SweetMama: Testing of a novel technology for diabetes education and support to pregnant women

NCT03240874

This supplement contains the following items:

1. Summary of protocol changes
2. Original protocol (approved July 12, 2017)
3. Final protocol (approved August 19, 2019)
4. Feasibility trial informed consent document

Summary of SweetMama Protocol Changes

Protocol version 2 (September 27, 2017, approved October 2, 2017)

- Corrected a typo on the Figure, part 1c.

Protocol version 3 (submitted July 11, 2018, approved July 12, 2018)

- Usability testing phase was modified to allow individual user interviews in the usability lab if focus groups were unable to be convened.
- Usability longitudinal testing was changed from four to two weeks.
- Timeline was updated based on the study progress.

Protocol version 4 (submitted October 8, 2018, approved November 6, 2018)

- Expanded the focus group phase to additionally conduct focus groups or individual interviews with up to 20 health care providers. Up to 20 clinicians (English speaking, age 18 or greater, who provide care for low-income individuals with diabetes), would be recruited to participate in 1-hour focus group or individual interview to provide feedback about SweetMama while testing it and discussing its potential clinical use. The focus group/interview guide was included. Consent process for health care providers, who experienced minimal risk, was reviewed and consent form was provided. Recruitment and remuneration process for health care provider participants was included.
- Timeline was updated based on the study progress.
- A library of dynamic content was added to the list of SweetMama features. The library includes recipes, handouts, worksheets, and links to other tips/advice.

Protocol version 5 (submitted February 8, 2019, approved February 26, 2019)

- Sample size for focus group/individual interviews for usability testing was expanded to up to 30 participants.
- Sample size for health care provider participants was expanded to up to 50 participants.
- Sample size for individual usability testing phase (2-week field testing) was expanded to up to 30 participants.
- Eligibility for the usability phase (focus groups and individual testing) was expanded to include gestational age 6 weeks or greater, up to 4 weeks postpartum.
- Timeline was updated based on the study progress.
- App description was clarified that SweetMama was modified to be web-enabled, and thus participants were not limited to Android phones. Individuals could use Apple phones.

Protocol version 6 (submitted March 15, 2019, approved March 21, 2019)

- Eligibility for participants was expanded to include individuals whose household income was <200% of poverty line for family size, in addition to those with publicly-supported insurance for prenatal care.

Protocol version 7 (submitted April 26, 2019, approved May 17, 2019)

- Enrollment procedures were modified to explain that enrolled individuals would be provided a “SweetMama timeline” document that explains the study activities, provides contact information, and outlines how to contact the team for technical help.

Protocol version 8 (submitted June 21, 2019, approved August 19, 2019)

- At the instruction of the IRB, the pilot randomized controlled trial phase was added to the usability phase protocol as a modification (rather than as a separate protocol). This modification describes the feasibility testing phase, which included a pilot RCT that included mixed methodology to assess the feasibility, acceptability, and pilot procedures for SweetMama. The pilot RCT would be performed in 40 individuals (up to 50 if needed to achieve saturation) as well as the providers of patient participants. The objectives of this phase were described, including the aim to determine feasibility among patient participants and to determine health care provider perspectives on SweetMama use during the feasibility trial. Eligibility criteria for pilot RCT were described (pregnant women who were initiating diabetes care at the study site and were less than 30 weeks of gestation). Eligibility was also expanded to include the general obstetrics/gynecology practice. Recruitment and

remuneration plans were described. Feasibility trial procedures, including 3:1 randomization (to favor exposure to SweetMama) and plans for SweetMama use, were described. Survey time points, survey measures at each study phase, sample size justification, plans for qualitative interviewing, and endpoints of the pilot trial were described. Qualitative and quantitative analysis plan for the feasibility trial was provided.

- Updates to SweetMama were described, including improved graphics, improved curriculum and algorithm for curriculum delivery, appointment reminders, technical support page, introductory videos, and other user-friendly features.
- Eligibility and procedures for clinicians participating in the feasibility trial were explained (clinicians caring for patients enrolled in the pilot trial). Up to 30 clinicians would participate in surveys and interviews after their patients completed participation.

PROTOCOL TITLE: SweetMama: Testing of a novel technology for diabetes education and support to pregnant women

SHORT TITLE: SweetMama usability and feasibility

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ABSTRACT
Gestational diabetes mellitus (GDM) and type 2 diabetes mellitus (T2DM) during pregnancy are rapidly rising in prevalence and both disproportionately burden minority women. The existing health disparities in diabetes mellitus (DM) prevalence and perinatal outcomes are substantial public health problems that are exacerbated by the obesity epidemic. Although effective intensive management and treatment can reduce the morbidity associated with perinatal DM, the self-management skills and engagement required to achieve optimal glycemic control during pregnancy are complex and burdensome, especially amount low-income, minority women. Prior data from our group and others have identified that the social, psychological, knowledge-based, resource-related, and logistical burdens of DM during pregnancy reduce women's ability to optimize glycemic control, which is directly related to adverse perinatal outcomes. Thus, we have drawn upon existing evidence, a rigorous theoretical foundation, and our preliminary data regarding barriers to and facilitators of DM care during pregnancy to develop a health behavior tool to educate and support low-income, minority pregnant women with GDM and T2DM. Mobile health (mHealth) technology is a promising avenue for behavioral health interventions, and our tool, SweetMama, incorporates educational, motivational and supportive elements to positively impact maternal health behaviors without amplifying

provider burdens. Our long-term hypothesis is that the use of an innovative and interactive mHealth tool can improve maternal glycemic control and maternal and neonatal outcomes.

To address this hypothesis, in this phase of research we will develop an optimized version of SweetMama via a 2-step sequential process of in-depth usability testing. We will perform focus groups and individual usability testing with low-income, minority pregnant women with DM followed by refinement of SweetMama based on participant input. Usability testing will apply mixed methodology. Accomplishing this step will be necessary prior to the performance of a pilot randomized controlled trial to field test SweetMama.

OBJECTIVES:

Diabetes mellitus (DM) poses a significant health burden to pregnant women.[1,2] Effective treatment can reduce the risk of adverse maternal and child health outcomes of T2DM and GDM.[3] However, successfully managing DM in pregnancy is challenging due to the complexity of self-management skills and high level of engagement in health care required for optimal glycemic control. Moreover, pregnancy is considered a window of opportunity for health behavior optimization due to both enhanced motivation and health care access. However, perinatal management of DM requires unique and advanced patient education and engagement. Existing support tools for this critical period of care are currently insufficient to address the identified multitude of logistical, informational, social, psychological, financial, and physical barriers to perinatal management of DM.[4-9]

To address these needs, we created a “first-of-its-kind” mHealth platform for pregnant women with GDM or T2DM. This platform, named SweetMama, is a theory-driven application that delivers an interactive, goal-oriented educational and motivational diabetes-focused curriculum.

The next steps include performing usability testing of SweetMama. The aim is to create a refined version of SweetMama via a 2-step sequential process of in-depth usability testing:

1. Focus groups with 10-20 low-income pregnant women with DM to evaluate tool functionality, design, and interpretability.
2. Individual usability testing with 20 women, who will use SweetMama for 4 weeks followed by qualitative (interviews) and quantitative (questionnaires and user interaction data) assessments of tool satisfaction and use.

The objectives are to:

- Develop SweetMama and optimize its functionality through laboratory and field usability testing.
- Optimize SweetMama for patient preferences and satisfaction.
- Prepare for a randomized controlled trial (RCT) comparing SweetMama use to standard of care.

Secondary aims include:

- Exploration of the mediating effects of adherence markers (e.g. use time, app launches, etc.), SweetMama content (e.g. logistical, supportive or educational messaging), and patient characteristics (e.g. demographic, clinical, or self-reported measures).
- Optimize support strategies and content within SweetMama.
- Explore and optimize strategies to incorporate SweetMama into routine clinical care for low-income pregnant women with diabetes.

BACKGROUND:

Diabetes mellitus (DM) during pregnancy is a major public health problem. Obesity and DM are serious pregnancy comorbidities with significant maternal and neonatal health implications. Driven by the obesity epidemic, the frequencies of gestational diabetes mellitus (GDM) and type 2 diabetes mellitus (T2DM) have risen significantly, creating a major public health problem.[10-16] DM has well-established relationships with adverse perinatal outcomes, including cesarean delivery, hypertensive disorders, macrosomia, and neonatal metabolic complications, resulting in short- and long-term decrements in health for both mother and child.[1,2]

Racial/ethnic disparities related to DM in pregnancy exist. Minority women experience pregnancy-related health disparities, including an approximately two-fold greater incidence of GDM, GDM recurrence, and subsequent T2DM after GDM.[1,2,16-20] Over half of women with GDM[21-23] and over two-thirds of women entering pregnancy with T2DM are from minority racial/ethnic groups.[11] Minority women with DM also experience more frequent adverse perinatal outcomes[12,21]; for example, non-Hispanic black women with GDM have a greater risk of cesarean delivery, macrosomia, and fetal demise than white women with GDM.[12,21-24] The increased prevalence of DM and higher risk for DM-associated adverse outcomes widen existing health disparities.

Treatment of abnormal glucose homeostasis during pregnancy reduces the risk of adverse outcomes.[1,3,25] Care is centered around goals of optimizing glycemic control and monitoring for complications. Multidisciplinary treatment plans include medical nutrition therapy, exercise, potential medication administration, and enhanced maternal-fetal surveillance.[1,2] Thus, perinatal care for DM necessitates advanced patient education and engagement.[8] While pregnancy already requires enhanced patient learning, DM management further complicates perinatal care.

Given the complexity of perinatal DM management, women must be equipped with communication, literacy, numeracy, problem-solving, and organizational skills to optimize outcomes. DM self-management during pregnancy is burdensome and challenging, particularly for women with greater social disadvantage.[4,5] Logistical, social, financial, informational, access-related, and attitudinal challenges to DM management have been identified in several cohorts[4-7,26] and our own data.[8,9]

While traditional DM behavior support interventions can be effective for non-pregnant adults,[27] scalable interventions that promote sustainable behavior change, address disparities, and are

specific to pregnancy are urgently needed. The expansion of mobile technology has made mobile health ("mHealth") applications a promising avenue for health promotion, especially in DM.[28-31] Text messages, for example, can be motivators, information sources, cues to action, reminders and reinforcements, and sources of support.[32] Outside of pregnancy, mHealth use is associated with improvements in glycemic control, self-care behaviors, adherence, engagement, self-efficacy and health care costs.[33-39]

Despite the proliferation of commercial mHealth "apps", evidence-based mHealth interventions for pregnant women are lacking. Interest in such programs is high, with data showing the majority of pregnant women are interested in and have access to mHealth.[40,41] Text4baby, for example, delivers health promotion messages to enhance general pregnancy health behaviors and may positively affect health attitudes.[42-45] Other text messaging programs for reproductive aged women have investigated smoking cessation, contraception, and weight loss.[46] Yet, many programs lack rigorous evidence-based or user-centered design,[31] and advanced or disease-specific perinatal mHealth interventions are lacking. Interventions designed for use by pregnant women with DM, particularly in low-income populations, are needed.[46]

To fill this gap, we ENREF 10 initiated a multiphase project to develop a behavioral health intervention to support pregnant women with DM, with particular attention to low-income women. In prior work we developed a model of barriers to self-care and factors that help to overcome these barriers.[8,9,47] We then applied those findings to develop a patient-driven text messaging curriculum to support DM self-care ("Texting for Diabetes Success"), which was performed at NMH within the Prentice Ambulatory Care clinic. The curriculum created for that program serves as the backbone for SweetMama.. Participants reported high satisfaction and perceived benefits from this curriculum, and desired that we extend it further with interactive and individualized features. Based on these findings, we created SweetMama, a supportive and educational theory-driven mHealth platform for pregnant women with GDM or T2DM. SweetMama delivers an interactive, goal-oriented educational and motivational diabetes-focused curriculum. Our long-term hypothesis is that use of a high quality mHealth tool can improve maternal glycemic control, positively impact maternal and neonatal outcomes, and thus contribute to reducing perinatal DM-related disparities.

Finally, effective perinatal mHealth interventions require a theoretical framework to derive the greatest benefit.[32,46] The Health Belief Model explains individuals' engagement in health behaviors via the constructs of perceived susceptibility, severity, barriers, and benefits.[48] Cognitive load refers to a task's cognitive demand[49,50] and suggests individuals have a limited capacity to process information.[51-53] The learning and decision making burdens of DM management demand self-efficacy, confidence in the ability to perform a particular set of behaviors.[54] DM self-efficacy is particularly salient in pregnancy, where in a short amount of time a woman must believe she can accomplish new health behaviors in order to successfully execute those changes.[55] We have applied these theories in the development of SweetMama.

SweetMama currently functions as a user-friendly application in which participants are delivered three library-based messages per week, in which messages derive from the

previously-developed and newly expanded curriculum, and one individualized goal-based message that is customized to the patient. All messages designed as dynamic messages that allow for receipt of novel educational, motivational, or supportive content when desired by patients. Messages can be "favorited" and archived, and can be viewed on WiFi or when outside of data/WiFi capacity. The intervention is designed to be a simple but consistent plan of supportive and reinforcing messages that promote self-efficacy, engagement, and knowledge during a pregnancy complicated by diabetes. We have previously tested and utilized the primary messaging content in the Texting for Diabetes Success study, and have now expanded both the content as well as transitioned from simple texting to smartphone-based technology. The technology has been tested with our core group of expert users and is now ready for patient-facing use and feedback, prior to a large-scale trial on the relationship between SweetMama use and perinatal outcomes.

Thus, this proposal will solicit in-depth user-centered feedback on SweetMama, allowing us to iteratively modify SweetMama. Accomplishment of this study will result in an optimized tool ready for longitudinal field testing via a pilot randomized controlled trial.

INCLUSION AND EXCLUSION CRITERIA:

Inclusion criteria:

- Age 18 and greater
- Gestational diabetes mellitus or type 2 diabetes mellitus
- English-speaking (as SweetMama currently does not exist for non-English speakers)
- Gestational age:
    - Focus groups: Confirmed intrauterine pregnancy at least 8 weeks' gestational age or postpartum until 12 weeks after delivery
    - Individual testing: Confirmed intrauterine pregnancy prior to 30 weeks' gestational age
- Patient at Prentice Ambulatory Care or in Maternal-Fetal Medicine practices at Northwestern Medicine
- Low income, defined as use of publicly-supported insurance for prenatal care
- Access to an Android-based smartphone (for longitudinal testing phase)

Exclusion criteria:

- Failure to meet the inclusion criteria above
- Non-viable pregnancy

Total number of participants: 40

- 10-20 women to participate in focus groups
- 20 women to participate in individual testing

We will specifically include pregnant women as pregnancy is a requirement for participation; the goal of the study is to develop a tool for use by pregnant women. This study does not include adults unable to consent, minors, or prisoners.

STUDY-WIDE NUMBER OF PARTICIPANTS: Not applicable, not a multi-center study

STUDY-WIDE RECRUITMENT METHODS: Not applicable, not a multi-center study

MULTI-SITE RESEARCH: Not applicable

STUDY TIMELINES:
Focus groups: Women recruited to the focus groups will have approximately 1 hour of study participation in which they will be asked to provide feedback about SweetMama while testing it and discussing its potential use during pregnancy. They will not be followed longitudinally.

Individual testing: Women recruited to the longitudinal usability testing phase of SweetMama will actively participate for four weeks, during which time they will have frequent contact with the study team. After this period of active use, we will request patient permission to follow up their pregnancy outcomes via record review, but we will not require further information nor study participation.

We plan to initiate focus groups in July 2017 and finish during this month. We will then modify SweetMama as needed in August-September 2017, and plan to start longitudinal individual testing by October 2017. Recruitment for the longitudinal testing will require approximately 8-12 months, after which we will complete study analyses and publications. The goal is to complete the study by early 2019.

STUDY ENDPOINTS:
Usability (a measure of the interactive user experience) testing is a primary element of user-centered design and is an iterative process in which groups of participants evaluate application features and then identify and fix problems. After a round of evaluation, a new group of participants are brought in to evaluate the application.

The **expected outcome** of this research will be a refined tool ready for field testing. The primary endpoint is completion of usability testing with the above described targeted population, which will inform the revision of SweetMama prior to a larger trial. The secondary endpoint will be the completion of all data analyses related to these testing phases.

PROCEDURES:
This is a prospective usability/feasibility study involving participant use of SweetMama. SweetMama will be evaluated in this population of low-income, minority women per a commonly used usability testing approach[56,57] with a two-step sequential process: a) sequential usability focus groups (between 10-20 participants, evenly distributed between women with GDM and T2DM, in group sizes of at least 3 women), followed by b) individual usability testing with 20 women (10 with GDM and 10 with T2DM), or until saturation of information on usability.

We will aim for a targeted distribution of patients stratified evenly by age (>30yo vs. <30yo), DM type (GDM vs. T2DM), gestational age at entry (by trimester), and with a racial/ethnic distribution reflective of the 90% minority demographic at the study site. Sample sizes were generated based on data illustrating that these sizes are sufficient to inform high quality user-centered design of a larger scale, next step behavioral intervention trial.[37,58-61] Improvements to SweetMama will be iteratively performed between focus groups, before and after individual testing, and between individual participants.

SweetMama overview: We have used our group's experience (prior published works; see citations) and theory to rigorously modify a curriculum of didactic and supportive messaging content developed in earlier work. SweetMama now includes a dynamic two-option response system. Because patients in earlier phases strongly desired access to more information, each message in the curriculum library will generate an option for the participant to connect further with SweetMama. In this dynamic setup, one option would be to end the interaction; for example, if a patient receives a message and does not desire more information, she selects the option that acknowledges the message and closes SweetMama. Alternatively, she may opt to receive more information, which will lead her to expert-driven novel content, a trusted website, or an alternative source of support. Using the modified Phase 2 content, messages include basic appointment reminders in addition to substantive didactic content and motivational messaging. In order to offer this interactive content, we have worked with an expert team to generate dynamic content for nearly 130 messages. This curriculum library serves as the foundation for SweetMama. This functionality has been designed to be scalable by intentionally building the capacity to pre-program the messaging library at the start of participant enrollment. SweetMama includes several other patient- and theory-driven components, including:

- Favorites and archiving: All messages will be retained in an archive organized by type and chronology. Participants will be also able to "favorite" preferred messages for later review.
- Goal-setting: Consistent with the Theory of Self-Efficacy, SweetMama includes individualized goal-setting activities. At each appointment, participants select a goal for the subsequent week with the clinical team; goals may be behavioral, nutritional, or other DM-related patient-driven goals. The goal will be entered into the SweetMama provider platform to be delivered as a patient reminder 4 days later. This individualized message's dynamic response option will ask participants whether they have accomplished the stated goal. A goal achievement log that encourages self-regulation behaviors will be maintained.
- Technical support: Participants will have access to "in-app" participant-initiated support.

Thus, upon enrollment in the usability testing phase, participants will receive an access token and then can download SweetMama (from the Google Play store) to their phone (or it will be pre-downloaded for those in the focus group phase), and create a user name. The research team will then use the researcher dashboard to create a schedule of messages using the pre-designed curriculum; these messages will be delivered on Monday, Wednesday, and Friday, at a time chosen by the participant. The individual "goal setting" message will be delivered on Saturday. Participants can go to their home page, favorites, or archive at any time to view pending or old messages.

Usability testing: focus groups. We will perform between 2 and 6 focus groups, with the number and size to be determined based on participant availability and the quality of feedback received from interviews. Groups will have at least 3 participants but no more than 6 participants, to maximize individual attention. Focus groups can be terminated once saturation has been achieved. Focus groups will take place at the CBITs usability laboratory or in the Prentice Ambulatory Care clinic.

Women will be identified via routine clinical care and approached in the clinical setting. They will be informed of the reason for the study and invited to participate. When a sufficient number of participants have agreed to participate, women will be directed to the usability lab at a mutually agreeable time.

The focus groups will assess tool functionality, design, interpretability, and acceptability (initial reaction, attitude, and receptiveness). The group format, performed at the CBITs' Usability Laboratory using a semi-structured interview guide and led by the research team, will generate feedback on areas that may not be revealed in a one-on-one interview. Group members will be informed that any information provided during their participation is confidential within the group; they will also be informed that they will not be asked sensitive questions about themselves or their health in the group setting.

The semi-structured focus group guide is attached (Appendix B). Participants will also be asked about general experiences with diabetes during pregnancy, use of smartphones, use of phone applications, and preferences for resources related to diabetes during pregnancy. Participants will be asked about their own smartphone use and about their need for pregnancy support information. Next, participants will be oriented to SweetMama, use its functions with guided support, and provide feedback about the content's relevance, clarity, delivery style, timing, tone, length and visual design. They will then use a phone with SweetMama loaded on it and will be asked to use the buttons, archive messages, choose favorites, and review the content. They will be given choices and asked preferences regarding the organization and content of the application. They will also be given the opportunity to make suggestions for the application. Messages will be sent in real time during the group. Focus groups will be audio recorded and research members will take notes during participation. This stage will inform modifications to best align SweetMama with curriculum goals and participant preferences. We will rigorously collect specific user feedback including these techniques:

- "Think alouds" – Participants speak aloud a running commentary while performing tasks involved in the operation of SweetMama. This is a common approach[62] to usability testing that permits investigators to evaluate the ease of learning the system and provides first-hand information about design problems.
- Cognitive testing – Participants will explain what specific words or images make them think and feel.
- Feasibility – All buttons, messaging, and archiving functionality will be tested by each participant.
- Research team observation of the problems participants have with SweetMama use.

After this phase, our team will spend 1-2 months making improvements in SweetMama based on participant feedback and focus group data.

Usability testing: individual testing. After SweetMama is modified based on focus group data, individual usability testing will occur with 20 eligible pregnant women. Women will be recruited to participate in the same manner as described above, via routine clinical interactions. In this phase, women will not require a visit to the usability lab; instead, they will be oriented to SweetMama use on their own Android-based phones. The goals of this phase are to collect data from diverse users that will (1) confirm that the mobile apps are functioning (not crashing) across a wide range of Android devices and operating systems, (2) provide basic information about app usage and user satisfaction (3) inform the development of future iterations by analyzing participant characteristics and use, and (4) collect quality assurance data that will allow the research team to refine the applications.

With the assistance of trained research staff, participants will undergo standardized orientation to SweetMama and the first message will be delivered upon enrollment; the training of the research team to perform standardized orientation and support enhances the fidelity of the intervention. At this time, we will collect baseline information on:

- Demographic and clinical characteristics
- Electronic health literacy, assessed via the eHealth Literacy Scale (eHEALS), an 8-item assessment of computer literacy as related to health information.[63]
- Health literacy, assessed via the Newest Vital Sign, a nutrition label-based 6-item measure of the ability to obtain and process health information.[64-66]
- Diabetes self-efficacy, assessed via the Diabetes Empowerment Scale–Short Form (DES-SF), an 8-item measure of psychosocial self-efficacy of individuals with diabetes.[55,67,68]
- Patient activation, assessed via the Patient Activation Measure (PAM), a 22-item measure of patient engagement in the care process.[69]

Women will then use SweetMama for 4 weeks, a length of time sufficient to obtain usability data.[56] Our usability testing protocol[56,57,70] includes weekly research assistant 10 minute "check-ins" to identify technical problems followed by an interview after 4 weeks consisting of qualitative and quantitative assessments:

- Interview – Semi-structured interview framed by the Health Belief Model on experiences with SweetMama. Information will be designed to elicit feedback about technical problems, ease of use, satisfaction & overall usefulness for various components of SweetMama.
- System Usability Scale (SUS) – A simple and technologically flexible 10-item scale to assess satisfaction with and usability of a product or service.[71,72]
- Usefulness, Satisfaction and Ease of Use (USE) Questionnaire – A 30-item scale to evaluate user interfaces across the three domains of usability, satisfaction, and perceived ease.[73]

Specific user interaction data (regarding study retention and interactivity) also will be gathered via the SweetMama provider research platform, including:

- Summary client events: number of times and days app was accessed, total usage length from first to last access, number of times used per week, number of episodes of active use (defined as use from 1-20 minutes), average length of active use, total number of messages viewed, total number of messages responded to, total number of messages "favorited", total number of individual goal messages received and achieved, total number of self-initiated access events (i.e., not triggered by a routine message).
- Curriculum events (per message): time interval from sending message to participant viewing, dynamic option chosen, action taken with a follow-up message (i.e., was a link or phone number used after being provided), identification of favorite messages, and number of times messages in archive were viewed.
- Goal-setting events: specific goal content, dynamic option chosen, total time from message delivery to response, cumulative goal achievement, number of favorited and archived goal messages.

Only data related to how and when SweetMama is used will be collected and the format in which it is stored will contain no identifying information about users. Furthermore, the information saved on the server will only be accessible to people provided with the proper credentials (members of the research team, research collaborators, and the users themselves).

At the end of the 4 week trial phase, participants will be informed that they may continue using the SweetMama on their phones (eg view archived messages) but will no longer have individualized messages. For any participants who do continue their use after the study period has ended, SweetMama will continue to collect phone and app data as before.

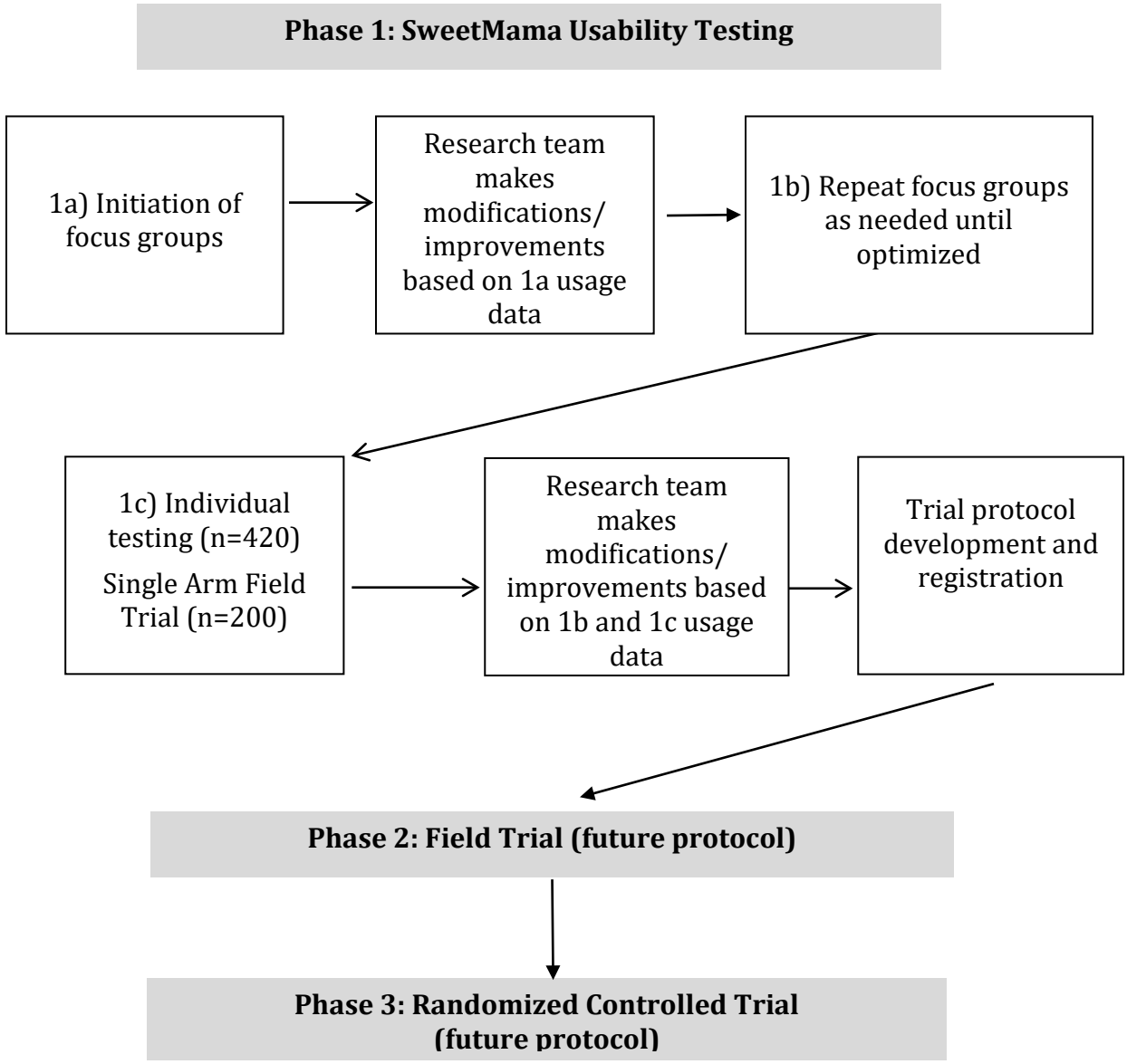
Finally, participants in the individual testing phase will be followed via their Epic and PowerChart records for pregnancy outcomes, including birth outcome and glycemic control (see Appendix A). No long-term follow up will be required.

All study activities will take place within Northwestern Medicine, specifically in the PAC clinic, Maternal-Fetal Medicine practice, and at the Center for Behavioral Intervention Technology.

No physical procedures will be performed and there are no specific procedures used to monitor participants for safety or minimize risks, as this poses no more than minimal risk to participants.

Source records for the study include the focus group, surveys, and chart data, as described above. All questionnaires will be collected on paper. No external approvals are required prior to commencing research; as this is not a clinical trial, registration at clinicaltrials.gov is not required.

Study outline



DATA AND SPECIMEN BANKING:
All participant data will be closely safeguarded. Participants will be tracked in NITRO StudyTracker. REDCap will be used as the secure online database for the study. Qualitative data from interviews will be stored in secure drives on password-protected computers in a locked office. Extensive measures will be taken to ensure data confidentiality. Written informed consent will be obtained and consent forms will be maintained in a secure locked location that only research team personnel will have access to, as well as scanned per requirements. Use of REDCap will allow for quality control, as data can only be entered securely and with limited range. All team members will be trained on data security and confidentiality, and will ensure the safe management of data. No specimens will be banked for future use.

DATA AND SPECIMEN MANAGEMENT:
Data management: Extensive efforts will be made to protect the confidentiality of participants. No biological specimens will be collected. All data are in the form of survey responses, interview/focus group responses, and SweetMama user data. All data will be stored in secure, locked offices in Prentice Women's Hospital or the Department of Obstetrics and Gynecology research facility on password-protected computers, and in REDCap, a secure, Northwestern-approved electronic data capture resource.

Participant contact information and protected health information will only be accessible to the research team. Following participant recruitment, a study ID will be assigned and survey/interview results will be deidentified. Any paper surveys do not contain any PHI and will only be identified by this unique study identification number. Participant identifiable information will be separated (and stored in StudyTracker) from research information (which will be stored in secure computers and REDCap). Data will be transported from the point of collection (i.e. clinic or the CBITs usability lab) to secure electronic data storage locations via direct upload on secure laptops. Dr. Yee and the study team will have responsibility for data transmission and storage. Data stored on the secure, password protected computers will be password protected and stored on hospital servers with automatic backup and active, updated antiviral software. Data will be stored for 5 years after analysis is complete and then data will be permanently removed from the computers that they have been stored on. Access to data will only be granted to the PI (Dr Yee) or the research assistant responsible for enrolling and entering data. Quality control will be assured via extensive training of research team members prior to patient recruitment. Further, information collected from the applications on the mobile phones will be transmitted to a secure server via encrypted, password-protected tunnels to protect users' privacy.

Sample size calculation: As this study is not a hypothesis-testing study but rather a usability/feasibility study, the sample size is not based on a statistical power calculation but on standard sample sizes for studies of this nature. Sample sizes were generated based on data illustrating that these sizes are sufficient to inform high quality user-centered design of a larger scale, next step behavioral intervention trial.[37,58-61]

Analysis: This is a mixed methods analysis. Descriptive statistics using bivariable analysis will be used to characterize the study populations. For statistical comparisons, all tests will be two sided and $p<0.05$ will be considered statistically significant. All statistics will be performed using STATA 14. Analyses will be performed as follows:

- Focus groups: During focus group sessions, we will take detailed notes and audio record in order to capture participant feedback. After each group, the research team will construct a brief preliminary summary report. Transcripts will then undergo rigorous and reproducible qualitative analysis techniques using the constant comparison method. Analysis will be performed in Dedoose, a secure qualitative data management and analysis software that facilitates collaborative exploration of data and identification of themes in accordance with the Health Belief Model and Theory of Self-Efficacy. Dedoose has been previously used for multiple studies performed in our Department and has data security approvals by NUIT; only deidentified data will be uploaded to Dedoose. We will ensure reproducible and rigorous interpretations are accomplished via use of memos, creation of a consensus code list with clear operational definitions, and calculation of agreement statistics for inter-coder reliability. The final report will compare focus groups and summarize themes. We will then iteratively modify SweetMama based on these results.
- Individual testing: Analysis of individual data will consist of qualitative and quantitative analyses with the goals of identifying user feedback to incorporate participant needs into design and determining user features associated with greater satisfaction and use. The primary outcome will be user adherence, based on user interactivity data. Given the small study size and aim of assessing usability, the analysis of user interactivity data will be largely descriptive (i.e., no comparison group) but we will also examine the effects of potential mediating factors, such as health literacy and self-efficacy. Secondary outcomes include both qualitative interview data and the quantitative data regarding use and patient characteristics, as described above. Qualitative data will be analyzed in the same manner as described above, with an additional mixed methods evaluation of interview data in concert with quantitative measures. Quantitative results for the SUS and USE will be used to assess satisfaction with and usability of SweetMama. User interaction data will be quantified to ensure tool functionality and determine areas for improvement. Using Stata v.14, we will perform bivariable and multivariable analyses to measure the relationships between baseline demographic/clinical characteristics, DES-SF, and PAM with user satisfaction and SweetMama interactivity.

PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF PARTICIPANTS:
Not applicable, as the study procedures pose no more than minimal risk of harm to participants.

WITHDRAWAL OF PARTICIPANTS:
There are no planned circumstances under which subjects will be withdrawn from research without their consent. Notably, as the study is of minimal harm to participants, there are no

safety reasons that would necessitate withdrawal. However, if participants request withdrawal from the study for any reason, their participation would be discontinued immediately. If participants request termination of their participation, they will be instructed (in the consent form) to contact Dr. Yee. Upon receiving this request, they will be immediately withdrawn and no further prospective data will be collected. Data collected prior to withdrawal will be maintained and analyzed. The only administrative reason for withdrawal of participants is loss to follow-up; if a focus group participant fails to present for the scheduled focus group, or if an individual testing patient fails to interact with SweetMama for the duration of participation (4 weeks), she will be considered lost to follow-up.

RISKS TO PARTICIPANTS:

Breach of confidentiality is a risk associated with this research, although all survey data will be maintained on a HIPAA complaint online database or stored in a locked, on-campus secure office. Additionally, in this phase, participants may be asked to use their own phone and data plans; patients who do not have unlimited data may experience either data charges or find that SweetMama is inaccessible until they are on WiFi. Extensive efforts will be made to orient subjects to SweetMama and help them reduce the risk of unanticipated data charges.

The participants are otherwise not subject to any risks from the intervention testing process or chart reviews. If participants feel increasing stress from participation, they may choose to terminate participation. The likelihood of discomfort from this study is very low, given that the study is focused on their perspectives on a health behavioral intervention.

There will be no effect on the woman's medical care, and there are no medical interventions in this study. There are no pregnancy-specific risks to the pregnant woman or her fetus due to participation in this survey study. No study-specific procedures have risks to subjects that are currently unforeseeable.

There are no risks to others who are not participants.

POTENTIAL BENEFITS TO PARTICIPANTS:

The goal of this study is to develop a supportive health behavioral intervention that improves maternal outcomes in the setting of diabetes during pregnancy. It is possible that some women may find the completion of the focus group interesting and it may provoke further discussions with their clinician; however, no clinical benefits are anticipated. Their involvement will hopefully improve the quality of care for future patients.

However, we do anticipate that the 4-week individual testing period may offer some benefits to patients; namely, we are offering a supportive and educational program that provides women information and other psychosocial support during a pregnancy complicated by diabetes. We do not believe there will be long term perinatal benefits with just this short period of

participation, but we do anticipate that participation in SweetMama testing may enhance the woman's knowledge, motivation, or engagement in care.

VULNERABLE POPULATIONS:
Pregnant women are the primary focus of this investigation. This study would not be possible in a non-pregnant population, as the goal is to assess the relationships described in the context of pregnancy. Women will be approached in the clinic setting, when they are not in pain and when they are medically stable. They will not undergo any medical procedures. Survey procedures do not involve more than minimal risk to pregnant women. There is no risk to the fetus or newborn. Careful attention will be paid to ensuring that all women are provided confidential study participation and that their PHI is carefully protected. Women are not asked to undergo any interventions or procedures, and their medical care will not be affected by study involvement. The checklist HRP-412 has been reviewed.

This study does not involve research with neonates of uncertain viability, nonviable neonates, prisoners, minors, or cognitively impaired adults.

COMMUNITY-BASED PARTICIPATORY RESEARCH: Not applicable

SHARING OF RESULTS WITH PARTICIPANTS:
Results of the focus group phase will be readily apparent to participants in each group; however, we will not be actively sharing data from all focus groups with participants, as this is not likely to benefit them. However any publications or presentations from this phase will be made available to participants on request. Similarly, results from the individual testing phase will be shared via publications or presentations upon request. No other information is clinically relevant that would require sharing with participants or others.

SETTING:
This project will include participation of the clinic staff and patients. Clinics to serve as study sites include the Prentice Ambulatory Care (PAC) clinic, and the Northwestern Medicine Group Maternal-Fetal Medicine practice. The focus of this work is to improve care for low-income women with diabetes during pregnancy, the majority of whom receive care in the PAC clinic. All patients deliver at Prentice Women's Hospital, a tertiary care, referral center.

The study will also take place at the Center for Behavioral Intervention Technology, a unique Northwestern core facility with extensive research expertise who have been key partners in this study. No research activities are taking place outside of Northwestern.

RESOURCES

All staff have sufficient research training and expertise to perform their roles for this study. Dr. Yee, Dr. Simon, and Ms. Niznik are clinicians who provide medical care in the inpatient and outpatient obstetrics setting and are thus very familiar with the institutional culture and study sites. Dr. Simon is Dr. Yee's mentor and has extensive research experience. Dr. Yee and Ms. Niznik are specialists in the care of women with diabetes during pregnancy, and thus have ample clinical expertise to support these patients. Both Drs. Yee and Simon are actively involved in clinical research in this department.

Additionally, our partnership with the Northwestern University Center for Behavioral Intervention Technology is a unique resource and strength of this study. The Behavioral Intervention Technology (BIT) Core is a Feinberg Core Facility that operates out of the Center for Behavioral Intervention Technologies (CBITs) in the Department of Preventive Medicine (DPM) at NU Feinberg School of Medicine. Behavioral Intervention Technologies are generally web and mobile apps and sensor-based tools designed to support behavior change. BIT Core consists of a multidisciplinary team of software designers, developers, clinical psychologists, technical project managers, quality assurance specialists and behavioral science researchers that has been the technology partner on over 40 NIH-funded research projects ranging from improving physical activity for individuals with arthritis, to treating mental health issues such as depression and anxiety.

BIT Core provides comprehensive software development services to support the unique needs of researchers who are evaluating behavioral intervention technologies. Further, BIT Core follows industry best practices to support the unique privacy and security needs of researchers throughout the Medical School and the University. All technologies created by BIT Core undergo a stringent quality assurance process that is led by our QA manager and are hosted and maintained by BIT Core on secure Northwestern University servers. There is also a fully equipped Usability Lab outfitted with a high-powered desk top computer to run test applications and capture screen activity, three multi angle HD cameras for external review of usability sessions, in environment microphones and audio digitization for full duplex communication and monitoring of subjects, and a monitoring workstation to interface directly with the environmental sensors for recording. The Usability Space also has the ability to support as needed additional sensor functions including eye track monitoring, EEG collection, galvanic skin response and infrared thermal imaging. CBITs has a scalable virtual server infrastructure capable of accommodating up to 10,000 users. CBITs follows a stringent data security plan and adheres to all data security processes required by Northwestern University and Northwestern Memorial Hospital.

Multiple additional resources are available to study investigators. First, based on the current volume of obstetric patients delivering at Prentice Women's Hospital and the number of patients seen in our practices with diabetes, the proposed number of subjects is feasible during the recruitment period. Second, Dr. Yee has protected time for research performance and oversight. Third, the facilities are adequate for the research proposed, as all investigators have access to locked office space, protected computers, and appropriate research management and statistical software for data analysis. The investigators plan to perform all analyses themselves

but additionally have access to statistical support if needed. Fourth, all personnel are already adequately informed and trained about protocols and procedures. All team members have had human subjects training. Our team will ensure the research assistants are fully trained and supported.

Participants:

- Lynn Yee is an Assistant Professor in the Division of Maternal and Fetal Medicine within the Department of Obstetrics and Gynecology. She has prior experience with clinical and public health research, including health systems research focusing on improving care for underserved women. She has a Masters in Public Health and extensive biostatistical and survey methodology expertise. She has also been performing research in the Northwestern system for four years, and has extensive familiarity with research administration and systems. Additionally, as scholar in the Women's Reproductive Health Research Career Development Program, Dr. Yee has 75% research time available for research proposals.
- Melissa Simon is the Vice Chair of Clinical Research in the Department of Obstetrics and Gynecology, and has extensive prior NIH funded experience with clinical research in the areas of health disparities and patient navigation.
- Charlotte Niznik, APN, is the lead diabetes nurse practitioner who cares for patients in the study sites. Her content expertise will be critical to recruitment of patients (as she cares for the majority of them) and in analysis of data. She has prior experience as a research clinician related to diabetes. Ms. Niznik (and Dr. Yee) are also available for clinical questions should the study raise any diabetes-specific clinical questions from patients.
- The Research Assistants will have experience with women's health research and clinical research. This person will have full-time responsibility for research coordination, and will be extensively trained by Dr. Yee.
- CBITs staff have been extensively trained both in the technological aims of this study and in the requirements of human subjects research. CBITs staff have project development and management expertise that will be critical to the success of this project.

PRIOR APPROVALS: Not applicable

RECRUITMENT METHODS:

Participants will be recruited from the obstetrics and gynecology practices at Northwestern Medicine described above; the majority of patients will be recruited from the Prentice Ambulatory Care Clinic at Northwestern Memorial Hospital, which provides obstetric care to low-income patients. This clinic cares for approximately 80 women with GDM or T2DM per year, and due to the low clinic volume, patients are well known to clinic and study staff. Participants will be identified via their Epic clinic record or through direct interaction with the study staff.

Patients will then be formally recruited by the research assistant or another study team member (such as Dr. Yee or Ms. Niznik) immediately before or after their clinic visit. Recruitment and provision of informed consent will occur by face-to-face interaction with the research assistant or the primary investigator. If she agrees to participate in the study, she will be consented by the research assistant via written informed consent. Potential subjects will be informed that participation is voluntary and confidential, that their participation or refusal to participate will not affect their medical care in any way, and that they may withdraw at any time.

The research team will conduct the study at CBITs (located at the Rubloff building) and the Galter pavilion (14th floor) clinic described above. Patients will be approached privately in their clinic appointments by a research team member.

No recruitment materials are required, as all recruitment will take place via the face-to-face interactions described above. Recruitment will not take place via any registries.

Participants who will be offered gift cards to thank them for their participation. Gift card amounts are as follows:

- Focus groups - $30 Visa gift card
- Individual testing - $30 Visa gift card upon initiation of the study and $30 Visa gift card upon completion of participation.

Participants who require transportation assistance in order to participate will also be offered such assistance via parking passes or bus passes. However, study activities are expected to take place around the time of already scheduled appointments, and so participants are not anticipated to have significant added transportation costs.

Food will be provided at the focus groups.

Participants in the individual testing phase will be required to have an Android phone with at least WiFi capacity. Participants will be informed that SweetMama will function if they have data enabled, and thus if they do not have an unlimited data plan, they may experience unanticipated data charges. Participants will be informed they can elect to have SweetMama only function when on WiFi, and will be instructed on how to do so if they desire this measure to prevent possible data overuse. There are no other anticipated costs to participants.

NUMBER OF LOCAL PARTICIPANTS: 40

CONFIDENTIALITY: Not applicable, not a multi-center study

PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS:
Participants will be informed that declining to participate will not affect their medical care and that they may discontinue study participation at any time. Participants will also be informed that their protected health information and study results will be strictly guarded and multiple steps will be taken to preserve confidentiality, as described above.

If a potential subject agrees to participate, the study will be explained in depth and multiple efforts will be made to make the participant as comfortable as possible. The study activities will take place either in focus groups or in private at a time that is mutually agreeable to the researcher and participant; if she desires the research assistant return at a different date, he/she can do that. Participants will be asked if they are free of immediate medical concerns that would take priority over their research participation. Participants will be informed that they may choose to not answer any question if they find a question to be uncomfortable. During focus groups, we will ask minimal private health information; all activities will be focused on the evaluation of SweetMama. Finally, participants will be informed that their responses will not be communicated to their health care providers and that their participation will not affect their medical care in any way.

Participants will be informed that their research information, including answers to interviews and surveys as well as user data, will be accessible to the research team. They will be informed that no other information about their personal mobile phone use can or will be collected. No long-term data will be collected. No specimen banking will be performed. Participants will be taught how to uninstall SweetMama if desired.

COMPENSATION FOR RESEARCH-RELATED INJURY: Not applicable, not a multi-center study

ECONOMIC BURDEN TO PARTICIPANTS:
Participants may incur costs due to the use of their personal phones; however, participants will be informed that SweetMama can function on WiFi and does not require data use, and can be instructed on how to set this up. No other costs are anticipated.

CONSENT PROCESS:
Each participant will be recruited in her outpatient clinic room or another private location in the clinic (for example, an available consultation room, if the clinic room needs to be turned over for other patients). Consent will be obtained by Dr. Yee or another research team member; no individuals obtaining consent will also be responsible for the medical care of the patient. If she agrees to participate in the study, she will be consented by the research assistant via Consent Form and HIPAA Authorization for Research. Consent will include permission for the focus group/individual testing completion as well as for prospective chart review for clinical information about the participant. Potential subjects will be informed that participation is

voluntary and confidential, that their participation or refusal to participate will not affect their medical care in any way, and that they may withdraw at any time.

There will not be a waiting period between informing the prospective patient and obtaining consent. There will not be a need for ensuring ongoing consent. The consent discussion can take as much time as the patient requires, although since the study is of minimal risk, we anticipate it will require less than 10 minutes. Participants will be informed that they will not be penalized for refusal to participate.

This study does not include non-English speaking individuals, minors, cognitively impaired adults or adults unable to consent.

PROCESS TO DOCUMENT CONSENT IN WRITING:
Our research presents no more than minimal risk of harm to subjects. We will obtain written informed consent per the guidelines in the SOP HRP-091. See attached consent document.

DRUGS OR DEVICES: Not applicable

APPENDIX A: Chart review data to be collected from individual testing participants

- Demographic data:
  - Maternal age
  - Maternal body mass index
  - Race/ethnicity
  - Insurance
  - Zip code
  - Marital status
- Diabetes data:
  - If GDM: method for diagnosis, gestational age at diagnosis
  - If T2DM: age at diagnosis
  - Level of glycemic control (serial HgbA1c)
  - Method of treatment: diet, oral hypoglycemic, insulin
  - Method of surveillance: home CBG monitoring versus clinic VBG monitoring
  - Number of medications used
- Pregnancy data:
  - Gestational age at first visit
  - Number of clinic visits
  - Gravidity and parity
  - Antepartum admission
  - Total weight gain in pregnancy
  - Comorbidities: chronic hypertension, tobacco use
  - Obstetric history: history of preterm delivery, history of GDM
- Delivery data:
  - Obstetric complications: gestational hypertension/preeclampsia, preterm birth
  - Obstetric outcomes: gestational age at delivery, induction of labor, reason for induction of labor, mode of delivery (SVD, VAVD/FAVD, CS), indication for operative vaginal or cesarean delivery, postpartum hemorrhage, shoulder dystocia
  - Mode of feeding
  - Participation in postpartum medical care

APPENDIX B: Focus group guide – see separate attachment

APPENDIX C: References

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PROTOCOL TITLE: SweetMama: Testing of a novel technology for diabetes education and support to pregnant women

SHORT TITLE: SweetMama usability and feasibility

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ABSTRACT
Gestational diabetes mellitus (GDM) and type 2 diabetes mellitus (T2DM) during pregnancy are rapidly rising in prevalence and both disproportionately burden minority women. The existing health disparities in diabetes mellitus (DM) prevalence and perinatal outcomes are substantial public health problems that are exacerbated by the obesity epidemic. Although effective intensive management and treatment can reduce the morbidity associated with perinatal DM, the self-management skills and engagement required to achieve optimal glycemic control during pregnancy are complex and burdensome, especially among low-income, minority women. Prior data from our group and others have identified that the social, psychological, knowledge-based, resource-related, and logistical burdens of DM during pregnancy reduce women's ability to optimize glycemic control, which is directly related to adverse perinatal outcomes. Thus, we have drawn upon existing evidence, a rigorous theoretical foundation, and our preliminary data regarding barriers to and facilitators of DM care during pregnancy to develop a health behavior tool to educate and support low-income, minority pregnant women with GDM and T2DM. Mobile health (mHealth) technology is a promising avenue for behavioral health interventions, and our tool, SweetMama, incorporates educational, motivational and supportive elements to positively impact maternal health behaviors without amplifying provider burdens. Our long-term hypothesis is

that the use of an innovative and interactive mHealth tool can improve maternal glycemic control and maternal and neonatal outcomes.

To address this hypothesis, this phase of research will focus on developing an optimized version of SweetMama via a sequential process of in-depth usability and feasibility testing. We will perform focus groups and individual usability testing with low-income, minority pregnant women with DM. Additionally, we will obtain feedback and evaluation of SweetMama from health care providers who serve this patient population. This will be followed by refinement of SweetMama based on participant input. Usability testing will apply mixed methodology. Accomplishing this step will be necessary prior to the performance of a pilot randomized controlled trial to field test SweetMama, which will then be performed as a part of the feasibility testing phase. The feasibility phase will also include mixed methodology.

OBJECTIVES:

Diabetes mellitus (DM) poses a significant health burden to pregnant women.[1,2] Effective treatment can reduce the risk of adverse maternal and child health outcomes of T2DM and GDM.[3] However, successfully managing DM in pregnancy is challenging due to the complexity of self-management skills and high level of engagement in health care required for optimal glycemic control. Moreover, pregnancy is considered a window of opportunity for health behavior optimization due to both enhanced motivation and health care access. However, perinatal management of DM requires unique and advanced patient education and engagement. Existing support tools for this critical period of care are currently insufficient to address the identified multitude of logistical, informational, social, psychological, financial, and physical barriers to perinatal management of DM.[4-9]

To address these needs, we created a “first-of-its-kind” mHealth platform for pregnant women with GDM or T2DM. This platform, named SweetMama, is a theory-driven application that delivers an interactive, goal-oriented educational and motivational diabetes-focused curriculum.

The next steps include performing usability testing of SweetMama. The aim is to create a refined version of SweetMama via a sequential process of in-depth usability and feasibility testing:

1. Focus groups and/or individual user interviews with 10-30 low-income pregnant women with DM to evaluate tool functionality, design, and interpretability.
2. Focus groups and/or individual interviews with up to 50 health care providers who serve the patient population to obtain expert feedback and to evaluate SweetMama’s clinical usability and feasibility
3. Individual usability testing with up to 30 women, who will use SweetMama for 2 weeks followed by qualitative (interviews) and quantitative (questionnaires and user interaction data) assessments of tool satisfaction and use.
4. Feasibility testing via a pilot randomized controlled trial (RCT) with up to 50 women in order to determine acceptability, feasibility, and pilot procedures for a fully powered RCT. Providers of patient participants will also provide feedback via surveys and interviews.

The objectives are to:

- Develop SweetMama and optimize its functionality through laboratory and field usability testing.
- Optimize SweetMama for patient preferences and satisfaction.

- Determine SweetMama feasibility; prepare for and conduct a pilot randomized controlled trial (RCT) comparing SweetMama use to standard of care.

Secondary aims include:

- Exploration of the mediating effects of adherence markers (e.g. use time, app launches, etc.), SweetMama content (e.g. logistical, supportive or educational messaging), and patient characteristics (e.g. demographic, clinical, or self-reported measures).
- Optimize support strategies and content within SweetMama.
- Explore and optimize strategies to incorporate SweetMama into routine clinical care for low-income pregnant women with diabetes. Optimize SweetMama for provider satisfaction and clinical efficiency.
- Determine health care provider perspectives on SweetMama use during feasibility assessments (pilot RCT).

BACKGROUND:

Diabetes mellitus (DM) during pregnancy is a major public health problem. Obesity and DM are serious pregnancy comorbidities with significant maternal and neonatal health implications. Driven by the obesity epidemic, the frequencies of gestational diabetes mellitus (GDM) and type 2 diabetes mellitus (T2DM) have risen significantly, creating a major public health problem.[10-16] DM has well-established relationships with adverse perinatal outcomes, including cesarean delivery, hypertensive disorders, macrosomia, and neonatal metabolic complications, resulting in short- and long-term decrements in health for both mother and child.[1,2]

Racial/ethnic disparities related to DM in pregnancy exist. Minority women experience pregnancy-related health disparities, including an approximately two-fold greater incidence of GDM, GDM recurrence, and subsequent T2DM after GDM.[1,2,16-20] Over half of women with GDM[21-23] and over two-thirds of women entering pregnancy with T2DM are from minority racial/ethnic groups.[11] Minority women with DM also experience more frequent adverse perinatal outcomes[12,21]; for example, non-Hispanic black women with GDM have a greater risk of cesarean delivery, macrosomia, and fetal demise than white women with GDM.[12,21-24] The increased prevalence of DM and higher risk for DM-associated adverse outcomes widen existing health disparities.

Treatment of abnormal glucose homeostasis during pregnancy reduces the risk of adverse outcomes.[1,3,25] Care is centered around goals of optimizing glycemic control and monitoring for complications. Multidisciplinary treatment plans include medical nutrition therapy, exercise, potential medication administration, and enhanced maternal-fetal surveillance.[1,2] Thus, perinatal care for DM necessitates advanced patient education and engagement.[8] While pregnancy already requires enhanced patient learning, DM management further complicates perinatal care.

Given the complexity of perinatal DM management, women must be equipped with communication, literacy, numeracy, problem-solving, and organizational skills to optimize outcomes. DM self-management during pregnancy is burdensome and challenging, particularly for women with greater social disadvantage.[4,5] Logistical, social, financial, informational, access-related, and attitudinal challenges to DM management have been identified in several cohorts[4-7,26] and our own data.[8,9]

While traditional DM behavior support interventions can be effective for non-pregnant adults,[27] scalable interventions that promote sustainable behavior change, address disparities, and are specific to pregnancy are

urgently needed. The expansion of mobile technology has made mobile health ("mHealth") applications a promising avenue for health promotion, especially in DM.[28-31] Text messages, for example, can be motivators, information sources, cues to action, reminders and reinforcements, and sources of support.[32] Outside of pregnancy, mHealth use is associated with improvements in glycemic control, self-care behaviors, adherence, engagement, self-efficacy and health care costs.[33-39]

Despite the proliferation of commercial mHealth "apps", evidence-based mHealth interventions for pregnant women are lacking. Interest in such programs is high, with data showing the majority of pregnant women are interested in and have access to mHealth.[40,41] Text4baby, for example, delivers health promotion messages to enhance general pregnancy health behaviors and may positively affect health attitudes.[42-45] Other text messaging programs for reproductive aged women have investigated smoking cessation, contraception, and weight loss.[46] Yet, many programs lack rigorous evidence-based or user-centered design,[31] and advanced or disease-specific perinatal mHealth interventions are lacking. Interventions designed for use by pregnant women with DM, particularly in low-income populations, are needed.[46]

To fill this gap, we_ENREF_10 initiated a multiphase project to develop a behavioral health intervention to support pregnant women with DM, with particular attention to low-income women. In prior work we developed a model of barriers to self-care and factors that help to overcome these barriers.[8,9,47] We then applied those findings to develop a patient-driven text messaging curriculum to support DM self-care ("Texting for Diabetes Success"), which was performed at NMH within the Prentice Ambulatory Care clinic. The curriculum created for that program serves as the backbone for SweetMama. Participants reported high satisfaction and perceived benefits from this curriculum, and desired that we extend it further with interactive and individualized features. Based on these findings, we created SweetMama, a supportive and educational theory-driven mHealth platform for pregnant women with GDM or T2DM. SweetMama delivers an interactive, goal-oriented educational and motivational diabetes-focused curriculum. Our long-term hypothesis is that use of a high quality mHealth tool can improve maternal glycemic control, positively impact maternal and neonatal outcomes, and thus contribute to reducing perinatal DM-related disparities.

Finally, effective perinatal mHealth interventions require a theoretical framework to derive the greatest benefit.[32,46] The Health Belief Model explains individuals' engagement in health behaviors via the constructs of perceived susceptibility, severity, barriers, and benefits.[48] Cognitive load refers to a task's cognitive demand[49,50] and suggests individuals have a limited capacity to process information.[51-53] The learning and decision making burdens of DM management demand self-efficacy, confidence in the ability to perform a particular set of behaviors.[54] DM self-efficacy is particularly salient in pregnancy, where in a short amount of time a woman must believe she can accomplish new health behaviors in order to successfully execute those changes.[55] We have applied these theories in the development of SweetMama.

SweetMama currently functions as a user-friendly application in which participants are delivered three library-based messages per week, in which messages derive from the previously-developed and newly expanded curriculum, and one individualized goal-based message that is customized to the patient. All messages designed as dynamic messages that allow for receipt of novel educational, motivational, or supportive content when desired by patients. Messages can be "favorited" and archived, and can be viewed on WiFi or when outside of data/WiFi capacity. The intervention is designed to be a simple but consistent plan of supportive and reinforcing messages that promote self-efficacy, engagement, and knowledge during a pregnancy complicated by diabetes. We have previously tested and utilized the primary messaging content in the Texting

for Diabetes Success study, and have now expanded both the content as well as transitioned from simple texting to smartphone-based technology. Modification of SweetMama throughout the early phases of this investigation have resulted in improvements in the curriculum, algorithm for curriculum delivery, graphics, and user-friendliness of the intervention.

Although the technology has been tested with our core group of expert users, further provider feedback in addition to in-depth user testing will allow for app optimization prior to a large-scale trial on the relationship between SweetMama use and perinatal outcomes.

Thus, this proposal will solicit in-depth user-centered feedback on SweetMama, allowing us to iteratively modify SweetMama. At each phase of usability and feasibility testing, we are making modifications that improve SweetMama and generate insight into the ability to conduct a larger randomized controlled trial to assess clinical outcomes. Accomplishment of usability phases will result in an optimized tool ready for longitudinal field testing via a pilot randomized controlled trial, which is the current stage of feasibility testing.

INCLUSION AND EXCLUSION CRITERIA:
Inclusion criteria

Patient focus groups and individual user testing:

- Age 18 and greater
- Gestational diabetes mellitus or type 2 diabetes mellitus
- English-speaking (as SweetMama currently does not exist for non-English speakers)
- Gestational age:
    - Focus groups and individual user interviews: Confirmed intrauterine pregnancy at least 8 weeks' gestational age or postpartum until 12 weeks after delivery
    - Individual testing: Pregnant with a confirmed intrauterine pregnancy at least 6 weeks' gestational age, up to 4 weeks postpartum
    - Pilot randomized trial: Pregnant women with a confirmed intrauterine pregnancy (at least 6 weeks' gestational age) who are initiating diabetes care at the study site and are less than 30 weeks' gestational age. Enrollment will be permitted until 30 weeks as data show even late treatment can improve DM-associated outcomes.[56,57]
- Patient at Prentice Ambulatory Care, General Obstetrics/Gynecology, or Maternal-Fetal Medicine practices at Northwestern Medicine
- Low income, defined as use of publicly-supported insurance for prenatal care or household income <200% of poverty line for family size
- Access to a smartphone (for longitudinal testing phases)

Health care provider testing:

- Practicing MD (resident, fellow, or faculty), nurse, diabetes educator, lactation consultant, medical assistant, patient services representative, or registered dietitian within Prentice Ambulatory Care/ Maternal-Fetal Medicine at Northwestern Medicine
    - Pilot randomized trial: Provider must be caring for a patient enrolled in the pilot randomized trial.
- Age 18 or greater

- English-speaking

Exclusion criteria:
- Failure to meet the inclusion criteria above
- Patient aims: Non-viable pregnancy

Maximum total number of participants: 180
- 10-30 women to participate in focus groups and individual user interviews
- Up to 30 women to participate in individual field testing
- Up to 50 health care providers to provide expert feedback in focus groups and interviews
- Up to 50 women to participate in the pilot RCT
- Up to 30 health care providers to participate in surveys and interviews affiliated with the pilot RCT

We will specifically include pregnant women as pregnancy is a requirement for participation; the goal of the study is to develop a tool for use by pregnant women. This study does not include adults unable to consent, minors, or prisoners.

STUDY-WIDE NUMBER OF PARTICIPANTS: Not applicable, not a multi-center study

STUDY-WIDE RECRUITMENT METHODS: Not applicable, not a multi-center study

MULTI-SITE RESEARCH: Not applicable

STUDY TIMELINES:
Focus groups and individual user interviews: Women recruited to the focus groups and individual user interviews will have approximately 1 hour of study participation in which they will be asked to provide feedback about SweetMama while testing it and discussing its potential use during pregnancy. They will not be followed longitudinally.

Longitudinal individual testing: Women recruited to the longitudinal usability testing phase of SweetMama will actively participate for two weeks, during which time they will have frequent contact with the study team. After this period of active use, we will request patient permission to follow up their pregnancy outcomes via record review, but we will not require further information nor study participation.

Provider testing: Health care providers recruited to a focus group or individual interview will have approximately 1 hour of study participation in which they will be asked to provide feedback about SweetMama while testing it and discussing its potential clinical use. Participation in the study will be over at the end of the focus group or interview.

Pilot RCT: Women recruited to the pilot RCT phase of SweetMama will enroll in the study upon initiation of prenatal care for diabetes, which could be early in pregnancy at the time of first prenatal visit, or at a later point if they have transferred care to this site. Women will actively participate for the duration of their pregnancy and postpartum period, which could be as long as 44 weeks (for example, of a woman enrolled at 6 weeks, delivered at 40 weeks, and continued through 10 weeks), or could be as few as 20 weeks (if enrolled at

30 weeks and delivered at 40 weeks). We will follow their patient-reported and medical record outcomes throughout this time period. We will not require further information or study participation after the postpartum exit interview. Health care providers who participate in the provider survey will complete a one-time survey at the time of their patients' enrollment and another survey upon exit; the exit survey will be repeated for each patient they have who is enrolled in the pilot trial. Healthcare providers will additionally complete a one-time in-depth interview after they have had enrolled patients complete their participation.

We plan to initiate focus groups and user interviews in July 2017 and finish by March 2019. We will then modify SweetMama as needed, and plan to start longitudinal individual testing by February 2019. Recruitment for the longitudinal testing will require approximately 8-12 months, after which we will complete study analyses and publications for that phase. Provider focus groups will begin October 2018 and be completed by February 2019. The pilot RCT phase will begin after analysis of the individual phase; we anticipate beginning to recruit for this phase in August 2019 at the earliest. The goal is to complete the study by mid-2020.

STUDY ENDPOINTS:
Usability (a measure of the interactive user experience) testing is a primary element of user-centered design and is an iterative process in which groups of participants evaluate application features and then identify and fix problems. After a round of evaluation, a new group of participants are brought in to evaluate the application.

The **expected outcome** of the first phase of research will be a refined tool ready for field testing. The expected outcome of the pilot RCT phase is a better understanding of feasibility of a SweetMama trial via field testing. The primary endpoint is completion of usability and feasibility testing with the above described targeted population, which will inform the revision of SweetMama prior to a larger trial to assess clinical outcomes. The secondary endpoint will be the completion of all data analyses related to these testing phases.

PROCEDURES:
This is a prospective usability/feasibility study involving participant use of SweetMama. SweetMama will be evaluated in this population of low-income, minority women per a commonly used usability and feasibility testing approach[58,59] with a sequential process:

a) Sequential usability focus groups and user interviews (between 10-30 participants, evenly distributed between women with GDM and T2DM, in group sizes of ideally 3 women), followed by
b) Longitudinal usability testing with up to 30 women (up to 15 with GDM and 15 with T2DM), or until saturation of information on usability.
c) Concurrent with usability testing, we will conduct provider focus groups or interviews in order to ensure the intervention under development is optimized based on provider experiences and needs.
d) Followed by completion of the above steps, we will initiate a pilot randomized trial of up to 50 eligible women (unbalanced to favor receipt of intervention) who will field test SweetMama by using it from initiation of care to the postpartum period, in order to identify the feasibility of this trial prior to a large clinical outcomes-oriented trial.

We will aim for a targeted distribution of patients stratified evenly by age (>30yo vs. <30yo), DM type (GDM vs. T2DM), gestational age at entry (by trimester), and with a racial/ethnic distribution reflective of the 90% minority demographic at the study site. Sample sizes were generated based on data illustrating that these sizes are sufficient to inform high quality user-centered design of a larger scale, next step behavioral

intervention trial.[37,60-63] For the pilot RCT, the sample size is set to provide sufficient data to make reasonable estimates regarding recruitment and feasibility but is not designed to assess clinical outcomes. Improvements to SweetMama will be iteratively performed between focus groups, before and after individual testing, and between individual participants. No major updates will be made during the pilot RCT unless technically necessary in order to fix errors.

We will also conduct surveys, focus groups, and individual interviews with health care providers who serve this patient population. Concurrent with patient usability testing, we will aim for a total of up to 50 participants with differing clinical roles (MD, RN, diabetes educators, medical assistants, nutritionists, others) who have varied types of encounters with patients and will therefore be able to provide robust feedback on the app's clinical potential. Concurrent with the patient feasibility testing (pilot RCT), up to 30 providers who care for enrolled participants will be recruited to complete entry and exit surveys about their patients as well as exit interviews about SweetMama.

SweetMama overview: We have used our group's experience (prior published works; see citations) and theory to rigorously modify a curriculum of didactic and supportive messaging content developed in earlier work. SweetMama now includes a dynamic two-option response system. Because patients in earlier phases strongly desired access to more information, each message in the curriculum library will generate an option for the participant to connect further with SweetMama. In this dynamic setup, one option would be to end the interaction; for example, if a patient receives a message and does not desire more information, she selects the option that acknowledges the message and closes SweetMama. Alternatively, she may opt to receive more information, which will lead her to expert-driven novel content, a trusted website, or an alternative source of support. Using the modified Phase 2 content, messages include basic appointment reminders in addition to substantive didactic content and motivational messaging. In order to offer this interactive content, we have worked with an expert team to generate dynamic content for nearly 130 messages, which has been refined to a total of 139 messages for the pregnancy and postpartum curriculum, including novel goal-setting messages and appointment messages.

Via experience with the early phases of SweetMama, we have additionally refined the curriculum such that all individuals will receive the same base curriculum, and individuals who require insulin therapy for their diabetes receive an additional supplementary 12-weeks of insulin curriculum; this functionality will take the place of prior versions in which there were different curricula for each treatment type.

This message curriculum library serves as the foundation for SweetMama. This functionality has been designed to be scalable by intentionally building the capacity to pre-program the messaging library at the start of participant enrollment based on a gestational age-specific algorithm.

SweetMama includes several other patient- and theory-driven components, including:

- Favorites: All messages will be retained in an archive organized by type and chronology. Participants will be also able to "favorite" preferred messages for later review.
- Library: The library will contain dynamic content, such as storage of the messages received, as well as static content, which will contain didactic information that will always be available to participants. This will include recommended recipes, handouts, and worksheets provided by the Health Learning Center, and other tips/advice for participants.

- Goal-setting: Consistent with the Theory of Self-Efficacy, SweetMama includes individualized goal-setting activities. At each appointment, participants select a goal for the subsequent week with the clinical team; goals may be behavioral, nutritional, or other DM-related patient-driven goals. The goal will be entered into the SweetMama provider platform to be delivered as a patient reminder 4 days later. Goals can be modified and customized as needed, and goals can be delivered up to once a week. This individualized message's dynamic response option will ask participants whether they have accomplished the stated goal. A goal achievement log that encourages self-regulation behaviors will be maintained.
- Technical support: Participants will have access to "in-app" participant-initiated support. The technical support page includes instructions to call the clinic or hospital for clinical questions.
- Appointment reminders: The home page contains the time of the next appointment, and participants receive appointment reminders as messages prior to the scheduled appointment.
- Information: The home page will also provide clinic contact information, names of clinical care team, and basic information about the purpose of SweetMama.
- Introductory video: A brief orientation video will display upon first interaction with SweetMama. This video has been created to demonstrate SweetMama's features in a concise and user-friendly manner; it additionally ensures standardization of the orientation process.

Thus, upon enrollment in the usability or field testing phase, participants can activate SweetMama via secure phone number-based web sign-in. The research team will then use the secure researcher dashboard to create a schedule of messages using the pre-designed curriculum algorithm; these messages will be delivered on Monday, Wednesday, and Friday, at noon. Appointment reminder messages are delivered the Monday before the scheduled appointment, also at noon. Insulin-specific messages will be delivered every Wednesday at noon, once the participant starts the insulin curriculum. The individual "goal setting" message will be delivered on Saturday at noon. Participants can go to their home page, favorites, or archive at any time to view pending or old messages.

Usability testing: focus groups and user interviews. We will perform between 2 and 6 focus groups, with the number and size to be determined based on participant availability and the quality of feedback received from interviews. Groups will have at least 3 participants but no more than 6 participants, to maximize individual attention. Focus groups can be terminated once saturation has been achieved. Recruited participants whose availability does not align with scheduled focus groups may be asked to participate in individual user interviews using the same interview guide as for focus groups. Focus groups and user interviews will take place at the CBITs usability laboratory or in the Prentice Ambulatory Care clinic.

Women will be identified via routine clinical care and approached in the clinical setting. They will be informed of the reason for the study and invited to participate. When a sufficient number of participants have agreed to participate, women will be directed to the usability lab at a mutually agreeable time. If a mutually agreeable time is not found, women will be asked to come to one of the spaces listed above for an individual user interview.

The focus groups and user interviews will assess tool functionality, design, interpretability, and acceptability (initial reaction, attitude, and receptiveness). The group format, performed at the CBITs' Usability Laboratory using a semi-structured interview guide and led by the research team, will generate feedback on areas that may not be revealed in a one-on-one interview. Group members will be informed that any information

provided during their participation is confidential within the group; they will also be informed that they will not be asked sensitive questions about themselves or their health in the group setting.

The semi-structured focus group guide is attached (Appendix B). This guide will also be used for women participating in individual user interviews. Participants will also be asked about general experiences with diabetes during pregnancy, use of smartphones, use of phone applications, and preferences for resources related to diabetes during pregnancy. Participants will be asked about their own smartphone use and about their need for pregnancy support information. Next, participants will be oriented to SweetMama, use its functions with guided support, and provide feedback about the content's relevance, clarity, delivery style, timing, tone, length and visual design. They will then use a phone with SweetMama loaded on it and will be asked to use the buttons, archive messages, choose favorites, and review the content. They will be given choices and asked preferences regarding the organization and content of the application. They will also be given the opportunity to make suggestions for the application. Messages will be sent in real time during the group. Focus groups and user interviews will be audio recorded and research members will take notes during participation. This stage will inform modifications to best align SweetMama with curriculum goals and participant preferences. We will rigorously collect specific user feedback including these techniques:

- "Think alouds" – Participants speak aloud a running commentary while performing tasks involved in the operation of SweetMama. This is a common approach[64] to usability testing that permits investigators to evaluate the ease of learning the system and provides first-hand information about design problems.
- Cognitive testing – Participants will explain what specific words or images make them think and feel.
- Feasibility – All buttons, messaging, and archiving functionality will be tested by each participant.
- Research team observation of the problems participants have with SweetMama use.

Modifications to SweetMama will be made between focus groups as needed. After this phase, our team will spend 1-2 months making improvements in SweetMama based on participant feedback and focus group data.

Provider feedback and evaluation: Before longitudinal individual testing, we will perform 1-3 focus groups with health care providers to get expert feedback on SweetMama and to evaluate the app's clinical potential. Health care providers will be approached by a researcher in the clinic, who will explain the purpose and basic functionality of SweetMama. The number and size of these provider focus groups will depend on individual availability and quality of feedback. Focus groups will be scheduled at a mutually agreeable time. If a health care provider is not able to attend a scheduled focus group but interested in participating, they will be asked to participate in an individual interview to obtain their feedback of SweetMama. If it is not possible to identify any mutually agreeable times for focus groups, an alternative strategy will be to primarily conduct individual interviews. Groups may have anywhere between 2-7 participants, depending on availability. We will aim to obtain feedback from a total of 20-50 health care providers. All focus groups and/or individual interviews will take place private rooms in the PAC Clinic or in Prentice Women's Hospital.

The semi-structured focus group guide is attached (Appendix C). These focus groups and interviews will serve as supplementary information to data gathered through the first phase of patient-facing user testing. This will allow us to integrate feedback from both patients and providers to develop an app that is both user-centered and clinically sustainable.

Usability testing: individual testing. After SweetMama is modified based on focus group data and feedback from individual user interviews, longitudinal usability testing will occur with up to 30 eligible pregnant women.

Women will be recruited to participate in the same manner as described above, via routine clinical interactions. After screening for eligibility, potentially eligible women will be provided a "SweetMama timeline" document that explains the study activities, provides contact information, and outlines how to contact the team for technical help. In this phase, women will not require a visit to the usability lab; instead, they will be oriented to SweetMama use on their own Apple or Android-based phones. The app has been modified to be web-enabled, and thus individuals are not limited to only Android phones. The goals of this phase are to collect data from diverse users that will (1) confirm that the mobile apps are functioning (not crashing) across a wide range of devices and operating systems, (2) provide basic information about app usage and user satisfaction (3) inform the development of future iterations by analyzing participant characteristics and use, and (4) collect quality assurance data that will allow the research team to refine the applications.

With the assistance of trained research staff, participants will undergo standardized orientation to SweetMama and the first message will be delivered upon enrollment; the training of the research team to perform standardized orientation and support enhances the fidelity of the intervention. At this time, we will collect baseline information on:

- Demographic and clinical characteristics
- Electronic health literacy, assessed via the eHealth Literacy Scale (eHEALS), an 8-item assessment of computer literacy as related to health information.[65]
- Health literacy, assessed via the Newest Vital Sign, a nutrition label-based 6-item measure of the ability to obtain and process health information.[66-68]
- Diabetes self-efficacy, assessed via the Diabetes Empowerment Scale–Short Form (DES-SF), an 8-item measure of psychosocial self-efficacy of individuals with diabetes.[55,69,70]
- Patient activation, assessed via the Patient Activation Measure (PAM), a 22-item measure of patient engagement in the care process.[71]

Women will then use SweetMama for 2 weeks, a length of time sufficient to obtain usability data.[58] Our usability testing protocol[58,59,72] includes weekly research assistant 10 minute "check-ins" to identify technical problems followed by an interview after 2 weeks consisting of qualitative and quantitative assessments:

- Interview – Semi-structured interview framed by the Health Belief Model on experiences with SweetMama. Information will be designed to elicit feedback about technical problems, ease of use, satisfaction and overall usefulness for various components of SweetMama (see Appendix D)
- System Usability Scale (SUS) – A simple and technologically flexible 10-item scale to assess satisfaction with and usability of a product or service.[73,74]
- Usefulness, Satisfaction and Ease of Use (USE) Questionnaire – A 30-item scale to evaluate user interfaces across the three domains of usability, satisfaction, and perceived ease.[75]

Specific user interaction data (regarding study retention and interactivity) also will be gathered via the SweetMama provider research platform, including:

- Summary client events: number of times and days app was accessed, total usage length from first to last access, number of times used per week, number of episodes of active use (defined as use from 1-20 minutes), average length of active use, total number of messages viewed, total number of messages responded to, total number of messages "favorited", total number of individual goal messages received and achieved, total number of self-initiated access events (i.e., not triggered by a routine message).

- Curriculum events (per message): time interval from sending message to participant viewing, dynamic option chosen, action taken with a follow-up message (i.e., was a link or phone number used after being provided), identification of favorite messages, and number of times messages in archive were viewed.
- Goal-setting events: specific goal content, dynamic option chosen, total time from message delivery to response, cumulative goal achievement, number of favorited and archived goal messages.

Only data related to how and when SweetMama is used will be collected and the format in which it is stored will contain no identifying information about users. Furthermore, the information saved on the server will only be accessible to people provided with the proper credentials (members of the research team, research collaborators, and the users themselves).

At the end of the 2 week trial phase, participants will be informed that they may continue using the SweetMama on their phones (eg view archived messages) but will no longer have individualized messages. For any participants who do continue their use after the study period has ended, SweetMama will continue to collect phone and app data as before.

Finally, participants in the individual testing phase will be followed via their Epic records for pregnancy outcomes, including birth outcome and glycemic control (see Appendix A). No long-term follow up will be required.

All study activities will take place within Northwestern Medicine, specifically in the PAC clinic and Maternal-Fetal Medicine practice.

No physical procedures will be performed and there are no specific procedures used to monitor participants for safety or minimize risks, as this poses no more than minimal risk to participants.

Source records for the study include the focus group, surveys, and chart data, as described above. All questionnaires will be collected on paper. No external approvals are required prior to commencing research; as this is not a clinical trial, registration at clinicaltrials.gov is not required but has been performed and updated.

<u>Feasibility testing: Pilot RCT (patient component)</u>
After SweetMama is modified based the usability testing phase and provider feedback, which we anticipate will take 1-2 months, feasibility testing will occur with up to 50 eligible pregnant women via field testing. The goals of this phase are to field test recruitment, retention, and assessment strategies, as well as delivery of SweetMama within a pilot RCT, to assess feasibility and inform the design of a full trial assessing behavior, glycemic control, and perinatal outcomes. We will collect feasibility data regarding recruitment, technical challenges, quality assurance, and retention, as well as clinical outcomes data and patient-reported outcomes.

Women will be recruited to participate in the same manner as described above, via routine clinical interactions. Medical records will be reviewed for eligibility and women with diabetes will then be approached for verbal in-person screening and recruitment using a recruitment script (Appendix E). Participants will sign written informed consent. Enrolled women will be provided a “SweetMama timeline” document that explains the study activities, provides contact information, and outlines how to contact the team for technical help or any other needs. We will then randomized participants. Randomization, via REDCap,[76] will be unbalanced to

offer greater odds of receiving the experimental treatment in order to enhance the research team's experience with SweetMama and incentivize participation, with a target sample of 40 (randomized 1:3, stratified by DM type). The target sample size is 40, but up to 50 women may be enrolled in order to account for drop-out or the requirements of the randomization schema.

Women who are randomized to usual care will receive no orientation to or enrollment in SweetMama. They will receive surveys at enrollment, during the delivery hospitalization, and at the postpartum visit (see details in table below). Women who receive usual care will not undergo interviews.

Women who are randomized to SweetMama testing will be oriented to SweetMama use on their own Apple or Android-based phones. Once enrolled, with the support of trained research staff, participants will undergo standardized orientation to SweetMama using the introductory video developed in the usability phase. The SweetMama introductory video will be updated between the usability and feasibility testing phases. The training of the research team to perform standardized orientation and support enhances the fidelity of the intervention. Women will then use SweetMama throughout pregnancy. The curriculum delivery will be performed as described above and will be automated based on entry gestational age. Their appointment reminders will be entered into the researcher dashboard prior to appointments, and their goal messages will be set via involvement of the clinical team at appointments as recommended by the APN. If a woman starts her participation already on insulin, she will receive the supplementary insulin curriculum from enrollment; if she initiates insulin after enrollment, she will initiate the insulin curriculum that week. SweetMama users will undergo every 2-week check-ins for technical and quality assurance; these brief check-ins will take place via text, phone, email, or in-person, depending on participant preference. Use of SweetMama will continue until the completion of the postpartum visit, with a curriculum that extends through postpartum week 8. They will receive surveys at enrollment, during the delivery hospitalization, and at the postpartum visit (see details in table below). SweetMama participants will also undergo a brief 2-part exit interview (see below) focusing on feedback for SweetMama use, areas for improvement and how SweetMama affected their engagement. The primary interview will take place during the delivery hospitalization or shortly thereafter if not feasible at the time; a brief follow-up interview focusing on the postpartum curriculum will occur at the postpartum visit.

The primary outcomes of Aim 2 are feasibility (≥80% retention; see below) and satisfaction (USE, SUS, interviews). Secondary outcomes are behavioral (DES-SF, PAM, adherence), clinical (hypertensive disorders, delivery mode, birthweight, neonatal hypoglycemia, NICU admission), and glycemic control outcomes. Glycemic control will be assessed as hemoglobin A1c (final and difference from enrollment to delivery) and as proportion of blood glucose measures out of goal. Adherence will be assessed as proportion of prenatal visits attended and with available glucose data.

In order to assess these outcomes, the measures in the following table will be collected via the medical record, user interaction reports, and patient report:

	All women	**Additional data gathered in SweetMama arm**
Baseline	• Demographics, clinical data, eHEALS, NVS, DES-SF, PAM, technology comfort questionnaire	
Monthly	• Retention (continuation in care and the study protocol)	• SweetMama retention and adoption • SweetMama functionality, quality assurance & content feedback (technical check-ins)
Delivery	• Retention (continuation in care and the study protocol)	• SweetMama functionality, quality assurance, & content feedback • Exit interview- feasibility, improvement, and engagement

	• Treatment adherence • Behavioral measures: DES-SF, PAM • Maternal and neonatal clinical data	• Satisfaction and usability: USE and SUS • User interaction data (see Aim 1)
Postpartum	• Behavioral measures: DES-SF, PAM	• Exit interview part 2 – postpartum curriculum - feasibility, improvement, and engagement

As in the usability testing phase, we will collect baseline information on (see details above):

- Demographic and clinical characteristics
- Electronic health literacy – measured the eHealth Literacy Scale (eHEALS)[65]
- Health literacy – measured via the Newest Vital Sign[66-68]
- Diabetes self-efficacy – measured via the Diabetes Empowerment Scale–Short Form (DES-SF[55,69,70]
- Patient activation – measured via the Patient Activation Measure (PAM)[71]
- Technology comfort – Using a modified version of the Technology Comfort Questionnaire (12 items), we will ask about smartphone familiarity and comfort.

We will also collect data from study and medical record upon completion on:

- Retention, measured as continuation in the study protocol
- Treatment adherence, measured as 1) retention in clinical care with completion of all recommended self-care measures (visits attended and with glucose data available), and 2) proportion of glucose values out of range when presenting to care
- Maternal and neonatal outcomes, including glycemic control (Appendix A)

For the SweetMama arm, we will collect unique data on:

- Quality assurance and technical functioning: At each technical check-in point, we will complete a short standardized check-in regarding any errors, technical problems, or content clarifications. In this field testing phase, the 2-item quality assurance check-in will be completed by completion of a brief mobile REDCap survey.
- Interview – Semi-structured interview framed by the Health Belief Model on experiences with SweetMama. Information will be designed to elicit feedback about technical problems, ease of use, satisfaction abd overall usefulness for various components of SweetMama (see Appendix F)
- Satisfaction – measured via the System Usability Scale (SUS).[73,74]
- Satisfaction and usability – measured via the Usefulness, Satisfaction and Ease of Use (USE) Questionnaire[75]
- User interaction data – client event data will be identical to data in the usability phase.

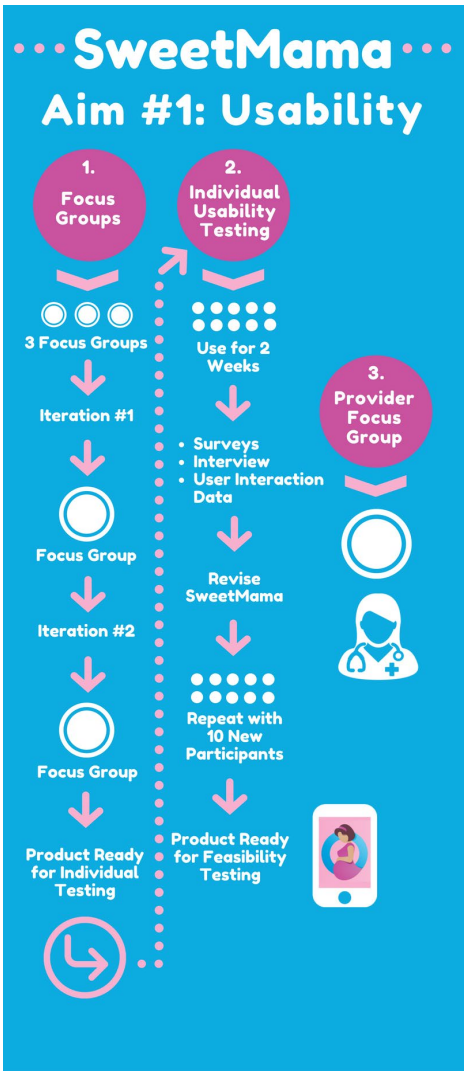
As in the usability phase, only data related to how and when SweetMama is used will be collected and the format in which it is stored will contain no identifying information about users. Furthermore, the information saved on the server will only be accessible to people provided with the proper credentials (members of the research team, research collaborators, and the users themselves). All study activities will take place within Northwestern Medicine, specifically in the PAC clinic, General Obstetrics/Gynecology practice, and Maternal-Fetal Medicine practice. No physical procedures will be performed and there are no specific procedures used to monitor participants for safety or minimize risks, as this poses no more than minimal risk to participants. Source records for the study include interviews, surveys, and chart data, as described above. All questionnaires will be collected using REDCap. The study has been updated in clinicaltrials.gov per requirements.

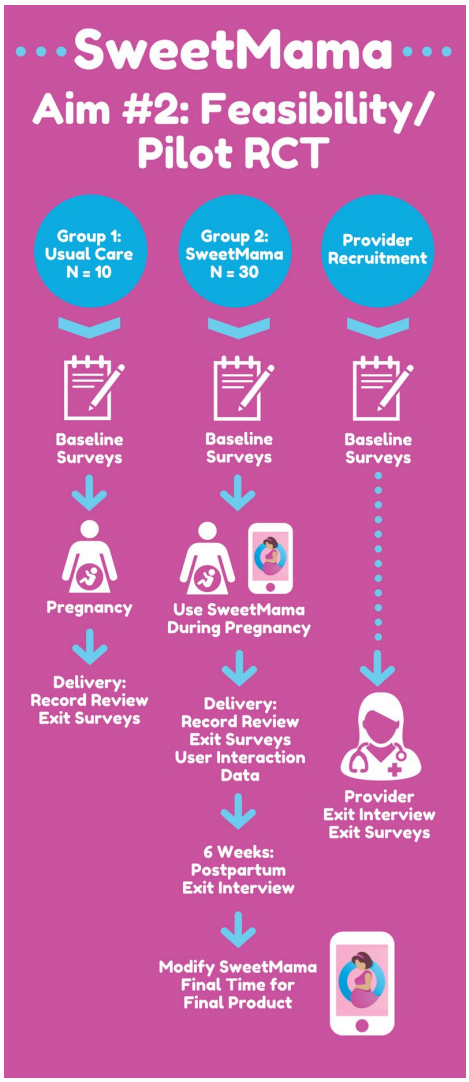
Feasibility testing: Pilot RCT (clinician phase)

Clinicians will be recruited using similar processes as described above for the clinician focus group phase. These stakeholders (nurses, physicians, nurse practitioners) will be individuals who care for enrollees in the pilot randomized trial, including both those who are SweetMama users and those receiving usual care. Providers will not be asked any personal questions about themselves. There will be three brief phases of provider enrollment:

- Upon patient participant enrollment, their primary provider will undergo a brief REDCap-based survey regarding perceptions of patient engagement in general, using an adapted version of the Clinician Support for Patient Activation (CSPAM) measure. The 14-item CSPAM addresses how far clinicians value people's role in the care process and indicates clinician level of endorsement about the importance of patient activation. This measure assesses a stable characteristic about a provider and thus will only be asked once. Additional questions will address their expectations for SweetMama involvement. At this point, the provider will also be provided brief education about SweetMama's goals and their involvement in the goal-setting component.
- Upon patient participant completion, providers will undergo a brief follow-up survey regarding their individual patient's engagement and adherence. Questions will be modified from the CSPAM and additional items will specifically query their opinions about SweetMama. Providers will complete this brief survey for each participant.
- Upon patient participant completion, providers will be asked to undergo a single in-depth interview. The qualitative interview will address if and how SweetMama affected provider roles, whether and how providers perceived benefit, and future suggestions. If a provider cared for multiple patients who used SweetMama, she will be asked to reflect on each individual participant's engagement as well as overall perspectives on the program.

Study outline





DATA AND SPECIMEN BANKING:

All participant data will be closely safeguarded. Participants will be tracked in NITRO StudyTracker. REDCap will be used as the secure online database for the study. Qualitative data from interviews will be stored in secure drives on password-protected computers in a locked office. Extensive measures will be taken to ensure data confidentiality. Written informed consent will be obtained and consent forms will be maintained in a secure locked location that only research team personnel will have access to, as well as scanned per requirements. Use of REDCap will allow for quality control, as data can only be entered securely and with limited range. All team members will be trained on data security and confidentiality, and will ensure the safe management of data. No specimens will be banked for future use.

DATA AND SPECIMEN MANAGEMENT:

Data management: Extensive efforts will be made to protect the confidentiality of participants. No biological specimens will be collected. All data are in the form of survey responses, interview/focus group responses, medical record review, and SweetMama user data. All data will be stored in secure, locked offices in Prentice Women's Hospital or the Department of Obstetrics and Gynecology research facility on password-protected computers, and in REDCap, a secure, Northwestern-approved electronic data capture resource.

Participant contact information and protected health information will only be accessible to the research team. Following participant recruitment, a study ID will be assigned and survey/interview results will be deidentified. Paper surveys do not contain any PHI and will only be identified by this unique study identification number. Participant identifiable information will be separated (and stored in StudyTracker) from research information (which will be stored in secure computers and REDCap). Data will be transported from the point of collection (i.e. clinic or the CBITs usability lab) to secure electronic data storage locations via direct upload on secure laptops. Dr. Yee and the study team will have responsibility for data transmission and storage. Data stored on the secure, password protected computers will be password protected and stored on hospital servers with automatic backup and active, updated antiviral software. Data will be stored for 5 years after analysis is complete and then data will be permanently removed from the computers that they have been stored on. Access to data will only be granted to the PI (Dr Yee) or the research assistants responsible for enrolling and entering data. Quality control will be assured via extensive training of research team members prior to patient recruitment. Further, information collected from the applications on the mobile phones will be transmitted to a secure server via encrypted, password-protected tunnels to protect users' privacy.

Sample size calculation: As this study is not a hypothesis-testing study but rather a usability/feasibility study, the sample size is not based on a statistical power calculation but on standard sample sizes for studies of this nature. Sample sizes were generated based on data illustrating that these sizes are sufficient to inform high quality user-centered design of a larger scale, next step behavioral intervention trial.[37,60-63] For the pilot RCT phase, the sample size is set to provide sufficient data to make reasonable estimates regarding recruitment and feasibility but is not designed to assess clinical outcomes.

Analysis: This is a mixed methods analysis. Descriptive statistics using bivariable analysis will be used to characterize the study populations. For statistical comparisons, all tests will be two sided and $p<0.05$ will be considered statistically significant. All statistics will be performed using STATA 15. Analyses will be performed as follows:

- Focus groups and user interviews (including provider focus groups and interviews): During focus groups and user interviews, we will take detailed notes and audio record in order to capture participant feedback. After each group, the research team will construct a brief preliminary summary report. Transcripts will then undergo rigorous and reproducible qualitative analysis techniques using the constant comparison method. Analysis will be performed in Dedoose, a secure qualitative data management and analysis software that facilitates collaborative exploration of data and identification of themes in accordance with the Health Belief Model and Theory of Self-Efficacy. Dedoose has been previously used for multiple studies performed in our Department and has data security approvals by NUIT; only deidentified data will be uploaded to Dedoose. We will ensure reproducible and rigorous interpretations are accomplished via use of memos, creation of a consensus code list with clear operational definitions, and calculation of agreement statistics for inter-coder reliability. The final report will compare data gathered from focus groups and user interviews and summarize themes. We will then iteratively modify SweetMama based on these results.
- Individual testing: Analysis of individual data will consist of qualitative and quantitative analyses with the goals of identifying user feedback to incorporate participant needs into design and determining user features associated with greater satisfaction and use. The primary outcome will be user adherence, based on user interactivity data. Given the small study size and aim of assessing usability, the analysis of user interactivity data will be largely descriptive (i.e., no comparison group) but we will also examine the effects of potential mediating factors, such as health literacy and self-efficacy.

Secondary outcomes include both qualitative interview data and the quantitative data regarding use and patient characteristics, as described above. Qualitative data will be analyzed in the same manner as described above, with an additional mixed methods evaluation of interview data in concert with quantitative measures. Quantitative results for the SUS and USE will be used to assess satisfaction with and usability of SweetMama. User interaction data will be quantified to ensure tool functionality and determine areas for improvement. Using Stata v.15, we will perform bivariable and multivariable analyses to measure the relationships between baseline demographic/clinical characteristics, DES-SF, and PAM with user satisfaction and SweetMama interactivity.

- Provider surveys (in pilot RCT): Provider surveys will be analyzed using descriptive statistics as needed. We will analyze provider perceptions of engagement via the CSPAM and the modified CSPAM questions about SweetMama.
- Pilot RCT phase:
    - *Qualitative and mixed methods:* Exit interviews will use qualitative techniques and behavioral theories described above. We will use Dedoose software to perform a mixed methods analysis of themes in the context of quantitative measurements. For example, we will analyze satisfaction-related themes stratified by user interaction data such as quantity of episodes of active use, a measure of intervention exposure. This method allows us to assess several specific questions, such as if there are differences based on gestational age at enrollment or "dose" of intervention received.
    - *Quantitative:* Using Stata, we will report baseline characteristics, recruitment and retention metrics (cumulatively and per month), and user interaction data. Outcomes will be compared a) within individuals (baseline vs. postpartum) and b) between groups (retention, behavioral measures and clinical outcomes). Bivariable analyses will be performed, with *a priori* subgroup analyses to assess differences by age, diabetes type, medication use/changes, and gestational age at entry (<20 weeks vs. ≥20 weeks). Regression modeling will be used to assess the relationship of SweetMama use to retention and other behavioral outcomes after controlling for potential confounders, such as length of exposure. Within the experimental group, although statistical power will be limited, we will also perform bivariable and multivariable analyses to assess relationships between user clinical/behavioral characteristics and satisfaction and use. Feasibility targets for study retention will be set at 80% retention in the study protocol. Feasibility target for SweetMama adoption will be 80% active use (defined as at least weekly interaction with SweetMama content). Targets are set at 80% based on prior literature using this threshold to represent greater engagement.[36,61]

PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF PARTICIPANTS:
Not applicable, as the study procedures pose no more than minimal risk of harm to participants.

WITHDRAWAL OF PARTICIPANTS:
There are no planned circumstances under which subjects will be withdrawn from research without their consent. Notably, as the study at all phases is of minimal harm to participants, there are no safety reasons that would necessitate withdrawal. However, if participants request withdrawal from the study for any reason, their participation would be discontinued immediately. If participants request termination of their participation, they will be instructed (in the consent form) to contact Dr. Yee. Upon receiving this request, they will be immediately withdrawn and no further prospective data will be collected. Data collected prior to withdrawal will be maintained and analyzed unless requested otherwise. The only administrative reason for

withdrawal of participants is loss to follow-up; if a focus group participant fails to present for the scheduled focus group, or if an individual testing patient fails to interact with SweetMama for the duration of participation (2 weeks), she will be considered lost to follow-up. If a pilot RCT participant fails to interact with the research team for the scheduled "check-ins" for 2 months or more, she will be considered lost to follow-up.

RISKS TO PARTICIPANTS:
Breach of confidentiality is a risk associated with this research, although all survey data will be maintained on a HIPAA complaint online database or stored in a locked, on-campus secure office. Additionally, in this phase, participants may be asked to use their own phone and data plans; patients who do not have unlimited data may experience either data charges or find that SweetMama is inaccessible until they are on WiFi. Extensive efforts will be made to orient subjects to SweetMama and help them reduce the risk of unanticipated data charges.

The participants are otherwise not subject to any risks from the intervention testing process or chart reviews. If participants feel increasing stress from participation, they may choose to terminate participation. The likelihood of discomfort from this study is very low, given that the study is focused on their perspectives on a health behavioral intervention.

There will be no effect on the woman's medical care, and there are no medical interventions in this study. There are no pregnancy-specific risks to the pregnant woman or her fetus due to participation in this survey study. No study-specific procedures have risks to subjects that are currently unforeseeable.

There are no risks to others who are not participants.

Health care provider participants in focus groups will be subject to minimal risk. Participants will not be asked any questions about their own personal health. All questions to health care providers/clinic staff will be about their experiences with patients and their opinions of SweetMama. Thus, few risks are anticipated aside from breach of confidentiality as described above. As above, provider participants will also be able to terminate participation at any time. There will be no effect of participation on the individual's employment or medical care.

POTENTIAL BENEFITS TO PARTICIPANTS:
The goal of this study is to develop a supportive health behavioral intervention that improves maternal outcomes in the setting of diabetes during pregnancy. It is possible that some women may find the completion of the focus group or user interview interesting and it may provoke further discussions with their clinician; however, no clinical benefits are anticipated. Their involvement will hopefully improve the quality of care for future patients.

However, we do anticipate that the 2-week individual testing period and the pilot RCT may offer some benefits to patients who are using SweetMama; namely, we are offering a supportive and educational program that provides women information and other psychosocial support during a pregnancy complicated by diabetes. We do not believe there will be long term perinatal benefits with just this short period of participation (usability testing phase) or in the small population of the pilot RCT phase (feasibility testing), but

we do anticipate that participation in SweetMama testing may enhance the woman's knowledge, motivation, or engagement in care.

VULNERABLE POPULATIONS:
Pregnant women are the primary focus of this investigation. This study would not be possible in a non-pregnant population, as the goal is to assess the relationships described in the context of pregnancy. Women will be approached in the clinic setting, when they are not in pain and when they are medically stable. They will not undergo any medical procedures. Survey procedures do not involve more than minimal risk to pregnant women. There is no risk to the fetus or newborn. Careful attention will be paid to ensuring that all women are provided confidential study participation and that their PHI is carefully protected. Women are not asked to undergo any interventions or procedures, and their medical care will not be affected by study involvement. The checklist HRP-412 has been reviewed.

This study does not involve research with neonates of uncertain viability, nonviable neonates, prisoners, minors, or cognitively impaired adults.

COMMUNITY-BASED PARTICIPATORY RESEARCH: Not applicable

SHARING OF RESULTS WITH PARTICIPANTS:
Results of the focus group phase will be readily apparent to participants in each group; however, we will not be actively sharing data from all focus groups and user interviews with participants, as this is not likely to benefit them. However any publications or presentations from this phase will be made available to participants on request. Similarly, results from the individual testing phase and pilot RCT phase will be shared via publications or presentations upon request. No other information is clinically relevant that would require sharing with participants or others.

SETTING:
This project will include participation of the clinic staff and patients. Clinics to serve as study sites include the Prentice Ambulatory Care (PAC) clinic, and the Northwestern Medicine Group Maternal-Fetal Medicine practice and the General Obstetrics/Gynecology practice. The focus of this work is to improve care for low-income women with diabetes during pregnancy, the majority of whom receive care in the PAC clinic. All patients deliver at Prentice Women's Hospital, a tertiary care, referral center.

The study will also take place at the Center for Behavioral Intervention Technology, a unique Northwestern core facility with extensive research expertise who have been key partners in this study. No research activities are taking place outside of Northwestern.

RESOURCES
All staff have sufficient research training and expertise to perform their roles for this study. Dr. Yee, Dr. Simon, and Ms. Niznik are clinicians who provide medical care in the inpatient and outpatient obstetrics setting and are thus very familiar with the institutional culture and study sites. Dr. Simon is Dr. Yee's mentor and has extensive research experience. Dr. Yee and Ms. Niznik are specialists in the care of women with diabetes during pregnancy, and thus have ample clinical expertise to support these patients. Both Drs. Yee and Simon are actively involved in clinical research in this department.

Additionally, our partnership with the Northwestern University Center for Behavioral Intervention Technology is a unique resource and strength of this study. The Behavioral Intervention Technology (BIT) Core is a Feinberg Core Facility that operates out of the Center for Behavioral Intervention Technologies (CBITs) in the Department of Preventive Medicine (DPM) at NU Feinberg School of Medicine. Behavioral Intervention Technologies are generally web and mobile apps and sensor-based tools designed to support behavior change. BIT Core consists of a multidisciplinary team of software designers, developers, clinical psychologists, technical project managers, quality assurance specialists and behavioral science researchers that has been the technology partner on over 40 NIH-funded research projects ranging from improving physical activity for individuals with arthritis, to treating mental health issues such as depression and anxiety.

BIT Core provides comprehensive software development services to support the unique needs of researchers who are evaluating behavioral intervention technologies. Further, BIT Core follows industry best practices to support the unique privacy and security needs of researchers throughout the Medical School and the University. All technologies created by BIT Core undergo a stringent quality assurance process that is led by our QA manager and are hosted and maintained by BIT Core on secure Northwestern University servers. There is also a fully equipped Usability Lab outfitted with a high-powered desk top computer to run test applications and capture screen activity, three multi angle HD cameras for external review of usability sessions, in environment microphones and audio digitization for full duplex communication and monitoring of subjects, and a monitoring workstation to interface directly with the environmental sensors for recording. The Usability Space also has the ability to support as needed additional sensor functions including eye track monitoring, EEG collection, galvanic skin response and infrared thermal imaging. CBITs has a scalable virtual server infrastructure capable of accommodating up to 10,000 users. CBITs follows a stringent data security plan and adheres to all data security processes required by Northwestern University and Northwestern Memorial Hospital.

Multiple additional resources are available to study investigators. First, based on the current volume of obstetric patients delivering at Prentice Women's Hospital and the number of patients seen in our practices with diabetes, the proposed number of subjects is feasible during the recruitment period. Second, Dr. Yee has protected time for research performance and oversight. Third, the facilities are adequate for the research proposed, as all investigators have access to locked office space, protected computers, and appropriate research management and statistical software for data analysis. The investigators plan to perform all analyses themselves but additionally have access to statistical support if needed. Fourth, all personnel are already adequately informed and trained about protocols and procedures. All team members have had human subjects training. Our team will ensure the research assistants are fully trained and supported.

Participants:

- Lynn Yee is an Assistant Professor in the Division of Maternal and Fetal Medicine within the Department of Obstetrics and Gynecology. She has prior experience with clinical and public health research, including health systems research focusing on improving care for underserved women. She has a Masters in Public Health and extensive biostatistical and survey methodology expertise. She has also been performing research in the Northwestern system for four years, and has extensive familiarity with research administration and systems. Additionally, as scholar in the Women's Reproductive Health Research Career Development Program, Dr. Yee has 75% research time available for research proposals.

- Melissa Simon is the Vice Chair of Clinical Research in the Department of Obstetrics and Gynecology, and has extensive prior NIH funded experience with clinical research in the areas of health disparities and patient navigation.
- Charlotte Niznik, APN, is the lead diabetes nurse practitioner who cares for patients in the study sites. Her content expertise will be critical to recruitment of patients (as she cares for the majority of them) and in analysis of data. She has prior experience as a research clinician related to diabetes. Ms. Niznik (and Dr. Yee) are also available for clinical questions should the study raise any diabetes-specific clinical questions from patients.
- The Research Assistants will have experience with women's health research and clinical research. This person will have full-time responsibility for research coordination, and will be extensively trained by Dr. Yee.
- CBITs staff have been extensively trained both in the technological aims of this study and in the requirements of human subjects research. CBITs staff have project development and management expertise that will be critical to the success of this project.

PRIOR APPROVALS: Not applicable

RECRUITMENT METHODS:
Participants will be recruited from the obstetrics and gynecology practices at Northwestern Medicine described above; the majority of patients will be recruited from the Prentice Ambulatory Care Clinic at Northwestern Memorial Hospital, which provides obstetric care to low-income patients. This clinic cares for approximately 80 women with GDM or T2DM per year, and due to the low clinic volume, patients are well known to clinic and study staff. Participants will be identified via their Epic clinic record or through direct interaction with the study staff.

Patients will then be formally recruited by the research assistant or another study team member (such as Dr. Yee or Ms. Niznik) immediately before or after their clinic visit. Recruitment and provision of informed consent will occur by face-to-face interaction with the research assistant or the primary investigator. For the individual usability testing phase, after screening for eligibility, potentially eligible women will be provided a "SweetMama timeline" document that explains the study activities, provides contact information, and outlines how to contact the team for technical help. For the feasibility testing phase, a recruitment script including screening questions will be used, and after consent is provided, the SweetMama timeline document (as above) will be provided. If she agrees to participate in the study, she will be consented by the research assistant via written informed consent. Potential subjects will be informed that participation is voluntary and confidential, that their participation or refusal to participate will not affect their medical care in any way, and that they may withdraw at any time.

Health care providers will be formally recruited by the research assistant or another study team member during clinical hours when the individual is not seeing any patients. Recruitment and provision of informed consent will occur by face-to-face interaction with the research assistant or the primary investigator. If the individual agrees to participate, he or she will be consented by the research assistant via written informed consent. Providers will be informed that participation is voluntary and confidential, that their participation or refusal to participate will not affect their employment in any way, and that they may withdraw at any time.

The research team will conduct the study at CBITs (located at the Rubloff building) and the Galter pavilion (14th floor) clinics described above. Patients will be approached privately in their clinic appointments by a research team member. Providers will be approached privately in the clinic when they are not seeing patients.

No recruitment materials beyond the above described scripts are required, as all recruitment will take place via the face-to-face interactions described above. Recruitment will not take place via any registries.

Participants who will be offered gift cards to thank them for their participation. Gift card amounts are as follows:

- Focus groups and user interviews - $30 gift card
- Provider focus groups and interviews - $30 gift card
- Individual testing - $30 gift card upon initiation of the study and $30 gift card upon completion of participation.
- Pilot RCT phase – $100 total remuneration over four time points ($25 upon enrollment, $50 at delivery visit, and $25 for completion of postpartum exit visit). Women who additionally complete the postpartum qualitative interviews will receive an additional $10 gift card.

Participants who require transportation assistance in order to participate will also be offered such assistance via parking passes or bus passes. However, study activities are expected to take place around the time of already scheduled appointments, and so participants are not anticipated to have significant added transportation costs.

Food will be provided at the focus groups.

Participants in the individual testing phase will be required to have a smartphone with at least WiFi capacity. Participants will be informed that SweetMama will function if they have data enabled, and thus if they do not have an unlimited data plan, they may experience unanticipated data charges. Participants will be informed they can elect to have SweetMama only function when on WiFi, and will be instructed on how to do so if they desire this measure to prevent possible data overuse. There are no other anticipated costs to participants.

NUMBER OF LOCAL PARTICIPANTS: Up to 190

CONFIDENTIALITY: Not applicable, not a multi-center study

PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS:
Participants will be informed that declining to participate will not affect their medical care (or employment, for providers) and that they may discontinue study participation at any time. Participants will also be informed that their protected health information and study results will be strictly guarded and multiple steps will be taken to preserve confidentiality, as described above.

If a potential subject agrees to participate, the study will be explained in depth and multiple efforts will be made to make the participant as comfortable as possible. The study activities will take place either in focus groups or in private at a time that is mutually agreeable to the researcher and participant; if she desires the research assistant return at a different date, he/she can do that. Participants will be asked if they are free of immediate medical concerns that would take priority over their research participation. Participants will be

informed that they may choose to not answer any question if they find a question to be uncomfortable. During focus groups and user interviews, we will ask minimal private health information; all activities will be focused on the evaluation of SweetMama. Finally, patients will be informed that their responses will not be communicated to their health care providers and that their participation will not affect their medical care in any way.

Participants will be informed that their research information, including answers to interviews and surveys as well as user data, will be accessible to the research team. They will be informed that no other information about their personal mobile phone use can or will be collected. No long-term data will be collected. No specimen banking will be performed. Participants will be taught how to uninstall SweetMama if desired.

COMPENSATION FOR RESEARCH-RELATED INJURY: Not applicable, not a multi-center study

ECONOMIC BURDEN TO PARTICIPANTS:
Participants may incur costs due to the use of their personal phones; however, participants will be informed that SweetMama can function on WiFi and does not require data use, and can be instructed on how to set this up. No other costs are anticipated.

CONSENT PROCESS:
Each participant will be recruited in her outpatient clinic room or another private location in the clinic (for example, an available consultation room, if the clinic room needs to be turned over for other patients). Consent will be obtained by Dr. Yee or another research team member; no individuals obtaining consent will also be responsible for the medical care of the patient. If she agrees to participate in the study, she will be consented by the research assistant via Consent Form and HIPAA Authorization for Research. Consent will include permission for the focus group/individual testing completion as well as for prospective chart review for clinical information about the participant. Potential subjects will be informed that participation is voluntary and confidential, that their participation or refusal to participate will not affect their medical care in any way, and that they may withdraw at any time.

Health care providers will be approached privately in the clinic at a time when they are not otherwise seeing patients. Consent will be obtained by the research assistant or another research team member via a written informed Consent Form. Consent will include permission for the focus group/individual interview completion. Potential participants will be informed that participation is voluntary and confidential, that their participation or refusal to participate will not affect their employment, and that they may withdraw at any time.

There will not be a waiting period between informing the prospective patient and obtaining consent. There will not be a need for ensuring ongoing consent. The consent discussion can take as much time as the patient requires, although since the study is of minimal risk, we anticipate it will require less than 10 minutes. Participants will be informed that they will not be penalized for refusal to participate.

This study does not include non-English speaking individuals, minors, cognitively impaired adults or adults unable to consent.

PROCESS TO DOCUMENT CONSENT IN WRITING:

Our research presents no more than minimal risk of harm to subjects. We will obtain written informed consent per the guidelines in the SOP HRP-582. See attached consent documents.

DRUGS OR DEVICES: Not applicable

APPENDIX A: Chart review data to be collected from individual testing participants

- Demographic data:
  - Maternal age
  - Maternal body mass index
  - Race/ethnicity
  - Insurance
  - Zip code
  - Marital status
- Diabetes data:
  - If GDM: method for diagnosis, gestational age at diagnosis
  - If T2DM: age at diagnosis
  - Level of glycemic control (serial HgbA1c)
  - Method of treatment: diet, oral hypoglycemic, insulin
  - Method of surveillance: home CBG monitoring versus clinic VBG monitoring
  - Number and doses of medications used
  - Results of postpartum oral glucose tolerance test
- Pregnancy data:
  - Gestational age at first visit
  - Number of clinic visits
  - Gravidity and parity
  - Antepartum admission
  - Total weight gain in pregnancy
  - Comorbidities: chronic hypertension, tobacco use
  - Obstetric history: history of preterm delivery, history of GDM
  - Retention in care
- Delivery data:
  - Obstetric complications: gestational hypertension/preeclampsia, preterm birth
  - Obstetric outcomes: gestational age at delivery, induction of labor, reason for induction of labor, mode of delivery (SVD, VAVD/FAVD, CS), indication for operative vaginal or cesarean delivery, postpartum hemorrhage, shoulder dystocia
  - Neonatal birthweight, NICU admission, glucose levels, bilirubin, and other complications
  - Mode of feeding
  - Participation in postpartum medical care and postpartum health (breastfeeding, weight retention, contraception choice)

APPENDIX B: Focus group and individual user interview guide – see separate attachment

APPENDIX C: Provider focus group and individual interview guide—see separate attachment

APPENDIX D: Individual usability testing interview guide – see separate attachment

APPENDIX E: Feasibility testing recruitment and screening script – see separate attachment

APPENDIX F: Feasibility testing patient participant interview guide – see separate attachment

APPENDIX G: Feasibility testing provider participant interview guide – see separate attachment

APPENDIX H: References

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Consent to Participate in Research

Title of Research Study: SweetMama: Usability testing of a novel technology for diabetes education and support to pregnant women – FIELD TESTING - PATIENT

Investigator*: Lynn M. Yee, MD, MPH*

Supported By: This research is supported by Northwestern University and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development.

Key information about this research study:
The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is listed later on in this form.

The purpose of this study is to determine patient acceptability and optimize the functionality of SweetMama, a novel pregnancy application that delivers an interactive, goal-oriented, educational and motivational diabetes-focused curriculum via your smartphone. If you enroll, you will be randomly assigned to use SweetMama or to receive usual care without SweetMama. If you are assigned to use SweetMama, you will be asked to use the SweetMama app for the duration of your pregnancy and up to 8 weeks postpartum. The app will send you messages on a regular basis, which you may read, respond to, and favorite. You will be asked to use the app's other features, including the library, goal tracker, and appointment reminders. Your interactions with the app, such as how many times you open the app, use different features of the app, and respond to messages will be recorded by our research team. After using SweetMama, you will be asked to participate in an exit interview to tell us about your experience using the app. All women will also be asked to take surveys about yourself at the beginning and end of their participation. The primary risk of participation is the potential for loss of confidentiality. The main benefit is the potential to gain increased support and knowledge in managing your diabetes care through a smartphone-based platform.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you are pregnant and have a diagnosis of diabetes.

How many people will be in this study?
We expect up to 50 people will be in this phase of the research study.

What should I know about participating in a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Consent to Participate in Research

What happens if I say, "Yes, I want to be in this research"?
If you choose to participate in this study, we will ask you to complete surveys and possible interviews. After enrolling in the study, you will be randomly assigned to either interact with SweetMama or undergo pregnancy without SweetMama (usual care).

If you are randomized to usual care, you will complete surveys upon enrollment, during your delivery hospitalization, and at your postpartum visit. No other activities are required. We will ask permission to review your medical record for information about your health. Nothing about your participation will affect your medical care.

If you are randomized to use SweetMama, we will ask you to interact with the new app called "SweetMama." We will train you in how to use SweetMama. You will access the app on your personal phone, and you will start to receive messages about diabetes and pregnancy throughout your pregnancy and postpartum period. During your participation, you will be required to check in with a research assistant every 2 weeks by text message or phone to troubleshoot any technical problems. You will also work with your clinical team to select goals for your diabetes care, and you will receive reminders of those goals on SweetMama. We will ask you to complete surveys about yourself at enrollment, during your delivery hospitalization, and at your postpartum visit. We will also ask you to complete brief interviews during your postpartum hospitalization and your postpartum visit. During the interviews, we will ask you questions about technical problems, ease of use, satisfaction, and overall usefulness of SweetMama. The exit interviews will take approximately 30 to 60 minutes and will take place in private on the Northwestern campus. These interviews will be audio recorded and transcribed, and will only be shared with the immediate research team. Audio recording is required for your participation. We will also track how you are using the app, but we will not track anything else about your use of your personal phone. Finally, we will ask permission to review your medical record for information about your health. Nothing about your participation will affect your medical care.

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. However, if you are randomized to experience the SweetMama app, possible benefits include feeling increased support and knowledge about diabetes during pregnancy. We hope that your involvement will help you feel better equipped for your pregnancy and more engaged in your care. We also hope it will help you with your diabetes-related goals.

Your involvement in this study will help investigators understand how smartphone apps can assist women in managing their diabetes during pregnancy. The results will hopefully assist research in designing an improved app that may benefit pregnant women diagnosed with diabetes in the future.

Is there any way being in this study could be bad for me?
There is no physical risk to you or to your fetus from being in this study. You may feel uncomfortable answering some questions on the survey or interview. If you do not wish to answer a question, you may skip it and go to the next question. It is okay if you do not know

the answers to any question. There is also the risk of a confidentiality breach but we have taken multiple measures to secure your information.

If you are randomized to use SweetMama, should you have a mobile phone data plan that is limited and choose to use SweetMama on a data plan rather than on WiFi, you may incur data charges. However, it is possible to use SweetMama on WiFi without a data plan.

What happens if I do not want to be in this research?
Participation in research is voluntary. You can decide to participate or not to participate.

What happens if I say "Yes", but I change my mind later?
You can leave the research at any time and it will not be held against you. If you have started to participate but choose to leave the study, we will continue to analyze the information from your participation up until that point unless you expressly request removal of that information from analysis. Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

HIPAA Authorization
In order to participate in this study, we need to obtain your health information from your past, present, and future medical providers. Your signature on this consent with HIPAA Authoriation is the means for getting access to that information. We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires

You have the right to inspect and copy the mental health and developmental disabilities records that will be collected as part of this study.

This consent expires on July 1, 2022. After this date, Northwestern University may not gather new information about you, use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless

Consent to Participate in Research

Northwestern University obtains permission to do so from you. Illinois State Law permits use and disclosure of your mental health information only to the extent specified in this document.

During this study, you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

Under the HIPAA Authorization, the following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy.

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Consent to Participate in Research

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

Also Federal law/ 42 CFR Part 2, prohibit unauthorized disclosure of these records.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire July 1, 2022.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Lynn Yee, MD, MPH
Institution: Northwestern University
Department: Department of Obstetrics and Gynecology
Address: 250 E. Superior Street #5-2145, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Data Sharing
De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What else do I need to know?
Compensation: If you agree to take part in this research study, you may receive payments up to a total of $110 for completion of the following study visits:. All participants will be paid a $25 Visa giftcard for the first study visit upon enrollment, $50 Visa giftcard for the study visit when you deliver, and $25 Visa giftcard for completion of the study at your postpartum visit.

Consent to Participate in Research

Participants who use SweetMama and who complete the postpartum interview will receive an additional $10.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team. You can call us with questions or concerns.

Lynn M. Yee, MD, MPH, is the person in charge of this research study. You can reach her by pager (312-695-9210) Monday through Friday from 8am to 5pm, or by email at lynn.yee@northwestern.edu with questions about this research study.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (312) 503-9338 or irb@northwestern.edu 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.

Optional Elements:
The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the principal investigator of this study.

Signature for Adult 18 or older
Your signature documents your permission to take part in this research.

_____ _____
Signature of participant Date

_____
Printed name of participant

_____ _____
Signature of person obtaining consent Date

_____
Printed name of person obtaining consent

Consent to Participate in Research

My signature below documents that the information in the consent document and assent process and any other written and verbal information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ _____
Signature of Witness to Consent Date

_____ _____
Printed Name of Person Witnessing Consent Date