STUDY TITLE:

Self-Management and Care Collaboration for Perinatal Depression

PRINCIPAL INVESTIGATOR:

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STUDENT INVESTIGATOR (complete this section only if the project is student-initiated):

N/A

VERSION DATE:

V.01 11/05/2019

Check any **applicable** boxes in the table below – you will be asked for further detail on these topics later in the protocol form:

Indicate Vulnerable Population(s) to be Enrolled	☐ Children ☐ Cognitively Impaired Adults ☒ Pregnant Women (IF the research activities will affect the pregnancy or the fetus) ☐ Prisoners (or other detained/paroled individuals)
International Research (check this box if you will collect data from individuals located outside the United States)	☐
Research involving external collaborators (some	

research activities will be carried out by individuals not employed by Northwestern or NU affiliates)	☐
Research has U.S. Federal government funding (e.g., NIH, NSF, other federal agencies/departments)	☒ National Institute of Mental Health T32 MH115882, National Institutes of Health's National Center for Advancing Translational Sciences #UL1TR001422, and National Institute of Mental Health P50MH119029.

1.0 Purpose of the study:

This research has two aims. The first aim is to understand how people experiencing perinatal depression (i.e., clients) manage their mental health when they are (or are not) actively seen or treated by mental health care managers. Some of the research questions that fall under this aim include: How do clients experience mental healthcare through Northwestern's COMPASS program (described below)? What technologies do clients use to manage their mental health care? How might technologies expand access to, and better support, perinatal mental health care?

The second aim is to understand how mental health care managers and other core stakeholders coordinate care for their clients. The research questions related to this aim include: What information do care managers/core stakeholders need to monitor, follow up, and coordinate care with their clients? What decisions do care managers/core stakeholders make about each client? Which additional stakeholders do the care managers/core stakeholders collaborate with in order to make these decisions? What tools do care managers/core stakeholders use to do their job? How can technologies better support care managers and core stakeholders in coordinating care for their clients?

These two aims serve a larger goal to design, build, and evaluate technologies that can better support clients and care managers/core stakeholders as they work to receive and deliver mental health care, respectively.

2.0 Background / Literature Review / Rationale for the study:

When left untreated, perinatal depression can have devastating consequences such as impaired maternal quality of life, and in its most extreme form, pregnancy-associated suicide, which is a leading contributor of maternal mortality. In addition, untreated perinatal depression contributes to adverse consequences for fetal and newborn health.[1,2] The majority of those who experience perinatal depression do not receive adequate treatment.[3–6] Studies have suggested that less than 10% of those who experience postpartum depression will receive adequate mental health treatment.[7]

Collaborative care—which integrates mental health care with primary care—is an opportunity to improve care access and delivery for people experiencing perinatal depression. Collaborative care models have been shown in randomized trials to improve perinatal mental health outcomes.[8,9] To deliver the benefits of collaborative care to its obstetrics patients, Northwestern Medicine implemented the COMPASS program (Collaborative Care Model for Perinatal Depression Support Services) in early 2017 and now serves as a referral for 3500 people annually.

However, key barriers of implementing collaborative care into real-world practice have been identified. For example, programs that do not exhibit fidelity to the collaborative care model have not shown the improved health outcomes that have been demonstrated in randomized control trials.[10] Moreover, of the over 2000 people who have been referred to COMPASS for mental health care since 2017, a minority are being actively managed by

care managers and other core stakeholders such as social workers and research assistants. There is a high demand and frequency of referrals to COMPASS, which has in turn created an ongoing, overwhelming caseload for care managers and core stakeholders. A combination of staff's overwhelming caseloads and barriers clients experience when seeking care mean that pregnant people are not receiving active mental health care management.

Technologies that support people in managing their mental health outside of active care management, and that support care managers/core stakeholders in handling their caseload, is a potential way to deliver efficient and effective collaborative care for perinatal depression without compromising the fidelity of collaborative care or overwhelm existing resources. The two aims of this study will inform how technologies should be designed to support the needs and experiences of patients (i.e., clients) and care managers. Moreover, the findings from this study could help serve as a guide for the implementation of collaborative care programs at other institutions and health care systems.

3.0 Inclusion and Exclusion Criteria:

Clients (i.e., people who are pregnant or postpartum) are considered a vulnerable population by the IRB and will be deemed eligible for the study if they meet the following criteria:

- Are at least 18 years old
- Are fluent in English
- Have been referred to the COMPASS program

Core stakeholders (e.g., social workers, research assistants, obstetricians, care managers) will be considered eligible for the study if they meet the following criteria:

- Are at least 18 years old
- Are fluent in English
- Had previous or have current duties related to COMPASS

Individuals will be excluded from participation if they meet the following criteria:

- Are under 18 years old
- Are not English speaking
- Are unable to provide informed consent
- Are prisoners or other detained individuals

4.0 Sample Size:

Our study has two sets of participants: clients (i.e., people referred to COMPASS) and care managers/core stakeholders. We plan to enroll up to 50 clients in our research, and up to 30 core COMPASS stakeholders (e.g., care managers, social workers, obstetricians, midwives, research assistants, etc.).

Because our study methods and procedures are qualitative in nature, and because we are addressing several research questions for both clients and core stakeholders, these numbers will allow us to reach saturation for our qualitative data analysis.

5.0 Recruitment and Screening Methods:

For clients, we will follow a combination of convenience and purposeful sampling techniques for recruitment. Research staff associated with the COMPASS program will assist the study's research team in contacting eligible clients and explaining the study. The COMPASS staff member responsible for the initial contact of clients and explanation of the study will also be associated with the research project as a research team member. This COMPASS staff member will identify potential individuals and provide a non-COMPASS research team member with the contact information of only the clients who express interest in participation. The non-COMPASS research team member who will follow up with interested clients to discuss the study in more detail and complete consent/study procedures.

Our sampling procedures will help ensure a representative sample of clients who are referred to COMPASS. The COMPASS staff member responsible for initial contact with clients will use the Electronic Data Warehouse to first identify patients who have opted-in to be contacted for research via the Northwestern Medicine Universal Consent form. Among those opt-in individuals, the COMPASS staff member will use demographic (e.g., age, ethnicity) and clinical (e.g., PHQ9) data contained in the Electronic Health Record to identify potentially interested participants until recruitment targets are met.

Additionally, we might recruit from a pool of clients who participated in our first phase of research (see Section 9.0) who agreed to be contacted about future studies related to our research aims. These prior participants, who meet our Inclusion/Exclusion criteria outlined in Section 3.0 and were recruited using the procedures described in this section, will be contacted by a non-COMPASS research team member who will provide details about our second phase of research (see Section 9.0), determine their interest in participating, answer any questions, and complete consent/study procedures.

To recruit care managers/core stakeholders, we will use a combination of convenience, word-of-mouth, and snowball sampling approaches. Eligible individuals will be contacted by a member of the research team to share information about the study and conduct the consent/study procedures. To identify additional individuals outside of those who are already known to the research team, each eligible or enrolled participant will be asked if they are aware of others who might be of interest for the study. In these cases, the research team will determine if these additional individuals are eligible for the study and, if eligible, contact them about study participation.

We might also recruit from a pool of core stakeholders who participated in our first phase of research (see Section 9.0) who agreed to be contacted about future studies related to our research aims. These prior participants meet our Inclusion/Exclusion criteria specified in Section 3.0 and were recruited using the procedures described in this section.

These participants will be contacted by a research team member who will share information about the second phase of our research (Section 9.0), determine their interest in participating, answer any questions, and complete study/consent procedures.

6.0 Research Locations:

Prior and after the COVID-19 pandemic: For any in-person observation, interview, and focus group study procedures (see section 9.0), the research team member will seek permission from the participant and other relevant personnel to conduct study procedures in places such as the participant's office or clinical setting. Alternatively, these study procedures will take place in closed-door offices, lab-associated conference and meeting rooms, reserved library rooms, or other similar locations.

During the COVID-19 pandemic: Study procedures that take place remotely with clients and core stakeholders will be conducted via remote tools (e.g., phone calls, video conferencing software such as NU Zoom). Participants will be asked for their permission before proceeding with study activities via these remote platforms and will be reminded to ensure they are comfortable with their surroundings, or have sufficient privacy, before starting. The research team members will conduct these study activities in a private location (e.g., closed-door rooms) to ensure the participants' privacy to the best of their ability.

7.0 Multi-site Research (research that involves external collaborating institutions and individuals):

N/A

8.0 International Research (where data collection will occur outside the United States and U.S. territories)

N/A

9.0 Procedures Involved:

We are conducting two phases of research in order to address our aims (mentioned in Section 1.0).

In the first phase of research: **(completed before COVID-19 pandemic)**:

We will conduct **semi-structured interviews** via phone with clients to understand how they manage their mental health and to learn about their experience with the COMPASS program. During this interview, we will ask questions such as: *What are some things you want to do, but currently have difficulty doing? How do you use technology in your day-to-day life for your mental health?* We will also ask clients questions about how future technologies might help them to achieve their goals and seek or receive mental health

care from COMPASS. Each client participant will be interviewed once. The anticipated duration of these interviews is ~60 minutes, and compensation for the interview will be a $25 gift card.

Additionally, we will find out how COMPASS care managers and core stakeholders currently do their work and handle their caseloads. We will do a series of in-person **observations** with participants who have care manager-related duties. The goal of these observations is to understand the duties, workflow, challenges, and touchpoints of the care manager role. Up to 5 observations will take place with each participant in the setting in which the participant does their work. The time duration of these observations will depend on the degree of care manager-related duties the participant has on the day of observation but is anticipated to take place within normal work hours (e.g., 9am-5pm). During the observations, the research team member will document extensive notes about topics such as the roles of other stakeholders the participant meets with, what types of information are discussed, and what types of decisions are made. The research team member will not be present during events such as in-person client consults, therapy sessions, etc. For other potentially sensitive events, the research team member will explain their presence to non-participants by stating their name, role, and that they are conducting an IRB-approved observation study to understand COMPASS workflows and processes. The research team member will then ask for verbal permission from participants and non-participants to be present for the event. If permission is not given, the research team member will excuse themselves from that event. In addition to observations, we will conduct **semi-structured interviews and focus groups**. The interviews will take place in-person or over the phone, while the focus groups will take place in-person. Participants will be individuals who have previous or current experience as care managers and core stakeholders of COMPASS. The goal of these interviews and focus groups is to learn their perspectives about their roles and the COMPASS program. For example, we will ask questions such as: *Describe what happens in a typical workday? What workarounds have you created, discovered, or shared to make COMPASS run smoothly? When during your workday would a technology help you do your job?* We may also ask questions about how future technologies might help them achieve their goals, better reach their clients, and deliver mental health care through COMPASS. Each participant will be asked to complete one interview and/or one focus group. The anticipated duration of the interviews and focus groups is ~60 minutes.

In the second phase of research: **(to be completed during COVID-19 pandemic)**:

We will gather input from clients and core stakeholders on the design of technologies that would support them in receiving and delivering mental health care, respectively. Clients will be individuals who have been referred to COMPASS, and core stakeholders will be individuals who have current or past experience as Care Managers or Providers (e.g., Obstetricians, Midwives, Psychiatrists, Therapists) for COMPASS. We will conduct a series of **1:1 interviews and/or focus groups via remote tools** (e.g., phone, video conferencing via NU Zoom) with clients and core stakeholders. In focus groups, participants may consist of clients and core stakeholders in the same, or separate, sessions. During these interviews and/or focus groups, research team members will ask

about their prior experiences with COMPASS and how technologies might improve COMPASS services.

In addition to these questions, we will also ask client and core stakeholder participants to provide their feedback on several prototypes that represent ideas for technologies to improve COMPASS services. These prototypes might be low-fidelity (i.e., rough sketches with little or no interactive functionality), mid-fidelity (i.e., fairly detailed with some interactive functionality), or high-fidelity (i.e., completely detailed with full functionality). The prototypes will be shared with participants via remote collaborative tools (e.g., Miro, Mural, Google Slides, InVision). We will ask participants to share their input on the design, usefulness, and value of these prototypes, as well as what changes they might make in order to improve the prototypes for future use. We may also ask participants to complete tasks with the prototypes to evaluate and discuss their design. The anticipated duration of these remote interviews and/or focus groups is ~60 minutes.

10.0 Research with Vulnerable Populations

To remove undue influence of COMPASS research staff on clients eligible for the study, our recruitment strategy involves COMPASS research staff providing a brief explanation to the study to contacted clients. Clients who express interest in the study to COMPASS research staff will be contacted separately by a non-COMPASS member of the study's research team to review the study details, answer study-related questions, explicitly acknowledge that their participation is voluntary, and determine their interest in participation.

For clients and stakeholders who have previously participated in the first phase of our research, a non-COMPASS research team member will be responsible for initial contact, sharing study details, answering questions, stating that their participation is voluntary, and determining their interest in participation.

Due to the retrospective nature of the interviews with clients who participate in this study, this research will not impact the course of the pregnancy or health of the fetus. Our interview questions will not ask about the health or viability of the fetus, nor about decisions the client must make related to the health or viability of the fetus.

11.0 Incomplete Disclosure or Deception:

N/A

12.0 Consent Process:

For the first phase of our research: (completed before COVID-19 pandemic):

For semi-structured interviews that take place via phone with clients and care managers/core stakeholders: at the time of the scheduled phone interview with the client,

a research team member will go through the verbal consent process over the phone, and will give the participant the option to ask any questions, before starting study procedures. If the participant agrees to share their email or other contact information when asked at the conclusion of the verbal consent process and/or interview, we will share an electronic copy of the written consent form for their records. For observations, semi-structured interviews, and focus groups that take place in-person with care managers/core stakeholders: we will go through the written consent process. We may share the consent document electronically with eligible participants before the scheduled study procedures, so they have time to review the information and ask questions beforehand. If consent forms are shared electronically beforehand, eligible participants will have the option to sign the consent form ahead of time and return it to the research team member. Otherwise, a research team member will guide participants through the written consent process in-person, be given time to ask questions, and be given the option to voluntarily provide their signature on the consent form before the observations, interviews, or focus groups begin.

For the second phase of our research: (to be completed during COVID-19 pandemic):

The consent process for clients and stakeholders will be done remotely. At the time of the scheduled 1:1 interview and/or focus group session, a research team member will review the verbal consent form and give the participant an opportunity to ask any questions before starting study procedures. We will share an electronic copy of the consent form for their records after the session is complete. We may also share a copy of the consent form with clients and stakeholders beforehand so they can review the information and prepare any questions to ask at the time of the scheduled session.

13.0 Research with Children – Parental Permission, Child Assent, and Other Considerations:

N/A

14.0 Waiver of Participant Signature on Consent Form:

For remote study procedures that take place over the phone or via video conferencing software, verbal consent is needed because participants might not have access to technologies (e.g., fax, scanner) to document their signature and return them to the research team. Obtaining written consent in these situations could be cumbersome and infeasible for both the eligible participant and research team.

15.0 Waivers and Alterations of Consent Information:

N/A

16.0 Financial Compensation:

For the first phase of research: (completed before COVID-19 pandemic):
Compensation is as follows for each of the study procedures:

- Semi-structured interviews: $25 gift card, sent after completion of the interview.
- Observations: $5 gift card given after each completed session for up to 5 sessions.
- Focus groups: refreshments provided by the research team that will be available throughout the meeting time.

For the second phase of research: (to be completed during COVID-19 pandemic):
Compensation of a $25 gift card will be given to each client and core stakeholder participant who completes a 1:1 interview and/or focus group session. We may invite clients and core stakeholders to participate in up to 3 sessions to provide feedback on low-, mid-, and high-fidelity versions of the prototypes. If so, each participant will receive a $25 gift card for each session that they complete (up to $75).

17.0 Audio/Video Recording/Photography

For the first phase of research: (completed before COVID-19 pandemic):

Eligible participants completing semi-structured interviews and focus groups will be required to consent to audio recording in order to enroll in the study. This requirement is because audio recordings are used to capture participant responses to discussion questions and are therefore the primary/only source of data produced from the chosen methodology. The recordings will be transcribed and personally identifying information (including identifiable health information) will be redacted. These redacted transcripts will then be used for qualitative analysis and publications/presentations.

Eligible participants for the observation sessions will not be audio recorded. However, they will be asked to optionally grant permission so the research team can take photographs during observation periods when appropriate. The purpose of these photographs is to visually capture the workflow of the care managers/core stakeholders. For example, pictures will be taken of meeting rooms, written or drawn artifacts, types of technologies stakeholders use, etc. Identifiable information captured within these photographs (e.g., client names, people's faces) will be edited to be blurred and/or masked before it is used for qualitative data analysis and publications/presentations.

Audio recordings, raw/redacted transcripts, observation notes, and unedited photographs will be stored electronically in HIPAA compliant locations (e.g., FSMResFiles Server) and accessed by research team members via Northwestern computers. Audio recordings and transcripts may also be shared with HIPAA-compliant transcription services.

For the second phase of research: (to be completed during COVID-19 pandemic):

As part of the verbal consent process (Section 12.0), eligible participants will be required to consent to audio and video recording of the interview/focus group session in order to

enroll in the study. Audio recordings are important for capturing participant responses to questions and is a primary source of data for this methodology. These audio recordings will be transcribed for qualitative analysis by the research team members. Personal identifiable information will be redacted from these transcripts.

Video recordings are also important to capture participants' feedback and interactions with the prototypes to be shared and discussed during each session. These recordings will be used as a reference for the research team to contextualize the discussion, especially pertaining to specific aspects of the prototypes that participants refer to when they share their feedback. We may also use video recordings to take screenshots of feedback, notes, or other interactions the participant has with the prototype via the online collaboration software that is used. These screenshots will be used for a qualitative analysis by research team members. Identifiable information will be blurred and/or masked before it is shared outside of the research team for publication/presentation.

Audio/video recordings and unedited screenshots will be stored electronically in HIPAA complaint, password-protected locations (e.g., FSMResFiles Servers). Audio recordings and transcripts may be shared with HIPAA-compliant transcription services.

18.0 Potential Benefits of this Research:

There is no direct benefit to the participants in this study. Rather, the findings of this study will be used to inform the design of technologies that could support future COMPASS clients and care managers/core stakeholders.

19.0 Risks to Participants:

Participants in this study will be asked about their experiences in managing mental health and coordinating mental health care. Discussing their experiences with the research team might lead to feelings such as discomfort, stress, anxiety, and the elevation or recurrence of depressive symptoms. Sharing their personal health information might also risk a breach of confidentiality.

20.0 Provisions to Protect Participant Privacy and Data Confidentiality:

Participants will be explicitly reminded throughout the consent and study procedures that their participation is voluntary, they have the right to withdraw at any point, and this withdrawal will not negatively impact the care they receive from Northwestern or other healthcare providers. To further protect privacy, data about the demographics of participants, gathered through this study, will be reported in aggregate in publications/presentations. Personally identifiable information (e.g., names of people or hospitals) will be excluded from any report or public sharing of study data.

Confidentiality may be broken if the research team uncovers information about the participant's intent to harm themselves or others, current or ongoing child abuse/neglect,

or other harms to public health. This information will be reported to the appropriate authorities.

Only members of the research team will have access to identified participant data. Digital data (e.g., audio and video recordings, photographs and screenshots, typed observation notes) containing personally identifiable/health information will be stored in HIPAA compliant locations (e.g., FSMResFiles Server). Each participant will be given a unique identifier (e.g., P#), and the digital key that matches the P# to their respective data will be stored separately in these protected locations. Paper-based data (e.g., consent forms, written observation notes) will be stored in a locked cabinet in a university office.

21.0 Data Monitoring Plan to Ensure the Safety of Participants:

Given that we will be studying clients who are considered a vulnerable population, and who have been referred to COMPASS because of suspected or exhibited depressive symptoms, we have a data monitoring procedure in place. At the start of every interview/focus group session, the research team member will begin by explicitly informing the client participant that the person conducting the interview is not a healthcare provider, psychologist, or therapist.

If the client interview/focus group session takes place on a weekday between 8am – 4:30pm, and if the client participant reveals implicit or explicit threats to oneself or others, mentions self-harm with the presence of a suicide plan, and/or intent to die, the research team member will notify the COMPASS care manager on call during this time to activate COMPASS protocols.

If the client interview/focus group session takes place after work hours or on the weekends, and if the client participant reveals implicit or explicit threats to oneself or others, mentions self-harm with the presence of a suicide plan, and/or intent to die, the research team member will notify the PI of this study ([redacted]) who will be "on-call" during the scheduled interview time. [redacted] will connect with the client and activate COMPASS protocols.

22.0 Long-term Data and Specimen Storage and Sharing:

For the first phase of research: (completed before COVID-19 pandemic):
Data containing personally identifying/health information will not be shared outside of the research team. Anonymized and deidentified data may be shared with external research collaborators. In these cases, appropriate data use agreements will be established before these materials are shared. Because this study is meant to gather preliminary data for a larger project to study the needs, design, and use of technologies that support COMPASS clients and care managers/core stakeholders, data will be kept for up to 7 years after the end study date.

For the second phase of research: (to be completed during COVID-19 pandemic): Data containing personally identifiable and health information will not be shared outside of the research team. Anonymized and deidentified data may be shared with external research collaborators. In these cases, appropriate data use agreements will be established before materials are shared. Data from interview/focus groups will be kept for up to 7 years after the end study date, after which point original audio/video recording files will be deleted from the shared drives in which they are stored.

23.0 Qualifications of Research Team to Conduct the Research:

This study will include members of COMPASS and the Center for Behavioral Intervention Technologies (CBITs) at NU, which conducts research to evaluate behavioral intervention technologies and technology enabled services. In addition, we will include members of the People, Information, and Technology Changing Health (PITCH) lab at NU, which focuses on addressing problems related to how technology can improve collaboration and communication in healthcare. The two research groups aim to improve the delivery of care through the better design, implementation, and evaluation of

health-related technologies. Research team members from CBITs and/or PITCH have experience in one or more of the following:

- Screening, identifying, and/or contacting eligible participants
- Conducting qualitative and/or quantitative human-subjects research
- Qualitative and/or quantitative methods and analysis
- Data safety monitoring and/or clinical psychology training

24.0 References

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