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

Patrick J Raue,[1] Jo Anne Sirey,[2] Amber Gum,[3] Matt Hawrilenko,[4] Dylan M Fisher [1]

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[1]Department of Psychiatry & Behavioral Sciences, University of Washington School of Medicine, Seattle, Washington State, USA
[2]Department of Psychiatry, Weill Cornell Medical College, New York, New York, USA
[3]Department of Mental Health Law & Policy, University of South Florida, Tampa, Florida, USA
[4]Spring Health, New York, New York, USA

**Correspondence to**
Dr Patrick J Raue; praue@uw.edu

## 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 $\alpha$=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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**ORCID iD**

Dylan M Fisher http://orcid.org/0000-0002-6879-0622

## REFERENCES

1 Mabli J, Gearan E, Choen R. *Evaluation of the effect of the older Americans act title III-C nutrition services program on participants' food security, socialization, and diet quality*. Princeton: Mathematica Policy Research, 2017.
2 Administration on Aging. *FY2015 report to Congress: older Americans act*. Washington, DC, 2016.
3 Pardasani MP. Senior centers: increasing minority participation through diversification. *J Gerontol Soc Work* 2004;43:41–56.
4 Turner KW. Senior citizens centers: what they offer, who participates, and what they gain. *J Gerontol Soc Work* 2004;43:37–47.
5 National Council on Aging (NCOA). Annual report: improving the lives of older Americans 2007.
6 Berman K, Furst L. Addressing the needs of depressed older new Yorkers: a public-private partnership: EASE-D and other interventions. *New York City Department for the Aging* 2014.
7 Raue PJ, Dawson A, Hoeft T, *et al*. Acceptability of a lay-delivered intervention for depression in senior centers. *Aging Ment Health* 2021;25:445–52.
8 Sirey JA, Raue PJ, Solomonov N, *et al*. Community delivery of brief therapy for depressed older adults impacted by Hurricane Sandy. *Transl Behav Med* 2020;10:539–45.
9 Eden J, Maslow K, Le M. *The mental health and substance use workforce for older adults: in whose hands?* Washington, DC: The National Academies Press, 2012.
10 Sirey JA. Engaging to improve engagement. *Psychiatr Serv* 2013;64:205.
11 Gum AM, Hirsch A, Dautovich ND, *et al*. Six-month utilization of psychotherapy by older adults with depressive symptoms. *Community Ment Health J* 2014;50:759–64.

12 Areán PA, Raue P, Mackin RS, *et al*. Problem-solving therapy and supportive therapy in older adults with major depression and executive dysfunction. *Am J Psychiatry* 2010;167:1391–8.
13 Kiosses DN, Leon AC, Areán PA. Psychosocial interventions for late-life major depression: evidence-based treatments, predictors of treatment outcomes, and moderators of treatment effects. *Psychiatr Clin North Am* 2011;34:377–401.
14 Alexopoulos GS, Raue PJ, Banerjee S, *et al*. Comparing the streamlined psychotherapy "Engage" with problem-solving therapy in late-life major depression. A randomized clinical trial. *Mol Psychiatry* 2021;26:5180–9.
15 Witkin M, Marpuri P, Tampi RR. Efficacy of second-generation antidepressants in late-life depression: a meta-analysis of the evidence. In: Tampi RR, Tampi DJ, Young JJ, *et al*, eds. *Essential reviews in geriatric psychiatry*. Cham: Springer International Publishing, 2022: 193–7.
16 Friedrich MJ. Depression is the leading cause of disability around the world. *JAMA* 2017;317:1517.
17 Alexopoulos GS. Depression in the elderly. *Lancet* 2005;365:1961–70.
18 Gallo JJ, Morales KH, Bogner HR, *et al*. Long term effect of depression care management on mortality in older adults: follow-up of cluster randomized clinical trial in primary care. *BMJ* 2013;346:f2570.
19 Jia H, Lubetkin EI. Incremental decreases in quality-adjusted life years (QALY) associated with higher levels of depressive symptoms for U.S. adults aged 65 years and older. *Health Qual Life Outcomes* 2017;15:8.
20 Substance Abuse and Mental Health Services Administration. SAMHSA. *Behavioral health, United States, 2012*. Rockville, MD, 2012.
21 Bartels SJ, Naslund JA. The underside of the silver tsunami--older adults and mental health care. *N Engl J Med* 2013;368:493–6.
22 Raue PJ, Sirey JA, Dawson A, *et al*. Lay-delivered behavioral activation for depressed senior center clients: pilot RCT. *Int J Geriatr Psychiatry* 2019;34:1715–23.
23 Raue PJ, Hawrilenko M, Corey M, *et al*. "Do more, feel better": pilot RCT of lay-delivered behavioral activation for depressed senior center clients. *Behav Ther* 2022;53:458–68.
24 Barnett ML, Gonzalez A, Miranda J, *et al*. Mobilizing community health workers to address mental health disparities for underserved populations: a systematic review. *Adm Policy Ment Health* 2018;45:195–211.
25 Stacciarini J-MR, Rosa A, Ortiz M, *et al*. Promotoras in mental health: a review of English, Spanish, and Portuguese literature. *Fam Community Health* 2012;35:92–102.
26 Weaver A, Lapidos A. Mental health interventions with community health workers in the United States: a systematic review. *J Health Care Poor Underserved* 2018;29:159–80.
27 Cernin PA, Lichtenberg PA. Behavioral treatment for depressed mood: a pleasant events intervention for seniors residing in assisted living. *Clin Gerontol* 2009;32:324–31.
28 Soucy Chartier I, Provencher MD. Behavioural activation for depression: efficacy, effectiveness and dissemination. *J Affect Disord* 2013;145:292–9.
29 Gallagher DE, Thompson LW. Treatment of major depressive disorder in older adult outpatients with brief psychotherapies. *Psychotherapy: Theory, Research & Practice* 1982;19:482–90.
30 Meeks S, Looney SW, Van Haitsma K, *et al*. BE-ACTIV: a staff-assisted behavioral intervention for depression in nursing homes. *Gerontologist* 2008;48:105–14.
31 Snarski M, Scogin F, DiNapoli E, *et al*. The effects of behavioral activation therapy with inpatient geriatric psychiatry patients. *Behav Ther* 2011;42:100–8.
32 Thompson LW, Gallagher D, Breckenridge JS. Comparative effectiveness of psychotherapies for depressed elders. *J Consult Clin Psychol* 1987;55:385–90.
33 MacPhillamy DJ, Lewinsohn PM. Depression as a function of levels of desired and obtained Pleasure. *J Abnorm Psychol* 1974;83:651–7.
34 MacPhillamy DJ, Lewinsohn PM. The pleasant events schedule: studies on reliability, validity, and scale intercorrelation. *J Consult Clin Psychol* 1982;50:363–80.
35 Manos RC, Kanter JW, Busch AM. A critical review of assessment strategies to measure the behavioral activation model of depression. *Clin Psychol Rev* 2010;30:547–61.
36 Raes F, Hoes D, Van Gucht D, *et al*. The Dutch version of the behavioral activation for depression scale (bads): psychometric properties and factor structure. *J Behav Ther Exp Psychiatry* 2010;41:246–50.
37 Lewinsohn PM, Sullivan JM, Grosscup SJ. Changing reinforcing events: an approach to the treatment of depression. *Psychotherapy: Theory Res Pract* 1980;17:322–34.
38 Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;16:606–13.
39 Hamilton M. A rating scale for depression. *J Neurol Neurosurg Psychiatry* 1960;23:56–62.
40 Epping-Jordan JUT. *The WHODAS-II: Leveling the playing field for all disorders*. WHO Mental Health Bulletin, 2000.
41 Brandt J, Spencer M, Folstein M. The telephone interview for cognitive status. *Neuropsychiatry Neuropsychol Behav Neurol* 1988;1:111–7.
42 Lejuez CW, Hopko DR, Acierno R, *et al*. Ten year revision of the brief behavioral activation treatment for depression: revised treatment manual. *Behav Modif* 2011;35:111–61.
43 First MB, Williams SR, *et al*. *Structured clinical interview for DSM-IV - patient version (SCID-P)*. Washington, DC: American Psychiatric Press, 1995.
44 Larsen DL, Attkisson CC, Hargreaves WA, *et al*. Assessment of client/patient satisfaction: development of a general scale. *Eval Program Plann* 1979;2:197–207.
45 Graham JW. Adding missing-data-relevant variables to FIML-based structural equation models. *Structural Equation Modeling: A Multidisciplinary J* 2003;10:80–100.
46 Hedeker D, Gibbons RD. Application of random-effects pattern-mixture models for missing data in longitudinal studies. *Psychol Methods* 1997;2:64–78.
47 Bollen K, Curran PJ. *Latent curve models: a structural equation perspective*. John Wiley & Sons, 2006.
48 Bryk AS, Raudenbush SW. *Hierarchical linear models : applications and data analysis methods*. 2nd edn. Thousand Oaks: Sage Publications, 2002.
49 Laird NM. Missing data in longitudinal studies. *Stat Med* 1988;7:305–15.
50 Cohen J. A power primer. *Psychol Bull* 1992;112:155.
51 Kraemer HC, Wilson GT, Fairburn CG, *et al*. Mediators and moderators of treatment effects in randomized clinical trials. *Arch Gen Psychiatry* 2002;59:877–83.
52 Valeri L, Vanderweele TJ. Mediation analysis allowing for exposure-mediator interactions and causal interpretation: theoretical assumptions and implementation with SAS and SPSS macros. *Psychol Methods* 2013;18:137–50.
53 Muthén LK, Muthén BO. How to use a Monte Carlo study to decide on sample size and determine power. *Structural Equation Modeling: A Multidisciplinary J* 2002;9:599–620.
54 Wampold BE, Brown GSJ. Estimating variability in outcomes attributable to therapists: a naturalistic study of outcomes in managed care. *J Consult Clin Psychol* 2005;73:914–23.
55 Kim D-M, Wampold BE, Bolt DM. Therapist effects in psychotherapy: a random-effects modeling of the National Institute of mental health treatment of depression Collaborative research program data. *Psychotherapy Res* 2006;16:161–72.
56 Trajković G, Starčević V, Latas M, *et al*. Reliability of the Hamilton rating scale for depression: a meta-analysis over a period of 49 years. *Psychiatry Res* 2011;189:1–9.
57 Cheong J, Mackinnon DP, Khoo ST. Investigation of mediational processes using parallel process latent growth curve modeling. *Struct Equ Modeling* 2003;10:5:238–62.
58 Benjamini Y, Hochberg Y. Controlling the false discovery rate: a practical and powerful approach to multiple testing. *J Royal Stat Soc: Series B* 1995;57:289–300.

**CONSENT TEMPLATE**
**Client Participants**
**Lay-delivered Behavioral Activation in Senior Centers**

**Researcher**

| | | | |
|---|---|---|---|
| [INSERT SITE PI NAME] | [INSERT SITE PI INFO] | [INSERT SITE PI DEPARTMENT] | [INSERT SITE PI PHONE NUMBER] |

**FOR ALL APPOINTMENT RELATED QUESTIONS (SCHEDULING, ETC) PLEASE CALL [*INSERT SITE SPECIFIC CONTACT INFORMATION*].**

**KEY INFORMATION ABOUT THIS STUDY**

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

You are being asked to take part in this study because you are 60 years or older and are experiencing symptoms of depression.

The purpose of this study is to compare 2 forms of interventions for senior center clients over 60 experiencing symptoms of depression. Some participants enrolled in the study will receive 9 weeks of a type of psychotherapy called "Behavioral Activation" as delivered by a Master's level mental health clinician. Other participants will receive 9 weeks of a program called "Do More, Feel Better" as delivered by a trained non-professional volunteer. If you are eligible and agree to be in the study, you will be assigned randomly (like the flip of a coin) to the intervention delivered by either a Master's level mental health clinician or a trained volunteer. "Behavioral Activation" is a psychotherapy aimed at re-engaging participants in activities they once found rewarding and enjoyed but have abandoned after they developed depression. "Do More, Feel Better" is a program also aimed at re-engaging participants in activities they once found rewarding and enjoyed but have abandoned after they developed depression.

You will participate in follow-up interview assessments via phone or video teleconferencing at weeks 3, 6, 9, 24 and 36 where we will ask you similar questions as the baseline assessment. These interviews will take approximately 1 hour. With your permission, we may also access data recorded by your senior center regarding the activities you participate in. Your total time commitment for the study, including "Behavioral Activation" or the "Do More, Feel Better" program sessions is approximately 14 hours over the course of 36 weeks. This study is funded by the National Institute for Mental Health.

**How many people will take part in this study?**
About 288 participants will take part in this part of the study.

**What will happen if I take part in this research study?**
If you agree, the following procedures will occur:

- First, you will participate in the baseline assessment which consists of two appointments to find out if you can participate in the main part of the study. During the baseline assessment we will ask you questions about your mood, health, quality of life, and cognition. Both baseline appointments will take 1 hour and 15 minutes. These will be completed by telephone or video teleconferencing (e.g., Skype, Zoom, Facetime) due to the COVID-19 pandemic. If COVID-19 restrictions lift, this assessment may be completed in person.
- If the baseline assessment interview shows that you can participate in the main part of the study and you choose to continue, the following will happen next:
    - You will begin 9 weeks of "Behavioral Activation" psychotherapy as delivered by a Master's level mental health clinician, or 9 weeks of the "Do More, Feel Better" program as delivered by a trained non-professional volunteer. You will be assigned to "Behavioral Activation" or the "Do More, Feel Better" program randomly (like the flip of a coin). You will meet weekly with a Master's level mental health clinician or trained volunteer for 30-45 minutes over the course of 9 weeks. These sessions will be completed by telephone or video teleconferencing (e.g. Skype, Zoom, Facetime) due to the COVID-19 pandemic. If COVID-19 restrictions lift, these sessions may be completed in person. If you agree, these sessions will be audio recorded for clinician and volunteer supervision. The audio recordings will be destroyed at the end of all relevant record retention requirements unless you consent to use of audio recording for future training purposes in which case we will retain the audio in our database on the secure server.

**Please agree or disagree with the following statements:** I give permission to audiotape assessments and sessions with study clinician or coach for training and supervision purposes. Study staff certified as trainers of "Behavioral Activation" or the "Do More, Feel Better" program will review some of the client sessions to ensure adherence and to provide feedback to the mental health clinician or volunteer.
____ Agree ____ Disagree

You give permission for the research team to use audio from a session with the study clinician or coach in future trainings as part of the research study. You may decline to give this permission and remain in the study.
____ Agree ____ Disagree

You give permission to the research team to audio record your meetings with the study clinician and assessors so they can be stored by the DMFB Study for future research purposes. You may decline to give this permission and remain in the study.
____ Agree ____ Disagree

- You will participate in follow-up interview assessments via phone or video teleconferencing at weeks 3, 6, 9, 24 and 36 where we will ask you similar questions as the baseline assessment. These interviews will take approximately 1 hour. With your permission, we may also access data recorded by your senior center regarding the activities you participate in. Your total time commitment for the study, including "Behavioral Activation" or the "Do More, Feel Better" program sessions are outlined below.

| Week | Study Event | Time Commitment | Compensation |
|---|---|---|---|
| 0 | Baseline Assessment 1 | 1 hour and 15 minutes | $15 |
| 0 | Baseline Assessment 2 | 1 hour and 15 minutes | $15 |
| 1 | Behavioral Activation/Do More, Feel Better Session 1 | 30 – 45 minutes | |
| 2 | Behavioral Activation/Do More, Feel Better Session 2 | 30 – 45 minutes | |
| 3 | Behavioral Activation/Do More, Feel Better Session 3 | 30 – 45 Minutes | |
| | Week 3 Assessment | 60 minutes | $20 |
| 4 | Behavioral Activation/Do More, Feel Better Session 4 | 30 – 45 minutes | |
| 5 | Behavioral Activation/Do More, Feel Better Session 5 | 30 – 45 minutes | |
| 6 | Behavioral Activation/Do More, Feel Better Session 6 | 30 – 45 minutes | |
| | Week 6 Assessment | 60 minutes | $20 |
| 7 | Behavioral Activation/Do More, Feel Better Session 7 | 30 – 45 minutes | |
| 8 | Behavioral Activation/Do More, Feel Better Session 8 | 30 – 45 minutes | |
| 9 | Behavioral Activation/Do More, Feel Better Session 9 | 30 – 45 minutes | |
| | Week 9 Assessment | 60 minutes | $20 |
| 24 | Week 24 Assessment | 60 minutes | $20 |
| 36 | Week 36 Assessment | 60 minutes | $20 |
| | ***Total:*** | Approx. 14 hours | $130 |

**Study Location**

All procedures will be completed via phone or video teleconferencing due to COVID-19 related restrictions. Should COVID-19 related restrictions lift, study appointments may be completed in-person.

**How long will I be in the study?**
Participation in the study will take approximately 14 hours over the course of 36 weeks.

**Can I stop being in the study?**
Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, or if the study is stopped. If you do not wish to continue with the study, the researcher will provide you with referrals for alternative treatments and will follow up to address any issues you may experience that arise as a result of withdrawing from the study.

**What side effects or risks can I expect from being in the study?**

- The assessment interviews may result in fatigue; however you are free to take breaks during these interviews and spread them out over the course of two visits if you choose.
- Some of the questions asked during the interviews might make you feel uncomfortable; however you may choose to decline to answer any question at any time and still continue with the study.
- There is the possibility that we may discover findings that affect your health over the course of the study, such as untreated medical conditions, thoughts of self-harm, manic or psychotic symptoms, or drug or alcohol abuse. We will inform you of the nature of these findings and encourage you to follow through on referrals we provide to contact your primary care physician or local medical or psychiatric services.
- There is a slight risk of loss of confidentiality. A breach of confidentiality may result in psychological or social harm (embarrassment, guilt, stress). To ensure participant confidentiality, the information about you will be numbered and linked to your name only on a master list that is password protected and will be kept until the end of all relevant record retention requirements. We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings. Study records are kept in a locked room in a locked cabinet or in a secure, password protected data system.

**Are there benefits to taking part in the study?**
You may experience a decrease in your depressive symptoms. In addition, the information that you provide may help health and social service professionals better understand how to treat older adults with depression.

**What other choices do I have if I do not take part in this study?**
You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do. In addition, you may seek therapy outside of this program.

**Will information about me be kept private?**
We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required

by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

**Please agree or disagree with the following statement:** In case of emergencies, I allow study staff to share and receive my relevant personal medical information (e.g., history of hospitalization or medical status in case of emergency) with the senior center I was referred by. This is completely voluntary. You may continue to participate in the study whether you agree with this information sharing or not.
____ Agree ____ Disagree

All identifying information collected as part of the study will be stored in a database on a secure server and will be password protected with limited access by the study team. Access will be limited to the research staff. No personally identifying information will be attached to study data or audio recordings. Study data and audio recordings will be labeled with a unique study identification number. The link between the personal identifiers and the related study data will be kept until the end of the study. At that time, the link to personal identifiers will be destroyed. Audio recordings will be in an electronic format and will be deleted at the end of all relevant record retention requirements unless you consent to use of audio recording for future training purposes in which case we will retain the audio in our database on the secure server.

The information and/or data that we obtain from you for this study might be used for future research. If we do so, that information and data may then be used for future research studies or given to another investigator without getting additional permissions from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, an independent review board will decide whether or not we need to get additional permissions from you.

We have a Certificate of Confidentiality from the federal National Institute of Mental Health. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;

- local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIH funding for this study ends. Currently this is November 30, 2025. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

**National Institute of Mental Health Data Archive**

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying depression to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed. We will collect information from you to create a unique ID code that cannot be linked to your identity. This information includes your legal name at birth, your date of birth, gender and city where you were born. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about depression more quickly than before.

During and after the study, the researchers will send deidentified information about your health and behavior to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults depression so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://data-archive.nimh.gov.

Please agree or disagree with the following statement: I wish to share my information using NDA.

☐ **I wish to share my information using NDA** .

☐ **I do not want to share my information using NDA** .

**What are the costs of taking part in the study?**
You will not be charged for any of the study treatments or procedures.

**Will I be paid for taking part in the study?**
You will receive $15 for completing the Baseline 1 Assessment and $15 for completing the Baseline 2 Assessment. You will receive $20 for completing assessments at weeks 3, 6, 9, 24, and 36. This results in a total for $130 if you complete all study assessment interviews. Study staff will discuss payment options, which may include check or gift codes, with you at the start of the study.

**What are my rights if I take part in this study?**
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

**Who can answer my questions about the study?**
You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact the study team at [*insert local study team contact info]*. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

If you think you have a medical problem or illness related to this research, contact [*insert site PI name]*, the study's principal investigator at [*insert site PI contact information]*. They will refer you for treatment.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the University of Washington Human Subjects Division at 206-543-0098.

**Future Contact**
Please agree or disagree with the following statement: I allow staff from the [*insert local site information*] to contact you in the future to ask if you may be interested in participating in future research studies.
___ Agreed ____Declined

**Consent**
Please agree or disagree with the following statement: This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this form. If I have questions about my rights as a research subject, I can call the Human Subjects Division listed on this form.
___ Agreed ___ Declined