Published in final edited form as:

Am J Geriatr Psychiatry. 2016 January ; 24(1): 94–102. doi:10.1016/j.jagp.2015.11.003.

Design and Recruitment for a Randomized Controlled Trial of Problem Solving Therapy to Prevent Depression among Older Adults with Need for Supportive Services

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Abstract

Background—Addressing subthreshold depression (indicated prevention) as well as vulnerabilities that increase the risk of major depression or anxiety disorders (selective prevention) is important for protecting mental health in old age. The Depression-Agency Based Collaborative is a prevention trial involving older adults recruited from aging services sites (home care agencies, senior housing senior centers) who meet criteria for subthreshold depression and disability.

Objective—To examine (i) the effectiveness of partnerships with aging services sites for recruiting at-risk older adults, (ii) the quality of recruitment and acceptability of the Dep-ABC assessment and intervention, and (iii) the baseline status of participants.

Methods—Dep-ABC is a single-blind randomized controlled prevention trial set in aging services settings but with centralized screening, randomization, in-home assessments, and follow-up. Its intervention arm involves 6–8 sessions of problem-solving therapy, in which older adults aged 60+ learn to break down problems that affect wellbeing and develop strategies to address them. We examined participation rates to assess quality of recruitment across sites and level of disability according to service use.

Results—Dep-ABC randomized 104 participants, 68.4% of eligible older adults. Screening using self-reported disability successfully netted a sample in which 74% received home care agency services, with remaining participants similarly impaired in structured self-reports of impairment and on observed performance tests.

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Conflicts of Interest: No conflicts to disclose.

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Conclusions—Direct outreach to aging services providers is an effective way to identify older adults with service needs at high risk of major depression. Problem solving therapy is acceptable to this population and can be added to current services.

Keywords

Depression; prevention; older adults; problem-solving therapy; disability; caregiving

INTRODUCTION

Depressive and anxiety episodes in older adults are prevalent and disabling (1), increase mortality risk (2), and raise the risk for disability and impaired quality of life (3). Subthreshold mild symptom states increase the risk of major depression and generalized anxiety disorders (4). To prevent syndromal disease, evidence is growing for the value of “upstream” efforts designed to target risk factors, such as disability (“selective” prevention), and subthreshold (subsyndromal) mental health symptoms (“indicated” prevention) (1). One review found that mild or subthreshold states may be more reversible than advanced clinical states, and may also be associated with neurobiological changes at an earlier, more modifiable stage of development (4). Though they involve more extensive screening, prevention interventions may still be cost effective relative to treatment of frank disease (5).

Disability in personal self-maintenance tasks (or the activities of daily living [ADL], including bathing, dressing, transfer from bed or chair, and using the toilet) is common in older adults, with recent surveys suggesting a prevalence of 26.3% in community-resident older adults aged 65 or older (6). About two thirds of older adults with disability receive personal assistance or use medical equipment (6). Depressive symptoms are common in these older adults. In seniors receiving home-delivered meals, for example, 12% reported clinically significant depression (PHQ9 > 9) (7). In seniors receiving home health nursing, 13.5% met criteria for major depression (8). The 1-year incidence of major depression in homebound elders was 3%, and the 1-year incidence for minor depression 7% (9).

Risk of depressive and anxiety symptoms in older adults is strongly related to severity of disability and need for assistance. For example, in the Women’s Health and Aging Study (WHAS-I), the proportion with depressed mood (as assessed by Geriatric Depression Scale [GDS] scores > 13) was 13.1% in women with “moderate disability” (limitations in upper extremity, lower extremity, or instrumental activities of daily living but no difficulty with ADL), 16.4% in women with ADL difficulty who were able to manage without personal assistance, and 29.3% in women with ADL difficulty who received personal assistance (10). High levels of anxiety (“felt extremely nervous or shaky inside” during the past week on the Hopkins Symptom Checklist) followed a similar pattern.

A number of randomized trials have shown the effectiveness of problem-solving therapy in reducing depressive symptoms among older adults in the setting of chronic health conditions (kidney failure [11], cardiovascular disease [12]); across different intervention modalities, including in-person, telephone, and telehealth delivery (13–14); as part of broader mental health interventions (as in PEARLS, the Program to Encourage Active Rewarding Lives for Seniors [15] and Healthy IDEAS, Identifying depression, Empowering Activities for Seniors

[16]); and tailored for particular vulnerable populations, such as financially-strained, older African-Americans (17). A review of PST in treatment trials of major depression found strong effects (mean effect size, 0.83) (18). However, findings for depression prevention trials are still emerging and are difficult to summarize because of differences in study populations (e.g., variation in definitions of subthreshold depression), endpoints, and intervention components.

For these reasons, we developed the Depression Agency-Based Collaborative (Dep-ABC), a randomized controlled prevention trial of problem-solving therapy (PST) for community-resident older adults with ADL disabilities requiring home care. The design of Dep-ABC builds on prior RCTs assessing problem-solving therapy in older adults for the prevention of depression and anxiety. Cuijpers et al. have shown that the 12-month incidence of major depression or anxiety disorders in participants with subsyndromal depression (CES-D score 16 but not meeting DSM-IV criteria for anxiety or depression over the prior 12 months) was 11.6% in patients receiving PST compared to 23.8% in a usual care control (19). An indicated prevention trial involving patients with neovascular age-related macular degeneration (AMD), a group at high risk of depression because of disability and complex medical care needs, showed that the incidence of major or minor depression was 11.6% in the PST group and 23.2% in usual care over 2 months of follow-up (20).

Pilot to Inform Design of Dep-ABC

In an earlier pilot, we sought to determine if aging services providers in the community could successfully screen older adults for depressive symptoms and, with guidance from the research team, deliver problem-solving therapy. Social workers in three care management agencies screened older adults receiving home care services with the two-item Patient Health Questionnaire (PHQ-2), and a psychiatric social worker at one of the agencies followed up screen positives by telephone with the PHQ-9. Participants with subthreshold disease, defined as PHQ-9 scores of 1–9, were referred to our team for problem-solving therapy, while people with scores greater than 9 were referred to physicians for evaluation and treatment.

Results from the pilot were mixed. Over 12 months, agencies were able to screen 78% of their caseloads. However, the agency psychiatric social worker was only able to screen a third of PHQ-2 screen positives. Of the 92 with PHQ-9 scores between 1–9, only 28 accepted a session of problem-solving therapy.

The pilot suggested that full integration of screening and delivery of problem-solving therapy in aging services providers was likely premature. Even highly motivated agencies were unable to screen their caseloads fully. Hand-offs between agencies for more intensive screening, and from agencies to the research team for delivery of the intervention, were challenging. We decided to rethink delivery of depression prevention in this setting and broadened recruitment to cover a variety of aging services providers (home care agencies, senior housing, senior centers). We also developed a more expanded model of collaboration with aging services providers. “Agency collaboration” in this research was not simply partnerships for recruitment. When we recruited home care consumers outside agency settings, we worked with their agencies and updated care managers about the onset of new

disability or cognitive decline identified in the course of follow-up. Likewise, for participants with disability who were not receiving agency care, we made referrals to agency care when interventionists noticed safety issues or other problems. Finally, we met regularly with a community advisory board of aging services providers.

Objectives of Current Study

The current report had three main objectives: (i) to examine the effectiveness of partnerships with aging services sites for recruiting older adults; (ii) to determine the quality of recruitment given study inclusion-exclusion criteria as well as acceptability of the interview schedule and intervention; and (iii) to examine sociodemographic, medical, psychiatric, functional, and cognitive status in this group of older adults with subthreshold depression and disability.

METHODS

Overall Study Design

Dep-ABC is a single-blinded randomized controlled trial conducted within the Advanced Center for Intervention and Services Research (ACISR) for Late-Life Depression Prevention at the University of Pittsburgh. The trial was registered at ClinicalTrials.gov (NCT156638). The University of Pittsburgh Institutional Review Board and an external data safety monitoring board reviewed all procedures and protocols. All participants provided signed informed consent. Recruitment began in May 2012. Follow-up will be completed in December 2015.

Older adults were screened for disability in an initial contact and then completed structured self-reports of impairment and an observed performance test of mobility disability. In screening for disability, we required that participants report “some,” “a lot,” or “complete inability” in at least one of the following tasks: “taking care of your home,” “taking care of household business and finances,” “taking care of your health,” “taking care of personal care needs,” “preparing meals,” and “taking care of local errands.” This approach drew upon current assessments of eligibility for home care services used in the PA Department of Aging Level of Care Determination tool.

Potential participants were screened using the Patient Health Questionnaire (PHQ-9) to exclude people with very low likelihood of depression (PHQ 0) and identify seniors with subthreshold symptoms (PHQ 1–9, with cardinal symptom of anhedonia or dysphoria). (A small number of participants had scores higher than 9 but did not meet criteria for major depressive disorder on more extensive clinical assessment.) The research team referred people with PHQ scores greater than 9 who met criteria for depression for treatment. Eligible older adults were followed over 14 months for incident depression (major or minor) and anxiety disorders (as defined by MINI/DSM-IV, PHQ-9, and GAD-7), administered by researchers who were not associated with the intervention.

Participants were randomly assigned to problem-solving therapy or enhanced usual care. The usual care control arm was considered “enhanced” because participants who reported new medical symptoms were referred for medical care, as in the intervention arm. An

important component of the study was our contact with aging services providers if respondents reported new unmet needs during the course of the study (or were discovered in our evaluation to need greater levels of service because of cognitive decline or medical morbidity) and agreed to such contact.

The primary outcome of the trial is time to onset of incident depression or anxiety disorder. The secondary outcome is change in depression and anxiety symptoms. To allow assessment of changes in symptomatology, participants were followed for a total of 14 months even if study endpoints were met.

Subjects

Inclusion criteria for the trial required participants to be aged 60+; meet criteria for mild depressive symptoms, as defined earlier; score above 80 on the Modified 3MS cognitive screen; and reporting disability consistent with need for aging services, which was later confirmed by reports of service use (Cornell Services Index-Primary Care) or physical disability (RAND-12 Physical Health Composite, Short Physical Performance Battery) in baseline assessments. Exclusion criteria involved current use of an antidepressant or regular use of anxiolytics (> 4/wk); major depressive episode or anxiety disorder in the past 12 months; history of CNS disease, bipolar disorder, or schizophrenia; or drug or alcohol treatment in the past 12 months.

Based on advice from our community advisory board, Dep-ABC was advertised as “a research study looking at ways to reduce stress.” Recruitment sites for the study included four large care management agencies, 21 senior housing apartment buildings, six senior centers, and 11 senior health fairs conducted at these senior centers. Clients of care management agencies received mailings or flyers. For all other sites we made presentations during resident meetings or activities, or set up a table at health fairs, after working with tenant councils and building and center managers. Research staff conducted telephone screening after potential respondents gave contact info or called in response to flyers.

Intervention

Problem-Solving Therapy—Participants were randomized using a 1:1 allocation to problem-solving therapy (PST) or enhanced usual care. The intervention arm received 6–8 sessions of PST, each session lasting 40–50 min. In the first four sessions participants identified problems and learned ways to break them down to manageable components and generate strategies to address them. Later sessions allowed participants to consolidate problem-solving skills. While not required, we encouraged therapists to explore sleep disturbance as a potential problem and introduced a course of Brief Behavioral Therapy for Insomnia (BBTI), if appropriate (21). Therapists completed a log of participant-generated problems and strategies after each session, along with a rating of participant engagement in therapy. Problems identified by participants could be interpersonal issues but also practical problems related to service needs, such as adequacy of services, need for home modification, and responsiveness of service providers.

Enhanced Usual Care—Participants randomized to usual care did not receive PST but were followed on the same assessment schedule. In the usual care control arm participants who met criteria for depression or anxiety disorders over follow-up, or who reported new medical symptoms, were referred for medical care, as in the intervention arm.

Training of Interventionists—Therapists had greater than 10 years experience in mental health. A PST master trainer supervised therapists, who conducted nearly all assessments in participants' homes, and also reviewed audiotapes of sessions to assess fidelity to training and suggest therapeutic strategies over the course of contact with participants.

Schedule of Assessments, Endpoints, and Boosters

The primary outcome of the trial is time to onset of major depression or anxiety disorder as well as changes in the course of symptoms over follow-up. Major depression or anxiety disorder are diagnosed by PHQ-9 score greater than 9 or GAD-7 score greater than 9, respectively, and meeting PRIME-MD/MINI criteria for syndromal depression or generalized anxiety disorder. Participants meeting diagnoses are referred for treatment but continue research follow-up.

Independent evaluators assess subjects by phone or in person. Participants in both arms are assessed at baseline, directly after the intervention period (12 weeks after baseline), and then at 3, 6, 9, and 12 months. Assessors blind to study assignment administer a 2-hour battery of tests and self-report assessments. Measures are shown in Table 1. Based on work by Rovner (20), participants in the treatment arm receive booster sessions at 6 and 9 months following the end of the prevention intervention.

Acceptability of the intervention was assessed in an open-ended post-intervention survey.

Data Safety and Monitoring

After the initial evaluation and prior to randomization, the subject's clinical history was reviewed at a clinical case consensus conference. Using the Suicide Ideation Scale and clinical interview, the study team determined risk for suicide and access to firearms. If subjects met study endpoints while receiving PST, they were removed from the active prevention intervention but were still followed and referred for treatment. Data were reviewed for missing values on a weekly basis. Safety measures included use of a 24/7 answering service for clinical emergencies and oversight from an external data and safety monitoring board (DSMB) comprised of a geriatrician, geropsychologist, geriatric psychiatrist, community leader, and biostatistician.

Outcomes, Planned Analyses, and Power

Key analyses for Dep-ABC will use survival models to assess time to onset of DSM-IV defined major depression and anxiety episodes, as well as generalized mixed models to assess the effect of the PST intervention over time on depression and anxiety symptoms as well as potential moderators and mediators. The trial is exploratory but powered to assess differences in the onset of major depression or anxiety disorders consistent with effects established by Cuijpers et al. (11.6% with PST vs. 23.8% in usual care over 12 months) (19).

Results

Recruitment ended in October 2014 with 112 providing informed consent and 104 randomized (Figure 1). The 8 participants who signed consent but were not randomized included 3 who withdrew consent, 2 who were unable to withdraw from current antidepressant medication, and 3 who were subsequently discovered to have major depression or generalized anxiety in the prior 12 months. Dep-ABC stopped recruitment at 77% of its projected randomized sample of 135 because of budgetary constraints and to allow complete follow-up for participants.

Effectiveness of Partnerships with Aging Services Sites for Recruiting At-Risk Older Adults

Recruitment of participants who met eligibility requirements and were successfully randomized varied by site. The most productive recruitment occurred after staff presentations in senior housing (41 of 196 screened were randomized, or 20.9%) and senior centers (9 of 59 screened were randomized, or 15.2%). The yield from direct recruiting through partnerships with care management agencies was slightly lower (25 randomized out of 192 screened, or 13%), suggesting that senior housing and senior centers may be as efficient for recruiting older people with subthreshold depression and disability as care management agencies.

Quality of Recruitment

As the CONSORT diagram (Figure 1) shows, 595 potential participants were screened. Of these, 430 (72.3%) did not meet eligibility criteria at screening. 53 who met inclusion-exclusion criteria declined to participate. All told, 67.9% (112/(112+53)) of potentially eligible participants signed consent.

Acceptability of Intervention

Participants in the PST arm of Dep-ABC were invited by mail or telephone (by someone other than the interventionist) to complete a satisfaction questionnaire at the conclusion of the study. Over three-quarters of eligible participants completed the survey. All were satisfied or very satisfied with appointments and the competency of therapists. One comment will speak for many: "Would like more frequent appointments. Very helpful in learning coping techniques and problem solving solutions to everyday problems. Taught me how to solve problems and gave me more confidence."

Characteristics upon Study Entry

Randomization in Dep-ABC resulted in 52 participants in each study arm. Participants in the two arms did not significantly differ in sociodemographic, medical, psychiatric, functional, or cognitive status (Table 2).

The mean age (SD) of Dep-ABC participants was 76.9 (9.3). 79.8% were women and 24.0% African-American. Participants completed a mean (SD) of 13.2 (2.6) years of school.

Consistent with the goal of recruiting participants with subthreshold depression or anxiety, the mean (SD) PHQ-9 score was 5.6 (2.3) and GAD-7 3.1 (2.7). Seven of 104 participants had PHQ-9 scores greater than 9 but did not meet criteria for major depressive disorder. The mean (SD) normalized mental health score for the RAND-12 was 43.9 (7.4), where the reference value for adults is 50.

Seventy-four percent of the sample received at least one in-home or community-based service: 54.8% transportation services, 39.4% home attendant services, 19.2% home-delivered meals, 9.6% home nursing, 9.6% occupational or physical therapy, and 1.9% short-term subacute rehabilitation (Table 3). Of the six services tracked, participants at baseline received a maximum of three. The 27 participants not reporting any service were as likely to be physically impaired as those receiving services. For example, the mean (SD) RAND-12 physical composite score was 33.0 (7.3) in people not receiving services and 33.6 (8.1) in people receiving one service. Thus, recruitment yielded a sample with high levels of impairment and service use overall, with physical impairment pronounced even among people not receiving services.

On average, the sample was nearly two standard deviations below population means for people of comparable ages in self-reported physical function. Mean (SD) RAND-12 scores were 31.7 (7.8) among participants, where the reference value for adults is 50. Individual items in the RAND-12 composite show that participants reported substantial levels of mobility limitation (60.2%), restrictions in activity (71.8%), fair-poor self-rated health (44.7%), and pain (59.2%).

Other measures are consistent with these high levels of impairment and service need. The mean (SD) number of affected systems noted in the Cumulative Illness Rating Scale (CIRS-G) was 6.6 (2.2). The most common chronic conditions were hypertension (85.6%), musculoskeletal problems (84.6%), ENT conditions (79.8%), endocrine-metabolic disorders (73.1%), respiratory conditions (65.4%), and genitourinary disorders (66.7%). The mean (SD) on the Short Physical Performance Battery (SPPB) for lower extremity strength was 5.2 (4.3), suggesting impaired mobility for most participants. Fifteen percent of the sample was unable to complete the 4-meter walk, and only 5.7% of the sample had a gait speed of 1 m/sec or faster. Gait speeds less than 1 m/sec have been associated with increased risk of mortality, hospitalization, nursing home admission, and functional decline (22–24).

Cognitive performance in the sample was on average lower than age- and education-scaled norms. Mean (SD) performance on the DKEFS Trail Making Test was 7.0 (3.9) for set shifting, about 1 SD below the norm. Scores on the RBANS visuospatial index were 1 SD below average (85.1, SD 16.8, where the age- and education-adjusted norm is 100, SD 15). Other RBANS indices ranged from 92–97.

Discussion

The current report had three main objectives. Our first objective was to examine the effectiveness of partnerships with aging services sites. Housing and senior centers may be as efficient for recruiting and successfully randomizing older people with subthreshold

depression and need for services as aging services providers (15–21% of all screened vs. 13%). This was surprising in that aging services providers serve a disabled older population at risk for depression.

A second goal was to determine the quality of recruitment, given study inclusion/exclusion criteria, and acceptability of the interview schedule and intervention. Targeting a variety of sites that provide aging services proved effective. We were able to screen 595, determine that 165 were eligible, and successfully consent 112 and randomize 104. Satisfaction with the intervention, based on exit questionnaires, was high.

Our third goal was to determine how well we met the goal of recruiting older adults with subthreshold depression who experienced disability consistent with the need for home care services. About three-quarters of participants received at least one in-home or community-based service, with some receiving up to three services. Notably, participants not reporting service use were as physically impaired as those receiving services. Thus, a subset of participants were not receiving services but had comparable levels of impairment, which may indicate unmet need. In subsequent analyses, it will be valuable to determine if the group receiving services differs in outcomes from the group not receiving services.

Recruitment using this approach was successful as well in enrolling a diverse sample (24% African-American in a community where only 11% of people aged 60+ are African-American) (25).

We conclude that direct outreach to senior housing sites and senior centers, in addition to care management social service agencies, is an effective way to identify vulnerable older adults at high risk of major depression and anxiety. As we complete follow-up for Dep-ABC, we will be able to determine if PST delivered in the community can prevent episodes of depression and anxiety among vulnerable older adults. Pending results of Dep-ABC, an implementation trial will be required to assess the feasibility of adding problem solving therapy to the set of services currently provided by aging services partners.

Acknowledgments

Funding: Supported in part by P30 MH090333, CTSI UL1RR024153 and UL1TR000005.

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Figure 1.
CONSORT, Dep-ABC

Table 1

Depression Agency-Based Collaboration: Assessments

<u>Domain</u>	<u>Measure</u>
Depression	Patient Health Questionnaire-9 (PHQ-9) MINI/Prime-MD
Anxiety	Generalized Anxiety Disorder-7 (GAD-7)
Medical burden/Medication Check List	Cumulative Illness Rating Scale (CIRS-G)
Impairment	Health-related quality of life (RAND12) Late-Life Functional Disability Inventory (LL-FDI)
Functional status, physical performance	Short Physical Performance Battery (SPPB)
Insomnia	Pittsburgh Sleep Quality Index (PSQI)
Pain	Numeric Rating Scale for Pain (NRS-20)
Cognitive Status	Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) Delis-Kaplan Executive Function System (DKEFS) Modified Mini-Mental Status (3MS)
Social Isolation/Support	Interpersonal Support Evaluation List (ISEL)
Caregiving Burden	Zarit Burden Index (ZBI)
Personal Mastery and Self-Efficacy	Pearlin Sense of Mastery Scale (PSE)
Problem Solving Skills	Problem Solving Skills Inventory (PSSI)
Health Services Utilization	Cornell Services Index-Primary Care
Biosignatures	Inflammatory Cytokines (IL6, TNF alpha) + mRNA Transcription (blood draw)

Table 2

Features of Depression-ABC Cohort, Baseline (n=104)

Age, yr (SD)	76.9 (9.3)
Female, %	79.8
Nonwhite, %	24.9
Education, yr (SD)	13.2 (2.6)
Body Mass Index (BMI)	31.65 (2.4)
Cumulative Illness Rating Scale: Total, range = 0–52, higher = worse (SD)	11.1 (4.1)
Cumulative Illness Rating Scale: Count, range = 0–13, higher = worse (SD)	6.6 (2.2)
RAND-12 Mental Health Component, T score [norm=50, SD =10] (SD)	43.9 (7.4)
RAND-12 Physical Health Component, T score [norm=50, SD =10] (SD)	31.7 (7.8)
Short Physical Performance Battery, range 0–12; higher = better (SD)	5.2 (4.3)
Patient Health Questionnaire (PHQ-9), range 0–27, higher = worse (SD)	5.6 (2.3)
Generalized Anxiety Questionnaire (GAD-7), range 0–21, higher = worse (SD)	3.1 (2.7)
Interpersonal Support Evaluation List – modified 12 item, range 0–48; higher = better (SD)	36.1 (6.5)
DKEFS Trail Making Test: Set Shifting, norm = 10, SD = 3	7.0 (3.9)
RBANS Visuospatial, norm = 100, SD = 15	85.1 (16.8)

Table 3

Receipt of Services and Disability in Depression-ABC Cohort

	% Reporting (n)	RAND12-Physical Composite, mean (sd)
In-Home and Community-Based Services (prior 3 months)¹		
Subacute rehabilitation center	1.9 (2)	
Home nursing	9.6 (10)	
Personal home attendant services	39.4 (41)	
Home delivered meals	19.2 (20)	
Transportation services	54.8 (57)	
Occupational or physical therapy	9.6 (10)	
Number of services received, 0–6		
0	26.0 (27)	33.0 (7.3)
1	29.9 (31)	33.6 (8.1)
2	27.9 (29)	31.4 (8.4)
3	16.3 (17)	26.8 (4.9)
Physical Health Composite²		
Fair-poor health	44.7 (46)	
Limited a lot in moderate activities	46.6 (48)	
Limited a lot in climbing stairs	60.2 (62)	
Accomplished less than would like	68.0 (70)	
Limited in activities	71.8 (74)	
Pain: Moderate/quite a bit/extreme	59.2 (61)	
Total (T score [norm=50, SD =10])		31.7 (7.8)

¹ Cornell Services index-Primary Care (n=104). 27% of the sample did not report current service but was as impaired as the groups receiving services on the RAND12 physical composite score.

² RAND12, Physical Health Composite (n=103).