Supplementary Online Content 1

Chibanda D, Weiss HA, Verhey R, et al. Effect of a primary care–based psychological intervention on symptoms of common mental disorders in Zimbabwe: a randomized clinical trial. *JAMA*. doi:10.1001/jama.2016.19102

Study Protocol

The Friendship Bench programme: A cluster randomised controlled trial of a brief psychological intervention for common mental disorders delivered by lay health workers in Zimbabwe – Study protocol

Trial registration: **PACTR201410000876178**

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Abstract

Background: Common mental disorders (CMD) are a leading cause of disability globally. Emerging evidence indicates that in low and middle income countries (LMIC) the treatment gap for CMD can be addressed through the use of trained and supervised lay health workers (LHWs). Few clinical trials have evaluated the use of such task-shifting approaches in sub-Saharan Africa. In Zimbabwe, we have successfully piloted a task-shifting intervention delivered by LHWs. This protocol describes a cluster randomised controlled trial to assess the effectiveness of this intervention.

Methods: Each of 24 randomly selected clinics from a pool of 42 in Harare will recruit 24 participants (N=576). The clinics are randomised in a 1:1 ratio to receive either the intervention package (a problem solving therapy package (PST) delivered over a 4-6 week period by LHWs (N=24) followed by a 6-week group support programme which focuses mainly on teaching a craft skill) or enhanced usual care, which includes usual care and psycho-education. Primary care attenders aged 18 years and above who score positive on a locally validated CMD screening questionnaire (Shona Symptom Questionnaire, SSQ-14) will be eligible for recruitment and asked for informed consent to participate in the trial. The primary measure is the SSQ score at 6 months.

Conclusion: This effectiveness trial using LHWs to address the treatment gap for CMD will contribute to the body of knowledge on the feasibility and ability for scale-up of interventions for CMD.

Keywords

Randomised clinical trial, depression, common mental disorders, task-shifting, low-income country, lay health workers

Background

Common mental disorders (CMD), which include depression, anxiety and somatoform disorders, are leading causes of disease burden globally [1]. In low and middle income countries (LMIC) CMD are poorly recognised and managed resulting in a large treatment gap [2]. Low cost packages of mental health care have been recommended for settings in sub-Saharan Africa, particularly stepped care approaches to managing depression [3]. This includes provision of simple psychological interventions, which can be delivered by non-specialists [4] , and referral of those who do not recover. For this to be feasible for LMIC, task-sharing approaches need to be developed due to very low numbers of mental health professionals [5]. Currently psychological interventions for depression are virtually absent in government services in most low-income African countries [3, 6].

In recent years a renewed effort to address the treatment gap through task-shifting has shown promising results in a number of LMIC [7-9]. Task-shifting involves shifting basic responsibilities to non-specialist health professionals or paraprofessionals (nurses, social and community workers) in an attempt to reduce population burden and to release specialised health resources for more complex tasks [4, 10]. There is a growing body of evidence suggesting that non-health cadres, such as LHWs, can work effectively in addressing a wide range of public health issues including mental health [11].

In Chile, low-intensity low-cost treatments for depression delivered by LHWs have been successfully integrated into primary health care [7, 12]. These types of interventions include psycho-education, components of cognitive behavioural therapy (CBT), problem solving therapy (PST) and self-help approaches [8, 9, 11]. LHWs are available and affordable and, thus, appear to be one of the most appealing cadres to incorporate in the implementation of task-shifting interventions in LMIC. However, in accordance with the World Health Organisation (WHO) guidelines, it is imperative to ensure that they receive adequate training, supervision, support, career incentives and clear job descriptions to prevent overloading of these vital resources and undermining retention rates.

In Zimbabwe, where prevalence above 20% for CMD has been reported amongst adult primary care attendees [11, 13, 14], we recently piloted a task-shifting programme called The Friendship Bench and showed evidence of

the feasibility and acceptability of using LHWs to deliver a psychological intervention for CMD [11]. However, despite these promising results, there have been no effectiveness trials of the intervention conducted to date.

This protocol describes design of a cluster randomised trial of the Friendship Bench across 24 clinics in the City of Harare Health Department. The intervention will be delivered by trained LHWs, supervised and supported by their existing supervisors, the District Health Promotion Officers (DHPOs), who are contacted in case of clients presenting with red flags, such as very high scores on the assessment tool, the Shona Symptom Questionnaire (SSQ) [15] or suicidality

Methods/Design

Preliminary work leading to the current protocol consisted of the identification, translation, back-translation and validation of study tools; working in partnership with the Harare City Health department to establish terms of engagement, to conduct a descriptive evaluation of all their clinics, and to administer an assessment of all 300 LHWs employed by this department through qualitative interviews with the aim of determining core competencies of this cadre; developing a technological platform using cloud computing to support the LHWs through task-shifting, as well as the collection and storage of data. Prior to this, 5 focus group discussions and 6 in-depth individual interviews were conducted with the LHWs, and 6 in-depth interviews were carried out with clients in order to gain their perspectives of having delivered or received the intervention. Findings from this qualitative work informed the adaptation of the intervention for the trial.

Setting: The study is being conducted in Harare, Zimbabwe. There are *at least* 42 primary health care clinics in operation around Harare with each one catering for 20,000 to 80,000 people, from the most socio-economically disadvantaged sectors of the population.

Design: The study is designed as a cluster randomised controlled effectiveness trial with a 6-month follow-up. It will be conducted in 24 primary care clinics, selected from the 42 clinics across Harare, Zimbabwe. All clinics in

Harare were eligible for selection based on a formal randomisation process attended by all City Health clinic senior staff members. Prior to randomisation, 24 of the busiest clinics were grouped into 5 strata based on HIV status, density of housing, clinic size and gender of clinic users. This stratification results in 112,000 possible allocations for allocating clinics between the two arms, and of these, 3268 allocations satisfied restricted randomisation criteria to ensure balance on HIV prevalence, clinic size, staff size and gender. An official public randomisation exercise facilitated by the Director of Health Services was carried out before commencement of the trial to select one allocation.

Sample size: The sample size of 24 clusters, each with 24 participants provides 80% power to detect an effect size of 0.75, assuming a coefficient of variation (k)=0.2. We would have 90% power to detect this effect size if the coefficient of variation is smaller (k=0.16), and 90% power to detect a larger effect size of 0.85 if k=0.19. The coefficient of variation is defined as the between-cluster variation divided by the mean value, for the outcome of interest (mean SSQ score). In the absence of this measure for each clinic, we based this on the value of k for HIV prevalence. The effect size is based on a recent systematic review, which identified 6 intervention trials of lay-health worker (LHW) led interventions with severity of CMD as an outcome. The pooled effect size for the LHW intervention vs. control at 6 months was 0.75 (95%CI 0.21 to 1.29) [4]

Subjects: All adult persons attending primary health care facilities will be sensitised verbally by a study team member who will initially inform all those waiting to be seen on the day about the study by explaining what common mental disorders are and how they can affect existing medical conditions such as hypertension, HIV, TB, diabetes. To ensure that all clinic attendees have an equal chance of being selected, 3 participants will be recruited per weekday in those clinics that have fixed days allocated for specific medical conditions such as HIV/AIDS, diabetes, hypertension. In clinics with no such medical condition-based services we will recruit participants until our total of 24 per site is reached, ensuring that the corresponding strata in the control sites receive the same approach. This will be followed by randomly selecting individuals based on randomly generated numbers from a computer. All those randomly selected will be screened with the SSQ-14, a locally validated tool with high sensitivity and specificity [15, 16]. If they score above the pre-determined cut-off point (≥9), they will

be assessed for eligibility immediately through checking exclusion criteria. Written consent will be obtained from each participant.

Inclusion criteria: All persons residing in the area and attending the local clinics who are aged 18 and above and are able to give written informed consent will be eligible for enrolment. Individuals scoring at or above a cut-off point of 9 on the *SSQ-14* [15] will be invited to participate.

Exclusion criteria: All persons who are unable to comprehend the nature of the study in either English or *Shona* (local language), have suicidal intent, end stage AIDS, are currently in psychiatric care, present with current psychosis, intoxication, and/or dementia will be excluded. All those excluded for medical reasons will be referred for appropriate care to one of two tertiary facilities in Harare. Those reported to be physically unwell by the clinic Nurse-in-Charge will be excluded. Pregnant women in the third trimester and women within the 3-months post delivery period will be excluded. All those not residing in the geographical locality or whose address can not be verified through the clinics' registry will also be excluded.

Primary outcome measure: The SSQ-14 at 6-months after entering the trial.

Secondary outcome measure: Depression as defined by the Patient Health Questionnaire (PHQ-9) using a cut point of 9 and above for caseness [17] at 6-months after entering the trial.

Intervention: The intervention consists of 6 sessions of a PST package which is delivered on a bench in a discrete area outside of the local clinic [11]. Each session will last approximately 30-45 minutes with the first session lasting up to an hour (Table 1). All sessions will be audio recorded for fidelity. LHWs will have access to immediate support through the physical presence of their immediate supervisor, a study clinical psychologist, the study coordinator and a mobile phone device to enable instant communication with team members and colleagues particularly during a home visit. The psychological approach is based on providing psycho-education (information, advice and support) together with a problem-solving module that includes a component of positive activity scheduling (behavioural activation). In addition, patients will receive up to 6 brief text messages and/or calls reinforcing the PST approach and encouraging adherence to treatment as our survey of patients utilizing

primary health facilities indicates that over 90% possess a mobile phone. Whenever necessary LHWs are encouraged to act as facilitators to help patients to get access to other sources of support using their mobile devices. The income generating component will be open to all persons assigned to the intervention arm if they chose to after receiving a minimum of 4 sessions of the PST. This component will focus on group peer support and sharing while actively crocheting a shopping bag from recycled plastic materials, the latter being a skill that can generate income for the participants. This forum will give participants an opportunity to learn through behaviour activation.

LHWs will receive supervision and support from the clinical team at site level or through mobile phones using voice calls, and where necessary SMS messaging. The SMS messaging/voice call will be sent by the LHW and where challenges such as being unable to contact participant are encountered the project coordinators will follow up with a voice call and if this yields no results a physical home visit will be carried out. The support structure is based on a pre-determined algorithym developed during the formative research. This consists of study screen tool cut-off scores, criteria for referral including assessment for "red flags" clients who are suicidal and procedure immediate referral to a tertiary facility.

The control group will receive enhanced usual care (EUC) care through the clinic which will include psychoeducation on CMD, medication if indicated and/or referral to a psychiatric facility. Participants will also receive between 2-3 supportive SMS messages or voice calls with the last SMS message or voice call being a reminder to attend the 6-months assessment.

Assessment instruments:

1. Common mental disorders (CMD) will be measured by the SSQ-14 which has been used extensively in Zimbabwe as a screening tool with reliable sensitivity and specificity [15]. The SSQ is a dichotomous 14-item questionnaire which will be administered by a research assistant who is blinded. The SSQ is a tool for detecting

CMD used largely at primary health care settings in Zimbabwe. Until recently the cut-off score for this tool was 8/14, however, following the re-validation of this tool in an HIV setting the cut-off score has been raised to 9/14.

2. Clinical diagnosis of depression will be measured by the Patient Health Questionnaire (PHQ-9). The PHQ-9 is a 9-item Likert scale which is used to make a diagnosis of depression [17]. This tool has recently been validated in Zimbabwe and the cut-off score for severe depression has been set at 20/30 following the piloting of the tool amongst LHWs. The PHQ-9 will be used to establish severity of symptoms in all participants who score above 11 on the SSQ-14. Furthermore, it will be used as a secondary outcome measure at 6 months. All participants in the intervention arm scoring $\geq$20 on the PHQ-9 will be immediately referred to a clinical psychologist for further assessment while in the control arm individuals will be referred to a tertiary facility offering psychiatric services.

Data management:

Data will be collected using tablet computers, all data is consecutively uploaded to a cloud enabling easy data handling for statistic purposes. The computing system is password protected, encrypted and only accessible to authorised study team members, any access to the system is automatically recorded. Data will be managed according to International Conference on Harmonisation guidelines for Good Clinical Practices. Participants will receive a unique study identification number recorded on all forms. Numbers will be maintained by the Project Director on a password protected, secure computer. Data will be entered into a password-protected database with independent double-data entry and a third person to resolve discrepancies. To minimize errors, range checks and skip patterns within data entry screens will be used. Database files will be exported in SAS format for bi-weekly batch error checking, monthly reporting and analysis. Data will be backed-up on an external hard-drive weekly. Recorded tapes will be transcribed into electronic records which will be backed-up on an external hard-drive after each session. All data will be kept confidential, under lock-and-key, accessible only to trained study

staff. Participants' data will be identified by an ID number only, and a link between names and ID numbers will be kept separately under lock-and-key.

Data analysis: Data will be exported to Stata for analysis. Baseline comparability will be assessed for individuals who did not consent to be part of the trial, and of participants who did not complete outcome assessments. Comparability of participants in the two arms will be assessed for potential confounding factors, notably: age, sex, HIV status and SSQ score. Due to the relatively small number of clusters, analyses will be based on cluster-level summary measures, as individual-level regression methods do not perform robustly when there are relatively few clusters per arm, especially for stratified cluster randomized trials[18]. For the primary outcome (SSQ score), the mean SSQ score for each cluster will be calculated and shown by strata and arm. The arithmetic mean and SD of these mean scores and associated 95%CI will be estimated by arm. Linear regression of the mean score on strata and arm (2-way analysis of variance (ANOVA) on arm and strata) will be used to estimate the difference in SSQ score and 95%CI associated with the intervention. For the binary outcome (proportion with depression), the risk for each cluster will be calculated, and shown by strata and arm. The mean and SD of the log risk will be used to estimate the geometric mean and associated 95%CI for each arm of the study. Linear regression of the log mean risk on strata and arm will be used to estimate the risk ratio and 95%CI. The approximate variance for the mean risks will be obtained based on the residual mean square from a 2-way ANOVA on arm and strata. A 95%CI for this will be calculated from the variance using a t-statistic with 18 degrees of freedom. Pre-defined sensitivity analyses included adjustment for the following baseline factors: age, sex, HIV prevalence, baseline SSQ score.

Ethical issues: The study will be conducted according to regulations, guidelines and principles that have been endorsed at local and international levels. The protocol was approved by the Medical Research Council of Zimbabwe (MRCZ), Kings College London (KCL), and London School of Hygiene and Tropical Medicine (LSHTM).

Discussion

The funding provided through Grand Challenges Canada has provided a unique opportunity to carry out a cluster randomized controlled trial of this promising intervention which has been running since 2006. The use of LHWs to address the treatment gap for mental, neurological and substance use disorders (MNS) particularly in LMIC has been recommended by the WHO [19]. Evidence from several LMIC indicates that this is feasible and cost-effective [7-9]. There is, however, a dearth of data on controlled trials in sub-Saharan Africa [20, 21]. This study will contribute to the much needed body of knowledge on the efficacy of psychological interventions delivered by LHWs in LMIC. Furthermore, the inclusion of a technological platform for both data collection and storage, as well as for support of the LHWs delivering the intervention, will give an opportunity to objectively assess the feasibility of supporting community health workers via e-health packages.

With HIV now considered a chronic disease this trial will also look at the feasibility of using LHWs to address the issue of co-morbidity between HIV and MNS, an approach that has been widely encouraged recently [22] .

Our study will be of interest to researchers involved in the development of psychological interventions for CMD in similar LMIC settings. It can also provide information on the feasibility of utilising the task-shifting approach promoted by the WHO.

Strengths of the study include the integration of three components (health, technological and income-generation). Moreover, the study will be innovatively addressing some of the most challenging barriers to mental health services, such as human resources, quality services, access to care facilities and medication as well as poverty. If successful, the results can be potentially scaled up to make a major contribution to improving access to treatment for CMD in Zimbabwe and secondly, it could possibly be adapted and applied across countries in the region.

With screening and treatment of CMD at primary care level becoming routine, recognition of these problems will increase and effective help will potentially be made accessible, thereby reducing suffering and decreasing referral to tertiary level.

Main weaknesses of the study include lack of blinding of some of the study team members particularly the study coordinators who will actively be involved in the recruitment process although they will not play a role in the collection and assessment of outcome measures. Despite these limitations this trial offers an opportunity to show the effectiveness of a lay health worker driven intervention to address the treatment gap for CMD in LMIC. .

Abbreviations

CBT, Cognitive Behavioural Therapy; CMD, Common Mental Disorders; EUC, Enhanced Usual Care; HIV/AIDS, Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome; LHW, Lay Health Worker; LMIC, Low- and Middle-Income Countries; MNS, Mental Neurological and Substance Use Disorders; PHQ, Patient Health Questionnaire; PST, Problem-Solving Therapy; SSQ-14, Shona Symptoms Questionnaire 14.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

- DC: review of first draft and subsequent drafts leading to the final manuscript
- TB: writing first draft and reviewing subsequent drafts leading to final manuscript
- RV: review of second, third and final draft
- SR: review of final draft
- MA: review of third and final draft
- HW: review of second and final draft
- RA: review of final draft

Acknowledgments

This cluster randomised controlled trial is funded by Grand challenges Canada (GCC).

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