

# BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email [info.bmjopen@bmj.com](mailto:info.bmjopen@bmj.com)

# BMJ Open

## Optimizing implementation strategies of the first scale-up of a primary care psychological intervention for common mental disorders in Sub-Saharan Africa: Study protocol for the Optimized Friendship Bench (OptFB)

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-045481
Article Type:	Protocol
Date Submitted by the Author:	05-Oct-2020
Complete List of Authors:	Verhey, Ruth ; University of Zimbabwe, Research Support Centre; Friendship Bench Chitiyo, Charmaine; Friendship Bench Zimbabwe Mboweni, Sandra; Friendship Bench Zimbabwe Chiriseri, Ephraim; Friendship Bench Zimbabwe Chibanda, Dixon; Friendship Bench Zimbabwe; University of Zimbabwe, Research Support Centre Healey, Andy; King's College London, IOPPN Wagenaar, Bradley; University of Washington, Department of epidemiology; University of Washington, Department of global health Araya, Ricardo; Centre for Global Mental Health and Primary Care Research,
Keywords:	MENTAL HEALTH, PRIMARY CARE, PUBLIC HEALTH, QUALITATIVE RESEARCH

SCHOLARONE™  
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

Optimizing implementation strategies of the first scale-up of a primary care psychological intervention for common mental disorders in Sub-Saharan Africa: Study protocol for the Optimized Friendship Bench (OptFB)

Author list:

Ruth Verhey <sup>a,b</sup>

Charmaine Chitiyo <sup>a</sup>

Sandra Mboweni <sup>a</sup>

Ephraim Chiriseri <sup>a</sup>

Dixon Chibanda <sup>a,b,d</sup>

Andy Healy <sup>c</sup>

Bradley H. Wagenaar <sup>e,f</sup>

Ricardo Araya <sup>c</sup>

<sup>a</sup> Friendship Bench Zimbabwe

<sup>b</sup> University of Zimbabwe

<sup>c</sup> King's College, London, UK

<sup>d</sup> London school of hygiene and tropical medicine, LSHTM, UK

<sup>e</sup> Department of Global Health, University of Washington, Seattle, WA, USA

<sup>f</sup> Department of Epidemiology, University of Washington, Seattle, WA, USA

Abstract word count: 281

Body word count: 3650

Corresponding author:

Ruth Verhey

Address: 4 Weale Road, Milton Park Harare Zimbabwe

Tel: +263773857376 Email: [ruth.verhey@friendshipbench.io](mailto:ruth.verhey@friendshipbench.io)

## Abstract

Introduction: Common mental disorders (CMDs) are a leading cause of disability globally. CMDs are highly prevalent in Zimbabwe and have been addressed by an evidence-based, task-shifting psychological intervention called the Friendship Bench (FB). The task-shifted FB program guides clients through problem solving therapy. It was scaled-up across 36 implementation sites in Zimbabwe in 2016.

Methods and analysis: This study will employ a mixed-methods framework. It aims to: (1) Use quantitative survey methodologies organized around the RE-AIM evaluation framework to assess the current scale-up of the FB intervention and classify 36 clinics according to levels of performance; (2) Use qualitative focus group discussions and semi-structured interviews organized around the Consolidated Framework for Implementation Research (CFIR) to analyze determinants of implementation success, as well as elucidate heterogeneity in implementation strategies through comparing high- and low-performing clinics; and (3) Use the results from aims 1 and 2 to develop strategies to optimize the Friendship Bench intervention and apply this model in a cluster randomized controlled trial to evaluate potential improvements among low-performing clinics. The trial will be registered with the Pan African Clinical Trial Registry ([www.pactr.org](http://www.pactr.org)). The planned randomized controlled trial for the third research aim will be registered after completing aims one and two because the intervention is dependent on knowledge generated during these phases.

Ethics and dissemination: The research protocol received full authorization from the Medical Research Council of Zimbabwe (MRCZ A/242). It is anticipated that changes in data collection tools and consent forms will take place at all three phases of the study and approval from MRCZ will be sought. All interview partners will be asked for informed consent. The research team will prioritize open access publications to disseminate research results.

## Strengths and limitations of this study

- Few evidence-based psychological interventions offered at primary health care level have been successfully scaled-up in Sub-Saharan Africa; this study is designed to deliver detailed knowledge about factors that influence the scale-up of a primary care psychological intervention (the Friendship Bench) in an African setting.
- Two widely used implementation science models, RE-AIM and CFIR, will be used to evaluate the implementation of this intervention, which was scaled up in 2016.
- This study focuses on evaluating the scaling up of evidence-based interventions and developing and testing implementation strategies to potentially optimize the routine delivery of the Friendship Bench.
- A limitation is that comprehensive implementation data is only collected three years after the scale up exercise.

Key words: Friendship Bench, Optimization, common mental disorders, CFIR, RE-AIM, Low- and middle-income countries

### 1. Introduction:

In the past 10 years, it has become apparent that mental, neurological and substance use disorders (MNS) are among the leading causes of the global disease burden <sup>1-3</sup>. Research has shown that 4 out of every 10 people in low-and-middle-income countries (LMICs) suffer from mental disorders (de Boer et al. 2008, World Health Organization, 2009a) and evidence-based mental health interventions have become a focus of research and interest <sup>4</sup>. It has been observed that the poor are disproportionately affected by mental disorders <sup>5 6</sup>. Less than 5% of people living in some LMIC receive any adequate treatment for mental health disorders <sup>7 8 9</sup>. Particularly in low- and

1  
2  
3 middle-income countries (LMIC) the lack of resources, especially trained mental health  
4 professionals, causes sub-optimal detection and management of CMD <sup>10-12</sup>.  
5 Worldwide, efforts have been made to create sustainable and affordable mental health  
6 interventions in primary care <sup>13-18</sup>. In a recent systematic review, only four studies  
7 were detected that had evaluated the implementation of a depression intervention  
8 scaled-up in routine care <sup>19</sup>. As it stands, the benefit of these evidence-based  
9 interventions is not yet reaching those populations most at need across LMICs.  
10  
11  
12  
13  
14  
15  
16

17 Zimbabwe, a country in Southern Africa with a population of 13 million has a large  
18 treatment gap for MNS. Studies show that over 30% of primary health care (PHC)  
19 users need mental health care services for mostly common mental disorders (CMD)  
20 and only 5% of these receive appropriate care <sup>20</sup>. Untreated CMD can also lead to  
21 worsening of clinical outcomes in chronic conditions such as HIV <sup>21</sup> and negatively  
22 affect economic outcomes too <sup>5</sup>. The Friendship Bench (FB) was developed in  
23 response to the existing treatment gap for mental health care in Zimbabwe and tested  
24 for its efficacy in a cluster randomized controlled trial (RCT) <sup>22</sup>.  
25  
26  
27  
28  
29  
30  
31

32 This task-shifted intervention is delivered by trained and supervised lay health workers  
33 (LHWs) who deliver problem solving therapy (PST) <sup>23</sup> on a bench located in primary  
34 health care clinics. In 2016, the FB intervention was scaled-up across Harare, Gweru  
35 and Chitungwiza and surrounding peri-urban communities in collaboration with the  
36 respective City Health departments <sup>24</sup>. The FB program was established in 72 City  
37 Health PHC clinics that are established in 36 sites (different clinic types can be found  
38 in the same site). This scaling-up exercise involved the training of more than 300  
39 LHWs in the 3 cities in Zimbabwe <sup>24</sup>. Maintenance funding for FB activities is provided  
40 by the City Health department.  
41  
42  
43  
44  
45  
46  
47  
48  
49

50 All lay health workers (LHWs) working for the FB PHC clinics in Harare, Gweru and  
51 Chitungwiza received the standard manualized training and supervision. While  
52 existing scientific evidence has shown that under ideal randomized trial conditions the  
53 FB intervention leads to clinically-significant reductions in symptoms, little  
54 implementation research has been carried out regarding the performance of  
55 Friendship Bench under routine conditions as the model is being further scaled-up  
56 across Zimbabwe.  
57  
58  
59  
60

1  
2  
3 This study will be of interest to implementation scientists, policymakers, and  
4 researchers working to scale-up primary care psychological interventions in low- and  
5 middle-income countries (LMICs) globally. Results from this study have the potential  
6 to inform future scale-up and maintenance of task-shared psychological interventions  
7 into routine Ministry of Health primary care settings.  
8  
9  
10  
11  
12

## 13 **2. Overall Study Goal**

14  
15 This research uses a mixed-methods study design and widely-used implementation  
16 frameworks to systematically analyze the performance of clinics, determinants of this  
17 performance, including implementation strategies that might differentiate high- versus  
18 low-performing clinics, and develop and test an enhanced implementation strategy to  
19 improve the performance of clinics in three cities in Zimbabwe. The study is designed  
20 to be conducted in three phases with corresponding aims.  
21  
22  
23  
24

25 Firstly (aim 1), we plan to examine how the FB is performing under real-world  
26 implementation conditions and classify existing clinics with FB into high- versus low-  
27 performing sites using differences in RE-AIM outcomes<sup>25 26</sup>.  
28  
29

30 Secondly (aim 2), we will analyse the determinants of heterogeneity in the results of  
31 phase 1 comparing high- versus low-performing clinics, mainly using the CFIR  
32 framework<sup>27</sup> and rigorously documenting changes to the original FB protocol and  
33 current implementation strategies in use.  
34  
35  
36

37 Thirdly (aim 3), we will develop and test an optimized package of FB implementation  
38 strategies based on the results of phase 2 and measure the improvement among low  
39 performing clinics using RE-AIM outcomes.  
40  
41  
42  
43  
44

## 45 **3. Study setting:**

46 The study will be conducted in primary health care clinics (PHC) in Harare, Gweru,  
47 and Chitungwiza.  
48

49 Most of the clinics in the 3 cities are located in comparable areas which are  
50 characterized by high population density and informal income generating activities  
51 often occurring in the vicinity of the clinics. Depending on their size, PHC clinics serve  
52 between 20,000-80,000 people from the most socio-economically disadvantaged  
53 sectors of the population. Clinics are differentiated into poly, satellite, and family health  
54 service clinics according to the size of the clinic and the range of services offered.  
55  
56  
57  
58  
59  
60



1  
2  
3 The most comprehensive services are offered in a Polyclinic such as pre-, post- and  
4 perinatal care, opportunistic infections (for example TB treatment), and specialized  
5 NGO-based programs (HIV testing and management, male circumcision,  
6 communicable disease awareness). Satellite and Family health clinics (FHS) offer less  
7 services. Medical doctors are not permanently present but hold clinics on specific days  
8 in poly clinics. This influences the clinic user population's composition on these  
9 particular days (for example HIV clinic day).

10  
11 Clinics in Harare, Chitungwiza and Gweru are grouped and located in the same  
12 geographical facility and these are counted as one Friendship Bench implementation  
13 site. Data will be collected in 36 implementation sites (n=28 in Harare; n=4 in Gweru;  
14 n=4 in Chitungwiza). Of these 26 Poly clinics, six are FHS and four satellite clinics  
15 (see figure 1).

16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26 Figure 1: Clinic type distribution for Harare, Gweru and Chitungwiza  
27  
28  
29  
30  
31

32  
33 Depending on their size and catchment area, FB implementation sites have between  
34 one (1) and fourteen (14) LHWs who deliver the FB intervention on benches in the  
35 clinic premises during clinic opening times. Clinic users are informed about the about  
36 FB services and mental health through group or individual talks in the clinic's waiting  
37 areas. Community members are also directly in contact with LHWs during outreach  
38 activities in the community.  
39  
40  
41  
42  
43  
44  
45  
46

#### 47 **4. Methods**

48 This study proposes a rigorous analysis of the multiple interconnecting factors using  
49 two internationally recognized implementation research methods – the RE-AIM model  
50 <sup>26</sup> and the CFIR <sup>27</sup> which will be described in more detail below. Both conceptual  
51 frameworks have been used widely in implementation research for health care delivery  
52 in order to deepen the understanding and evaluation of interventions such as the  
53 Friendship Bench. The study has three research aims which are linked contextually to  
54 each other and are described in detail below.  
55  
56  
57  
58  
59  
60

#### 4.1 Methods Aim 1

A thorough analysis of the existing routine health information system data collected by the Harare, Gweru and Chitungwiza City Health authorities will be carried out to learn about the Friendship Bench activities at individual clinic level. This data consists of user numbers, age, gender, HIV status, clients' screening tool scores, and number of sessions.

We will use the RE-AIM evaluation framework to evaluate the current implementation performance of the FB intervention after three years of implementation experience. Routinely collected data will be used to assess the FB intervention's real-world and pragmatic performance: Reach, Effectiveness, Adoption, Implementation, and Maintenance. The research team which consists of experienced global mental health researchers and clinicians will develop indicators for each of the RE-AIM domains based on expert consensus and availability of data. These indicators will then be used to design a questionnaire to guide the RE-AIM related data collection. Each indicator will comprise a numerator and a denominator populated with data collected from the clinic records and the planned observations.

The data on the FB implementation will be analyzed for each of the 36 participating clinics. Routinely collected data includes clinical registries for both nurses and LHWs and data from the FB Register (commonly known as the "green book") where the LHWs record beneficiary information.

In addition, LHWs will be observed during all aspects of their work, including giving health talks, interacting with clients, and delivering the FB intervention. We will observe and record whether all FB related tools such as questionnaires and intervention tools are used.

In order to collect additional necessary data for AIM 1, key respondents will be interviewed using a questionnaire that will be developed by the research team.

We plan to interview at least 2 LHWs per clinic and in clinics with more than 2 LHWs, we will interview 50% of the present LHWs by randomly selecting them. Papers with their names will be put in a container from which a RA will pull out the appropriate number in the LHWs' presence. We will always interview the supervisor LHW of each clinic if this position is taken in a particular clinic. We will also interview the nurse in

1  
2  
3 charge in every clinic and the associated district health promoting officers (DHPOs)  
4 (n=10). Data will be collected from June to September 2019 in all participating sites.  
5  
6  
7

8 The data collection will be carried out by two research coordinators who will lead two  
9 teams of four trained and supervised research assistants (RAs). The teams will visit  
10 each clinic for two days. The clinics will be sensitized about the FB team visit a week  
11 prior. The research assistants will be trained to interview, to observe and record the  
12 FB related activities in the clinic and how to enter the data digitally using tablet  
13 computers. They will be trained on data checking, cleaning and uploading.  
14  
15  
16  
17  
18  
19

20 Furthermore, we are planning to audio-record FB sessions with consenting clients (two  
21 per site, n=72). The recordings will be translated, transcribed and rated according to  
22 the Friendship Bench fidelity checklist.  
23  
24

25 The FB fidelity checklist assesses for communication skills of the counselor, the level  
26 of psychoeducation that is done, and the adherence to the problem-solving therapy  
27 steps that the FB counselor is trained to deliver (see Supplementary Appendix A for  
28 full fidelity checklist which was developed for the RCT <sup>22</sup>). The assessments of audio  
29 recordings will be done by trained FB research team members who will prepare an  
30 audio-recorder which will be left with the FB counselor after a client has given consent.  
31 The audio recording device will be retrieved by the research assistant when the LHW  
32 has indicated that the session is done.  
33  
34  
35  
36  
37  
38

39 In the event that no clients come to the clinic on both days that the FB team visits the  
40 site or no client consents to have their session audio-recorded, this will be entered as  
41 missing. Due to logistic and financial constraints a repeat visit to a particular clinic will  
42 not be possible.  
43  
44  
45

46 All respondents will be asked to answer the questions with regards to FB activities in  
47 the past month. According to their position with regards to FB activities, questions  
48 might be formulated slightly differently.  
49  
50  
51  
52

53 The questionnaires will be administered using tablet computers (Lenovo), all  
54 observational data will be entered digitally after their correctness has been ascertained  
55 by asking interviewees to show evidence as applicable. Questionnaires and  
56 observation guides are programmed into the tablets using Kobotoolbox  
57  
58  
59  
60

(<https://www.kobotoolbox.org>) which is a data collection tool. Collected data will be cleaned and uploaded daily to a password secured server.

The research team will also observe FB specific activities such as health and 'mobilization' talks that are given by the clinic staff including the LHWs whilst patients are waiting to be seen.

A stakeholder meeting will be held once Aim 1 data is completed and the data is analyzed. At this meeting, the research team will present the results from Aim 1 and discuss potential reasons why we might see the differences in implementation across sites with stakeholders. This meeting will be attended by all relevant clinic staff, health authority officers as well as clients. Information from stakeholders will be used to select and prioritize CFIR constructs to include in qualitative interview guides for Aim 2.

#### **4.1.1 Data Analysis Aim 1**

The goal of Aim 1 is to classify the 36 FB implementation sites on their performance based on the RE-AIM outcomes. Our methods will follow similar classification efforts previously published<sup>28</sup>. Clinics will be first ranked according to their performance within each individual measure. Clinics score on all indicators within one construct (for example reach) will be averaged. For each of the RE-AIM constructs, every clinic will thus have an averaged ranking.

These domain-based rankings will be averaged per clinic rankings giving an overall ranking by calculating simple means of all domain rankings. In case of same outcomes for clinics, we will treat these particular clinics as being on the same rank. This will give us a final composite rank for each clinic which will be used to determine the 10 highest and 10 lowest performing clinics that will be qualitatively assessed in Aim 2.

#### **4.2 Methods Aim 2**

With the aim to understand the determinants of implementation success, as well as differences in implementation strategies employed, Aim 2 will utilize focus-group discussions organized around the Consolidated Framework for Implementation Research (CFIR)<sup>29-31</sup>. Through these qualitative methods, we aim to gain a deeper

1  
2  
3 understanding of the factors that contribute to the successful implementation  
4 comparing high- with low-performing clinics. The CFIR framework focuses on an  
5 overview of potential multi-level determinants of health care delivery. It was designed  
6 to help understand integrated implementation determinants across multiple levels  
7 (clients; implementers; organizations; contexts; processes).  
8  
9

10  
11  
12  
13 For the present study, we will focus on determinants of implementation success, taking  
14 lessons from both high- and low-performing clinics to inform the development of an  
15 improved package of implementation strategies targeting identified barriers.

16  
17 Focus group discussions (FDGs) with key informants (LHWs, nurses, DHPOs, clients)  
18 of the 10 high and 10 low performing clinics will be carried out by trained qualitative  
19 researchers. The FB specific interview guides for these group discussions and  
20 interviews will be developed by the study team in a sequence of internal project  
21 meetings using the online technical support website [www.cfirguide.org](http://www.cfirguide.org). The results of  
22 Aim 1 will guide us in designing the interview guides for the focus group discussions.  
23 The outcome of the stakeholders meeting in which we present the results of Aim 1 will  
24 also give us insight on the importance of constructs which we will take into account  
25 when designing the CFIR interview guides.  
26  
27

28  
29 Interview guides will be translated into the local language Shona and all group  
30 discussions will be audio-recorded, transcribed and translated to English. All  
31 discussions will be held in the local language.  
32  
33

34  
35 The FGD participants will be selected from all 10 low and high performing clinics,  
36 respectively. We will interview LHWs, nurses, DHPOs in their role as implementers  
37 as well as clients as recipients of the intervention. Focus group discussions will take  
38 place in clinics or, if not possible, in the Friendship Bench office in Harare.  
39  
40

#### 41 42 43 44 45 46 47 48 **4.2 1 Data Analysis Aim 2**

49  
50 CFIR analyses will follow the original Damschroder methodology previously published  
51 <sup>30</sup>. Briefly, two independent local Zimbabwean reviewers will code each FGD transcript  
52 according to the selected CFIR constructs. Differences will be discussed and revised  
53 until final codes are agreed on. Facility-level case memos will be organized by the  
54 relevant CFIR construct, using each new transcript to confirm and refine statements  
55 until all transcripts are coded. This process will be closely supported by the whole  
56  
57  
58  
59  
60

1  
2  
3 research team. Each clinic will have two case memos, one for LHWs and other  
4 implementers and one for clients.

5  
6 Using case memos and supporting transcripts, the same two coders will independently  
7 rate CFIR constructs on valence (X (mixed); 0 (neutral); + (construct has a positive  
8 effect on implementation) or – (construct has a negative influence on implementation).  
9  
10 Once drafted, the entire research team will meet and use a deliberated consensus to  
11 finalize memos, constructs, and valence. These data will be mapped on a matrix  
12 template with the goal of identifying constructs that differ between facilities with high  
13 and low performance to identify factors relevant for the success of the implementation.  
14  
15 Analyses will progress with visual inspection of patterns in constructs and valence by  
16 high versus low performing clinics, as well as examining median and mean valence  
17 by high versus low performing clinics. Once distinguishing constructs are identified,  
18 the team will re-review case memos and coded transcripts to gather more information  
19 on constructs.  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30

### 31 **4.3 Aim 3**

32 In Aim 3, we will develop a package of optimized Friendship Bench (OptFB)  
33 implementation strategies matched to key barriers identified in the previous phases of  
34 this study. Using CFIR data on barriers / facilitators to high-quality FB implementation,  
35 we will use the CFIR-ERIC matching tool to examine and select implementation  
36 strategies to address key CFIR constructs discriminating between high and low  
37 performing clinics in Aim 1 (<https://cfirguide.org/choosing-strategies/>)<sup>32 33</sup>. Once a  
38 preliminary list is developed by our team, the CFIR-Expert Recommendation for  
39 Implementation Change (ERIC) matching tool<sup>32</sup> will be used to prioritize those  
40 strategies that are found to be most likely to address CFIR barriers in low-performing  
41 clinics<sup>33 34</sup>.

42  
43 We will engage in a participatory stakeholder Delphi rating exercise to select specific  
44 strategies. This will be followed by the research team specifying and tailoring the  
45 strategies for the Zimbabwean context by including the additional information gained  
46 from the stakeholders. Aspects of feasibility, affordability and effectiveness will guide  
47 this process in order for the package to be meaningful and effective<sup>35</sup>. Strategies  
48 currently in use by high performing clinics will be also considered for the optimized  
49 Friendship Bench (OptFB) implementation strategies.  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 This OptFB package or intervention of improved strategies will be tested in low-  
4 performing clinics. Ongoing RE-AIM data is being collected on a monthly basis in each  
5 clinic. Using these data on RE-AIM outcomes, we will re-classify clinics using a similar  
6 process as in Aim 1. We will then identify the 18 lowest performing clinics and  
7 randomly select 12 clinics to deliver the OptFB and 6 to act as control clinics over a  
8 period of 6 months. The primary outcome will be a composite measure of RE-AIM  
9 indicators (Reach, Effectiveness, Adoption and Implementation and Maintenance)  
10 estimated at 6-month after the commencement of the implementation of the OptFB  
11 intervention. We will estimate changes in this composite measure of implementation  
12 before and at 6 months after starting the delivery of OptFB in all clinics. We will  
13 compare the difference in means or proportions between the clinics receiving the  
14 OptFB and the control clinics using the routinely collected data. Secondary outcomes  
15 will examine performance of each of the RE-AIM outcomes separately and clinical  
16 effectiveness results at individual level. The latter will be based on individual scores to  
17 SSQ on a minimum of 20 random individuals per clinic during the 6-month period.  
18 No sample size calculation has been estimated since there are no previous studies on  
19 which to estimate an effect size, the number of clinics is small, and the main outcomes  
20 are averaged data representing clusters. Nonetheless, we expect to see larger  
21 improvements in the RE-AIM composite index score in the clinics receiving OptFB  
22 compared to the control clinics over the 6 months. As a secondary outcome measure,  
23 clinical effectiveness will be assessed based on changes on SSQ scores from baseline  
24 to 6 months for a sample of 360 individuals (18 clinics with 20 individuals each), but  
25 we do not expect this sample would have enough power to detect small differences in  
26 effectiveness across the two group of clinics. Thus, comparisons on clinical  
27 effectiveness must be considered purely descriptive and exploratory and interpreted  
28 with caution. In any case, the main outcomes of interest in this study are  
29 implementation outcomes subsumed under the domains included in the RE-AIM  
30 framework.

### 4.3.1 Data analysis Aim 3

51  
52  
53 We will use a difference-in-differences analysis comparing the groups over time.  
54 Means or proportions on outcome data will be compared across groups using  
55 descriptive statistics. Regression models will be used to estimate the effect of the  
56 intervention on the main outcomes. General estimating equations with robust  
57  
58  
59  
60



1  
2  
3 standard errors will be used to control for clustering. Potential confounders will be  
4 determined a priori and included in the regression models. Standard errors,  
5 confidence intervals, and p-values will be obtained. A similar secondary analysis will  
6 be conducted with the secondary outcome measures.  
7  
8  
9

#### 10 11 12 **4.4 Health economic analysis** 13

14  
15 Site-level data will be collected on fidelity to the OptFB implementation strategies,  
16 along with activities and resource inputs required to deliver improvement strategies  
17 and OptFB delivery costs. Economic modelling will be used to combine this information  
18 with data and evidence on clinical impact and implementation effectiveness to  
19 evaluate the cost-effectiveness of the OptFB program <sup>36</sup>.  
20  
21

22 We will also revisit clinics and re-engage with stakeholders into FGD to explore level  
23 of change in the identified CFIR domains in the intervention arm clinics.  
24

25 After completion of the trial, the strategy will also be implemented in the control arm  
26 clinics to increase the overall performance in all of participating lower performing  
27 clinics.  
28  
29  
30  
31  
32  
33  
34  
35

### 36 **5. Discussion** 37

38 This study will contribute to the knowledge about scaling up of an evidence-based  
39 task-shifted intervention in a LMIC. This is a unique opportunity to analyze the  
40 Friendship Bench in a real-world setting. As mentioned above, not many  
41 interventions have been scaled up from LMICs and therefore there is a dearth of  
42 information on how implementation strategies can be used in order to ensure a  
43 strong scaling up. With this study we hope to learn which barriers and enablers are  
44 at play in the FB scale up process. This is particularly important for us as we are  
45 expanding the FB services throughout Zimbabwe and beyond to meet the  
46 population's needs for accessible and acceptable mental health care. This effort has  
47 to be undertaken with the aim of having high fidelity to the program while considering  
48 contextual aspects. Using implementation science principles will help us to give  
49 theoretical justification and describe specifications for application for those  
50 implementation strategies that we will devise after having gone through the different  
51 stages of this research process. Evidence-based, clear and applicable guidelines of  
52  
53  
54  
55  
56  
57  
58  
59  
60



1  
2  
3 how to implement our evidence-based intervention in primary health care settings  
4 will be created and can then subsequently be used to ensure a strong  
5 implementation of FB.  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22

## References

1. Vigo D, Thornicroft G, Atun R. Estimating the true global burden of mental illness. *Lancet Psychiatry* 2016;3(2):171-8. doi: 10.1016/S2215-0366(15)00505-2 [published Online First: 2016/02/07]
2. Kessler RC, Aguilar-Gaxiola S, Alonso J, et al. The global burden of mental disorders: an update from the WHO World Mental Health (WMH) surveys. *Epidemiol Psychiatr Soc* 2009;18(1):23-33. doi: 10.1017/s1121189x00001421 [published Online First: 2009/04/22]
3. Whiteford HA, Ferrari AJ, Degenhardt L, et al. The global burden of mental, neurological and substance use disorders: an analysis from the Global Burden of Disease Study 2010. *PLoS One* 2015;10(2):e0116820. doi: 10.1371/journal.pone.0116820 [published Online First: 2015/02/07]
4. Steel Z, Marnane C, Iranpour C, et al. The global prevalence of common mental disorders: a systematic review and meta-analysis 1980–2013. *International journal of epidemiology* 2014:dyu038.
5. Lund C, De Silva M, Plagerson S, et al. Poverty and mental disorders: breaking the cycle in low-income and middle-income countries. *The Lancet* 2011;378(9801):1502-14.
6. Evans-Lacko S, Aguilar-Gaxiola S, Al-Hamzawi A, et al. Socio-economic variations in the mental health treatment gap for people with anxiety, mood, and substance use disorders: results from the WHO World Mental Health (WMH) surveys. *Psychological medicine* 2018;48(9):1560-71. doi: 10.1017/S0033291717003336 [published Online First: 2017/11/28]
7. Wang PS, Aguilar-Gaxiola S, Alonso J, et al. Use of mental health services for anxiety, mood, and substance disorders in 17 countries in the WHO world mental health surveys. *The Lancet* 2007;370(9590):841-50.
8. Mojtabai R, Olfson M, Sampson NA, et al. Barriers to mental health treatment: results from the National Comorbidity Survey Replication. *Psychological medicine* 2011;41(8):1751-61. doi: 10.1017/S0033291710002291 [published Online First: 2010/12/08]

- 1  
2  
3 9. Kohn R, Saxena S, Levav I, et al. The treatment gap in mental health care. *Bull World Health Organ* 2004;82(11):858-66. doi: /S0042-96862004001100011 [published Online First: 2005/01/11]
- 7 10. Prince M, Patel V, Saxena S, et al. No health without mental health. *The lancet* 2007;370(9590):859-77.
- 9 11. Alonso J, Liu Z, Evans-Lacko S, et al. Treatment gap for anxiety disorders is global: Results of the World Mental Health Surveys in 21 countries. *Depress Anxiety* 2018;35(3):195-208. doi: 10.1002/da.22711 [published Online First: 2018/01/23]
- 13 12. Wang PS, Angermeyer M, Borges G, et al. Delay and failure in treatment seeking after first onset of mental disorders in the World Health Organization's World Mental Health Survey Initiative. *World Psychiatry* 2007;6(3):177-85. [published Online First: 2008/01/12]
- 18 13. Araya R, Rojas G, Fritsch R, et al. Treating depression in primary care in low-income women in Santiago, Chile: a randomised controlled trial. *Lancet* 2003;361(9362):995-1000. doi: 10.1016/S0140-6736(03)12825-5
- 22 14. Patel V, Thornicroft G. Packages of care for mental, neurological, and substance use disorders in low-and middle-income countries: PLoS Medicine Series. *PLoS medicine* 2009;6(10):e1000160.
- 25 15. Chatterjee S, Chowdhary N, Pednekar S, et al. Integrating evidence-based treatments for common mental disorders in routine primary care: feasibility and acceptability of the MANAS intervention in Goa, India. *World Psychiatry* 2008;7(1):39-46.
- 29 16. Rahman A, Malik A, Sikander S, et al. Cognitive behaviour therapy-based intervention by community health workers for mothers with depression and their infants in rural Pakistan: a cluster-randomised controlled trial. *The Lancet* 2008;372(9642):902-09.
- 32 17. Bolton P, Bass J, Neugebauer R, et al. Group interpersonal psychotherapy for depression in rural Uganda: a randomized controlled trial. *Jama* 2003;289(23):3117-24.
- 35 18. Lund C, Alem A, Schneider M, et al. Generating evidence to narrow the treatment gap for mental disorders in sub-Saharan Africa: rationale, overview and methods of AFFIRM. *Epidemiol Psychiatr Sci* 2015;24(3):233-40. doi: 10.1017/S2045796015000281 [published Online First: 2015/04/03]
- 40 19. Wagenaar BH, Hammett, W.H., Jackson, C., Atkins, D.L., Belus, J.M. and Kemp, C.G. Implementation outcomes and strategies for depression interventions in low-and middle-income countries: a systematic review. . *Global Mental Health* 2020;7
- 44 20. Chibanda D, Mesu P, Kajawu L, et al. Problem-solving therapy for depression and common mental disorders in Zimbabwe: piloting a task-shifting primary mental health care intervention in a population with a high prevalence of people living with HIV. *BMC public health* 2011;11:828. doi: 10.1186/1471-2458-11-828 [published Online First: 2011/10/28]
- 49 21. Antelman G, Kaaya S, Wei R, et al. Depressive symptoms increase risk of HIV disease progression and mortality among women in Tanzania. *Journal of acquired immune deficiency syndromes* 2007;44(4):470-7. doi: 10.1097/QAI.0b013e31802f1318
- 53 22. 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* 2016;316(24):2618-26. doi: 10.1001/jama.2016.19102 [published Online First: 2016/12/28]
- 57 23. Chibanda D, Bowers T, Verhey R, et al. The Friendship Bench programme: a cluster randomised controlled trial of a brief psychological intervention for common mental

- 1  
2  
3 disorders delivered by lay health workers in Zimbabwe. *Int J Ment Health Syst*  
4 2015;9:21. doi: 10.1186/s13033-015-0013-y [published Online First: 2015/01/01]  
5  
6 24. Chibanda D, Verhey R, Munetsi E, et al. Scaling up interventions for depression in sub-  
7 Saharan Africa: lessons from Zimbabwe. *Glob Ment Health (Camb)* 2016;3:e13. doi:  
8 10.1017/gmh.2016.8 [published Online First: 2016/04/11]  
9  
10 25. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health  
11 promotion interventions: the RE-AIM framework. *Am J Public Health*  
12 1999;89(9):1322-27.  
13  
14 26. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health  
15 promotion interventions: the RE-AIM framework. *American journal of public health*  
16 1999;89(9):1322-7. doi: 10.2105/ajph.89.9.1322 [published Online First: 1999/09/04]  
17  
18 27. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services  
19 research findings into practice: a consolidated framework for advancing  
20 implementation science. *Implement Sci* 2009;4:50. doi: 10.1186/1748-5908-4-50  
21 [published Online First: 2009/08/12]  
22  
23 28. Farris RP, Will JC, Khavjou O, et al. Beyond effectiveness: evaluating the public health  
24 impact of the WISEWOMAN program. *American journal of public health*  
25 2007;97(4):641-47.  
26  
27 29. Breimaier HE, Heckemann B, Halfens RJ, et al. The Consolidated Framework for  
28 Implementation Research (CFIR): a useful theoretical framework for guiding and  
29 evaluating a guideline implementation process in a hospital-based nursing practice.  
30 *BMC Nurs* 2015;14:43. doi: 10.1186/s12912-015-0088-4 [published Online First:  
31 2015/08/14]  
32  
33 30. Damschroder LJ, Lowery JC. Evaluation of a large-scale weight management program  
34 using the consolidated framework for implementation research (CFIR). *Implement Sci*  
35 2013;8:51. doi: 10.1186/1748-5908-8-51 [published Online First: 2013/05/15]  
36  
37 31. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services  
38 research findings into practice: a consolidated framework for advancing  
39 implementation science. *Implementation science* 2009;4(1):50.  
40  
41 32. Powell BJ, Waltz TJ, Chinman MJ, et al. A refined compilation of implementation  
42 strategies: results from the Expert Recommendations for Implementing Change  
43 (ERIC) project. *Implement Sci* 2015;10:21. doi: 10.1186/s13012-015-0209-1  
44 [published Online First: 2015/04/19]  
45  
46 33. Waltz TJ, Powell BJ, Fernandez ME, et al. Choosing implementation strategies to address  
47 contextual barriers: diversity in recommendations and future directions. *Implement*  
48 *Sci* 2019;14(1):42. doi: 10.1186/s13012-019-0892-4 [published Online First:  
49 2019/05/01]  
50  
51 34. Godbee K, Gunn J, Lautenschlager NT, et al. Refined conceptual model for implementing  
52 dementia risk reduction: incorporating perspectives from Australian general  
53 practice. *Aust J Prim Health* 2020;26(3):247-55. doi: 10.1071/PY19249 [published  
54 Online First: 2020/05/28]  
55  
56 35. Cooper LA, Hill MN, Powe NR. Designing and evaluating interventions to eliminate racial  
57 and ethnic disparities in health care. *J Gen Intern Med* 2002;17(6):477-86. doi:  
58 10.1046/j.1525-1497.2002.10633.x [published Online First: 2002/07/23]  
59  
60 36. Briggs A, Sculpher, M., & Claxton, K. . Decision modelling for health economic  
evaluation. Oxford: Oup Oxford 2006.

## Footnotes

## Contributors

RA designed the study and received the grant. RA is the overall PI. RV and DC are leading the study locally. CC will have oversight as project coordinator together with SM as her assistant over the data collection in all phases. BW is leading on the implantation science aspects. EC is conducting data cleaning and assisting with analysis. AH is leading on the health economics analysis. All authors will contribute to the development of questionnaires, interview guides and the strategies for the intervention. RV wrote the first version of the protocol paper. All authors contributed by critically reviewing all further drafts and approving of the final paper.

## Funding

This work was supported by Global Alliance for Chronic Diseases (GACD) through the Medical Research Council Grant number: MRC UKRI MR/S004270/1.

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public will be involved in the stakeholder meetings, they were not involved in the design, nor will they be involved in the study conduct, or reporting, or dissemination plans of this research project.

**Patient consent for publication** Not required.

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

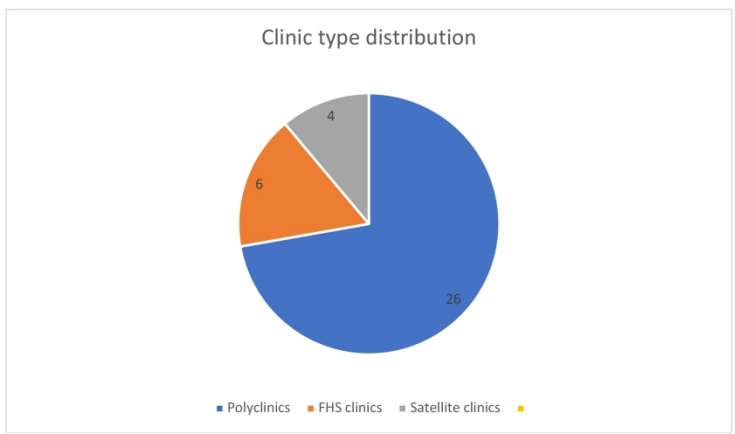


Figure 1: Clinic type distribution for Harare, Gweru and Chitungwiza



**Table 1. Checklist for audio-recorded sessions**

**LHW FIDELITY CHECKLIST**

LHW Name _____ Client's Name _____		Date        /        /        Site Code <input type="checkbox"/> <input type="checkbox"/>	
<i>(Tick where appropriate)</i>		<b>YES</b>	<b>NO</b>
1.	LHW introduced self to client and asked client to introduce self	<input type="checkbox"/>	<input type="checkbox"/>
2.	Psycho-education done properly	<input type="checkbox"/>	<input type="checkbox"/>
	a. Linked HIV to kufungisisa	<input type="checkbox"/>	<input type="checkbox"/>
	b. Adherence	<input type="checkbox"/>	<input type="checkbox"/>
	c. Diet advise done	<input type="checkbox"/>	<input type="checkbox"/>
3.	Problems presented by client	<input type="checkbox"/>	<input type="checkbox"/>
4.	LHW listening and acknowledging	<input type="checkbox"/>	<input type="checkbox"/>
5.	LHW gives summary of problems	<input type="checkbox"/>	<input type="checkbox"/>
6.	Client selected problem, not LHW	<input type="checkbox"/>	<input type="checkbox"/>
7.	LHW and client discuss problem identified by client	<input type="checkbox"/>	<input type="checkbox"/>
8.	Client identifies solutions to the problem identified	<input type="checkbox"/>	<input type="checkbox"/>
9.	LHW and client identify task for client to work with	<input type="checkbox"/>	<input type="checkbox"/>
10.	Session closure and next correct review date	<input type="checkbox"/>	<input type="checkbox"/>
<b>Total</b>		___/10	___/10

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. *BMJ*. 2013;346:e7586

		Reporting Item	Page Number
<b>Administrative information</b>			
Title	<a href="#">#1</a>	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet registered, name of intended registry	n/a
Trial registration: data set	<a href="#">#2b</a>	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	<a href="#">#3</a>	Date and version identifier	
Funding	<a href="#">#4</a>	Sources and types of financial, material, and other support	2
Roles and responsibilities: contributorship	<a href="#">#5a</a>	Names, affiliations, and roles of protocol contributors	17

1	Roles and	<a href="#">#5b</a>	Name and contact information for the trial sponsor	n/a
2	responsibilities:			
3	sponsor contact			
4	information			
5				
6				
7				
8	Roles and	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study design;	n/a
9	responsibilities:		collection, management, analysis, and interpretation of data;	
10	sponsor and funder		writing of the report; and the decision to submit the report for	
11			publication, including whether they will have ultimate authority	
12			over any of these activities	
13				
14				
15				
16	Roles and	<a href="#">#5d</a>	Composition, roles, and responsibilities of the coordinating	n/a
17	responsibilities:		centre, steering committee, endpoint adjudication committee,	
18	committees		data management team, and other individuals or groups	
19			overseeing the trial, if applicable (see Item 21a for data	
20			monitoring committee)	
21				
22				
23				
24	<b>Introduction</b>			
25				
26	Background and	<a href="#">#6a</a>	Description of research question and justification for undertaking	3
27	rationale		the trial, including summary of relevant studies (published and	
28			unpublished) examining benefits and harms for each intervention	
29				
30				
31				
32	Background and	<a href="#">#6b</a>	Explanation for choice of comparators	n/a
33	rationale: choice of			
34	comparators			
35				
36				
37	Objectives	<a href="#">#7</a>	Specific objectives or hypotheses	4
38				
39				
40	Trial design	<a href="#">#8</a>	Description of trial design including type of trial (eg, parallel	4
41			group, crossover, factorial, single group), allocation ratio, and	
42			framework (eg, superiority, equivalence, non-inferiority,	
43			exploratory)	
44				
45				
46	<b>Methods:</b>			
47	<b>Participants,</b>			
48	<b>interventions, and</b>			
49	<b>outcomes</b>			
50				
51				
52				
53	Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic, academic	5
54			hospital) and list of countries where data will be collected.	
55			Reference to where list of study sites can be obtained	
56				
57				
58				
59				
60				



1	Eligibility criteria	<a href="#">#10</a>	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
2				
3				
4				
5				
6	Interventions:	<a href="#">#11a</a>	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-11
7	description			
8				
9				
10	Interventions:	<a href="#">#11b</a>	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a
11	modifications			
12				
13				
14				
15	Interventions:	<a href="#">#11c</a>	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	n/a
16	adherence			
17				
18				
19				
20	Interventions:	<a href="#">#11d</a>	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
21	concomitant care			
22				
23				
24	Outcomes	<a href="#">#12</a>	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-10
25				
26				
27				
28				
29				
30				
31				
32				
33				
34	Participant timeline	<a href="#">#13</a>	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	n/a
35				
36				
37				
38				
39				
40	Sample size	<a href="#">#14</a>	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	n/a
41				
42				
43				
44				
45	Recruitment	<a href="#">#15</a>	Strategies for achieving adequate participant enrolment to reach target sample size	n/a
46				
47				
48				
49	<b>Methods: Assignment</b>			
50	<b>of interventions (for</b>			
51	<b>controlled trials)</b>			
52				
53				
54	Allocation: sequence	<a href="#">#16a</a>	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be	n/a
55	generation			
56				
57				
58				
59				
60				

provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism	<a href="#">#16b</a>	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a
Allocation: implementation	<a href="#">#16c</a>	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
Blinding (masking): emergency unblinding	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
<b>Methods: Data collection, management, and analysis</b>			
Data collection plan	<a href="#">#18a</a>	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7-10
Data collection plan: retention	<a href="#">#18b</a>	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a
Data management	<a href="#">#19</a>	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9-10
Statistics: outcomes	<a href="#">#20a</a>	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9-10, 12

1	Statistics: additional	<a href="#">#20b</a>	Methods for any additional analyses (eg, subgroup and adjusted	n/a
2	analyses		analyses)	
3				
4	Statistics: analysis	<a href="#">#20c</a>	Definition of analysis population relating to protocol non-	n/a
5	population and missing		adherence (eg, as randomised analysis), and any statistical	
6	data		methods to handle missing data (eg, multiple imputation)	
7				
8				
9				
10	<b>Methods: Monitoring</b>			
11				
12	Data monitoring:	<a href="#">#21a</a>	Composition of data monitoring committee (DMC); summary of	n/a
13	formal committee		its role and reporting structure; statement of whether it is	
14			independent from the sponsor and competing interests; and	
15			reference to where further details about its charter can be found,	
16			if not in the protocol. Alternatively, an explanation of why a	
17			DMC is not needed	
18				
19				
20				
21				
22	Data monitoring:	<a href="#">#21b</a>	Description of any interim analyses and stopping guidelines,	n/a
23	interim analysis		including who will have access to these interim results and make	
24			the final decision to terminate the trial	
25				
26				
27	Harms	<a href="#">#22</a>	Plans for collecting, assessing, reporting, and managing solicited	n/a
28			and spontaneously reported adverse events and other unintended	
29			effects of trial interventions or trial conduct	
30				
31				
32				
33	Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial conduct, if any, and	n/a
34			whether the process will be independent from investigators and	
35			the sponsor	
36				
37				
38	<b>Ethics and</b>			
39	<b>dissemination</b>			
40				
41				
42	Research ethics	<a href="#">#24</a>	Plans for seeking research ethics committee / institutional review	2
43	approval		board (REC / IRB) approval	
44				
45				
46	Protocol amendments	<a href="#">#25</a>	Plans for communicating important protocol modifications (eg,	2
47			changes to eligibility criteria, outcomes, analyses) to relevant	
48			parties (eg, investigators, REC / IRBs, trial participants, trial	
49			registries, journals, regulators)	
50				
51				
52				
53	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from potential trial	8
54			participants or authorised surrogates, and how (see Item 32)	
55				
56				
57				
58				
59				
60				

1	Consent or assent:	<a href="#">#26b</a>	Additional consent provisions for collection and use of	n/a
2	ancillary studies		participant data and biological specimens in ancillary studies, if	
3			applicable	
4				
5				
6	Confidentiality	<a href="#">#27</a>	How personal information about potential and enrolled	n/a
7			participants will be collected, shared, and maintained in order to	
8			protect confidentiality before, during, and after the trial	
9				
10				
11	Declaration of interests	<a href="#">#28</a>	Financial and other competing interests for principal investigators	17
12			for the overall trial and each study site	
13				
14				
15	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial dataset, and	
16			disclosure of contractual agreements that limit such access for	
17			investigators	
18				
19				
20	Ancillary and post trial	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care, and for	n/a
21	care		compensation to those who suffer harm from trial participation	
22				
23				
24	Dissemination policy:	<a href="#">#31a</a>	Plans for investigators and sponsor to communicate trial results	2
25	trial results		to participants, healthcare professionals, the public, and other	
26			relevant groups (eg, via publication, reporting in results	
27			databases, or other data sharing arrangements), including any	
28			publication restrictions	
29				
30				
31				
32				
33	Dissemination policy:	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended use of	n/a
34	authorship		professional writers	
35				
36				
37	Dissemination policy:	<a href="#">#31c</a>	Plans, if any, for granting public access to the full protocol,	n/a
38	reproducible research		participant-level dataset, and statistical code	
39				
40				
41	<b>Appendices</b>			
42				
43	Informed consent	<a href="#">#32</a>	Model consent form and other related documentation given to	18
44	materials		participants and authorised surrogates	
45				
46				
47	Biological specimens	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and storage of	n/a
48			biological specimens for genetic or molecular analysis in the	
49			current trial and for future use in ancillary studies, if applicable	
50				
51				

None The SPIRIT checklist is distributed under the terms of the Creative Commons Attribution License CC-BY-ND 3.0. This checklist can be completed online using <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)

# BMJ Open

## Optimizing implementation strategies of the first scale-up of a primary care psychological intervention for common mental disorders in Sub-Saharan Africa: A Mixed Methods Study protocol for the Optimized Friendship Bench (OptFB)

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-045481.R1
Article Type:	Protocol
Date Submitted by the Author:	22-Mar-2021
Complete List of Authors:	Verhey, Ruth ; University of Zimbabwe, Research Support Centre; Friendship Bench Chitiyo, Charmaine; Friendship Bench Zimbabwe Mboweni, Sandra; Friendship Bench Zimbabwe Chiriseri, Ephraim; Friendship Bench Zimbabwe Chibanda, Dixon; Friendship Bench Zimbabwe; University of Zimbabwe, Research Support Centre Healey, Andy; King's College London, IOPPN Wagenaar, Bradley; University of Washington, Department of epidemiology; University of Washington, Department of global health Araya, Ricardo; Centre for Global Mental Health and Primary Care Research,
<b>Primary Subject Heading</b>:	Mental health
Secondary Subject Heading:	Global health, Communication
Keywords:	MENTAL HEALTH, PRIMARY CARE, PUBLIC HEALTH, QUALITATIVE RESEARCH

SCHOLARONE™  
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1  
2  
3 1  
4  
5 2  
6  
7 3  
8 4 Optimizing implementation strategies of the first scale-up of a primary care  
9 psychological intervention for common mental disorders in Sub-Saharan Africa: A  
10 5 Mixed Methods Study protocol for the Optimized Friendship Bench (OptFB)  
11 6  
12 7

15 8 Author list:

17 9 Ruth Verhey <sup>a,b</sup>

19 10 Charmaine Chitiyo <sup>a</sup>

21 11 Sandra Mboweni <sup>a</sup>

23 12 Ephraim Chiriseri <sup>a</sup>

25 13 Dixon Chibanda <sup>a,b,d</sup>

27 14 Andy Healey <sup>c</sup>

29 15 Bradley H. Wagenaar <sup>e,f</sup>

31 16 Ricardo Araya <sup>c</sup>

34 19 <sup>a</sup> Friendship Bench Zimbabwe

36 20 <sup>b</sup> University of Zimbabwe

38 21 <sup>c</sup> King's College, London, UK

40 22 <sup>d</sup> London school of hygiene and tropical medicine, LSHTM, UK

42 23 <sup>e</sup> Department of Global Health, University of Washington, Seattle, WA, USA

44 24 <sup>f</sup> Department of Epidemiology, University of Washington, Seattle, WA, USA

46 26 Abstract word count: 281

48 27 Body word count: 3650

51 29 Corresponding author:

53 30 Ruth Verhey

55 31 Address: 4 Weale Road, Milton Park Harare Zimbabwe

57 32 Tel: +263773857376 Email: [ruth.verhey@friendshipbench.io](mailto:ruth.verhey@friendshipbench.io)

59 33

60 34

## Abstract

Introduction: Common mental disorders (CMDs) are a leading cause of disability globally. CMDs are highly prevalent in Zimbabwe and have been addressed by an evidence-based, task-shifting psychological intervention called the Friendship Bench (FB). The task-shifted FB program guides clients through problem solving therapy. It was scaled-up across 36 implementation sites in Zimbabwe in 2016.

Methods and analysis: This study will employ a mixed-methods framework. It aims to: (1) Use quantitative survey methodologies organized around the RE-AIM evaluation framework to assess the current scale-up of the FB intervention and classify 36 clinics according to levels of performance; (2) Use qualitative focus group discussions and semi-structured interviews organized around the Consolidated Framework for Implementation Research (CFIR) to analyze determinants of implementation success, as well as elucidate heterogeneity in implementation strategies through comparing high- and low-performing clinics; and (3) Use the results from aims 1 and 2 to develop strategies to optimize the Friendship Bench intervention and apply this model in a cluster randomized controlled trial to evaluate potential improvements among low-performing clinics. The trial will be registered with the Pan African Clinical Trial Registry ([www.pactr.org](http://www.pactr.org)). The planned randomized controlled trial for the third research aim will be registered after completing aims one and two because the intervention is dependent on knowledge generated during these phases.

Ethics and dissemination: The research protocol received full authorization from the Medical Research Council of Zimbabwe (MRCZ A/242). It is anticipated that changes in data collection tools and consent forms will take place at all three phases of the study and approval from MRCZ will be sought. All interview partners will be asked for informed consent. The research team will prioritize open access publications to disseminate research results.



## Strengths and limitations of this study

- Few evidence-based psychological interventions offered at primary health care level have been successfully scaled-up in Sub-Saharan Africa; this study is designed to deliver detailed knowledge about factors that influence the scale-up of a primary care psychological intervention (the Friendship Bench) in an African setting.
- Two widely used implementation science models, RE-AIM and CFIR, will be used to evaluate the implementation of this intervention, which was scaled up in 2016.
- This study focuses on evaluating the scaling up of evidence-based interventions and developing and testing implementation strategies to potentially optimize the routine delivery of the Friendship Bench.
- A limitation is that comprehensive implementation data is only collected three years after the scale up exercise.

Key words: Friendship Bench, Optimization, common mental disorders, CFIR, RE-AIM, Low- and middle-income countries

### 1. Introduction:

In the past 10 years, it has become apparent that mental, neurological and substance use disorders (MNS) are among the leading causes of the global disease burden<sup>1-3</sup>. Research has shown that 4 out of every 10 people in low-and-middle-income countries (LMICs) suffer from mental disorders (de Boer et al. 2008, World Health Organization, 2009a) and evidence-based mental health interventions have become a focus of research and interest<sup>4</sup>. It has been observed that the poor are disproportionately affected by mental disorders<sup>5,6</sup>. Less than 5% of people living in some LMIC receive any adequate treatment for mental health disorders<sup>7,8,9</sup>. Particularly in low- and

1  
2  
3 1 middle-income countries (LMIC) the lack of resources, especially trained mental health  
4 professionals, causes sub-optimal detection and management of CMD <sup>10-12</sup>.  
5 2  
6 Worldwide, efforts have been made to create sustainable and affordable mental health  
7 3  
8 interventions in primary care <sup>13-18</sup>. In a recent systematic review, only four studies  
9 4  
10 were detected that had evaluated the implementation of a depression intervention  
11 5  
12 scaled-up in routine care <sup>19</sup>. As it stands, the benefit of these evidence-based  
13 6  
14 interventions is not yet reaching those populations most at need across LMICs.  
15 7  
16 8

17 9 Zimbabwe, a country in Southern Africa with a population of 13 million has a large  
18 10  
19 treatment gap for MNS. Studies show that over 30% of primary health care (PHC)  
20 11  
21 users need mental health care services for mostly common mental disorders (CMD)  
22 12  
23 and only 5% of these receive appropriate care <sup>20</sup>. Untreated CMD can also lead to  
24 13  
25 worsening of clinical outcomes in chronic conditions such as HIV <sup>21</sup> and negatively  
26 14  
27 affect economic outcomes too <sup>5</sup>. The Friendship Bench (FB) was developed in  
28 15  
29 response to the existing treatment gap for mental health care in Zimbabwe and tested  
30 16  
31 for its efficacy in a cluster randomized controlled trial (RCT) <sup>22</sup>.  
32 17

33 18 This task-shifted intervention is delivered by trained and supervised lay health workers  
34 19  
35 (LHWs) who deliver problem solving therapy (PST) <sup>23</sup> on a bench located in primary  
36 20  
37 health care clinics. In 2016, the FB intervention was scaled-up across Harare, Gweru  
38 21  
39 and Chitungwiza and surrounding peri-urban communities in collaboration with the  
40 22  
41 respective City Health departments <sup>24</sup>. The FB program was established in 72 City  
42 23  
43 Health PHC clinics that are established in 36 sites (different clinic types can be found  
44 24  
45 in the same site). This scaling-up exercise involved the training of more than 300  
46 25  
47 LHWs in the 3 cities in Zimbabwe <sup>24</sup>. Maintenance funding for FB activities is provided  
48 26  
49 by the City Health department.  
50 27

51 28 All lay health workers (LHWs) working for the FB PHC clinics in Harare, Gweru and  
52 29  
53 Chitungwiza received the standard manualized training and supervision. While  
54 30  
55 existing scientific evidence has shown that under ideal randomized trial conditions the  
56 31  
57 FB intervention leads to clinically-significant reductions in symptoms, little  
58 32  
59 implementation research has been carried out regarding the performance of  
60 33  
34 Friendship Bench under routine conditions as the model is being further scaled-up  
across Zimbabwe.

1 This study will be of interest to implementation scientists, policymakers, and  
2 researchers working to scale-up primary care psychological interventions in low- and  
3 middle-income countries (LMICs) globally. Results from this study have the potential  
4 to inform future scale-up and maintenance of task-shared psychological interventions  
5 into routine Ministry of Health primary care settings.

## 6 7 **2. Overall Study Goal**

8 This research uses a mixed-methods study design and widely-used implementation  
9 frameworks to systematically analyze the performance of clinics, determinants of this  
10 performance, including implementation strategies that might differentiate high- versus  
11 low-performing clinics, and develop and test an enhanced implementation strategy to  
12 improve the performance of clinics in three cities in Zimbabwe. The study is designed  
13 to be conducted in three phases with corresponding aims.

14 Firstly (aim 1), we plan to examine how the FB is performing under real-world  
15 implementation conditions and classify existing clinics with FB into high- versus low-  
16 performing sites using differences in RE-AIM outcomes <sup>25 26</sup>.

17 Secondly (aim 2), we will analyse the determinants of heterogeneity in the results of  
18 phase 1 comparing high- versus low-performing clinics, mainly using the CFIR  
19 framework <sup>27</sup> and rigorously documenting changes to the original FB protocol and  
20 current implementation strategies in use.

21 Thirdly (aim 3), we will develop and test an optimized package of FB implementation  
22 strategies based on the results of phase 2 and measure the improvement among low  
23 performing clinics using RE-AIM outcomes.

## 24 25 **3. Study setting:**

26 The study will be conducted in primary health care clinics (PHC) in Harare, Gweru,  
27 and Chitungwiza.

28 Most of the clinics in the 3 cities are located in comparable areas which are  
29 characterized by high population density and informal income generating activities  
30 often occurring in the vicinity of the clinics. Depending on their size, PHC clinics serve  
31 between 20,000-80,000 people from the most socio-economically disadvantaged  
32 sectors of the population. Clinics are differentiated into poly, satellite, and family health  
33 service clinics according to the size of the clinic and the range of services offered.

1  
2  
3 1 The most comprehensive services are offered in a Polyclinic such as pre-, post- and  
4 perinatal care, opportunistic infections (for example TB treatment), and specialized  
5 2  
6 3 NGO-based programs (HIV testing and management, male circumcision,  
7 4  
8 5 communicable disease awareness). Satellite and Family health clinics (FHS) offer less  
9 6  
10 7 services. Medical doctors are not permanently present but hold clinics on specific days  
11 8  
12 9 in poly clinics. This influences the clinic user population's composition on these  
13 10  
14 11 particular days (for example HIV clinic day).

15 12 Clinics in Harare, Chitungwiza and Gweru are grouped and located in the same  
16 13  
17 14 geographical facility and these are counted as one Friendship Bench implementation  
18 15  
19 16 site. Data will be collected in 36 implementation sites (n=28 in Harare; n=4 in Gweru;  
20 17  
21 18 n=4 in Chitungwiza). Of these 26 Poly clinics, six are FHS and four satellite clinics  
22 19  
23 20 (see figure 1).  
24 21  
25 22

26 23 Figure 1: Clinic type distribution for Harare, Gweru and Chitungwiza  
27 24  
28 25  
29 26  
30 27  
31 28  
32 29  
33 30  
34 31  
35 32  
36 33  
37 34  
38 35  
39 36  
40 37  
41 38  
42 39  
43 40  
44 41  
45 42  
46 43  
47 44  
48 45  
49 46  
50 47  
51 48  
52 49  
53 50  
54 51  
55 52  
56 53  
57 54  
58 55  
59 56  
60 57

18 Depending on their size and catchment area, FB implementation sites have between  
19 one (1) and fourteen (14) LHWs who deliver the FB intervention on benches in the  
20 clinic premises during clinic opening times. Clinic users are informed about the about  
21 FB services and mental health through group or individual talks in the clinic's waiting  
22 areas. Community members are also directly in contact with LHWs during outreach  
23 activities in the community.  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34

#### 4. Methods

27 This study proposes a rigorous analysis of the multiple interconnecting factors using  
28 two internationally recognized implementation research methods – the RE-AIM  
29 model <sup>26</sup> and the CFIR <sup>27</sup> which will be described in more detail below. Both  
30 conceptual frameworks have been used widely in implementation research for health  
31 care delivery in order to deepen the understanding and evaluation of interventions  
32 such as the Friendship Bench. The study has three research aims which are linked  
33 contextually to each other and are described in detail below.

34 Patient and Public Involvement

1 Patients and/or the public will be involved in the stakeholder meetings, they were not  
2 involved in the design, nor will they be involved in the study conduct, or reporting, or  
3 dissemination plans of this research project.

---

#### 4.1 Methods Aim 1

8 A thorough analysis of the existing routine health information system data collected by  
9 the Harare, Gweru and Chitungwiza City Health authorities will be carried out to learn  
10 about the Friendship Bench activities at individual clinic level. This data consists of  
11 user numbers, age, gender, HIV status, clients' screening tool scores pre- and post-  
12 intervention as well as complete use of screening tool, and number of sessions.

14 We will use the RE-AIM evaluation framework to evaluate the current implementation  
15 performance of the FB intervention after three years of implementation experience.  
16 Routinely collected data will be used to assess the FB intervention's real-world and  
17 pragmatic performance: Reach, Effectiveness, Adoption, Implementation, and  
18 Maintenance. The research team which consists of experienced global mental health  
19 researchers and clinicians will develop indicators for each of the RE-AIM domains  
20 using the [www.re-aim.org](http://www.re-aim.org) website to support us and base our decisions on expert  
21 consensus and availability of data. These indicators will then be used to design a  
22 questionnaire to guide the RE-AIM related data collection. Each indicator will comprise  
23 a numerator and a denominator populated with data collected from the clinic records  
24 and the planned observations.

26 The data on the FB implementation will be analyzed for each of the 36 participating  
27 clinics. Routinely collected data includes clinical registries for both nurses and LHWs  
28 and data from the FB Register (commonly known as the "green book") where the  
29 LHWs record beneficiary information.

30 In addition, LHWs will be observed during all aspects of their work, including giving  
31 health talks, interacting with clients, and delivering the FB intervention. We will observe  
32 and record whether all FB related tools such as questionnaires and intervention tools  
33 are used.

1  
2  
3 1 In order to collect additional necessary data for AIM 1, key respondents will be  
4 2 interviewed using a questionnaire that will be developed by the research team.

5 3 We plan to interview at least 2 LHWs per clinic and in clinics with more than 2 LHWs,  
6 4 we will interview 50% of the present LHWs by randomly selecting them. Papers with  
7 5 their names will be put in a container from which a RA will pull out the appropriate  
8 6 number in the LHWs' presence. We will always interview the supervisor LHW of each  
9 7 clinic if this position is taken in a particular clinic. We will also interview the nurse in  
10 8 charge in every clinic and the associated district health promoting officers (DHPOs)  
11 9 (n=10). Data will be collected from June to September 2019 in all participating sites.

12 10  
13 11 The data collection will be carried out by two research coordinators who will lead two  
14 12 teams of four trained and supervised research assistants (RAs). The teams will visit  
15 13 each clinic for two days. The clinics will be sensitized about the FB team visit a week  
16 14 prior. The research assistants will be trained to interview, to observe and record the  
17 15 FB related activities in the clinic and how to enter the data digitally using tablet  
18 16 computers. They will be trained on data checking, cleaning and uploading.

19 17  
20 18 Furthermore, we are planning to audio-record FB sessions with consenting clients  
21 19 (two per site, n=72). We will approach, where possible, all incoming clients seeking  
22 20 services and ask them for informed consent to allow us to record their session with  
23 21 the FB LHWs. We aim to record as many as possible but at least 2 per site.

24 22 The recordings will be translated, transcribed and rated according to the Friendship  
25 23 Bench fidelity checklist.

26 24 The FB fidelity checklist assesses for communication skills of the counselor, the level  
27 25 of psychoeducation that is done, and the adherence to the problem-solving therapy  
28 26 steps that the FB counselor is trained to deliver (see Supplementary Appendix A for  
29 27 full fidelity checklist which was developed for the RCT <sup>22</sup>). The assessments of audio  
30 28 recordings will be done by trained FB research team members who will prepare an  
31 29 audio-recorder which will be left with the FB counselor after a client has given consent.  
32 30 The audio recording device will be retrieved by the research assistant when the LHW  
33 31 has indicated that the session is done.

34 32 In the event that no clients come to the clinic on both days that the FB team visits the  
35 33 site or no client consents to have their session audio-recorded, this will be entered as

1 missing. Due to logistic and financial constraints a repeat visit to a particular clinic will  
2 not be possible.

3 All respondents will be asked to answer the questions with regards to FB activities in  
4 the past month. According to their position with regards to FB activities, questions  
5 might be formulated slightly differently.

6  
7 The questionnaires will be administered using tablet computers (Lenovo), all  
8 observational data will be entered digitally after their correctness has been ascertained  
9 by asking interviewees to show evidence as applicable. Questionnaires and  
10 observation guides are programmed into the tablets using Kobotoolbox  
11 (<https://www.kobotoolbox.org>) which is a data collection tool. Collected data will be  
12 cleaned and uploaded daily to a password secured server.

13  
14 The research team will also observe FB specific activities such as health and  
15 'mobilization' talks that are given by the clinic staff including the LHWs whilst patients  
16 are waiting to be seen.

17  
18 A stakeholder meeting will be held once Aim 1 data is completed and the data is  
19 analyzed. At this meeting, the research team will present the results from Aim 1 and  
20 discuss potential reasons why we might see the differences in implementation across  
21 sites with stakeholders. This meeting will be attended by all relevant clinic staff, health  
22 authority officers as well as clients. Information from stakeholders will be used to  
23 select and prioritize CFIR constructs to include in qualitative interview guides for Aim  
24 2.

#### 25 26 27 **4.1.1 Data Analysis Aim 1**

28 The goal of Aim 1 is to classify the 36 FB implementation sites on their performance  
29 based on the RE-AIM outcomes. Our methods will follow similar classification efforts  
30 previously published <sup>28</sup>. Clinics will be first ranked according to their performance  
31 within each individual measure. Clinics score on all indicators within one construct (for  
32 example reach) will be averaged. For each of the RE-AIM constructs, every clinic will  
33 thus have an averaged ranking.



1  
2  
3 1 These domain-based rankings will be averaged per clinic rankings giving an overall  
4 ranking by calculating simple means of all domain rankings. This procedure will be  
5 2 carried out by two independent individuals and any differences will lead to a redoing  
6 3 of the process. In case of same outcomes for clinics, we will treat these particular  
7 4 clinics as being on the same rank. This will give us a final composite rank for each  
8 5 clinic which will be used to determine the 10 highest and 10 lowest performing clinics  
9 6 that will be qualitatively assessed in Aim 2.  
10 7  
11 8

## 17 9 **4.2 Methods Aim 2**

18 10 With the aim to understand the determinants of implementation success, as well as  
19 11 differences in implementation strategies employed, Aim 2 will utilize focus-group  
20 12 discussions organized around the Consolidated Framework for Implementation  
21 13 Research (CFIR) <sup>29-31</sup>. Through these qualitative methods, we aim to gain a deeper  
22 14 understanding of the factors that contribute to the successful implementation  
23 15 comparing high- with low-performing clinics. The CFIR framework focuses on an  
24 16 overview of potential multi-level determinants of health care delivery. It was designed  
25 17 to help understand integrated implementation determinants across multiple levels  
26 18 (clients; implementers; organizations; contexts; processes).  
27 19

28 20 For the present study, we will focus on determinants of implementation success, taking  
29 21 lessons from both high- and low-performing clinics to inform the development of an  
30 22 improved package of implementation strategies targeting identified barriers.

31 23 Focus group discussions (FDGs) with key informants (LHWs, nurses, DHPOs, clients)  
32 24 of the 10 high and 10 low performing clinics will be carried out by trained qualitative  
33 25 researchers. The FB specific interview guides for these group discussions and  
34 26 interviews will be developed by the study team in a sequence of internal project  
35 27 meetings using the online technical support website [www.cfirguide.org](http://www.cfirguide.org). The results of  
36 28 Aim 1 will guide us in designing the interview guides for the focus group discussions.  
37 29 The outcome of the stakeholders meeting in which we present the results of Aim 1 will  
38 30 also give us insight on the importance of constructs which we will take into account  
39 31 when designing the CFIR interview guides.

40 32 Interview guides will be translated into the local language Shona and all group  
41 33 discussions will be audio-recorded, transcribed and translated to English. All  
42 34 discussions will be held in the local language.



1 The FGD participants will be selected from all 10 low and high performing clinics,  
2 respectively. We will interview LHWs, nurses, DHPOs in their role as implementers  
3 as well as clients as recipients of the intervention. Nurses and DHPOs will be invited  
4 to joined meetings. We will conduct FGDs for all available LHWs at every selected  
5 clinic. We will ask the selected LHWs to purposively suggest 2 clients each, whom  
6 we will then invite to FGDs in each of the selected clinics. In case a client declines  
7 participation, we will ask for another suggestion.

8 Focus group discussions will take place in clinics or, if not possible, in the Friendship  
9 Bench office in Harare.

#### 10 11 **4.2 1 Data Analysis Aim 2**

12 CFIR analyses will follow the original Damschroder methodology previously published  
13 <sup>30</sup>. Briefly, two independent local Zimbabwean reviewers will code each FGD transcript  
14 according to the selected CFIR constructs. Differences will be discussed and revised  
15 until final codes are agreed on. Facility-level case memos will be organized by the  
16 relevant CFIR construct, using each new transcript to confirm and refine statements  
17 until all transcripts are coded. This process will be closely supported by the whole  
18 research team. Each clinic will have two case memos, one for LHWs and other  
19 implementers and one for clients.

20 Using case memos and supporting transcripts, the same two coders will independently  
21 rate CFIR constructs on valence (X (mixed); 0 (neutral); + (construct has a positive  
22 effect on implementation) or – (construct has a negative influence on implementation).  
23 Once drafted, the entire research team will meet and use a deliberated consensus to  
24 finalize memos, constructs, and valence. These data will be mapped on a matrix  
25 template with the goal of identifying constructs that differ between facilities with high  
26 and low performance to identify factors relevant for the success of the implementation.  
27 Analyses will progress with visual inspection of patterns in constructs and valence by  
28 high versus low performing clinics, as well as examining median and mean valence  
29 by high versus low performing clinics. Once distinguishing constructs are identified,  
30 the team will re-review case memos and coded transcripts to gather more information  
31 on constructs.

#### 32 33 34 35 **4.3 Aim 3**

1  
2  
3 1 In Aim 3, we will develop a package of optimized Friendship Bench (OptFB)  
4 2 implementation strategies matched to key barriers identified in the previous phases of  
5 3 this study. Using CFIR data on barriers / facilitators to high-quality FB implementation,  
6 4 we will use the CFIR-ERIC matching tool to examine and select implementation  
7 5 strategies to address key CFIR constructs discriminating between high and low  
8 6 performing clinics in Aim 1 (<https://cfirguide.org/choosing-strategies/>)<sup>32 33</sup>. Once a  
9 7 preliminary list is developed by our team, the CFIR-Expert Recommendation for  
10 8 Implementation Change (ERIC) matching tool<sup>32</sup> will be used to prioritize those  
11 9 strategies that are found to be most likely to address CFIR barriers in low-performing  
12 10 clinics<sup>33 34</sup>.

13 11 We will engage in a participatory stakeholder Delphi rating exercise to select specific  
14 12 strategies. This will be followed by the research team specifying and tailoring the  
15 13 strategies for the Zimbabwean context by including the additional information gained  
16 14 from the stakeholders. Aspects of feasibility, affordability and effectiveness will guide  
17 15 this process in order for the package to be meaningful and effective<sup>35</sup>. Strategies  
18 16 currently in use by high performing clinics will be also considered for the optimized  
19 17 Friendship Bench (OptFB) implementation strategies.

20 18 This OptFB package or intervention of improved strategies will be tested in low-  
21 19 performing clinics. Ongoing RE-AIM data is being collected on a monthly basis in each  
22 20 clinic. Using these data on RE-AIM outcomes, we will re-classify clinics using a similar  
23 21 process as in Aim 1. We will then identify the 18 lowest performing clinics and  
24 22 randomly select 12 clinics to deliver the OptFB and 6 to act as control clinics over a  
25 23 period of 6 months. The primary outcome will be a composite measure of RE-AIM  
26 24 indicators (Reach, Effectiveness, Adoption and Implementation and Maintenance)  
27 25 estimated at 6-month after the commencement of the implementation of the OptFB  
28 26 intervention. We will estimate changes in this composite measure of implementation  
29 27 before and at 6 months after starting the delivery of OptFB in all clinics. We will  
30 28 compare the difference in means or proportions between the clinics receiving the  
31 29 OptFB and the control clinics using the routinely collected data. Secondary outcomes  
32 30 will examine performance of each of the RE-AIM outcomes separately and clinical  
33 31 effectiveness results at individual level. The latter will be based on individual scores to  
34 32 on the SSQ on a minimum of 20 random individuals per clinic during the 6-month  
35 33 period.

1  
2  
3 1 No sample size calculation has been estimated since there are no previous studies on  
4 2 which to estimate an effect size, the number of clinics is small, and the main outcomes  
5 3 are averaged data representing clusters. Nonetheless, we expect to see larger  
6 4 improvements in the RE-AIM composite index score in the clinics receiving OptFB  
7 5 compared to the control clinics over the 6 months. As a secondary outcome measure,  
8 6 clinical effectiveness will be assessed based on changes on SSQ scores from baseline  
9 7 to 6 months for a sample of 360 individuals (18 clinics with 20 individuals each), but  
10 8 we do not expect this sample would have enough power to detect small differences in  
11 9 effectiveness across the two group of clinics. Thus, comparisons on clinical  
12 10 effectiveness must be considered purely descriptive and exploratory and interpreted  
13 11 with caution. In any case, the main outcomes of interest in this study are  
14 12 implementation outcomes subsumed under the domains included in the RE-AIM  
15 13 framework.  
16 14

#### 15 **4.3.1 Data analysis Aim 3**

16 We will use a difference-in-differences analysis comparing the groups over time.  
17 Means or proportions on outcome data will be compared across groups using  
18 descriptive statistics. Regression models will be used to estimate the effect of the  
19 intervention on the main outcomes. General estimating equations with robust  
20 standard errors will be used to control for clustering. Potential confounders will be  
21 determined a priori and included in the regression models. Standard errors,  
22 confidence intervals, and p-values will be obtained. A similar secondary analysis will  
23 be conducted with the secondary outcome measures.  
24

#### 25 **4.4 Health economic analysis**

26  
27 Site-level data will be collected on fidelity to the OptFB implementation strategies,  
28 along with activities and resource inputs required to deliver improvement strategies  
29 and OptFB delivery costs. Economic modelling will be used to combine this information  
30 with data and evidence on clinical impact and implementation effectiveness to  
31 evaluate the cost-effectiveness of the OptFB program <sup>36</sup>.

32 We will also revisit clinics and re-engage with stakeholders in in-depth-FGD to explore level  
33 of change in the identified CFIR domains in the intervention arm clinics.

1  
2  
3 1 After completion of the trial, the strategy will also be implemented in the control arm  
4 2 clinics to increase the overall performance in all of participating lower performing  
5 3 clinics.  
6  
7  
8  
9  
10  
11

## 12 6 **5. Discussion**

13 7 This study will contribute to the knowledge about scaling up of an evidence-based  
14 8 task-shifted intervention in a LMIC. This is a unique opportunity to analyze the  
15 9 Friendship Bench in a real-world setting. As mentioned above, not many  
16 10 interventions have been scaled up from LMICs and therefore there is a dearth of  
17 11 information on how implementation strategies can be used in order to ensure a  
18 12 strong scaling up. With this study we hope to learn which barriers and enablers are  
19 13 at play in the FB scale up process. This is particularly important for us as we are  
20 14 expanding the FB services throughout Zimbabwe and beyond to meet the  
21 15 population's needs for accessible and acceptable mental health care. This effort has  
22 16 to be undertaken with the aim of having high fidelity to the program while considering  
23 17 contextual aspects. Using implementation science principles will help us to give  
24 18 theoretical justification and describe specifications for application for those  
25 19 implementation strategies that we will devise after having gone through the different  
26 20 stages of this research process. Evidence-based, clear and applicable guidelines of  
27 21 how to implement our evidence-based intervention in primary health care settings  
28 22 will be created and can then subsequently be used to ensure a strong  
29 23 implementation of FB.  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45

## 46 25 **6. Ethics and dissemination**

47 26 This research protocol has been approved by the Medical Research Council  
48 27 Zimbabwe (MRCZ), MRCZ/A/2428 and the Joint Research Council (JREC),  
49 28 79/19. Results will be disseminated in peer-reviewed journals and conferences.  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## References

1. Vigo D, Thornicroft G, Atun R. Estimating the true global burden of mental illness. *Lancet Psychiatry* 2016;3(2):171-8. doi: 10.1016/S2215-0366(15)00505-2 [published Online First: 2016/02/07]
2. Kessler RC, Aguilar-Gaxiola S, Alonso J, et al. The global burden of mental disorders: an update from the WHO World Mental Health (WMH) surveys. *Epidemiol Psychiatr Soc* 2009;18(1):23-33. doi: 10.1017/s1121189x00001421 [published Online First: 2009/04/22]
3. Whiteford HA, Ferrari AJ, Degenhardt L, et al. The global burden of mental, neurological and substance use disorders: an analysis from the Global Burden of Disease Study 2010. *PLoS One* 2015;10(2):e0116820. doi: 10.1371/journal.pone.0116820 [published Online First: 2015/02/07]
4. Steel Z, Marnane C, Iranpour C, et al. The global prevalence of common mental disorders: a systematic review and meta-analysis 1980–2013. *International journal of epidemiology* 2014:dyy038.
5. Lund C, De Silva M, Plagerson S, et al. Poverty and mental disorders: breaking the cycle in low-income and middle-income countries. *The Lancet* 2011;378(9801):1502-14.
6. Evans-Lacko S, Aguilar-Gaxiola S, Al-Hamzawi A, et al. Socio-economic variations in the mental health treatment gap for people with anxiety, mood, and substance use disorders: results from the WHO World Mental Health (WMH) surveys. *Psychological medicine* 2018;48(9):1560-71. doi: 10.1017/S0033291717003336 [published Online First: 2017/11/28]
7. Wang PS, Aguilar-Gaxiola S, Alonso J, et al. Use of mental health services for anxiety, mood, and substance disorders in 17 countries in the WHO world mental health surveys. *The Lancet* 2007;370(9590):841-50.
8. Mojtabai R, Olfson M, Sampson NA, et al. Barriers to mental health treatment: results from the National Comorbidity Survey Replication. *Psychological medicine* 2011;41(8):1751-61. doi: 10.1017/S0033291710002291 [published Online First: 2010/12/08]
9. Kohn R, Saxena S, Levav I, et al. The treatment gap in mental health care. *Bull World Health Organ* 2004;82(11):858-66. doi: /S0042-96862004001100011 [published Online First: 2005/01/11]
10. Prince M, Patel V, Saxena S, et al. No health without mental health. *The lancet* 2007;370(9590):859-77.
11. Alonso J, Liu Z, Evans-Lacko S, et al. Treatment gap for anxiety disorders is global: Results of the World Mental Health Surveys in 21 countries. *Depress Anxiety* 2018;35(3):195-208. doi: 10.1002/da.22711 [published Online First: 2018/01/23]
12. Wang PS, Angermeyer M, Borges G, et al. Delay and failure in treatment seeking after first onset of mental disorders in the World Health Organization's World Mental Health Survey Initiative. *World Psychiatry* 2007;6(3):177-85. [published Online First: 2008/01/12]
13. Araya R, Rojas G, Fritsch R, et al. Treating depression in primary care in low-income women in Santiago, Chile: a randomised controlled trial. *Lancet* 2003;361(9362):995-1000. doi: 10.1016/S0140-6736(03)12825-5
14. Patel V, Thornicroft G. Packages of care for mental, neurological, and substance use disorders in low-and middle-income countries: PLoS Medicine Series. *PLoS medicine* 2009;6(10):e1000160.

15. Chatterjee S, Chowdhary N, Pednekar S, et al. Integrating evidence-based treatments for common mental disorders in routine primary care: feasibility and acceptability of the MANAS intervention in Goa, India. *World Psychiatry* 2008;7(1):39-46.
16. Rahman A, Malik A, Sikander S, et al. Cognitive behaviour therapy-based intervention by community health workers for mothers with depression and their infants in rural Pakistan: a cluster-randomised controlled trial. *The Lancet* 2008;372(9642):902-09.
17. Bolton P, Bass J, Neugebauer R, et al. Group interpersonal psychotherapy for depression in rural Uganda: a randomized controlled trial. *Jama* 2003;289(23):3117-24.
18. Lund C, Alem A, Schneider M, et al. Generating evidence to narrow the treatment gap for mental disorders in sub-Saharan Africa: rationale, overview and methods of AFFIRM. *Epidemiol Psychiatr Sci* 2015;24(3):233-40. doi: 10.1017/S2045796015000281 [published Online First: 2015/04/03]
19. Wagenaar BH, Hammett, W.H., Jackson, C., Atkins, D.L., Belus, J.M. and Kemp, C.G. Implementation outcomes and strategies for depression interventions in low-and middle-income countries: a systematic review. . *Global Mental Health* 2020;7
20. Chibanda D, Mesu P, Kajawu L, et al. Problem-solving therapy for depression and common mental disorders in Zimbabwe: piloting a task-shifting primary mental health care intervention in a population with a high prevalence of people living with HIV. *BMC public health* 2011;11:828. doi: 10.1186/1471-2458-11-828 [published Online First: 2011/10/28]
21. Antelman G, Kaaya S, Wei R, et al. Depressive symptoms increase risk of HIV disease progression and mortality among women in Tanzania. *Journal of acquired immune deficiency syndromes* 2007;44(4):470-7. doi: 10.1097/QAI.0b013e31802f1318
22. 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* 2016;316(24):2618-26. doi: 10.1001/jama.2016.19102 [published Online First: 2016/12/28]
23. Chibanda D, Bowers T, Verhey R, et al. 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. *Int J Ment Health Syst* 2015;9:21. doi: 10.1186/s13033-015-0013-y [published Online First: 2015/01/01]
24. Chibanda D, Verhey R, Munetsi E, et al. Scaling up interventions for depression in sub-Saharan Africa: lessons from Zimbabwe. *Glob Ment Health (Camb)* 2016;3:e13. doi: 10.1017/gmh.2016.8 [published Online First: 2016/04/11]
25. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health* 1999;89(9):1322-27.
26. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *American journal of public health* 1999;89(9):1322-7. doi: 10.2105/ajph.89.9.1322 [published Online First: 1999/09/04]
27. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 2009;4:50. doi: 10.1186/1748-5908-4-50 [published Online First: 2009/08/12]
28. Farris RP, Will JC, Khavjou O, et al. Beyond effectiveness: evaluating the public health impact of the WISEWOMAN program. *American journal of public health* 2007;97(4):641-47.



- 1  
2  
3 1 29. Breimaier HE, Heckemann B, Halfens RJ, et al. The Consolidated Framework for  
4 2 Implementation Research (CFIR): a useful theoretical framework for guiding and  
5 3 evaluating a guideline implementation process in a hospital-based nursing practice.  
6 4 *BMC Nurs* 2015;14:43. doi: 10.1186/s12912-015-0088-4 [published Online First:  
7 5 2015/08/14]  
8 6  
9 30. Damschroder LJ, Lowery JC. Evaluation of a large-scale weight management program  
10 7 using the consolidated framework for implementation research (CFIR). *Implement Sci*  
11 8 2013;8:51. doi: 10.1186/1748-5908-8-51 [published Online First: 2013/05/15]  
12 9  
13 31. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services  
14 10 research findings into practice: a consolidated framework for advancing  
15 11 implementation science. *Implementation science* 2009;4(1):50.  
16 12  
17 32. Powell BJ, Waltz TJ, Chinman MJ, et al. A refined compilation of implementation  
18 13 strategies: results from the Expert Recommendations for Implementing Change  
19 14 (ERIC) project. *Implement Sci* 2015;10:21. doi: 10.1186/s13012-015-0209-1  
20 15 [published Online First: 2015/04/19]  
21 16  
22 33. Waltz TJ, Powell BJ, Fernandez ME, et al. Choosing implementation strategies to address  
23 17 contextual barriers: diversity in recommendations and future directions. *Implement*  
24 18 *Sci* 2019;14(1):42. doi: 10.1186/s13012-019-0892-4 [published Online First:  
25 19 2019/05/01]  
26 20  
27 34. Godbee K, Gunn J, Lautenschlager NT, et al. Refined conceptual model for implementing  
28 21 dementia risk reduction: incorporating perspectives from Australian general  
29 22 practice. *Aust J Prim Health* 2020;26(3):247-55. doi: 10.1071/PY19249 [published  
30 23 Online First: 2020/05/28]  
31 24  
32 35. Cooper LA, Hill MN, Powe NR. Designing and evaluating interventions to eliminate racial  
33 25 and ethnic disparities in health care. *J Gen Intern Med* 2002;17(6):477-86. doi:  
34 26 10.1046/j.1525-1497.2002.10633.x [published Online First: 2002/07/23]  
35 27  
36 36. Briggs A, Sculpher, M., & Claxton, K. . Decision modelling for health economic  
37 28 evaluation. Oxford: Oup Oxford 2006.  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1

**2 Footnotes****3 Contributors**

4 RA designed the study and received the grant. RA is the overall PI. RV and DC are  
5 leading the study locally. CC will have oversight as project coordinator together with  
6 SM as her assistant over the data collection in all phases. BW is leading on the  
7 implantation science aspects. EC is conducting data cleaning and assisting with  
8 analysis. AH is leading on the health economics analysis. All authors will contribute  
9 to the development of questionnaires, interview guides and the strategies for the  
10 intervention. RV wrote the first version of the protocol paper. All authors contributed  
11 by critically reviewing all further drafts and approving of the final paper.

**12 Funding**

---

13 This work was supported by Global Alliance for Chronic Diseases (GACD) through  
14 the Medical Research Council Grant number: MRC UKRI MR/S004270/1.

17 **Competing interests** None declared.

18 **Patient consent for publication** Not required.

---

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40

41

42

43

44

45

46

47

48

49

50

51

52

53

54

55

56

57

58

59

60



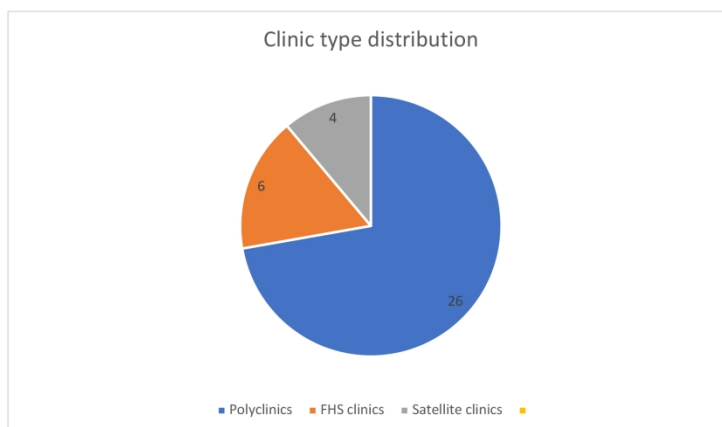


Figure 1: Clinic type distribution for Harare, Gweru and Chitungwiza



**Table 1. Checklist for audio-recorded sessions**

**LHW FIDELITY CHECKLIST**

LHW Name _____ Client's Name _____		Date            /            /            Site Code <input type="checkbox"/> <input type="checkbox"/>	
<i>(Tick where appropriate)</i>		<b>YES</b>	<b>NO</b>
1.	LHW introduced self to client and asked client to introduce self	<input type="checkbox"/>	<input type="checkbox"/>
2.	Psycho-education done properly	<input type="checkbox"/>	<input type="checkbox"/>
	a. Linked HIV to kufungisisa	<input type="checkbox"/>	<input type="checkbox"/>
	b. Adherence	<input type="checkbox"/>	<input type="checkbox"/>
	c. Diet advise done	<input type="checkbox"/>	<input type="checkbox"/>
3.	Problems presented by client	<input type="checkbox"/>	<input type="checkbox"/>
4.	LHW listening and acknowledging	<input type="checkbox"/>	<input type="checkbox"/>
5.	LHW gives summary of problems	<input type="checkbox"/>	<input type="checkbox"/>
6.	Client selected problem, not LHW	<input type="checkbox"/>	<input type="checkbox"/>
7.	LHW and client discuss problem identified by client	<input type="checkbox"/>	<input type="checkbox"/>
8.	Client identifies solutions to the problem identified	<input type="checkbox"/>	<input type="checkbox"/>
9.	LHW and client identify task for client to work with	<input type="checkbox"/>	<input type="checkbox"/>
10.	Session closure and next correct review date	<input type="checkbox"/>	<input type="checkbox"/>
<b>Total</b>		___/10	___/10

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. *BMJ*. 2013;346:e7586

		Reporting Item	Page Number
<b>Administrative information</b>			
Title	<a href="#">#1</a>	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet registered, name of intended registry	n/a
Trial registration: data set	<a href="#">#2b</a>	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	<a href="#">#3</a>	Date and version identifier	
Funding	<a href="#">#4</a>	Sources and types of financial, material, and other support	2
Roles and responsibilities: contributorship	<a href="#">#5a</a>	Names, affiliations, and roles of protocol contributors	17

1	Roles and	<a href="#">#5b</a>	Name and contact information for the trial sponsor	n/a
2	responsibilities:			
3	sponsor contact			
4	information			
5				
6				
7				
8	Roles and	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study design;	n/a
9	responsibilities:		collection, management, analysis, and interpretation of data;	
10	sponsor and funder		writing of the report; and the decision to submit the report for	
11			publication, including whether they will have ultimate authority	
12			over any of these activities	
13				
14				
15				
16	Roles and	<a href="#">#5d</a>	Composition, roles, and responsibilities of the coordinating	n/a
17	responsibilities:		centre, steering committee, endpoint adjudication committee,	
18	committees		data management team, and other individuals or groups	
19			overseeing the trial, if applicable (see Item 21a for data	
20			monitoring committee)	
21				
22				
23				
24	<b>Introduction</b>			
25				
26				
27	Background and	<a href="#">#6a</a>	Description of research question and justification for undertaking	3
28	rationale		the trial, including summary of relevant studies (published and	
29			unpublished) examining benefits and harms for each intervention	
30				
31				
32	Background and	<a href="#">#6b</a>	Explanation for choice of comparators	n/a
33	rationale: choice of			
34	comparators			
35				
36				
37	Objectives	<a href="#">#7</a>	Specific objectives or hypotheses	4
38				
39				
40	Trial design	<a href="#">#8</a>	Description of trial design including type of trial (eg, parallel	4
41			group, crossover, factorial, single group), allocation ratio, and	
42			framework (eg, superiority, equivalence, non-inferiority,	
43			exploratory)	
44				
45				
46	<b>Methods:</b>			
47	<b>Participants,</b>			
48	<b>interventions, and</b>			
49	<b>outcomes</b>			
50				
51				
52				
53	Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic, academic	5
54			hospital) and list of countries where data will be collected.	
55			Reference to where list of study sites can be obtained	
56				
57				
58				
59				
60				

1	Eligibility criteria	<a href="#">#10</a>	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
2				
3				
4				
5				
6	Interventions:	<a href="#">#11a</a>	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-11
7	description			
8				
9				
10	Interventions:	<a href="#">#11b</a>	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a
11	modifications			
12				
13				
14				
15	Interventions:	<a href="#">#11c</a>	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	n/a
16	adherence			
17				
18				
19				
20				
21	Interventions:	<a href="#">#11d</a>	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
22	concomitant care			
23				
24				
25	Outcomes	<a href="#">#12</a>	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-10
26				
27				
28				
29				
30				
31				
32				
33				
34	Participant timeline	<a href="#">#13</a>	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	n/a
35				
36				
37				
38				
39				
40	Sample size	<a href="#">#14</a>	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	n/a
41				
42				
43				
44				
45	Recruitment	<a href="#">#15</a>	Strategies for achieving adequate participant enrolment to reach target sample size	n/a
46				
47				
48				
49	<b>Methods: Assignment</b>			
50	<b>of interventions (for</b>			
51	<b>controlled trials)</b>			
52				
53				
54	Allocation: sequence	<a href="#">#16a</a>	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be	n/a
55	generation			
56				
57				
58				
59				
60				

provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism	<a href="#">#16b</a>	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a
Allocation: implementation	<a href="#">#16c</a>	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
Blinding (masking): emergency unblinding	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
<b>Methods: Data collection, management, and analysis</b>			
Data collection plan	<a href="#">#18a</a>	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7-10
Data collection plan: retention	<a href="#">#18b</a>	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a
Data management	<a href="#">#19</a>	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9-10
Statistics: outcomes	<a href="#">#20a</a>	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9-10, 12

1	Statistics: additional	<a href="#">#20b</a>	Methods for any additional analyses (eg, subgroup and adjusted	n/a
2	analyses		analyses)	
3				
4	Statistics: analysis	<a href="#">#20c</a>	Definition of analysis population relating to protocol non-	n/a
5	population and missing		adherence (eg, as randomised analysis), and any statistical	
6	data		methods to handle missing data (eg, multiple imputation)	
7				
8				
9				
10	<b>Methods: Monitoring</b>			
11				
12	Data monitoring:	<a href="#">#21a</a>	Composition of data monitoring committee (DMC); summary of	n/a
13	formal committee		its role and reporting structure; statement of whether it is	
14			independent from the sponsor and competing interests; and	
15			reference to where further details about its charter can be found,	
16			if not in the protocol. Alternatively, an explanation of why a	
17			DMC is not needed	
18				
19				
20				
21				
22	Data monitoring:	<a href="#">#21b</a>	Description of any interim analyses and stopping guidelines,	n/a
23	interim analysis		including who will have access to these interim results and make	
24			the final decision to terminate the trial	
25				
26				
27	Harms	<a href="#">#22</a>	Plans for collecting, assessing, reporting, and managing solicited	n/a
28			and spontaneously reported adverse events and other unintended	
29			effects of trial interventions or trial conduct	
30				
31				
32				
33	Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial conduct, if any, and	n/a
34			whether the process will be independent from investigators and	
35			the sponsor	
36				
37				
38	<b>Ethics and</b>			
39	<b>dissemination</b>			
40				
41				
42	Research ethics	<a href="#">#24</a>	Plans for seeking research ethics committee / institutional review	2
43	approval		board (REC / IRB) approval	
44				
45				
46	Protocol amendments	<a href="#">#25</a>	Plans for communicating important protocol modifications (eg,	2
47			changes to eligibility criteria, outcomes, analyses) to relevant	
48			parties (eg, investigators, REC / IRBs, trial participants, trial	
49			registries, journals, regulators)	
50				
51				
52				
53	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from potential trial	8
54			participants or authorised surrogates, and how (see Item 32)	
55				
56				
57				
58				
59				
60				



1	Consent or assent:	<a href="#">#26b</a>	Additional consent provisions for collection and use of	n/a
2	ancillary studies		participant data and biological specimens in ancillary studies, if	
3			applicable	
4				
5				
6	Confidentiality	<a href="#">#27</a>	How personal information about potential and enrolled	n/a
7			participants will be collected, shared, and maintained in order to	
8			protect confidentiality before, during, and after the trial	
9				
10				
11	Declaration of interests	<a href="#">#28</a>	Financial and other competing interests for principal investigators	17
12			for the overall trial and each study site	
13				
14				
15	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial dataset, and	
16			disclosure of contractual agreements that limit such access for	
17			investigators	
18				
19				
20	Ancillary and post trial	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care, and for	n/a
21	care		compensation to those who suffer harm from trial participation	
22				
23				
24	Dissemination policy:	<a href="#">#31a</a>	Plans for investigators and sponsor to communicate trial results	2
25	trial results		to participants, healthcare professionals, the public, and other	
26			relevant groups (eg, via publication, reporting in results	
27			databases, or other data sharing arrangements), including any	
28			publication restrictions	
29				
30				
31				
32				
33	Dissemination policy:	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended use of	n/a
34	authorship		professional writers	
35				
36				
37	Dissemination policy:	<a href="#">#31c</a>	Plans, if any, for granting public access to the full protocol,	n/a
38	reproducible research		participant-level dataset, and statistical code	
39				
40				
41	<b>Appendices</b>			
42				
43	Informed consent	<a href="#">#32</a>	Model consent form and other related documentation given to	18
44	materials		participants and authorised surrogates	
45				
46				
47	Biological specimens	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and storage of	n/a
48			biological specimens for genetic or molecular analysis in the	
49			current trial and for future use in ancillary studies, if applicable	
50				
51				

None The SPIRIT checklist is distributed under the terms of the Creative Commons Attribution License CC-BY-ND 3.0. This checklist can be completed online using <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)

# BMJ Open

## Optimizing implementation strategies of the first scale-up of a primary care psychological intervention for common mental disorders in Sub-Saharan Africa: A Mixed Methods Study protocol for the Optimized Friendship Bench (OptFB)

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-045481.R2
Article Type:	Protocol
Date Submitted by the Author:	29-Jun-2021
Complete List of Authors:	Verhey, Ruth ; University of Zimbabwe, Research Support Centre; Friendship Bench Chitiyo, Charmaine; Friendship Bench Zimbabwe Mboweni, Sandra; Friendship Bench Zimbabwe Chiriseri, Ephraim; Friendship Bench Zimbabwe Chibanda, Dixon; Friendship Bench Zimbabwe; University of Zimbabwe, Research Support Centre Healey, Andy; King's College London, IOPPN Wagenaar, Bradley; University of Washington, Department of epidemiology; University of Washington, Department of global health Araya, Ricardo; Centre for Global Mental Health and Primary Care Research,
<b>Primary Subject Heading</b>:	Mental health
Secondary Subject Heading:	Global health, Communication
Keywords:	MENTAL HEALTH, PRIMARY CARE, PUBLIC HEALTH, QUALITATIVE RESEARCH

SCHOLARONE™  
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1  
2  
3 1  
4  
5 2  
6  
7 3  
8 4 Optimizing implementation strategies of the first scale-up of a primary care  
9 psychological intervention for common mental disorders in Sub-Saharan Africa: A  
10 5 Mixed Methods Study protocol for the Optimized Friendship Bench (OptFB)  
11 6  
12 7  
13  
14

15 8 Author list:

16 9 Ruth Verhey <sup>a,b</sup>

17 10 Charmaine Chitiyo <sup>a</sup>

18 11 Sandra Mboweni <sup>a</sup>

19 12 Ephraim Chiriseri <sup>a</sup>

20 13 Dixon Chibanda <sup>a,b,d</sup>

21 14 Andy Healey <sup>c</sup>

22 15 Bradley H. Wagenaar <sup>e,f</sup>

23 16 Ricardo Araya <sup>c</sup>

24 17  
25 18  
26 19 <sup>a</sup> Friendship Bench Zimbabwe

27 20 <sup>b</sup> University of Zimbabwe

28 21 <sup>c</sup> King's College, London, UK

29 22 <sup>d</sup> London school of hygiene and tropical medicine, LSHTM, UK

30 23 <sup>e</sup> Department of Global Health, University of Washington, Seattle, WA, USA

31 24 <sup>f</sup> Department of Epidemiology, University of Washington, Seattle, WA, USA  
32  
33  
34

35 25  
36 26 Abstract word count: 281

37 27 Body word count: 3650  
38  
39  
40

41 28  
42 29 Corresponding author:

43 30 Ruth Verhey

44 31 Address: 4 Weale Road, Milton Park Harare Zimbabwe

45 32 Tel: +263773857376 Email: [ruth.verhey@friendshipbench.io](mailto:ruth.verhey@friendshipbench.io)  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## Abstract

Introduction: Common mental disorders (CMDs) are a leading cause of disability globally. CMDs are highly prevalent in Zimbabwe and have been addressed by an evidence-based, task-shifting psychological intervention called the Friendship Bench (FB). The task-shifted FB program guides clients through problem solving therapy. It was scaled-up across 36 implementation sites in Zimbabwe in 2016.

Methods and analysis: This study will employ a mixed-methods framework. It aims to: (1) Use quantitative survey methodologies organized around the RE-AIM evaluation framework to assess the current scale-up of the FB intervention and classify 36 clinics according to levels of performance; (2) Use qualitative focus group discussions and semi-structured interviews organized around the Consolidated Framework for Implementation Research (CFIR) to analyze determinants of implementation success, as well as elucidate heterogeneity in implementation strategies through comparing high- and low-performing clinics; and (3) Use the results from aims 1 and 2 to develop strategies to optimize the Friendship Bench intervention and apply this model in a cluster randomized controlled trial to evaluate potential improvements among low-performing clinics. The trial will be registered with the Pan African Clinical Trial Registry ([www.pactr.org](http://www.pactr.org)). The planned randomized controlled trial for the third research aim will be registered after completing aims one and two because the intervention is dependent on knowledge generated during these phases.

Ethics and dissemination: The research protocol received full authorization from the Medical Research Council of Zimbabwe (MRCZ A/242). It is anticipated that changes in data collection tools and consent forms will take place at all three phases of the study and approval from MRCZ will be sought. All interview partners will be asked for informed consent. The research team will prioritize open access publications to disseminate research results.

## Strengths and limitations of this study

- Few evidence-based psychological interventions offered at primary health care level have been successfully scaled-up in Sub-Saharan Africa; this study is designed to deliver detailed knowledge about factors that influence the scale-up of a primary care psychological intervention (the Friendship Bench) in an African setting.
- Two widely used implementation science models, RE-AIM and CFIR, will be used to evaluate the implementation of this intervention, which was scaled up in 2016.
- This study focuses on evaluating the scaling up of evidence-based interventions and developing and testing implementation strategies to potentially optimize the routine delivery of the Friendship Bench.
- A limitation is that comprehensive implementation data is only collected three years after the scale up exercise.

Key words: Friendship Bench, Optimization, common mental disorders, CFIR, RE-AIM, Low- and middle-income countries

### 1. Introduction:

In the past 10 years, it has become apparent that mental, neurological and substance use disorders (MNS) are among the leading causes of the global disease burden<sup>1-3</sup>. Research has shown that 4 out of every 10 people in low-and-middle-income countries (LMICs) suffer from mental disorders (de Boer et al. 2008, World Health Organization, 2009a) and evidence-based mental health interventions have become a focus of research and interest<sup>4</sup>. It has been observed that the poor are disproportionately affected by mental disorders<sup>5,6</sup>. Less than 5% of people living in some LMIC receive any adequate treatment for mental health disorders<sup>7,8,9</sup>. Particularly in low- and

1  
2  
3 1 middle-income countries (LMIC) the lack of resources, especially trained mental health  
4 2 professionals, causes sub-optimal detection and management of CMD <sup>10-12</sup>.  
5 3 Worldwide, efforts have been made to create sustainable and affordable mental health  
6 4 interventions in primary care <sup>13-18</sup>. In a recent systematic review, only four studies  
7 5 were detected that had evaluated the implementation of a depression intervention  
8 6 scaled-up in routine care <sup>19</sup>. As it stands, the benefit of these evidence-based  
9 7 interventions is not yet reaching those populations most at need across LMICs.  
10 8

11 9 Zimbabwe, a country in Southern Africa with a population of 13 million has a large  
12 10 treatment gap for MNS. Studies show that over 30% of primary health care (PHC)  
13 11 users need mental health care services for mostly common mental disorders (CMD)  
14 12 and only 5% of these receive appropriate care <sup>20</sup>. Untreated CMD can also lead to  
15 13 worsening of clinical outcomes in chronic conditions such as HIV <sup>21</sup> and negatively  
16 14 affect economic outcomes too <sup>5</sup>. The Friendship Bench (FB) was developed in  
17 15 response to the existing treatment gap for mental health care in Zimbabwe and tested  
18 16 for its efficacy in a cluster randomized controlled trial (RCT) <sup>22</sup>.  
19 17

20 18 This task-shifted intervention is delivered by trained and supervised lay health workers  
21 19 (LHWs) who deliver problem solving therapy (PST) <sup>23</sup> on a bench located in primary  
22 20 health care clinics. In 2016, the FB intervention was scaled-up across Harare, Gweru  
23 21 and Chitungwiza and surrounding peri-urban communities in collaboration with the  
24 22 respective City Health departments <sup>24</sup>. The FB program was established in 72 City  
25 23 Health PHC clinics that are established in 36 sites (different clinic types can be found  
26 24 in the same site). This scaling-up exercise involved the training of more than 300  
27 25 LHWs in the 3 cities in Zimbabwe <sup>24</sup>. Maintenance funding for FB activities is provided  
28 26 by the City Health department.  
29 27

30 28 All lay health workers (LHWs) working for the FB PHC clinics in Harare, Gweru and  
31 29 Chitungwiza received the standard manualized training and supervision. While  
32 30 existing scientific evidence has shown that under ideal randomized trial conditions the  
33 31 FB intervention leads to clinically-significant reductions in symptoms, little  
34 32 implementation research has been carried out regarding the performance of  
35 33 Friendship Bench under routine conditions as the model is being further scaled-up  
36 34 across Zimbabwe.



1 This study will be of interest to implementation scientists, policymakers, and  
2 researchers working to scale-up primary care psychological interventions in low- and  
3 middle-income countries (LMICs) globally. Results from this study have the potential  
4 to inform future scale-up and maintenance of task-shared psychological interventions  
5 into routine Ministry of Health primary care settings.

#### 6 Preliminary observations

7 Preliminary work had revealed that FB activities were irregular over the  
8 implementation sites. FB related data collection was often unreliable due to various  
9 reasons such as the delivering agents not having been trained on data collection, and  
10 the FB program data not being reported to the authorities as part of the clinic activities.  
11 Only estimates for client numbers for 2016-2018 with a program reach decline from  
12 27,967 clients in 2016 to 6,688 in 2018 for all of the 36 sites were available. Sites in  
13 Harare had continued to offer the program. In the two other cities (Gweru and  
14 Chitungwiza) the health authorities had ceased to support the FB program and  
15 delivering agents had been told to focus on other programs such as HIV related  
16 activities. It was unclear how many FB activities had been carried out. In order to  
17 receive continued support, the FB program should be integrated with other PHC  
18 programs such as HIV care. Data collection efforts need to be simplified and delivering  
19 agents trained. Data needs to be gathered and analysed regularly using  
20 implementation science principles. Furthermore, the FB organization should engage  
21 closely with health care providers and policy makers to ensure successful and  
22 continued program implementation.

## 23 24 **2. Overall Study Goal**

25 This research uses a mixed-methods study design and widely-used implementation  
26 frameworks to systematically analyze the performance of clinics, determinants of this  
27 performance, including implementation strategies that might differentiate high- versus  
28 low-performing clinics, and develop and test an enhanced implementation strategy to  
29 improve the performance of clinics in three cities in Zimbabwe. The study is designed  
30 to be conducted in three phases with corresponding aims.

31 Firstly (aim 1), we plan to examine how the FB is performing under real-world  
32 implementation conditions and classify existing clinics with FB into high- versus low-  
33 performing sites using differences in RE-AIM outcomes<sup>25 26</sup>.

1  
2  
3 1 Secondly (aim 2), we will analyse the determinants of heterogeneity in the results of  
4 phase 1 comparing high- versus low-performing clinics, mainly using the CFIR  
5 2 framework <sup>27</sup> and rigorously documenting changes to the original FB protocol and  
6 3 current implementation strategies in use.  
7 4

8  
9  
10 5 Thirdly (aim 3), we will develop and test an optimized package of FB implementation  
11 6 strategies based on the results of phase 2 and measure the improvement among low  
12 7 performing clinics using RE-AIM outcomes.  
13 8

### 17 9 **3. Study setting:**

18  
19 10 The study will be conducted in primary health care clinics (PHC) in Harare, Gweru,  
20 11 and Chitungwiza.

21  
22 12 Most of the clinics in the 3 cities are located in comparable areas which are  
23 13 characterized by high population density and informal income generating activities  
24 14 often occurring in the vicinity of the clinics. Depending on their size, PHC clinics serve  
25 15 between 20,000-80,000 people from the most socio-economically disadvantaged  
26 16 sectors of the population. Clinics are differentiated into poly, satellite, and family health  
27 17 service clinics according to the size of the clinic and the range of services offered.

28  
29 18 The most comprehensive services are offered in a Polyclinic such as pre-, post- and  
30 19 perinatal care, opportunistic infections (for example TB treatment), and specialized  
31 20 NGO-based programs (HIV testing and management, male circumcision,  
32 21 communicable disease awareness). Satellite and Family health clinics (FHS) offer less  
33 22 services. Medical doctors are not permanently present but hold clinics on specific days  
34 23 in poly clinics. This influences the clinic user population's composition on these  
35 24 particular days (for example HIV clinic day).

36 25 Clinics in Harare, Chitungwiza and Gweru are grouped and located in the same  
37 26 geographical facility and these are counted as one Friendship Bench implementation  
38 27 site. Data will be collected in 36 implementation sites (n=28 in Harare; n=4 in Gweru;  
39 28 n=4 in Chitungwiza). Of these 26 Poly clinics, six are FHS and four satellite clinics  
40 29 (see figure 1).  
41 30

42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55 31 Figure 1: Clinic type distribution for Harare, Gweru and Chitungwiza  
56 32  
57 33  
58 34  
59  
60

1  
2  
3 1 Depending on their size and catchment area, FB implementation sites have between  
4 2 one (1) and fourteen (14) LHWs who deliver the FB intervention on benches in the  
5 3 clinic premises during clinic opening times. Clinic users are informed about the about  
6 4 FB services and mental health through group or individual talks in the clinic's waiting  
7 5 areas. Community members are also directly in contact with LHWs during outreach  
8 6 activities in the community.  
9 7  
10 8

#### 9 **4. Methods**

10 This study proposes a rigorous analysis of the multiple interconnecting factors using  
11 two internationally recognized implementation research methods – the RE-AIM  
12 model <sup>26</sup> and the CFIR <sup>27</sup> which will be described in more detail below. Both  
13 conceptual frameworks have been used widely in implementation research for health  
14 care delivery in order to deepen the understanding and evaluation of interventions  
15 such as the Friendship Bench. The study has three research aims which are linked  
16 contextually to each other and are described in detail below.

##### 17 Patient and Public Involvement

18 Patients and/or the public will be involved in the stakeholder meetings, they were not  
19 involved in the design, nor will they be involved in the study conduct, or reporting, or  
20 dissemination plans of this research project.  
21  
22  
23

#### 24 **4.1 Methods Aim 1**

25 A thorough analysis of the existing routine health information system data collected by  
26 the Harare, Gweru and Chitungwiza City Health authorities will be carried out to learn  
27 about the Friendship Bench activities at individual clinic level. This data consists of  
28 user numbers, age, gender, HIV status, clients' screening tool scores pre- and post-  
29 intervention as well as complete use of screening tool, and number of sessions.  
30

31 We will use the RE-AIM evaluation framework to evaluate the current implementation  
32 performance of the FB intervention after three years of implementation experience.

33 Routinely collected data will be used to assess the FB intervention's real-world and  
60

1 pragmatic performance: Reach, Effectiveness, Adoption, Implementation, and  
2 Maintenance. The research team which consists of experienced global mental health  
3 researchers and clinicians will develop indicators for each of the RE-AIM domains  
4 using the [www.re-aim.org](http://www.re-aim.org) website to support us and base our decisions on expert  
5 consensus and availability of data. These indicators will then be used to design a  
6 questionnaire to guide the RE-AIM related data collection. Each indicator will comprise  
7 a numerator and a denominator populated with data collected from the clinic records  
8 and the planned observations.

9  
10 The data on the FB implementation will be analyzed for each of the 36 participating  
11 clinics. Routinely collected data includes clinical registries for both nurses and LHWs  
12 and data from the FB Register (commonly known as the “green book”) where the  
13 LHWs record beneficiary information.

14 In addition, LHWs will be observed during all aspects of their work, including giving  
15 health talks, interacting with clients, and delivering the FB intervention. We will observe  
16 and record whether all FB related tools such as questionnaires and intervention tools  
17 are used.

18 In order to collect additional necessary data for AIM 1, key respondents will be  
19 interviewed using a questionnaire that will be developed by the research team.

20 We plan to interview at least 2 LHWs per clinic and in clinics with more than 2 LHWs,  
21 we will interview 50% of the present LHWs by randomly selecting them. Papers with  
22 their names will be put in a container from which a RA will pull out the appropriate  
23 number in the LHWs’ presence. We will always interview the supervisor LHW of each  
24 clinic if this position is taken in a particular clinic. We will also interview the nurse in  
25 charge in every clinic and the associated district health promoting officers (DHPOs)  
26 (n=10). Data will be collected from June to September 2019 in all participating sites.

27  
28 The data collection will be carried out by two research coordinators who will lead two  
29 teams of four trained and supervised research assistants (RAs). The teams will visit  
30 each clinic for two days. The clinics will be sensitized about the FB team visit a week  
31 prior. The research assistants will be trained to interview, to observe and record the  
32 FB related activities in the clinic and how to enter the data digitally using tablet  
33 computers. They will be trained on data checking, cleaning and uploading.

1  
2  
3 1 Furthermore, we are planning to audio-record FB sessions with consenting clients  
4 (two per site, n=72). We will approach, where possible, all incoming clients seeking  
5 2 services and ask them for informed consent to allow us to record their session with  
6 3 the FB LHWs. We aim to record as many as possible but at least 2 per site.  
7 4

8  
9 5 The recordings will be translated, transcribed and rated according to the Friendship  
10 6 Bench fidelity checklist.

11  
12 7 The FB fidelity checklist assesses for communication skills of the counselor, the level  
13 8 of psychoeducation that is done, and the adherence to the problem-solving therapy  
14 9 steps that the FB counselor is trained to deliver (see Supplementary Appendix A for  
15 10 full fidelity checklist which was developed for the RCT <sup>22</sup>). The assessments of audio  
16 11 recordings will be done by trained FB research team members who will prepare an  
17 12 audio-recorder which will be left with the FB counselor after a client has given consent.  
18 13 The audio recording device will be retrieved by the research assistant when the LHW  
19 14 has indicated that the session is done.

20 15 In the event that no clients come to the clinic on both days that the FB team visits the  
21 16 site or no client consents to have their session audio-recorded, this will be entered as  
22 17 missing. Due to logistic and financial constraints a repeat visit to a particular clinic will  
23 18 not be possible.

24 19 All respondents will be asked to answer the questions with regards to FB activities in  
25 20 the past month. According to their position with regards to FB activities, questions  
26 21 might be formulated slightly differently.  
27 22

28 23 The questionnaires will be administered using tablet computers (Lenovo), all  
29 24 observational data will be entered digitally after their correctness has been ascertained  
30 25 by asking interviewees to show evidence as applicable. Questionnaires and  
31 26 observation guides are programmed into the tablets using Kobotoolbox  
32 27 (<https://www.kobotoolbox.org>) which is a data collection tool. Collected data will be  
33 28 cleaned and uploaded daily to a password secured server.  
34 29

35 30 The research team will also observe FB specific activities such as health and  
36 31 'mobilization' talks that are given by the clinic staff including the LHWs whilst patients  
37 32 are waiting to be seen.  
38 33

1  
2  
3 1 A stakeholder meeting will be held once Aim 1 data is completed and the data is  
4 2 analyzed. At this meeting, the research team will present the results from Aim 1 and  
5 3 discuss potential reasons why we might see the differences in implementation across  
6 4 sites with stakeholders. This meeting will be attended by all relevant clinic staff, health  
7 5 authority officers as well as clients. Information from stakeholders will be used to  
8 6 select and prioritize CFIR constructs to include in qualitative interview guides for Aim  
9 7 2.

#### 10 **4.1.1 Data Analysis Aim 1**

11 The goal of Aim 1 is to classify the 36 FB implementation sites on their performance  
12 based on the RE-AIM outcomes. Our methods will follow similar classification efforts  
13 previously published <sup>28</sup>. Clinics will be first ranked according to their performance  
14 within each individual measure. Clinics score on all indicators within one construct (for  
15 example reach) will be averaged. For each of the RE-AIM constructs, every clinic will  
16 thus have an averaged ranking.

17 These domain-based rankings will be averaged per clinic rankings giving an overall  
18 ranking by calculating simple means of all domain rankings. This procedure will be  
19 carried out by two independent individuals and any differences will lead to a redoing  
20 of the process. In case of same outcomes for clinics, we will treat these particular  
21 clinics as being on the same rank. This will give us a final composite rank for each  
22 clinic which will be used to determine the 10 highest and 10 lowest performing clinics  
23 that will be qualitatively assessed in Aim 2.

#### 25 **4.2 Methods Aim 2**

26 With the aim to understand the determinants of implementation success, as well as  
27 differences in implementation strategies employed, Aim 2 will utilize focus-group  
28 discussions organized around the Consolidated Framework for Implementation  
29 Research (CFIR) <sup>29-31</sup>. Through these qualitative methods, we aim to gain a deeper  
30 understanding of the factors that contribute to the successful implementation  
31 comparing high- with low-performing clinics. The CFIR framework focuses on an  
32 overview of potential multi-level determinants of health care delivery. It was designed  
33 to help understand integrated implementation determinants across multiple levels  
34 (clients; implementers; organizations; contexts; processes).



1  
2  
3  
4  
5 2 For the present study, we will focus on determinants of implementation success, taking  
6 3 lessons from both high- and low-performing clinics to inform the development of an  
7 4 improved package of implementation strategies targeting identified barriers.

8  
9  
10 5 Focus group discussions (FDGs) with key informants (LHWs, nurses, DHPOs, clients)  
11 6 of the 10 high and 10 low performing clinics will be carried out by trained qualitative  
12 7 researchers. The FB specific interview guides for these group discussions and  
13 8 interviews will be developed by the study team in a sequence of internal project  
14 9 meetings using the online technical support website [www.cfirguide.org](http://www.cfirguide.org). The results of  
15 10 Aim 1 will guide us in designing the interview guides for the focus group discussions.  
16 11 The outcome of the stakeholders meeting in which we present the results of Aim 1 will  
17 12 also give us insight on the importance of constructs which we will take into account  
18 13 when designing the CFIR interview guides.

19 14 Interview guides will be translated into the local language Shona and all group  
20 15 discussions will be audio-recorded, transcribed and translated to English. All  
21 16 discussions will be held in the local language.

22 17 The FGD participants will be selected from all 10 low and high performing clinics,  
23 18 respectively. We will interview LHWs, nurses, DHPOs in their role as implementers  
24 19 as well as clients as recipients of the intervention. Nurses and DHPOs will be invited  
25 20 to joined meetings. We will conduct FGDs for all available LHWs at every selected  
26 21 clinic. We will ask the selected LHWs to purposively suggest 2 clients each, whom  
27 22 we will then invite to FGDs in each of the selected clinics. In case a client declines  
28 23 participation, we will ask for another suggestion.

29 24 Focus group discussions will take place in clinics or, if not possible, in the Friendship  
30 25 Bench office in Harare.

#### 31 26 32 27 **4.2 1 Data Analysis Aim 2**

33 28 CFIR analyses will follow the original Damschroder methodology previously published  
34 29 <sup>30</sup>. Briefly, two independent local Zimbabwean reviewers will code each FGD transcript  
35 30 according to the selected CFIR constructs. Differences will be discussed and revised  
36 31 until final codes are agreed on. Facility-level case memos will be organized by the  
37 32 relevant CFIR construct, using each new transcript to confirm and refine statements  
38 33 until all transcripts are coded. This process will be closely supported by the whole



1 research team. Each clinic will have two case memos, one for LHWs and other  
2 implementers and one for clients.

3 Using case memos and supporting transcripts, the same two coders will independently  
4 rate CFIR constructs on valence (X (mixed); 0 (neutral); + (construct has a positive  
5 effect on implementation) or – (construct has a negative influence on implementation).  
6 Once drafted, the entire research team will meet and use a deliberated consensus to  
7 finalize memos, constructs, and valence. These data will be mapped on a matrix  
8 template with the goal of identifying constructs that differ between facilities with high  
9 and low performance to identify factors relevant for the success of the implementation.  
10 Analyses will progress with visual inspection of patterns in constructs and valence by  
11 high versus low performing clinics, as well as examining median and mean valence  
12 by high versus low performing clinics. Once distinguishing constructs are identified,  
13 the team will re-review case memos and coded transcripts to gather more information  
14 on constructs.

### 4.3 Aim 3

19 In Aim 3, we will develop a package of optimized Friendship Bench (OptFB)  
20 implementation strategies matched to key barriers identified in the previous phases of  
21 this study. Using CFIR data on barriers / facilitators to high-quality FB implementation,  
22 we will use the CFIR-ERIC matching tool to examine and select implementation  
23 strategies to address key CFIR constructs discriminating between high and low  
24 performing clinics in Aim 1 (<https://cfirguide.org/choosing-strategies/>)<sup>32 33</sup>. Once a  
25 preliminary list is developed by our team, the CFIR-Expert Recommendation for  
26 Implementation Change (ERIC) matching tool<sup>32</sup> will be used to prioritize those  
27 strategies that are found to be most likely to address CFIR barriers in low-performing  
28 clinics<sup>33 34</sup>.

29 We will engage in a participatory stakeholder Delphi rating exercise to select specific  
30 strategies. This will be followed by the research team specifying and tailoring the  
31 strategies for the Zimbabwean context by including the additional information gained  
32 from the stakeholders. Aspects of feasibility, affordability and effectiveness will guide  
33 this process in order for the package to be meaningful and effective<sup>35</sup>. Strategies  
34 currently in use by high performing clinics will be also considered for the optimized  
35 Friendship Bench (OptFB) implementation strategies.

1 This OptFB package or intervention of improved strategies will be tested in low-  
2 performing clinics. Ongoing RE-AIM data is being collected on a monthly basis in each  
3 clinic. Using these data on RE-AIM outcomes, we will re-classify clinics using a similar  
4 process as in Aim 1. We will then identify the 18 lowest performing clinics and  
5 randomly select 12 clinics to deliver the OptFB and 6 to act as control clinics over a  
6 period of 6 months. The primary outcome will be a composite measure of RE-AIM  
7 indicators (Reach, Effectiveness, Adoption and Implementation and Maintenance)  
8 estimated at 6-month after the commencement of the implementation of the OptFB  
9 intervention. We will estimate changes in this composite measure of implementation  
10 before and at 6 months after starting the delivery of OptFB in all clinics. We will  
11 compare the difference in means or proportions between the clinics receiving the  
12 OptFB and the control clinics using the routinely collected data. Secondary outcomes  
13 will examine performance of each of the RE-AIM outcomes separately and clinical  
14 effectiveness results at individual level. The latter will be based on individual scores to  
15 on the SSQ on a minimum of 20 random individuals per clinic during the 6-month  
16 period.

17 No sample size calculation has been estimated since there are no previous studies on  
18 which to estimate an effect size, the number of clinics is small, and the main outcomes  
19 are averaged data representing clusters. Nonetheless, we expect to see larger  
20 improvements in the RE-AIM composite index score in the clinics receiving OptFB  
21 compared to the control clinics over the 6 months. As a secondary outcome measure,  
22 clinical effectiveness will be assessed based on changes on SSQ scores from baseline  
23 to 6 months for a sample of 360 individuals (18 clinics with 20 individuals each), but  
24 we do not expect this sample would have enough power to detect small differences in  
25 effectiveness across the two group of clinics. Thus, comparisons on clinical  
26 effectiveness must be considered purely descriptive and exploratory and interpreted  
27 with caution. In any case, the main outcomes of interest in this study are  
28 implementation outcomes subsumed under the domains included in the RE-AIM  
29 framework.

### 31 **4.3.1 Data analysis Aim 3**

32 We will use a difference-in-differences analysis comparing the groups over time.  
33 Means or proportions on outcome data will be compared across groups using  
34 descriptive statistics. Regression models will be used to estimate the effect of the

1  
2  
3 1 intervention on the main outcomes. General estimating equations with robust  
4 2 standard errors will be used to control for clustering. Potential confounders will be  
5 3 determined a priori and included in the regression models. Standard errors,  
6 4 confidence intervals, and p-values will be obtained. A similar secondary analysis will  
7 5 be conducted with the secondary outcome measures.  
8  
9

#### 10 6 11 7 **4.4 Health economic analysis** 12 8

13 9 Site-level data will be collected on fidelity to the OptFB implementation strategies,  
14 10 along with activities and resource inputs required to deliver improvement strategies  
15 11 and OptFB delivery costs. Economic modelling will be used to combine this information  
16 12 with data and evidence on clinical impact and implementation effectiveness to  
17 13 evaluate the cost-effectiveness of the OptFB program <sup>36</sup>.

18 14 We will also revisit clinics and re-engage with stakeholders in ~~int~~-FGD to explore level  
19 15 of change in the identified CFIR domains in the intervention arm clinics.

20 16 After completion of the trial, the strategy will also be implemented in the control arm  
21 17 clinics to increase the overall performance in all of participating lower performing  
22 18 clinics.  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34

### 35 21 **5. Discussion**

36 22 This study will contribute to the knowledge about scaling up of an evidence-based  
37 23 task-shifted intervention in a LMIC. This is a unique opportunity to analyze the  
38 24 Friendship Bench in a real-world setting. As mentioned above, not many  
39 25 interventions have been scaled up from LMICs and therefore there is a dearth of  
40 26 information on how implementation strategies can be used in order to ensure a  
41 27 strong scaling up. With this study we hope to learn which barriers and enablers are  
42 28 at play in the FB scale up process. This is particularly important for us as we are  
43 29 expanding the FB services throughout Zimbabwe and beyond to meet the  
44 30 population's needs for accessible and acceptable mental health care. This effort has  
45 31 to be undertaken with the aim of having high fidelity to the program while considering  
46 32 contextual aspects. Using implementation science principles will help us to give  
47 33 theoretical justification and describe specifications for application for those  
48 34 implementation strategies that we will devise after having gone through the different

1 stages of this research process. Evidence-based, clear and applicable guidelines of  
2 how to implement our evidence-based intervention in primary health care settings  
3 will be created and can then subsequently be used to ensure a strong  
4 implementation of FB.

## 6. Ethics and dissemination

This research protocol has been approved by the Medical Research Council Zimbabwe (MRCZ), MRCZ/A/2428 and the Joint Research Council (JREC), 79/19. Results will be disseminated in peer-reviewed journals and conferences.

## References

1. Vigo D, Thornicroft G, Atun R. Estimating the true global burden of mental illness. *Lancet Psychiatry* 2016;3(2):171-8. doi: 10.1016/S2215-0366(15)00505-2 [published Online First: 2016/02/07]
2. Kessler RC, Aguilar-Gaxiola S, Alonso J, et al. The global burden of mental disorders: an update from the WHO World Mental Health (WMH) surveys. *Epidemiol Psychiatr Soc* 2009;18(1):23-33. doi: 10.1017/s1121189x00001421 [published Online First: 2009/04/22]
3. Whiteford HA, Ferrari AJ, Degenhardt L, et al. The global burden of mental, neurological and substance use disorders: an analysis from the Global Burden of Disease Study 2010. *PLoS One* 2015;10(2):e0116820. doi: 10.1371/journal.pone.0116820 [published Online First: 2015/02/07]
4. Steel Z, Marnane C, Iranpour C, et al. The global prevalence of common mental disorders: a systematic review and meta-analysis 1980–2013. *International journal of epidemiology* 2014:dyy038.
5. Lund C, De Silva M, Plagerson S, et al. Poverty and mental disorders: breaking the cycle in low-income and middle-income countries. *The Lancet* 2011;378(9801):1502-14.
6. Evans-Lacko S, Aguilar-Gaxiola S, Al-Hamzawi A, et al. Socio-economic variations in the mental health treatment gap for people with anxiety, mood, and substance use disorders: results from the WHO World Mental Health (WMH) surveys. *Psychological medicine* 2018;48(9):1560-71. doi: 10.1017/S0033291717003336 [published Online First: 2017/11/28]
7. Wang PS, Aguilar-Gaxiola S, Alonso J, et al. Use of mental health services for anxiety, mood, and substance disorders in 17 countries in the WHO world mental health surveys. *The Lancet* 2007;370(9590):841-50.

- 1  
2  
3 1 8. Mojtabai R, Olfson M, Sampson NA, et al. Barriers to mental health treatment: results  
4 2 from the National Comorbidity Survey Replication. *Psychological medicine*  
5 3 2011;41(8):1751-61. doi: 10.1017/S0033291710002291 [published Online First:  
6 4 2010/12/08]
- 7 5 9. Kohn R, Saxena S, Levav I, et al. The treatment gap in mental health care. *Bull World*  
8 6 *Health Organ* 2004;82(11):858-66. doi: /S0042-96862004001100011 [published  
9 7 Online First: 2005/01/11]
- 10 8 10. Prince M, Patel V, Saxena S, et al. No health without mental health. *The lancet*  
11 9 2007;370(9590):859-77.
- 12 10 11. Alonso J, Liu Z, Evans-Lacko S, et al. Treatment gap for anxiety disorders is global: Results  
13 11 of the World Mental Health Surveys in 21 countries. *Depress Anxiety* 2018;35(3):195-  
14 12 208. doi: 10.1002/da.22711 [published Online First: 2018/01/23]
- 15 13 12. Wang PS, Angermeyer M, Borges G, et al. Delay and failure in treatment seeking after  
16 14 first onset of mental disorders in the World Health Organization's World Mental  
17 15 Health Survey Initiative. *World Psychiatry* 2007;6(3):177-85. [published Online First:  
18 16 2008/01/12]
- 19 17 13. Araya R, Rojas G, Fritsch R, et al. Treating depression in primary care in low-income  
20 18 women in Santiago, Chile: a randomised controlled trial. *Lancet* 2003;361(9362):995-  
21 19 1000. doi: 10.1016/S0140-6736(03)12825-5
- 22 20 14. Patel V, Thornicroft G. Packages of care for mental, neurological, and substance use  
23 21 disorders in low-and middle-income countries: PLoS Medicine Series. *PLoS medicine*  
24 22 2009;6(10):e1000160.
- 25 23 15. Chatterjee S, Chowdhary N, Pednekar S, et al. Integrating evidence-based treatments for  
26 24 common mental disorders in routine primary care: feasibility and acceptability of the  
27 25 MANAS intervention in Goa, India. *World Psychiatry* 2008;7(1):39-46.
- 28 26 16. Rahman A, Malik A, Sikander S, et al. Cognitive behaviour therapy-based intervention by  
29 27 community health workers for mothers with depression and their infants in rural  
30 28 Pakistan: a cluster-randomised controlled trial. *The Lancet* 2008;372(9642):902-09.
- 31 29 17. Bolton P, Bass J, Neugebauer R, et al. Group interpersonal psychotherapy for depression  
32 30 in rural Uganda: a randomized controlled trial. *Jama* 2003;289(23):3117-24.
- 33 31 18. Lund C, Alem A, Schneider M, et al. Generating evidence to narrow the treatment gap  
34 32 for mental disorders in sub-Saharan Africa: rationale, overview and methods of  
35 33 AFFIRM. *Epidemiol Psychiatr Sci* 2015;24(3):233-40. doi:  
36 34 10.1017/S2045796015000281 [published Online First: 2015/04/03]
- 37 35 19. Wagenaar BH, Hammett, W.H., Jackson, C., Atkins, D.L., Belus, J.M. and Kemp, C.G.  
38 36 Implementation outcomes and strategies for depression interventions in low-and  
39 37 middle-income countries: a systematic review. . *Global Mental Health* 2020;7
- 40 38 20. Chibanda D, Mesu P, Kajawu L, et al. Problem-solving therapy for depression and  
41 39 common mental disorders in Zimbabwe: piloting a task-shifting primary mental  
42 40 health care intervention in a population with a high prevalence of people living with  
43 41 HIV. *BMC public health* 2011;11:828. doi: 10.1186/1471-2458-11-828 [published  
44 42 Online First: 2011/10/28]
- 45 43 21. Antelman G, Kaaya S, Wei R, et al. Depressive symptoms increase risk of HIV disease  
46 44 progression and mortality among women in Tanzania. *Journal of acquired immune*  
47 45 *deficiency syndromes* 2007;44(4):470-7. doi: 10.1097/QAI.0b013e31802f1318
- 48 46 22. Chibanda D, Weiss HA, Verhey R, et al. Effect of a Primary Care-Based Psychological  
49 47 Intervention on Symptoms of Common Mental Disorders in Zimbabwe: A



- 1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60
- 1 Randomized Clinical Trial. *JAMA* 2016;316(24):2618-26. doi:  
2 10.1001/jama.2016.19102 [published Online First: 2016/12/28]
- 3 23. Chibanda D, Bowers T, Verhey R, et al. The Friendship Bench programme: a cluster  
4 randomised controlled trial of a brief psychological intervention for common mental  
5 disorders delivered by lay health workers in Zimbabwe. *Int J Ment Health Syst*  
6 2015;9:21. doi: 10.1186/s13033-015-0013-y [published Online First: 2015/01/01]
- 7 24. Chibanda D, Verhey R, Munetsi E, et al. Scaling up interventions for depression in sub-  
8 Saharan Africa: lessons from Zimbabwe. *Glob Ment Health (Camb)* 2016;3:e13. doi:  
9 10.1017/gmh.2016.8 [published Online First: 2016/04/11]
- 10 25. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health  
11 promotion interventions: the RE-AIM framework. *Am J Public Health*  
12 1999;89(9):1322-27.
- 13 26. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health  
14 promotion interventions: the RE-AIM framework. *American journal of public health*  
15 1999;89(9):1322-7. doi: 10.2105/ajph.89.9.1322 [published Online First: 1999/09/04]
- 16 27. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services  
17 research findings into practice: a consolidated framework for advancing  
18 implementation science. *Implement Sci* 2009;4:50. doi: 10.1186/1748-5908-4-50  
19 [published Online First: 2009/08/12]
- 20 28. Farris RP, Will JC, Khavjou O, et al. Beyond effectiveness: evaluating the public health  
21 impact of the WISEWOMAN program. *American journal of public health*  
22 2007;97(4):641-47.
- 23 29. Breimaier HE, Heckemann B, Halfens RJ, et al. The Consolidated Framework for  
24 Implementation Research (CFIR): a useful theoretical framework for guiding and  
25 evaluating a guideline implementation process in a hospital-based nursing practice.  
26 *BMC Nurs* 2015;14:43. doi: 10.1186/s12912-015-0088-4 [published Online First:  
27 2015/08/14]
- 28 30. Damschroder LJ, Lowery JC. Evaluation of a large-scale weight management program  
29 using the consolidated framework for implementation research (CFIR). *Implement Sci*  
30 2013;8:51. doi: 10.1186/1748-5908-8-51 [published Online First: 2013/05/15]
- 31 31. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services  
32 research findings into practice: a consolidated framework for advancing  
33 implementation science. *Implementation science* 2009;4(1):50.
- 34 32. Powell BJ, Waltz TJ, Chinman MJ, et al. A refined compilation of implementation  
35 strategies: results from the Expert Recommendations for Implementing Change  
36 (ERIC) project. *Implement Sci* 2015;10:21. doi: 10.1186/s13012-015-0209-1  
37 [published Online First: 2015/04/19]
- 38 33. Waltz TJ, Powell BJ, Fernandez ME, et al. Choosing implementation strategies to address  
39 contextual barriers: diversity in recommendations and future directions. *Implement*  
40 *Sci* 2019;14(1):42. doi: 10.1186/s13012-019-0892-4 [published Online First:  
41 2019/05/01]
- 42 34. Godbee K, Gunn J, Lautenschlager NT, et al. Refined conceptual model for implementing  
43 dementia risk reduction: incorporating perspectives from Australian general  
44 practice. *Aust J Prim Health* 2020;26(3):247-55. doi: 10.1071/PY19249 [published  
45 Online First: 2020/05/28]

- 1  
2  
3 1 35. Cooper LA, Hill MN, Powe NR. Designing and evaluating interventions to eliminate racial  
4 2 and ethnic disparities in health care. *J Gen Intern Med* 2002;17(6):477-86. doi:  
5 3 10.1046/j.1525-1497.2002.10633.x [published Online First: 2002/07/23]  
6 4 36. Briggs A, Sculpher, M., & Claxton, K. . Decision modelling for health economic  
7 5 evaluation. Oxford: Oup Oxford 2006.  
8  
9

10 6  
11  
12  
13 7  
14 8  
15 9  
16  
17  
18 10  
19  
20 11  
21 12  
22  
23 13  
24  
25 14  
26  
27 15  
28  
29  
30 16  
31  
32 17 **Footnotes**

33  
34 18 **Contributors**

35  
36  
37 19 RA designed the study and received the grant. RA is the overall PI. RV and DC are  
38 20 leading the study locally. CC will have oversight as project coordinator together with  
39 21 SM as her assistant over the data collection in all phases. BW is leading on the  
40 22 implantation science aspects. EC is conducting data cleaning and assisting with  
41 23 analysis. AH is leading on the health economics analysis. All authors will contribute  
42 24 to the development of questionnaires, interview guides and the strategies for the  
43 25 intervention. RV wrote the first version of the protocol paper. All authors contributed  
44 26 by critically reviewing all further drafts and approving of the final paper.  
45  
46

47 27 **Funding**

---

48  
49 28 This work was supported by Global Alliance for Chronic Diseases (GACD) through  
50 29 the Medical Research Council Grant number: MRC UKRI MR/S004270/1.  
51  
52 30  
53 31

54 32 **Competing interests** None declared.

55  
56 33 **Patient consent for publication** Not required.

---

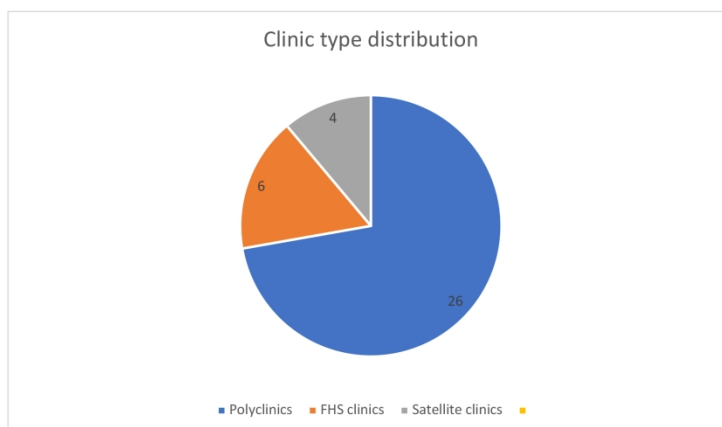


Figure 1: Clinic type distribution for Harare, Gweru and Chitungwiza





**Table 1. Checklist for audio-recorded sessions**

**LHW FIDELITY CHECKLIST**

LHW Name _____ Client's Name _____		Site Code <input type="text"/> <input type="text"/>	
Date            /            /			
<b><i>(Tick where appropriate)</i></b>		<b>YES</b>	<b>NO</b>
1.	LHW introduced self to client and asked client to introduce self	<input type="checkbox"/>	<input type="checkbox"/>
2.	Psycho-education done properly	<input type="checkbox"/>	<input type="checkbox"/>
	a. Linked HIV to kufungisisa	<input type="checkbox"/>	<input type="checkbox"/>
	b. Adherence	<input type="checkbox"/>	<input type="checkbox"/>
	c. Diet advise done	<input type="checkbox"/>	<input type="checkbox"/>
3.	Problems presented by client	<input type="checkbox"/>	<input type="checkbox"/>
4.	LHW listening and acknowledging	<input type="checkbox"/>	<input type="checkbox"/>
5.	LHW gives summary of problems	<input type="checkbox"/>	<input type="checkbox"/>
6.	Client selected problem, not LHW	<input type="checkbox"/>	<input type="checkbox"/>
7.	LHW and client discuss problem identified by client	<input type="checkbox"/>	<input type="checkbox"/>
8.	Client identifies solutions to the problem identified	<input type="checkbox"/>	<input type="checkbox"/>
9.	LHW and client identify task for client to work with	<input type="checkbox"/>	<input type="checkbox"/>
10.	Session closure and next correct review date	<input type="checkbox"/>	<input type="checkbox"/>
<b>Total</b>		___/10	___/10

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. *BMJ*. 2013;346:e7586

		Reporting Item	Page Number
<b>Administrative information</b>			
Title	<a href="#">#1</a>	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet registered, name of intended registry	n/a
Trial registration: data set	<a href="#">#2b</a>	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	<a href="#">#3</a>	Date and version identifier	
Funding	<a href="#">#4</a>	Sources and types of financial, material, and other support	2
Roles and responsibilities: contributorship	<a href="#">#5a</a>	Names, affiliations, and roles of protocol contributors	17

1	Roles and	<a href="#">#5b</a>	Name and contact information for the trial sponsor	n/a
2	responsibilities:			
3	sponsor contact			
4	information			
5				
6				
7				
8	Roles and	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study design;	n/a
9	responsibilities:		collection, management, analysis, and interpretation of data;	
10	sponsor and funder		writing of the report; and the decision to submit the report for	
11			publication, including whether they will have ultimate authority	
12			over any of these activities	
13				
14				
15				
16	Roles and	<a href="#">#5d</a>	Composition, roles, and responsibilities of the coordinating	n/a
17	responsibilities:		centre, steering committee, endpoint adjudication committee,	
18	committees		data management team, and other individuals or groups	
19			overseeing the trial, if applicable (see Item 21a for data	
20			monitoring committee)	
21				
22				
23				
24	<b>Introduction</b>			
25				
26				
27	Background and	<a href="#">#6a</a>	Description of research question and justification for undertaking	3
28	rationale		the trial, including summary of relevant studies (published and	
29			unpublished) examining benefits and harms for each intervention	
30				
31				
32	Background and	<a href="#">#6b</a>	Explanation for choice of comparators	n/a
33	rationale: choice of			
34	comparators			
35				
36				
37	Objectives	<a href="#">#7</a>	Specific objectives or hypotheses	4
38				
39				
40	Trial design	<a href="#">#8</a>	Description of trial design including type of trial (eg, parallel	4
41			group, crossover, factorial, single group), allocation ratio, and	
42			framework (eg, superiority, equivalence, non-inferiority,	
43			exploratory)	
44				
45				
46	<b>Methods:</b>			
47	<b>Participants,</b>			
48	<b>interventions, and</b>			
49	<b>outcomes</b>			
50				
51				
52				
53	Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic, academic	5
54			hospital) and list of countries where data will be collected.	
55			Reference to where list of study sites can be obtained	
56				
57				
58				
59				
60				

1	Eligibility criteria	<a href="#">#10</a>	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
2				
3				
4				
5				
6	Interventions:	<a href="#">#11a</a>	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-11
7	description			
8				
9				
10	Interventions:	<a href="#">#11b</a>	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a
11	modifications			
12				
13				
14				
15	Interventions:	<a href="#">#11c</a>	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	n/a
16	adherence			
17				
18				
19				
20	Interventions:	<a href="#">#11d</a>	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
21	concomitant care			
22				
23				
24	Outcomes	<a href="#">#12</a>	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-10
25				
26				
27				
28				
29				
30				
31				
32				
33				
34	Participant timeline	<a href="#">#13</a>	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	n/a
35				
36				
37				
38				
39				
40	Sample size	<a href="#">#14</a>	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	n/a
41				
42				
43				
44				
45	Recruitment	<a href="#">#15</a>	Strategies for achieving adequate participant enrolment to reach target sample size	n/a
46				
47				
48				
49	<b>Methods: Assignment</b>			
50	<b>of interventions (for</b>			
51	<b>controlled trials)</b>			
52				
53				
54	Allocation: sequence	<a href="#">#16a</a>	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be	n/a
55	generation			
56				
57				
58				
59				
60				

provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism	<a href="#">#16b</a>	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a
Allocation: implementation	<a href="#">#16c</a>	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
Blinding (masking): emergency unblinding	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
<b>Methods: Data collection, management, and analysis</b>			
Data collection plan	<a href="#">#18a</a>	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7-10
Data collection plan: retention	<a href="#">#18b</a>	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a
Data management	<a href="#">#19</a>	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9-10
Statistics: outcomes	<a href="#">#20a</a>	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9-10, 12

1	Statistics: additional	<a href="#">#20b</a>	Methods for any additional analyses (eg, subgroup and adjusted	n/a
2	analyses		analyses)	
3				
4	Statistics: analysis	<a href="#">#20c</a>	Definition of analysis population relating to protocol non-	n/a
5	population and missing		adherence (eg, as randomised analysis), and any statistical	
6	data		methods to handle missing data (eg, multiple imputation)	
7				
8				
9				
10	<b>Methods: Monitoring</b>			
11				
12	Data monitoring:	<a href="#">#21a</a>	Composition of data monitoring committee (DMC); summary of	n/a
13	formal committee		its role and reporting structure; statement of whether it is	
14			independent from the sponsor and competing interests; and	
15			reference to where further details about its charter can be found,	
16			if not in the protocol. Alternatively, an explanation of why a	
17			DMC is not needed	
18				
19				
20				
21				
22	Data monitoring:	<a href="#">#21b</a>	Description of any interim analyses and stopping guidelines,	n/a
23	interim analysis		including who will have access to these interim results and make	
24			the final decision to terminate the trial	
25				
26				
27	Harms	<a href="#">#22</a>	Plans for collecting, assessing, reporting, and managing solicited	n/a
28			and spontaneously reported adverse events and other unintended	
29			effects of trial interventions or trial conduct	
30				
31				
32				
33	Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial conduct, if any, and	n/a
34			whether the process will be independent from investigators and	
35			the sponsor	
36				
37				
38	<b>Ethics and</b>			
39	<b>dissemination</b>			
40				
41				
42	Research ethics	<a href="#">#24</a>	Plans for seeking research ethics committee / institutional review	2
43	approval		board (REC / IRB) approval	
44				
45				
46	Protocol amendments	<a href="#">#25</a>	Plans for communicating important protocol modifications (eg,	2
47			changes to eligibility criteria, outcomes, analyses) to relevant	
48			parties (eg, investigators, REC / IRBs, trial participants, trial	
49			registries, journals, regulators)	
50				
51				
52				
53	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from potential trial	8
54			participants or authorised surrogates, and how (see Item 32)	
55				
56				
57				
58				
59				
60				

1	Consent or assent:	<a href="#">#26b</a>	Additional consent provisions for collection and use of	n/a
2	ancillary studies		participant data and biological specimens in ancillary studies, if	
3			applicable	
4				
5				
6	Confidentiality	<a href="#">#27</a>	How personal information about potential and enrolled	n/a
7			participants will be collected, shared, and maintained in order to	
8			protect confidentiality before, during, and after the trial	
9				
10				
11	Declaration of interests	<a href="#">#28</a>	Financial and other competing interests for principal investigators	17
12			for the overall trial and each study site	
13				
14				
15	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial dataset, and	
16			disclosure of contractual agreements that limit such access for	
17			investigators	
18				
19				
20	Ancillary and post trial	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care, and for	n/a
21	care		compensation to those who suffer harm from trial participation	
22				
23				
24	Dissemination policy:	<a href="#">#31a</a>	Plans for investigators and sponsor to communicate trial results	2
25	trial results		to participants, healthcare professionals, the public, and other	
26			relevant groups (eg, via publication, reporting in results	
27			databases, or other data sharing arrangements), including any	
28			publication restrictions	
29				
30				
31				
32				
33	Dissemination policy:	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended use of	n/a
34	authorship		professional writers	
35				
36				
37	Dissemination policy:	<a href="#">#31c</a>	Plans, if any, for granting public access to the full protocol,	n/a
38	reproducible research		participant-level dataset, and statistical code	
39				
40				
41	<b>Appendices</b>			
42				
43	Informed consent	<a href="#">#32</a>	Model consent form and other related documentation given to	18
44	materials		participants and authorised surrogates	
45				
46				
47	Biological specimens	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and storage of	n/a
48			biological specimens for genetic or molecular analysis in the	
49			current trial and for future use in ancillary studies, if applicable	
50				
51				

None The SPIRIT checklist is distributed under the terms of the Creative Commons Attribution License CC-BY-ND 3.0. This checklist can be completed online using <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)