Reaching and Engaging Depressed Senior Center Clients (REDS)

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BACKGROUND

Approximately 10,000 senior centers operate in the US and serve 1.25 million persons nationwide.1 Most of their clients have low income,2-4 and in NYC, 68% are non-Caucasian.5 About 10% have clinically significant depression5 but most receive no care6. We developed SMART-MH,7 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.8 With our senior center partners and our mobile technology team, we redesigned Engage-M so that it can be used in a group format by licensed clinical social workers (LCSWs) of Senior Centers. 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 have integrated the SMART-MH model and Engage-M into a comprehensive community care model "Reaching and Engaging Depressed Senior Center Clients" (REDS). We will compare the performance of REDS with a comparison condition in four senior centers, two randomly assigned to REDS and two to a comparison condition. The comparison centers will use SMART-MH for recognition of depression and referral to mental health services plus weekly group meetings on "Wellness of Mind and Body" (W-MH). 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.

STUDY DESIGN

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. With our senior center partners and our mobile technology team, we redesigned Engage-M so that it can be used in a group format by licensed clinical social workers (LCSWs) of Senior Centers. 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 have integrated SMART-MH and Engage-M into a comprehensive community care model "Reaching and Engaging Depressed Senior Center Clients" (REDS). The specific aims of this developmental project are to: 1. Finalize the REDS protocol and assess feasibility of training; 2. Prepare an Operations' Manual; 3. Examine reach, feasibility, and acceptability of REDS; 4. Examine engagement of behavioral targets and preliminary effectiveness; and 5) Collect information on REDS cost, barriers to implementation, and potential savings in health care utilization. We will randomly assign four senior centers to offer either Engage-M (N=40), the treatment offered by REDS (1 individual and 8 weekly group sessions) or 8 group sessions "Wellness in Mind and Body" plus mental health referral (W-MH; N=20). The participants will have clinically significant depressive symptoms (PHQ-9>10) and will be older and middle-aged adults (55+); 12.6% of the NYC senior center clients are aged 55-65 years. Clients will be identified by senior center staff trained in SMART-MH strategies. We will offer additional training to staff of all centers on SMART-MH outreach, depression screening, and treatment engagement. We will train and provide weekly supervision to 2 or more LCSWs per center of the two centers assigned to Engage-M. We will not offer training or supervision to senior center staff leading the groups of W-MH but we will provide oversight so that clients receive mental health referrals and are

encouraged to attend weekly Wellness group meetings. Our findings will set be used in a R01 study to formally test the feasibility, acceptability, effectiveness, non-billable costs, and barriers of REDS beyond NYC. If proven effective, with administrative support, REDS can be extended nationally and supported by billable services.

We will continue to work with senior centers' staff and our mobile technology team to finalize REDS for both English and Spanish-speaking participants. We will record the training hours to achieve certification in Engage-M (part of REDS), and the success rate of LCSWs engaged by the senior centers to offer behavioral services.

Across conditions we will evaluate:1) Reach: Number of clients screened with PHQ-9 score greater than or equal to 10 vs. all eligible for screening, and those who receive REDS or W-MH; 2) Feasibility: Number of clients who initiate therapy and research procedures (sessions attended, smartphone use); 3) Acceptability to clients [Client Satisfaction Questionnaire 10,11 (CSQ), session completion rate] at baseline, 6, 9, and 12 weeks. Satisfaction of LCSWs, center staff will be assessed every 6 months throughout the study. Benchmarks: Feasibility: >80% will participate in each session of Engage-M. Acceptability: Engage-M participants will have a mean CSQ score ≥ 3 (out of 4) at the end of treatment. 70% of Engage-M clients will enter their smartphone ratings in more than 70% of study days (59 out of the 85 days).

We will be recruiting 60 subjects in total from all sites (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. For the RCT, 20 clients will be recruited from each of 2 centers randomly assigned to REDS (n=40), and 10 from each of 2 centers assigned to the Wellness groups plus mental health referral (W-MH; n=20) 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. We estimate that our sample will be similar to the sample of the demographic profile of NYC senior center members indicate a mean age of 76 year; 67% women; 32% White, 26% Hispanic, 23% Asian, 17% African-American, and 2% other. Support services to investigators and projects will be organized by the Research Methods Core (RMC) Data Group, directed by Dr. Banerjee assisted by two data managers: C. Pollari, MPH, and A. Artis, MS, MPH. The Team will meet weekly to: 1) review the pace and quality of data entering; 2) determine priorities; and 3) provide consultation and conduct analyses. Investigators will join the Work Group as needed to inform the Group of their progress and needs and to be directed to offer their specialized expertise to other Center supported studies. We have used this model successfully over 20 years in our NIMH supported Center. Instrument Sharing: The Intervention Management Work Group (IMG) of the Administrative Core consults with investigators using Center resources to ensure that they select from measurement instruments used in the Center's ongoing studies so that results can be compared across studies. Data Collection Forms: In addition to

harmonizing the selection of instruments across studies, investigators will also be encouraged to use data elements (e.g. demographic definitions and variable names) that have been used on previous studies. This again will harmonize the study data to allow easier merging of data across studies for hypothesis generation and exploratory analyses for future studies. Prototype Database: We have developed a relational database system and a tracking system in Microsoft Access that serve as the prototype for implementing each Center study database. Our database system ensures that the procedures are standardized and administered as intended by the design and that the collection of other data elements is standardized. The tracking system monitors patient appointments and assessments and produces reports of missing and delinquent data. Data from Community Agencies: We have worked with community agencies to facilitate the transfer of de-identified data to Weill Cornell. Each agency compiles patient data from its databases (e.g., CMS OASIS, Medication, Service Utilization) according to our specifications and removes identifying information.

INCLUSION AND EXCLUSION CRITERIA

Client Inclusion Criteria Referral to study (stage 1): 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. Research assessment (stage 2): 1. MOCA greater than or equal to 24. 2. Capacity to provide written consent for both research assessment and the Engage-M intervention.

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).

DATA AND SAFETY MONITORING PLAN

We will monitor depressive symptoms and functioning for each participant via clinical research assessments throughout the study period. Feedback will be collected from participants on their use of the data collection app. In addition, a DSMB board assembled for the entire ALACRITY Center NIMH grant (1 P50 MH113838-01, PI: Alexopoulos) will review the study design, IRB protocol, adverse events, and interim reports of the ongoing study.

If investigators note increasing rates of adverse events or suicidal ideation, we would stop the study. We do not anticipate this will be the case.

Some participants may find the daily questions of the HR application boring or tedious, or they may be bothered by the phone battery usage required to keep the app running, and may choose to discontinue using the application or withdraw from the study. Participants may become seriously medically ill and decide not to participate. In addition, if new psychiatric symptoms develop or change in severity, we may recommend removal from the study and provide referrals for the appropriate treatment needed. Referrals will include psychotherapy or medication management referrals in the community.

Cornell research staff will also assess changes in depressive symptoms at regular intervals. Patient's health and clinical care will always take priority over study participation. Participants may not want to continue completing daily questions via the HR app and will be free to discontinue usage at any time. Participants will also have the option to disable cellular data use for the app through their device settings.

Study interviewers will be Weill Cornell research staff who are trained in assessments with older adults. They will specifically inquire about depressive symptoms, falls, and hospitalizations. Study therapist are also trained to monitor the participant's mental state and will report symptom severity to Weill Cornell staff and the principal investigator. If any moderate to severe symptom changes (or new symptoms) are noted, we will consider alternative options to maximize the participant's well-being. In addition, we will ask all participants about the burden of active and passive sensing and daily smartphone usage, to identify any potential negative consequences of using the HR app. We do not expect any additional risk of adverse events by adding active and passive sensing data collection.

Referrals to external mental health agencies will be offered to participants who drop out of the study in order to address any ongoing depressive symptoms. For those subjects who are removed from the study due to active suicidal ideation or clinically worsening symptoms of depression referrals will be provided for the appropriate treatment needed. Referrals will include psychotherapy or medication management referrals in the community.

The study will adhere to the adverse event grading guidelines provided by Weill Cornell's Office of Research Integrity and Assurance. All adverse events will be reported to the Weill Cornell IRB in the timeline indicated by the Weill Cornell Human Research Protection Program Immediate Reporting Policy.

We will periodically report adverse events to the DSMB, in addition to reporting to the IRB as per Weill Cornell's policy.