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Effect of a Primary Care–Based Psychological Intervention on Symptoms of Common Mental Disorders in Zimbabwe
A Randomized Clinical Trial

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IMPORTANCE Depression and anxiety are common mental disorders globally but are rarely recognized or treated in low-income settings. Task-shifting of mental health care to lay health workers (LHWs) might decrease the treatment gap.

OBJECTIVE To evaluate the effectiveness of a culturally adapted psychological intervention for common mental disorders delivered by LHWs in primary care.

DESIGN, SETTING, AND PARTICIPANTS Cluster randomized clinical trial with 6 months' follow-up conducted from September 1, 2014, to May 25, 2015, in Harare, Zimbabwe. Twenty-four clinics were randomized 1:1 to the intervention or enhanced usual care (control). Participants were clinic attenders 18 years or older who screened positive for common mental disorders on the locally validated Shona Symptom Questionnaire (SSQ-14).

INTERVENTIONS The Friendship Bench intervention comprised 6 sessions of individual problem-solving therapy delivered by trained, supervised LHWs plus an optional 6-session peer support program. The control group received standard care plus information, education, and support on common mental disorders.

MAIN OUTCOMES AND MEASURES Primary outcome was common mental disorder measured at 6 months as a continuous variable via the SSQ-14 score, with a range of 0 (best) to 14 and a cutpoint of 9. The secondary outcome was depression symptoms measured as a binary variable via the 9-item Patient Health Questionnaire, with a range of 0 (best) to 27 and a cutpoint of 11. Outcomes were analyzed by modified intention-to-treat.

RESULTS Among 573 randomized patients (286 in the intervention group and 287 in the control group), 495 (86.4%) were women, median age was 33 years (interquartile range, 27-41 years), 238 (41.7%) were human immunodeficiency virus positive, and 521 (90.9%) completed follow-up at 6 months. Intervention group participants had fewer symptoms than control group participants on the SSQ-14 (3.81; 95% CI, 3.28 to 4.34 vs 8.90; 95% CI, 8.33 to 9.47; adjusted mean difference, −4.86; 95% CI, −5.63 to −4.10; $P < .001$; adjusted risk ratio [ARR], 0.21; 95% CI, 0.15 to 0.29; $P < .001$). Intervention group participants also had lower risk of symptoms of depression (13.7% vs 49.9%; ARR, 0.28; 95% CI, 0.22 to 0.34; $P < .001$).

CONCLUSIONS AND RELEVANCE Among individuals screening positive for common mental disorders in Zimbabwe, LHW-administered, primary care–based problem-solving therapy with education and support compared with standard care plus education and support resulted in improved symptoms at 6 months. Scaled-up primary care integration of this intervention should be evaluated.

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Supplemental content

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Depression and anxiety are the most common mental disorders globally and major causes of disease burden in sub-Saharan Africa.[1,2] Few people with common mental disorders in low-income settings have access to effective treatments.[3] When left untreated, common mental disorders can impair role functioning, self-care, and adherence to treatments and are associated with reduced productivity and increased health care costs.[4]

Zimbabwe has a large treatment gap for common mental disorders, with only 10 psychiatrists serving a population of 13 million. Prevalence of common mental disorders above 25% has been reported among adult primary care attendees,[5-8] but there are no psychological services in primary health care. A potentially feasible approach to improve this situation would require task shifting, allowing properly trained and supervised lay health workers (LHWs) in primary care to contribute to the treatment of common mental disorders. Mental health interventions delivered by LHWs must be simple and brief so that LHWs can effectively provide care for a range of common mental health problems.[9]

Problem-solving therapy is a brief psychological therapy that has been shown to be effective for many common mental health conditions seen in primary care in high-income settings.[10,11] A problem-solving therapy intervention locally termed the Friendship Bench has been shown in piloting to be acceptable for LHWs to deliver in Zimbabwe, with promising results.[7,12,13] In the Friendship Bench model, trained and supervised LHWs provided 6 sessions of individual problem-solving therapy to all patients with common mental disorders and referred those not improving or with suicidal ideation to their immediate supervisors for treatment adjustments.[14] Participants were also invited to an optional 6-session peer-led group support program. The aim of this trial was to evaluate the effectiveness of this culturally adapted intervention for common mental disorders delivered by existing LHWs in primary care in Harare, Zimbabwe.

Key Points

Question Does a lay health worker–delivered psychological intervention improve symptoms of depression and anxiety in Zimbabwe?

Findings In a cluster randomized clinical trial of 573 randomized patients with common mental disorders and symptoms of depression, the group who received the intervention had significantly lower symptom scores after 6 months compared with a control group who received enhanced usual care.

Meaning The use of lay health workers in resource-poor countries like Zimbabwe may be effective primary care–based management of common mental disorders.

Methods

The study protocol has been published[14] and is available in Supplement 1. We conducted a cluster randomized clinical trial in 24 primary care clinics (clusters) in Harare, Zimbabwe, with a 1:1 allocation ratio. A cluster design was used because the intervention involved training staff at the clinic level (**Figure 1**).

The protocol was approved by the ethics committees of the Medical Research Council of Zimbabwe and London School of Hygiene and Tropical Medicine. Eligible participants provided written informed consent to participate in the trial.

Setting

In each of the 12 districts of Harare there were 5 to 8 clinics of varying size. The largest, known as polyclinics, provided broad acute and chronic services and maternity care and were staffed by up to 14 nurses, 8 nurse aides, and 12 LHWs. A physician visited every 2 weeks. Small satellite clinics provided acute services and home-based nursing care and were staffed by 1 to 2 nurses and nurse aides and 3 to 4 LHWs. From 42 primary care clinics in Harare, we selected 24 of the largest clinics that were in accessible locations with mobile network coverage, had reliable data on stratification variables, and were willing to be involved in the study.

Randomization and Allocation Concealment

Clinics were randomized in a 1:1 ratio within 5 strata based on human immunodeficiency virus (HIV) status, housing density, clinic size, and sex of patients. Restricted randomization was used to minimize imbalance in key factors (HIV prevalence, clinic size, staff size, and sex ratio) as described previously.[14] The research assistants responsible for outcome assessment were masked to the allocation.

Participants

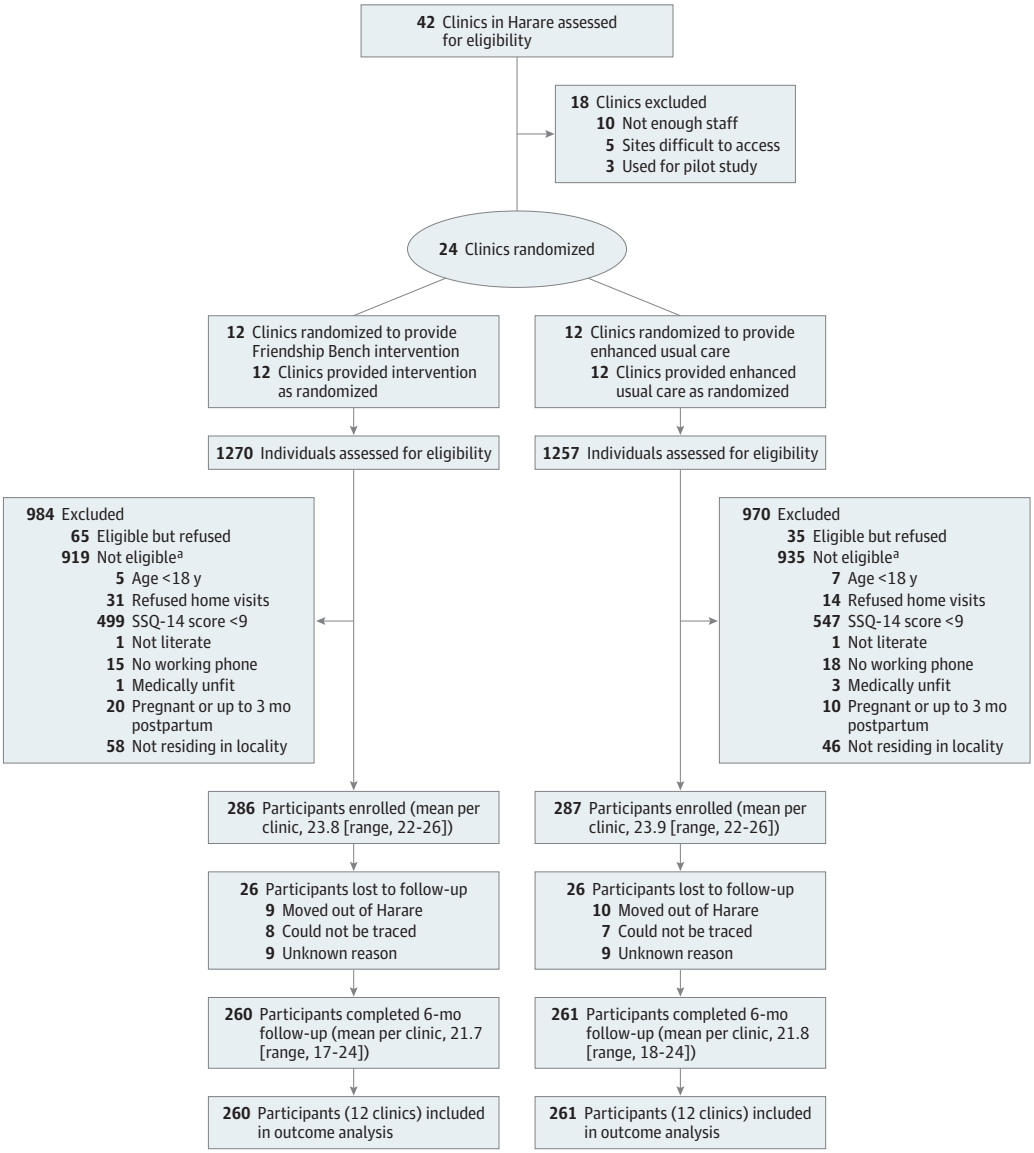
All adults attending trial clinics during a 2-week period were informed about the study, including explanation about common mental disorders and how these can affect other conditions, such as hypertension, HIV, and diabetes. After providing informed consent for screening, patients completed the Shona Symptom Questionnaire (SSQ-14), a locally validated screening tool for common mental disorders,[15] revalidated for this study population.[8] On each day of screening, computer-generated preprinted random numbers were used to select clinic attenders based on their queue position number. All persons randomly selected who were 18 years or older and resident in the area were eligible for further assessment if they screened positive with an SSQ-14 score of 9 or higher. Screening ended when 24 participants had been enrolled in each clinic.

All persons who were unable to comprehend the nature of the study in either English or Shona (local language), had suicidal intent, had end-stage AIDS, were currently in psychiatric care, were pregnant or up to 3 months' postpartum, or presented with current psychosis, intoxication, and/or dementia were excluded. Those excluded for psychiatric reasons were referred to a tertiary health care facility in Harare. Those with suicidal ideation on the SSQ-14 but not subsequently assessed as having suicidal intent were included in the study.

Intervention

The Friendship Bench intervention has been developed over a 20-year period from community research,[16-18] as described

Figure 1. Flow Diagram of Trial Clinics and Participants



[a] Numbers do not sum to totals because reason for noneligibility was not retained at the clinic level for 2 intervention group clinics and 2 control group clinics (age <18 years, 3; refused home visits, 26; Shona Symptom Questionnaire [SSQ-14] score <9, 504; not literate, 4; no working phone, 7; medically unfit, 2; pregnant or up to 3 mo postpartum, 8; not residing in locality, 24).

previously.[14] This intervention is problem-solving therapy, in which the patient identifies a problem (eg, unemployment) rather than a diagnosis or symptom, and has been shown to be feasible and acceptable in this resource-poor setting.[7,13] The psychological approach of problem-solving therapy works through enabling a more positive orientation toward resolving problems and empowering people to have a sense of greater coping and control over their lives.[19]

In practical terms, participants were taught a structured approach to identifying problems and finding workable solutions.[20] Lay health workers followed a detailed script contained in a manual to conduct 6 sessions on a bench located in a discreet area outside the clinic.[7] The first session includes 3 components called Opening the Mind (*kuvhura pfungwa*), Uplifting (*kusimudzira*), and Strengthening (*kusimbisa*),[12] with subsequent sessions building on the first.[21] Opening the Mind refers to the therapeutic process by which, through asking questions, clients were encouraged to open their minds to identify their problems, choose one to work on, identify a feasible solution, and agree on an action plan through an iterative process guided by the LHWs.

The care model was driven by a trained and supervised LHW attached to the clinic and employed by the local health authority. After 6 sessions of individual therapy, the LHW referred those not improving or with suicidal ideation to a supervisor trained in mental health to reassess and manage the

case if needed. Participants in the intervention group received up to 6 text messages, phone calls, or both during the intervention, which reinforced the problem-solving therapy approach and encouraged participants, particularly those attending fewer than 3 sessions during the first 4 weeks, to follow their action plan. As part of the improved management program, participants were reassessed by the LHW after the third session using the SSQ-14, and those whose score had worsened by 1 scale point or more or who had suicidal ideation were assessed by a psychiatrist. These results were not used for research purposes. If participants missed a session, the LHWs followed up with a phone call, a home visit, or both if there was no response.

All LHWs in the study were female, with a mean age of 53 years and a mean of 10 years of education, able to use a mobile phone, and resided near their respective clinic. They were supervised and supported by trained senior health promotion officers who were part of the existing supervisory systems for LHWs. The LHWs were trained over 9 days using a manual written by the Friendship Bench team.[21] Topics included common mental disorders, counseling skills, problem-solving therapy, and self-care. All sessions were audio-recorded for fidelity and assessed using a checklist to ensure LHWs had covered all the critical components.

After 4 individual sessions, all intervention group participants were invited to join a peer-led group called Circle Kubatana Tose, or "holding hands together," which was part of the intervention as described in the protocol.[14] This component provided group support from women who had attended the Friendship Bench prior to the trial and who had received basic group management training by study clinicians. These weekly meetings consisted of sharing personal experiences while crocheting a bag from recycled plastic materials, the latter activity being a skill for generating income through making and selling the bags. Participants in the intervention group were also offered enhanced usual care (EUC).

Enhanced Usual Care

The control group received the standard usual care consisting of a nurse-led evaluation, brief support counseling and option for medication, as well as information, education, and support on common mental disorders including assessment for antidepressant medication prescribed by the clinic nurse, referral to a psychiatric facility, or both, if needed. Participants also received 2 to 3 supportive Short Message Service messages or calls, with the last message being a reminder to attend the 6-month assessment. Participants in both groups were not aware which group was the intervention. Further details of both the intervention and EUC have been previously reported.[14]

Outcomes

The primary outcome was SSQ-14 symptom score,[15] measured as a prespecified continuous variable at 6 months. The SSQ-14 was developed and validated in Zimbabwe and has good psychometric properties in a primary care population. It is scored from 0 to 14, with higher scores indicating worse symptoms; a cutpoint of 9 or higher has 84% sensitivity and 73% specificity for any common mental disorder.[8] The secondary outcome was prevalence of symptoms of major depressive disorder based on the 9-item Patient Health Questionnaire (PHQ-9), defined as a total score of 11 or greater on a range of 0 to 27, fulfilling criteria through a diagnostic algorithm[22] and with higher scores indicating worse symptoms. The protocol originally had the PHQ-9 cutpoint at 9 (Supplement 1). However, this was altered after validation of the PHQ-9 in the study population found that 11 was a more appropriate cutpoint.[14] Analysis of PHQ-9 scores as binary variables was prespecified in the trial protocol; however, analysis of PHQ-9 scores as continuous variables was not prespecified. Tertiary outcomes were Generalized Anxiety Disorder 7-item Scale (GAD-7) score,[8,23] with a range of 0 (best) to 12; World Health Organization Disability Assessment Schedule version 2.0 (WHODAS 2.0), a 12-item score for disability with a range of 0 (best) to 48; and EuroQOL 5D (EQ-5D) total score for health-related quality of life, with a range of 0 (best) to 25.

Sample Size

A sample of 24 clinics, each with 24 participants, provided 80% power to detect an effect size (standardized mean difference) in SSQ-14 score of 0.75 at follow-up, with 80% power and type I error of 5%, assuming a between-cluster coefficient of variation of 0.2. The effect size was based on a recent systematic review of LHW interventions, with severity of common mental disorders as an outcome.[14,24]

Statistical Analysis

Data were collected using tablet computers, uploaded to a secure server using cloud computing technology, and exported to Stata version 14.0 (StataCorp) for cleaning and analysis. Baseline characteristics were compared by trial group and follow-up status. Analyses were by intention-to-treat at the cluster level and followed a prespecified analysis plan (Supplement 2) according to CONSORT guidelines,[25] with type I error of .05 and 2-sided testing. Because of a high 6-month follow-up rate (91%), complete-case analysis was used, and missing data were not imputed at the individual level (ie, modified intention-to-treat). Analyses were based on cluster-level summary measures to take clustering by site into account, because individual-level regression methods are not robust when there are few clusters.[26]

For continuous outcomes with normally distributed residuals, the intervention effect was estimated as the difference in mean scores between groups using linear regression of the mean score (adjusted for HIV status, sex, baseline SSQ-14 score, age, and education). An approximate variance was obtained from the residual mean square from a 2-way analysis of variance of mean score on strata and group. The 95% CI was estimated from this variance with a stratified *t* test with 18 *df*. For binary outcomes, the measure of effect was the prevalence ratio, analyzed by analogous methods using logistic regression. Predefined sensitivity analyses included adjustment for age, sex, HIV prevalence, and baseline SSQ-14 score, and effect-modification by HIV status, sex, and baseline symptom severity. Education was added to the model after examining baseline characteristics by study

group. Effect modification was assessed by fitting an interaction term between intervention group and the potential effect modifier on the cluster-level regression analysis, with *P* value estimated by the *t* test using robust standard errors.

Results

Study Participants

Across 24 clinics, 2527 people were assessed for eligibility (Figure 1) and 1854 (73.4%) were excluded. The main reason for exclusion was an SSQ-14 score less than 9 (n = 1550), followed by nonresidence in the locality (n = 128). Of 673 people eligible for the study, 100 (15%) did not consent, leaving 573 participants enrolled (286 in the intervention group and 287 in the EUC control group). Recruitment took place from September to December 2014 (median of 4 days of screening per clinic). The mean number of participants per cluster was 23.9 (range, 22-26). Most participants were women (86.4%), married (67.5%), with a median age of 33 years (interquartile range [IQR], 27-41) (**Table 1**). The mean SSQ-14 score at baseline was almost the same across groups (10.4 [SD, 1.33] and 10.5 [SD, 1.33]) (Table 1). HIV status was known for 498 participants (87.3%), and prevalence was high (41.7%), as was the proportion with suicidal ideation (13.1%). Participants in the intervention group were more likely to be women, younger and better educated, and less likely to be HIV positive. At enrollment, most participants (n = 431 [75.1%]) listed 3 or more problems that they were experiencing, with 74.1% reporting physical illness, 70.1% domestic violence/upheaval, and 66.2% loss of income. Prevalence of hypertension was 9.6%, and 1.6% had diabetes.

Overall, 521 participants (91%) completed a 6-month follow-up interview (Figure 1), with similar follow-up in men and women (92% and 91%). The median time between enrollment and follow-up was 171 days (IQR, 166-176) in the intervention group and 173 days (IQR, 168-176) in the control group.

Outcome Evaluation

The primary outcome of SSQ-14 scores for common mental disorders was lower in the intervention group than in the EUC control group (mean, 3.81; 95% CI, 3.28 to 4.34 vs 8.90; 95% CI, 8.33 to 9.47; adjusted mean difference [AMD] in SSQ-14 score, −4.86; 95% CI, −5.63 to −4.10; $P < .001$) (**Table 2**). The prevalence ratio for symptoms of depression via prespecified binary variable analysis was lower in the intervention group than in the control group (13.7% vs 49.9%; adjusted rate ratio, 0.28; 95% CI, 0.22 to 0.34; $P < .001$). Similarly, there was improvement in depression symptoms as measured by nonprespecified continuous variables for the PHQ-9 scores (AMD, −6.36; 95% CI, −6.45 to −5.27; $P < .001$). There was also improvement in the tertiary outcomes symptoms of generalized anxiety measured by GAD-7 scores (AMD, −5.73; 95% CI, −6.61 to −4.85; $P < .001$), disability measured by WHODAS 2.0 scores (AMD, −6.08; 95% CI, −7.46 to −4.71; $P < .001$), and health-related quality of life measured by EQ-5D scores (AMD, 0.12; 95% CI, 0.08 to 0.17; $P < .001$) (Table 2). The prevalences of depression symptoms, anxiety symptoms, and disability were each lower in the intervention group compared with the control group at follow-up (adjusted risk ratios: PHQ-9 diagnostic algorithm, 0.23; 95% CI, 0.15 to 0.33; GAD-7, 0.26; 95% CI, 0.19 to 0.35; SSQ-14, 0.21; 95% CI, 0.15 to 0.29; WHODAS 2.0, 0.27; 95% CI, 0.16 to 0.44) (Table 2). There was some evidence of a stronger intervention effect among participants with a higher baseline SSQ-14 score (SSQ-14 ≥11 vs <11) for tertiary outcomes (GAD-7, $P = .02$ for interaction; WHODAS 2.0, $P = .02$ for interaction) but not for SSQ-14 ($P = .19$ for interaction), PHQ-9 ($P = .10$ for interaction), or EQ-5D ($P = .20$ for interaction) (**Figure 2**).

Following sensitivity analysis, there was no evidence of effect modification by HIV status or sex for any of the outcomes. The coefficient of variation was 0.21 for the SSQ-14 and 0.24 for the PHQ-9. Missing outcome was associated with baseline SSQ-14, PHQ-9, and WHODAS 2.0 scores. Baseline SSQ-14 score was already adjusted for, and adjusting for baseline PHQ-9 and WHODAS 2.0 scores had no effect on any results.

There was no evidence of harm associated with the intervention. At follow-up, 32 participants (12.3%) in the control group and 6 (2.3%) in the intervention group were identified as having suicidal ideation.

Adherence to the Intervention

The number of problem-solving therapy sessions attended was ascertained for 267 participants (93.4%) in the intervention group. Each session lasted approximately 30 to 45 minutes, with the first session lasting about 1 hour. The median number of sessions received was 5 (IQR, 4-6), and 97 participants (39.9%) received all 6 sessions. Sessions were a median of 3 days apart (IQR, 2-4). Data on participation in the peer support group was available for 274 participants; of these, 187 (68.3%) attended at least 1 meeting. At follow-up, 8.1% of control group participants and 5.4% of intervention group participants reported receiving counseling in the previous 6 months, and 11.1% of control group participants and 7.7% of intervention group participants reported visiting a spiritual healer. Fifteen participants in the intervention group and 34 in the control group were referred to tertiary care and prescribed fluoxetine.

Discussion

Among individuals screening positive for common mental disorders in Zimbabwe, LHW administration of a primary care-based problem-solving therapy with education and support compared with standard care plus education and support resulted in improved symptomatic outcomes. There was little evidence that this effect was moderated by severity of symptoms as measured with the SSQ-14 or PHQ-9. There was some evidence of an interaction for the tertiary outcomes of disability as measured by WHODAS 2.0, anxiety as measured by GAD-7, and health-related quality of life as measured by EQ-5D, in which individuals with more severe symptoms at baseline had better outcomes, as seen in previous trials.[27]

Our findings are consistent with evidence on problem-solving therapy from high-income countries.[11] Problem-solving

Table 1. Baseline Characteristics of Study Participants by Group

Variable	Group	
	Intervention (n = 286)	Control (n = 287)
Sex, No. (%)		
Men	32 (11.2)	46 (16.0)
Women	254 (88.8)	241 (84.0)
Age group, No. (%)		
18-24 y	64 (22.4)	43 (15.0)
25-34 y	107 (37.5)	112 (39.0)
35-44 y	81 (28.4)	71 (24.7)
≥45 y	33 (11.6)	61 (21.3)
Age, mean (SD), y	33.4 (10.6)	36.7 (12.5)
Religion, No. (%)		
Christian	269 (94.7)	260 (90.6)
Other	15 (5.3)	27 (9.4)
Education, No. (%)		
Did not complete primary	21 (7.4)	32 (11.2)
Completed primary	143 (50.4)	159 (55.4)
Secondary or more	120 (42.3)	96 (33.5)
Marital status, No. (%)		
Married/cohabiting	197 (69.1)	189 (65.9)
Divorced/separated/widowed	71 (24.9)	84 (29.3)
Single	17 (6.0)	14 (4.9)
HIV status, No. (%)		
Positive	104 (36.6)	134 (46.7)
Negative	135 (47.5)	125 (43.6)
Not known	45 (15.9)	28 (9.8)
SSQ-14 score, mean (SD)[a]	10.5 (1.4)	10.4 (1.3)
PHQ-9 score, No. (%)[b]		
<11	98 (34.5)	119 (41.5)
≥11	186 (65.5)	168 (58.5)
WHODAS 2.0 score, No. (%)[c]		
<20	244 (85.9)	254 (88.5)
≥20	40 (14.0)	33 (11.5)
GAD-7 score, No. (%)[d]		
≤10	106 (39.7)	110 (40.9)
≥10	161 (60.3)	159 (59.1)
Suicidal ideation, No. (%)		
No	248 (86.7)	250 (87.1)
Yes	38 (13.3)	37 (12.9)
Reason for initial clinic visit, No. (%)		
Bringing sick family member to clinic	113 (39.5)	97 (33.8)
Medical condition other than HIV	66 (23.1)	68 (23.7)
HIV	49 (17.1)	68 (23.7)
Routine clinic visit	28 (9.8)	34 (11.8)
Antenatal	6 (2.1)	3 (1.0)
Depression	1 (0.3)	3 (1.0)
Other	21 (7.3)	14 (4.9)
Missing	2 (0.7)	0

Abbreviations: GAD-7, Generalized Anxiety Disorder 7-item Scale; HIV, human immunodeficiency virus; PHQ-9, 9-item Patient Health Questionnaire; SSQ-14, Shona Symptom Questionnaire; WHODAS 2.0, World Health Organization Disability Assessment Schedule version 2.0.

[a] Range, 0 (no symptoms) to 14 (worst possible symptoms).

[b] Range, 0 (no symptoms) to 27 (worst possible symptoms).

[c] Range, 0 (no difficulty) to 48 (worst possible difficulty).

[d] Range, 0 (no symptoms) to 21 (worst possible symptoms).

therapy is an attractive option in a low-resource context because, unlike cognitive behavior therapy, it does not require extensive training or complex skills. The trial showed benefits with peer support as a voluntary option but was not able to isolate the mechanism of action or the relative contribution of each component. Of note, peer support meetings continued after study closure and were subsequently integrated into clinic activities.

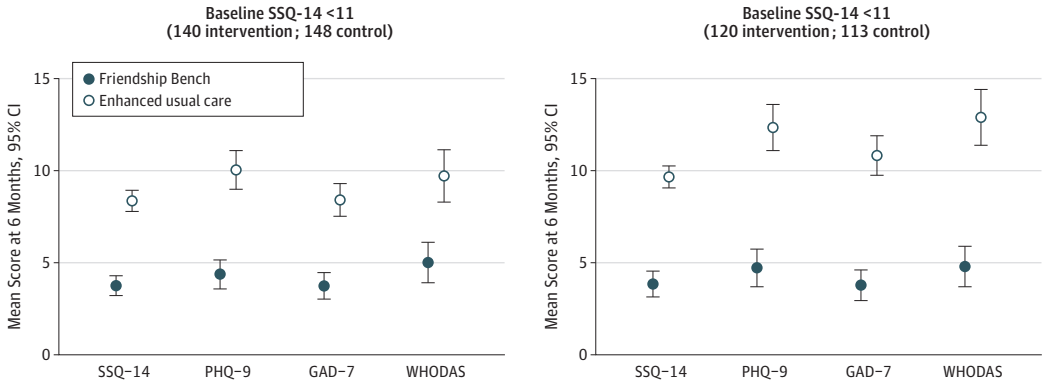
Table 2. Effect of the Friendship Bench Intervention on Scores for Common Mental Disorders, Depression Symptoms, Anxiety Symptoms, Disability, and Quality of Life at 6 Months

Outcome	Mean (95% CI)		Analysis			
	Intervention (n = 260)	Control (n = 261)	Unadjusted Mean Difference (95% CI)	*P* Value	Adjusted Mean Difference (95% CI)[a]	*P* Value
Continuous						
Primary						
SSQ-14 score	3.81 (3.28 to 4.34)	8.90 (8.33 to 9.47)	−5.09 (−5.86 to −4.31)	<.001	−4.86 (−5.63 to −4.10)	<.001
Nonprespecified secondary						
PHQ-9 score	4.50 (3.95 to 5.05)	11.01 (9.78 to 12.24)	−6.52 (−7.71 to −5.33)	<.001	−6.36 (−6.45 to −5.27)	<.001
Tertiary						
GAD-7 score	3.74 (3.27 to 4.21)	9.46 (8.68 to 10.24)	−5.71 (−6.71 to −4.71)	<.001	−5.73 (−6.61 to −4.85)	<.001
WHODAS 2.0 score	4.87 (4.32 to 5.42)	11.05 (9.56 to 12.54)	−6.18 (−7.70 to −4.67)	<.001	−6.08 (−7.46 to −4.71)	<.001
EQ-5D score	0.85 (0.83 to 0.87)	0.72 (0.68 to 0.76)	0.12 (0.08 to 0.17)	<.001	0.12 (0.08 to 0.17)	<.001
Binary	**No. (Cluster-Level Mean %)**	**No. (Cluster-Level Mean %)**	**Unadjusted Prevalence Ratio (95% CI)**		**Adjusted Prevalence Ratio (95% CI)**	
Secondary						
PHQ-9 ≥ 11	35 (13.7)	129 (49.9)	0.28 (0.22 to 0.35)	<.001	0.28 (0.22 to 0.34)	<.001
Tertiary						
PHQ-9 diagnostic algorithm	20 (8.0)	96 (35.8)	0.22 (0.15 to 0.33)	<.001	0.23 (0.15 to 0.33)	<.001
GAD-7 ≥10	31 (12.2)	123 (48.0)	0.25 (0.18 to 0.36)	<.001	0.26 (0.19 to 0.35)	<.001
SSQ-14 ≥9	37 (12.7)	171 (64.0)	0.20 (0.14 to 0.28)	<.001	0.21 (0.15 to 0.29)	<.001
WHODAS 2.0 ≥20	9 (4.6)	48 (17.8)	0.26 (0.15 to 0.44)	<.001	0.27 (0.16 to 0.44)	<.001

Abbreviations: GAD-7, Generalized Anxiety Disorder 7-item Scale; PHQ-9, 9- item Patient Health Questionnaire; SSQ-14, Shona Symptom Questionnaire; WHODAS 2.0, World Health Organization Disability Assessment Schedule version 2.0.

[a] Adjusted for age, sex, human immunodeficiency virus status, SSQ-14 score at baseline, and education.

Figure 2. Mean Scores for Common Mental Disorder Severity, Depressive Symptoms, Anxiety Symptoms, and Disability at 6 Months' Follow-up, by Group and Baseline Severity on the SSQ-14



Error bars indicate 95% CIs. For interaction: Shona Symptom Questionnaire (SSQ-14), *P* = .19; 9-item Patient Health Questionnaire (PHQ-9), *P* = .10; Generalized Anxiety Disorder 7-item Scale (GAD-7), *P* = .02; World Health Organization Disability Assessment Schedule version 2.0 (WHODAS 2.0), *P* = .02.

A strength of our study was the use of tools with local cultural validity, together with well-known measures that had been rigorously tested in our setting.[8] The intervention, developed in consultation with stakeholders, was designed to be delivered with available resources in the primary health care system.[12] Having a contextually relevant cadre of health workers to deliver the psychological therapy who were perceived as mature and trustworthy by the community is likely to have been important in forming a strong therapeutic alliance.[13,28] The study was well powered, outcome measures were locally validated, the intervention was carefully monitored, and attrition rates were very low. Friendship Bench delivered by LHWs was effective at reducing severity of common mental disorders, as measured by a range of validated tools. Several successful psychological interventions have been delivered by LHWs in Africa, but none has been scaled up.[29-32] Designing

an intervention delivered within the health system and using existing workers is key to ensuring future scalability.

Limitations

This trial had several limitations. First, end points were at 6 months, and sustainability of effect beyond this time is unknown. Second, there were few men in the study, as they are less likely to attend primary care clinics. However, in this trial men were as likely as women to join the peer support groups and to remain in follow-up. The program scale-up includes male-only peer support groups. Third, research assistants conducting follow-up interviews in the clinics could have ascertained allocation by the presence of the bench, but we attempted to minimize bias by keeping research assistants independent of intervention delivery and implementation. Fourth, some symptoms, such as insomnia and inability to function, could be due to distress as opposed to depression; however, the use of validated outcome tools for a range of common mental disorders should have minimized this risk. Few participants in either group reported receiving any form of counseling in addition to the trial, but participants may have sought help elsewhere. We were unable to collect reliable information on the prescription of medications, but we do not expect this to be high, based on our previous research[7] and the small number of people referred to tertiary care across both groups. Similarly, we were unable to ascertain whether those stepped up to see a nurse or specialist received any other more intensive treatment apart from fluoxetine. At the initial assessment, the proportion of individuals regarded as at high risk were comparable across groups. More people were referred to tertiary care in the control group than the intervention group, so any additional treatment would have reduced the differences observed between groups.

In addition, the intervention group had a lower proportion of people assessed as at higher risk of suicide at follow-up. However, as with many cluster randomized trials with relatively few clusters,[26] there was some imbalance between groups, which was adjusted for in the analysis. Moreover, data were not imputed for 9% of participants lost to follow-up and with missing data. However, missing outcome was associated with baseline SSQ-14, PHQ-9, and WHODAS 2.0 scores, and the complete-case analysis should therefore be unbiased. Last, this trial included a combination of supportive therapies (problem-solving therapy and the peer-led group) and did not permit isolated assessment of the effect of each specific therapy.

Conclusions

Among individuals screening positive for common mental disorders in Zimbabwe, LHW-administered, primary care–based problem-solving therapy with education and support compared with standard care plus education and support resulted in improved symptoms at 6 months. Scaled-up primary care integration of this intervention should be evaluated.

ARTICLE INFORMATION

Correction: This article was corrected online on February 22, 2017, to add an author missing from the Author Contributions section.

Author Contributions: Drs Weiss and Simms had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Drs Abas and Araya contributed equally.

Study concept and design: Chibanda, Weiss, Verhey, Rusakaniko, Chingono, Bere, Manda, Abas, Araya.
Acquisition, analysis, or interpretation of data: Weiss, Verhey, Simms, Munjoma, Rusakaniko, Chingono, Munetsi, Abas.
Drafting of the manuscript: Chibanda, Weiss, Verhey, Chingono, Bere, Manda, Araya.
Critical revision of the manuscript for important intellectual content: Weiss, Verhey, Simms, Munjoma, Rusakaniko, Chingono, Munetsi, Bere, Abas, Araya.
Statistical analysis: Weiss, Simms, Munjoma, Rusakaniko, Araya.
Obtained funding: Chibanda, Abas, Araya.
Administrative, technical, or material support: Verhey, Munjoma, Rusakaniko, Munetsi, Bere, Manda, Abas.
Study supervision: Chibanda, Verhey, Rusakaniko, Chingono, Bere, Abas.

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