Building Community Capacity for Disability Prevention for Minority Elders

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Brief Study Protocol and Methods

Descriptive methods

The Positive Minds component (adapted from the CERED manualized intervention) is a psychosocial intervention that utilizes psychoeducation and cognitive behavioral therapy (CBT) to treat symptoms of depression and anxiety, including noticing and overcoming unhelpful thoughts. It also presents a range of mindfulness practices, communication techniques, and behavioral activation, by engaging the participant in pleasant activities, and encouraging supportive relationships. Sessions are tailored to the participant's needs using a collaborative approach. The 10-session intervention is culturally adapted for use among a wide group of minority elders and conducted in the participant's language of preference (English, Spanish, Cantonese or Mandarin). Community Health Workers used motivational enhancement strategies to engage the participants. The 10 one-hour sessions were completed over a 6-month period. Every other week the CHWs evaluated participants with the PHQ-9 and GAD-7 and, if necessary, the 5-item Paykel suicide questionnaire, both for participant safety and to ensure the participant's mental health was not deteriorating to the point where immediate intervention or referral was necessary. As part of an emergency protocol, we connected participants to an emergency responder as required. This symptom assessment was administered for both intervention and enhanced usual care groups.

Participants were simultaneously offered the Strong Bodies exercise sessions. Group sessions with an Exercise Trainer (3-5 elders per group) were provided 3 times per week for 12-14 weeks, for a total of 36 sessions. The functional disability prevention component of the Strong Bodies intervention emphasizes building resistance or power training. The intervention consists of a series of exercises that are conducted while wearing a weighted vest. Resistance progresses in 2% body weight increments and weights were distributed evenly within the vests.

To decrease barriers to engagement in the combined intervention, we designed the program to be deliverable both in person and over the phone. Study participants assigned to receive the Strong Bodies intervention were offered an instructional video of the exercises for at-home use. If participants were unable to attend the small-group exercise sessions in-person 3 times per week for 12 weeks, they received training from their Exercise Trainer to use the instructional video and perform the exercises at home. The video was intended to supplement the in-person classes and provide an opportunity for participants to engage in exercises when they are unable to attend the class in person. To this end, we discussed important considerations for phone delivery during the training of study clinicians. For instance, we discussed the need to ask participants whether they were in a private place with no distractions, the importance of vocal intonation, referring to the participant manual, and verbal affirmations to convey empathy.

Community Health Workers (CHWs) deliver the Positive Minds component of the intervention. We drew on the Bureau of Labor Statistics model of CHWs who "implement programs in the community that promote, maintain, and improve individual and community health" (Standard Occupational Classification 21-1094 Community Health Workers. 2017; https://www.bls.gov/oes/2017/may/oes211094.htm)

CHWs were selected and trained from each collaborating community-based organization (CBO) and the Disparities Research Unit. Each CBO had a designated site leader who oversaw the intervention process locally. Part of the Site Leaders' role was to identify staff – either within the organization or identified externally – who would carry out the CHW position. Our recruitment criteria included identifying individuals with work experience that was relevant to the intervention; who were bilingual/bicultural; and who exhibited interpersonal skills in communication, trust, warmth and rapport-building.

We devoted significant time to training the CHWs to offer the clinical intervention at the study sites. Over a four-month period, they were trained on the core elements of the intervention and on understanding the skills and objectives of the intervention. CHWs began with a 2-day training including didactic instruction and role play. The training included two intensive days of workshops and practice sessions, including

attention to research objectives, ethics in research design, and participant privacy and confidentiality (standard HIPAA training). We included procedures recommended by Sterling-Turner and colleagues (1) involving modeling, role playing, rehearsal, and feedback associated with higher levels of treatment fidelity, treatment effectiveness and successful implementation. The second phase of training included role-play of all 10 sessions with two practice participants and then two pilot participants. These sessions were audio recorded, and supervisors reviewed audio-recordings and offered feedback. CHWs were certified to begin seeing patients from the clinical trial once they could administer the intervention with at least 75% fidelity in the pilot cases.

We used a five-stage approach to structure our cultural and linguistic adaptation process (2). This included information gathering, preliminary adaptation and translation, preliminary testing, further adaptation, refinement, and a final adaptation trial. We used our brief, evidence-based CBT intervention, CERED (3) as the starting point for the study.

Latino, Chinese and African American study staff conducted a review of the intervention for fit among elders. We held focus groups to ask diverse elders specifically about their beliefs in mental illness, disability prevention and willingness to complete specific tasks. Study staff summarized the feedback received, which included: 1) lack of awareness of need for treatment; 2) stigma; 3) interest in traditional treatments or prayer rather than CBT, and the 4) need for a balanced authoritative and caring role for the CHW. We then modified the manual and workbook materials to address this feedback.

For linguistic adaptation, bilingual study staff undertook a first translation of the manuals and materials. These were thoroughly reviewed and edited by a supervising staff member. In the case of our Chinese-language materials, we also contracted out with a professional translation service to fine tune the content. We then convened a multicultural committee to test translation and back translation protocols of intervention materials.

As the pilot cases and then formal trial began, we incorporated edits needed to reflect the materials at hand most accurately. We used weekly supervision conducted in diverse languages and discussion in bi-weekly meetings to identify materials and components that needed adaptation by language or for one or more cultural group. We conducted weekly discussions among the supervisors by teleconference where they could also raise concerns, enabling us to linguistically adapt the manual and materials.

Analytical methods

Satisfaction with the PMSB treatment was measured using six questions from the 12-month follow-up assessment. Three of these questions asked about satisfaction with the Positive Minds sessions, and three about satisfaction with the Strong Bodies sessions. A sample item from these six questions was "*How satisfied or unsatisfied were you with the care you received from the Exercise Trainer?*" Response options were 1 (*very unsatisfied*), 2 (*not that satisfied*), 3 (*somewhat satisfied*), and 4 (*very satisfied*).

We first analyzed the means, variances, skewness/kurtosis, and minimum and maximum values for the satisfaction questions. Although participants could choose among four options ranging from 1 (*very unsatisfied*) to 4 (*very satisfied*), the distributions were skewed, suggesting that the primary decision among participants was whether they were *very satisfied* with the sessions. To account for these extreme distributions, we recoded the questions to be binary (with values 1, 2 and 3 coded as zero, and 4 coded as one) and created a single satisfaction measure as the mean of these six binary variables (scale ranges from 0 to 1), such that higher values represent a higher proportion of participants who were *very satisfied*.

We carried out descriptive analysis to examine patterns of missing data and how they were related to sample baseline characteristics. We defined two types of missing data: complete missing (if a specific follow-up assessment was missing because of participant withdrawal or lost-to-follow-up) and partial missing (when follow-up assessments were conducted but variables were missing due to "refused to answer" or "don't know" responses). Because most data were complete missing, we examined baseline characteristics between participants who completed all follow-up assessments versus those who missed at least one.

Although missing a follow-up assessment did not seem to be related to participants' demographic characteristics, to account for missing data we used multiple imputation methods in Stata version 15.1 via the *mi impute chained* command (5). Multiple imputation was carried out in three steps. First, we imputed the missing data for all the variables considered, creating 20 imputed datasets each one consisting of 307 participants with three follow-up assessments per participant. In the second step we ran analysis on each individually imputed data set. Finally, we aggregated the individual estimates to obtain final estimates and adjusted standard errors for the uncertainty due to imputation (6).

Each imputation was carried out using the chained equations method (7). In what follows, we refer to variables with missing data as incomplete variables and those with non-missing data as complete variables. Each incomplete variable x_j was specified as a conditional function (g_j) given the set of all other variables used in the imputation, comprising both incomplete ($x_1, \dots, x_m$) and complete variables (Z). We fitted the conditional model g_j to generate the predicted values of x_j using an iterative method. Specifically, each incomplete variable x_j was iteratively estimated and in each iteration the variable x_j^t was then updated to x_j^{t+1} based on the conditional model. This updated variable was then used in the estimations of the other variables, following the conditional model specification

$$x_j^{t+1} \sim g_j\left(x_j \mid x_1^{t+1}, \dots, x_{j-1}^{t+1}, x_{j+1}^{t}, \dots Z, \phi_j\right),$$

for $j \in \{1 \dots m\}$, where ϕ_j were parameters of the conditional model g_j. These steps were repeated for all variables $x_1, \dots, x_m$ and, after an initial burn-in phase, the procedure was stopped once convergence was reached.

The variables used for imputation included main outcome variables and their baseline measures, participant socio-demographics, clinical characteristics, and study design variables, such as site and intervention indicators, as well as dummy indicators for each follow-up assessment.

We used interval regressions to incorporate the theoretical bounds of the clinical outcome variables to increase the efficiency and accuracy of the imputation procedure (e.g., we restricted the imputed values of PHQ-9 to lie within the 0 to 27 intervals). We used logistic regression models to impute binary variables, and linear regression models to impute continuous variables.

For Analysis, first, we compared distributions of baseline characteristics between participants who received the PMSB intervention and participants in the usual care group, to assess the balance of the observed covariates. For each follow-up assessment, we compared the baseline covariates to detect any significant baseline differences between those who completed assessment versus those who did not.

Second, to assess the effect of the intervention, we conducted an intent-to-treat (ITT) analysis, using a multilevel, multivariate regression model to assess changes in outcome variables over time in the treatment and control groups. To account for the nature of longitudinal data, the ITT analysis was carried out by fitting multilevel mixed-effects models to allow for valid variance calculation and statistical inference. The multilevel models computed included random effects at both participant- and site-level to account for within-participant and within-site correlations, as well as robust clustered standard errors to account for within-site correlations due to participants nesting within same site. Letting Y_{itj} denote the outcome measured at time t after the baseline for participant i at site j, we estimated the following model:

$$(1)\quad Y_{itj} = \beta_{0i} + \beta_{0j} + \beta_1 Intervention_i + \beta_2 Time_t + \beta_3 Intervention_i \times Time_t + \beta_4 (Time_t - t^*) + \beta_5 Intervention_i \times (Time_t - t^*) + \beta_6 X_i + \varepsilon_{itj}$$

where the participant-specific random intercept can be written as ($\beta_{0i} = \alpha_{00} + \omega_{0i}$) and the site-specific random intercept can be written as ($\beta_{0j} = \gamma_{00} + \epsilon_{0j}$). We fitted only linear models as all our outcomes were continuous.

In the ITT analysis, individuals were assigned to the study arm to which they were randomized. Thus, $Intervention_i$ is equal to 1 if participant i is randomized to the intervention arm and 0 otherwise. $Time_t$ is a continuous measure of time capturing differences in months between assessment t and assessment $t-1$. Because the intervention ended by the time of the 6-month assessment, we centered the time variable at 6-month follow-up in the following way: $Time_t$ equals to -4 for 2-month follow-up, 0 for 6-*month* follow up, and 6 for 12-month follow-up. To model the pattern of outcome changes over time, our primary analysis employed linear spline models to divide the time axis into two segments, and within each segment consider piecewise linear trends (e.g., having a different time trend before and after the intervention ended). Specially, we denote t^* to be the month when the intervention stopped, i.e., 6 months after baseline and $(Time_t - t^*)_+$ to be the post-intervention time trend, which equals to $(Time_t - t^*)$ if $Time_t > t^*$ and 0 otherwise. This choice of linear spline models allows for the ability to test whether the time trends differ before and after the intervention was finished and that treatment effect could attenuate over time once participants do not receive more intervention.

Since the time variable is centered at 6-month follow-up, the beta coefficient on $Intervention_i$ can be interpreted as the treatment effect on outcome levels evaluated at the end of the intervention. That is, testing for the significance of β_1 tests the hypothesis that the treatment was more effective than enhanced usual care in improving the outcomes, as evaluated at 6 months after the baseline. The coefficient of intervention by time interaction β_3, tests whether the pattern of outcomes over time would be no different between treatment and enhanced usual care groups. Similarly, β_5 tests whether changes in outcome responses over time were different between treatment and control groups after the intervention had ended. The constant term $(\alpha_{00} + \gamma_{00})$ in equation (1) represents the level of the outcome variables in the absence of the intervention ($Intervention_i = 0$) at 6-month follow-up ($Time_t = 0$ and $(Time_t - t^*) = 0$). The term ω_{0i} denotes the participant-specific random effect, ϵ_{0j} the site-specific random effect, and ε_{itj} denotes the

residual error term. X_i includes the baseline measure of the outcomes to control for severity of the outcome at baseline. We also estimated the effect of the intervention six months after it ended, i.e., 12-months after baseline, using the time-by-intervention interactions. Given $Time_t = 6$ for the 12-month follow-up and $t^* = 6$ since PMSB lasted six months, the intervention effect evaluated 12 months after baseline is given by $\beta_1 + \beta_2 \times 6 + \beta_3 \times 6$.

In assessing the effectiveness of PMSB on physical function outcomes (SPPB (8), LLDFI and WHODAS 2.0 (9)), 35 participants in the intervention condition were excluded from the analysis because they could not receive the Strong Bodies treatment due to lack of medical clearance (9 participants), death (2 participants), medical condition (e.g., surgery, knee replacement; 5 participants), lack of access to facilities following the hurricanes in Florida and Puerto Rico (18 participants), or they had to be referred to treatment due to active suicidality (1 participant). Their control counterparts, according to the 2-person block randomization, were also excluded to rebalance the sample. We applied this exclusion because the lack of sessions in Strong Bodies was not related to the intervention but to these other external factors. In total, 70 participants were excluded in all analyses where the outcomes were physical function measures. We confirmed that baseline characteristics between control and intervention participants remained balanced after this exclusion.

We conducted four sets of sensitivity analyses. First, to account for multiple outcome assessment, we estimated a multivariate multilevel regression (10) to test treatment effects obtained from a joint model instead of modeling the outcomes separately. This strategy accounts for the correlation among outcomes and provides more powerful tests of treatment effects compared to more traditional approaches (e.g., Bonferroni adjustments or combining the outcomes into a composite measure)(11). To estimate this multivariate model, we created a long data set where each outcome (SPPB, LLFDI, WHODAS 2.0, HSCL-25 and GAD-7) at each follow-up assessment (2-, 6-, and 12-months) was stacked for each individual, meaning a data set where each participant had 15-observations (five outcomes times three follow-up assessments). The values for each outcome were combined into a single outcome variable Y_{hitj}, where h indexes the outcome measure. Instead of estimating equation (1) separately for each outcome, we produced a single equation

$$
\begin{aligned}
(2)\quad Y_{hitj} = {} & \beta_{0hi} Outcome_h + \beta_{0hj} Outcome_h + \beta_{1h} Intervention_i \times Outcome_h \\
& + \beta_{2h} Time_t \times Outcome_h + \beta_{3h} Intervention_i \times Time_t \times Outcome_h \\
& + \beta_{4h} (Time_t - t^*) \times Outcome_h + \beta_{5h} Intervention_i \times (Time_t - t^*) \times Outcome_h \\
& + \beta_{6h} X_i \times Outcome_h + \varepsilon_{hitj} Outcome_h
\end{aligned}
$$

where $h = 1$ for SPPB, $h = 2$ for LLFDI, $h = 3$ for WHODAS 2.0, $h = 4$ for HSCL-25, and $h = 5$ for GAD-7. Since the time variable is centered at 6-month follow-up, the beta coefficients on $Intervention_i * Outcome_h$, β_{1h}, can be interpreted as the treatment effect on outcome h evaluated at the end of the intervention. After modeling the outcomes jointly, we conducted a joint global test to evaluate the null hypothesis that all treatment effects were zero, i.e., $\beta_{11} = \beta_{12} = \beta_{13} = \beta_{14} = \beta_{15} = 0$. This joint test considers the correlation among measures, which is likely to be different from zero in our context, e.g., participants with low SPPB scores are likely to also self-report lower LLFDI scores.

Second, we examined whether our intent-to-treat results were robust to more traditional models that included only an indicator for intervention, three indicators of time (2-, 6- and 12-months) and their two-way interactions using the following model:

$$
\begin{aligned}
(3)\quad Y_{itj} = {} & \beta_{0i} + \beta_{0j} + \beta_1 Intervention_i + \beta_{21} Time_1 + \beta_{22} Time_2 + \beta_{23} Time_3 \\
& + \beta_{31} Intervention_i \times Time_1 + \beta_{32} Intervention_i \times Time_2 \\
& + \beta_{33} Intervention_i \times Time_3 + \varepsilon_{itj}
\end{aligned}
$$

where Y_{itj} denotes the outcome measured at baseline, 2-, 6- and 12-months ($t = 0, 1, 2,$ and 3, respectively) for participant i at site j, $Time_1$, $Time_2$, $Time_3$ are indicator variables for the 2-, 6- and 12-month follow-ups, respectively (baseline is the reference period), and $Intervention_i \times Time_1$, $Intervention_i \times Time_2$, $Intervention_i \times Time_3$ are the two-way interactions between the intervention indicator and the time indicators. The coefficient β_{32} represents the effect of PMSB at the end of the intervention (6-months), while β_{33} represents the effect of PMSB six-months post-intervention (12-months).

Our study sample was composed of a multicultural population across multiple clinical sites in three states and Puerto Rico. Intervention materials and protocols included translation and back translation of standard English measures. In a third sensitivity analysis, we tested whether our results were influenced by cultural differences in the intervention protocols, by examining if the intervention had a different effect based on race/ethnicity, language, or clinical site. To perform such test, besides the baseline measure of the outcome, X_i included either race/ethnicity, language or clinical site in equation (1), and we also included a test of whether the interaction between the intervention and any of these variables was statistically significant. Although evaluating the significance of the interaction effects is not a formal test that our results were not influenced by differences in the intervention protocols, observing a consistent pattern of significant interactions can provide some insight. For example, finding that the intervention was more effective for Latinos, for Spanish-speakers (80% of Latinos in our sample), and in sites were most participants received the intervention in Spanish, could indicate that the intervention was not culturally equivalent.

In additional sensitivity analyses, we also examined whether our results changed after adjusting for baseline fitness (SPPB, LLFDI and WHODAS 2.0) or pharmacotherapy (GAD-7 and HSCL-25) service use, as well as whether the intervention was more effective among participants with moderate to severe baseline physical functioning (SPPB, LLFDI and WHODAS 2.0) or moderate to severe mental health symptoms (GAD-7 and HSCL-25). Baseline severity of physical functioning was measured with a dummy-coded variable equal one if participant's baseline SPPB score was between 3 and 7 and equal zero otherwise. Baseline severity of mental health symptoms was measured with a dummy-coded variable equal one if participant's baseline PHQ-9>=10 or GAD-7>=10 or GDS>=8 and equal zero otherwise. As before, X_i included either baseline service use or severity in equation (1), and we tested whether the interaction between the intervention and any of these variables was statistically significant.

In secondary analyses, we used *compliance* (defined as number of treatment sessions received) as the independent variable of interest, categorized as compliance equal to zero (control group or intervention participants with no PM and no SB sessions), 1+ session (at least one PM or SB session without full compliance), and full compliance to the treatment protocol (10 PM and 25-36 SB sessions). While this analysis no longer relies on random assignment, it serves to provide confirmation of the results from the intent-to-treat analysis and provides further estimates of the magnitude of the intervention effects on the main outcomes evaluated at 6 and 12 months after the baseline. Because *compliance* made use of both number of PM and number of SB sessions, all compliance analyses excluded the 35 participants who did not receive the SB sessions and their 35 control counterparts.

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