PROTOCOL TITLE: EM/PROTECT: Improving Depression in Elder Mistreatment Victims

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BACKGROUND

Elder mistreatment (EM) is prevalent and has serious adverse consequences. The CDC defines elder abuse or mistreatment as "an intentional act, or failure to act, by a caregiver or another person in a relationship involving an expectation of trust that causes or creates a risk of harm to an older adult." Mistreatment includes physical, financial, and psychological abuse, as well as caregiver neglect. EM is estimated to affect 1 in 10 older adults (60+) in the US (5,600,000 victims nationwide). In NY State, the Elder Abuse Prevalence Study found that 141 out of 1000 older adults experienced mistreatment since turning 60. Mistreatment victims are usually young-old, socially isolated women, and perpetrators are

often adult children or spouses. Perpetrators are likely to be male, socially isolated, unemployed, have substance abuse, mental or physical health problems, a police record, or financial problems. Mistreatment victims have high rates of depressive symptoms. Victims of EM have one of the highest rates of depression among older adults (http://www.aoa.acl.gov/). A population-based study found that mistreatment victims had significantly higher rates of depressive symptoms (31.6% vs. 6.8%) and suicidal ideation (16.4% vs. 3.4%) than non-mistreated older adults. In a 7.6 year follow-up of an urban sample, adults with concurrent mistreatment and depressive symptoms had higher rates of mortality than non-depressed victims of mistreatment. In our own work in NYC, 34% of victims endorsed significant depressive symptoms and 16% reported suicidal ideation. Consistent with our Center's deployment focused model, EM/PROTECT has been developed through an iterative process with the NYC DFTA Elderly Crime Victim Resource Center (ECVRC). EM aims to install protection measures, while PROTECT targets the behavioral Page 23 of 34 5/9/19 1:02 PM consequences of stress on the CCN and the reward networks thus reducing the experience of stress.

STUDY DESIGN

EM/PROTECT, a behavioral intervention for depressed elder mistreatment (EM) victims, was designed to work in synergy with EM mistreatment resolution services that provide safety planning, support services, and links to legal services. PROTECT is built on a model which postulates that chronic stress promotes dysfunction of the cognitive control (CCN) and reward networks, impairing the victims' ability to flexibly respond to the environment and limits their rewarding activities. PROTECT therapists work with EM victims to develop action plans to reduce stress, and to increase rewarding experiences. EM/PROTECT has been designed in an iterative process with community EM providers of the New York City (NYC) Dept. for Aging (DFTA) to use agencies' routine depression screening and referral for service. We propose to collect data on feasibility and acceptability of EM/PROTECT. We will compare the effectiveness and target engagement of EM/PROTECT with EM enriched with training of EM staff in linking EM victims to mental health services (EM/MH) in order to position us for a fully powered R01. To ensure rigor and reproducibility, EM/PROTECT or EM/MH will be offered to randomly assigned depressed EM victims, and standardized assessments will be conducted by trained raters blind to participant assignment and our hypotheses. The training of staff and therapists will follow high standards of intervention fidelity. EM staff will screen using routine standardized measures and refer depressed victims to study staff who will describe the study and obtain consent and conduct research assessments. We will use brief validated instruments to assess the outcomes, explore the added value of mobile technology measures, and study the effect of sex in each aim. The EM agencies of NYC are overseen and funded by DFTA. We will Page 22 of 34 5/9/19 1:02 PM begin by working with the Elderly Crime Victims Resource Center (ECVRC), as we have successfully partnered with them in the past for our initial exploratory work (Sirey et al., 2015a and b). We will then work with DFTA to identify a second site. At both sites we will provide refresher training in depression screening and strategies for linking victims to mental health using the Open Door approach we jointly developed with DFTA. Randomization at the participant level will be conducted by the Methods Core (random numbers in blocks of varying size). Both agencies will conduct depression screening. EM workers will not be blind to treatment arm. We are aware that their knowledge of treatment assignment may influence the EM services they provide. For this reason, we will record and compare their services between the two treatment arms to inform the design of the R01 proposal that will follow this R34 study.

The primary objective of the EM/PROTECT project will be to evaluate the effectiveness of EM/PROTECT compared to EM/MH. We also propose to examine the reach, feasibility, and acceptability of EM/PROTECT for depressed EM victims. 1) Effectiveness: In both conditions, the reduction of clinically significant depressive symptoms (as measured on the Montgomery Asberg Depression Rating Scale [MADRS]) and improved quality of life. 2) Reach: In both conditions, number of clients screened vs. all eligible for screening, and clients who meet study criteria. 3) Feasibility: Number of victims who initiate EM/PROTECT, number of EM/MH victims who make contact with mental health services, number who attend research procedures. EM/PROTECT: session completion rate; smartphone use. 4) Acceptability: Victims satisfaction (CSQ) in both treatments; EM/PROTECT session completion at 6, 9, 12, and 16 weeks.

We plan to recruit 4.5 subjects per month over 14 months to achieve a final sample of 80 subjects. We will recruit 2 licensed clinical social workers to administer the PROTECT therapy sessions with clients. The larger number of EM/PROTECT participants will allow a better view of effectiveness and reach/feasibility/acceptability. Effectiveness objective: In separate linear mixed models, we will analyze primary (MADRS, WHOQOL assessed at baseline, 6, 9 and 12 weeks) and secondary measures of effectiveness (PAM, ratings of mood and anhedonia assessed daily) with a subject-specific random intercept and slope and fixed effects for time, treatment, EM agency, LCSW, treatment x time interaction. We will use model building and fitting strategies. In the final model, we will also estimate end of treatment improvements in outcome (from baseline) within each treatment group. As Page 24 of 34 5/9/19 1:02 PM this is an inadequately powered R34 study, we will control for false discovery rate using the Benjamini-Hochberg approach, and not the Family-Wise Error Rate, to adjust for multiple comparisons of secondary outcomes. The focus of our analysis would be to obtain preliminary signals of effectiveness by estimating effect sizes (95% CI) and assessing clinical relevance. Using approaches of Initiative 2.1 (Methods Core), we will conduct exploratory joint analysis of primary and secondary longitudinal outcomes. We will also test between group differences in smartphone measures using the time series approach of Initiative 2.1 (Methods Core). Reach/feasibility/acceptability objective: We will calculate estimates and 95% CI of the following measures for all subjects and for each sex separately. Reach: Proportions screened and met study criteria in both conditions. Feasibility: Among EM/PROTECT clients, proportions of: treatment drop-outs, assessment completions, smartphone use. Proportion of EM/MH victims who contacted mental health services. Acceptability by clients: We will analyze victim satisfaction (CSQ) recorded at baseline, 6, 9, 12 and 16 weeks as in Aim 4. Benchmark tests of feasibility (75% session attendance rate and 70% smartphone ratings) and acceptability will be performed using one-sample z-test of proportions.

INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria: 1) 55 years of age or older 2) capacity to consent (per EM staff) 3) significant depression (per EM staff) as indicated by a score of 10 or above on the Patient Health Questionnaire-9 (PHQ-9), a widely used screening tool routinely administered in EM agency settings (the PHQ-9 has a sensitivity of 88% and a specificity of 88% for major depression) 4) need for EM services.

Exclusion Criteria: 1) Active suicidal ideation (MADRS item 10 >4) 2) inability to speak English 3) Axis 1 DSM-5 diagnoses other than unipolar depression or generalized anxiety disorder (by SCID) 4) MOCA

score of 23 or less 5) Severe or life-threatening medical illness 6) EM emergency and or referral out of EM agency (per EM staff

DATA AND SAFETY MONITORING PLAN

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, or the abuse situation escalates, we may recommend removal from the study and provide referrals for the appropriate treatment needed. All EM victims will continue to receive EM resolution services from DFTA regardless of their participation or termination of participation in the study intervention.

14. Describe the anticipated adverse events and risks of study intervention(s), agent(s) and/or device(s) in detail (e.g., potential risk of the study drug, including potential drug interactions, psychological risks; physical risks). Assess their seriousness and incidence of complications or adverse events when known. Include animal data if trials in humans have not been performed. As all participants will be DFTA clients receiving EM resolution services, we can expect to receive weekly updates from EM staff regarding the participant's depressive symptoms and functioning. 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 application 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.

15. Given the risks identified, describe what monitoring is needed to immediately recognize the adverse events that do occur. 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. DFTA EM staff are also trained to monitor the Page 18 of 34 5/9/19 1:02 PM participant's mental state (in addition to abusive incidents) and will report any notice of falls, hospitalizations, and increasing 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.

16. Describe what measures will be taken to minimize any negative impact on subjects resulting from study closure or a subject being terminated from the study. All participants will continue to receive EM resolution services from DFTA if they choose to withdraw from the study. 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.

17. Describe the adverse event grading based on severity, attribution, and expectedness (including frequency) that will be used, to whom they will be reported and how often. 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.

18. In addition to the IRB, specify to whom you will be reporting unexpected adverse events to promptly. PLEASE NOTE all reportable AEs should be reported to the WCMC IRB as per WCMC AE reporting policy. We will periodically report adverse events to the DSMB, in addition to reporting to the IRB as per Weill Cornell's policy.

19. Will you be using a medical monitor? No

20. Please justify why no monitor is being used. Medical information will be self-reported by participants during the baseline and follow-up research assessments.