

1 **Effect of a primary care-based psychological intervention on symptoms**
2 **of common mental disorders in Zimbabwe: a randomized clinical trial**

3
4 Dixon Chibanda MD
5 Zimbabwe AIDS Prevention Project-University of Zimbabwe Department of Community Medicine, 92 Prince
6 Edward Street, Harare, Zimbabwe
7 Email: dichi@zol.co.zw
8 Tel: +263 4 70 7289
9 Fax: +263 4 70 7291

10
11 Helen Anne Weiss D.Phil
12 MRC Tropical Epidemiology Group, London School of Hygiene and Tropical Medicine, London, UK
13 Email: helen.weiss@lshtm.ac.uk

14
15 Ruth Verhey MSc
16 Zimbabwe AIDS Prevention Project-University of Zimbabwe Department of Community Medicine, Harare,
17 Zimbabwe
18 Email: ruth.verhey@zol.co.zw

19
20 Victoria Simms PhD
21 MRC Tropical Epidemiology Group, London School of Hygiene and Tropical Medicine, London, UK
22 Email: victoria.simms@lshtm.ac.uk

23
24 Ronald Munjoma SLC
25 Zimbabwe AIDS Prevention Project-University of Zimbabwe Department of Community Medicine, Harare,
26 Zimbabwe

27 Email: simbiso@gmail.com

28

29 Simbarashe Rusakaniko PhD

30 Zimbabwe AIDS Prevention Project-University of Zimbabwe Department of Community Medicine, Harare,

31 Zimbabwe

32 Email: srusakaniko@gmail.com

33

34 Alfred Chingono MSc

35 University of Zimbabwe College of Health Sciences, Harare, Zimbabwe

36 Email: alfred@uz-ucsf.co.zw

37

38 Epiphania Munetsi MPhil

39 Zimbabwe AIDS Prevention Project-University of Zimbabwe Department of Community Medicine, Harare,

40 Zimbabwe

41 Email: emunetsi2005@yahoo.co.uk

42

43 Tarisai Bere BA

44 Zimbabwe AIDS Prevention Project-University of Zimbabwe Department of Community Medicine, Harare,

45 Zimbabwe

46 Email: tdzuda@gmail.com

47

48 Ethel Manda BSc

49 Zimbabwe AIDS Prevention Project-University of Zimbabwe Department of Community Medicine, Harare,

50 Zimbabwe

51 Email: ecmanda@gmail.com

52

53 *Melanie Abas MD
54 King's College London, Institute of Psychiatry, Psychology and Neuroscience, London, UK
55 Email: melanie.abas@kcl.ac.uk
56
57 *Ricardo Araya PhD
58 London School of Hygiene and Tropical Medicine, London, UK
59 Email: riaraya.psych@gmail.com
60 *These authors contributed equally
61
62 Word count: 3057 words

63 **Key Points**

64 **Question:** Does a lay health worker-delivered psychological intervention improve symptoms of
65 depression and anxiety in Zimbabwe?

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

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

71

72 **Abstract**

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

76 **Objective:** To evaluate the effectiveness of a culturally-adapted psychological intervention for common
77 mental disorders delivered by LHWs in primary care .

78 **Design, setting and participants:** Cluster-randomized clinical trial with 6 months follow-up conducted from
79 1 September 2014-25 May 2015 in Harare, Zimbabwe. Twenty four clinics were randomised 1:1 to the
80 intervention or enhanced usual care. Participants were clinic attenders aged ≥ 18 years who screened
81 positive for common mental disorders on the locally-validated Shona Symptom Questionnaire (SSQ-14).

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

86 **Main outcome measures:** Primary outcome was common mental disorder measured at 6 months as a
87 continuous variable via the SSQ-14 score, with a range of 0 (best)to 14 (worst) and a cut-point 9. The

88 secondary outcome was depression symptoms measured as a binary variable with the Patient Health
89 Questionnaire-9 (PHQ-9), with a range of 0 (best) to 27 (worst) and a cut-point 11). Outcomes were
90 analyzed by intention-to-treat.

91 **Results:** Among 573 randomized patients (286 in the intervention group and 287 control group), 495
92 (86.4%) were women, median age was 33 years (interquartile range 27-41 years), 238 41.7% were HIV
93 positive, and 521 (90.9%) completed follow up at 6 months. Intervention group participants had fewer
94 symptoms than control group participants on the SSQ-14 (3.81 (95% CI 3.28, 4.34) vs 8.90 (95% CI 8.33,
95 9.47), adjusted mean difference (AMD)=-4.86; 95% CI -5.63, -4.10, p<0.001; adjusted risk ratio(ARR)=0.21,
96 95% CI 0.15, 0.29, p<0.001). Intervention participants also had lower risk of symptoms of depression
97 (13.7% vs 49.9%, ARR=0.28, 95% CI 0.22, 0.34, p<0.001).

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

102 **Trial registration:** PACTR201410000876178.

103 [http://www.pactr.org/ATMWeb/appmanager/atm/atmregistry? nfpb=true& windowLabel=BasicSearchU
pdateController_1&BasicSearchUpdateController_1 actionOverride=%2Fpageflows%2Ftrial%2FbasicSearc
hUpdate%2FviewTrail&BasicSearchUpdateController_1id=876](http://www.pactr.org/ATMWeb/appmanager/atm/atmregistry? nfpb=true& windowLabel=BasicSearchU
104 pdateController_1&BasicSearchUpdateController_1 actionOverride=%2Fpageflows%2Ftrial%2FbasicSearc
105 hUpdate%2FviewTrail&BasicSearchUpdateController_1id=876)

106

107

108
109
110
111
112
113
114
115
116
117
118
119
120
121
122
123
124
125
126
127
128
129
130
131
132

Introduction

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 treatments³. When left untreated, common mental disorders can impair role functioning, self-care and adherence to treatments, and are associated with reduced productivity and increased healthcare costs⁴.

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 attendees⁵⁻⁸ 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 they can effectively provide care for a range of common mental health problems⁹. Problem solving therapy is a brief psychological therapy which 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 adjustments¹⁴. 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.

Methods

133 *Trial Design:* The study protocol has been published previously¹⁴ and is available in the Supplement. We
134 conducted a cluster-randomized clinical trial in 24 primary care clinics (clusters) in Harare, Zimbabwe, with
135 a 1:1 allocation ratio. A cluster design was used because the intervention involved training staff at clinic
136 level.

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

140 *Setting:* In each of the 12 districts of Harare there were 5-8 clinics of varying size. The largest, known as
141 polyclinics, provided broad acute and chronic services and maternity care and were staffed by up to 14
142 nurses, 8 nurse aides and 12 LHWs. A physician visited every 2 weeks. Small satellite clinics provided acute
143 services and home-based nursing care and were staffed by 1-2 nurses and nurse aides and 3-4 LHWs. From
144 42 primary care clinics in Harare, we selected 24 clinics of the largest clinics that were in accessible
145 locations with mobile network coverage, had reliable data on stratification variables, and were willing to
146 be involved in the study.

147 *Randomization and allocation concealment:* Clinics were randomized in a 1:1 ratio within 5 strata based on
148 HIV status, housing density, clinic size, and sex of patients. Restricted randomization was used to minimize
149 imbalance in key factors (HIV prevalence, clinic size, staff size, and sex ratio) as described previously¹⁴. The
150 research assistants responsible for outcome assessment were masked to the allocation.

151 *Participants:* All adults attending trial clinics during a 2-week period were informed about the study,
152 including explanation about common mental disorders and how these can affect other conditions, such as
153 hypertension, HIV, and diabetes. Following informed consent for screening, patients completed the Shona
154 Symptom Questionnaire (SSQ-14), a locally validated screening tool for common mental disorders¹⁵, re-
155 validated for this study population⁸. On each day of screening, computer-generated preprinted random
156 numbers were used to select clinic attenders based on their queue position number. All persons randomly
157 selected who were aged ≥ 18 years and resident in the area were eligible for further assessment if they
158 screened positive (≥ 9) on the SSQ-14. Screening ended when 24 participants had been enrolled. All persons

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

164 *Intervention:* The Friendship Bench intervention has been developed over a 20-year period from
165 community research¹⁶⁻¹⁸, as described previously¹⁴. This intervention is problem-solving therapy, in which
166 the patient identifies a problem (eg, unemployment) rather than a diagnosis or symptom. is the
167 intervention has been shown to be feasible and acceptable in this resource-poor setting^{7,13}. The
168 psychological approach of problem-solving therapy works through enabling a more positive orientation
169 towards resolving problems and empowering people to have a sense of greater coping and control over
170 their lives¹⁹. In practical terms participants were taught a structured approach to identifying problems and
171 finding workable solutions²⁰. Lay health workers followed a detailed script contained in a manual to
172 conduct 6 sessions on a bench located in a discreet area outside the clinic⁷. The first session includes three
173 components named Opening the Mind (*kuvhura pfungwa*), Uplifting (*kusimudzira*) and Strengthening
174 (*kusimbisa*)¹² with subsequent sessions building on the first²¹. Opening the mind refers to the therapeutic
175 process by which, through asking questions, clients were encouraged to open their minds to identify their
176 problems, choose one to work on, identify a feasible solution, and agree an action plan through an
177 iterative process guided by the LHWs. The care model was driven by a trained and supervised LHW
178 attached to the clinic and employed by the local health authority. After 6 sessions of individual therapy, the
179 LHW referred those not improving or with suicidal ideation to a supervisor trained in mental health to re-
180 assess and manage the case if needed. Participants in the intervention group received up to 6 text
181 messages and/or phone calls during the intervention, which reinforced the problem-solving therapy
182 approach and encouraged clients, particularly those attending less than 3 sessions during the first 4 weeks,
183 to follow their action plan. As part of the improved management program, clients were re-assessed by the
184 LHW after the third session using the SSQ-14, and those whose score had worsened by 1 or more or who

185 had suicidal ideation were assessed by a psychiatrist. These results were not used for research purposes. If
186 participants missed a session, the LHWs followed up with a phone call and/or a home visit if there was no
187 response.

188 All LHWs in the study were female with a mean age of 53, mean of 10 years of education, able to use a
189 mobile phone and residing near their respective clinic. They were supervised and supported by trained
190 senior health promotion officers who were part of the existing supervisory systems for LHWs. The LHWs
191 were trained over 9 days using a manual written by the Friendship Bench team²¹. Topics included Common
192 mental disorders, counselling skills, problem-solving therapy , and self-care. All sessions were audio-
193 recorded for fidelity, and assessed using a checklist to ensure LHWs had covered all the critical
194 components.

195 After 4 individual sessions, all intervention group participants were invited to join a peer-led group called
196 Circle Kubatana Tose, or “holding hands together” which was part of the intervention as described in the
197 protocol¹⁴. This component provided group support from women who had attended the Friendship Bench
198 prior to the trial and who had received basic group management training by study clinicians. These weekly
199 meetings consisted of sharing personal experiences while crocheting a bag from recycled plastic materials,
200 the latter being an income-generating skill for participants through selling the bags. Participants in the
201 intervention group were also offered enhanced usual care.

202 *Enhanced Usual Care (EUC)*: The control group received the standard usual care consisting of a nurse-led
203 evaluation, brief support counselling and option for medication, as well as information, education and
204 support on common mental disorders including assessment for anti-depressant medication prescribed by
205 the clinic nurse and/or referral to a psychiatric facility if needed. Participants also received 2-3 supportive
206 SMS messages or calls with the last message being a reminder to attend the 6-months assessment.

207 Participants in both groups were not aware which group was the intervention. Further details of both the
208 intervention and EUC have been previously reported¹⁴.

209 *Outcomes*: The primary outcome was SSQ-14 symptom score¹⁵ measured as a prespecified continuous
210 variable at 6 months. The SSQ-14 was developed and validated in Zimbabwe and has good psychometric

211 properties in a primary care population. It is scored from 0-14 with higher score meaning worse symptoms,
212 and a cut-point of ≥ 9 has 84% sensitivity and 73% specificity for any CMD.⁸ The secondary outcome was
213 prevalence of symptoms of major depressive disorder based on the Patient Health Questionnaire 9 (PHQ-
214 9), defined as a total score ≥ 11 on a range of 0-27, fulfilling criteria through a diagnostic algorithm²² and
215 with higher scores meaning worse symptoms. The protocol originally had the PHQ-9 cut-point at 9
216 (Supplement). However, this was altered after validation of the PHQ-9 in the study population found that
217 11 was a more appropriate cut-point.¹⁴ Analysis of PHQ-9 scores as binary variables was prespecified in the
218 trial protocol; however, analysis of PHQ-9 scores as continuous variables was not prespecified. Tertiary
219 outcomes were generalized anxiety disorder score (GAD-7)^{8,23} on a range of 0=best-12; WHO-DAS 2.0 12-
220 item score for disability (range 0=best-48); and EQ-5D total score for health-related quality of life (range
221 0=best-25).

222 *Sample size:* A sample of 24 clinics, each with 24 participants provided 80% power to detect an effect size
223 (standardised mean difference) in SSQ-14 score of 0.75 at follow-up, with 80% power and Type I error of
224 5%, assuming a between-cluster coefficient of variation (k)=0.2. The effect size was based on a recent
225 systematic review of LHW interventions with severity of CMD as an outcome^{14,24}.

226 *Statistical analysis:* Data were collected using tablet computers, uploaded to a secure server using cloud
227 computing technology and exported to Stata 14.0 for cleaning and analysis. Baseline characteristics were
228 compared by trial group and follow-up status. Analyses were intention-to-treat and followed a pre-
229 specified analysis plan according to CONSORT guidelines²⁵, with Type 1 error of 0.05 and 2-sided testing.
230 Due to a high follow-up response rate (91%) we used complete case analysis and missing data were not
231 imputed. Analyses were based on cluster-level summary measures to take clustering by site into account,
232 because individual-level regression methods are not robust when there are few clusters²⁶. For continuous
233 outcomes with normally distributed residuals, the intervention effect was estimated as the difference in
234 mean scores between groups using linear regression of the mean score (adjusted for HIV status, sex,
235 baseline SSQ-14 score, age and education (education appeared imbalanced between groups at baseline)).
236 An approximate variance was obtained from the residual mean square from a 2-way ANOVA of mean score

237 on strata and group. The 95% CI was estimated from this variance with a stratified t-test with 18 degrees of
238 freedom. For binary outcomes, the measure of effect was the prevalence ratio, analysed by analogous
239 methods using logistic regression. Pre-defined sensitivity analyses included adjustment for the following
240 factors: age, sex, HIV prevalence and baseline SSQ-14 score, and effect-modification by HIV status, sex,
241 and baseline symptom severity. Education was added to the model after examining baseline characteristics
242 by arm. Effect-modification was assessed by fitting an interaction term between intervention group and
243 the potential effect modifier on the cluster-level regression analysis, with p-value estimated by the t-test
244 using robust standard errors.

245

246 **Results**

247 *Study Participants:* Across 24 clinics 2527 people were assessed for eligibility (Figure 1 and supplement
248 table 1) and 1854 (73.4%) were excluded. The main reason for exclusion was an SSQ-14 score below 9
249 (n=1550) followed by non-residence in the locality (n=128). Of 673 people eligible for the study, 100 (15%)
250 did not consent, leaving 573 participants enrolled (287 in the intervention group and 286 in the EUC
251 group). Recruitment took place from September to December 2014 (median 4 days of screening per clinic).
252 The mean number of participants per cluster was 23.9 (range 22-26). Most participants were female
253 (86.4%), married (67.5%), with a median age of 33 years (interquartile range 27-41) (Table 1). The mean
254 SSQ-14 score at baseline was almost the same across groups [10.4 (SD 1.33) and 10.5 (SD 1.33)] (Table 1).
255 HIV status was known for 498 (87.3%) participants, and prevalence was high (41.7%), as was the
256 proportion with suicidal ideation (13.1%). Participants in the intervention group were more likely to be
257 female, younger and better educated, and less likely to be HIV positive. At enrolment, most participants
258 (n=431, 75.1%) listed ≥ 3 problems that they were experiencing, with 74.1% reporting physical illness,
259 70.1% domestic violence/upheaval, and 66.2% loss of income. Prevalence of hypertension was 9.6% and
260 1.6% had diabetes.

261 Overall, 521 participants (91%) completed a 6-month follow-up interview (Figure 1), with similar follow-up
262 in men and women (92% and 91%). The median time between enrolment and follow-up was 171 days (IQR
263 166-176) in the intervention group and 173 days (IQR 168-176) in the EUC group.

264 *Outcome evaluation:* The primary outcome of SSQ-14 scores for common mental disorders was lower in
265 the intervention than in the control group (mean 3.81 (95% CI 3.28-4.34) vs 8.90 (95% CI 8.33-9.47);
266 adjusted mean difference (AMD) in SSQ-14 score=-4.86; 95% CI -5.63, -4.10; p<0.001; Table 2). The
267 prevalence ratio for symptoms of depression via prespecified binary variable analysis was lower in the
268 intervention group than in the control group (13.7% vs 49.9%, adjusted rate ratio (ARR)=0.28, 95% CI 0.22,
269 0.34, p<0.001). Similarly, there was improvement in depression symptoms as measured by non-
270 prespecified continuous variables for the PHQ-9 scores (AMD=-6.36, 95% CI -6.45, -5.27; p<0.001). There
271 was also improvement in the tertiary outcomes: symptoms of generalized anxiety measured by GAD-7
272 (AMD=-5.73, 95%CI -6.61, -4.85; p<0.001); disability measured by WHO-DAS (AMD=-6.08, 95%CI -7.46, -
273 4.71; p<0.001); and health-related quality of life measured by EQ-5D scores (AMD=0.12, 95%CI 0.08, 0.17;
274 p<0.001) (Table 2). The prevalence of depression symptoms, anxiety symptoms and disability were each
275 lower in the intervention group compared to the control at follow-up (adjusted risk ratios: PHQ-9
276 diagnostic algorithm=0.23, 95% CI 0.15, 0.33; GAD-7=0.26, 95% CI 0.19, 0.35; SSQ-14=0.21, 95% CI 0.15,
277 0.29; WHO-DAS=0.27, 95% CI 0.16, 0.44; Table 2). There was some evidence of a stronger intervention
278 effect among participants with a higher baseline SSQ-14 score (SSQ-14 \geq 11 vs <11) for tertiary outcomes
279 (GAD-7, p-interaction=0.02; WHO-DAS, p-interaction=0.02) but not for SSQ-14 (p-interaction=0.19), PHQ-9
280 (p-interaction=0.10) or EQ-5D (p-interaction=0.20) (Figure 2). Following sensitivity analysis, there was no
281 evidence of effect-modification by HIV status or sex for any of the outcomes. The coefficient of variation
282 (k) was 0.21 for the SSQ-14 and 0.24 for the PHQ-9. Missing outcome was associated with baseline SSQ,
283 PHQ-9 and WHO-DAS scores. Baseline SSQ score was already adjusted for, and adjusting for baseline PHQ-
284 9 and WHO-DAS had no effect on any results. The complete-case analysis should therefore be unbiased.

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

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

296

297 **Discussion**

298 Among individuals screening positive for common mental disorders in Zimbabwe, LHW administration of a
299 primary care-based problem solving therapy with education and support compared with standard care plus
300 education and support resulted in improved symptomatic outcomes. There was little evidence that this
301 effect was moderated by severity of symptoms as measured with the SSQ-14 or PHQ-9, but some evidence
302 of an interaction for tertiary outcomes (statistically significant ($p=0.02$) for WHO-DAS and GAD-7 but not
303 for EQ-5D) in which those with more severe symptoms at baseline had better outcomes, as seen in
304 previous trials²⁷.

305 Our findings are consistent with evidence on problem-solving therapy from high income countries¹¹.
306 Problem-solving therapy is an attractive option in a low resource context because unlike cognitive
307 behaviour therapy it does not require extensive training or complex skills. The trial showed benefits with
308 peer support as a voluntary option but was not able to isolate the mechanism of action or the relative
309 contribution of each component. Of note, peer support meetings continued after study closure and were
310 subsequently integrated into clinic activities.

311 A strength of our study was the use of tools with local cultural validity together with well-known measures
312 that had been rigorously tested in our setting⁸. The intervention, developed in consultation with

313 stakeholders, was designed to be delivered with available resources in the primary health care system¹².
314 Having a contextually relevant cadre of health workers to deliver the psychological therapy who were
315 perceived as mature and trustworthy by the community is likely to have been important in forming a
316 strong therapeutic alliance^{13,28}. The study was well powered, outcome measures were locally validated, the
317 intervention was carefully monitored, and attrition rates were very low. Friendship Bench delivered by
318 LHWs was effective at reducing severity of common mental disorders as measured by a range of validated
319 tools. Several successful psychological interventions have been delivered by LHWs in Africa but none has
320 been scaled up²⁹⁻³². Designing an intervention that is delivered within the health system and using existing
321 workers is key to ensuring future scalability.

322
323 *Limitations:* This trial had several limitations. Endpoints were at 6 months and sustainability of effect
324 beyond this time is unknown. There were few men in the study, as they are less likely to attend primary
325 care clinics. However, in this trial men were as likely as women to join the peer support groups and to
326 remain in follow-up. The program scale-up includes male-only peer support groups. Research assistants
327 conducting follow-up interviews in the clinics could have ascertained allocation by the presence of the
328 Bench, but we attempted to minimize bias by keeping research assistants independent of intervention
329 delivery and implementation. Some symptoms such as insomnia and inability to function could be due to
330 distress as opposed to depression, however, the use of validated outcome tools for a range of common
331 mental disorders should have minimised this risk. Few participants in either group reported receiving any
332 form of counselling in addition to the trial, but participants may have sought help elsewhere. We were
333 unable to collect reliable information on the prescription of medications, but we do not expect this to be
334 high based on our previous research⁷ and the small number of people referred to tertiary care across both
335 groups. Similarly, we were unable to ascertain whether those stepped up to see a nurse or specialist
336 received any other more intensive treatment apart from fluoxetine. At the initial assessment the
337 proportion of individuals regarded as high-risk were comparable across groups. More people were referred
338 to tertiary care in the control than the intervention group so any additional treatment would have reduced

339 the differences observed between groups. The intervention group had a lower proportion of people
340 assessed as at higher risk of suicide at follow-up. However, as with many cluster-randomized trials with
341 relatively few clusters²⁶, there was some imbalance between groups which was adjusted for in the analysis.
342 Finally, this trial included a combination of supportive therapies (problem solving therapy and the peer-led
343 group) and did not permit isolated assessment of the effect of each specific therapy.

344 *Conclusions*

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

349

350 **Abbreviations**

351 CBT, Cognitive Behavioural Therapy; EUC, Enhanced Usual Care; LHW, Lay Health Worker; PHQ, Patient
352 Health Questionnaire; SSQ-14, Shona Symptoms Questionnaire 14.

353

354 **Competing interests**

355 The authors declare that they have no competing interests.

356 **Acknowledgements**

357 This cluster-randomized clinical trial is funded by Grand Challenges Canada (GCC) (Grant number: KCU-
358 0087-042). Helen Weiss and Victoria Simms had full access to all the data in the study and take
359 responsibility for the integrity of the data and the accuracy of the data analysis. We thank Zimbabwe
360 Health Training Support (ZHTS) for donating funds to the Friendship Bench project, and Grand Challenges
361 Canada for contributing to funding this research. We thank the City of Harare Health department for their
362 support especially Dr Prosper Chonzi MPH; the lay health workers who participated; Peta Searle MSc,
363 project coordinator for ZEEbags, for Circle Kubatana Tose innovations; and Dr Lorna Gibson PhD of the
364 London School of Hygiene and Tropical Medicine for assistance with data management. Grand Challenges

365 Canada and ZHTS had no involvement in the design and conduct of the study; collection, management,
366 analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision
367 to submit the manuscript for publication. All those acknowledged were not compensated for their
368 involvement.

369

370

371 References

372

- 373 1. Baxter AJ, Scott KM, Vos T, Whiteford HA. Global prevalence of anxiety disorders: a
374 systematic review and meta-regression. *Psychological Medicine*. 2013;43(05):897-910.
- 375 2. Ferrari AJ, Charlson FJ, Norman RE, et al. Burden of depressive disorders by country, sex,
376 age, and year: findings from the global burden of disease study 2010. *PLoS Medicine*.
377 2013;10(11):e1001547.
- 378 3. Wang PS, Aquilar-Gaxiola S, Alonso J, et al. Use of mental health services for anxiety, mood,
379 and substance disorders in 17 countries in the WHO world mental health surveys. *Lancet*.
380 2007;370(9590):841-850.
- 381 4. Patel V, Chisholm D, Parikh R, et al. Addressing the burden of mental, neurological, and
382 substance use disorders: key messages from Disease Control Priorities, 3rd edition. *Lancet*.
383 2016;387(10028):1672-1685.
- 384 5. Broadhead J, Abas M. Life events, difficulties and depression among women in an urban
385 setting in Zimbabwe. *Psychological Medicine*. 1998;28:29.
- 386 6. Patel V, Todd C, Winston M, et al. Common mental disorders in primary care in Harare,
387 Zimbabwe: associations and risk factors. *British Journal of Psychiatry*. 1997;171:60-64.
- 388 7. Chibanda D, Mesu P, Kajawu L, Cowan F, Araya R, Abas M. Problem-solving therapy for
389 depression and common mental disorders in Zimbabwe: piloting a task-shifting primary
390 mental health care intervention in a population with a high prevalence of people living with
391 HIV. *BMC Public Health*. 2011;11(1):828.
- 392 8. Chibanda D, Verhey R, Gibson LJ, et al. Validation of screening tools for depression and
393 anxiety disorders in a primary care population with high HIV prevalence in Zimbabwe.
394 *Journal of Affective Disorders*. 2016;198:50-55.
- 395 9. Patel V, Chowdhary N, Rahman A, Verdeli H. Improving access to psychological treatments:
396 lessons from developing countries. *Behavioural Research and Therapy*. 2011;49(9):523-528.
- 397 10. Seekles W, van Straten A, Beekman A, van Marwijk H, Cuijpers P. Effectiveness of guided
398 self-help for depression and anxiety disorders in primary care: a pragmatic randomized
399 controlled trial. *Psychiatry Research*. 2011;187(1-2):113-120.
- 400 11. Bell AC, D'Zurilla TJ. Problem-solving therapy for depression: a meta-analysis. *Clinical
401 Psychology Review*. 2009;29(4):348-353.
- 402 12. Chibanda D, Verhey R, Munetsi E, Cowan FM, Lund C. Using a theory driven approach to
403 develop and evaluate a complex mental health intervention: the friendship bench project in
404 Zimbabwe. *International Journal of Mental Health Systems*. 2016;10(16).
- 405 13. Abas M, Bowers T, Manda E, et al. 'Opening up the Mind': problem-solving therapy delivered
406 by lay health workers to improve access to evidence-based care for depression through the
407 Friendship Bench Project in Zimbabwe. *International Journal of Mental Health Systems*.
408 2016. 2016;10(39).

- 409 14. Chibanda D, Bowers T, Verhey R, et al. The Friendship Bench programme: a cluster
410 randomised controlled trial of a brief psychological intervention for common mental
411 disorders delivered by lay health workers in Zimbabwe. *International Journal of Mental*
412 *Health Systems*. 2015;9(1):21.
- 413 15. Patel V, Simunyu E, Gwanzura F, Lewis G, Mann A. The Shona Symptom Questionnaire: the
414 development of an indigenous measure of common mental disorders in Harare. *Acta*
415 *Psychiatrica Scandinavica*. 1997;95(6):469.
- 416 16. Abas M, Baingana F, Broadhead J, Iacoponi E, Vanderpyl J. Common mental disorders and
417 primary health care: Current practice in low-income countries. *Harvard Review of Psychiatry*.
418 2003;11(3):166.
- 419 17. Abas M, Broadhead JC, Mbape P, Khumalo-Sakatukwa G. Defeating depression in the
420 developing world: a Zimbabwean model. *The British Journal of Psychiatry*. 1994;164(3):293-
421 296.
- 422 18. Patel V, Mann A. Etic and emic criteria for non-psychotic mental disorder: a study of the CISR
423 and care provider assessment in Harare. *Social Psychiatry & Psychiatric Epidemiology*.
424 1997;32(2):84.
- 425 19. Nezu AM, Perri MG. Social problem-solving therapy for unipolar depression: An initial
426 dismantling investigation. *Journal of Consulting and Clinical Psychology*. 1989;57(3):408-413.
- 427 20. D'Zurilla TJ, Nezu AM. *Problem-solving therapy: A positive approach to clinical Intervention*.
428 third ed. New York: Spring Publishing Company; 2007.
- 429 21. Verhey R, Turner J, Chibanda D. *Friendship Bench Training Manual for Health Promoters*.
430 Harare: Zimbabwe AIDS Prevention Project;2014.
- 431 22. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity
432 measure. *Journal of General Internal Medicine*. 2001;16(9):606-613.
- 433 23. Spitzer RL, Kroenke K, Williams JB, Lowe B. A brief measure for assessing generalized anxiety
434 disorder: the GAD-7. *Archives of Internal Medicine*. 2006;166(10):1092-1097.
- 435 24. van Ginneken N, Tharyan P, Lewin S, et al. Non-specialist health worker interventions for the
436 care of mental, neurological and substance-abuse disorders in low- and middle-income
437 countries. *The Cochrane database of systematic reviews*. 2013;11:CD009149.
- 438 25. Campbell MK, Piaggio G, Elbourne DR, Altman DG, Group C. Consort 2010 statement:
439 extension to cluster randomised trials. *British Medical Journal*. 2012;345:e5661.
- 440 26. Hayes RJ, Moulton LH. *Cluster Randomised Trials*. Chapman and Hall/CRC Press; 2009.
- 441 27. Driessen E, Hollon SD. Cognitive behavioral therapy for mood disorders: efficacy, moderators
442 and mediators. *Psychiatr Clin North Am*. 2010;33(3):537-555.
- 443 28. Martin DJ, Gaske JP, Davis MK. Relation of the therapeutic alliance with outcome and other
444 variables: a meta-analytic review. *Journal of Consulting and Clinical Psychology*.
445 2000;68(3):438-50.
- 446 29. Nakimuli-Mpungu E, Wamala K, Okello J, et al. Group support psychotherapy for depression
447 treatment in people with HIV/AIDS in northern Uganda: a single-centre randomised
448 controlled trial. *Lancet HIV*. 2015;2(5):e190-e199.
- 449 30. Bolton P, Bass J, Neugebauer R, et al. Group interpersonal psychotherapy for depression in
450 rural Uganda: a randomized controlled trial. *JAMA*. 2003;289(23):117-124.
- 451 31. Bass J, Annan J, Mclvor Murray S, et al. Controlled trial of psychotherapy for Congolese
452 survivors of sexual violence. *New England Journal of Medicine*. 2013;368(23):2182-2191.
- 453 32. Ventevogel P, Spiegel P. Psychological treatments for orphans and vulnerable children
454 affected by traumatic events and chronic adversity in sub-Saharan Africa. *JAMA*.
455 2015;314(5):511-512.

456

457

458

Table 1: baseline characteristics of study participants by group

Variable	Variable parameters	Intervention group (N=286)	Control group (N=287)
Gender - no. (%)			
Male		32 (11.2)	46 (16.0)
Female		254 (88.8)	241 (84.0)
Age group (years) – no. (%)			
18-24		64 (22.4)	43 (15.0)
25-34		107 (37.5)	112 (39.0)
35-44		81 (28.4)	71 (24.7)
>=45		33 (11.6)	61 (21.3)
Mean (SD)		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)	

Variable	Variable parameters	Intervention group (N=286)	Control group (N=287)
Negative		135 (47.5)	
Not known		45 (15.9)	
SSQ-14 score	0 =no symptoms, 14=worst possible symptoms		
Mean (SD)		10.5 (1.4)	10.4 (1.3)
PHQ-9 score – no. (%)	0=no symptoms, 27=worst possible symptoms		
<11		98 (34.5)	119 (41.5)
>=11		186 (65.5)	168 (58.5)
WHO-DAS score – no. (%)	0 =no difficulty, 48=worst possible difficulty		
<20		244 (85.9)	254 (88.5)
>=20		40 (14.0)	33 (11.5)

Variable	Variable parameters	Intervention group (N=286)	Control group (N=287)
GAD-7 score - no. (%)	0 =no symptoms, 21=worst possible symptoms		
<=9		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	97
Medical condition other than HIV		66	68
HIV		49	68
Routine clinic visit		28	34
Antenatal		6	3
Depression		1	3
Other		21	14
Missing		2	0

460

461

462

463 **Table 2: Effect of the Friendship Bench intervention on scores for common mental**
 464 **disorders, depression symptoms, anxiety symptoms, disability and quality of life at 6**
 465 **months**

Outcome	Interventio	Control	Unadjusted analysis		Adjusted analysis	
	n group	group				
	N=260	N=261				
	Mean (95% CI)	Mean (95% CI)	Unadjusted mean difference (95% CI)	P value	Adjusted mean difference (95% CI) ^a	P value
Primary (continuous)						
SSQ-14 score	3.81 (3.28-4.34)	8.90 (8.33-9.47)	-5.09 (-5.86, -4.31)	<0.001	-4.86 (-5.63, -4.10)	<0.001
Non Prespecified Secondary (continuous)						
PHQ-9 score	4.50 (3.95-5.05)	11.01 (9.78-12.24)	-6.52 (-7.71, -5.33)	<0.001	-6.36 (-6.45, -5.27)	<0.001
Tertiary (continuous)						
GAD-7 score	3.74 (3.27-4.21)	9.46 (8.68-10.24)	-5.71 (-6.71, -4.71)	<0.001	-5.73 (-6.61, -4.85)	<0.001

Outcome	Interventio n group N=260	Control group N=261	Unadjusted analysis		Adjusted analysis	
WHO-DAS score	4.87 (4.32- 5.42)	11.05 (9.56- 12.54)	-6.18 (-7.70, -4.67)	<0.001	-6.08 (-7.46, -4.71)	<0.001
EQ-5D score	0.72 (0.68- 0.76)	0.85 (0.83- 0.87)	0.12 (0.08, 0.71)	<0.001	0.12 (0.08, 0.17)	<0.001
	n (cluster level mean %)	n (cluster level mean %)	Unadjusted prevalence ratio (95% CI)	p value	Adjusted prevalence ratio (95% CI)	p value
Secondary (binary)						
PHQ-9 ≥11	35 (13.7%)	129 (49.9%)	0.28 (0.22, 0.35)	<0.001	0.28 (0.22, 0.34)	<0.001
Tertiary (binary)						
PHQ-9 diagnostic algorithm	20 (8.0%)	96 (35.8%)	0.22 (0.15, 0.33)	<0.001	0.23 (0.15, 0.33)	<0.001
GAD-7 ≥10	31 (12.2%)	123 (48.0%)	0.25 (0.18, 0.36)	<0.001	0.26 (0.19, 0.35)	<0.001

Outcome	Interventio	Control	Unadjusted analysis		Adjusted analysis	
	n group	group				
	N=260	N=261				
SSQ-14 ≥9	37 (12.7%)	171 (64.0%)	0.20 (0.14, 0.28)	<0.001	0.21 (0.15, 0.29)	<0.001
WHO-DAS ≥20	9 (4.6%)	48 (17.8%)	0.26 (0.15, 0.44)	<0.001	0.27 (0.16, 0.44)	<0.001

466 ^aAdjusted for age, sex, HIV status, SSQ-14 score at baseline, and education.

467

468 **Supplement table 1: reasons for patient ineligibility by group**

	Intervention group (10 clinics)	Control group (10 clinics)	Reason for non-eligibility was not retained at clinic level (2 intervention group clinics and 2 control group clinics)
Age less than 18 years	5	7	3
Refused to allow home visits	31	14	16
SSQ score <9	499	547	504
Not literate	1	1	4
No working phone	15	18	7
Medically unfit	1	3	2
Pregnant or up to 3 months postpartum	20	10	8
Not residing in locality	58	46	24

469

Figure 1: CONSORT flow diagram of trial clinics and participants. ^aSee supplement table 1 for a complete list of reasons for patient ineligibility

Figure 2: Mean and 95% confidence interval of common mental disorder severity, depressive symptoms, anxiety symptoms and disability scores at 6 months follow-up, by group and baseline severity on the SSQ-14. Interaction p-values: SSQ-14 $p=0.19$, PHQ-9 $p=0.10$, GAD-7 $p=0.02$, WHO-DAS $p=0.02$.