
Article:
Gilbody, Simon orcid.org/0000-0002-8236-6983, Brabyn, Sally orcid.org/0000-0001-5381-003X, Mitchell, Alex Steven orcid.org/0000-0001-9311-2092 et al. (7 more authors) (2022) Can we prevent depression in at-risk older adults using self-help? : The UK SHARD trial of Behavioural Activation. American journal of geriatric psychiatry. pp. 197-207. ISSN 1064-7481

https://doi.org/10.1016/j.jagp.2021.06.006

Am J of Geriatric Psychiatry 30:2 (2022) 197–207

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.ajgponline.org

Regular Research Article

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

Simon Gilbody, D.Phil, Sally Brabyn, M.Sc, Alex Mitchell, M.Sc, David Ekers, Ph.D, Dean McMillan, Ph.D, Della Bailey, M.Sc, Deborah Hems, M.Sc, Carolyn A. Chew Graham, M.D., Ada Keding, M.Sc, Kate Bosanquet, Ph.D, on behalf of the SHARD collaborative

ARTICLE INFO

Article history:
Received April, 27 2021
Revised June, 12 2021
Accepted June, 14 2021

Key Words:
Depression
older adults
prevention
behavioral activation
RCT

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 2022; 30:197–207)

From the Department of Health Sciences (SG, SB, AM, DE, DM, DB, DH, AK, KB), University of York, UK; Hull York Medical School (SG, DM), UK; York Trials Unit (AM, AD), University of York, UK; Tees Esk and Wear Valleys NHS Foundation Trust (DE), North Yorkshire, UK; and the School of Medicine (CAG), Keele University, UK. Correspondence and reprint requests to Professor Simon Gilbody D.Phil, Department of Health Sciences, University of York, Heslington YO10 5DD, UK. e-mail: simon.gilbody@york.ac.uk

https://doi.org/10.1016/j.jagp.2021.06.006

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.

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 (EuroQol - 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 ≥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.

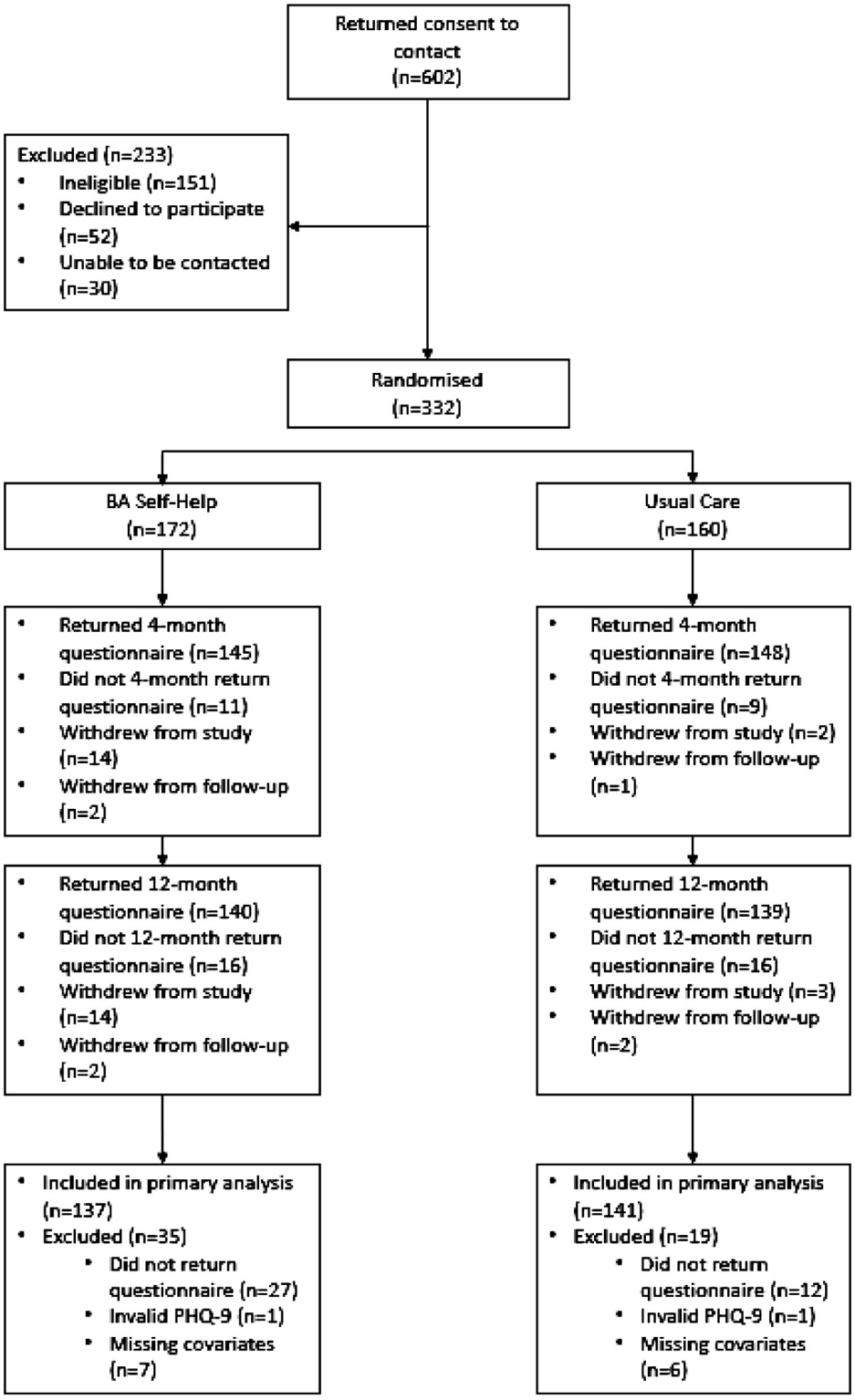

TABLE 1. Baseline Characteristics of Randomized Participants

	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.

AUTHOR CONTRIBUTIONS

Sally Brabyn was the trial manager.

Alex Mitchell (statistician) designed and conducted the clinical analysis

Simon Gilbody was the Chief Investigator of the SHARD programme of research and chaired the Trial Management Group

The report writing team consisted of Simon Gilbody, Sally Brabyn, Alex Mitchell, David Ekers, Dean McMillan, Della Bailey, Deborah Hems, Carolyn A. Chew Graham, Ada Keding, Kate Bosanquet

DATA SHARING

Reasonable requests for patient level data should be made to the corresponding author and will be considered by the SHARD publications management group. Consent for data sharing was not obtained but the presented data are anonymised, and risk of identification is low.

The authors thank especially the patients from Primary Care who agreed to be recruited to take part in this trial.

This project was funded by the UK NIHR Health Technology Assessment programme (project number HTA 10/57/43). Deborah Hems designed the self-help materials which form the basis of the behavioural activation intervention in the SHARD trial. Whilst these materials are free to use in the UK NHS, copyright is held by the University of York. The authors have no conflicts of interest to disclose related to the manuscript. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, NHS or the Department of Health. The funder played no role in the study design, in the collection, analysis or interpretation of the data, in the writing of the paper or in the decision to submit the article for publication. All authors were independent from the funders. All authors had full access to all of the study data and take responsibility for the integrity of the data and the accuracy of the data. The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and if relevant registered) have been explained.

The results of the SHARD trial have previously been presented by Professor Gilbody at the 2018 Global Consortium for the Prevention of Depression (GCPD) in Mallorca Spain on October 25, 2018.

https://gcdp2018.uib.eu/Submitted-Abstracts/

References

1. Patel V, Chisholm D, Parikh R, et al: Addressing the burden of mental, neurological, and substance use disorders: key messages from Disease Control Priorities. Lancet North Am Ed 2016; 387:1672–1685
2. Rapp S, Parsi S, Walsh D: Psychological dysfunction and physical health among elderly medical inpatients. J Consult Clin Psychol 1998; 56:851–855
3. Chachamovich E, Fleck M, Laidlaw K, et al: Impact of major depression and subsyndromal symptoms on quality of life and attitudes toward aging in an international sample of older adults. Gerontologist 2008; 48:593–602
4. Baldwin RC, Anderson D, Black S, et al: Guideline for the management of late-life depression in primary care. Int J Geriatr Psychiatry 2003; 18:829–838
5. Judd LL, Akiskal HS, Maser JD: A prospective 12-year study of subsyndromal and syndromal depressive symptoms in unipolar major depressive disorders. Arch Gen Psych 1998; 55:694–700
6. Lee Y, Stockings E, Harris M, et al: The risk of developing major depression among individuals with subthreshold depression: a systematic review and meta-analysis of longitudinal cohort studies. Psychol Med 2019; 49:92–102
7. Munoz RF, Mrazek PJ, Haggerty RJ: Institute of Medicine report on prevention of mental disorders: summary and commentary. Am Psychol 1996; 51:1116
8. Ekers D, Richards D, McMillan D, et al: Behavioural activation delivered by the non-specialist: phase II randomised controlled trial. Br J Psychiatry 2011; 198:66
9. Ekers D, Richards D, Gilbody S: A meta-analysis of randomized trials of behavioural treatment of depression. Psychol Med 2008; 38:611–623
10. Ekers D, Webster L, Van Straten A, et al: Behavioural activation for depression; an update of meta-analysis of effectiveness and sub group analysis. PLoS One 2014; 9:e100100
11. Samad Z, Brealey S, Gilbody S: The effectiveness of behavioural therapy for the treatment of depression in older adults: a meta-analysis. Int J Geriatr Psychiatry 2011; 26:1211–1220
12. Orgeta V, Brede J, Livingston G: Behavioural activation for depression in older people: systematic review and meta-analysis. Br J Psychiatry 2017; 211:274–279
13. Mitchell N, Hewitt C, Adamson J, et al: A randomised evaluation of CollAborative care and active surveillance for Screen-Positive ElderRs with sub-threshold depression (CASPER): study protocol for a randomized controlled trial. Trials 2011; 12:225
14. Gilbody S, Lewis H, Adamson J, et al: Effect of collaborative care vs usual care on depressive symptoms in older adults with subthreshold depression: the CASPER randomized clinical trial. JAMA 2017; 317:728–737

15. Pasterfield M, Bailey D, Hems D, et al: Adapting manualized behavioural activation treatment for older adults with depression. Cognitive Behav Therapist 2014; 7:e5
16. Lovell K, Richards D: Multiple access points and levels of entry (MAPLE): ensuring choice, accessibility and equity for CBT services. Behav Cogn Psychother 2000; 28:379–391
17. Bower P, Richards D, Lovell K: The clinical and cost-effectiveness of self-help treatments for anxiety and depressive disorders in primary care: a systematic review. Br J Gen Pract 2001; 51:838–845
18. National Institute for Health and Clinical Excellence: Depression in adults: the treatment and management of depression in adults (Update - NICE clinical guideline 90). Manchester: National Institute for Health and Clinical Excellence, 2009
19. Gellatly J, Bower P, Hennessy S, et al: What makes self-help interventions effective in the management of depressive symptoms? Meta-analysis and meta-regression. Psychol Med 2007; 37 (9):1217–1217−28;doi:10.1017/S0033291707000062 https://www.cambridge.org/core/journals/psychological-medicine/article/abs/what-makes-selfhelp-interventions-effective-in-the-management-of-depressive-symptoms-metaanalysis-and-metaregression/F1B4AD383CF9F7D9D9B448B918BF64BF
20. Bower P, Kontopantelis E, Sutton A, et al: Influence of initial severity of depression on effectiveness of low intensity interventions: meta-analysis of individual patient data. BMJ 2013; 346: f540;doi:10.1136/bmj.f540
21. Lewis H, Adamson J, Atherton K, et al: CollAborative care and active surveillance for Screen-Positive ElderRs with subthreshold depression (CASPER): a multicentred randomised controlled trial of clinical effectiveness and cost-effectiveness. Health Technol Assess 2017; 21:1
22. Whooley MA, Avins AL, Miranda J, et al: Case finding instruments for depression two questions as good as many. J Gen Intern Med 1997; 12:439–445
23. American Psychiatric Association: Diagnostic and statistical manual. 4th Edition Washington DC: American Psychiatric Association, 1994
24. Sheehan DV, Lecrubier Y, Sheehan KH, et al: The Mini-International Neuropsychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. J Clin Psychiatry 1998; 59(Suppl 20):22–33
25. Kanter JW, Manos RC, Bowe WM, et al: What is behavioral activation?: A review of the empirical literature. Clin Psychol Rev 2010; 30:608–620
26. Kroenke K, Spitzer RL: The PHQ-9: a new depression and diagnostic severity measure. Psychiatr Ann 2002; 32:509–521
27. Manea L, Gilbody S, McMillan D: Optimal cut-off score for diagnosing depression with the Patient Health Questionnaire (PHQ-9): a meta-analysis. Can Med Assoc J 2012; 184:E191–E1E6
28. Ware JE, Kosinski M, Keller SD: SF 12: How to score the SF12 physical and mental health summary scales. Boston Mass: New England Medical Centre, 1995
29. Ekers D, Curran J, McMillan D, Houghton S: Behavioural activation Dryden W, ed.. Cognitive behaviour therapies. London: SAGE Publications Ltd, 2012
30. Cuijpers P, Pineda BS, Quero S, et al: Psychological interventions to prevent the onset of depressive disorders: a meta-analysis of randomized controlled trials. Clin Psychol Rev 2021; 83:101955; doi:10.1016/j.cpr.2020.101955 https://www.sciencedirect.com/science/article/pii/S0272735820301434
31. Katon W, Schulberg HC: Epidemiology of depression in primary care. Gen Hosp Psychiatry 1992; 14:237–247
32. Dias A, Azariah F, Cohen A, et al: Intervention development for the indicated prevention of depression in later life: the "DIL" protocol in Goa, India. Contemporary Clin Trials Commun 2017; 6:131–139
33. Jimenez DE, Syed S, Perdomo-Johnson D, et al: ¡ HOLA, Amigos! Toward preventing anxiety and depression in older latinos. Am J Geriatr Psychiatry 2018; 26:250–256
34. Moriarty AS, Gilbody S, McMillan D, et al: Screening and case finding for major depressive disorder using the Patient Health Questionnaire (PHQ-9): a meta-analysis. Gen Hosp Psychiatry 2015; 37:567–576
35. The Lancet Psychiatry: A good enough measure. Lancet Psychiatry 2020; 7:825
36. Ebert DD, Harrer M, Apolinário-Hagen J, et al: Digital interventions for mental disorders: key features, efficacy, and potential for artificial intelligence applications. Frontiers in Psychiatry: Adv Exp Med Biol 2019: 583–627;doi:10.1007/978-981-32-9721-0_29 https://link.springer.com/chapter/10.1007/978-981-32-9721-0_29
37. Karyotaki E, Riper H, Twisk J, et al: Efficacy of self-guided internet-based cognitive behavioral therapy in the treatment of depressive symptoms: a meta-analysis of individual participant data. JAMA psychiatry 2017; 74:351–359
38. Gilbody S, Littlewood E, Hewitt C, et al: Computerised cognitive behaviour therapy (cCBT) as treatment for depression in primary care (REEACT trial): large scale pragmatic randomised controlled trial. BMJ 2015; 351:h5627
39. Choi NG, DiNitto DM: The digital divide among low-income homebound older adults: internet use patterns, eHealth literacy, and attitudes toward computer/Internet use. J Med Internet Res 2013; 15:e93
40. Bower P, Gilbody S: Stepped care in psychological therapies: access, effectiveness and efficiency. Narrative literature review. Br J Psychiatry 2005; 186:11–17
41. van Zoonen K, Buntrock C, Ebert DD, et al: Preventing the onset of major depressive disorder: a meta-analytic review of psychological interventions. Int J Epidemiol 2014; 43:318–329
42. Willemse G, Smit F, Cuijpers P: Minimal-contact psychotherapy for sub-threshold depression in primary care. Br J Psychiatry 2004; 185:416–421