PROTOCOL TITLE:
Investigation of Care Managed Patient Experience and Interest in Technology Enabled Mental Health Care Delivery

PRINCIPAL INVESTIGATOR:

[redacted]

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1.0 Purpose of the Study: Describe the purpose, specific aims, or objectives. State the hypotheses to be tested or the research questions that will guide the study.

Aim 1: To investigate the challenges to getting mental health care faced by patients enrolled in care management.

Aim 2: To examine patient interest in digital mental health tools and technology-enabled mental health services.

2.0 Background / Literature Review / Rationale for the study:

Depression and anxiety are the most common mental health disorders in the United States with estimated 12-month prevalence rates of 18.1% and 9.5% respectively (Kessler, Chiu, Demler, Merikangas, & Walters, 2005). Primary care is the de facto treatment setting for depression in the United States; more than half of all patients with depression are treated only by their primary care physician while only 20% receive care by a mental health specialist and one quarter receive no treatment at all (Burns, Ryan Wagner, Gaynes, Wells, & Schulberg, 2000; Unutzer, Schoenbaum, Druss, & Katon, 2006). Nearly 20% of primary care visits involve an anxiety disorder and more than 20% have a depressive disorder, whether or not the physician diagnoses it (Coyne, Fechner-Bates, & Schwenk, 1994; Kroenke, Spitzer, Williams, Monahan, & Lowe, 2007). Through overuse and misuse of medical services, depression and anxiety add billions in annual healthcare costs. The average annual health care costs of patients diagnosed with depression are nearly twice that of those without and costs are higher for every category of care (e.g., primary care, specialty care, inpatient, pharmacy, and laboratory; (Simon, VonKorff, & Barlow, 1995).

Primary care has enormous challenges meeting the needs of patients with common mental health problems, resulting in poor outcomes, with only 20% of patients showing substantive improvement after 8 months of treatment (Schulberg et al., 1997). For example, around 2/3rds want help, preferring psychological treatment over pharmacotherapy, but most patients are not referred to therapy, and increasingly, when they are referred, 75% face barriers that prevent access, and often encounter waiting lists of 3-6 months and longer. This is evident in our own Northwestern Medicine Physician Care Partners (NMPP). As NMPP expands west of Chicago, specialty mental health care is simply not available. Where care is available, waiting lists often exceed 6 months. The availability of services simply does not match the need.

Digital mental health, such as mobile apps and web-based interventions, are increasingly being viewed as a potential solution. Over the last 15 years, more than 50 efficacy trials have shown these interventions to be effective for the treatment of depression and anxiety, with effects similar to psychotherapy and pharmacotherapy when accompanied by low-intensity coaching. However, there is not a single example of a successful, sustainable implementation of a digital mental health intervention, and several examples of failures. This research-to-practice gap is not unusual in medicine. In this case, it is due in large part to the fact that these tools have been developed outside the care setting, and do not meet the needs of primary patients, providers, and have not been designed to fit into the context of the care system.

This project, a companion to STU[redacted], will produce an understanding of the challenges to getting mental health care faced by patients enrolled in care management, and of patient interest in digital mental health tools and technology-enabled mental health services.

3.0 Inclusion and exclusion criteria:

Inclusion/ exclusion criteria: We seek to recruit current patients enrolled in Care Management services within Northwestern Medicine Physician Partners who have a self-reported history of depression and/or anxiety within the last 12 months or who are currently experiencing elevated symptoms of anxiety and/or depression (as defined by a score of 10 or greater on the PHQ-9 and/or the GAD-7). This study will not include special populations such as prisoners, adults unable to consent, and individuals under 18. Any patient that happens to be pregnant women will not be excluded due to pregnancy. A minimum of 10 and a maximum of 30 participants will be enrolled in this study.

4.0 Procedures Involved:

1. **Provide a description of all research procedures and activities.**

   To understand the challenges to getting mental health care faced by patients enrolled in care management and to examine patient interest in digital mental health tools and technology-enabled mental health services, we will conduct semi-structured interviews over the phone. Northwestern Medicine Physician Partners (NMPP) care management has agreed to provide the Northwestern study team with the contact details (name, address, and email address) of all patients currently enrolled in care management in order for the team to contact potential participants via a personalized letter delivered by mail or email (see attached documents). The letter or email, written in partnership with NMPP, briefly outlines the purpose of the study, what is involved in participation, and provides the contact details of a member of the study team. Members of the care management team continue to have information on this study, and will continue to identify potential participants directly from their caseloads. Care managers will briefly describe the study and ask potential participants if they are interested in having their contact information being sent to the study team so that a member of the study team can contact them.

   Potential participants who are interested will contact a member of the study team directly for more information. The study team member will then invite the potential participant to engage in a brief study screening. Potential participants will provide verbal consent to the study screening, and if eligible, they will schedule their interview with a member of the study team. At the time of the interview, potential participants will be provided with consent information over the phone, time will be allotted for the information to be discussed, and verbal consent will be provided. After consent is provided, the audio-recorded interview will begin. The screening data from individuals who screen ineligible or who screen eligible but decline consent for the interview will not be used in the research.

2. I**nclude when they are performed, and any procedures being used to monitor participants for safety or minimize risks.**

   Mood symptom screening measures (PHQ-9 and GAD-7) and semi-structured interview will be conducted over the phone by a trained member of the study staff. While there is not a focus on suicidality within this study, participants will be asked item 9 of the PHQ-9 which concerns suicidal ideation. Specifically, should any participants rate item 9 on the PHQ-9 as greater than “1,” they will be prompted to answer the Beck Depression Inventory (BDI), item 9 (“Suicidal Thoughts or Wishes, 0 = I don’t have any thoughts of killing myself, 1 = I have thoughts of killing myself, but I would not carry them out, 2 = I would like to kill myself, 3 = I would kill myself if I had the chance”). Should a participant rate a “2” or higher on the BDI item, the interviewer will enact the Suicidality protocol included in the documents (Columbia-Suicide Risk Assessment) via telephone. This protocol will also be enacted if the participant endorses suicidality at any point during the semi-structured interview.

3. **Describe the study timelines including: the duration of an individual participant's participation in the study and the overall anticipated duration of the project.**

   We anticipate that the semi-structured interviews will take no longer than 60 minutes of the participant's time. The project is anticipated to take place over the course of Fall 2017 and early Winter 2018.

4. **Describe the actual source records or measures that will be used to collect data about participants. (All surveys, interview scripts, and data collection forms will be attached elsewhere in the application. Do not add other documents to the protocol.) Describe what data will be collected and how it will be collected at all measurement/data collection time-points.**

   Interview data will be audio-recorded. Mood symptom assessment measures (PHQ-9 and GAD-7) will be administered over phone as part of the screening, and the study staff member serving as the interviewer will record responses into REDCap. All audio-recordings and notes taken during the interview will be uploaded and stored in the Northwestern University digital secure data storage. A copy of the semi-structured interview guide, the mood symptom assessment measures (PHQ-9 and GAD-7) as well as the Columbia Suicide Risk Assessment are attached to this application.

5.0 Multiple sites:

N/A

6.0 Incomplete Disclosure or Deception:

N/A

7.0 Recruitment:

1. **Describe when, where, and how potential participants will be recruited**.

   Potential participants are patients currently enrolled in NMPP care management. Potential participants will receive a letter about the study in the mail, or via email (see attached documents) outlining the study's purpose, what is involved in participation, and inviting them to contact the study team for more information if they are interested in participating. NMPP care management will provide the Northwestern study team the contact information of current NMPP care management patients (name, address, and email address). No other information about the patient, including information about the patient's mental health diagnosis or mental health treatment history, will be provided to the research team.

   Potential participants can also be referred directly from NMPP care management staff. Care management staff members will identify patients who may eligible and interested in participating in this study, and will request permission to give the patient's name and phone number to the study team. Care managers will be instructed to describe the study to participants who they think could be interested in participating (see attached information script) and ask for permission to pass along the patient's contact information to the study team. Care managers will not be providing any information about the patient's mental health diagnoses or mental health treatment history to the research team.

Current patients intererested in participating will contact the study team by phone or email, or, if they previously discussed the study with their care manager and indicated their willingness to be contacted via phone, a member of the study team will contact the potential participant directly by telephone for recruitment purposes. Members of the study team will briefly outline the purpose and nature of the study and administer a brief eligibility screening measure (see attached document) to those interested. If a participant is eligible, the study team member will schedule the telephone-based interview. The screening data from individuals who screen ineligible or who screen eligible but decline consent for the interview will not be used in the research.

This research will be conducted over the Fall 2017 and early Winter 2018 time period.

2. **Describe the types of strategies and materials that will be used to recruit participants.**

   Potential participants will be recruited via mail or email with a personalized letter inviting them to participate (see attached letter and email). The letter was drafted in partnership with NMPP care management leadership and has been approved by all relevant NMPP care management departments.Patients interested in participating will contact the study team by phone or email. Members of the study team will then provide more information about the study and assess interested pateints for eligibility.

   Members of the NMPP care management staff may continue to ask permission from patients to pass on their contact information to the study team. Patients in care management will then be recruited by phone calls from study staff (see attached for script).

8.0 Consent Process (see also the Process of Obtaining Consent guidance on the web site.

Prior to beginning the telephone-based interviews, participants will provide verbal consent. A member of the study staff will be consenting participants. The consent process is anticipated to take 5-10 minutes. Participants will be informed of the optional nature of this study, and that all questions are optional. The consent document (see attached) will be reviewed with participants over the phone, and time will be allotted to address any questions that participants may have regarding the research.

9.0 Process to Document Consent:

1. **Describe whether and how consent of the participant will be documented in writing**.

   A verbal consent will be used, and a study staff member will document each participant's consent.

2. **If you will document consent in writing, you will attach a consent document. You must use [SOCIAL BEHAVIORAL TEMPLATE CONSENT DOCUMENT (HRP-583)" to create the consent document or script.]**

   Attached.

10.0 Risks to Participants:

The proposed study poses minimal risks. All potential risks associated with participation in this study will be disclosed in consent documents. Any potential risks that might exist fall into two categories: (a) risks associated with the semi-structured interview, consisting of questions about depression and personal functioning, and other mental and emotional problems; (b) risks associated with potential loss of confidentiality; and (c) risks of worsening mental or emotional state and/or self harm thoughts/events.

We address each in turn below.

Risks associated with the semi-structured: Research assessments include questions about depression, anxiety, and other mental and emotional problems. Participants will give voluntary responses to interview questions; they are told that they can decline to answer any questions that they choose. The instruments and methodologies are well tested and are not known to cause problems or distress on the part of the participants. All interviews are audio-recorded, for the purpose of review to ensure quality assurance ratings of assessment performance, including ensuring that patients are comfortable with the interview procedures. Audiotapes will be maintained on a secure server with no identifying information in the labels for the duration of the funded study, unless other arrangements are made. On occasion patients request that audio files be deleted before the end of the study, in which case we will comply.

Risks associated with potential loss of confidentiality. There is a slight risk of loss of confidentiality. Confidentiality may be broken by research staff to ensure the patient's safety if there is an imminent threat to self or others. There is also the remote possibility that research records will be subpoenaed by a court of law. All of these potential losses of confidentiality will be disclosed in the consent documents.

Risks of worsening mental or emotional state and/or self-harm thoughts/events: Some participants may show a worsening of depressive symptoms, suicidality or problems during the study period. The development of suicidal ideation during the study remains the most serious risk. However, these are risks inherent in the population and would occur whether or not they were enrolled in the study. It is not believed that the risk of these depressive, suicidal, or other adverse outcomes are increased as a function of being enrolled in this study.

All potential risks associated with participation in this study will be disclosed in consent documents.

Antidepressant medications are permissible within this study.

Withdrawal of Participants:

a. **Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.**

   If the participant includes demographic information that explicitly makes them ineligible to participate (for example, state that they are under 18).

b. **Describe procedures that will be followed when participants withdraw from the research, including withdrawal from some but not procedures with continued data collection.**

   If participants wish to withdraw, we can remove their study record. If participants contact study staff after the interview, both the screening records and interview records (and all related recordings) can be removed and deleted.

c. **Describe the use of data after withdrawal.**

   N/A

11.0 Potential Benefits to Participants:

There may be no direct benefit to participants.

12.0 Financial Compensation

Participants will be compensated $50 for participation in the interview. Payments to participants will be issued in one of the following ways:

a. Amazon.com credits

b. By check

c. Through Northwestern University Payroll (if the participant is a Northwestern University employee)

The Amazon.com credits can be used for making online purchases through the Amazon.com website and there are no fees associated with this type of payment. Amazon.com credits typically take 1-2 weeks to process. Hard copy checks typically take 3-4 weeks to process.

13.0 Provisions to Protect the Privacy Interests of Participants:

1. **Describe the steps that will be taken to protect participants' privacy interests**

   All questions will be optional, so participants do not have to answer anything they do not wish to. To further protect privacy, all data presented to NMPP administration will be done in aggregate form without any personal identifiers.

2. **Indicate who on the research team and how the research team is permitted to access any sources of information about the participants.**

   All study staff will be able to access information.

14.0 Confidentiality and Data Management:

1. **Describe how data (and if applicable, biological specimens) will be handled study-wide including:**

   a. **Information that will be included as data: consent forms, surveys, interview notes, audio recordings, and notes of observations.**

      Initial contact information provided by NMPP and all data gathered will be uploaded and stored on Northwestern computers and servers.

   b. **Where and how will data (or specimens) be stored? How will data be transported from the point of collection to where they will be stored? Note: electronic storage of data in both domestic and international research must be secured using adequate protections.**

      Following IRB policy, data will be kept 7 years after the completion of the study. Immediately following the interviews, audio data will be transferred to a Northwestern computer, which will be password protected and within the firewall of the University's network.

   c. **Who will have access to the stored data or specimens?**

      Researchers on the IRB

   d. **Who is responsible for receipt or transmission of the data or specimens?**

      Researchers on the IRB

2. **Describe the steps that will be taken secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.**

   All research files are kept on secure, password protected departmental and medical school servers. All electronic data will be stored on secure servers behind firewalls. Any paper documentation is kept in locked file cabinets or a locked assigned a numerical code for identification in the files. Names and other identifiers will be kept in separate password protected files. Audio data will be stored on secure servers for coding by study staff. All data presentation will be of aggregate-level data; participants are never individually named.

3. **Describe any procedures that will be used for quality control of collected data. If conducting online research, specify if you will be using any attention check measures. If yes, you need to indicate what you will be doing and what happens if a participant fails the attention checks.**

   Because the study consists of single time point interviews, no quality control procedures are necessary.

4. **Describe the data analysis plan, including any statistical procedures is applicable.**

   Qualitative data will be analyzed using a six-phase thematic analysis as described by Braun and Clarke (Braun, 2014). This six-step analytical approach facilitates the process of becoming familiar with the data, systematically identifying individual codes, grouping those codes into preliminary themes, defining and naming the final themes that commonly occurred across the entire data set, and then selecting examples from the data to accurately illustrate each theme. In thematic analysis, current theories or prior research can be used to identify critical concepts. These initial categories will be starting points for the data analysis. From the analysis, we will identify core concepts to determine patient needs and preferences. This information will be synthesized to create user needs analysis documentation.

15.0 Data Monitoring Plan to Ensure the Safety of Participants:

Data pertaining to suicide risk assessments will be reviewed twice weekly to ensure that all participants who endorsed suicidal ideation during the screening and/or semi-structured interview were followed up with appropriately using the Columbia Suicide Risk Assessment. Data monitoring will be done by the PI, [redacted], who is a licensed clinical psychologist or [redacted], also a clinical psychologist.
If a screening or interview in which the Columbia Suicide Risk assessment is triggered is conducted by a study staff member other than the PI, that study staff member will contact either [redacted]attie or [redacted] immediately following their contact with the participant to review the case and determine if any additional steps need to be taken.

16.0 Data and if applicable, Specimen Banking:

N/A

17.0 Qualifications to Conduct Research and Resources Available:

[redacted]

[redacted] Facilities for meetings and data storage will be provided by CBITs.

18.0 References:

Braun, V., V. Clarke, and G. Terry. (2014). Thematic analysis. *Qual Res Clin Health Psychol, 3*(2), 77-101.

Burns, B. J., Ryan Wagner, H., Gaynes, B. N., Wells, K. B., & Schulberg, H. C. (2000). General medical and specialty mental health service use for major depression. *International Journal of Psychiatry in Medicine, 30*(2), 127-143.

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Simon, G. E., VonKorff, M., & Barlow, W. (1995). Health care costs of primary care patients with recognized depression. *Archives of General Psychiatry, 52*(10), 850-856.

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