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

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BACKGROUND

Elder mistreatment (EM) is estimated to affect 1 in 10 older adults (60+) in the US2 (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 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 our own work in NYC, 34% of victims endorsed significant depressive symptoms (PHQ-9≥10) and 16% reported suicidal ideation. EM/ PROTECT recognizes that resignation of depression acts a barrier to the use of EM services. Thus, mistreatment resolution services alone, while necessary, may be insufficient. Similarly, treatment of depression alone may be insufficient when victims continue to be exposed to the chronic stress of mistreatment. For this reason, EM/PROTECT acts in synergy with mistreatment resolution services. In EM/PROTECT, staff of EM services staff offer mistreatment resolution services. EM/PROTECT is neurobiologically informed and simplified to fit within EM agencies. Consistent with our Center's deployment focused model, EM/PROTECT has been developed through an iterative process with the NY City Elderly Crime Victim Resource Center (ECVRC). EM aims to install protection measures, while PROTECT targets the behavioral consequences of stress on the CCN and the reward networks thus reducing the experience of stress. Accordingly, PROTECT therapists work with victims to implement action plans promoting self-protective behaviors and expanding their meaningful rewarding activities.

STUDY DESIGN

Aims: Due to the limited recruitment time available (the study ends on 8/31/21), we propose to offer Virtual PROTECT (video preferred) to all subjects (N=40) and test the acceptability of Virtual PROTECT by depressed victims of mistreatment abuse and by community clinicians. Our early experience during the COVID-19 crisis, suggests that it is possible to deliver therapy via video or telephone to this vulnerable population. Accordingly, the Primary Aim of this study is to test the acceptability of Virtual PROTECT by depressed victims of mistreatment and by community-based clinicians (licensed clinical social workers, LCSW). A secondary aim of the study is to examine whether Virtual PROTECT is more effective than in-person EM/PROTECT in reducing symptoms of depression and in improving quality of life. We expect that participants receiving Virtual PROTECT will have an even greater decrease in depressive symptoms than a historical comparison group (N=24) who received EM/PROTECT in person because of the enhanced strategies for "reward exposure" and the introduction of behavioral economics incentives for pursuing rewarding activities. EM/PROTECT did not improve quality of life more to EM/MH (elder mistreatment services plus mental health referral). The reasons may be that quality of life in depressed victims of mistreatment abuse is influenced by more factors than severity of depression. We will examine, however, if Virtual PROTECT will improve quality of life more than EM/PROTECT because of the enhanced "reward exposure" strategies and the adherence incentives of behavioral economics.

Primary Hypotheses:
H1) More than 75% of Virtual PROTECT will attend each scheduled session.
H2) Victims 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 project.

Secondary Hypotheses: Compared to EM/PROTECT (9 sessions, in-person), Virtual PROTECT participants will have: SH1) greater reduction (effect size) and clinically significant reduction in depression (Δ MADRS ≥3 pts by 12 weeks); SH2) improved quality of life (Primary Outcome:

WHOQOL-BRF).
In addition, to the above comparison, we will compare Virtual PROTECT with a historical comparison group (EM/MH, N=16) who received elder mistreatment services plus mental health referral as part of the first project.

Power analysis: The primary goal of this study is to establish the acceptability of Virtual PROTECT and obtain preliminary estimates of effect sizes for the improvement in depressive symptoms among Virtual PROTECT participants compared to PROTECT participants. Therefore, we estimated that with 40 Virtual-PROTECT participants, we will have a 95% confidence interval width of 24% for the acceptability (assuming a benchmark of 75%). With 40 Virtual PROTECT and 24 EM/PROTECT (in-person) participants, we can obtain an estimate of the difference in reduction of depression (MADRS) over the course of treatment between the two treatment groups with a 95% confidence interval half-width of 3.0 points. Therefore, we have adequate sample size to test our acceptability hypotheses and obtain a preliminary estimate of effect size with reasonable confidence in order to carry out an adequate powered trial.

Aim 1. Finalize the Manual and Training: We will finalize the EM/PROTECT Manual and use it to train Licensed Clinical Social Workers (LCSWs) at each EM agency. We will record the training hours needed to achieve certification in EM/PROTECT, the success rate of LCSWs in achieving certification and problems encountered during this process.

Aim 2. PROTECT Operations Manual: We will create an Operations Manual with the staff of EM agencies describing how PROTECT will be integrated into the agency, i.e. communication between EM staff, LCSWs, and research staff, PHQ-9 tracking and hand-off, and review of ongoing activities.

Aim 3. Evaluate the reach, feasibility and acceptability: 1) Reach: The number of clients screened vs. all eligible for screening, and the number clients referred who meet study criteria. 2) Feasibility: Number of victims who initiate EM/PROTECT or EM/MH (elder mistreatment services plus mental health referral) victims who make contact with mental health services and the number who attend research procedures. EM/PROTECT: session completion rate; smartphone use; 3) Acceptability: Victims satisfaction (CSQ)8 in both treatments; EM/PROTECT session completion at 6, 9, and 12 weeks. EM/PROTECT Benchmarks: More than 75% will attend each session. LCSWs staff satisfaction will be assessed throughout the study.

Aim 4. Preliminary Effectiveness Pilot: Primary H1 Compared to EM/MH, EM/PROTECT (9 sessions) participants will have greater (effect size) and clinically significant reductions in depression (Δ MADRS ≥3 pts by 12 weeks); Primary H2 improved quality of life (Primary Outcome: WHOQOL-BRF).11,12 As both EM/MH and EM/PROTECT are active conditions we will examine within-treatment differences in outcomes.

Aim 5. Target Engagement: Secondary H (SH): The differential effect of EM/PROTECT vs. EM/MH in reducing depression over 12 weeks is mediated by changes in: Primary target stress change from baseline to 6 weeks on the Perceived Stress Scale. Secondary target exposure to meaningful, rewarding activities at 6 weeks [Primary Measure: Behavioral Activation Scale (BADS).

INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria:

- 55 years of age or older
- Capacity to consent (per Elder Mistreatment staff)
- Significant depression (per Elder Mistreatment 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 Elder Mistreatment (EM) agency settings (the PHQ-9 has a sensitivity of 88% and a specificity of 88% for major depression)
- Need for EM services

Exclusion Criteria:

- Active suicidal ideation (Montgomery Asberg Depression Rating Scale item 10>4)
- Inability to speak English or Spanish
- Axis 1 Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) diagnoses other than unipolar depression or generalized anxiety disorder (by Structured Clinical Interview for DSM-5)
- Severe or life-threatening medical illness

EM emergency and or referral out of EM agency (per EM staff)

DATA AND SAFETY MONITORING PLAN

Some participants may find the questions asked as part of the research interview to be distressing or tedious. Participants are given the option to refuse to answer any question and always have the right to withdraw from the study should they find it distressing or tedious. 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.

Cornell research staff will 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 research assessments or activities and will be free to discontinue participation at any time.

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. Referring elder abuse staff are also trained to monitor the 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.

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 elder mistreatment resolution services from their referring agency 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.

21.