Regular Research Article

Can We Prevent Depression in At-Risk Older Adults Using Self-Help? The UK SHARD Trial of Behavioral Activation

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ABSTRACT

Background: Treatment of established depression is the dominant approach to care of older adults, but prevention holds much promise. Self-help interventions are a feasible preventive approach, since they are scalable and low cost. There are few trials in this area. Behavioral Activation (BA) is a credible candidate psychological approach, which has been shown to work in therapist led care but not been trialled in a self-help form. Aim: To test the effectiveness of an unguided self-help intervention based on BA for older adults. Methods: We compared a self-help intervention based on BA for older people (n = 172) to usual care (n = 160) in a pragmatic randomized controlled trial. Outcomes were depression status and severity (PHQ9) and health related quality of life (SF12). The primary timepoint of the primary outcome was depression at 4 months, with longer term follow up at 12 months to test sustained impact of the primary outcome. Results: At 4 months adjusted PHQ-9 scores for BA self-help were 0.79 lower (95% CI: -1.70 to 0.13; p = 0.09) and the proportion of participants with case-level depression was significantly reduced (BA 31/137 (22.6%) versus usual care 41/141 (29.1%); Odds Ratio 0.48; 95% CI: 0.26−0.92; p = 0.03). There was no PHQ-9 difference at 12 months or for health related quality of life at any point (4 or 12 months). Discussion: Self-help using BA for older people at risk of depression is a feasible and scalable intervention with potential short-term benefits in preventing depression. (Am J Geriatr Psychiatry 2021; ■■:■■−■■)

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Preventing Depression in At-Risk Older Adults

Highlights

- **What is the primary question addressed by this study?**—can we treat lower severity depressive symptoms and prevent the onset of depression in at risk older adults using a low-technology self-help approach based on behavioural activation.
- **What is the main finding of this study?**—Older people readily engaged with self-help (using bibliotherapy) based on behavioural activation principles. There was evidence of benefit in reducing the severity and incidence of depression in the short term, but this was not sustained at 12 months.
- **What is the meaning of the finding?**—Low intensity self-help interventions are a feasible intervention to potentially mitigate short term risk of depression in older adults. Low intensity self-help interventions can increase access to care and expansion of provision of evidence-supported models of psychological therapy.

INTRODUCTION

Depression is the leading cause of mental health-related disease burden globally, affecting an estimated 300 million people worldwide.[1] By the age of 65, one in seven older people meet formal diagnostic criteria for depression ("case-level depression"). Amongst older people, depressive syndromes often affect people with long-term physical conditions.[2] Depression worsens the outcomes of many disorders and increases disability, hospitalization and risk of death. The impairments in quality of life associated with depression are comparable to those of major physical illness.[3]

Less attention has been paid to those with mild depressive disorders/sub-threshold depression syndromes, or those who give positive responses to screening questions, but do not have sufficient levels of depressive symptoms to meet diagnostic criteria.[4] Those with less severe depression and symptoms that do not meet formal diagnostic criteria (sometimes called "sub-clinical", "sub-threshold" or "sub-syndromal" depression) also suffer impairments in their quality of life and level of functioning, and hold a negative view toward aging.[3] Sub-threshold depression is also a clear risk factor for progression to and the development of more severe depressive illness.[5,6] It is this population of older people with lower severity depressive symptoms who are at risk of severe depression that is the focus of the current research. Strategies to prevent the onset of disorders in this group are sometimes called "indicated prevention."[7]

Behavioral activation (BA) has been shown to be effective in the treatment of depression[8–10] and recent meta-analyses show that it can be readily applied in older adults.[11,12] Our recent experience in the UK CASPER trials of collaborative primary care[13] shows that BA is especially adaptable for use amongst older people and can readily incorporate the problems that cause or perpetuate depression in this population.[14] For example, BA can be usefully adapted to manage the loss of function and lack of positive reinforcement which follows on from problems of poor mobility, long term health problems or change in role following retirement or bereavement.[15]

One way in which access to psychological therapies such as BA can be enhanced is via its provision as a low-intensity scalable self-help intervention.[16,17] Guidance for depression defines self-help interventions to treat depression as those which make use of a range of books or other self-help materials derived from an evidence-based intervention and designed specifically for that purpose.[18] There is evidence from trials to show that self-help interventions in general can effectively treat symptoms of depression,[19,20] and that the effectiveness of low-intensity interventions for depression can be enhanced by the offer of support.[19] However, to our knowledge there are no large scale trials of BA self-help conducted among older adults. The purpose of this study was to address this evidential gap for older people with low severity depression who are at risk of developing more severe forms of depressive disorder.

METHODS

Study Design and Participants

The Self Help for those At Risk of Depression (SHARD) trial was designed to examine the

Box 1   Whooley brief case-finding questions for depression

> 1. "Over the past month have you often been bothered by feeling down, depressed or hopeless?"
> 2. "Over the past month, have you often been bothered by having little interest or pleasure in doing things?" A positive answer to one or both of these questions raises the possibility of depression and necessitates a full assessment for the presence or absence of clinically significant depressive syndrome.

effectiveness of self-help using BA to prevent or mitigate depression in older people in primary care who have symptoms, but do not meet the diagnostic threshold for clinical depression. The SHARD trial was registered at ISRCTN95270332.

SHARD participants were identified by a screening strategy established in primary care to form a comprehensive cohort of older people with all severities of depression. The cohort has been described elsewhere[13] and has also been used to populate two large scale trials of older people with case level depression[21] and subthreshold depression[14] (the UK CASPER trials). People entered the cohort if they were older people (aged 65 and above) who screen-positive for depression on a brief depression questionnaire (sometimes referred to as the "Whooley" questions after their initial validation study),[22] but who on further assessment do not fulfil full criteria for DSM-IV Major Depressive Disorder, and therefore have "subthreshold depression."[23] The Whooley questions are detailed in Box 1.

All participants were identified by general practices: people fulfilling inclusion criteria and potentially eligible for the SHARD trial were sent an invitation pack (letter of invitation, Participant Information Sheet, consent form, decline form, background information form). Patients wishing to join the study were asked to return completed consent and background information forms by post to the study center. All consenting participants were then asked to complete a baseline questionnaire. Those who answered "yes" to at least one Whooley question then received a diagnostic telephone interview. We established the presence of subthreshold depression using a criterion-based assessment of depression according to the American Psychiatric Association DSM-IV (established by the validated interviewer-administered diagnostic schedule MINI).[24] Those with case-level DSM-IV Major Depressive Disorder were offered the opportunity to partake in a further trial of face to face

BA as part of a multi-component intervention reported elsewhere.[21]

This was a primary care pragmatic trial, and we only excluded participants if they were judged by their general practitioner to be (1) currently experiencing psychotic symptoms, (2) to have alcohol dependency (as recorded on GP records), (3) to have significant cognitive impairment or be unable to give informed consent (4) to have experienced recent bereavement (as recorded on GP records), (5) to have a terminal illness, including a terminal malignancy. Participants who were prescribed psychotropic medication were not excluded.

Intervention arm: Participants were sent a specially-designed BA self-help booklet produced for the purposes of the SHARD trial. This booklet was entitled *"Helping you to maintain a positive mood in older age: a self-help workbook"* and comprised 20 printed pages. The workbook was based on clear principles of BA for depression.[25] The core purpose of the workbook was to introduce simple behavioral strategies for improving mood.[15] The rationale for the workbook was to enable patients to regain functionality; lost or reduced as part of low mood. By using principles of BA, participants were encouraged to (1) re-establish their daily routine, (2) increase meaningful or important activities, and (3) reduce avoidance behaviors.

The SHARD self-help booklet was tested for readability and designed after consultation with older people with depression and their carers. After consenting to partake in a self-help trial, participants to this arm of the trial were sent a copy of the self-help booklet with an explanatory cover letter. Participants also received a series of three telephone calls designed to check that the materials had arrived and to offer practical advice and encouragement to use the materials (but with no advice on BA techniques or modality-specific psychotherapeutic instructions). Calls were offered following a 1 day training programme, and support was from graduates with no requirement for prior clinical experience. Calls lasting 5-10 minutes were offered at 1 week, 3 weeks and 6 weeks following the delivery of the self-help booklet. Support workers were offered supervision to ensure the quality of support and adherence to the manual. In addition, all participants received the usual care of their general practitioner and access to UK National Health Service (NHS) primary care services.

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Comparator arm: All participants in the control group were offered usual care from their general practitioner and access to NHS primary care services.

Randomization and Masking

Simple randomization was performed using a computer-generated random number sequence. At the end of the baseline appointment study researchers telephoned a secure randomization line at the York Trials Unit and were given participant allocation, thereby maintaining concealment of allocation until after random allocation. Participants were informed immediately. After assignment, all outcomes were collected by self-report and all researchers who contacted participants were blind to treatment allocation.

Outcome Measures

Primary outcome measure: the pre-specified primary outcome was depression severity and symptomatology as measured on a validated self-report measure (the Patient Health Questionnaire-9 [PHQ9])[26] and the primary timepoint was 4 months. We analysed the primary outcome of depression as a continuous measure (PHQ-9 score) and in terms of caseness, with caseness defined as a score of ≥10 on the PHQ-9.[27] We also measured any sustained benefit for the primary outcome at 12 months (as a continuous and dichotomous measure).

Secondary outcome measures: Health-related quality of life (measured by the SF-12 mental component scale and physical component scale),[28] at 4 and 12 months. We also measured health-state utility (Euro-Qol - EQ5D) as part of cost per QALY health economic analysis and this is not reported here.

Sample size calculation: We aimed to recruit 156 participants per arm. Assuming 15% attrition, the trial had 90% power to detect at the 5% significance level a difference of 0.4 standard deviations (approximately 2 PHQ-9 score points) in the PHQ-9 score between the two arms. We powered our trial on the basis of the results of a meta-analyses of the effectiveness of self-help interventions for depression where the mean pooled effect size was 0.43 (95% CI 0.30−0.57).[19]

Statistical Analysis

The PHQ-9 score at 4 months was analyzed under the intention-to-treat principle using a linear regression model adjusting for treatment allocation, gender, age at randomization, baseline PHQ-9 score and the physical and mental components of the SF-12 at baseline. Covariates were pre-specified. Participants were analysed as part of the group to which they had been randomised (intention-to-treat) and were included in the model if they had valid primary outcome data at 4 months, and had valid data on gender, age at randomisation, baseline PHQ-9 score and the physical and mental components of the SF-12 at baseline. The PHQ-9 score at 12 months, and the SF-12 physical component scale and mental component scale at 4 months and 12 months, were analyzed in the same manner. The number of participants with a PHQ-9 score ≥ 10 (both at 4 months and 12 months) was analyzed using a logistic regression model, adjusting for the same covariates as the primary outcome model, and in addition adjusted for whether the PHQ-9 at baseline was more than or equal to 10. Participants with missing outcome and/or covariate data were excluded from the analyses. Estimates of effect were presented alongside corresponding 95% confidence intervals (CI), test statistics (F-statistic and number of degrees of freedom for linear regression; chi-squared statistic and number of degrees of freedom for logistic regression; t-score and number of degrees of freedom for t test) and the p value resulting from the statistical test. Hypothesis testing was two-sided and used a 5% significance level. In addition, Cohen's d was presented for the PHQ-9 score at 4 months. An unadjusted analysis was carried out for the PHQ-9 at 4 months, using a t test. Statistical analyses were performed in Stata version 15.0. In addition, we also carried out a post-hoc sensitivity analysis, to assess the impact of missing data on the analysis of the primary outcome at 4 months. The sensitivity analysis was carried out using multiple imputation by chained equations. The imputation model included the primary and secondary outcomes at each time point, the treatment group, the baseline covariates included in the primary analysis model, and in addition any baseline covariates that were found to be associated with the primary outcome being missing at 4 months. The imputation model was then used to create 100 imputed datasets, on each of which the primary

analysis model was repeated. The resulting estimates were then combined using Rubin's rules to produce a final estimate of the treatment effect, alongside a 95% confidence interval and p-value.

Ethical Approval and Role of the Funding Source

This study was undertaken as a suite of trials for older people with depression commissioned by the UK National Institute for Health Research (NIHR) Health Technology Assessment Programme (project reference HTA 10/57/43). The funder had no role in study design, data collection, analysis or interpretation, or writing of the report. Ethical approval was granted by NRES Committee Yorkshire & The Humber - Leeds, on 23/12/2013 (REC ref: 10/H1306/61). The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

RESULTS

A total of 332 participants were randomized to the two-armed comparison of BA self-help booklet versus usual care, n = 172 and n = 160 respectively. The first permission to contact was received on February 14, 2014, and the first participant was randomized on March 10, 2014. The final participant was randomized on August 11, 2014. The flow of participants through the trial is shown in the CONSORT diagram (Fig. 1).

The treatment groups were well-balanced in terms of age and gender, and we noted high levels of concurrent long-term physical conditions. The commonly reported comorbidities being hypertension and heart disease, osteoarthritis, respiratory, and eye conditions. One fifth of participants (68/332, 20.5%) were prescribed antidepressant medication (BA self-help 37/172, 21.5%; usual care 31/160, 19.4%). There were baseline imbalances in levels of depression despite randomization (mean PHQ scores: BA self-help mean score 8.6, SD = 4.6; usual care mean score 7.7, SD = 4.2), and these were adjusted for in the between group comparisons as part of the pre-planned statistical analysis. Retention rates at 4 months were 145 (84.3%) for BA self-help and 148 (92.5%) for usual care. At 12 months retention rates were 140 (81.4%) for BA self-help and 139 (86.9%) for usual care. Table 1

PHQ-9 score: At the 4 month primary outcome time point the adjusted between-group difference in PHQ-9 scores was 0.79 points (95% CI: -1.70 to 0.13; $F_{(1, 271)} = 2.85$; p = 0.09) in favor of BA self-help, with a Cohen's d of -0.17 (95% CI: -0.41 to 0.06; $F_{(1, 271)} = 2.85$; p = 0.09). At 12 months there was no longer evidence of a between-group difference in PHQ-9 scores (adjusted mean difference 0.15 ;95%: CI -0.95 to 1.25; $F_{(1, 257)} = 0.07$; p = 0.79).

Depression "caseness" using PHQ-9 as a dichotomous outcome: After 4 months 31/137 (22.6%) of the participants in the BA self-help and 41/141 (29.1%) of the usual care group had a PHQ-9 score greater than or equal to 10. The odds of being depressed (defined as PHQ-9 $\geq$10) at 4 months were reduced by half in the BA self-help group compared to usual care (adjusted odds ratio [OR] 0.48; 95% CI: 0.26 to 0.92; $\chi^2(1) = 4.89$; p = 0.03). There was no sustained evidence of benefit of BA self-help at 12 months ([adjusted OR 1.56; 95% CI: 0.88 to 2.77; $\chi^2(1) = 2.27$; p = 0.13) (Table 2).

Health related quality of life: we found no differences in health related quality of life as measured by the SF12 in either the physical or mental health component scores at 4 or 12 months (Table 2). **Post-hoc sensitivity analysis:** Using multiple imputation by chained equations, the adjusted mean difference in the PHQ-9 score at 4 months was -0.82 points (95% CI: -1.71 to 0.08; p=0.07) and the adjusted odds ratio for depression 'caseness' using the PHQ-9 as a dichotomous outcome at 4 months was 0.53 (95% CI: 0.29 to 0.96; p=0.04).

DISCUSSION

The main finding of the SHARD trial is that a brief minimally supported form of BA self-help via a workbook (sometimes called bibliotherapy) was potentially effective at our 4 month primary outcome point in preventing case level depression as measured by the PHQ-9. The odds of developing depression in this at risk population were halved at 4 months, and this was statistically significant. The size of effect was in line with previous estimates, but we could not exclude the possibility that the results were by chance since by continuous measure of the PHQ9. The effect had attenuated by 12 months, and we also found no

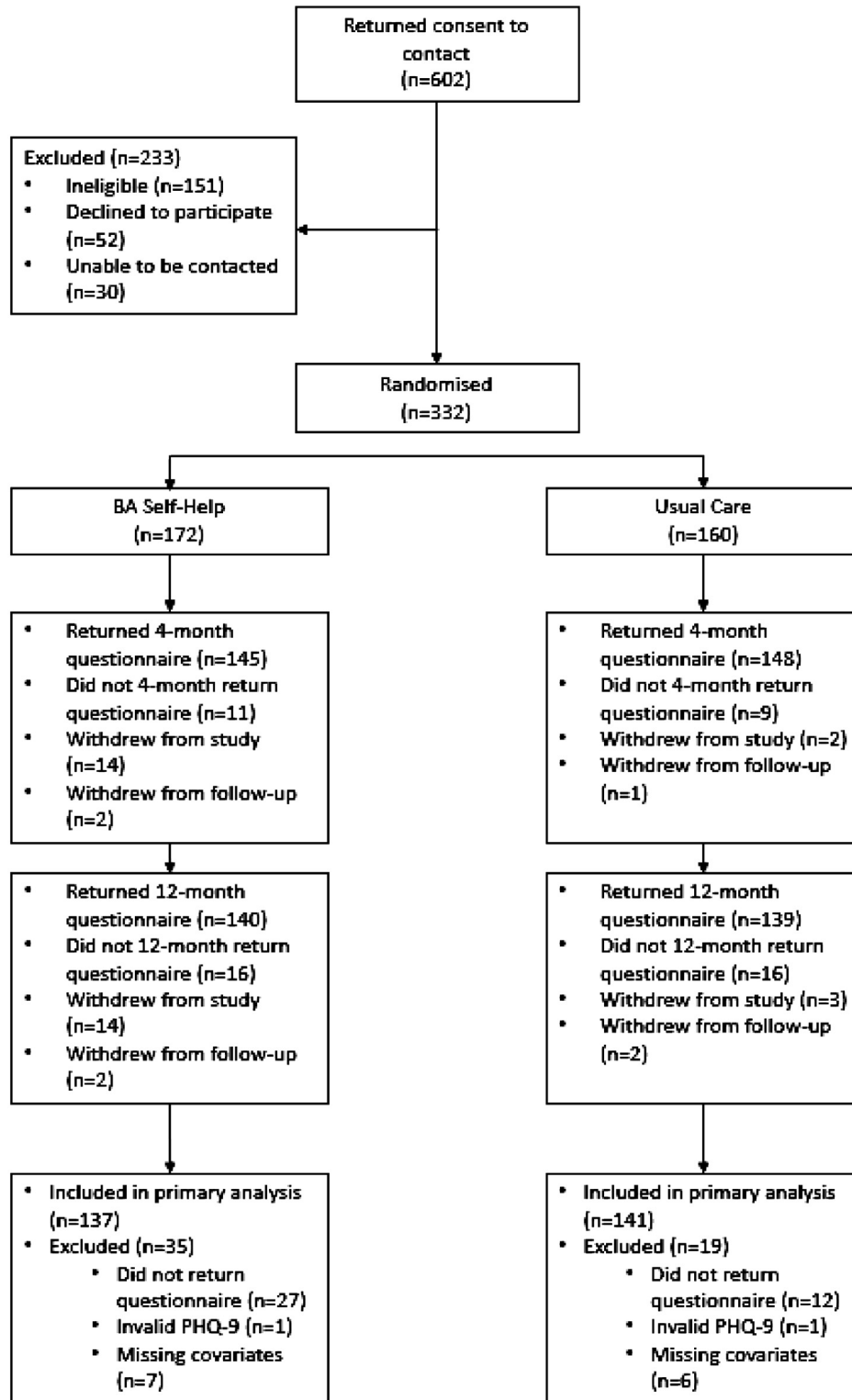FIGURE 1. Consolidated standards of reporting trials (CONSORT) diagram.

TABLE 1.   Baseline Characteristics of Randomized Participants

	As Randomized (n = 332)		As analyzed (n = 278)	
	BA Self-Help (n = 172)	Usual Care (n = 160)	BA Self-Help (n = 137)	Usual Care (n = 141)
Age, years				
n (%)	170 (98.8)	159 (99.4)	137 (100)	141 (100)
Mean (SD)	74.9 (6.7)	73.9 (6.7)	74.2 (6.5)	73.8 (6.7)
Median (IQR)	73.8 (69.0, 79.9)	72.3 (68.2, 78.2)	72.6 (68.6, 79.4)	72.0 (68.0, 77.6)
Min, Max	65.3, 91.1	65.7, 92.1	65.3, 90.2	65.7, 92.1
Gender, n (%)				
Male	70 (40.7)	72 (45.0)	58 (42.3)	66 (46.8)
Female	99 (57.6)	84 (52.5)	79 (57.7)	75 (53.2)
Missing	3 (1.7)	4 (2.5)	0 (0)	0 (0)
Continued education after school leaving age, n (%)				
Yes	93 (54.1)	87 (54.4)	76 (55.5)	81 (57.4)
No	77 (44.8)	70 (43.8)	61 (44.5)	58 (41.1)
Missing	2 (1.2)	3 (1.9)	0 (0)	2 (1.4)
Smoker, n (%)				
Yes	15 (8.7)	11 (6.9)	13 (9.5)	10 (7.1)
No	153 (89.0)	143 (89.4)	122 (89.1)	127 (90.1)
Don't know	0 (0)	3 (1.9)	0 (0)	2 (1.4)
Missing	4 (2.3)	3 (1.9)	2 (1.5)	2 (1.4)
Ethnicity, n (%)				
White	167 (97.1)	157 (98.1)	134 (97.8)	139 (98.6)
Other	0 (0)	1 (0.6)	0 (0)	1 (0.7)
Missing	5 (2.9)	2 (1.3)	3 (2.2)	1 (0.7)
Number of health problems, n (%)				
0	11 (6.4)	11 (6.9)	9 (6.6)	7 (5.0)
1	44 (25.6)	26 (16.3)	38 (27.7)	26 (18.4)
2	44 (25.6)	44 (27.5)	35 (25.5)	40 (28.4)
3+	71 (41.3)	78 (48.8)	55 (40.1)	68 (48.2)
Missing	2 (1.2)	1 (0.6)	0 (0)	0 (0)
Health problems, n (%)				
Diabetes	29 (16.9)	40 (25.0)	22 (16.1)	34 (24.1)
Osteoporosis	17 (9.9)	14 (8.8)	13 (9.5)	10 (7.1)
High blood pressure	72 (41.9)	84 (52.5)	52 (38.0)	74 (52.5)
Rheumatoid arthritis	19 (11.0)	26 (16.3)	13 (9.5)	22 (15.6)
Osteoarthritis	51 (29.7)	49 (30.6)	42 (30.7)	42 (29.8)
Stroke	9 (5.2)	8 (5.0)	7 (5.1)	7 (5.0)
Cancer	17 (9.9)	23 (14.4)	14 (10.2)	22 (15.6)
Respiratory conditions	36 (20.9)	52 (32.5)	30 (21.9)	49 (34.8)
Eye condition	46 (26.7)	45 (28.1)	39 (28.5)	39 (27.7)
Heart disease	52 (30.2)	42 (26.3)	40 (29.2)	35 (24.8)
Other	50 (29.1)	43 (26.9)	43 (31.4)	40 (28.4)
PHQ-9 Score				
n (%)	172 (100)	160 (100)	137 (100)	141 (100)
Mean (SD)	8.6 (4.6)	7.7 (4.2)	8.5 (4.6)	7.5 (4.2)
Median (IQR)	8 (5, 11.5)	7 (4, 10)	8 (5, 11)	7 (4, 10)
Min, Max	0, 25	0, 20	0, 25	0, 20
Whooley Question 1, n (%)				
Yes	147 (85.5)	125 (78.1)	115 (83.9)	110 (78.0)
No	25 (14.5)	35 (21.9)	22 (16.1)	31 (22.0)
Whooley Question 2, n (%)				
Yes	120 (69.8)	102 (63.8)	97 (70.8)	89 (63.1)
No	52 (30.2)	58 (36.2)	40 (29.2)	52 (36.9)
Self-reported use of any antidepressant medication, n (%)				
Yes	37 (21.5)	31 (19.4)	30 (21.9)	30 (21.3)
No	108 (62.8)	100 (62.5)	86 (62.8)	87 (61.7)
Don't know	1 (0.6)	4 (2.5)	1 (0.7)	3 (2.1)
Missing	26 (15.1)	25 (15.6)	20 (14.6)	21 (14.9)

TABLE 2. Depression (PHQ-9) and Health Related Quality of Life (SF12) at Each Time Point

	BA Self-Help		Usual care			
	No. in Model	Mean (95% CI)	No. in Model	Mean (95% CI)	Mean Difference (95% CI)F(df_1, df_2)/t(df)	p value
PHQ-9 Score						
Primary [adjusted]						
Month 4	137	6.81 (6.16, 7.46)	141	7.59 (6.95, 8.23)	-0.79 (-1.70, 0.13) F(1, 271) = 2.85	0.09
Month 12	133	7.18 (6.41, 7.95)	131	7.03 (6.25, 7.80)	0.15 (-0.95, 1.25) F(1, 257) = 0.07	0.79
Unadjusted						
Month 4	144	7.07 (6.41, 7.73)	147	7.38 (6.58, 8.18)	-0.31(-1.34, 0.72) t(289) = 0.59	0.55
		n/No. in Model (%)		n/No. in Model (%)	Odds Ratio (95% CI) χ^2(df)	p value
PHQ-9 ≥10 [adjusted]						
Month 4		31/137 (22.6)		41/141 (29.1)	0.48 (0.26, 0.92) χ^2(1) = 4.89	0.03
Month 12		41/133 (30.8)		28/131 (21.4)	1.56 (0.88, 2.77) χ^2(1) = 2.27	0.13
	No. in Model	Mean (95% CI)	No. in Model	Mean (95% CI)	Mean Difference (95% CI) F(df_1, df_2)	p value
SF-12 PCS [adjusted]						
Month 4	131	38.77 (37.46, 40.07)	138	38.36 (37.09, 39.64)	0.40 (-1.43, 2.23) F(1, 262) = 0.19	0.67
Month 12	125	38.42 (37.00, 39.84)	126	36.99 (35.57, 38.41)	1.43 (-0.59, 3.45) F(1, 244) = 1.95	0.16
SF-12 MCS [adjusted]						
Month 4	131	44.59 (43.13, 46.04)	138	44.26 (42.84, 45.68)	0.33 (-1.71, 2.37) F(1, 262) = 0.10	0.75
Month 12	125	45.16(43.49, 46.84)	126	46.36 (44.69, 48.02)	-1.19 (-3.56, 1.18) F(1, 244) = 0.98	0.32

Notes: PCS: physical component scale; MCS: mental component scale.

evidence of impact on domains of health-related quality of life at any point.

Strengths of the SHARD Trial

SHARD is one of the largest trials of unguided self-help undertaken to date. In addition, to our knowledge, this is the first self-help trial undertaken in a population of older adults using BA (an intervention previously shown to be effective in face to face delivery and in case level depression).[12,29] The SHARD trial adds to emerging evidence of the potential for indicated prevention in depression[30] and extends this evidence to include older adults. We used a pragmatic design and there were few exclusion criteria. We recruited in primary care and achieved the planned sample size. SHARD participants had high

levels of multi-morbidity in line with the prevalence of long-term conditions for older people, the impact of ill health on psychological health.[31] This is helpful in judging the external validity and applicability of the results to the large population of older people with subthreshold symptoms. In most healthcare settings such patients receive little or no care for psychological symptoms and their heightened risk of developing more severe disorders. We also included a long period of follow up (with high follow up rates) and this is helpful in establishing what the maximal effect for a low intensity interventions are in the short term. The SHARD study demonstrates a modest clinical effect and this was achieved with minimal intervention. The support calls were brief and focused on encouragement to use the booklet, with no requirement for skilled psychotherapeutic support. As such

the SHARD intervention indicates a possible first step approach for those at risk of major depression and adds to an emerging evidence base for this approach in older adults, including those in lower resource countries,[32] and underserved populations.[33]

Limitations of the SHARD Trial

We identify three limitations. First, though we achieved high levels of follow up, there was differential attrition between arms (retention 84.3% for BA self-help and 92.5% for usual care at 4 months). This has the potential to bias the results in either direction, and the results of the trial must be interpreted with some caution. However, the post-hoc sensitivity analysis we carried out gave similar results to the primary analysis. Second, this was a test of the ability of a low-intensity intervention to prevent the occurrence of case level depression at 4 months and the design could have been enhanced with the application of a criterion-referenced diagnostic interview to judge the presence of depression. However we used an instrument with established diagnostic properties as a proxy[27,34] and the PHQ9 has now been adopted as a global standard measure by the NIMH and the Wellcome Trust.[35] We also minimized observer bias by the use of masking and participant self-report of the primary outcome measure. Third, though this was a large trial compared to the existing trials literature, we were still underpowered to detect a small effect in line with other estimates from self help interventions. Our primary endpoint of a continuous measure of depression severity might therefore have not been able to detect a difference if one existed at 3 months and at 12 months. The interpretation of confidence interval estimates and p values should therefore also consider possible type II errors.

Implications and Need for Further Research

BA is a form of psychological therapy with an established efficacy in working age[10] and older adult populations with depression.[12] However, the capacity to extend treatments to people with subthreshold depression is always going to be limited by health services resources. By identifying a minimal intervention that is likely to be effective in mitigating symptoms in the short term, there is scope to integrate such treatments at low cost and with high levels of patient access.[16]

We also note trends in the development and evolution of self-help interventions over recent years.[36] There is now a movement towards the offer of structured forms of psychological therapy as a form of self-help, delivered via the internet or via digital technology. Previous trials (and meta-analyses of trials) have shown some evidence of effect for guided digital interventions,[37] whilst pragmatic trials have demonstrated minimal effect and lower levels of uptake.[38] There are concerns that the shift to digital delivery of self-help interventions may inadvertently exclude certain sections of the population and widen inequalities in treatment and access. The "digital divide" is a particular issue for lower-income populations and for older people[39] and we deliberately chose a low technology form of self-help in the form of bibliotherapy based around BA principles to minimize barriers to access. The provision of self-help materials such as those used in the SHARD trial could form a first treatment offer in a stepped care approach[40] for older people with low severity depressive symptoms or at risk of depression.

The results of the SHARD trial also raise the possibility of preventing the onset of depression in populations at risk by reason of pre-existing symptoms. This approach aligns with the strategy of "indicated prevention" under the classification of preventative strategies offered by the Institute of Medicine.[7] The results of the SHARD trial should be viewed alongside other positive trials of BA and collaborative care in preventing the onset of depression in older people with subthreshold depression.[14] There is also accumulating evidence for the role of structured psychological therapies in prevention,[41] but the SHARD trial is one of only a small number of trials of a self-help intervention in an indicated risk population.[42]

Finally, we note that the support offered alongside BA was minimal and only involved three information-giving phone calls from a person without extensive clinical experience and following only brief training. There is trial-based evidence that the effectiveness of bibliotherapy self-help is enhanced with greater levels of support.[17] This raises the possibility that the effect could have been larger or more durable with a greater level of support or support delivered over a longer period. More research is needed to explore the additional benefits of greater levels of support.

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