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Protocol for a collaborative randomised effectiveness trial of lay-delivered versus clinician-delivered behavioural activation in senior centres

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ABSTRACT

Introduction Depression is common among community-dwelling older adults who make use of senior centre services yet remains undertreated due to a lack of acceptable and available treatments. Emerging evidence suggests that lay health providers can offer psychosocial interventions for mental health disorders experienced by older adults. We developed a streamlined Behavioural Activation intervention (called 'Do More, Feel Better'; DMFB) to be delivered by older adult volunteers and propose to compare its effectiveness to that of clinician-delivered behavioural activation (BA).

Methods and analysis This study is a type I collaborative randomised effectiveness trial testing the effect of DMFB in comparison to BA among 288 senior centre clients (aged 60+). Participant clients will be recruited from 6 Seattle, 6 New York City and 6 Tampa area senior centres serving economically and ethnically diverse communities. Primary outcomes will be increased activity level (target) and decreased depressive symptoms. Secondary outcomes will be functioning and client satisfaction, and an exploratory outcome will be treatment fidelity.

Ethics and dissemination The study received ethics approval from the University of Washington Institutional Review Board (STUDY00011434). Client, volunteer and clinician participants will all provide informed consent for study procedures through in-person or remote contact with investigators. Results of this study will be presented in peer-reviewed journals and at professional conferences.

Trial registration number NCT04621877; ClinicalTrials.gov.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study is a collaborative randomised effectiveness trial of 288 client participants that is fully powered to test a lay health-delivered behavioural activation intervention for treating older adults suffering from depression.
⇒ Randomisation to intervention condition at the client level using blocked randomisation will ensure equivalent distribution of client sociodemographic and clinical characteristics.
⇒ Rigorous intervention training procedures and documentation of fidelity will strengthen the internal validity of the study.
⇒ A limitation of this study is that client participants and intervention providers will not be blind to the client's treatment condition, a common problem for all psychotherapy studies.

INTRODUCTION

Senior centres offer opportunities to provide acceptable mental health services to older adults, a vulnerable and underserved group. Individuals who attend senior centres represent large numbers of mid to low-income seniors with multiple social service needs, nutritional insecurity and financial vulnerability.[1–5] The approximately 10 000 senior centres in the USA are part of a national, multilevel ageing service network overseen by the Administration for Community Living. The mission of senior centres is to help older adults live in their community as independently as possible. Centres provide a variety of social, health promotion, nutritional, case assistance and recreational services.[2]

Our research teams have documented that 10%–25% of older adults who make use of senior centre services experience clinically significant depression.[6–8] Although some centres conduct mental health screening, a National Academy of Medicine report highlighted the insufficient number of geriatric mental health providers who can provide needed care.[9] Moreover, few depressed older adults accept mental health referrals or engage in treatment,[10 11] in spite of the existence of evidence-based treatments for late-life depression, including multiple forms of psychotherapy and medications.[12–15] These findings are particularly concerning given associations between untreated depression in later life and negative health,

mental health and quality of life outcomes, including mortality.[16–19]

As one solution, SAMSHA and the National Council on Aging have recommended integrating mental health programmes into ageing service settings[5 20] and employing non-traditional providers to meet the needs of older adults.[9 21] Research has shown that lay health providers can offer psychosocial interventions for mental health disorders experienced by older adults.[21 22] These interventions may be less costly than clinician-delivered interventions, equally or more acceptable to older adults, and equally effective in improving target and clinical outcomes.[7 22 23] Expanding the network of non-traditional providers also offers the opportunity to enhance the racial and ethnic diversity of the geriatric workforce, benefiting the growing population of culturally diverse older adults across the US.[24–26]

We developed a lay-delivered Behavioural Activation intervention ('Do More, Feel Better'; hereafter termed DMFB) to grow the field capable of providing geriatric mental health services in community settings. We have demonstrated the feasibility of older lay volunteers delivering DMFB to fidelity and ability to conduct two pilot randomised controlled trials documenting client improvements in activity level and depressive symptoms.[22 23] This pilot research demonstrates the promise of transferring such an evidence-based intervention to the hands of lay providers, calling for a definitive effectiveness trial as described here.

We propose to compare two models of care for depressed senior centre clients: lay-delivery of simplified Behavioural Activation (DMFB) versus clinician-delivery of traditional Behavioural Activation (hereafter termed 'BA'). We chose BA given its potential as a straightforward evidence-based intervention for depression. Decades of research demonstrate its effectiveness for depression with diverse populations, including older adults,[27–32] with clear evidence that BA's effect on depressive symptoms is mediated by increased activity level.[23 33–37] Studies have also found it easier to train and sustain provider skill in BA than other behavioural interventions for depression.[14] We chose clinician-delivered BA as the comparison condition to control for receipt of BA and to allow us to determine whether lay-delivery leads to comparable engagement of target variables and clinical outcomes.

Study objectives

The purpose of this paper is to publish the protocol of a collaborative study recently funded by the National Institute of Mental Health to determine the impact of DMFB compared with BA. Our specific aims and hypotheses are:

Aim 1. Client outcomes

Tests the effectiveness of DMFB in comparison to clinician-delivered BA for depressed (Patient Health Questionnaire-9 (PHQ-9)[38] ≥10 and Hamilton Rating Scale for Depression (Ham-D)[39] ≥14) older adults (≥60) on increasing primary outcomes of overall activity level (target) and reducing depression symptoms. We will detect a non-inferiority margin for Cohen's *d* effect size>0.2.

Hypothesis 1: (activity level)

DMFB is non-inferior to BA in increasing overall activity level (Behavioural Activation for Depression Scale; BADS)[36] over 9 weeks.

Hypothesis 2: (depression)

DMFB is non-inferior to BA in reducing depressive symptoms (Ham-D) over 9 weeks.

Aim 2. Activity target mechanism

tests whether increased activity level predicts greater reduction in depression severity and whether increased activity's impact on depression is non-inferior across conditions.

Hypothesis 3: (mechanism)

Change in activity level (BADS) at each assessment time (baseline-2 weeks, 4–5 weeks, 7–8 weeks) predicts severity of depression (Ham-D) at next assessment time (3, 6, 9 weeks) across conditions.

Secondary aims: (S1) functioning

DMFB is non-inferior to BA in reducing the secondary outcome of disability (WHO Disability Assessment Schedule II; WHODAS-II)[40] over 9 weeks. (S2) Satisfaction with treatment. DMFB and BA clients will report similarly high satisfaction scores as a secondary outcome. (S3) Client-level moderators. The effect of DMFB versus BA will be moderated by client baseline characteristics, including sociodemographic factors, diagnostic status (Major Depressive Disorder (MDD) vs subthreshold), depression severity and disability.

Exploratory aims: (E1) longer term benefits

Outcomes of DMFB are non-inferior to those of BA at 24 and 36 weeks: BADS, Ham-D, WHODAS-II. (E2) Delivery cost: We will explore whether delivery is less costly for DMFB than BA. (E3) Preparing for sustainability: We will explore client, provider and centre factors related to intervention fidelity.

METHODS AND ANALYSIS

Study design

This clinical trial follows the Standard Protocol Items: Recommendations for Interventional Trials guidelines. The trial was registered on clinicaltrials.gov and was approved by the University of Washington (STUDY00011434).

This study is a type I collaborative randomised effectiveness trial testing the effect of DMFB in comparison to BA on increased activity level and decreased depressive symptoms. Each lay volunteer and clinician will provide the respective intervention to four eligible depressed clients over the trial's course.

Participants

We will recruit a total of 288 English-speaking older individuals (60+) with elevated depressive symptoms (PHQ-9 ≥10 and Ham-D ≥14) from Seattle, NYC and Tampa-area senior centres serving economically and ethnically diverse communities. Participants with active suicidal ideation or a diagnosis of bipolar or psychosis will be excluded and referred to appropriate care. Participants with dementia or Telephone Interview for Cognitive Status-modified (TICS-M)[41] scores below 21 will be excluded. Current regular psychotherapy or antidepressant use, unless at stable doses for 12 weeks will be exclusions. We will not exclude participants with other psychiatric comorbidities. Two lay volunteer participants (age 60+) and two clinician participants per centre will provide the respective interventions.

Recruitment methods

We will recruit and obtain informed consent (see online supplemental material) from clients with elevated depressive symptoms (PHQ-9 ≥10) from participating senior centres. We will recruit and obtain informed consent from lay volunteers and per-diem clinicians for each centre.

Participating senior centers

Six senior centres located in Seattle, six in NYC and six in Tampa will participate. We chose these regions and centres to represent diverse geographical areas and client sociodemographic characteristics. Each site will stagger recruitment by first working with two senior centres, followed by two other centres 12 months later, and the final two centres 12 months later (see table 1 for timeline).

Interventions

'Do More, Feel Better': We streamlined BA into the highly structured DMFB intervention that lay providers can learn and administer.[22] A written manual includes scripts, agendas and supporting materials that retain key elements of BA. DMFB involves 9 weekly 30–45 min in-person or

Table 1 Study timeline

Task	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12
Year 1												
Finalise protocol, IRB, DSMB	XX	XX	XX									
Participant recruitment (n=90)				XX	XX	XX	XX	XX	XX	XX	XX	XX
Intervention delivery				XX	XX	XX	XX	XX	XX	XX	XX	XX
Participant follow-up							XX	XX	XX	XX	XX	XX
Progress report, DSMB												XX
Year 2												
Participant recruitment (n=180)	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
Intervention delivery	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
Participant follow-up	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
Progress report, DSMB												XX
Years 3												
Participant recruitment (n=270)	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
Intervention delivery	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
Participant follow-up	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
Progress report, DSMB												XX
Years 4												
Participant recruitment (n=360)	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
Intervention delivery	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
Participant follow-up	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
Progress report, DSMB												XX
Year 5												
Intervention delivery	XX	XX	XX									
Participant follow-up	XX	XX	XX	XX	XX	XX	XX	XX	XX			
Data analysis							XX	XX	XX	XX	XX	XX
Final progress report, DSMB												XX
Manuscript development							XX	XX	XX	XX	XX	XX

DSMB, Data and Safety Monitoring Board; IRB, institutional review board.

remote sessions. Key strategies involve: (1) psychoeducation about depression and DMFB's rationale, (2) compilation of a list of pleasant and rewarding social, physical and recreational activities, (3) daily activity scheduling and (4) self-monitoring activities and mood.

Comparison condition: clinician-delivered brief Behavioural Activation for Depression (BADT-R)[42] will be provided in 9 weekly 30–45 min sessions and includes psychoeducation, activity listing, daily activity scheduling and self-monitoring activities and mood.

Training and fidelity assessment

Study investigators will lead group training for volunteers and separately for clinicians at each centre. Volunteers require four 2-hour sessions and clinicians two 2-hour sessions. Training for each consists of didactic on late-life depression, the respective intervention and step-by-step role playing. Trainees achieve preliminary certification if they successfully complete a session role play (minimum=1 attempt, maximum=5 attempts), defined as ≥3 (satisfactory) on the DMFB and BA Fidelity forms. Approved trainees then see a 'practice case' and must achieve fidelity scores >3 on two sessions. Their fidelity scores will be assigned by consultants external to the research team. Ratings are made on a 6-point scale ranging from 'very poor' to 'very good'. Individual items reflect key elements of each intervention with a final global rating integrating all sets of skills. Trainees who do not achieve certification will not serve as providers for the randomised controlled trial (RCT). Study investigators will provide weekly group supervision for volunteers, and separately for clinicians. Consultants will assess ongoing fidelity on 10% of randomly selected audiotaped sessions. All sessions will be recorded, and providers will not be aware of which sessions will be rated.

Randomisation

Depressed clients will be randomised by the study statistician within each senior centre to DMFB (n=144) or BA (n=144) using a 1:1 allocation ratio, and blocked randomisation with randomly selected block sizes. The randomisation unit for analytic purposes will be the client to ensure equivalent distribution of client characteristics.

Assessment measures, methods and timeline

Clients will be involved in the study for a total of 36 weeks. They will participate in a baseline assessment and five follow-up assessments (3, 6, 9, 24 and 36 weeks) administered by trained and blinded Research Assistants, for which they will be reimbursed (see table 2).

Sociodemographics: participants will complete a survey to determine gender, age, ethnicity, income categories and education.

Structured Clinical Interview for DSM-V (SCID).[43] The SCID is a semistructured clinical interview for making Axis I diagnoses based on DSM-V. Diagnosis will be assigned after review by investigators of information collected by research assistants on the depression, generalised anxiety, psychosis and current alcohol and substance abuse sections.

24-item Hamilton Rating Scale for Depression (Ham-D).[39] The Ham-D 24-item scale will be used as a primary outcome. The HAM-D is a semistructured clinical interview that assesses depression severity. Scores 0–7 represent transient to no depressive symptoms; 8–13 mild depression; 14–18 moderate depression; 19–22 severe depression and above 22 very severe depression.

PHQ-9.[38] The PHQ-9 consists of nine depression items. The participant rates each item over the last 2 weeks on a 0 ('not at all')–3 ('nearly every day') point scale. Scores >10 indicate depressive symptoms of at least moderate severity.

TICS-M.[41] The TICS-M is a 13-item test of global cognitive functioning. Scores range from 0 to 39, with scores <21 indicating cognitive impairment.

BADS.[36] The BADS will be used as a primary outcome. The BADS is a 25-item scale assessing overall activity level

Table 2 Schedule of assessments

	Timepoint						
			Assessments				
Assessments	Screening	Baseline	3	6	9	24	36
Demographics		X					
9-Item Patient Health Questionnaire (PHQ-9)	X						
Hamilton Psychiatric Rating Scale For Depression (HAM-D)		X	X	X	X	X	X
Structured Clinical Interview for DSM-V (SCID).		X					
Telephone Interview for Cognitive Status-modified (TICS-M)		X					
Behavioural Activation for Depression Scale (BADS).		X	X	X	X	X	X
The WHO Assessment Schedule II (WHODAS-II)		X	X	X	X	X	X
Client Satisfaction Questionnaire (CSQ)					X		

Assessments are collected via REDCap at all timepoints.
REDCap, Research Electronic Data Capture.

based on four factors: activation, avoidance/rumination, work/school impairment and social impairment. Each item ranges from 0 ('not at all') to 6 ('completely'); total scores range from 0 to 150.

WHODAS II.[40] The WHODAS-II will be used as a secondary outcome. The WHODAS-II assesses overall functioning based on six domains: understanding and communicating, getting around, self-care, getting along with others, household and work activities and participation in society. Items assess difficulty level with scores ranging from 1 (none) to 5 (extreme/cannot do) and total ranges of 12–60.

Client Satisfaction Questionnaire (CSQ).[44] Three items (1–4 Likert scale) will be used from the CSQ (range: 3–12) as a secondary outcome, that is, 'Did treatment meet your needs? Are you satisfied with treatment services? Would you use the same treatment again if needed?'

Data analysis plan

Data management

We will use Research Electronic Data Capture (REDCap) for data entry and management. REDCap is a secure, Health Insurance Portability and Accountability Act (HIPAA) compliant web-based application for building and managing online surveys, data collection forms and databases. REDCap provides an interface to enter data and enforces time validation rules (with automated data type and range checks) at time of entry. REDCap provides a data manipulation interface, custom reporting capabilities, audit trail functionality and real-time data monitoring/querying of records. REDCap has multiple data export options to common statistical packages (SPSS v27, SAS v9.4, Stata, R). Data from all centres will be uploaded to the University of Washington's Secure FTP site.

Missing data

We estimated 20% attrition in clients for power analyses. Using intent-to-treat analyses with full information maximum likelihood estimation, all outcome data will be included in the models. We will use the saturated correlates method[45] to improve analytic accuracy and power relative to other missing data methods. We will examine the sensitivity of findings to differential patterns of attrition (mid vs late dropout) using pattern mixture models.[46]

General analysis strategy

To evaluate the effectiveness of DMFB, we will use latent growth curve models within a structural equation modelling framework.[47] This approach will account for the data's hierarchical structure, given the three-level data structure with time-varying measures of activity level and depression (level 1) nested within clients (level 2) nested within providers (level 3). Failing to account for this structure may result in biased estimates.[48] In latent growth curve models, levels 1 and 2 are analysed in a single-level model, where repeated measures are used as latent indicators of intercepts (baseline levels) and slopes (rates of change over time). Providers are included at level 3. We will use intent-to-treat models, where all participants are included in analyses regardless of dropout status. Latent growth models with full information maximum likelihood estimation allow use of partial outcome data on subjects with missing data, producing unbiased estimates when the reason for missingness is related to observed covariates or observed levels of the dependent variable itself (ie, missing at random),[49] potentially ameliorating effects of selection bias due to dropout.

Non-inferiority hypothesis testing

We will assume non-inferiority if the difference between DMFB and BA falls below a non-inferiority margin that separates clinically meaningful from clinically negligible differences. If we reject the null, we will assume that DMFB is no worse than BA. Accordingly, we will use a one-sided test at α=5%, compute a one-sided 95% CI of the post-treatment difference (DMFB–BA) and conclude non-inferiority if the upper bound of this CI is less than the non-inferiority margin. We chose a margin of d>0.2, because lower values are widely considered to be 'very small' effects in psychotherapy studies.[50]

Analysis for primary outcomes

We hypothesise that DMFB is non-inferior to BA in H1: increasing overall activity level (BADS) over 9 weeks and H2: decreasing depression symptoms (Ham-D) over 9 weeks. H1 and H2 will be tested by the effect of intervention condition on the slopes of activity level and depression symptoms, using a one-sided alpha level of 5%. A significant test would be interpreted as DMFB having a differential rate of change over follow-up. Both linear and curvilinear trajectories of change will be considered and determined based on model fit. Although we expect randomisation to prevent bias between treatment arms, we will test for differences between groups on baseline demographic and clinical variables. Baseline variables significantly different between groups will be used as covariates in sensitivity analyses.

Analysis for H3

Building on the latent growth models developed in aim 1, a parallel process latent growth curve model will test whether changes in activity levels are associated with changes in depressive symptoms. This is a multivariate structural equation model where growth processes are measured in tandem, and the growth process for depressive symptoms is regressed on the growth process for activity level. A significant path would indicate that change in activity level is associated with changes in depressive symptoms. To establish temporal precedence of the mechanism changing before the outcome,[51] changes in the mediators (0–2 weeks, 4–5 weeks and 7–8 weeks) are measured before changes in the outcome (3, 6, 9 weeks). If tests of aim 1 reveal that DMFB is inferior to BA, we will further investigate what drives the difference by examining two potential causes: whether differences are driven

by (1) differential changes in activity levels or (2) whether intervention condition interacted with the mediator such that activity levels were more effective in the BA group than the DMFB group (eg, it is possible that clinicians will assist in selecting more reinforcing activities or a wider range of activities).[52] We will begin by testing for a treatment–mediator interaction. If it is non-significant, it will be excluded from the final model and we will apportion the total treatment effect into the indirect effect of treatment acting through changes in activity levels plus the controlled direct effect of the intervention (differences in the treatment effect due to factors other than activity levels). If the treatment-mediator interaction is significant, we will include it in the final model and further apportion the indirect effect across conditions. Indirect effects will be calculated by multiplying changes in activity levels by the effects of activity levels in each condition. Because the distribution of the product term may be non-normal, we will use bias-corrected bootstrapping to allow for the estimation of asymmetric CIs.

Power and sample size

H1 and H2

We used Monte Carlo simulation studies to determine power and sample size.[53] Data were simulated from a two-level structural equation model (repeated measures and growth factors at level 1, provider at level 2). The test statistic was the effect of intervention condition on the slopes of activity level and depression. The model was parameterised such that the slope represented the total amount of change from baseline to 9 weeks. We powered the trial to detect a non-inferiority margin for Cohen's *d* effect size >0.2. We set the ICC to 5%, consistent with meta-analyses that suggest therapist effects explain 5% of the variability in psychotherapy outcomes.[54 55] We set the intercept variance to 0.80 and residual variance of the repeated measures to 0.2, implying a reliability for HAM-D of 0.80, consistent with meta-analysis.[56] Growth factor variances were set to levels typically observed, with the within-cluster slope variance set to 10% of the intercept variance.[56] We also conservatively assumed a 20% attrition rate over the course of the study. We used a Type 1 one-sided error rate of 0.05, and equal numbers of clients within providers and across conditions. To determine sample size, we simulated 2000 data sets each across a range of possible sample sizes. Results indicated that to achieve 80% power, we would need a total sample size of 288 clients, 144 in each condition.

H3

Data were simulated from a parallel process growth curve model.[57] To reduce model complexity (ie, keep the number of model parameters < the number of clusters), we ignored clustering at the provider level, but otherwise kept the sample size fixed at 288 and used the same parameters described for the aim 1 simulations. We varied the size of the effect across simulations to determine the minimum possible effect identifiable with 80% power. We found that we have 81% power to detect effects as small as b=0.4.

Analysis for secondary outcomes

The secondary outcomes of S1 functioning and S2 satisfaction with treatment will be tested with a two-level model, where clients are nested within providers, and the test statistic is the effect of condition on each outcome. We hypothesise S3 that the effect of DMFB versus BA will be moderated by client baseline characteristics, including gender, minority status, diagnostic status (MDD vs subthreshold), depression severity and disability. These will be tested by including demographics as predictors of the slope of depressive symptoms in the two-level latent growth curve model. Multiple testing across all secondary aims will be managed using the Benjamini-Hochberg correction.[58]

Analysis for exploratory aims

(E1) Longer term benefits: Are outcomes of DMFB non-inferior to those of BA at 24 and 36 weeks: BADS, Ham-D, WHODAS-II. E1 will be tested using a piecewise latent growth curve model, with data over treatment coded as the first epoch, and change from the end of treatment through 36 weeks coded as the second epoch. We will use the delta method to obtain model-based point estimates at 24 and 36 weeks. (E2) Delivery cost: we will explore whether delivery is less costly for DMFB than BA. E2 will be tested by t test comparing total number of hours training time, including additional training time due to turnover, plus additional supervision time required above scheduled times. (E3) Preparing for sustainability: we will explore client, provider and centre factors related to intervention fidelity. E3 will be tested using gold-standard expert fidelity assessments in a three-level multilevel model, with assessments (level-1) nested within clients (level-2) nested within providers (level-3). Predictors will be included as fixed effects and multiple testing will be managed with the Benjamini-Hochberg correction with the false discovery rate set to 5%.

Patient and public involvement

None.

Recruitment status and trial dates

We began recruitment for this study in April 2021 and will continue to recruit through March 2025. Data collection is planned to be completed by August 2025, with data analysis and dissemination to be conducted between August 2025 and November of 2025.

ETHICS AND DISSEMINATION

Ethics

This study has been approved by the University of Washington's IRB (STUDY00011434), which serves as the single IRB, with Weill Cornell Medical College and the University of South Florida relying on University of Washington's Institutional Board (UW's IRB). All protocol

modifications and amendments will be submitted to UW's IRB for review and approval prior to updates to the study's ClinicalTrials.gov listing.

Consent

Client, volunteer and clinician participants will all provide informed consent for study procedures through in-person or remote contact with investigators. Consent forms will provide detailed information about the study and its procedures and will assure participants that they may discontinue at any time. Follow-up questions will be asked to ensure that participants have clearly understood the main aspects of the consent form. Correct answers to questions assessing participants' understanding will be necessary to sign the consent form and advance to the baseline assessment. Records of each participant having signed the consent form will be kept in a secure database.

Harms

If participants are determined to be in need of higher levels of psychiatric care than what can be provided by the study and/or express any risk of suicide, study investigators will be responsible for appropriate referrals. Adverse events, including those reported by participants, are routinely reported to the UW IRB. Should any unexpected serious adverse events occur, our study protocol will be modified to prevent other similar events. If this effort fails to prevent additional similar adverse events, the study will be discontinued.

Data safety and monitoring plan

We have convened a Data and Safety Monitoring Board (DSMB) prior to participant recruitment and will engage this external body to provide critical evaluation of our protocol and to provide on-going oversight to ensure participant safety and high-quality research conduct. The DSMB will be comprised of at least three members who can represent expertise in psychology/psychiatry, clinical trial methodology/biostatistics and ethics.

Dissemination

We will deposit participant data into the National Institute of Mental Health (NIMH) informatics infrastructure to enable sharing of clinical research data. We will submit to the NIMH Data Archive and Sage Bionetworks' Synapse Repository Data. Data will be made available as a part of the process of manuscript publication and presentation. Manuscripts will be submitted for publication to high-quality peer-reviewed journals, following the NIH Public Access Policy guidelines. Findings will be presented at public lectures, scientific institutions and relevant national conferences, such as the *American Psychological and Psychiatry Associations, Association for Behavioural and Cognitive Therapy* and *NIH Dissemination and Implementation Conference*.

We will create an advisory council of dissemination experts that will guide us in reviewing: programme roll out; funding and dissemination opportunities for senior centres; feedback from clients, volunteers, centre staff and administrators and study findings and their implications. We will seek feedback from staff and administrators at participating centres about their experience implementing and hosting the intervention throughout the study, including their reactions to our training, supervision and fidelity assessment procedures. We will create a procedural and training manual and materials that will be provided at no cost.

Contributors Each author has contributed significantly to, and is willing to take public responsibility for, one or more aspects of the study. PJR, JAS, AG, MH and DMF participated integrally in the study design. All authors contributed to design of the study protocol, data acquisition and analysis plan. PJR drafted the initial manuscript; all other authors provided critical revisions and approved the final revisions.

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