PROTOCOL TITLE: Reaching and Engaging Depressed Senior Center Clients

PRINCIPAL INVESTIGATOR: Dr. Patricia Marino, PhD, Weill Cornell Medicine

IRB Protocol #: 19-09020810-02

ClinicalTrials.gov Identifier: NCT04289298

Current Version: January 6, 2022

Prior Version Dates:

Version July 20, 2020 Version
December 1,2020 Version
October 11, 2021 Version

Protocol Summary

Full title: *Reaching and Engaging Depressed Senior Center Clients Phase II (REDS II)*
Principle Investigator: *Patricia Marino*
Admin Contact: Iris Yang
21 Bloomingdale Road, 7 South, White Plains, NY 10605
(914) 997-4327
iry4001@med.cornell.edu

Study Description

In response to the large numbers of senior center clients who suffer from untreated depression, we have partnered with the NYC Department for the Aging (DFTA) to develop SMART-MH, a community care model that can be embedded in senior centers to improve recognition, referral, and adherence to depression treatment. We also developed and tested Engage, a stepped-care therapy streamlined to use "reward exposure" as its principal intervention based on the assumption that dysfunction of the reward networks is central to the pathogenesis of depression. Mobile technology provides probes for client adherence and offers to therapists easy to review summary records of mood, activity, and social interaction that can be used to target their sessions. We integrated SMART-MH and Engage-M into a comprehensive community care model "Reaching and Engaging Depressed Senior Center Clients" (REDS). In REDS Phase II, we plan to introduce behavioral economics principles to increase adherence to interventions and to the use of mobile technology active ratings and passive sensing of behavior. Augmented Engage (Engage-A) will be offered to patients in this study. This treatment is similar to Engage-M, but augmented with mobile technology and behavioral economics. During the peak of the COVID 19 pandemic, we were unable to offer group sessions but continued to monitor our depressed participants remotely. Our impression has been that depressed participants were happy to hear from us and eager to engage in remote sessions. These observations led to our decision to retain the SMART-MH as part of REDS because it made identification and referral to care organic to the senior centers' function. However, we decided to change the format of Engage into individual, virtually administered sessions and augment it with mobile technology and incentives to adhere to treatment assignments based on principles of behavioral economics.

Sample Size: Patient/Subjects N = 60

Therapist/subjects N= 10

Study Population: The study will include adults (ages 49+, all genders), who are experiencing symptoms of depression.

Enrollment Period: 12 weeks

Study Design

Senior centers will offer "Augmented Engage (Engage-A)," which is Engage, the treatment offered by REDS, augmented with a mobile technology and behavioral economics . The intervention consists of 9

individual sessions (sessions 1 through 9). These sessions can be in-person, over the phone, or over video call.

The principal intervention of Engage-A is "reward exposure" with additional interventions (for negativity bias, apathy, or emotional distress) for participants with barriers to "reward exposure". Participants are instructed to use a Pocket Weekly Planner (on paper) to schedule a rewarding activity daily and also record preparatory steps. In each week, at least one of the activities should be done with a person important to the patient and at least one activity should be expected to generate a sense of accomplishment. We based this decision on an analysis of Engage study preliminary data, which showed that a higher percentage of interpersonal-individual activities (but not solitary or social-group activities) predicted subsequent increase in behavioral activation and improvement of depression (Solomonov et al *Am J Geriatr Psychiatry*, 2019 Jan 10. pii: S1064-7481(19)30006-5. doi: 10.1016/j.jagp.2018.12.033).

Study Location

New York Presbyterian Westchester Division, 21 Bloomingdale Road, White Plains, NY 10605; Council Center for Senior Citizens 1001 Quentin Road Brooklyn, NY 11223; JCC of Staten Island 1466 Manor Road Staten Island, NY 10314; United Senior Center of Sunset Park 475 53rd Street Brooklyn, NY 11220; Diana H. Jones Innovative Senior center 9 Noll Street Brooklyn, NY 11206; JCC Center You Avis Neighborhood Senior Center 1297 Arthur Kill Road Staten Island, NY 10312

Participants

The participants will have clinically significant depressive symptoms (PHQ-9≥10) and will be older and middle-aged adults (55+). This study will recruit from four senior centers overseen and funded by the Department for the Aging in New York City.

Objectives: The specific aims of this developmental project are to: 1. Examine reach, feasibility, and acceptability of REDS II; 2. Examine engagement of behavioral targets and preliminary effectiveness; and 3. Collect information on REDS II cost, barriers to implementation, and potential savings in health care utilization.

1.1 Study Objectives

1.1.1 Objectives: The specific aims of this developmental project are to: 1. Examine reach, feasibility, and acceptability of REDS II; 2. Examine engagement of behavioral targets and preliminary effectiveness; and 3. Collect information on REDS II cost, barriers to implementation, and potential savings in health care utilization.

1.1.2 Hypotheses/Research Questions: Primary: H1) More than 80% of Virtual ENGAGE-A participants will attend each scheduled session. H2) Seniors will have an average satisfaction (CSQ) score greater than 3 (out of 4) at 3, 6, and 12 weeks follow-up. H3) Community clinicians (LCSW) will have an average satisfaction (CSQ) score greater than 3 (out of 4) at the end of the study.

Secondary: Compared to ENGAGE (9 sessions, in-person), Virtual ENGAGE-A participants will have: SH1) Greater (effect size) and clinically significant reductions in depressive symptoms ($\Delta \geq 3$ pts difference in 24-item HAM-D over 12 weeks); SH2) In the Virtual Engage-A group, increase in behavioral activation (Activation subscale of the Behavioral Activation for Depression Scale) will be followed by reduction in subsequent depression scores (HAM-D); and SH3) in quality of life [Primary Outcome: WHOQL-BREF].

Comparisons with Virtual ENGAGE-A: In addition to the above comparisons we will compare the reach, feasibility, acceptability, preliminary effectiveness, and target engagement of Engage-A with those of Engage-M administered in a group format.

2. **Background and Significance:** Approximately 10,000 senior centers operate in the US and serve 1.25 million persons nationwide. Most of their clients have low income, and in NYC, 68% are non-Caucasian. About 10% have clinically significant depression5 but most receive no care6. We developed SMART-MH, a community care model that can be embedded in senior centers to improve recognition of depression, referral, and adherence to depression treatment. We also developed Engage, a stepped-care therapy, streamlined based on the assumption that a dysfunction of the reward network is central to the pathogenesis of depression and using "reward exposure" as its principal intervention. Engage also targets negativity bias, apathy, and inadequate emotion regulation if they act as barriers to reward exposure. Mobile technology provides probes for client adherence and offers to therapists easy to review summary records of mood, activity, and social interaction that can be used to target their sessions. We integrated the SMART-MH model and Engage-M into a comprehensive community care model "Reaching and Engaging Depressed Senior Center Clients" (REDS). In REDS Phase II, we plan to introduce behavioral economics principles to increase adherence to interventions and to the use of mobile technology active ratings and passive sensing of behavior. Augmented Engage (Engage-A) will be offered to patients in this study. This treatment is similar to Engage-M, but augmented with mobile technology and behavioral economics. During the peak of the COVID 19 pandemic, we were unable to offer group sessions but continued to monitor our depressed participants remotely. Our impression has been that depressed participants were happy to hear from us and eager to engage in remote sessions. These observations led to our decision to retain the SMART-MH as part of REDS because it made identification and referral to care organic to the senior centers' function. However, we decided to change the format of Engage into individual, in-person or virtually

administered sessions and augment it with mobile technology and incentives to adhere to treatment assignments based on principles of behavioral economics. Our relationship with the NYC Dept. for Aging (DFTA) offers the opportunity to embed and rapidly deploy REDS in NYC Senior Centers, and may make the REDS model part of a sustainable service reimbursable by Medicare.

3. Study Design and Methods

Overall Design:

Senior centers will offer "Augmented Engage (Engage-A)," which is Engage, the treatment offered by REDS, augmented with a mobile technology and behavioral economics. The intervention consists of 9 individual sessions (sessions 1 through 9). The sessions can be in-person, over the phone, or over video call.

Intervention: The principal intervention of ENGAGE-A is "reward exposure" with additional interventions (for negativity bias, apathy, or emotional distress) for participants with barriers to "reward exposure". Participants are instructed to use a Pocket Weekly Planner (on paper) to schedule a rewarding activity daily and also record preparatory steps. In each week, at least one of the activities should be done with a person important to the patient and at least one activity should be expected to generate a sense of accomplishment. We based this decision on an analysis of ENGAGE study preliminary data, which showed that a higher percentage of interpersonal-individual activities (but not solitary or social-group activities) predicted subsequent increase in behavioral activation and improvement of depression (Solomonov et al *Am J Geriatr Psychiatry*, 2019 Jan 10. pii: S1064-7481(19)30006-5. doi: 10.1016/j.jagp.2018.12.033). We plan to introduce behavioral economics principles to increase adherence to interventions and to the use of mobile technology active ratings and passive sensing of behavior. This is approach has not been used in mid- and late-life depression, but there is significant literature from U Penn showing that older, medical patients (obese or patients with ischemic heart disease) can meet health behavior goals using this approach (please see https://www.waytohealth.org/publications). A Booklet will be used as a reference by participants to ENGAGE A (in **Appendix to REDS**). The Booklet outlines concepts on depression and on "reward exposure", and offers examples of meaningful rewarding activities (i.e. activities with a person important to participant, activities likely to give a sense of accomplishment, self-care activities, pleasurable activities, and social group activities) and gives examples of preparatory steps likely to be needed before each planned activity. In addition, the Booklet describes interventions for barriers to reward exposure (for negativity bias, apathy, or emotional distress). Therapists identify a barrier specific to an individual participant, if one exists, teaches the participant how to use the intervention corresponding to the barrier, points out the Booklets section describing the intervention and helps participants to schedule and practice each intervention in their Pocket Weekly Planner.

3.1 Mobile Technology: Mobile technology is designed to augment the in-person or remote sessions of Engage-A. A smart phone and a Withings watch will be the vehicles for mobile technology interventions.

3.1.1 Augmentation of Engage-A consists of:

1) Daily ratings of mood, interest or pleasure in activities, stress, and pain. A text message sent by Way to Health prompts participants to rate these 4 items on a scale of 1 to 10.
2) Daily reminders to pursue preparatory steps and scheduled meaningful, rewarding activities.

3) Passive sensing of movement (steps) and sleep daily. Participants are reminded to review their step count and deep and light sleep duration daily and receive a weekly summary of both on Fridays.
4) Participants receive a text message at 7 pm asking them whether they engaged in their daily planned activity and to rate the sense of pleasure (scale 1 to 10) and the sense of satisfaction (scale 1 to 10) they derived.
5) At the end of each week, participants receive a text message indicating to them the reward level they achieved. Based on studies of non-depressed older adults by U. Penn investigators, we are using an incentive plan based on the following behavioral economics principles: Loss is valued more than gain, variable reinforcement is more effective than constant reinforcement, "fresh start" increases desirable behavior, and long term-gains are reinforcing. Accordingly, patients are given 100 points on each Monday and they will be rewarded if they can keep these points by pursuing their scheduled activities. They lose 10 points each time they fail to perform and record their daily activity. All patients start at the Silver level. If a patient has 70 points at the end of a week (Sunday), he/she advances to a higher level (gold, platinum). Patients are informed that if they finish the study at the Gold level they will receive a $50 gift certificate.

4. **Study Design**

4.1 **Study Population**: The study population involves seniors (aged at least 55 years) with depression.

4.2 **Inclusion Criteria**

Criteria Referral to study:

1. Age at least 55 years.
2. PHQ-9 score of 10 or higher via routine screening by senior center staff
3. English or Spanish speaking.
4. Capacity to provide written consent for both research assessment and the Engage-M intervention.

4.3 **Exclusion Criteria**

Client Exclusion Criteria:

1. Current active suicidal ideation defined by MADRS Suicide Item 10 greater than or equal to 4 (Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention).
2. Presence of psychiatric diagnoses other than unipolar, non-psychotic major depression or generalized anxiety disorder by SCID-V.
3. Severe or life-threatening medical illness (e.g., end stage organ failure).

4.4 Strategies for Recruitment and Retention: Senior center staff will refer participants they believe may benefit from the intervention. Due to COVID-19, recruitment will occur remotely, and participants can be referred from wellness calls made by our clinicians as well as from 311 calls. Flyers and advertisements will also be used for recruitment. We will be recruiting 60 subjects in total from the site (WCM only site) and ten licensed clinical social worker subjects. 1. Recruitment and referral sources: We are working with Grace Brandi and Jaquelin Berman of the NYC Department for the Aging (DFTA) to plan implementation of the REDS project at 6 NYC senior centers. Older and middle-aged (55+) senior center clients with elevated depressive symptoms (LCSW training phase n=10 clients; Effectiveness Pilot n=60) will be recruited from the participating senior centers. We have chosen to partner with senior centers that represent clients from diverse backgrounds. Each partnering senior center documents at least 800 active members each, with a daily participation rate of

at least 200 members. Given an expected 10% rate of eligible clients (PHQ-9 > 10), we expect at least 80 clients at each center to meet inclusion criteria to be referred to the study. Excluding those with severe mental illness or dementia as assessed via research measures, we anticipate that over 60 clients at each center will meet inclusion criteria for the RCT. This study will recruit from four senior centers overseen and funded by the Department for the Aging in New York City.

5. Data Collection
6. **Regulatory Considerations**

6.1 **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.

6.2 **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.

6.3 Informed Consent: Due to COVID-19, informed consent will be obtained over the phone. In our experience, many individuals do not have access to technology that would allow them to consent electronically. Prior to consenting, an information sheet will be mailed to the participant so that it can be viewed by the participant during the consent process. The consent form describes the nature of the study and time requirements, potential risks, confidentiality of information, the absence of direct benefits other than reimbursement for completion of research assessments, and the rights of research participants, including their right to withdraw at any time without any loss of benefits. The consent makes it explicit that the protocol involves follow-up research assessments at specified time points. Participants are informed of the amount of time required for participation. In particular, the consent form indicates that the study provides all subjects with baseline assessments and 6, 9, and 12 week follow-up interviews to assess the effectiveness of the therapy. It is described in the consent form that this study is a trial to evaluate the benefits of Engage therapy augmented with technology. Participants are encouraged to discuss the study with the research team and allowed sufficient time to review the consent form, consult with family members, and ask questions of the principal investigator or another member of the research team.

7. **Statistical Considerations:** Senior center staff will refer participants they believe may benefit from the intervention. Due to COVID-19, recruitment will occur remotely, and participants can be referred from wellness calls made by our clinicians as well as from 311 calls. Flyers and advertisements will also be used for recruitment. We will be recruiting 60 subjects in total from the site (WCMC only site) and six licensed clinical social worker subjects. 1. Recruitment and referral sources: We are working with Grace Brandi and Jaquelin Berman of the NYC Department for the Aging (DFTA) to plan implementation of the REDS project at 4 NYC senior centers. Older and middle-aged (55+) senior center clients with elevated depressive symptoms (LCSW training phase n=10 clients; Effectiveness Pilot n=60) will be recruited from the 4 participating senior centers. Clients in the startup phase, during which LCSWs are trained, will be recruited from each of 2 centers randomly assigned to REDS (n=10) over a 4-month period. 60 clients will be recruited to the Engage-A intervention over approximately a 14-month period. We have chosen to partner with senior centers that represent clients from diverse backgrounds. Each partnering senior center documents at least 800 active members each, with a daily participation rate of at least 200 members. Given an expected 10% rate of eligible clients (PHQ-9 > 10), we expect at least 80 clients at each center to meet inclusion criteria to be referred to the study. Excluding those with severe mental illness or dementia as assessed via research measures, we anticipate that over 60 clients at each center will meet inclusion criteria for the RCT. This study will recruit from four senior centers overseen and funded by the Department for the Aging in New York City.