The Feasibility of Engage Therapy With Video Support for Homebound Older Adults

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Confidentiality Statement

This document is confidential and is to be distributed for review only to investigators, potential investigators, consultants, study staff, and applicable independent ethics committees or institutional review boards. The contents of this document shall not be disclosed to others without written authorization from WCM.

Weill Cornell Medical College

Institution Name

List of Abbreviations

AE	Adverse Event
CFR	Code of Federal Regulations
CRF	Case Report Form
CTSC	Clinical Translational Science Center
DSMB	Data Safety Monitoring Board
DSMP	Data Safety Monitoring Plan
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act of 1996
HRBFA	Human Research Billing Analysis Form
HUD	Humanitarian Use Device
ICF	Informed Consent Form
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
PHI	Protected Health Information
PI	Principal Investigator
REDCap	Research Electronic Data Capture
REDS	Reaching and Engaging Depressed Senior Center Clients
SAE	Serious Adverse Event
SUSAR	Suspected Unexpected Serious Adverse Reaction
UIRTSO	Unanticipated Problem Involving Risks to Subjects or Others
WCM	Weill Cornell Medicine

1. Study Objectives

1.1. Objectives

Our primary aim in this in this pilot project is to test the feasibility, acceptability and impact of a brief behavioral treatment for depression (Engage) combined with video social support (PRISM 2.0) among socially isolated/lonely case management clients who endorse depressive symptoms. Secondarily, we will assess technology-related outcomes.

We plan to recruit 50 subjects based on a proposed recruitment of at least 3 subjects per month (17 months). Eligible participants will be offered the combination of Engage and Prism 2.0, called Engage-Prism.

1.2. Hypotheses / Research Questions

We hypothesize that the intervention will be acceptable by participants and that it will improve social connection, perceived social support, and reduce loneliness and depressive symptoms.

2. Background and Significance

Older adults who are homebound are socially disconnected with high rates of loneliness and depression. Social isolation places individuals at risk of all-cause mobility and mortality (Holt-Lunstad & Hawkley 2016) including suicidal attempts (Calati et al., 2019). In the Health and Retirement study social disconnectedness is associated with 5% risk of falls, and social isolation combined with loneliness is associated with a 33% increase in falls (Quach & Burr, 2020). In a sample of 1,885 homebound and semi-homebound older adults from the National Health and Aging Trends Study (NHATS) 15.62% scored above the suicide risk cutoff, 23.73% of homebound older adults reported a history of suicidal ideation or behavior, 65 adults in this sample (13.18%) indicated the possibility of attempting suicide in the future (Xiang & Brooks, 2017). Social isolation and depression may be bidirectional (Santini et al, Lancet 2020). Aging services providers are not trained to distinguish loneliness, depression and disconnection making links to appropriate services challenging (Choi NG, Sirey JA, Bruce ML, 2013).

Brief behavioral interventions have shown an increase in social interaction, a decrease in loneliness, depression and disability (Choi and Bruce, 2020). Engage is a brief therapy designed to offer a structured, stepped approach and interventions to reduce barriers to increased engagement with rewarding activities to improve depression (Alexopoulos et al, 2020). The goal is to increase participation in meaningful activities. Recent research supports the importance of engagement in social interpersonal-individual predicting subsequent increases in behavioral activation and improvement of depression (Solomonov et al, 2019). Homebound older adults have limited social interaction given their restricted mobility and medical burden. Innovative steps to improve interactions have used technology to link clients who are homebound. In an intervention targeting social engagement with a technology intervention (PRISM 2.0), participants reported increased social support, decreased loneliness, increased feelings of well-being, more positive attitudes about computers, and gains in computer proficiency (Czaja et al., 2017). These gains were maintained improvements at 12 month follow-up.

3. Study Design and Methods

3.1 Overall Design

The study will include the following steps:

1. Referral from case management service, determination of eligibility, collection of informed consent
2. Baseline assessment and training with the Engage-Prism technology
3. 9 Engage sessions (1 per week) and use of the Prism platform (9 weeks total)
4. Brief interim assessments at 3 and 6 weeks
5. Post-therapy assessment and follow-up interview at week 9
6. Follow-up assessment at week 12

Details related to the questionnaires in the baseline and Week 9assessment as well as the follow-up interview are described in the subsequent sections.

3.2 Baseline assessment/training, Engage sessions, technology use, post-study assessment and interview

3.2.1 Baseline assessment and training

Participants will be mailed the Prism technology or provided the technology in-person. Participants will be provided a tablet and trained in the utilization of Prism by a study team member and technology specialist. Trainings will occur virtually (via Zoom or telephone) or in-person. In-person training will be conducted by research assistants and occur in the participants' home as many are homebound. The determination for in-person versus virtual training will be based on the preference of the participant the research regulations of Weill Cornell Medicine pertaining to the on-going COVID-19 pandemic. Following the training, baseline questionnaire data will be collected with the study team member reading the questions aloud and marking the responses of the participant. Included questionnaires are described in the subsequent section.

3.2.2 Questionnaires

Questionnaires collected during the baseline and study assessments include (attached to IRB application):

1. Hamilton Depression Rating Scale (HAMD) for depression severity
2. Behavioral Activation for Depression Scale (BADS) for behavioral activation*
3. Duke social interaction subscale – to assess social connection
4. Duke perceived support subscale – to assess perceived social support
5. UCLA 3-item scale – to assess loneliness
6. 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0)- to assess different domains of disability**

7. Technology readiness questionnaire (Jay & Willis, 1992)*
8. Mobile Device Proficiency Scale (MDPQ-16)
9. Computer tablet opinions questionnaire (Czaja et al., 2018)*
10. Demographics**
11. Client Satisfaction Questionnaire 3-item for therapy satisfaction
12. Intent to Participate – to assess intention to continue study

*Pre and post only (i.e. not at 3, 6 or 9 weeks)
**Pre only

3.2.3. Engage therapy sessions

Participants will complete 9 Engage therapy sessions. Engage is a form of personalized, stepwise treatment for late-life depression. The main intervention of Engage is an adapted form of behavioral activation tailored to older adults focused on "reward exposure," namely encouraging patients to engage in (i.e., expose themselves to) rewarding activities between sessions to enhance activation of the reward system. At each session, patients will be guided to select a rewarding activity they had not engaged in recently or wanted to do more often. Then, the clinician will help patients develop a plan to engage in the selected activity and to cope with potential difficulties when exposed to such rewarding situations. If a patient does not successfully engage in planned rewarding activities and show clinical improvement by the third session, the clinician will add techniques to address barriers to reward exposure (Solmonov et al, 2019). Weekly depression severity is tracked using the PHQ-9. Engage has previously demonstrated efficacy for decreasing depressive symptoms in older adults (Alexopoulos et al, 2016).

3.2.4. Prism system

Throughout the 12-week study, participants will be given the Prism 2.0 system to use. Participants will be provided a tablet with internet access, pre-loaded with the Prism 2.0 software. The Prism software involves a suite of programs for improving the social support and interaction felt by older adults. Previous studies have demonstrated that Prism system reduces loneliness and increases perceived social support and computer proficiency (Czaja et al., 2017). Prism software includes: Internet browser access (with vetted links to sites such as NIHSeniorHealth.Gov), an annotated resource guide, a dynamic classroom feature, a calendar, a photo feature, E-mail, games, and online help. Clinicians will incorporate elements of the Prism system into therapy as appropriate, and participants will be instructed to use the Prism system at their leisure or as it pertains to their chosen "reward exposure" activities.

3.2.5 Post-study interviews

Following completion of week 9 questionnaires, participants will discuss semi-structured interview questions with a study team member related to barriers and facilitators to the Engage therapy and use of the Prism technology platform (script attached). Interviews will be audio recorded with the consent of the participant.

4. Study Design

4.1 Study Population

The study population involves socially isolated/lonely older adult case management clients who endorse depressive symptoms.

4.2 Inclusion Criteria

Criteria Referral to study:

1. Age at least 60 years.
2. English speaking.
3. Currently enrolled in case management at in 2 included agencies
4. Major depression on the SCID and 24-item Hamilton Depression Rating Scale (HAM-D) ≥ 19
5. Report of loneliness social isolation as determined by the UCLA 3-item scale and Duke social interaction subscale, respectively

Following referral, participants must be willing and able to consent to the study procedures and related activities.

4.3 Exclusion Criteria

1. Psychotic depression by SCID-V, i.e. presence of delusions
2. High suicide risk, i.e. intent or plan to attempt suicide in the near future
3. Presence of any Axis I psychiatric disorder or substance abuse other than unipolar major depression
4. History of psychiatric disorders, hypomania, are excluded
5. Acute or severe medical illness, i.e. delirium, metastatic cancer, decompensated cardiac, liver, or kidney failure, major surgery, stroke, or myocardial infarction during the three months prior to entry; or drugs often causing depression, e.g. steroids, reserpine, alpha-methyl-dopa, tamoxiphen, vincristine
6. Current involvement in psychotherapy
7. Cognitive impairment (i.e. telephone administered MoCA < 11)
8. Currently dwelling in non-community dwelling (e.g. prison, nursing home)
9. Hearing that would not allow participants to complete sessions with the RA/therapist
10. Vision impairment that would not allow the participant to use the study provided tablet
11. Inability to speak English
12. Aphasia interfering with communication
13. Literacy – assessed by reading a paragraph designed for those at 6th grade reading level

INSTRUMENTS	Administered by:	Screening	Baseline	Wk 3	Wk 6	Wk 9	Wk 12
Screening Assessment							
Demographic Questionnaire	Research Assistant (RA)	X	X				
Medication List	RA	X					
Health Information Questionnaire	RA	X					
Functional status (WHODAS 12-item)	RA		X			X	X
Telephone- MoCa	RA	X					
Dx, Depression Severity and Anhedonia							
Hamilton Depression Rating Scale (HAMD)	Research Assistant	X	X	X	X	X	X
Structured Clinical Interview for DSM -V	Clinician	X					
SCID Score Sheet	RA	X					
PHQ-9	Clinician		Weekly during clinician sessions				
Behavioral Activation							
Behavioral Activation for Depression Scale (BADS)	RA		X	X	X	X	X
Social Connection and Loneliness							
Duke (social interaction and perceived support subscales)	RA		X	X	X	X	X
UCLA Loneliness Scale 3-item	RA		X	X	X	X	X
Technology							
Technology readiness questionnaire	RA		X			X	
Mobile Device Proficiency Scale (MDPQ-16)	RA		X			X	X
Computer Tablet Opinions Questionnaire	RA		X			X	
Other							
Client Satisfaction Questionnaire 3-item	RA			X	X	X	X

Intent to Participate	RA		X	X	X	X	

4.4 Strategies for Recruitment and Retention

Case managers will inform the potential participants of the study and let them know that a study team member will contact them. Following referral by case management, eligible participants will be contacted by study staff via phone to provide the initial consent. Eligibility will be confirmed by the study personnel, and potential participants will be invited to participate in the study.

Subjects participating in this study will be compensated approximately $25 for each research assessment ($125 total) for completion of the study. Subjects will receive $25 via check or gift card in the mail for remote visits. There is no charge or compensation for the weekly psychotherapy sessions.

If participants do not "log on" to the Prism system for 7 consecutive days, a study team member will call them to make sure they do not have questions, technical issues, or require re-training.

5. Registration Procedures

5.1 Subject Registration (WCM only)

Not applicable.

5.2 Subject Registration (Sub-sites)

Not applicable.

6. Data Reporting / Regulatory Considerations

6.1. Data Collection

6.1.1. Study outcomes: Feasibility and Acceptability

To evaluate acceptability and feasibility we will record the number of clients who are meet eligibility criteria and accept the intervention (versus refuse). Acceptability will be assessed based on client satisfaction with the therapy and the technology. The Clients Satisfaction Questionnaire will be administered at weeks 9 and 12 with benchmarks will be set at $\geq$3 (out of 4).

This will be recorded by the study team member who interviews the potential study participants. No personal information will be stored for ineligible persons or persons who do not consent to participate. Only descriptives regarding whether or not the person contacted was eligible and consented will be recorded. This will be recorded by the study team member performing recruitment using an online form.

6.1.2. Questionnaires (baseline and post-study)

Personnel conducting the study will verbally ask questions of contained in the questionnaires described, and record the participants answers using pen/paper or electronic form. Study investigators will write the participant number on each questionnaire so questionnaires from the same participant can be matched. Assessments will be collected prior to the first Engage session and following the final Engage session.

6.1.3. Expert assessment

Weekly depression severity is tracked using the PHQ-9 by the clinician. Each session, clinicians will also record when a new participant initiates therapy and whether or not the patient attends each therapy session using an online form.

Acceptability will be evaluated based on the client and therapist satisfaction participating in Engage-Prism using the Client Satisfaction Questionnaire (CSQ 3-item).

6.1.4. Technology utilization

The Prism system collects de-identified statistics regarding the frequency and duration of utilization of each of the Prism applications (e.g. calendar, web browser, classroom), but does not collect surveillance data such as message content or search history. The data is stored on a secure, encrypted server where only study team members will have access.

As described above, if participants do not “log on” to the Prism system for 7 consecutive days, a study team member will call them to make sure they do not have questions, technical issues, or require re-training.

6.1.5. Post-study Interviews

Interviews will be audio-recorded. The team member conducting the interview will take notes to supplement the recording. As feasible, audio recordings will be sent to a HIPAA-compliant, CITI-certified transcription service or transcribed by a study team member. Although participants will be instructed not to provide any PHI during the interview, the transcription service will omit PHI if it is accidentally verbalized by the participant. The transcripts and investigator notes will serve as the data to be analyzed related to the interviews. Audio recording and transcripts will be kept on a secure server that only study personnel have access to through password protected logins.

6.1. Data Analysis

Baseline, interim, and post-study assessment data will be analyzed using statistical hypothesis testing with appropriate parametric or non-parametric tests as dictated by the nature of the assessment output and the distribution of the data collected.

Technology utilization data will be analyzed and reported using aggregated descriptive statistics. Secondary analyses may involve comparing differences in time using the various applications included in Prism, and differences in use based on participant demographics.

Qualitative data from the follow-up interviews be analyzed using inductive methods and the constant comparative process. Coding will be accomplished by multiple coders using consensus coding to elicit key themes from the data.

We will conduct a comparison with a matched sample of case management clients obtained from our prior research project (R01 MH075900, PI - Arean; R01 MH075897, PI - Alexopoulos) .We will compare the Engage-Prism participants response and remission rates with the rates found in the CARE-D study. We expect equal response rates (33-42.5% and remission rates (31- 37.9%) (Alexopoulos, 2016)

7. Regulatory Considerations

7.1. Institutional Review Board/Ethics Committee Approval

As required by local regulations, the Investigator will ensure all legal aspects are covered, and approval of the appropriate regulatory bodies obtained, before study initiation.

Before initiation of the study at each study center, the protocol, the ICF, other written material given to the patients, and any other relevant study documentation will be submitted to the appropriate Ethics Committee. Written approval of the study and all relevant study information must be obtained before the study center can be initiated or the IP is released to the Investigator. Any necessary extensions or renewals of IEC/IRB approval must be obtained for changes to the study, such as amendments to the protocol, the ICF, or other study documentation. The written approval of the IEC/IRB together with the approved ICF must be filed in the study files.

The Investigator will report promptly to the IEC/IRB any new information that may adversely affect the safety of the subjects or the conduct of the study. The Investigator will submit written summaries of the study status to the IEC/IRB as required. On completion of the study, the IEC/IRB will be notified that the study has ended.

All agreed protocol amendments will be clearly recorded on a protocol amendment form and will be signed and dated by the original protocol approving signatories. All protocol amendments will be submitted to the relevant institutional IEC/IRB for approval before implementation, as required by local regulations. The only exception will be when the amendment is necessary to eliminate an immediate hazard to the trial participants. In this case, the necessary action will be taken first, with the relevant protocol amendment following shortly thereafter.

Once protocol amendments or consent form modifications are implemented at the lead site, Weill Cornell Medicine, updated documents will be provided to participating sites. Weill Cornell Medicine must approve all consent form changes prior to local IRB submission.

Relevant study documentation will be submitted to the regulatory authorities of the participating countries, according to local/national requirements, for review and approval before the beginning of the study. On completion of the study, the regulatory authorities will be notified that the study has ended.

7.2. Ethical Conduct of the Study

The Investigators and all parties involved will conduct this study in adherence to the ethical principles based on the Declaration of Helsinki, GCP, ICH guidelines and the applicable national and local laws and regulatory requirements.

This study will be conducted under a protocol reviewed and approved by the applicable ethics committees and investigations will be undertaken by scientifically and medically qualified persons, where the benefits of the study are in proportion to the risks.

7.3 Informed Consent

Patients will provide verbal informed consent (script and information sheet attached).

7.2.4 Compliance with Trial Registration and Results Posting Requirements

Not applicable – not a clinical trial

7.2.5 Record Retention

Essential documents are those documents that individually and collectively permit evaluation of the study and quality of the data produced. After completion of the study, all documents and data relating to the study will be kept in an orderly manner by the Investigator in a secure study file. Essential documents should be retained for 2 years after study conclusion. In addition, all subjects' medical records and other source documentation will be kept for the maximum time permitted by the hospital, institution, or medical practice.

8. Statistical Considerations

8.1 Sample Size/Accrual Rate

The goal of this early-stage pilot feasibility study is to assess feasibility, acceptability and impact of a brief behavioral treatment for depression (Engage) combined with social support (Prism). Though we have planned statistical hypothesis testing for a comparison with a historical sample, our goal is not to demonstrate definitive significant differences or establish but understand whether this is a feasible, acceptable, promising intervention that warrants further exploration with a larger sample of participants. The sample size is based on previous work by the investigators in similar feasibility assessments of the Engage therapy (Alexopoulos et al., 2016).

9. Adverse Event Reporting Requirements

Not applicable, this is not a clinical intervention.

10. Unanticipated Problems Involving Risks to Subjects or *Others*

Not applicable

10.1 Definition of Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO)

Not applicable

10.1.1 Unanticipated Problem Reporting

Not applicable