Mass General Brigham

PEERS Plus - mHealth Enhanced Peer Support to Reduce Depression Among Low-income and Ethnic Minority Older Adults

Study Protocol

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Intervention/Interaction Detailed Protocol

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1. Background and Significance

Depression affects up to 15% of older adults, is the leading cause of disability worldwide and decreases quality of life and increases mortality.[1,2] For many ethnic minority participants, traditional mental health services fail to meet their depression care needs. Minority persons disproportionately experience risk factors for depression, such as low socioeconomic status and education, may have greater distrust of medical professionals and negative experiences with the mental health system.[3,4] Despite greater risk of poorer health, up to 70% of older ethnic minority participants with mood disorders do not receive depression care.[1,5,6] In primary care where majority of older adults gets mental health care, and patients who are referred to specialty mental health care often do not follow up, even when given transportation to appointments that are free of charge.[7] This problem may be due in part to a misalignment of what patients want and what is offered. Minority persons may prefer psychosocial treatments for depression compared to antidepressants, have non-biomedical explanations of their illness, and desire relationship-based care.[8-11] Given these challenges, the use of peer mentors for hard-to reach populations has the potential to provide depression care to those who do not engage in traditional depression treatment and serve as bridges to clinical care and community-based resources.[12]

Peer support involves connecting a person who has a health problem to another person who has experienced a similar health condition. [13,14] Persons who have overcome adversity can offer useful encouragement, hope and mentorship, including self-care skills to others facing similar situations and insight that can complement professional health care.[15,16] Depression is a chronic illness that requires self-management skills to maintain emotion-wellbeing on a daily basis and peer support can be useful for patients who struggle with depression.[17] Peer support has been recognized as useful for depression self-management, [17-19] particularly, among low-income, minority groups, for whom experiential learning through peers rather than teaching from

professionals may be preferred.[20] Despite the potential of peer support, the evidence is lacking regarding the use of peer support for minority participants with depression.[17,21-28]
The evidence for peer support has been established for diverse populations and multiple conditions such as persons with severe mental illness and substance abuse as well as diabetes care. The evidence is lacking regarding the use of peer support among minority participants with depression.[17,21-28] Two meta-analyses have shown that peer approaches can decrease depressive symptoms with moderate effect sizes; however, [29,30] these studies included non-randomized studies. Additionally, the majority of studies used a peer support group format rather than one-to-one peer support, and few studies focus on participants. Furthermore, peer models of care for depression are limited, although delineation of roles and training are important given the diversity of what peers do in different contexts.[15,31] Development of a one-to-one peer support program anchored in a conceptual framework with clearly defined peer roles and rigorously tested in a randomized controlled trial has the potential to increase access for minority participants, to bridge them to clinical treatment and have an impact on mental health disparities.

The COVID-19 pandemic has irreversibly changed the way in which healthcare services are delivered, especially for older adults. Peer support is no exception. The use of telehealth and video conferencing has increased the reach and access for patients and the use of technology-enhanced peer support interventions has followed. [32,33] A majority of older adults participants report positive attitudes towards technology [6,7 8 9] and are willing to use technology to help them remain independent and maintain their health and wellness.[10] Over 50% of participants use technology and studies suggest a combination of in-person contact and technology may be more effective rather than technology alone.[34] Evidence regarding technology enhanced peer interventions is emerging in depression research but has not been well studied among ethnic older adults. [35,36]

We are conducting a clinical trial of Peer Enhanced Depression Care (IRB# 2022P001675) to test the effectiveness of peer support on depression among low-income and minority older adults. We hypothesize that the participants who are randomized to the peer intervention will experience greater reduction in depressive symptoms compared to those randomized to an active control condition. The core components of the manualized Peers intervention are: (1) relationship building, active listening, emotionally responsive and patient-centered communication, (2) sharing of experiential knowledge by peer mentors, sharing of coping skills, modeling, and communication of positive health messages regarding self-care (3) linkage to community and clinical mental health resources. To date, we have recruited 149 older adult participants who have completed the intervention phase and continue to conduct follow up assessments. Preliminary analysis of post study qualitative interviews of participants who completed the Peers intervention suggest positive experiences of the intervention with a variety of benefits. They expressed comfort being able to speak to someone regarding their emotional distress, described adoption of coping skills and being helped with resources. **In Peers plus, we propose to integrate technology such as video chats and texting in the manualized Peers intervention to enhance the ability of a lay workforce such as peer mentors**

to meet mental health service needs of participants with depression and link them to professional care as needed.

Preliminary studies

1.Feasibility and acceptability of a peer support intervention for depression. We developed a peer support intervention and evaluated the feasibility and acceptability of peer support for participants. We examined participant and peer experiences of the program. We found that engagement was high (90% percent of participants attended all 8 meetings with the peer). The majority was African American participants (74%) and 85% had decrease in PHQ-9 scores [Mean 7.1 (SD 7.1) p-value < 0.001].[37] Loneliness decreased (pre-study mean 36.7 ± 5.4; post-study mean 31.4 ± 16.7, p-value 0.03) and coping skills increased (pre-study mean 65.6 ± 13.2, post-study mean 69.9 ± 10.4, p-value 0.006). Participants emphasized the importance of a trusting relationship, credibility of the peer and usefulness of professional supervision in the program. Participants described benefits such as hope, changes in attitude, behavior, and insight. The program also successfully connected participants to community and clinical resources during and after the study. We successfully contacted 85% of patients at 12 months and assessed depression with the PHQ-9 by telephone. Sixty-eight percent of patients had PHQ-9 scores that remained below baseline scores by 5 points or more. After completion of the feasibility study, we recruited 27 additional participants (total of 57 participants) seeking to obtain greater experience with a larger sample of peers and participants to refine the peer program. We tried telephone delivery of the program for two participants. Although peers found the telephone convenient, relationship building was more difficult, and two participants missed telephone calls more frequently but attended in-person meetings regularly. Given the importance of problems of loneliness among our study participants, we continued with in-person meetings and used telephone calls infrequently when peers were unable to meet in person due to weather. We concluded that use of supervised peer mentors is a promising model of depression care delivery for participants. We conducted an analysis using data from 57 participants in the pilot study to assess whether self-efficacy predicted change in depression. We found that improvement in self-efficacy was associated with a decline in depression. **Relevance: Intervention manual and protocol were developed. Feasibility and acceptability were demonstrated.**

2.Communication analysis to assess peer mentor training. We studied peer mentor communication that would inform peer training and role development. Our aim was to describe and associate communication behaviors used by supervised peer mentors with working alliance and depression.[38] We used the Roter Interaction Analysis System, a quantitative method to analyze health communication between peers and participants in the pilot study. We looked at a variety of communication behaviors similar to other studies on communication behaviors in mental health. [39,40] We found that peers used a variety of skills learned in training. This included participant-centered talk, positive rapport building, emotional responsiveness, and education and counseling. Specific communication behaviors such as emotionally responsive talk and

education about psychosocial topics were associated with decreased depression. We concluded that trained peer mentors can use skilled communication behaviors that is participant-centered to provide depression care services to participants. **Relevance: Specific communication behaviors in peer mentors training was shown to impact depression.**

2. Specific Aims and Objectives

1. To design and test components, such as video chats and supportive texts, for a technology-enhanced peer support intervention for depression among community-dwelling minority older adults 50 years of age and older called Peers plus;
2. To determine the feasibility and acceptability of Peers plus to reduce depression among community-dwelling and ethnic minority adults 50 years of age and older.

3. General Description of Study Design

We propose a two-step study: (1) a usability study to design and assess the user experience of Peers plus; and (2) a pilot study to assess the intervention feasibility and acceptability. In the usability study, we will test Peers plus in two iterations of five dyads (participants and peer mentors, see Table 1). The RA will use zoom to conduct the usability survey and semi-structured interview at 2 weeks and upon completion of the peer support meetings. Analytics (e.g. duration of the video chat, content of the texts) will provide data regarding the intervention components during a 4 week period.

Table 1. Study flow for usability (Phase 1) and feasibility study (Phase 2). The studies are sequential. Recruitment and enrollment procedures are identical. Intervention duration and data collection procedures of the studies differ and are described in this table.

Aim 1. Usability study Recruitment and enrollment (two cohorts of 5 dyads) • RA receives referrals, conducts telephone screen • Clinician conducts clinical assessment (zoom) and obtains verbal informed consent • RA conducts baseline assessment (Redcap) • RA conducts technology training as needed (e.g. access texting on zoom) • Eligible participant is matched with a peer mentor who schedules a video chat
User experience assessment of *Peers plus* • PM conducts weekly 4 video chats and sends daily texts to the participant over 4 weeks. • RA conducts usability survey and brief semi-structured interview at 2 weeks [midpoint] and at 4 weeks with the participant and the peer mentor.
Aim 2: Feasibility study (20 older adult participants) • **Recruitment and enrollment procedures are identical to the usability study**
Peers plus Intervention • PM conducts 8 weekly video chats and sends daily texts to the participant over 8 weeks.
Assessments • RA conducts baseline assessment, post-study assessment and semi-structured interview at 8 weeks with the participant. RA conducts semi-structured interview at 8 weeks with PMs.

We will use the knowledge gained from the usability study to

revise our intervention procedures and contents as needed. In the feasibility study, we will use identical recruitment and enrollment procedures to recruit depressed older adults to participate in a prototype of the 8-week, zoom-delivered Peers plus intervention. It will consist of peer support delivered through video chats (45-60 min duration) and daily texts: 1) peer mentors (PM) will video chat with participants and provide emotional support and encourage use of self-care strategies for depression, linking to community and clinical resources as needed, and 2) the PMs will provide one-way supportive texting by SMS to encourage and reinforce use of self-care strategies and exchange community and clinical resource information.

Participants with depression will be recruited from the community with the assistance of community-based organizations that will help study staff disseminate study flyers to their members. This will enable older adults in the community to self-refer. The research assistant will screen the older adults and provide study information by telephone. Then, eligible older adults will be scheduled for a clinical assessment to be conducted by a mental health professional (MHP such as a clinical social worker or a clinical psychologist) by zoom. The MHP will gather depression history and psychosocial information as well as assess for inclusion and exclusion criteria. Eligible and interested older adults will be consented verbally by the mental health professional. Upon completion of the clinical assessment, the RA will conduct a baseline assessment by zoom. The RA will obtain verbal consent that participants are comfortable accepting one-way SMS texts during the study. Upon completion of the baseline assessment, the RA will call the PM to inform the older adult participant of the match with the PM. Then the PM will contact the participant by phone and schedule weekly video chats and send daily texts that are developed with supervision. PMs will not engage in exchange of texts with the participant.

4. Subject Selection

Eligibility criteria

Identification of peer mentors. Peer mentors who have been trained in the study, Peer Enhanced Depression Care, (IRB #2022P001675) and who are interested in the Peers plus will be interviewed. These peer mentors (PM) were recruited with the help of our community collaborators. They were chosen based on interviews with study staff who evaluated them on factors such as prior experience with depressive illness, communication and relationship building skills, time in recovery from depression, volunteering and mental health experience. Those PMs who exhibit core peer skills and commitment and meet eligibility criteria will be invited to enroll in the study. The verbal consent form will be emailed to the candidate to facilitate the verbal consent process prior to the process of obtaining consent for participation in the study. Verbal consent will be obtained by the Mental Health Professional.

Inclusion/exclusion criteria for Peer Mentors (PM): Inclusion criteria: (1) 50 years and older, (2) history of depression, (3) at least 5 years in recovery, (4) received basic training in behavioral health or have volunteer experience in mental health, (5) access to personal computer and (6) can provide informed consent. Exclusion criteria: (1) meet current diagnostic criteria for Major

Depressive Disorder; (2) meet current diagnostic criteria for a manic episode or a psychotic disorder; (3) meet current diagnostic criteria for substance abuse disorder; (4) will be comfortable using a personal device or a device provided by to use for video chats and texting for the study.

Peer mentor training
The Research Assistant and the PI will conduct ten hours of training remotely that will be a review of prior training. We developed a peer training program [41] that includes use of effective communication skills, including appropriate self-disclosure, participant and peer safety and confidentiality, expression of empathy, active listening, goal-setting, sharing coping skills and other depression self-care skills. Training on establishing relationship boundaries is critical to ensuring that participants benefit from peer support and will be provided. Training will include didactics, discussion, experiential learning, and role-play. In addition, PMs will receive training in use of zoom for video chats, making audio recordings and sending texts, confidentiality, and ethics. Zoom interactions will occur using the MGB Enterprise Zoom platform. After completion of training, study staff will review peer mentors for suitability to be matched, taking into consideration attendance, active participation, commitment and demonstration of interpersonal and communication skills and mastery of technology skills.

Participant participants
Inclusion criteria are: (1) 50 years and older; (2) depressive symptoms with PHQ-9 scores greater 10 or greater (2) self-identify as belonging to an ethnic minority group, (3) willing to give informed consent. Exclusion criteria are: (1) meet diagnostic criteria for mania or hypomania; (2) meet diagnostic criteria for psychotic syndrome; (3) meet diagnostic criteria for substance abuse or dependence; (4) acutely suicidal; and (5) those without technology will accept and use a device to use for video chats and texting for the study. Participants who meet diagnostic criteria for severe depression, cognitive impairment, mania, hypomania, a psychotic disorder, or substance abuse or dependence will require clinical treatment.

Recruitment
We will establish relationships with community organizations that serve older adults e.g. BDS Health Aging Network. This is a network of minority older adults that provides information about social and government services and support groups locally and nationally. We will conduct webinars and provide information about the study and distribute IRB approved study flyers to their members so that interested older adults can contact the study staff. We will track recruitment methods and their results by community organization that includes number referred, eligible, enrolled and retained. The research assistant will make 3 calls to the referred participant and track the number of screening attempts and the result of those attempts.

5. Subject Enrollment

For all referred older adults, the research assistant will screen them by telephone for eligibility. We will ask about demographic information, such as age and gender, depressive symptoms

with the PHQ-9, a self-report instrument that is keyed to DSM-IV-R criteria for Major Depression and widely used in primary care,[42,43] access to technology. Upon completion of screening, eligible participants will be asked if they would like to proceed with a clinical assessment and those who are interested will be scheduled with a mental health professional and the verbal consent form will be emailed or mailed to the participant to facilitate the verbal consent process. The clinical assessment will be conducted by zoom. Any participants who are not interested in participation will be given information about mental health resources or clinic information.

Brief clinical assessment. A mental health professional (MHP) will perform the clinical assessment by zoom. She will assess for exclusion criteria, i.e. suicidal ideation, manic episodes, alcohol abuse, substance abuse and psychotic disorders using the MINI (Mini-International Neuropsychiatric Interview),[44] a yes/no instrument that derives DSM-IV-R diagnoses on the basis of respondent's reports of their symptoms The clinical assessment will include history of present illness, psychiatric and medical history as well as a psychosocial assessment that will ensure that the participants are appropriate for the study. If the participant expresses suicidal ideation, the MHP will assess further, ensure the safety of the participant while ensuring receipt of appropriate clinical services. The clinical assessment will be documented and saved on a secure server, MGH OneDrive. If the participant meets eligibility criteria, verbal consent will be obtained. The MHP will explain that participation is completely voluntary and that they can have as much time as they need to make their decision to participate or not. We will ask them to call the study team when they have decided. They will be given up to 48 hours to make a decision. If the older adult agrees to participate, they will be scheduled for a baseline assessment.

6. STUDY PROCEDURES

Upon enrollment of the older adult participant, the RA will arrange delivery of devices by courier to those who do not have personal devices and provide any technology training that is needed to participants and PMs. Those participants will be given a WIFI enabled device to be returned when the study is completed. **Baseline assessment.** The RA will schedule and conduct the baseline assessment that lasts about 1 hour by zoom. The assessment will consist of questions regarding demographic information, medication use, depression care history, technology, and questionnaires to measure depression and function. Data will be entered directly into REDCAP MGH. All study documents will be in electronic form and stored on MGH OneDrive. **Matching and scheduling of visits.** After delivery and training in technology and the baseline assessment have been conducted, the PM will contact the participant to schedule weekly video chats. The weekly video chats will last for 45 – 60 minutes. Each video chat will be recorded. The peer mentor will be supervised by a mental health professional who will also review the audio recordings for quality assurance, on a weekly basis.

AIM1: Usability study to design and test Peers plus components

The usability study will assess user experience so that the intervention manual (currently being tested in a clinical trial called Peer Enhanced Depression Care) can be adapted in an iterative process of trial and revision. Peers plus will consist of peer support delivered through two technology components: 1) PMs will video chat with participants and they will provide emotional support and encourage use of self-care strategies for depression and linkage to community and clinical resources, 2) PMs will provide supportive texting (one-way, SMS) to encourage and reinforce use of self-care strategies, and exchange community and clinical resource information to reduce depression. We will test Peers plus in 10 older adults (see Table 2 below).

Sample size considerations. Determination of sample size for Aim 1 design procedures is based on recommendations within the user-centered design literature.[48,49] Previous research suggests that a sample size of 5 users detects, on average, 85% of the usability errors of a system. Recommendations also include additional iterations of usability testing rather than large samples of users. Based on these suggestions, our approach to conducting two iterations of usability testing with 5 participants in two cohorts (N=10) is likely to provide sufficient feedback to identify a substantial amount of design errors in our Peers plus intervention.

Component 1: Video chats. During the video chats, peer mentors will serve as persons who have experienced depression, serve as models of recovery, possess self-care skills learned from life experience, and know how to use and navigate community and clinical services – all valuable for someone with depression who may not otherwise access mental health resources. Studies have shown the participants will engage more easily with technology when support is provided, so peers will be trained to support participants in technology use. Peer mentors, in their role, will identify goals with each participant during their video chats and share self-care strategies that are relevant to the participants (see Table 2 below). The video chats will be audio recorded on zoom for quality assurance and reviewed by the mental health professional. The recordings will be stored in MGH OneDrive to which only the study team who have completed IRB training will have access.

Component 2: Supportive texting. In each dyad, the participant will receive one-way tailored text SMS messages delivered by the peer mentor daily during the 4 weeks of video chats. Supportive texts will be developed and conceptualized as “micro-interventions” informed by Motivational Interviewing that uses affirmations to motivate behavior change, e.g. use self-care skills for depression. To ensure that the texts are helpful, the peer mentor and the participant will discuss relevant self-care strategies during the video chats first. Based on discussion during the video chats, the peer mentors will send motivational and educational texts that are personalized, consisting of relevant affirmations (e.g. “you are taking great care of your loved one”), coping skills and community-based resources (e.g. “take time out for yourself” , “do something you enjoy”, “connect with a mental health professional”) daily to participants. Texts will serve to reinforce the trusting relationship, express empathy, encouragement, and self-care skills discussed during the video chats. The idea is that such texts encourage and support use of self-care behaviors that are related to depressive symptoms identified by the participant. The

texts will be declarative and posed as questions so that the effect is not to direct behavior but to stimulate thinking in the participant who then decides. All text messages will be co-developed by the mental health professional and the peer mentor before it is sent. The PM will keep a log of texts specifying the day and time when it was sent and will review this process with the MHP during supervision meetings.

Content of PM-Participant meetings. In the usability phase, Peers plus will be 4 weeks in duration. This is abbreviated from 8 weeks (the original duration of the Peer Enhanced Depression Care intervention) because the focus is on the usability of technological components. The primary role of the peer mentors is to build relationship, provide social support (emotional, appraisal, informational support) facilitate simple goal setting, share coping skills and depression self-care skills, and connect to clinical and community resources for depression. The program is relationship-based and takes an empowerment strategy to increase self-efficacy in depression self-care.[45] We will use strategies to enhance cultural appropriateness of our program for minority participants such as avoiding stigmatizing clinical language about mental health, respecting non-medical self-care methods such as religious coping, taking a non-judgmental attitude, accommodating participant preferences.[46] The peer mentor will be supervised by a mental health professional that will consist of weekly meetings by zoom.

Table 2. Peers plus intervention content for usability study

Phase	Process and Content
Introductory phase: Meetings 1 (1 hour)	Orient participant to the program and build trust Share personal story of depression recovery. Discuss participant goals for the meetings and logistics of meetings.
Middle phase: Meetings 2-3 (1 hour)	Listen actively, support emotionally and motivate for self-care Focus on depressive symptoms and participant goals Active listening, empathy, emotional and appraisal support regarding psychosocial stressors Discussion, modeling and encouragement of self-care skills, e.g. positive affirmations, pursuing activities they enjoy, journaling, joining social activities.
Coming to a close: Meetings 4 (1 hour)	Review, reinforce skills learned and plan for the future Provide information regarding clinical and community-based services as requested

Supervisory role of the mental health professional such as a social worker or a clinical psychologist (MHP). Supervision is important to sustain the quality of the program and to support peer mentors. Peer mentors will meet in groups of 2 on a weekly basis concurrent with meetings with participants for supervision. During meetings, the MHP will elicit insights from PMs, discuss progress and problem-solve challenges e.g., lack of engagement and motivation. The MHP will document the activities of supervisory meetings, maintain logs of peer meetings with participants and review audio-recordings of meetings. The PI, who is a geriatric

psychiatrist, will be available for consultation to the MHP to problem–solve difficult situations as appropriate. PMs will have access to the MHP by telephone as needed outside of supervision meetings.

Standard of Care/Referral to clinical care. The participant will be asked if they want referral to specialty mental health care if not engaged in professional care at initial clinical evaluation, during the meetings with the peer mentor and upon completion of the study. If at any time the participant asks for referral to professional care, the participant will receive information about specialty mental health care services so they can make an appointment.

AIM 2. Feasibility study of Peer plus

Knowledge gained from the usability study will be used to revise the Peers plus intervention manual and we will conduct a feasibility study with 20 ethnic minority, community-dwelling older adults with depression. In this study, recruitment, and enrollment procedures as well as eligibility criteria will be identical to the usability study in Aim 1. For the feasibility study, the duration of the Peers plus intervention will be 8 weeks with identical intervention content and process. Data collection procedures will consist of assessment at baseline assessment, post-study assessment and a 3 month follow-up. We will conduct a post-study semi-structured interview.

Data collection

Quantitative data
Listed in Table 3 is the timeline of study measures for the usability and feasibility studies. Data obtained from participants recruited for this protocol will include sociodemographic information (e.g., age, race, ethnicity, etc.), attitudes toward technology and technology use, self-reported clinical information (past history of depression services, current mental health service use), self-reported psychosocial measures (physical, social and emotional function, depression, self-efficacy, coping and loneliness) and social determinants of health. We will measure engagement defined in two ways: 1) as attendance of 80% of meetings as reported by peer mentors [47] and 2) score on the Working Alliance Inventory-SR.

Aim 1 Usability study

Quantitative data A baseline assessment will be conducted by the RA with participants recruited for this protocol. Baseline assessments will include demographic information (e.g. age, ethnicity, gender, education). We will use self-report measures to collect information on depression, medical comorbidity, social determinants of health, self-efficacy, loneliness, coping skills, social, physical, and emotional functioning, attitudes toward technology and technology use. **Assessments at 2 and 4 weeks.** With both the peer mentor and participant at 2 and 4 weeks, we will collect measures of usability with a widely used self-report scale (i.e. System Usability Scale (SUS),[50,51] an objective measure of user engagement with the texting and video

chatting system (i.e. background analytics of supportive texting). This measure is a simple, ten-item Likert scale with five response options that measures the perception of usability by users. Background analytical information on various factors will also be collected, including frequency and duration of platform use, number of messages sent, word count in messages, number of video calls, and time spent on video calls.

Qualitative data We will conduct a semi-structured interview with the peer mentors and participants at 2 weeks and 4 weeks. The study staff will assess peer and participants' experiences with sending and receiving texts, the content and wording, the timing and frequency of the text messages received and engagement with the texting system. We will gather information about satisfaction with the interactions with the peer using the video chat. Consistent with the user-centered design principle of ideation, qualitative and quantitative data collected will be used to revise the intervention. The interviews will be audio recorded, professionally transcribed and themes extracted regarding user experience.

Aim 2. Feasibility study

Quantitative assessments The RA will conduct a baseline assessment that includes demographic information (e.g. age, ethnicity, gender, education), self-report measures on depression, medical comorbidity, social determinants of health, self-efficacy, loneliness, coping skills, social, physical, and emotional functioning, technology use and attitudes (see Table 3 below). The peer mentor will fill out a Working Alliance Inventory on a weekly basis to assess the quality of the bond, agreement on tasks and goals. Background analytical information on various factors will be collected, including frequency and duration of zoom use, number of messages sent, number of video calls, and time spent on video calls.

Qualitative data We will conduct a semi-structured interview lasting approximately 45 minutes with the peer mentors and participants upon completion of the intervention at 8 weeks by zoom. We will gather information about satisfaction with the interactions with the peer using the video chat. The purpose will be to understand peer and participant experience in the intervention. The interviews will be audio recorded, professionally transcribed and themes extracted using a thematic analytic framework.

Table 3. Assessments

Variable	Measure
Demographic information	Age, gender, ethnicity, education, marital status, mental health history
Depression (self-report)	PHQ-9 [37] a widely used, self-report instrument that is keyed to DSM-IV-R criteria for Major Depression
Physical, social and emotional function	Medical Outcomes Study Short Form 36 [48] 10 item measure of overall health, composed of sub-sections that assess emotional, physical and social functioning,
Medical comorbidity	Medical comorbidity will be measured with the WHO WMH CIDI that has been established for use among older adults and has proven validity and reliability.[49]

Coping skills	The Brief Cope is widely used in depression studies which assesses trait and state coping developed from the COPE inventory which assesses different coping dimensions.[50]
Self-efficacy	General Self-efficacy Scale [51] 10-item measure that has been used among participants and found to be sensitive to changes in psychosocial interventions for depression.
Loneliness	R-UCLA Loneliness Scale [52] a commonly used, 20-item, self-report questionnaire.[53]
Technology use and attitudes on technology	Questions adapted from a validated survey assessing technology and media usage and attitudes [54 55]
Working alliance	Working Alliance Inventory-Short Revised -a short 7-item questionnaire that measures affective bond, agreement on tasks and goals, and has been used to measure working alliance in non-professional relationships in mental health. [56]
User experience (in usability study only)	System Usability Testing[57] 10 item survey for measuring assessments of systems usability.

Only trained study staff will have access to these data. Participants' data will be identified by an ID number only, and a link between names and ID numbers will be kept separately under lock and key. Staff will have a password-protected account for downloading the data. All PM-participant meetings will be audio-recorded to ensure fidelity. The MHP will review the recordings and provide feedback during weekly supervision (e.g., problem solve challenging cases). All study staff will have up-to-date Collaborative Institutional Training Initiative (CITI) certifications. All data will be collected by telephone and zoom. To protect participants' confidentiality, we will not use participants' names during supervision meetings of peer mentors.

Standard of care

Participants will be informed during the clinical assessment and reminded throughout the study that professional mental health care is the standard of care for depression. PMs are persons who have had positive experiences in depression treatment and are trained to encourage professional mental health care use in study participants. At any point, if the participants express desire for information or referral to professional mental health care, the study will provide that.

Premature termination

Participants may drop out at any point in the study. We will terminate participants who are not able to conform to study expectations such as meeting regularly and undergoing the assessments. If they are unable to engage in study activities per protocol, study staff will have a discussion with the participant to explain requirements of the study and reasons for inability to complete study requirements. Information or clinical information will be offered to those who are terminated or decide to drop out.

Remuneration

Usability study: **Participants** will receive $30 for each assessment(4) and meeting(4) with the peer mentor. Assessments will include baseline, 2 weeks, post-study assessment and semi-structured interview for a total $240. **Peer mentors** will receive $50 for each meeting and supervision (4) and $20 post study semi-structured interview. Total provided for completing all study activities will be $220.

Feasibility study: **Participants** will receive $30 for each assessment and interview (4). Assessments will include baseline, post-study assessment, 3 month follow-up and semi-structured interview for a total $120. **Peer mentors** will receive $50 for each meeting with the participant and supervision (8) and $20 post study semi-structured interview. Total payment provided for completing activities with one participant will be $420.

1. Risks and Discomforts

Psychosocial risks

We recognize that older individuals, especially those with chronic illness, can easily feel overwhelmed or fatigued by what would be minimally demanding tasks for others, and, therefore, we include this discomfort in the potential risks. A minority of participants may respond to certain interview questions with feelings of sadness and grief (e.g., upon being reminded of interpersonal problems and social isolation). To address undue emotional stress, multiple strategies was used to prevent adverse events: 1) rigorous screening of the older adult's appropriateness for a peer mentor intervention, performed by a mental health professional prior to matching, 2) rigorous training and continuous supervision of the peer to prevent escalating emotional distress, and 3) availability of professional staff to address peer mentor's concerns by phone at all times. In the event that the peer mentor needs assistance, the peer will contact the supervising MHP (with geriatric psychiatrist backup) who will speak with the participant regarding the problem. In our experience, peers have been able to detect signs in the participant of escalating distress and able to follow the established protocol without adverse events. Peer mentors will be trained to recognize and provide support to manage undue emotional distress. In the case that a participant is distressed, the peer mentor will listen actively, provide empathy and ask if they would like to speak with a mental health professional on the study team. If the participant answers in the affirmative, the PM will inform the MHP and the MHP will call the participant and conduct a clinical assessment with appropriate triage to connect with community or clinical resources. If the participant declines speaking with the MHP, the PM will inform the MHP during weekly supervision and also follow up with the participant at the next meeting. The MHP will be available by telephone during the week 9-5pm and a geriatric psychiatrist will be available in the case that the MHP is unable to manage the participant's distress.

Suicidal ideation

When conducting studies with depressed patients, expression of suicidal ideation is a risk. We will address this risk in multiple ways. We will conduct a clinical evaluation prior to matching to assess the participant's appropriateness for the study in terms of depression severity and risk for suicidal ideation. In our previous work, expressions of suicidal ideation were rare because we assessed for depression severity and appropriateness for peer services during the initial clinical evaluation and such persons were excluded and referred for appropriate care. Also, peer mentors recruited for this study will receive training in a protocol for those participants who express suicidal ideation, to ensure the safety of the participants. If the participant

expresses suicidal ideation during a meeting, the peer mentor will immediately call the MHP who will call the participant and manage the situation. Assessment by the MHP may involve the following questions: (1) Do you have a desire to hurt yourself that you think you might act on? (2) Do you have a plan for hurting yourself and intend to carry the plan out? Participants may also be identified as a high risk for suicide if the participant reports a specific plan to commit suicide, or if the participant has risk factors for suicide. Risk factors may include multiple suicide attempts, moderate to severe depression, a high level of hopelessness, immediate access to a lethal method, a lack of reasons for living, psychosis or mania, poor social support or a recent stressful life event. Additional probing may be necessary to identify any other risk factors (e.g., access to a firearm). The MHP will ensure and facilitate urgent referral of high risk patients to the Emergency Department near their home where an evaluation to assess need for treatment is done. A geriatric psychiatrist (Dr. Joo) will be available for consultation in situations where the social worker needs assistance. In our experience, one instance of suicidal ideation (1 participant) did arise, the trained peer mentor contacted the PI who spoke with the participant and managed the situation without adverse events.

Confidentiality and privacy

For participant participants, risks regarding breach of confidentiality and disclosure of clinical information exist and may be heightened due to use of non-professional peer mentors in the proposed study. Should confidentiality safeguards fail, there is potential harm in the form of social risks and disclosure of private information. However, the risks of participation should be no more than minimal, with effective confidentiality safeguards. The safeguards include the following: 1) Peer mentors sign a contract of confidentiality agreement before participating in the project, receive confidentiality training and the importance of confidentiality will be stressed throughout training and supervision sessions on a weekly basis. 2) Participant participants will be informed that absolute confidentiality cannot be guaranteed but study staff put rigorous procedures in place. In our experience, there were no known breaches of confidentiality in our pilot study or in our clinical trial, participants did not express concern about this during the consent process, and none dropped out of the study for this reason. All information collected will be coded with a study identification number and will be stored in secure servers that only IRB approved staff associated with the study can access. These records will be protected by the confidentiality system of MGH and are not disclosed except as required by law. Audio recordings are saved on a secure server, MGH OneDrive.

2. Benefits

The proposed study could benefit the participant participants in terms of psychoeducation and self-care skills associated with depression, services delivered by a PM who is under a mental health professional's supervision. The peer may benefit from increased sense of self-efficacy in helping another person and have an increased knowledge base from the mental health training provided by the study. Benefits to society may include new knowledge regarding the provision of mental health services in the community. If the peer program is successful, new ways to provide depression care services in the community setting to low-income minority participants

are established. The risks to the patient for participating in this project are minimal and the possibility of improving depression care is substantial.

This research intends to inform the development of peer programs whose aim is to improve access and engagement of depression care among minority populations. Given that minority participants receive inadequate or no mental health care and are less likely to access traditional mental health services, developing novel methods of delivering depression services is important.

3. Statistical and Qualitative Analysis

Statistical analysis We will screen data for quality and integrity. We will obtain descriptive statistics to characterize study participants. Percentage of session attended and engagement will be reported as percentages. Inferential analysis of depressive symptoms over time will be conducted using longitudinal linear regression taking into account clustering (via multi-level modeling) since peer mentors will meet with several patients. The quantitative data will identify measured factors that are related to engagement and depression reduction so that the mHealth components for peer delivery can be refined.

Qualitative data analysis All audio recordings will be professionally transcribed. The transcripts will be analyzed using thematic analysis which is a flexible and commonly used approach in qualitative analysis.[58] The study team members will proceed through 4 phases: 1) immersion in the data by reading and re-reading the data, 2) generation of initial codes, 3) sorting of codes into themes, and 4) review and refinement of themes based on coded extracts and relevance to the entire dataset. The PI and members of the study team have conducted and published numerous qualitative studies and are experienced in qualitative methods.[9,38,59] To ensure trustworthiness, the PI and trained study team members will code a subset of transcripts independently, compare their agreement on segments of coded data and resolve disagreements through in-depth discussion. The PI and study team members will meet on a weekly basis during the data analysis period to discuss in depth the rationale for coding and theme generation, and will resolve disagreements by negotiated agreement. Qualitative data analytic software, NVIVO11, (QSR Intl, Durham UK) will be used. The manual of the intervention will be revised based on review and analysis of the qualitative and quantitative data.

4. Monitoring and Quality Assurance

Research-Related Risks Dr. Joo will lead weekly meetings to review study operations and compliance (e.g., data collection and management), to discuss any emerging concerns, to identify any training needs, and to address any human subjects issues. Dr. Joo and the study team will work to ensure compliance with study procedures.

- *Preparation*: An existing intervention manual (created for Peer Enhanced Depression Care) will be adapted for Peers plus, an intervention that integrates technology to deliver peer support. Any changes during the implementation is noted and noted,

- *Ongoing monitoring*: After each intervention meeting, PM activities will be reviewed by the mental health professional during weekly supervision meetings. All meetings will be audio-recorded. **Protocol Fidelity and Investigator Compliance.** The PI and team will record and report all protocol violations.

Participant Confidentiality All study materials will identify participants only by study ID, visit number, and visit date. The study research assistant will be trained in procedures to protect study participant confidentiality. Recordings of each PM-participant meeting will be immediately de-identified (e.g., only ID, visit number and date) and stored on a password protected computer; the recording will be made on zoom and stored on MGH dropbox. The research team will report to the IRB any instances of participant confidentiality breach and corresponding plans for corrective action.

Data Validity and Security. The research team will develop standard operating procedures for data collection, data management, and quality control. Dr. Joo will oversee all procedures related to secure data collection and management. Data activities will be conducted using (Research Electronic Data Capture (REDCap), a software and workflow tool for research data collection and management, with assistance from Partners HealthCare Research Computing, Enterprise Research Infrastructure & Services (ERIS) group. REDCap will provide secure web-based applications with an intuitive user interface data and real time validation rules.

Privacy and Confidentiality

- ☒ Study procedures will be conducted in a private setting
- ☒ Only data and/or specimens necessary for the conduct of the study will be collected
- ☒ Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)
- ☐ Specimens collected will be maintained in a secure location with appropriate protections (e.g. locked storage spaces, laboratory areas)
- ☒ Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol
- ☒ Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.)
- ☒ All electronic communication with participants will comply with Mass General Brigham secure communication policies
- ☒ Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research
- ☒ All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens

- ☒ The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research
- ☒ Additional privacy and/or confidentiality protections

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APPENDIX A

Data Monitoring Committee / Data and Safety Monitoring Board Appendix

A Data Monitoring Committee (DMC) or Data and Safety Monitoring Board (DSMB) will be convened for safety monitoring of this research study. The following characteristics describe the DMC/DSMB convened for this study (Check all that apply):

☐ The DMC/DSMB is independent from the study team and study sponsor.

☐ A process has been implemented to ensure absence of conflicts of interest by DMC/DSMB members.

☐ The DMC/DSMB has the authority to intervene on study progress in the event of safety concerns, e.g., to suspend or terminate a study if new safety concerns have been identified or need to be investigated.

☐ Describe number and types of (i.e., qualifications of) members:
5 members
1.Geriatric psychiatrist and researcher with experience of clinical trials of depression care interventions, NIH funded
2.Geriatrician and researcher in mental health and use of paraprofessionals in medical care
3.Social worker, PhD, health services research with expertise in peer support
4.Statistician, PhD, with experience in NIH studies in geriatric mental health
5.Study statistician, PhD, with experience in NIH studies in geriatric mental health

☐ Describe planned frequency of meetings
DSMB meetings are held every 12 months.

☐ DMC/DSMB reports with no findings (i.e., “continue without modifications”) will be submitted to the IRB at the time of Continuing Review.

☐ DMC/DSMB reports with findings/modifications required will be submitted promptly (within 5 business days/7 calendar days of becoming aware) to the IRB as an Other Event.