide Number of Participants: indicate the total number of participants to be accrued across all sites. Study-Wide Recruitment Methods: If this is a multicenter study and participants will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Describe when, where, and how potential participants will be recruited. Describe the methods that will be used to identify potential participants. Describe materials that will be used to recruit participants. Describe the processes to ensure communication among sites. See "WORKSHEET: Communication and Responsibilities (HRP-830)." All sites have the most current version of the protocol, consent document, and HIPAA authorization. All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site's IRB of record). All modifications have been communicated to sites and approved (including approval by the site's IRB of record) before the modification is implemented. All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies. All local site investigators conduct the study in accordance with applicable federal regulations and local laws. All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy Describe the method for communicating to engaged participating sites (see "WORKSHEET: Communication and Responsibilities (HRP-830)"):	☒ **Yes**
• Problems (inclusive of reportable events). • Interim results. • The closure of a study	
If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality. (See "WORKSHEET: Communication and Responsibilities (HRP-830).")	
• Where and how data or specimens will be stored locally? • How long the data or specimens will be stored locally? • Who will have access to the data or specimens locally? • Who is responsible for receipt or transmission of the data or specimens locally? • How data and specimens will be transported locally?	