Development and scaling up of a psychological intervention for common mental disorders among people living with HIV in Zimbabwe

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Thesis presented for the degree of Doctor of Philosophy



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This thesis is dedicated to the lay health workers who have made a difference to the lives of thousands of people in Zimbabwe and have taught me a great deal about how not to conduct psychotherapy

Statement of original authorship

This thesis is presented in fulfilment of the requirements for the degree of Doctor of Philosophy (PhD), University of Cape Town. Academic supervisors were Prof Crick Lund and Prof Frances Cowan. The work on which the thesis is based is original research and has not, in whole or in part, been submitted for another degree at this or any other university. The contents of this doctoral thesis are entirely the work of the candidate, who conceptualised and carried out the research project. The five co-authored journal articles included in this thesis are directly based on the research project, and constitute work for which the candidate was the lead author and the academic supervisor was the second author or last author. The inclusion of papers is outlined in the preface of this thesis, and the role of each author described in the introduction to each paper.

Dixon Chibanda 15th October 2015

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Acronyms

AIDS Acquired Immunodeficiency Syndrome

ART Antiretroviral Therapy

CBT Cognitive Behaviour Therapy

CHC Child Health Card

CHW Community Health Worker

CMD Common mental Disorders

GAD-7 Generalized anxiety disorder questionnaire

HAART Highly Active Anti-Retroviral Therapy

HAQol HIV AIDS quality of life scale

HIV Human Immunodeficiency Virus

LHW Lay Health Worker

LMIC Low and middle income country

PHQ-9 Patient health Questionnaire

PLWV People living with HIV and AIDS

PMTCT Prevention of Mother to Child Transmission of HIV

PST Problem Solving Therapy

SCID Structured Clinical Interview for DSM IV

SSQ-14 Shona Symptom Questionnaire-14

TOC Theory of Change

Abstract

Common mental disorders (CMD) which primarily include depression, anxiety disorders and mixed anxiety depression are leading causes of disability in sub-Saharan Africa. They are particularly common in people living with HIV (PLWH) and may hasten HIV disease progression.

This thesis consists of 5 articles which have been submitted for publication and provide evidence on the requirements for developing a psychological intervention to be delivered by lay health workers (LHW) and a strategy for scaling up this intervention to over 50 primary health care clinics in Harare, Zimbabwe. The thesis formed part of formative research leading to a cluster randomized controlled trial (RCT) of a psychological intervention and provides supplementary research to the RCT to support the scale up of the intervention.

The first chapter describes the magnitude of the problem and the lack of resources to reduce the treatment gap for CMD. It highlights the growing evidence of using Lay Health Workers (LHW) to reduce this treatment gap.

Chapter two describes the results of a systematic literature review of psychological interventions carried out in low and middle-income countries (LMIC) for CMD among PLWH. Key findings of the review include the lack of evidence-based interventions in this field with only 5 studies identified. Of the 5 eligible studies, four did not meet the Consolidated Standards of Reporting Trials (CONSORT) guidelines, highlighting the need for well-designed interventions in this area.

Chapter three describes a cross-sectional study that examines the prevalence and correlates of CMD in a high HIV prevalence setting in Zimbabwe. Of the 264 participants, 165 (62.5%) were PLWH, and 152 (92%) of these were on Highly Active Anti-Retroviral Therapy (HAART). The prevalence of CMD as measured by the Shona Symptom Questionnaire (SSQ14>=9) and depression according to the Patient Health Questionnaire (PHQ9>=11) were higher among people living with HIV than among those without HIV (67.9% and 64.9% (p=0.02) vs 51.4% and 44.4%

(p=0.003) respectively). The study further shows that CMD in PLWH is associated with negative life events and female gender.

The fourth chapter describes the results of a qualitative study that examined the experience of LHWs in delivering a psychological intervention based on problem solving therapy for PLWH. This study reveals that over a 4-year period LHWs themselves developed three key concepts to navigate delivery of the problem solving therapy based intervention. These included opening the mind (kuvhura pfungwa), uplifting (kusimudzira) and strengthening (kusimbisa). Through these concepts, which they developed through knowledge sharing, it was possible to adapt a western developed therapy to address local mental health needs of Zimbabweans.

The fifth chapter describes a series of workshops conducted using the theory of change model (ToC) as a way of building consensus and defining the overall objective of the trial with an emphasis on integrating a package of care for PLWH with CMD. The ToC workshops led to development of a ToC map describing the causal pathway for the initiative with interventions, indicators, barriers, and rationale outlined for each point along the pathway to impact.

In the sixth chapter the thesis focuses on the development of a strategy for scaling up the intervention to over 50 primary health care clinics in Harare. This chapter focuses on the core competencies of LHWs, putting in place a supervision strategy, bringing on board key stakeholders and accessing funding for the scale up.

The final chapter provides a summary of key findings and recommendations for future research, which include looking into the use of mobile phone technology to provide supervision, and expanding the use of LHWs for other mental, neurological and substance use disorders.

Preface

This doctoral thesis includes published/to be published journal articles, as per general provision 6.7 in the General Rules for the Degree of Doctor of Philosophy (PhD) of the University of Cape Town. The University Doctoral Degree Board approved the submission of the thesis in this format on 29th March 2013. The thesis itself is not simply a compilation of relevant publications. All papers are directly on the thesis topic, forming a single-themed, cohesive body of work.

All papers include the candidate and the two supervisors as main authors, while those who contributed in data collection and or analysis are included as authors for some of the papers. The candidate is the lead and corresponding author for all papers. He provided the lead intellectual drive in every case through formulation of the research project, design, data collection, analysis, and writing of the journal articles. The last and second authors are his academic supervisors: Prof Crick Lund and Prof Frances Cowan. The contribution of the supervisors was to ensure that the methodology was sound, findings stated clearly, and papers written in the format required by journals. The supervisors also critically reviewed and approved the manuscripts before submission to journals. The candidate assessed their comments and integrated them, where necessary.

The following five papers are included as part of this thesis:

- Chibanda D., Cowan F., Healy J., Abas M., & Lund C. (2015) Psychological interventions for common mental disorders for people living with HIV in low and middle-income countries: Systematic Review. *Trop Med Int Health* 2015. 20(7): 830-839
- Chibanda D., Cowan F., Weiss H., & Lund C. Prevalence and correlates of probable common mental disorders in a population with high prevalence of HIV in Zimbabwe. *Under review BMC Psychiatry*
- Chibanda D., Cowan F., Verhey R., Machando D., Abas M., & Lund C. Lay Health workers' experience of delivering a cognitive behaviour therapy based intervention for common mental disorders among people living with HIV: A qualitative study from Zimbabwe. *Under review Community mental Health Journal*.

- 4. Chibanda D., Verhey R., Munetsi E., Cowan F., & Lund C. Using a theory driven approach to develop and evaluate a complex mental health intervention: The Friendship Bench project in Zimbabwe. *Under review International Journal of Mental Health Systems*.
- 5. Chibanda D., Verhey R., Munetsi E., Rusakaniko S., Cowan F., & Lund C. Scaling up interventions for depression in sub-Saharan Africa: lessons from Zimbabwe. *Under review Journal of Global mental health*

All papers were submitted to different journals in the style required by the respective journals, however, in this thesis document the referencing used has been standardized.

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Chapter 1

Introduction

1.1 Common Mental Disorders and HIV

Common Mental Disorders (CMD), by which we mean depression, anxiety disorders and somatoform disorders are projected to become leading causes of disease burden by 2020 [1, 2]. Common mental disorders share similar manifestation, particularly in primary health care settings where they present with a spectrum of somatic, anxiety including posttraumatic and depressive symptoms that respond to similar treatment modalities [3-5]. In recent years the term 'CMD' has become synonymous with a public health approach to mental health service delivery and care [6-9]. This is reflected in the World Health Organization's (WHO) mental health Gap Action Programme (mhGAP) treatment care package which outlines treatment algorithms for common mental, neurological and substance use disorders in low and middle income countries [10, 11].

Low and middle-income countries (LMIC) report the highest disease burden due to CMD [5, 12], as well as a substantial treatment gap ranging from 75% to 90% [13] [14]. This treatment gap is largely due to inadequate resources and trained personnel [10, 15]. There is, however, growing evidence from LMIC as well as from High Income Countries suggesting that the treatment gap for CMD can be at least partially addressed using psychological interventions [16-19]. In Africa only a small proportion of those affected with CMD have access to such interventions [15]. In recent years evidence is growing on how best traditional healers could be incorporated into structured programs for CMD [16].

In Zimbabwe, CMD prevalence rates of over 25% have been reported in primary health care facilities and maternal health services [20-23]. Among people living with HIV (PLWH) data on CMD remains limited [21]. However, unpublished data from two of the largest HIV clinics indicate that the prevalence of CMD among PLWH is estimated to be 40% [24]. Studies elsewhere indicate that depression, a common feature of CMD, is the most frequent DSM IV Axis I psychiatric disorder among PLWH [25-28] and is a risk factor for poor retention in care, risky sexual behavior

[37] and is associated with rapid disease progression [29-33]. In LMIC, depression has been found to be the most common psychiatric condition among PLWH taking highly active anti-retroviral treatments [21, 31, 34-36].

These findings have major public health implications as more people in Sub Saharan Africa are commenced on HAART. With the new WHO guidelines released in September 2015 indicating that HAART should be initiated in all adults living with HIV regardless of CD4 count, adherence to treatment will be critical. Effective HAART requires adherence of over 95% for optimal efficacy. In Zimbabwe, for CMD using a locally validated instrument, the Shona Symptom screening Questionnaire (SSQ-14) [38] has consistently shown high rates of CMD to be associated with female gender, recent life events, poor socio-economic background and HIV infection [5, 21, 39-41]. Depression for instance is known to independently hasten HIV disease progression and is associated with risky behavior, poor adherence to HAART and relationship difficulties [25, 28, 37]. The SSQ-14 is a 14item screening tool for common mental disorders, locally referred to as kufungisisa, which contains indigenous idioms of distress. It has a high level of internal consistency (Cronbach's alpha =0.85). It has sensitivity at cut-off of 7/8 of 96%, specificity of 83%, and positive predictive value and negative predictive value of 66% and 83% respectively [38, 42]. Using local idioms of distress the word 'Kufungisisa' which means 'thinking too much' has become synonymous with the western equivalent of depression [38, 42, 43].

1.2 Lay health workers and task shifting in mental health services

Common mental disorders are treatable and low cost psychological interventions delivered by lay health workers (commonly referred to as task shifting interventions) have shown promising results in several LMIC [17, 18, 44, 45]. Interventions that have been found to be effective for CMD, and in particular depression, include group interpersonal therapy in Uganda [46], individual based interpersonal therapy, cognitive behavior therapy (CBT) and problem solving therapy (PST) [17, 43, 47]. These interventions have been successfully delivered by non-specialized health cadres [18, 43, 47, 48]. Non-specialists include community health workers or lay

health workers with varying educational background but lacking professional expertise in mental health [43].

The use of non-specialized health cadres is in line with the call to scale up global health interventions using lay health workers as a way of reducing the treatment gap for mental, neurological and substance use disorders [11, 49] with specific frameworks available on how to achieve this scale up [10, 50]. There is a growing body of evidence suggesting that lay health workers can be effective in delivering interventions to address a wide range of public health issues including those relating to mental health [44, 45, 54]. In Sub Saharan Africa where the ratio of mental health professionals to the population is approximately 1: 2.5 million for psychologists, 1: 1 million for mental health nurses and 1 per 2 million for psychiatrists [15] there is an urgent need to explore the use of lay health workers to address the mental health treatment gap [10, 43, 50].

Current evidence shows that improving mental health is a low cost way to improve quality of life and reduce disability [44, 54]. In Chile, for instance, low intensity, low-cost treatments for depression delivered by lay health workers have been successfully integrated into primary health care [18, 54, 55]. Low intensity, low cost interventions include, for example, psycho-education, problem-solving therapy (PST) and self help approaches [43, 44, 54, 56].

In Zimbabwe, using locally developed screening tools [38, 57, 58] lay health workers employed by the city health department have managed to screen patients for common mental disorders at primary health care level. Recently we obtained preliminary data to suggest that using lay health workers to provide a structured psychological intervention based on problem solving therapy for depression and CMD may be effective [43]. Such findings have been found in several studies conducted in LMIC [9,18].

It is in this context that the Friendship Bench programme was developed – as a locally developed psychological intervention for CMD, delivered by lay health workers supported through a stepped care model within primary health care facilities.

1.3 History and Development of the Friendship Bench

The Friendship Bench project was developed in 2006 after a government resettlement programme that left over 500 000 people homeless. The 'clean up' operation aimed at removing illegal settlements in the country's urban areas was characterized by the destruction of structures that were deemed illegal; these included business, and accommodation structures [64]. At the time, *Mbare*, a high-density township outside central Harare, was seen as the most affected by the clean up exercise with an estimated 140 000 people made homeless [64]. A baseline survey of CMD among the general population of Mbare at that time found rates of over 40% [65].

It was against this background that local stakeholders with the support of the City Health department, Ministry of Health and Child Welfare (MoHCW) and several NGO's, identified the need for a community mental health intervention. This had to be at no extra cost to the primary health clinics, to utilize space outside the overcrowded clinic rooms, and to use methods already tested locally. A pilot intervention based on a problem-solving approach was identified [57]. It was suggested that lay health workers deliver this, as the nursing staff had no time to provide structured talk therapy. A team comprising psychologists, a primary care nurse and a psychiatrist (DC) adapted existing training materials on problem solving therapy [57, 59, 66].

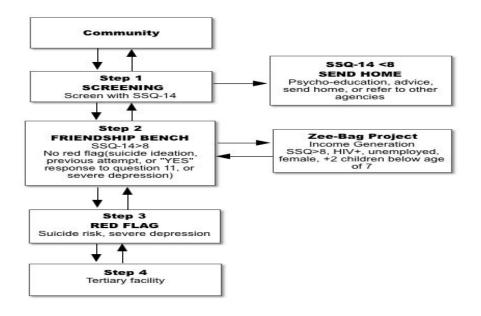
The initial interaction on the Friendship Bench consists of screening and assessment, which is then followed by either giving advice, psychosocial support, referral, or advise for those who score less than the cut-off score of 8 out of 14 on the Shona Symptom Questionnaire (SSQ) [38]. Step 2 consists of the problem solving therapy for those who score 8 or above on the SSQ (Figure 1.1).

The intervention is carried out on a Bench situated within the grounds of the clinic in a quiet and discrete area. The LHW covering the Bench on a given day will receive referrals from the clinic nurses and community. Referred clients will go directly to the Bench where the session will commence after baseline data have been collected, which includes the SSQ-14 variables.

The Friendship Bench intervention is adapted from an earlier seven-step plan previously used in partnership with government; lay and traditional healers to treat CMD [57]. Up to a maximum of 6 sessions are offered with the second session taking place at the client's home and sometimes one of the later sessions. Those most in financial need are referred to a local income-generating project, the Zee Bag Project, which currently operates from the main tertiary hospital.

Between 2007-2010, lay workers in the pilot site of Mbare have screened over 5,870 people for mental health problems, with 9% (511) of these being PLWH. This roughly reflects the prevailing prevalence of HIV of 14% [67]. However, these figures are low for PLWH because at the time the site clinic in Mbare did not provid HIV treatment and care services. The clinic nursing staff and community organizations were the main source of referral while some members of the community approached the Bench directly. All 5,870 were given advice (referred to as Step 1 of the intervention (see Figure 1.1) and nearly 10% (570 persons) were treated with an additional 3-6 sessions of problem-solving therapy, referred to as step 2 of the intervention [43]. Those identified as most vulnerable and economically disadvantaged were further referred to the income generation component, the Zee-Bag project based on criteria described in Figure 1.

Figure 1.1 Profile of Friendship Bench Intervention



1.4 Problem solving therapy

Problem solving therapy (PST) includes identification and exploration of problems, and identification and implementation of solutions [59-61]. It is based on cognitive behavior therapy (CBT) techniques and can be used in primary care [60]. It is a cost-effective way of addressing factors leading to common mental disorders [61]. PST assumes that CMD are a result of negative life events and reflect common everyday problems. It thus aims to teach people better coping strategies, by setting goals, brain-storming solutions to a given problem and reducing negative feelings [62]. It is efficacious as a treatment for CMD [63] and there is recent evidence to suggest that it is feasible in resource poor settings where it can be delivered by lay health workers [17, 43]. In Zimbabwe, we have piloted problem solving therapy through the Friendship Bench Intervention [43] and the PMTCT programme [47].

Currently, LHWs trained by clinical psychologists and psychiatrists deliver the intervention and have access to a senior counselor who assists with complex cases. The senior counselor refers difficult cases directly to either the psychologist or psychiatrist according to the Friendship Bench protocol [43].

No effectiveness or cost-effectiveness trial has been carried out of this intervention since it's inception and it still remains unclear which components of the intervention contribute to it's appeal to the local community. Furthermore, with the introduction of an HIV care component to all local clinics the need to identify aspects of the intervention that will address CMD among PLWH has become critical.

1.5 The Problem

The Friendship Bench programme is currently the only task shifting mental health intervention for CMD in Zimbabwe. A large number of PLWH have recently started utilizing this service after HIV care was integrated in primary care facilities in 2012. Previously PLWH received care and treatment at tertiary level health facilities only.

No rigorous evaluation of the intervention has been carried out since its inception in 2006, and specific mental health needs of the HIV population are not well documented. Based on available data, the delivery of the intervention has not been consistent over the years, thus it remains unclear which components of the intervention should be considered in a scale up of the Friendship Bench.

1.6 Aim of thesis

The aim of this study is to establish key components of the Friendship Bench psychological intervention delivered by lay health workers for CMD in PLWH, adapt it for use in a cluster randomized controlled trial (RCT) and devise and evaluate a scale-up strategy. The results of the cluster RCT are not included in this thesis.

1.7 Objectives

The objectives of this thesis are:

- 1) To conduct a systematic review of psychological interventions for CMD delivered through task shifting for HIV in LMIC.
- 2) To establish prevalence and correlates of probable common mental disorders in a population with high prevalence of HIV in Zimbabwe.
- 3) To explore the views and experience of LHWs and PLWH of the PST based task-shifting intervention for CMD.
- 4) To use a theory driven approach to develop and evaluate a complex intervention.
- 5) To scale up the Friendship Bench interventions for common mental disorders and generate lessons from Zimbabwe that may be relevant for other LMIC.

1.8 Relationship of this thesis to the Friendship Bench RCT

This thesis was a sub-study of a larger formative research project conducted to prepare for a cluster randomized controlled trial (RCT) which is described in the RCT protocol of the Friendship Bench programme [68]. The RCT has now been completed and generated evidence for the effectiveness of the intervention, which was used to justify the need for the scale up. Although the trial data are not yet published it showed a significant difference between the intervention and the enhanced usual care in several outcome variables which included the SSQ -14, the

Patient Health Questionnaire (PHQ-9), the Generalized Anxiety Disorder scale (GAD-7), World Health Organization-Disability Adjusted Scale (WHO-DAS,) and the Economic Questionnaire (EQ05). Details of the RCT findings are not included in this thesis.

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Chapter 2

Psychological interventions for Common Mental Disorders for People Living With HIV in Low- and Middle-Income Countries: systematic review

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Dixon Chibanda was lead author for this article and primarily responsible for designing the study, conducting the data analysis and drafting the manuscript. This work was carried out as part of the formative work leading to a cluster randomized control trial of the friendship Bench with his role being the principle investigator.

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2.1 Abstract

Background

Common mental disorders (CMD) such as depression and anxiety disorders are associated with poor HIV disease outcomes. There is a growing body of evidence suggesting that structured psychological interventions can be effective in the treatment of CMD but little is known about the effectiveness of these interventions in low and middle income countries (LMIC).

Methods

In May 2013 we carried out a systematic review of psychological interventions for CMD from LMIC for PLWH. A two-stage screening was carried out independently by 2 of the authors.

Results

Out of 190 studies, 5 met inclusion criteria. All 5 studies were randomized controlled trials based on principles of cognitive behavior therapy (CBT) and were effective in reducing CMD symptoms in PLWH. Follow-up of study participants ranged from 6 weeks to 12 months with multiple tools utilized to measure the primary outcome. Four of the studies showed a high risk of bias while 1 study from Iran met low risk of bias in all 6 domains of the Cochrane risk of bias tool and all 22 items of the CONSORT instrument.

Conclusion

There is need for more robust and adequately powered studies to further explore CBT based interventions in PLWH. Future studies should report on components of the psychological interventions, fidelity measurement and training, including supervision of delivering agents, particularly where lay health workers are the delivering agent.

2.2 Introduction

People living with HIV (PLWH) have a higher prevalence of common mental disorders than non-HIV infected individuals (1-4). Common Mental Disorders (CMD), which consist of depression, anxiety disorders and mixed depression and anxiety disorders, are amongst the most prevalent mental neurological and substance use (MNS) conditions with prevalence of over 30% among PLWH reported across studies in some low and middle income countries (LMIC), particularly for depression (1, 5-11). Common mental disorders share similar manifestation particularly in primary health care settings where they present with a spectrum of symptoms that respond to similar treatment modalities (12-14). The term 'CMD' has become synonymous with a public health approach to mental health service delivery and care for depression, anxiety and somatoform disorders (15-19).

CMD contribute significantly to poor HIV disease outcomes such as increased HIV treatment failure and increased risk of HIV acquisition (2, 20), particularly in LMIC where the highest proportion of PLWH is found (10, 21). In recent years the identification of effective treatments for HIV and expanded access to highly active antiretroviral treatments (HAART) has resulted in a new global health challenge: increased chronic disease comorbidities, which include CMD in PLWH (22-25).

A large treatment gap for CMD, in particular depression, exists in sub Saharan Africa (10, 26). The current ratio of mental health professionals to the population in sub Saharan Africa stands at 1 per 2.5 million for psychologists, 1 per 1 million for mental health nurses and 1 per 2 million for psychiatrists (26). A call to explore ways of addressing this treatment gap (26-31) has yielded encouraging results from LMIC, particularly, on the development and effectiveness of interventions that tackle CMD through task shifting in non-HIV populations (32-36), where task shifting has been defined as the delegation of responsibilities to lower level carders who are supported and supervised by more senior professionals (37). However, little is known about task shifting for CMD within the context of HIV in LMIC. As NCDs become a more prominent feature among PLWH there is a need to better understand interventions for CMD and other MNS disorders in PLWH in LMIC that can be scaled up (10, 29, 38, 39).

This review builds on earlier systematic reviews that assessed interventions for depression in PLWH (38, 40). The aim of this study is to review the current evidence for the effectiveness of psychological interventions for PLWH in LMIC, identify common features of these interventions and specifically highlighting the effectiveness of task-shifting as a way of addressing the treatment gap for CMD in LMIC.

2.3 Methods

Search Strategy

In May 2013 we searched the following databases; Embase, Medline, Psych Info and Global Health using OVID. The search terms for HIV were; HIV(exp)/human virus(word search)/AIDS(word immunodeficiency search)/acquired immunodeficiency syndrome(word search)/HIV (word search). This ensured all synonyms of HIV would be included, including HIV-1 and HIV-2 and was done in all search databases. AND mental disorders(exploded) This ensured that anxiety, schizophrenia, sleep, substance related, eating, mood, psychotic and cognitive disorders, as well as dementia and delirium were included, and this was done in all search databases to ensure that co-morbid conditions with CMDs were captured AND Africa(exp)/Asia(exp)/South America(exp)/Eastern Europe(exp)/low or middle income countr*(word search)Exploding the continents in Medline, Embase and Global health ensured all countries within them would be included, low or middle income countr* was also used as a word search within these databases. Using (low or middle) adj2 income countr*) or LMIC or developing countr*) in psych info ensured all papers with these words situated together would be picked up, as continents cannot be exploded in psych info. Specific African countries were also searched for as word searches within psych info only, these were for instance Nigeria* Zimbabwe*, Uganda* (for all African countries and other specific LMIC) this was to help pick out studies which were not labeled specifically as LMIC. AND psychotherapy(exp)/psychotropic drugs or psychotropic agents(exp)/applied psychology(exp)/problem solving(word search)/counsel*(word search)/screen*(word search)-Psychotherapy was exploded to include a number of therapies including; behavior therapy, cognitive behavior therapy, psychoanalytic therapy, interpersonal

therapy and psychotherapy, this was done in Medline, Embase and Global Health. -Psychotropic drugs (in Medline and Global Health) and psychotropic agents (in Embase) were exploded to encompass tranquilizing agents, hallucinogens and antidepressive agents. Although the review was aimed at psychological interventions, psychotropic drugs were included to ensure that studies that utilized psychological interventions in conjunction with psychotropic drugs were not omitted.-Applied psychology was exploded in Medline to cover counseling and educational psychology. Psychology was exploded in global health to cover counseling. While psychology was not used in the Embase search as it was too vague, and too many references were pulled up using it.-counsel* and (problem adj2 solving) and screen*were used as word searches within Medline, Embase and Global Health.-These search terms were not used in psych info database, because the previous 3 search requirements had given 48 references, which was small enough to limit manually.

Criteria for including studies

The main criteria for inclusion were that the study had to be conducted 1) in an HIV population; 2) in a LMIC; 3) using a psychological intervention; and 4) for a population with a MNS diagnosis. We included quantitative research papers in English language that reported on interventions with a control group/comparison group or cohort studies that looked at before and after measures, with an outcome of either CMD, depression, anxiety, as measured by either a self-report questionnaire, or clinical observation in PLWH. We excluded abstracts from conferences, unpublished thesis, studies carried out in children and adolescents, computer based interventions, and all papers not written in English, with the last search carried out on the 30th May 2013.

All psychological interventions as defined by Sherr et al (cognitive behavior therapy, coping effectiveness intervention, interpersonal therapy, group therapy, spiritual self schema therapy, psycho-education therapy, peer support, counseling) (38) regardless of delivering agent provided they were for PLWH in LMIC and assessed outcomes for MNS conditions were included. We included all studies that validated screening tools for CMD in PLWH to ensure that we captured validation studies that

also reported on psychological interventions. After identifying the articles that met our inclusion criteria we manually searched for task shifting, and CMD or depression in the full text of these articles.

Two reviewers (DC and JH) read all titles and abstracts independently after duplicates were deleted. For the first stage, studies were removed if they did not meet at least 3 of the 4 inclusion criteria. Using these broad inclusion criteria in the initial stage ensured that studies that were identified by a LMIC city as opposed to a country were not left out. Where the two reviewers differed or could not come to an agreement, the third reviewer (MA) was consulted. In the second stage, papers extracted from the first stage were then reviewed again for all 4 criteria. This 2-stage approach was used to ensure that as many studies that were close to the full inclusion were captured in the initial search.

Data extraction and analysis

Data from studies meeting the full criteria were extracted for the following: year of publication, setting/country, sample size, and sampling procedure, measure of CMD, type of intervention/description of intervention, comparison group where relevant and delivering agent. The CONSORT guidelines (41, 42) and the Cochrane Risk of bias tools (43) were used to assess quality of the studies. We assessed each study against the 22 items of the CONSORT Non-pharmacologic (Consort NP) Treatment (42) and the 6 domains of the Cochrane Risk of bias tools (43). Each psychological intervention was further assessed for the following: presence of a structured and manualized psychotherapy intervention (availability of a protocol with detailed description of the intervention), compliance with a recognized and evidence based approach, background of delivering agent, training protocol, fidelity, supervision and support. We followed the PRISMA (44) guidelines for the final report.

2.4 Results

From the 1329 papers that were initially identified, 190 met our inclusion criteria for stage 1 of our review. Of the 190 papers 11 met full criteria (Fig 2.1).

Of the 11 studies that were reviewed in full, we excluded 6. One study from Uganda was excluded because it was for a computer-based intervention (45). A study from

Tanzania, which described a task-shifting approach, was excluded because it was based on the administration of amitriptyline and had no psychological component except for a nurse-led explanation of the effects of amitriptyline (46). A cohort study from Kenya was excluded because it was a cognitive behavioral therapy intervention for alcohol use reduction rather than CMD in PLWH (47), while two studies from South Africa were excluded because one was a non-psychological intervention utilizing 'art therapy' for children (48), while the other was an abstract (power point presentation) from a conference (Ziphamandla Study). A study from Zimbabwe was excluded because it looked at a mixed population of HIV+ and HIV- participants and findings were not stratified by HIV status (49).

Characteristics of included studies

A total of 5 studies all of which were randomized controlled trials with an intervention and concurrent or wait list control group were included in the final review (Table 2.1).

Characteristics of studies

Table 2.1 shows the characteristics of the studies that were selected. There were four randomized controlled trials (RCT) from Asia, including two from China (50, 51), one from Thailand (52), and one from Iran (53). There was one RCT study from Africa, conducted in Nigeria(54). It was not possible to carry out a meta-analysis due to the use of diverse and multiple scales for outcome measures, delivering agent, duration of intervention and content of intervention. All 5 studies used different outcome measures; two locally validated tools, the Profile of Mood States (POMs), and a 15-item depressive symptomatology-screening tool were used in the study from China and Thailand respectively (51, 52). Although a website to download the Thailand study tool was provided the content was in the Thai local language. The author responded to a request for an e-version of the intervention package, which gave a detailed description of the intervention but did not include the screening tool (52). The Symptoms Checklist-90 Revised (SCL-90R) was used in Iran but there was no mention of it being validated in this population (53). The Centre for Epidemiology Studies-Depression scale (CES-D) was used in China but was not validated (50). The Hospital Anxiety and Depression Scale (HADS) was used in Nigeria and was validated locally (54).

Follow up of study participants ranged from 6 weeks to 3, 6, 9, and 12 months. Attrition rates were only reported in two studies (24% in China (51) and 13.3% in Thailand (54). The study population differed across studies with the Iran study consisting of 273 (92%) male participants who were asymptomatic with a CD4 count above 250, not on HAART, and having acquired HIV through intravenous drug use. The study from Hong Kong by Molassiotis recruited symptomatic participants of whom 32 (91%) were male, and 6 (17%) of whom were homosexual. This study did not report on baseline CD4 count and had a loss to follow up of 24% (51). The study population from Thailand was poorly described although it consisted of a greater proportion of women 340 (67%) (52). The study from China by Chan revealed that of 62 PLWH who met inclusion criteria only 20 (32%) signed consent to participate; however reasons for not participating were not described (50). The sample size of studies varied significantly with the lowest sample size of 13 in the Hong Kong study by Chan (50) and the largest of 507 reported in Thailand (52).

Quality Assessment

Table 2.2 shows the quality of the studies as assessed by the Cochrane risk of bias tool and the CONSORT NP. Four of the studies showed high risk of bias for one or more key domains outlined in the Cochrane Collaboration's tool for assessing risk of bias. In the four studies the allocation sequence was not adequately generated or concealed. Furthermore, incomplete outcome data was not adequately addressed. Sample sizes of 13 (50) and 36 (51) in the two studies from Hong Kong contributed to the poor quality of the results. The study from Iran by Sayedalinaghi had a low risk of bias with all 6 domains of the Cochrane Collaboration's tool adequately covered. This study by Sayedalinaghi fulfilled all 22 criteria of the CONSORT instrument.

Interventions

Four out of the five interventions contained elements of cognitive behavior therapy (CBT) with themes including: how to teach patients to identify and challenge irrational beliefs, adapting a feel-think-do model to promote positive cycle of cause and effect, the use of mindfulness meditation with CBT elements, and evaluating and changing maladaptive distorted belief systems. Two studies from Asia emphasized

elements of Yoga and Buddhism within their CBT packages (52, 53). The study from Nigeria used the term "counseling" to describe a package that consisted of supportive care based on a World Health Organization basic counselling guide for HIV. The actual counseling package retrieved from the WHO website had strong elements of problem solving therapy, however, this was not highlighted in the paper. Two studies described session content, duration of each session and provided access to a detailed manual of the intervention (52, 53). One study used a group therapy approach based on CBT; however, there was no description of how this was adapted for local use (51). Only one study provided a website where a training protocol could be downloaded, however, this was not in English. One study author responded to a request for an intervention training protocol. All the studies followed some structured manual although the description of how this was done was not clearly stated. The training process of the delivering agent was not described in all the studies.

None of the studies described how fidelity was measured or maintained. None of the studies described criteria used to select the delivering agent. The delivering agents were diverse with two out of five studies using psychologists, one using a nurse, and two not commenting on delivering agent. The study by Molassiotis used a qualified nurse experienced in counseling PLWH to deliver the intervention (51), however, no further description of the delivering agent was given or the training prior to the intervention. The other component of the Molassiotis intervention consisted of peer support/counseling group, which was also facilitated by the same nurse. A clinical psychologist together with a trainee psychologist led the study by Chan, using a group therapy approach, however, no mention of formative work is made (50). The study from Nigeria did not indicate who delivered the intervention and there was no response to an email request for further information (54). The study from Thailand described the intervention in detail and provided a full training protocol with a detailed break down of each step but there was no mention of a delivering agent or supervision strategy (52). The study from Iran used a psychologist trained in mindfulness-based stress reduction (MBSR) (53). All studies generally seemed to not use a task shifting approach, as there was no clear definition of the stages or steps of the referral pathways within the intervention arm. None of the studies

described how they dealt with severe cases such as severe depression or suicidal cases needing to be assessed by a psychiatrist or doctor for medication. In general the studies did not emphasize task shifting as described by the World health organization (21, 27).

Outcome measures

Table 2.3 shows before and after scores by Intervention and control arm. All the outcome measures showed statistically significant differences between the intervention and the control arm suggesting that the interventions were all effective in improving symptoms of CMD among PLWH. All studies compared a mean baseline score with a score on the same instrument administered after the intervention except the study from Nigeria which did not provide before or after mean scores but reported a greater reduction as a proportion in both anxiety and depression in the intervention group in comparison to the control group (anxiety 137 (34%), depression 35 (19.2%) reduction in the control arm against 199 (50%) and 90 (43% reduction in the intervention arm) respectively (54). All outcome measures were recorded using recognized tools except the Thailand study, which used a locally developed and validated tool that was accessible only in the local language (52). Three tools were validated in the local setting (51, 52, 54) and of these two provided Cronbach alpha scores of 0.95 (51) and 0.91 (52), indicating high reliability. There was no description of how the tools had been validated and no mention of the process of adapting the tools to the local context.

2.5 Discussion

Our findings suggest there is limited evidence from LMIC on psychological interventions for CMD in PLWH despite the wealth of data from observational studies reflecting a high burden of CMD in this population (1-3, 39). The trials included in this review examined psychological interventions for CMD based largely on CBT principles with active therapeutic interventions or waiting list controls in-group and individual settings. Despite the finding that four of the five trials were at high risk of bias, all trials reported benefits in the intervention arm compared to the control and these were statistically significant in all the studies. The findings of this review

suggest that psychological interventions for CMD among PLWH are likely to be an effective way of reducing symptoms of CMD in comparison to both waiting list and active control. However, larger adequately powered and well-designed trials are needed to examine the effectiveness and cost-effectiveness of psychological interventions for CMD in PLWH. The formative stage of such trials is particularly important to ensure interventions and tools are consistent with cultural expressions of CMD (55, 56)

There are several well-documented studies from non-HIV settings in LMIC that support the use of psychological interventions delivered by lay health workers (32-34, 57). In South Africa, a study using trained community lay health workers managed to improve the quality of mother infant engagement (58). Similarly, in Pakistan it was possible to integrate a cognitive behavior therapy based intervention in the routine work of community health workers which showed better outcomes than usual care in reducing depression among the participants (34). In India, it has been possible to show that a trained lay counselor-led collaborative stepped care intervention can result in an improvement and recovery from CMD among patients attending primary health care facilities (33).

While in Chile, a multicomponent stepped care intervention has been shown to be more effective than usual care for depression at public health care level (59).

While no consensus exists on the most appropriate type of psychological interventions for CMD in PLWH in LMIC, a number of studies have reported on several approaches (2, 3, 34, 38, 60, 61), with a recent meta-analysis showing that treatment using psychological therapies which largely consisted of CBT based interventions improved adherence to HAART (62). There is, however, evidence of the effectiveness of interpersonal therapy (IPT) in developing countries (63) with one study from Tanzania showing efficacy of an IPT approach in a non- HIV population (64).

No mention is made on the use of lay health workers in the studies reviewed here but there is evidence from studies in non-HIV populations to support the use of this cadre particularly as a way of addressing the treatment gap for CMD through task-shifting (65). The huge treatment gap for CMD in LMIC (26), may justify this approach (66-68). Evidence from HIV care particularly at community level has shown encouraging results over the years in support of a task-shifting approach to home based care programs(37).

As more PLWH are commenced on HAART in LMIC the burden of CMD and it's negative impact on HIV disease outcomes such as adherence to HAART needs to be addressed (22). People living with HIV are twice as likely to suffer from CMD, particularly depression in comparison to matched non-HIV infected populations (8, 69, 70). The use of psychological interventions, delivered through a task sharing approach therefore has the potential to address some of this burden.

Limitations

The small number of studies (n=5) eligible for this review limits the generalizability of the findings. Furthermore, although all 5 studies showed statistically significant findings in support of psychological interventions, there are several other limitations, which include small sample size, poorly described study populations, particularly with regards to HIV stage, CD4 and viral load counts, and hospital environment where the studies were carried out can be generalized to the community setting. Most of the trials did not adequately describe how the intervention or the control arms were delivered; furthermore none of the trials indicate how fidelity or supervision was carried out. The diversity of outcome tools, which in some cases were not validated in the local setting, also limits the conclusions that can be drawn. The high attrition rate, the heterogeneity, and the small sample size limit the generalizability of the findings. Of note, in all the reviewed studies, is the absence of a stepped care approach to the management of participants. Other limitations include the strict inclusion criteria, which excluded non-English, unpublished studies, and computer based studies. Although several studies that were carried out subsequent to this review addressed some of these limitations, they were largely pilot studies that utilized non-random samples or were uncontrolled and all had sample sizes of less than 100 (71-73).

Conclusion

For future research it is important that locally validated tools emphasizing the use of local idioms of distress be utilized. Trials should have a clearly defined formative phase, which includes the development of study tools using a process that involves local stakeholders. Studies should have in place measures aimed at objectively assessing fidelity and a referral and or supervision plan in place. With the high treatment gap for CMD in LMIC, future trials should consider incorporating a task sharing approach, which works closely with generalist health providers who are supported by specialists. Emphasis should be on the development of interventions that can be scaled up to address the large treatment gap in LMIC HIV populations

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Table 2.1. Characteristics of studies meeting full eligibility criteria

Author year, country	Setting	Sample size (N)	Female n(%)	Design and Follow-up	Outcom e measur e	Delivering agent	Intervention	Control
Molassiotis 2002/China	Hospital	Symptomatic (N=35)	3(8.6)	RCT Pre.post 3, 6mnth	POMS	Nurse	GCBT, Peer support	Usual care
Chan 2005 China	Hospital	Symptomatic Heterosexual men (N=13)	0(0)	RCT Pre.post 7 weeks	CES-D	Clinical psycholo- gist	GCBT	Wait list
Abasiubong 2007 /Nigeria	Hospital	Newly diagnosed heterosexual (N=392)	199(51)	RCT Post 7 weeks	HADS	Unspecified	Counseling	Unspecified
Li 2010 Thailand	Hospital	Heterosexual 7.5 mean yrs since HIV diagnosis (N=507)	175(67)	RCT Pre.pos, 6,12mnth	MOS	Unspecified	CBT based with components of Buddhism	Unspecified
Sayedalinag hi-hi 2012 Iran	Hospital	Heterosexual CD4>250 not yet receiving ART(N=173)	53(31)	RCT Pre.post 3,6,9mnth 12mnth	SCL-90	Psychology -gist	MBSR	Usual care + education and support

Symptomatic=stage 3 and above of AIDS, POMS=profile of Mood states, GCBT= Group Cognitive behaviour therapy, CES-D=Centre for epidemiologic studies-depression scale, HADS=Hospital and Anxiety depression Scale, MOS=medical outcomes study instrument, SCL-90R=Symptoms checklist-90-Revised

Table 2.2. Quality of studies as assessed by the Cochrane risk of bias tool and the CONSORT NP*

Author	Risk of bias domains	22 item CONSORT NP*			
Molassiotis et al (2002)	High risk in 2/6 domains	10/22			
Chan et al (2005)	High risk in all 6 domains	13/22			
Abasiobong et al (2007)	High risk in 3/6 domains	14/22			
Li et al (2010)	High risk in 3/6 domains	16/22			
Sayedalinaghi et al (2012)	Low risk in all 6 domains	22/22			

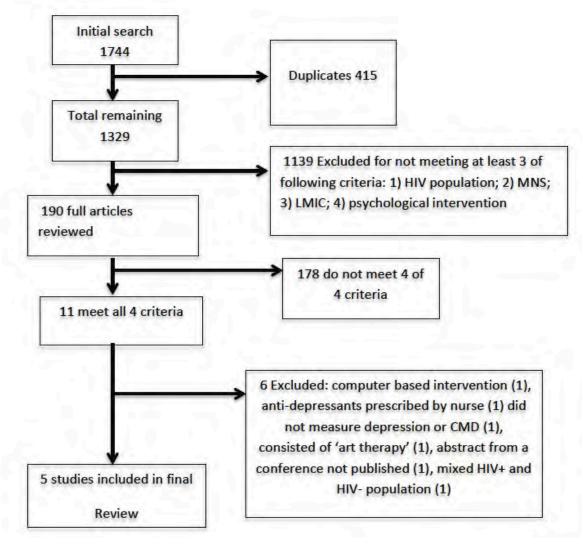
[•] CONSORT Non-Pharmacologic Treatment

Table 2.3. Before and after scores by intervention and control arm

	Intervention						Control			
Author, year, country	Tool	n	Score before	Score after	Pooled SD	n	Score before	Score after	Pooled SD	P value
Molassiotis (2002) China	POMS	10	33.3	32.4	11.8	26	44.9	48.4	33.5	0.01
Chan (2005) China	CES- D	6	16.6	13.7	5.95	7	13.57	13.71	9.69	0.00
¹ Abasiubong (2007) Nigeria	HADS	182				210				
² Li (2010) Thailand	MOS	260	12.2			247	12.4			0.02
Sayedalinaghi	SCL-	87	109.3	116.1	64.5	86	109.2	110.6	59.9	0.001
(2012) Iran	90									

^{1.} Study did not provide mean scores before and after of the HADS but provided difference in proportion before and after for the outcome measure. ^{2.} Study used mixed effect models to assess impact of the intervention and had no after scores.

Figure 2.1 Search results



Chapter 3

Prevalence and correlates of probable common mental disorders in a population with high prevalence of HIV in Zimbabwe

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Description of contribution of candidate

Dixon Chibanda was lead author for this article and primarily responsible for designing the study, training of researchers, designing the data collecting tools, initial data analysis, and drafting the manuscript. This work was carried out as part of the formative work leading to the identification of common factors associated with CMD, thus enabling the development of an intervention with specific focus on these key factors for a cluster randomized control trial of the friendship Bench. Dr Chibanda was the principle investigator.

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3.1 Abstract

In 2014 close to 10 million people living with HIV (PLWH) in sub-Saharan Africa were on highly active anti-retroviral therapy (HAART). The incidence of non-communicable diseases has increased markedly in PLWH as mortality is reduced due to use of HAART. Common mental disorders (CMD) are highly prevalent in PLWH. We aimed to determine factors associated with probable CMD and depression, assessed by 2 locally validated screening tools in a population with high prevalence of HIV in Harare, Zimbabwe.

Methods: We carried out a cross-sectional survey of a systematic random sample of patients utilizing the largest primary health care facility in Harare. Adults aged ≥18 were eligible, excluding those who were critically ill or unable to give written informed consent. Two locally validated screening tools the Shona symptom questionnaire (SSQ-14) and the Patient Health Questionnaire (PHQ-9) were administered by trained research assistants to identify probable CMD and depression.

Results: Of the 264 participants, 165 (62.5%) were PLWH, and 92% of these were on HAART. The prevalences of probable CMD (SSQ14>=9) and depression (PHQ9>=11) were higher among people living with HIV than among those without HIV (67.9% and 64.9% vs 51.4% and 44.4% respectively). Multivariable analysis showed female gender and recent negative life events to be associated with probable CMD and depression among PLWH (gender: OR=2.32 95%CI: 1.07-5.05; negative life events: OR=4.14; 95%CI 1.17-6.49) and with depression (gender: OR=1.78 95%CI: 0.81-3.91; negative life events: OR=9.42; 95%CI 2.05-43.37).

Conclusion: Elevated scores on self-report measures for CMD and depression are highly prevalent in this high HIV prevalence population. There is need to integrate packages of care for CMD and depression in existing primary health care programs for HIV/AIDS.

Key words: Common mental disorders, Depression, HIV, highly active antiretroviral therapy

3.2 Introduction

Common mental disorders (CMD) affect people across the world with a global lifetime prevalence of 29% [1]. Presenting as a mixture of somatic, anxiety, and depressive symptoms [2], CMD increase the risk of developing both non-communicable and communicable diseases [3]. Amongst people living with HIV (PLWH), CMD are a leading cause of disability [4-7] and are known to hasten HIV disease progression [8], particularly in LMIC [4, 6, 9] where low levels of CMD detection at primary health care level [10] are confounded by a large treatment gap for CMD [11, 12]. In sub-Saharan Africa it is estimated that there is one psychologist for every 2.5 million people, one mental health nurse for every million people and one psychiatrist for every 2 million people [13]. In contrast, in high income countries the ratio of psychiatrists to the population is estimated to be 1:10000 [14].

In recent years the development of interventions that emphasize task-shifting as a way to address the treatment gap for CMD has gained recognition [15-18] with specific structured packages being developed and evaluated [19-21]. The key elements of task-shifting involve the delegation of responsibilities to lower level cadres, often non-professionals, to deliver services while the more qualified professionals provide support and supervision [22] However, use of targeted task-shifting psychological interventions to address CMD in PLWH requires a thorough understanding of factors associated with CMD in this population [4, 23], due partially to the need for greater monitoring and supervision of work delivered by non-specialists [24-26].

Much is known about factors associated with CMD in non-HIV populations in LMIC [27-31], contrasting with sparse data on CMD among PLWH [6]. In four LMIC, namely India, Zimbabwe, Chile and Brazil, female gender, poverty and recent life events were found to be common correlates of CMD in non-HIV populations [29]. In other parts of the world, correlates of CMD in PLWH include death of a significant other [32], family history of mental illness, negative coping style, alcohol dependency, food insecurity [33] and recent negative life events [34, 35]. Other studies from poor resource settings have found that CMD in PLWH is correlated with trauma, posttraumatic

stress disorder (PTSD), stigma and social barriers such as peoples' attitudes towards disabilities, physical and organizational obstacles, however, these differences appear to be due to a difference in the study setting and study population [36-39].

Early studies of CMD in PLWH in Zimbabwe were based on HAART-naïve populations using the Shona Symptom Questionnaire (SSQ-14) [40] as the main outcome instrument. Findings were inconsistent, with correlates of CMD including being female, having a male partner who was older by 10 or more years, multi-parity (having borne a number of children), and negative life events [34, 41, 42].

The aim of this study was to determine the prevalence and correlates of probable CMD in a primary health care setting with a high prevalence of HIV, and to compare these correlates of CMD by HIV status. The study was part of the validation of screening tools for CMD in a population with a high prevalence of HIV, which was preparatory work for a randomized controlled trial of a psychological intervention to reduce depression. The trial used the SSQ-14 and the 9-item Patient Health Questionnaire (PHQ-9) as primary and secondary outcome measures respectively. Establishing the prevalence of CMD among primary health care patients helped determine the possible duration of recruitment of participants for the trial, and analysis of correlates of CMD contributed towards the development of appropriate interventions [43].

3.3 Methods

Study setting and population

The study was carried out in the largest HIV primary health care clinic in Harare where up to 200 PLWH are seen daily. The primary health facility, which runs a daily HIV clinic, focuses mainly on prescribing HAART and treating other HIV-related conditions, whilst also catering for both adults and children with non-HIV related conditions. All adults aged ≥18 years presenting to the clinic during the 2-week study period were eligible for recruitment. Patients were excluded if they were critically ill (being physically incapacitated), had a psychotic episode at presentation, or were unable to comprehend the consenting procedure or declined to give written informed consent.

Study procedure

Study personnel (four research assistants, six LHWs and four psychiatrists) attended a 2-week training using a guide initially developed by the author (DC). The research assistants were trained on data collection methods using the socio-demographic forms and the screening tools. While the project coordinators were trained in screening of participants to minimize bias. The psychiatrists were trained in the use of the structured clinical interview (SCID-IV) through a discussion forum led by DC which involved going through the diagnostic criteria, building consensus on how to manage clinically severe cases during the validation, and procedures for ensuring fidelity. The referral pathways for participants meeting criteria for major depression and other acute medical conditions was that they should be seen by the medical officer first, for assessment, before being referred to a tertiary psychiatric facility if needed. A 2-day pilot of the full study procedure was carried out after training of the entire study team.

Ethical considerations

Ethical approval was obtained from the Medical Research Council of Zimbabwe (MRCZ/A/1732), and the Human Research Ethics Committee of the Faculty of Health Sciences, University of Cape Town (HREC Ref: 090/2014) and the London School of Hygiene and Tropical Medicine (Ref 8457), and written informed consent was sought from all participants in accordance with good clinical practice. All participants requiring immediate attention due to severe CMD were referred to an existing service for people with psychological distress based on problem solving therapy running at the clinic [44].

Recruitment and sample size

The clinic register of clients attending the clinic over the study period was used as the sampling frame. Based on this sampling frame, computer generated random numbers were used to select participants waiting to be attended to at the study site: random numbers were allocated to patients based on their position in the clinic queue while waiting to be attended to by the clinic nurse. This exercise was carried out while all the patients were in the waiting room waiting to be triaged to nursing evaluation. All

those selected were sensitized, informed briefly about the study before they were asked if they were willing to participate. All interested were then given further details of the study and written consent was sought from eligible adults, while those not meeting the criteria outlined above were excluded at this point. After obtaining written consent the socio-demographic questionnaire and study tools which included the SSQ-14[40] and the PHQ-9[45] were administered by data collectors. It took approximately 15-20 minutes to administer tools to each participant.

The sample size (N=264) was chosen to provide good precision for the primary aim of the validation study, to estimate sensitivity and specificity for screening tools against the gold standard (SCID), allowing for stratification by HIV status. This sample size enables us to estimate a prevalence of CMD of 28% with good precision (95%CI 22%-34%), and to have 80% power to detect odds ratio of 2.5 for an exposure, which is 50% prevalent in the controls.

Study measures

Socio-demographic variables were measured using an adapted locally developed questionnaire previously used in similar studies where variables such as unemployment, recent negative life events, poverty and female gender had been found to be associated with CMD [30, 31, 34, 46]. Participants were asked about recent negative life events. The list of possible negative life events was based on a previous study [34] and focus group discussions with both the lay health workers and participants utilizing a local CMD based intervention [44]. These included life events such as death in the family, physical assault, sexual assault, forced eviction, an HIV diagnosis, and an illness resulting in admission to a tertiary hospital of either the participant or an immediate family member.

Screening tools

The Shona Symptom Questionnaire (SSQ14) was used as the primary outcome measure for CMD screening. The SSQ14 is a locally developed 14-item screening tool validated using exemplary cross cultural methods [40]). It consists of 14 dichotomous questions based on how an individual has been feeling in the past week. It has been used previously in epidemiological studies in Zimbabwe [41, 44, 47] and

has sensitivity of 96%, specificity of 83%, and positive predictive value and negative predictive value of 66% and 83% respectively, using a cut-off of 7/8 [40]. In this study population, we found an optimal cut-off score of 8/9 in a validation exercise carried out by senior doctors in the Department of Psychiatry using the structured clinical interview (SCID-IV) as the gold standard (results not published - sensitivity and specificity at cut-off of 8/9 were 85.9% and 70.2% respectively).

The 9-item Patient Health Questionnaire (PHQ-9) [45] was the instrument used to screen for probable depression. The PHQ-9 is amongst the most commonly used screening instrument for depression in LMIC [48], and uses a Likert scale giving a score ranging from 0 to a maximum of 27 with each of the 9 items giving a response ranging from: Not at all (0); Several days (1); More than half the days (2); and Nearly every day (3), and a higher score indicating more severe depression [45]. The PHQ-9 was validated during the formative stage of the current study using the structured clinical interview of the diagnostic statistical manual (SCID-IV), and showed a sensitivity of 85.9%, for depression and specificity of 67.8% at a cut-off of 11/12 (results not published). We therefore used this validated cut-off score of 11 and above for moderate depression.

Statistical analysis

Data were entered directly into the study desk-top computer by a data entry clerk using a predesigned data entry program containing automated range checks, and data cleaning was carried out at the end of each day. Data were transferred to STATA version 13.0 for analysis. Analysis was based on outcome measures of the SSQ-14 for CMD and PHQ-9 for depression. Following tests for effect modification of HIV status and factors associated with CMD, results were presented stratified by HIV status. Socio-demographic variables of the two groups (cases vs. non-cases) meeting SSQ-14 and PHQ-9 criteria for CMD and depression respectively were initially compared to establish differences. Variables with p<0.10 on univariate logistic regression analyses were included in multivariable regression, to estimate adjusted odds ratios (OR) and 95% confidence intervals (CI).

3.4 Results

Characteristics of study participants

A total of 332 people were approached during the study period. Of these 297 (89%) were eligible, and 264 (89%) of those who were eligible gave consent to take part. Of the 264 included in the study, 208 (79%) were female and 155 (59%) were married, of these 120 (72%) were female. The majority (237; 89%) reported experiencing a negative life event in the 6-month period before the study. HIV was highly prevalent, with 165 (62.5%) reported as living with HIV according to self reports confirmed with clinic HIV test records, while 72 (27%) were HIV negative. A total of 27 (10%) were unaware of their HIV status because they had never been tested. All participants approached were forthcoming with their HIV status. Of the 165 who were confirmed HIV positive, almost all (92%) were on HAART, with most of these (85%) on HAART for more than 6 months.

Table 3.1 shows characteristics of the study population by HIV status. People living with HIV were more likely to be female (75.2.% vs 24.8%; p=0.008), older (47.2% vs 26.4% aged >=40 years; p=0.009), and divorced/widowed (25.5% vs 5.6%; p=0.001).

Association of probable CMD and depression by HIV status

The prevalence of probable CMD (SSQ14>=9) and depression (PHQ9>=11) were higher among people living with HIV than among those without HIV (67.9% and 64.9% vs 51.4% and 44.4% respectively; Table 3.1). On univariable analyses, both probable CMD and depression were associated with being female, and having experienced negative life events (Table 3.2).

On multivariable analyses, female gender and negative life events were independently associated with both probable CMD and depression among participants with HIV (Table 3.3). The small number of HIV negative participants reduced the ability to look at associations in this group, but there was some evidence that females were at higher risk of probable CMD (OR=2.92, 95%CI 0.53-16.14) and that negative life events were associated with depression (OR=3.75, 95%CI 0.74-19.09).

3.5 Discussion

In this study we found a high prevalence of elevated scores on self-report measures for CMD and depression (both over 60%) among PLWH, underpinning the importance of detecting and addressing CMD and depression in this population. Our results indicate that probable CMD and depression in PLWH, as measured by the SSQ-14 and the PHQ-9, are associated with recent negative life events and female gender. These findings reflect those from non-HIV infected populations [29-31, 49]. In a recent systematic review of screening tools used in LMIC rates between 11%-55% were reported, however, none of the studies looked at HIV populations on HAART [48]. While the risk of false positive screening results from self-report measures is a concern such tools if appropriately validated can still contribute towards identifying those most at risk of CMD in resource poor settings within primary health care facilities [6, 7].

Although we did not measure adherence to HAART in our study population, there is growing evidence showing the association of CMD and depression with increased risk of poor adherence to HAART [8, 50, 51]. There is also evidence suggesting that treatment of depression increases adherence to HAART [50, 52]. Despite being on HAART, PLWH face a magnitude of problems and they are twice as likely to suffer from depression when compared to non-HIV infected matched controls [34, 53, 54]. The findings of our study have implications for some of the newer WHO initiatives such as the Option B+ [55] which advocate for immediate commencement of HAART for HIV infected pregnant women. Over 30% of women attending the Prevention of Mother to Child Transmission of HIV (PMTCT) program in Zimbabwe have signs of post-natal depression [34], therefore the inclusion of CMD packages of care within these initiatives is critical as this will contribute towards improving outcomes for PLWH.

In LMIC the improvement of HAART access will need to be matched with an equally focused integration of evidence-based CMD and depression care packages [6] because there is a large body of data showing that treating CMD among PLWH improves adherence to HAART and quality of life [56-58]. There is a need to introduce

and integrate psychological interventions aimed at addressing CMD and depression among PLWH at primary health care level, especially because evidence from other studies indicates that treating CMD and depression is likely to improve adherence to HAART, quality of life, reduce risk of substance use, and other co-morbid mental, neurological and substance use (MNS) disorders [6]. Both HIV positive and HIV negative women are more likely to be affected by CMD and depression in our setting [29, 34]. Furthermore they are more likely to utilize primary health care facilities than their male counterparts [59]. Therefore focusing on women who are living with HIV at primary health care level, particularly those with negative life events who screen positive on the SSQ-14 and PHQ-9 will strengthen existing HIV related programs such as the PMTCT and the newer Option B+. There is evidence showing the feasibility of using screening tools at primary health care level in Zimbabwe [34, 41, 44, 60] but these tools are not integrated into HIV care programs.

There are several psychological interventions that have been shown to work in LMIC, which could be adapted for use among PLWH [61-64]. However, most of the studies evaluating the effectiveness of these interventions for PLWH have been of poor quality [25]. Therefore there is need to carry out well designed formative research to design interventions and then rigorously evaluate them before they are introduced or integrated into health care facilities in LMIC. Part of this process should involve establishing factors that are associated with CMD and depression, and using this information to determine the content of interventions for specific populations. Our findings support the use of a problem solving therapy approach because of the strong association between negative life events and CMD [65]. Problem solving therapy has shown promising results in earlier pilot studies in Zimbabwe, particularly among participants who have experienced negative life events [44, 61]. Problem solving therapy enables participants through a guided process to list the problems (negative events) that they face, select a problem to tackle based on the client's priorities, develop a specific and measurable way of addressing the problem and execute an action plan aimed at addressing the problem while motivating and encouraging the participant to be pro-active in the process [44].

There is evidence supporting the use of lay health workers to deliver such

interventions for CMD in LMIC [24] with a number of well designed randomized controlled trials (RCT) suggesting that this is a cost effective way of addressing the treatment gap for MNS [21, 66-68].

Our study's main limitation includes the lack of availability of data on HIV staging and viral load markers. These factors can be associated with increased risk of developing CMD and depression [69-71]. Although similar high rates of CMD and depression have been reported from other LMIC [6, 72], the use of a clinic-based sample of people predominately visiting the clinic for physical ailments reduces the generalizability of our findings. Furthermore, the use of screening tools without a gold standard to confirm diagnosis may result in the inclusion of participants who are not actually clinically depressed [73]. Nevertheless, our cut-off score was based on a validation study conducted in Zimbabwe and provide an indication of the likely margin of error on these measures. Studies utilizing clinical interviews have found lower rates but these are still higher than those found in non-HIV infected people [7]. In addition, data on the type of HAART being taken by study participants was not available. A number of HAART drugs can increase the risk of psychiatric disorders including depression [74-76]. Although education and employment have been shown in previous studies to be associated with CMD and depression, our study findings indicate that this was not the case. This may have been due to the homogenous nature of the study population recruited from the same geographical location with similar socio-economic status. The low uptake of male participants is consistent with previous studies carried out in primary health care facilities in the country and other parts of the world [44, 77-79].

Conclusion

Despite these limitations this study highlights as in previous earlier studies in non-HIV infected populations the association of gender and negative life events with CMD and depression. Of note is the important finding of high probable CMD/depression prevalence in PLWH on HAART. This highlights the need to introduce interventions within HIV care clinics at primary health care level aimed at addressing this burden, which if left unchecked could negatively impact the gains made in the fight against HIV/AIDS in the last 2 decades. We further recommend the use of a two stage

screening process particularly where resources are scarce to avoid the inclusion of false positives, with the second stage consisting of a diagnostic screen. However, in resource poor settings with large numbers of LHWs a greater sensitivity and a lower specificity would be recommended to ensure that all possible cases are included. We further recommend that the Option B+ program be administered with a psychological intervention. Further studies are needed to look into the development of multiple stage screening delivered by LHWs.

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Contribution

DC Study design, developing first draft and preliminary analysis of data review of subsequent drafts leading to final manuscript

FC Study design, review first and final draft

HW Sampling strategy, statistical analysis, review first draft and third draft

CL Study design, review all drafts leading to final manuscript

3.6 References

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Table 3.1. Characteristics of study participants by HIV status

HIV status (column %)	HIV positive (n=165)		HIV negative (n=72)		p-value
	N	%	N	%	
Gender					0.008
male	41	24.8%	7	9.7%	
female	124	75.2%	65	90.3%	
Age group					0.009
<30	26	16.1%	22	32.4%	
30-39	59	36.6%	28	41.2%	
40-49	56	34.8%	12	17.6%	
50+	20	12.4%	6	8.8%	
marital status					0.001
married/steady	87	52.7%	57	79.2%	
divorced/widowed	42	25.5%	4	5.6%	
single	36	21.8%	11	15.3%	
Education					0.21
primary or less	38	23.0%	14	19.4%	
secondary or more	127	77.0%	58	80.6%	
Current employment status					0.78
unemployed	69	41.8%	33	45.8%	
permanent FT or PT	16	9.7%	7	9.7%	
casual/self-employed	80	48.5%	32	44.4%	
Main income source					0.20
own business/salary	96	58.2%	35	48.6%	
partner/family	58	35.2%	34	47.2%	
no income	11	6.7%	3	4.2%	
Suffer from chronic illness					0.49
no	86	52.1%	41	56.9%	
yes	79	47.9%	31	43.1%	
Reason for clinic visit					0.02
routine/family/antenata	63	38.2%	39	54.2%	
other reason	102	61.8%	33	45.8%	
Negative life events in last six months					0.15
no	13	7.9%	10	13.9%	
yes	152	92.1%	62	86.1%	
SSQ >=9					0.02
no	53	32.1%	35	48.6%	
yes	112	67.9%	37	51.4%	
PHQ>=12					0.003
no	58	35.2%	40	55.6%	
yes	107	64.9%	32	44.4%	

able 3.2. . Characteristics of HIV + participants by SSQ-14 and PHQ-9 scores

			SSQ >	>=9				PH	Q>=12	
		crude logistic regression					CI	rude logistic reg	ression	
	Total N	%	OR	95% CI	p- value	Total N	%	OR	95% CI	p-value
Gender					0.03					0.04
male	41	53.7%	1.00	-		41	51.2%	1.00	-	
female	124	72.6%	2.29	(1.10-4.74)		124	69.4%	2.16	(1.05-4.44)	
Age group					1.00					0.85
<30	26	69.2%	1.00	-		26	65.4%	1.00	-	
30-39	59	67.8%	0.94	(0.35-2.53)		59	64.4%	0.96	(0.36-2.52)	
40-49	56	67.9%	0.94	(0.34-2.56)		56	66.1%	1.03	(0.39-2.74)	
50+	20	70.0%	1.04	(0.29-3.69)		20	75.0%	1.59	(0.43-5.80)	
marital status					0.75					0.56
married/steady	87	65.5%	1.00	-		87	63.2%	1.00	-	
divorced/widowed	42	69.0%	1.17	(0.53-2.59)		42	61.9%	0.95	(0.44-2.02)	
single	36	72.2%	1.37	(0.58-3.21)		36	72.2%	1.51	(0.65-3.54)	
Education					0.93					0.08
primary or less	38	68.4%	1.00	-		38	76.3%	1.00	-	
secondary or	127	67.7%	0.97	(0.44-2.11)		127	61.4%	0.49	(0.22-1.13)	
more					0.50					0.04
Currently working?	60	74.00/	4.00		0.53	60	00.70/	4.00		0.91
unemployed	69	71.0%	1.00	(0.47.4.00)		69	66.7%	1.00	- (0.07.0.50)	
permanent FT or PT	16	56.3%	0.52	(0.17-1.60)		16	62.5%	0.83	(0.27-2.58)	
casual/self- employed	80	67.5%	0.85	(0.42-1.71)		80	63.8%	0.88	(0.45-1.73)	
Main income source					0.51					0.06
own business/salary	96	65.6%	1.00	-		96	59.4%	1.00	-	
partner/family	58	69.0%	1.16	(0.58-2.34)		58	69.0%	1.52	(0.76-3.03)	
no income	11	81.8%	2.36	(0.48-11.55)		11	90.9%	6.84	(0.84-55.6)	
Chronic medical condition					0.07					0.22
no	86	61.6%	1.00	-		86	60.5%	1.00	-	
yes	79	74.7%	1.84	(0.94-3.58)		79	69.6%	1.50	(0.79-2.86)	
Suffer from other chronic illness					0.75					0.60
no	127	68.5%	1.00	-		127	63.8%	1.00	-	
yes	38	65.8%	0.88	(0.41-1.91)		38	68.4%	1.23	(0.57-2.67)	
Negative life events					0.004					0.001
no	13	30.8%	1.00	-		13	23.1%	1.00	-	
yes	152	71.1%	5.52	(1.62-18.87)		152	68.4%	7.22	(1.90-27.44)	
ARV medication					0.35					0.96
no	14	78.6%	1.00	-		14	64.3%	1.00	-	
yes	151	66.9%	0.55	(0.15-2.06)		151	64.9%	1.03	(0.33-3.22)	
Disclosure to partner					0.78					0.37
no	69	66.7%	1.00	-		69	60.9%	1.00	-	
yes	96	68.8%	1.10	(0.57-2.13)		96	67.7%	1.35	(0.71-2.57)	

Table3.3. Multivariate analysis of HIV + participants by SSQ and PHQ

SSQ-14>=9	adjusted* OR	95% CI	p-value
			0.03
male	1.00		
female	2.32	(1.07-5.05)	
Chronic medical condition			0.09
No	1.00		
Yes	1.87	(0.92-3.81)	
Negative life events			0.03
No	1.00		
Yes	4.14	(1.17- 14.69)	
PHQ>=12	adjusted** OR	95% CI	p-value
Gender			0.15
male	1.00	-	
female	1.78	(0.81-3.91)	
Education			0.06
primary or less	1.00	-	
secondary or more	0.41	(0.16-1.02)	
Main income source			0.23
own business/salary	1.00	-	
partner/family	1.28	(0.62-2.65)	
no income	6.17	(0.71- 53.44)	
Negative life events			0.004
No	1.00	-	
Yes	9.42	(2.05- 43.37)	na nativa life a

^{*} adjusted for gender, chronic medical condition, negative life events
** adjusted for gender, education, income, negative life events

Chapter 4

Lay health workers' experience of delivering a cognitive behavior therapy based intervention for common mental disorders among people living with HIV: A qualitative study from Zimbabwe

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Description of contribution of candidate

Dixon Chibanda was lead author for this article and primarily responsible for designing the study, conducting the qualitative interviews, data analysis and drafting the manuscript. This work was carried out as part of the formative work leading to the design of the intervention for a cluster randomized control trial of the friendship Bench with Dr Chibanda's role being the principle investigator.

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4.1 Abstract

There is growing evidence supporting the use of lay health workers (LHWs) to address the treatment gap for common mental disorders (CMD) through task shifting. This study looks at the experience of LHWs delivering a problem solving therapy (PST) intervention for CMD for people living with HIV (PLWH) in a primary health care setting.

Methods: Semi-structured interviews of LHWs (n=7) and PLWH (10) who received PST were carried out using thematic content analysis.

Results: Over a 4-year period LHWs developed indigenous concepts of PST, which were: Opening the mind (Kuvhura pfungwa), Uplifting (kusimudzira), strengthening and strengthening further (kusimbisa and kusimbisisa) respectively. Using terms locally conceived through knowledge sharing amongst LHWs made it acceptable to deliver PST as part of their daily work.

Conclusion: Indigenous terms conceived and developed by LWHs to describe components and processes of PST contribute to the therapy's acceptability and continued use in primary care facilities.

4.2 Introduction

Common mental disorders (CMD), which consist of mixed anxiety, somatic and depressive symptoms [1, 2] affect 1 in 5 adults globally during their lifetime [3]. A large treatment gap for CMD exists [4] particularly in low and middle income countries (LMIC) where this treatment gap is over 75% [5]. The burden of disease attributable to mental and substance use disorders in sub-Saharan Africa is expected to increase by 130% by the year 2050 [6].

The use of lay health workers (LHWs) to address the treatment gap for CMD through task shifting or stepped care approaches has gained attention in recent years [7-10]. This has led to a number of studies showing feasibility, acceptability, efficacy and cost-effectiveness of such approaches [11-15]. In India, the MANAS trial, which involved 24 primary health care clusters, showed improved outcomes for depression and anxiety disorders in participants who received a stepped care intervention delivered by trained and supported lay counselors [16]. In Pakistan, a cognitive behavior therapy (CBT) based intervention delivered by LHWs for mothers with perinatal depression and their infants delivered by trained LHWs was superior to enhanced usual care [15]. Similarly, in South Africa trained and supervised community LHWs provided a pilot CBT based intervention that resulted in improvement in measures for depression [17]. Several studies have also looked at the cost-effectiveness of using LHWs to provide mental health care and have found that task shifting is cost effective [18, 19].

In Zimbabwe, the last 10 years have seen a growing interest in the use of LHWs to deliver interventions for CMD as a way of reducing the treatment gap [11, 20-22]. Of these initiatives, the Friendship Bench project [11] is the most established, providing a CBT based intervention with an emphasis on problem solving therapy (PST) [23-25]. The Friendship Bench programme is delivered by trained and supervised LHWs who reside in the community and are employed by the City Health Services. The PST sessions are carried out on a Bench (The Friendship Bench) which is located in a quiet and discrete area outside of the clinic building[11]. Clients are referred to the Friendship Bench after being screened as at risk of CMD using a locally validated screening tool the Shona Symptoms Questionnaire (SSQ-14) with good internal

consistency and a Cronbach alpha of 0.85 [26]. Although the PST approach has previously been shown to be acceptable, feasible and effective [11, 22], in the last 4 years, LHWs and their supervisors have reported that they are deviating from the PST sessions as originally devised for the Friendship Bench (Table 1) [11] based on Mynors-Wallis' approach [27].

This paper reports on a qualitative study conducted amongst LHWs and clients receiving the CBT-based PST programme delivered through the Friendship Bench over the last 4 years. The study sought to describe the LHWs' experience of delivering the Friendship Bench intervention with the aim of using this information to inform the finalization of an intervention package for a planned cluster randomized controlled trial. We deliberately focused on PLWH because over 80% of those using the Friendship Bench were PLWH.

Of particular interest, we sought to establish the local indigenous terms that were being used by both LHWs and clients (PLWH) to describe the different components of the Friendship Bench sessions and the number of sessions they were having with clients. Furthermore, we intended to ascertain how the LHWs dealt with difficult cases and how clients experienced their interaction with LHWs on the Friendship Bench.

4.3 Methods

Setting

The study was conducted from June to December 2014 at Edith Opperman clinic, the largest of three primary care clinics in the suburb of Mbare, Harare. The Friendship Bench project has been running in this clinic since 2006 [11]. An estimated 200 patients most of whom are HIV infected attend the clinic each day. Fourteen LHWs provide general health awareness to patients as well as delivering the PST intervention to all patients who score above 8 on the SSQ-14[26]. The LHWs who all reside in the surrounding community have an average age of 58 years, with an education of at least 8-10 years (Table 4.1).

Study design and sampling

We carried out 17 in-depth semi-structured interviews with both LHWs (n=7) and clients living with HIV (n=10). We used purposive sampling to select LHWs whom we thought would have had the most experience of working on the Bench, based on the senior LHW supervisor's advice. Based on this information we selected 7 LHWs who had been working on the Friendship Bench for more than 4 years. Clients who were HIV infected and had received the PST intervention in the last 2 years after scoring above 8 on the SSQ-14[26] were purposively identified by the supervisor. These clients had all completed a minimum of three of six sessions. We aimed to continue our interviews until theme saturation was reached.

Data collection

Semi-structured interviews for both LHWs and clients lasted between 45 and 60 minutes. Interviews were carried out by three Zimbabwean interviewers who had attended a 5-day qualitative research training course and previously conducted qualitative interviewing [28]. An interview guide was developed by DC, which was shared with the rest of the study team for further input. This was translated into Shona by a Shona-speaking clinical psychologist and then back translated to English. We used a constant comparative approach to data collection, discussing emerging themes throughout the data collecting process [29] as a way of determining when saturation was reached [30, 31] and a collective understanding of themes emerged. All sessions were audio-recorded and transcribed verbatim and then translated into English.

Data analysis

Three members of the team (RV, EM, DC,) independently reviewed 3 selected transcripts using line-by-line coding with themes and sub-themes being proposed. The group worked under the guidance of an experienced qualitative researcher. An initial coding framework was developed with specific emphasis on LHWs' interaction with PLWH. Where new themes and sub-themes were proposed, the group discussed this until consensus was reached. The research team then sorted the codes into categories and determined how these categories were related, followed by putting them into selective coding which resulted in descriptive models [32]. All

transcripts were then coded using a common coding framework, using the identified themes and sub-themes. Selected quotes are used to illustrate specific themes derived from this exercise.

Ethical considerations

Written informed consent was obtained from all participants with participants being reimbursed for their participation in accordance with local regulatory research and ethics bodies.

Institutional review boards

Ethical approval to carry out the study was obtained from the Medical Research Council of Zimbabwe (Ref: MRCZ /A/1732) as part of the formative phase of a cluster trial on the Friendship Bench, and from the Human Research Ethics Committee at the Faculty of Health Sciences, University of Cape Town (REC Ref: 090/2014). All the listed authors declare no conflict of interest in their work leading to this paper.

4.4 Results

The experiences described by the LHWs and their clients emphasize the use of indigenous concepts to navigate the PST approach. These locally conceived concepts described by the LHWs evolved over a 4-year period through a gradual process of peer discussion and sharing of the Friendship Bench experience.

LHWs described three overarching concepts or categories that highlighted the steps of the PST intervention and how they linked to each other (Figure 4.1). These concepts were: "Opening of the mind" (Kuvhura pfungwa) which mainly included the introductions, creating rapport, being non-judgmental, listening and giving a summary of the listed problems; Uplifting (kusimudzira) which was mainly the discussion of the listed problems and getting the client to decide which problem to focus on; Strengthening (kusimbisa) which was a process of encouraging the client to stay focused once a problem had been selected and then brain storming of solutions and developing an action plan; and finally Strengthening further (kusimbisia) which was described as a process of reinforcing achievements made during kusimbisa.

LHW1 "After working on the Bench for a while we just slowly started using quite specific terms to describe what we were doing and these (terms) just became normal after some time and we all then understood what was meant when one of us said kuvhura pfungwa (opening the mind) or Kusimudzira (to uplift)"

Kuvhura pfungwa (opening up the mind)

The LHWs mostly agreed that they always aimed to cover the three components of *kuvhura pfungwa* (opening of the mind), *kusimudzira* (to uplift) and *kusimbisa* (to Strengthen) during the first session. Ensuring that the bulk of the work was done in the first session was critical because sometimes clients were unable to come back for subsequent sessions. Furthermore, LHWs felt that waiting for a week before a problem was reviewed was discouraging for clients.

LHW6 "When am working with a client I have to make sure that the client goes home with something after the first session because they may not return since our people are very mobile, so I do opening the mind (kuvhura pfungwa), and this will lead to easier work in kusimudzira (uplifting).

The LHWs described the first session as the key to the success of their work referring to it as "the stage of clearing the mind/opening the mind" which ultimately flowed into the other therapeutic components. The LHWs felt that this first session, unlike as originally conceived (see Table 1), needed greater time and emphasis and that subsequent sessions could be shorter and delivered over 3-4 weeks.

Key ingredients for successfully opening up of the mind (kuvhura pfungwa) included an ability to show empathy, connecting with the client, being able to reflect and summarise key issues, being non-judgmental and not being prescriptive or instructive.

LHW3 "I always start off by greeting and discussing general issues to make the client feel relaxed then I introduce the issue of their SSQ score being high and suggest to them they may have kufungisisa (thinking too much)....Often they break down and cry when you suggest they have kufungisisa"

Connecting with clients came in several forms from touching the hand and other culturally appropriate parts of the body, offering a tissue paper to a crying client, and praying. It was not unusual for the LHWs to use their own life examples to help create rapport.

LHW2 "because I (LHW) also live with HIV, when I show understanding (empathy), they are grateful and when I share my own experience this helps to further open up their mind."

LHW5 "It's important to be non-judgmental even when you are talking to a sex worker and this really leads to (kuvhura pfungwa & kusimudzira).

Living in the community they worked in seemed to be an added benefit for the LHWs as they felt that this brought a certain level of respect and trust, making the opening of the mind more possible.

LHW1 "So because we are known as Ambuya Utano (Lady health worker) there is a certain level of trust we get from PLWH. We have lived here for more than 20 years so we are known because with most of them we see each other at the market, we have helped them in the past maybe during the cholera outbreak, or when we carried out a home visit to see if they had medication for the HIV illness..."

Opening of the mind was further described as the stage where the client was now in free flow, revealing their challenges and problems. At this stage the LHWs will sometimes ask about how things were before these challenges arose with a focus on the things that the client used to do that they are not doing anymore because of *kufungisisa* (thinking too much).

LHW8 "So we discuss and I give a summary of what they tell me (problems).....yes this is all done in the first visit... then I try look at how they

used to cope before and what has changed...like what have they stopped doing. See, it can be small things like going to church, or like neighbors don't talk to me anymore, stopped sweeping the front of the house...."

The final component of the *kuvhura pfungwa* was described as the point where the client now had to decide which problem to focus on. It seemed from the LHWs that clients hardly ever presented with one problem and as a result it often was difficult for them to select a single problem to work with.

LHW6 "We have to find one problem to start with and this is the client's job. So I briefly summarise then I just listen and encourage them to think and select one problem. Sometimes this takes time".

The LHWs sometimes felt there was pressure from clients for them to provide solutions.

LHW3 "because we are LHWs they think we have answers and we should tell them which problem to start with, so it can take going forward and backward before they identify one problem on their own and sometimes it can be an unusual one like someone who is HIV+ and not taking medication once said to me 'I want to focus on problem for school fees for my child'".

The LHWs generally indicated that the first session would take up to an hour and in some instances it would be longer than an hour or would be carried over to the following day at the clinic or as a home visit.

Kusimudzira (Uplifting)

The Uplifting (kusimudzira) component was described as the part of the therapy where problem listing and selection of one problem was finalized and the focus moved from many problems to focusing on a single problem that had been chosen by the client.

LHW1 "They are uplifted (kusimudzira) when they select a problem to work on even if it's a small problem this gives them a new focus I think".

LHW4 "Just listening and summarizing what the client presents with helps to open the clients mind (kuvhura pfungwa) which then leads to the client being uplifted and deciding what they want to focus on (Kusimudzira) because they know they have support".

The type of problem selected by the client to focus on appeared not to be of primary concern to the LHWs, although at times they were dismayed at the choices that clients made.

LHW7 "Sometimes they focus on things I would not think were important. Once I had a client who was HIV+ and with low CD4 count and a child with kwash (malnutrition) and she had stopped taking her HIV medication and she listed several problems and decided the most important one to focus on was how she could find money to go and visit her mother's grave in the village".

Success depended on the LHWs ability to work with any problem presented to her by a client.

LHW2 "So we talk about how they are going to sort out this problem identified which was a money problem. So once this lady who decided after opening the mind and kusimudzira she would address her lack of money by growing vegetables and selling them and she needed \$5 to buy the seedlings. So we focused on how she would get \$5 dollars to start her business (kusimbisa)".

Kusimbisa (strengthening)

The *kusimbisa* component appeared to consist of brain-storming, exploring options, with emphasis on facilitating and not instructing. Through this process, a specific plan was agreed on which included when and how it would be carried out.

LHW2 "So we talk about how they are going to sort out this problem identified during kusimudzira...... so she needed \$5 to buy the seedlings to start her vegetable garden. So we focused on how she would get \$5 dollars to start her

business. She came up with several ways including asking her sister, her friend from the market, offering to sweep the shop floors for a fee..... "

The emphasis on ensuring that clients walked away from the Bench with a tangible solution after the first session was a recurring theme raised by LHWs.

LHW3 "Yes, identifying a problem after listing is important but what is more important was if the client left the Bench with a plan for that problem, even if it was just a simple plan, like something to do, even to just make a phone call and talk to the church elder and then give feedback on this."

LHW7 "Agreeing on things to do makes them feel supported (kusimbisa) because they feel you are interested in working with them. Yes, what is important is that we (LHWs) don't tell them what to do but we provide quidance".

Kusimbisisa

This section was described as a continuation of kusimbisa which focused on reinforcing strategies agreed upon in the kusimbisa section.

LHW3 "I listen to the client when they come back to see me and I encourage them to stay focused and here sometimes I even tell them I will visit them at home to see how it is going."

Duration of sessions

The LHWs indicated that the first session would take up to an hour and in some instances it would be over an hour.

LHW4 "The first visit which is kuvhura pfungwa is important and this feeds into the others (kusimudzira and kusimbisa), so it takes time to go through about an hour or even more ..."

Difficult cases

The LHWs described three main referral criteria for difficult cases (red flags) which they defined as: 1) suicidal cases; 2) clients where the problem selected seemed

impossible to resolve and 3) any case with an SSQ-14 score of 11 and above. They indicated that over the years the rate of referral to the supervisor had reduced significantly because they now felt confident with the provision of counseling of some of these difficult clients. They differed on the issue of referring clients who scored 11 and above on the SSQ-14, with 3 of the LHWs saying they only referred scores of 11 and above if the clients responded "yes" to question 11 which inquired about suicidal ideation. The remaining LHWs tended to refer all high scores to the supervisor regardless of suicidal ideation.

LHW4 "When I have a person who is suicidal and is red flag and appears to have thought about how they would kill themselves and the SSQ response to question 11 is "Yes" I immediately take the client to Ethel (Supervisor)".

LHW1 "Sometimes they would be so sad and they talk of ending it all, for me this is an emergency to take to our supervisor".

With clients who presented with a problem that is related to finances LHWs generally indicated that these tended to be difficult but over the years the approach they generally took was to look at the reason for needing the money and focus on that.

LHW6 "So they come and elect a money related [problem]they say money mainly for school fees, their child is two weeks not at school because she has no money for school fees. We use the same approach of opening up the mind and kusimudzira but in relation to the money for school fees...."

LHW3 "One woman who needed \$30 for school fees after we talked about ways of making \$30 she came up with several solutions like firstly going to the school and asking the headmaster to take her son and giving a written guarantee to the school that she would bring the money in 3 weeks. See this helped her to relax, then we looked at how to find the money and she ended up deciding to borrow \$10 dollars from her friend and she went to Norton where the fishermen are and she bought fresh fish for \$7 and used the \$3 for transport. She sold the fish for \$15 and went back to the fishermen two times until she had \$40, now she goes there regularly....."

The LHWs described innovative solutions for generating funds that clients explored during sessions and then went on to try out.

LHW4 "I had a woman who lives here in Mbare who came with an SSQ-14 score of 10. So she was also HIV+ and she was desperate to have regular money to feed her family, her husband had died. We spent close to an hour doing kusimudzira (selecting and exploring a solution) and then we came up with a list of 6 different things she could try. Eventually she tried the money club program where she joined a group where she gave \$1 each week and when it was her turn after 4 weeks she received all the group money".

Characteristics of clients

A total of 10 clients (6 women and 4 men) living with HIV for over 3 years were included in the interviews. All had secondary education with 2 had achieved tertiary education. They were aged between 22 and 35. The clients were all residents of the catchment area of Mbare and were familiar with the work of LHW in the community.

Clients' perception of the Friendship Bench

Clients described four features or stages that they went through during the sessions on the Bench. These were an initial feeling of relief (kusununguka) that their HIV status was not going to be used against them, followed by feeling supported (kubatsirikana) in their efforts to try and resolve the problem, leading to a sense of being empowered (kukwanisa) and overcoming the problem (kukunda) diagram 1.

CL6 "When the counselor (LHW) told me that she too was living with HIV I felt an instant relief (kusununguka) and felt I could open up to her about my husband and his not wanting to use protection during sex".

CL3 "The counseling I got when I was started on HIV tablets at the HIV clinic did not look into how I felt or my concerns about the tablets but the ambuya utano (LHW) asked me about my feelings about it which has never happened before".

CL5 " They listen to what you say and encourage you to keep talking (kusununguka), it does not happen that way when you talk to the clinic

nurses" CL1 " The ambuya utano seemed to always have time and was prepared to listen and never judged me for being HIV (kubatsirikana)"

CL 3 "When I told her (LHW) my problems which were about my husband beating me, my daughter also living with HIV and being sick, and me not having a job, and no money for rent or school fees... she said I was carrying a heavy load and she wanted to help me start working on one problem first"

The clients went on to indicate that an intensive approach to the PST was helpful as it helped them to stay focused. They were comfortable with the sessions being covered over a short period of two weeks, sometimes three weeks.

CL4 " It was very helpful to have ambuya utano focus on my issues over the three sessions which were carried out over a week".

4.5 Discussion

This qualitative study provides an in-depth understanding of locally generated indigenous terms and concepts used during the delivery of a PST intervention. This study highlights how a PST approach to CMD has been adapted to be culturally relevant and appropriate by LHWs over four years through incorporating indigenous concepts, iteration, peer interaction and sharing of personal experiences on the Friendship Bench. Importantly these new concepts do not provide literal translation of the traditional PST components as defined by Mynors-Wallis [27] but have enabled the LHWs, who have minimal education, to easily navigate through the stages of PST adapting it where necessary while still maintaining the fidelity of the Friendship Bench program.

Earlier qualitative work in Zimbabwe explored the use of etic and emic approaches to understand indigenous idioms of distress resulting in the endorsement of terms such as kufungisisia (thinking too much) and Mwoyo unorwadza (heavy heart) as non-Western concepts to describe common mental disorders (CMD) [33-35]. This study has taken a step further by unpacking the components of PST as experienced by LHWs and their clients. As in our previous work, kufungisisa appears to be a central

feature among PLWH and is associated with a wide range of factors, which include poverty, stigma, and marital upheavals [11, 28].

Significant adjustments to the original PST components have been necessitated by the LHWs desire to ensure that the client takes home a solution that is specific, measurable and achievable after the first visit. This is because they found that clients are often not able to attend sessions regularly. Other changes have included fluidity of session content incorporating the three overarching themes described in diagram 1. Such adjustments to Western developed psychological interventions have been reported to increase acceptability, feasibility and effectiveness when delivered in non-Western settings [36]. Other aspects of the intervention include the LHWs openness and ability to share their own personal challenges as a way to create rapport, use of prayer to contain a stressful situation, and the use of home visits as a way of supporting clients. These aspects of the LHWs work are not usually incorporated into western based therapies but seem to be acceptable in this setting where the LHWs are seen as a source of wisdom[11]. Table 2 illustrates the stages of PST as defined by the LHWs in comparison to the classic PST steps.

There appears to be no real consensus on what aspects of PST contribute to the therapeutic change. One meta-analysis on PST concluded that there is need for further studies to establish the actual components of this approach that contribute to it's effectiveness[37]. However, another meta-analysis concluded that effective interventions consisted of the 4 key problem solving skills (i.e. problem definition, generation of alternatives, decision making and solution implementation)[38]. Other studies suggest that PST works because it empowers the patient to take control [39, 40].

While no consensus on how long a PST session should take exists [37], there is evidence indicating that PST can be delivered in as little as 20 minutes and such short sessions may contribute to increased structure to therapy [41]

A key feature of the PST delivered by LHWs in this study is the emphasis on the first session which resulted in a major shift in session content to ensure it included all three components of "opening the mind", "uplifting" and strengthening". Neither LHWs nor clients felt that 6 sessions were necessary; they felt that the duration

between sessions needed to be shorter than a week. An emphasis on the first session or single session therapy has been reported in several studies. In the USA, Steve Safran has developed and validated a single session of a CBT based intervention which focuses on adherence to HAART [42] while Perkins showed efficacy of a single session therapy for mental disorders among adolescents [43]. Other studies have shown similar findings supporting the use of single session therapy approaches [44-46]. In our setting, this single session therapy approach was primarily driven by the high mobility of people living in the study area of Mbare.

Our study further reveals that PLWH receiving therapy on the Friendship Bench often came with several problems needing to be addressed and that the main objective for the LHW was to guide the client through the process of selecting one of these to focus on. LHWs felt it was critical to not adopt a prescriptive role when encouraging the client to brainstorm possible solutions. Clients reported finding it empowering to have found their own solutions, highlighting the importance of ensuring that the client drives the therapeutic process. This is often a challenge in African settings where older people particularly those in authority are automatically assumed to be the best people to determine what needs to be done.

There is sufficient evidence to support the use of LHWs to address the treatment gap for CMD [10]. In the context of HIV, interventions delivered by LHWs could improve outcomes related to HIV such as adherence to HAART but there is a need to evaluate outcomes using rigorous methods, such as randomized controlled trials. There is also a need to develop and validate user-friendly tools for screening that can be utilized by the LHWs with minimal supervision [47]. Efforts to develop alternative tools for illiterate populations have been encouraging, with visual screening tools now being considered in Africa [48]. There are, however, few psychological interventions for CMD among PLWH that have rigorously addressed challenges related to feasibility, acceptability and scalability of interventions delivered by LHWs in LMIC [49]. In a recent systematic review [49]we highlighted the need to report on the components, fidelity, and training of LHWs when developing interventions intended to be delivered by LHWs.

Within the context of CMD, among non-HIV infected populations, there are a number of well-defined and rigorously tested interventions delivered by LHWs [13, 15, 16]. As demand for further research to develop and test specific interventions for CMD in PLWH grows there is need to learn from strategies used in the development of interventions for non-HIV populations. A limitation of our study is the small sample size of LHWs recruited for the qualitative interviews.

Conclusion

In this study we have managed to show that a locally adapted PST, driven by local concepts as defined by LHWs and their clients, is acceptable and user friendly and reflects the objectives of a traditional CBT based approach. Further clinical trials are needed to test the efficacy of such LHW driven interventions in LMIC.

Author contribution

DC was responsible for the design of the study conducting interviews, analysis of data and drafting of first draft leading to the final manuscript

FC was responsible for reviewing the design and reviewing of second and final draft DM was responsible for conducting interviews, transcribing of data and review of the third draft

RV was responsible for analysis, coding of data of the interviews and review of the first and last draft

MA was responsible for analysis, coding of data and review of final draft

CL was responsible for reviewing the design of the study, first draft and all subsequent drafts leading to the final manuscript

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Compliance with Ethical Standards

All necessary approval to carry out this study was obtained from both the Medical and Research Council of Zimbabwe and the University of Cape Town Ethics Board.

Conflict of Interest

All the authors declare no conflict of interest.

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 Table 4.1. Components of the Friendship Bench problem solving therapy

Theoretical basis	Based on problem-solving therapy (Mynors-Wallis 2001)
Delivering agent	LHWs (Health promoters). Mean age 58 sd 8.3, all female, mean years of education 8 sd 3.3, previous training in home based care for people living with HIV & AIDS, in community follow-up of persons on TB treatment and in delivering community health education and promotion e.g. through encouraging immunisation and methods to control disease outbreaks
Structure of intervention	Six weekly sessions each of 30-45 minutes delivered through the Friendship Bench over six weeks, including one or two home visits.
Structure of sessions and areas covered.	Session week 1. Problem identification : A) Share Shona Symptom Questionnaire (SSQ) information with client, explain symptoms in relation to <i>kufungisisa</i> , B) Actively listen to clients story, identify problems raised, clearly define problem/s. Session week 2. C) Summarise session 1, Explore Problems further D) select one problem to focus on, Discuss the advantages and disadvantages of problem selected E) Home visit before next session/prayer with family. Session week 3. F) Summarise session 2, G) Brain storm solutions to problem selected in session 2, H) List possible solutions then identify solution that is feasible, provide information on referral where necessary. Action plan: I) Zero in on a specific solution, focus on what client wants to do, J) How, when, what assistance is needed? Referral if necessary. K). Identify activities the person used to find rewarding and which matter to them and encourage these Session week 4. L) Brief review of session 3, Implementation: M) How will it be done? Motivate; homework. Session week 5) Home visit. Follow up: L) What has been achieved? What were/are the obstacles if any? Go back to session 3 and 4. Session week 6: M) Reinforce sessions 3, 4 and 5. What has been achieved, repeat SSQ score. N) No improvement refer to nurse counsellor

1.Kusununguka (relief)

2.Kusimudzira (supported)

1.Kuvhura Pfungwa (opening the mind)

4.Kusimbisisa (strengthening)

4.Kukunda (overcoming)

Lay health worker components

Client living with HIV components

Figure 4.1. Components of the sessions as described by LHWs and PLWH

Chapter 5

Using a theory driven approach to develop and evaluate a complex mental

health intervention: The Friendship Bench Project in Zimbabwe

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Description of contribution of candidate

Dixon Chibanda was lead author for this article and primarily responsible for

designing the study, leading in all of the workshops, training of the Friendship Bench

team on how to conduct workshops for ToC, designing the data collecting tools,

initial, developing the ToC map, and drafting the manuscript. This work was carried

out as part of the formative work leading to the engagement of key-stakeholders in

the development of the intervention and it's evaluation through a cluster RCT

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5.1 Abstract

There is a paucity of data on how to deliver complex interventions that seek to reduce the treatment gap for mental disorders, particularly in sub-Saharan Africa. This article describes the use of a theory of change (ToC) model to develop and evaluate a cluster randomized controlled trial in Zimbabwe.

Method: A total of 8 ToC workshops were carried out with stakeholders over a 6-month period with a focus on 4 key components of the program: formative work, piloting, evaluation and scale-up. A ToC map was developed as part of the process with defined causal pathways leading to the desired impact. Interventions, indicators, assumptions and rationale for each point along the causal pathway were considered.

Results: Key interventions with specific indicators, assumptions and rationale formed part of the ToC map, which graphically illustrated the causal pathway leading to a successful implementation of the cluster randomized controlled trial.

Conclusion: ToC workshops can enhance stakeholder engagement through an iterative process leading to a shared vision that can improve outcomes of complex mental health interventions particularly where scaling up of the intervention is desired.

Keywords: Theory of change, mental health, complex intervention, stakeholder involvement

5.2 Introduction

Mental neurological and substance use (MNS) disorders contribute significantly to the global burden of disease, particularly in low and middle income countries (LMIC) [1], where the largest treatment gap for MNS disorders exists [2]. In recent years scaling up of MNS services has been recommended [3] through the development of packages of care that emphasize task shifting as a way of addressing this treatment gap [3-5]. There is growing evidence suggesting that appropriately trained and supported lay health workers can deliver interventions for MNS in low resource settings [6] with a number of clinical trials showing efficacy of this approach [7-10]. However, there is a paucity of data and capacity on how to deliver such complex interventions in routine primary care settings in a manner that reduces the treatment gap for MNS, particularly in sub-Saharan Africa [11, 12].

The need for well documented protocols which clearly describe the development and the scale-up of programs and interventions is necessary if such interventions are to be replicated elsewhere [13]. In recent years the theory of change (ToC) approach has become widely used as a tool for developing and evaluating complex interventions [14], because of it's theory driven approach to evaluation [15], ability to facilitate stakeholder participation, explicit identification of causal pathways, and potential for linking indicators to the design of complex interventions [16]. Existing recommended evaluation guidelines for complex interventions such as the Medical Research Council (MRC) [17] framework do not describe the mechanism of change through which a given intervention or program leads to real-world impact [18]. The ToC defines how and why an initiative works through the use of evidence based measures and indicators to explain an initiative's causal pathway to impact [14].

The process of developing a ToC starts early during an initiative with key stakeholders invited to develop a common vision that describes the causal pathway leading to the program/initiative/intervention goal. During this process, specific outcomes, indicators, assumptions, barriers and interventions are identified to ensure that the desired outcomes are realized [14]. ToC therefore offers a roadmap for the necessary change leading to a desired outcome [19]. This map offers information on assumptions such as the final destination, the context for the map and

the process to engage in during the journey. Furthermore, the ToC map outlines the belief system that underlies the steps in the causal pathway, and describes the input and outcome of the different level interaction. A series of meetings and workshops with relevant stakeholders is the main vehicle for developing a theory of change map. Such an approach has been used in the program for improving mental health care (PRIME) [5], a multi-country complex intervention aimed at generating evidence on how to integrate mental health into primary care through the development, implementation and evaluation of district level mental health care plans for priority disorders [16].

Little is known about the use of the Theory of Change approach in the development and evaluation of mental health interventions in the context of HIV in sub-Saharan Africa. There is evidence suggesting that the ToC approach can be a useful tool for developing and evaluating such interventions including establishing evaluation frameworks, and obtaining the necessary buy-in of key stakeholders [14].

We recently utilized a ToC approach to develop, and evaluate through a cluster randomized controlled trial the Friendship Bench project [20], an intervention utilized predominantly by people living with HIV (PLWH). The Friendship Bench has been running in 3 large primary care clinics in Harare Zimbabwe for over 8 years. It is a task shifting program that uses lay health workers to deliver a structured cognitive behavior therapy (CBT) based intervention that emphasizes problem solving (PST) [21]. A decision to scale-up the intervention to 60 primary care facilities employing over 300 LHWs was recently made by the city health authorities. This paper describes the manner in which the ToC model was used to design and evaluate a successful cluster randomized controlled trial (RCT) and a scale-up plan [20].

5.3 Methods

Eight (n=8) ToC workshops were held with relevant stakeholders over a six-month period. Stakeholders included policy makers from the Ministry of Health and Child Care and City of Harare Health Department staff. Table 5.1 shows the full list of workshop participants by type of workshop and category of participant. Key groups

of the stakeholders attended all workshops (City of Harare Health staff, and the research team from the Friendship Bench project).

Invitations to relevant stakeholders were sent out together with the objective of the first meeting. The initial workshop aimed to draw on various sources of information as the first step towards planning for the RCT of the Friendship Bench. This first workshop, which was part of a formal launch of the initiative focused on defining the main components of the process.

Areas addressed during ToC workshops

Five specific areas related to the Friendship Bench and it's evaluation through a cluster RCT were addressed during workshops. These included: a) the perceived impact of the intervention on the care of patients utilizing primary health care facilities particularly PLWH, b) establishing intermediate and early outcomes which would be arranged on a causal pathway, c) interventions needed to initiate each short, medium, and long term outcomes, d) the conditions required for each step to be achieved, and e) the resources required to implement the intervention. Assumptions made during the ToC meetings were based on information gathered over the last 8 years of work carried out on the Friendship Bench in the area of Mbare [22]. We included assumptions that certain conditions would be met in the development of the ToC map as described in previous studies [19].

The first author (DC) facilitated the workshops and constructed the ToC diagrams, while a co-facilitator appointed for each workshop took notes or audio-recorded the meetings. Different workshops for different groups were held to avoid power differentials. Meetings were held at the study sites, University of Zimbabwe Department of Psychiatry, study administrative offices, and City Health Department and lasted between 2-4 hours. After the first workshop, a sub-group of workshop members continued to work on the ToC under the guidance of the first author DC with scheduled larger workshops including all stakeholders running roughly monthly for 6 months. Informal communication through email, telephone calls, and one on

one meetings with specified stakeholders contributed to information that was used in framing the larger group meetings and workshops.

Issues perceived to be important in the development of a successful ToC based on the literature [23, 24] were addressed under 4 broad themes of (1) Formative work, (2) Piloting, (3) Evaluation, and (4) Scale-up.

1. Formative work (Official launch/intervention development)

The first formative ToC workshop was part of the official launch of the project, which was attended by both the Director of City Health Services, the Minister of Health and several stakeholders described in Table 5.1. A series of presentations highlighting the need to integrate mental health care into primary care, the evidence, resources available and the processes required were highlighted. These were then discussed with suggestions, comments, from the 54 participants recorded by DC. Through a participatory discussion initiated by the Director of City Health Services and facilitated by DC, broad consensus was reached on the program's desired impact of having screening and treatment for mental neurological and substance use disorders integrated into all primary health care facilities. Specific issues highlighted during this first ToC workshop included the need to better understand the key components of the intervention and how it would be delivered. Furthermore it was suggested that core competencies for LHWs meant to deliver the PST on the Friendship Bench be established. One follow-up meeting with a smaller group (n=28) recommended that more information on what the LHWs were capable of doing in terms of workload and competency be collected through the existing site of Mbare [22] and the HIV clinics.

The third workshop focusing on the formative stage included senior clinic managers of the City Health Department, their supervisors, and the Director of City Health services (n=28). This workshop focused on the role of the clinic nurses and how 24 clinics out of the existing 60 eligible clinics would be selected for the trial. Barriers and challenges to the selection of the 24 clinics were discussed and interventions aimed at clarifying the issue related to these barriers discussed. While the original plan for the program was to utilize clinic-nursing staff to provide supervision to the LHWs at clinic level during the cluster RCT, the ToC workshop noted that nurses

were already over-stretched and could not provide supervision and support counseling to LHWs. Therefore there was need to present an acceptable role for the nurses in the 24 cluster RCT clinic sites which was not related to the provision of counseling supervision.

2. Piloting

The pilot ToC workshops looked at specific assumptions made in relation to running the pilot RCT in 4 clinic sites. These assumptions were used to develop research questions that were included in the final pilot. Members of staff working at the pilot sites were consulted on issues related to recruitment, reimbursement and referral of critical cases. The integration of mental health into general primary health care programs was considered and obstacles such as lack of supervision, possibility for appropriate referral, availability of medication for MNS conditions and support for LHWs were considered. Workshop participants initially assumed that clinics would embrace the idea of integrating mental health into existing primary care services as was the case in the clinic site of Mbare [22]. However, because of the diversity of clinics the ToC process highlighted the need to explore this assumption further, through individual assessment of the 24 clinics proposed for inclusion in the cluster RCT. Further assumptions included the acceptability of the Friendship Bench by PLWH who often had to deal with stigma and victimization at community level.

Assumptions about the acceptability of asking LHWs to use 8-inch computer "tablets" for communication purposes were discussed and it was concluded that an intervention to establish the barriers and enablers of using technological components for the RCT be carried out. Attending LHWs, however, expressed concern that the \$230 8-inch "tablet" computers would expose them to possible mugging, theft, and jealousy from LHWs from clinics not included in the cluster RCT. Instead, they suggested exploring the use of the simple and readily available \$30 mobile phones.

3. Evaluation (Cluster RCT)

Two workshops focused on the cluster RCT with the first workshop attended by all key stakeholders (n=24) scrutinizing the results of the two pilot feasibility trials described above. During the workshops a framework to identify interventions that

would be feasible to improve the final cluster RCT were considered. The resources, the contextual barriers and facilitating factors for the implementation of the cluster RCT were carefully considered during these workshops. For instance exploring the use of WhatsApp as an alternative form of providing support to the supervisors was specified in the ToC workshop including the consideration of having all study team members and LHWs use one specific mobile phone service provider.

The assumption that the Friendship Bench would expand beyond the 24 clinics included in the trial to the 60 city health clinics throughout the city was highlighted, with the main rationale being that a reduction of CMD symptoms in PLWH utilizing the Friendship Bench would lead to an improvement of other key HIV related outcomes such as adherence. During this workshop, a sub-group consisting of DC, the Director City Health Services and RV was set up to focus on exploring further, critical conditions for scale up including funding opportunities.

4. Scale up

Scale up was defined as the expansion of the Friendship Bench from the original 3 clinics in Mbare [22], initially to the 12 intervention clinics included in the cluster RCT followed by an expansion to the remaining 48 clinics including the control clinics in the cluster RCT(n=12) [20].

Political buy-in from key stakeholders particularly the City Health Department and the Ministry of Health was specified as a critical component for successful scale up. Input, process, output and outcome indicators were consolidated into a visual ToC for the entire program which highlighted the causal pathway to scale up with assumptions and interventions considered along the path. For the purposes of this ToC the "ceiling of accountability" which is the point at which the study team relinquishes control over the possible outcomes of the intervention, and therefore does not employ further indicators to measure those outcomes [14] was set for the ToC map.

Workshop Participants

Through out the process, some unexpected interactions and relationships developed between workshop participants, for instance on several occasions informal meetings over lunch, or coffee between small groups managed to address specific issues resulting in subsequent workshops being more productive and cohesive. The director for district health promoters (DHPOs) commented during one of the meetings that " All these meetings, particularly the small group meetings have really opened my mind on the need to integrate mental health in all our clinics".

Ethical considerations

Ethical approval was obtained for all interventions carried out to address issues raised during ToC workshops, through the Human Research Ethics Committee of the UCT Health Sciences Faculty (REC Ref: 090/2014 and the Medical Research Council of Zimbabwe (Ref: MRCZ /A/1732). Written informed consent was sought from all participants. The ToC development complied with the requirements of the Declaration of Helsinki [25].

Data management and Entry

All data collected during ToC meetings were managed in accordance with the Medical Research Council of Zimbabwe (MRCZ). Data were collected from a number of sources, including process documentation about the workshops and meetings, existing documentation from the Friendship Bench, email correspondence, telephone communication, formative qualitative work and piloting. The project coordinator was responsible together with the study data clerk for compiling data into folders based on the subject matter. Priority areas from each folder including recommendations were noted and further explored either by contacting facilitators of the respective meeting/workshop or carrying out systematic reviews [26]. Where formal interviews were used, semi-structured interviews were the desired approach [27]. Data was gathered into themes based on content and members of the study team met regularly over the six month period to discuss the emerging themes which were then summarized and sent back to the larger group and refined based on the feedback. This process was carried out until consensus was reached on issues such as outcomes, indicators, and interventions required to move from one point to the next.

5.4 Results

A final ToC map (figure 5.1) with a narrative description of the different components including assumptions, interventions, indicators and rationale for the hypothesized causal pathway to impact was developed after a total of 8 workshops and 10 small group meetings (Figure 5.1).

Getting political buy-in and building capacity particularly among LHWs were two themes highlighted in the ToC map, including the development of an acceptable, user friendly and feasible psychological intervention. A number of interventions were recommended leading to the modification of the existing PST with an emphasis on PLWH [26, 27]. Transparency was emphasized through out the process. For instance all clinic directors, district health directors and representatives of LHWs were invited to the official randomization exercise, which used computer generated random numbers to identify 24 clinics for the cluster RCT and allocate them by either intervention or control arm. The specific components of the ToC including outcomes required to reach impact are further illustrated in the ToC map (Figure 5.1).

Causal pathway

The starting point for the Friendship Bench ToC map is the establishment of political buy-in (1a) together with identification of key resources, which included human, facility/infrastructure, communication and supervision resources. The Minister of Health's participation as guest speaker at the launch was seen as a key step towards obtaining political buy-in. The use of existing LHWs (1e), city health clinics and supervisors employed by city health services was critical to ensure sustainability of the program post funding. Furthermore, integration of the Friendship Bench into the University of Zimbabwe's Department of Community Medicine and Psychiatry were identified as key strategies for sustainability. The ToC pathway further indicated the need for protocols and standard operating procedures (SOP) defining the pathway (1b) from community to tertiary facility and stipulated that both community nurses and tertiary level nurses should be in constant communication about such referrals. The establishment of a community liaison / outreach team would contribute towards strengthening the integration of mental health in the work carried out by LHWs (2b, 2d). While availability of functional Internet and mobile phone services

(2a) would strengthen supervision and fidelity checks (2c) leading to a successful intervention (3a-3d). Scaling up of the Friendship Bench after the RCT (3e) would depend on availability of funding (4a), which could lead to the expansion of the initiative to all primary care clinics (3f) and a reduction of CMD among patients utilizing local clinics (3g).

Intervention

The nature and design of interventions required to ensure smooth flow from one outcome to another were different for the four components described above (figure 1). While ample evidence from previous work on the Friendship Bench [22] supported the feasibility and acceptability of the initiative, the acceptability outside the pilot sites was a leading assumption on the ToC map (2b). Furthermore, the views, buy-in and input of patients particularly PLWH were identified as a requirement to move to the next stage in the causal pathway.

Assumptions

Our ToC included several assumptions that were deemed necessary to be in place in order for the outcomes to be achieved; these included complete political buy-in throughout the entire initiative and adequate funding particularly for the scale-up to the 60 clinics. The ToC further assumed that all the 60 clinics would appreciate the need for mental health integration leading to an expansion of the initiative (2b), and that the use of a technological platform to provide supervision and support would be acceptable (2c). For all levels of human resources involved in the initiative, the ToC stipulated that these had to be from existing systems such as the City Health Department, Ministry of Health and University.

Indicators

The ToC outlined several indicators, which included input, process, output, and outcome indicators. The critical input indicators were political buy-in which included the availability of a formal support document from the Director of City Health and the Minister of Health as evidence for buy-in (1a), and programme resources including funding. Process indicators included capacity building, fidelity measurement through the analysis of audio-recorded sessions (2c), +adherence to standard operation

procedures (SOPs), and referral pathways of study participants. Output indicators included use of mobile devices for supervision and support, screening, recruitment, treatment, follow-up. Outcome indicators included the study primary and secondary outcome measures which was reduction in symptoms of common mental disorders, depression, and generalized anxiety disorder at 6 months as described in the cluster RCT protocol.

Rationale

The key rationale of our ToC causal pathway to impact was that the intervention would lead to a reduction of CMD symptoms among those receiving care through the Friendship Bench RCT (3g).

5.5 Discussion

This study shows how the use of ToC workshops with a focus on enhancing stakeholders' engagement through an iterative process contributed to the strengthening of key components of a complex intervention. Our ToC workshops systematically addressed 4 inter-related steps along the causal pathway which consisted of: formative work, piloting, evaluating and implementation of a complex mental health intervention.

This approach of using ToC workshops has been recommended by several researchers in the field [14, 23, 28, 29]. Our emphasis on an interactive approach during all the ToC workshops contributed to several positive outcomes including the building of rapport and enhancing stakeholder engagement during the four year period of the study. Key stakeholders involved in the ToC workshops were researchers, policy-makers, clinic staff, community health workers (LHWs) and user groups.

Service providers such as nurses, clinic administrators, LHWs and their supervisors provided detailed contextual information which resulted in the final study protocol being revised four times before submission for ethical approval. Some issues raised

by service providers during the workshops included the risks associated with providing LHWs with tablet computers (2a), the need to use mobile phone money deposit as a way of reimbursement for study participants, and the need for all clinic staff to be invited to the randomization of clinics so as to avoid tension from clinics that would be excluded from participation in the study as a result of not being randomly allocated.

As has been recommended in previous ToC protocols [14, 16, 23] our initial ToC workshop commenced with a description of the desired impact and building consensus around it (1a). We then used an iterative approach going through the causal pathway by identifying barriers, interventions, formulating rationale and making assumptions about the pathway leading to impact. Sub-groups were formed to avoid tension and hierarchical approach to workshops as has been recommended in similar ToC workshops [16, 29, 30]. There is evidence indicating that hierarchical structures and division of labour found in many organizations often produce a differentiation of decision makers, implementers, and program users [31]. We therefore ran the ToC in groups that were less hierarchical based on these dynamics. This formal consensus development method which involved learning across disciplines has been described as yielding effective results in multidisciplinary mental health teams [32], through the collective selection of strategies that can be applied to promote change [31].

Understanding why and how a complex intervention works contributes significantly to it's effectiveness, sustainability, and scalability through the provision of evidence based explanations of the mechanisms of change [14]. The ToC workshops for the Friendship Bench managed to provide a clear explanation of the mechanisms of change through the development of the ToC map, which gave a clear visual pathway of the study. This enabled all workshop participants regardless of level of research, monitoring and evaluation expertise to have an understanding of the program theory and the implementation theory as described by Weiner [31].

The implementation theory defines the how and why of implementation activities such as planning, training, and resource allocation and how they are linked together

to generate the desired results [33]. By providing every workshop participant with a graphic representation of the causal pathway, all were able to understand the need for specific interventions and indicators through the causal pathway. This helped to answer the question "How will we know we are ready to move to the next step?"

While nursing staff at local clinics was reluctant to provide counselling supervision to LHWs, their ability to participate in the workshops and sub-group meetings contributed to their appreciation of both the program theory and implementation theory. This contributed to the overall success of the trial as they facilitated interviewing space, recruitment, and the prescription of anti-depressants to participants who were severely depressed before they referred them to the tertiary mental health services for further management.

Although the use of ToC in mental health programs is in it's infancy [14, 16], it's use in settings with complex bureaucratic procedures can be of great value as it brings together stakeholders, increasing the probability that such complex interventions will be more successful. Policy makers often require simple and easy to understand processes, which they can run through without needing expert opinion.

Limitations

There are several limitations to the development of this ToC, which include the prominence of the first author (DC) and the Friendship Bench team in most of the activities leading to the desired outcome. This could have contributed to a social desirability bias. Secondly, the analysis of the data from the workshops was carried out by the Friendship Bench team under the guidance of the project coordinator (EM); this too may have contributed to a bias. However, due to the need for stakeholders to stay focused on the ToC process over a 6 month period, the principle investigator (DC) was seen as the most appropriate person to drive the process as he was the only team member familiar with the ToC approach. Furthermore, other stakeholders, although keen to participate in the ToC activities were reluctant to take on the responsibility of leading the process.

Another limitation was the minimal involvement of service users in some of the ToC workshops due to the lack of funds to transport them to workshop venues.

Despite these limitations, key lessons learnt from the ToC approach include the need to have a committed person responsible for putting together the different results from the ToC workshops and sharing these with the larger group through an iterative process. The importance of the visual ToC map which can be the most unifying component of the exercise bringing together participants including LHWs with minimal education to contribute towards describing outcomes, interventions, and indicators.

Conclusion

The use of ToC workshops in the development, piloting, evaluation and implementation of complex interventions in mental health should be encouraged as this increases the likelihood of successful implementation through a combined use of theory and practice and the development of a more transparent causal pathway.

Author Contribution

DC: design of the study approach and the writing of first draft leading to the final draft

RV: facilitating group meetings leading to a consolidated ToC map and review of the

third draft

EM: Coordinating all ToC meetings and review of third draft

FC: development of study design and review of final draft

CL: design of the study protocol, review of first and all subsequent drafts leading to

final draft.

Conflict of interest

All authors declare they have no conflict of interest

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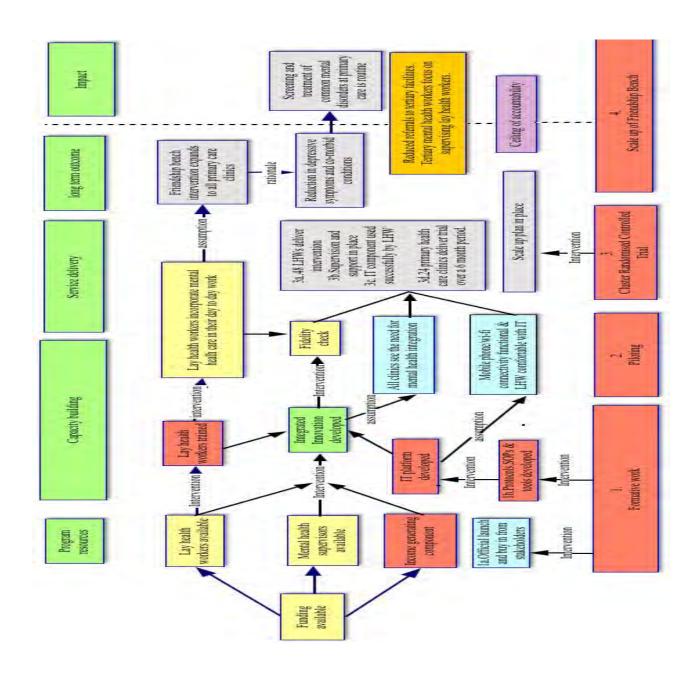
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Table 5.1. Participants by Workshop

		Type of Workshop				
	Official	Intervention	Pilot RCT	Cluster RCT	Scale-up	
	launch	Development)				
(n=number of workshops)	(n=1)	(n=2)	(n=2)	(n=2)	(n=1)	
Total number of participants:	54	28	29	24	14	
Policy makers						
Health ministry	8	1	1	0	2	
City health	6	2	1	2	2	
University lecturer	4	1	1	1	1	
Community level workers	6	2	2	2	2	
Nurse in charge	8	2	4	2	0	
*DHPO	2	4	2	2	2	
** LHW	8	8	2	4	1	
Research team	6	3	4	4		
Psychiatrist	3	1	1	1	1	
Senior Psychologist	1	1	1	1	1	
Psychologist	1		2	2	0	
Project coordinator	1	1	2	1	1	
Study participants		2	2	0	1	
Research assistants	0		4	2	0	

^{*}District Health Promoting Officer ** Lay Health Worker

Figure 5.1. Theory of Change Map



Chapter 6

Scaling Up Interventions for depression in sub-Saharan Africa: Lessons from Zimbabwe

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Description of contribution of candidate

Dixon Chibanda was lead author for this article and primarily responsible for designing the study, collecting both qualitative and quantitative data, with the help of the study project coordinator, data analysis and drafting the manuscript. This work was carried out as part of the preparation for the scale-up of the Friendship Bench after the completion of the cluster RCT in 24 primary care clinics in Harare. Formative.

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6.1 Abstract

There is growing evidence from low and middle-income countries (LMIC) of the effectiveness of psychological interventions delivered by lay health workers (LHW). There is however, a dearth of information on how such interventions can be scaled up in sub-Saharan Africa, particularly within the context of existing HIV programs. This paper describes the development of a strategy for the scale-up of an intervention delivered by LHWs to 60 primary health care facilities in Zimbabwe.

Methods

A mixed methods approach was utilized as follows: 1) Needs assessment using a semi-structured questionnaire to obtain information from nurses (n=48) and focus group discussions (FGD) with District Health Promoters (DHPOs) (n=12) to identify key priority areas; 2) Skills assessment to identify core competencies and current gaps of LHWs (n=300) employed in the 60 clinics; 3) Consultation workshops (n=2) with key stakeholders to determine referral pathways; and 4) In-depth interviews and consultations to determine funding mechanisms for the scale up.

Results

Five cross cutting issues were identified as critical and needing to be addressed for a successful scale-up. These included: the lack of training in mental health, poor availability of psychiatric drugs, depleted clinical staff levels, lack of time for counseling, and poor and unreliable referral systems for people suffering with depression. Consensus was reached by stakeholders on the supervision and support structure to address the cross-cutting issues described above and funding was successfully secured for the scale-up.

Conclusion

Key requirements for success included early buy-in from key stakeholders, extensive consultation at each point of the scale up journey, financial support both locally and externally, and a coherent sustainability plan which was formally endorsed by both government and private sectors.

6.2 Introduction

There is growing evidence supporting the use of lay health workers (LHWs) through task-shifting to address the treatment gap for depression and other common mental disorders in low and middle-income countries [1]. While this evidence seems relatively robust [2], there is a dearth of well documented examples of packages of care that have been taken to scale [3].

Addressing critical knowledge gaps related to policy and systems that would encourage scaling up of evidence based mental health interventions is needed [4]. A key strategy on how to achieve this includes sustained advocacy by diverse stakeholders, targeting multilateral agencies, donors, and governments [5]. In addition the new role of psychiatrists and clinical psychologists should emphasise a public mental health approach, encompassing design and management of mental health initiatives at community level [6].

Zimbabwe, with a population of 13 million people has 8 psychiatrists and 16 clinical psychologists who are largely involved in clinical work in both tertiary and private facilities. In response to the high burden of depression in primary health care facilities, particularly among people living with HIV (PLWH) an intervention (The Friendship Bench) utilizing a task shifting approach was introduced in the city of Harare in 2006 [7]. The Friendship Bench is an intervention delivered by trained and supervised lay health workers who provide basic cognitive behavior therapy (CBT) and problem solving therapy (PST) [8]. The intervention has been running as a pilot program in 3 primary care clinics for over 8 years with a focus on screening and treating depression, locally referred to as kufungisisa [9], using locally validated tools [10]. It is delivered on a Bench (The Friendship Bench) in a discrete part of the grounds of the clinics. A team consisting of a clinical psychologists, mental health supervisors, and a psychiatrist provide the stepped care support to the LHWs [7]. Recently, the Friendship Bench was evaluated through a cluster randomized controlled trial (RCT) which involved 24 primary care clinics [11]. Although

preliminary results of the RCT showed promising impact the challenge facing the research team and key stakeholders was how to scale-up this evidence based intervention to 60 existing primary health care clinics in the city. This article describes the process undertaken by key stakeholders to ensure that a scale-up plan, which was feasible and acceptable, was in place for commencement in October 2015 to be delivered in the 60 clinics.

6.3 Method

A mixed methods approach was utilized to collect data from key sources to inform the team on an effective strategy for the scale up. Four specific methods were used:

1) Needs assessment using a semi-structured questionnaire to obtain information from nurses (n=48) and focus group discussions (FGD) with District Health Promoters (DHPOs) (n=12) to identify key priority areas; 2) Skills assessment to identify core competencies and current gaps of LHWs (n=300) employed by City Health Services; 3) Consultation workshops (n=2) with key stakeholders to determine referral pathways; and 4) In-depth interviews and consultations to determine funding mechanisms for the scale up.

1) The needs assessment consisted of an initial visit to all 60 clinics by one of the authors (EM) and research assistants to establish what challenges clinics were facing with regard to integrating depression care packages into primary healthcare. Nurses from all the clinics were interviewed; using an interview guide developed by the team aimed at establishing clinic priorities. Key issues highlighted by each clinic were compared and similar issues grouped together. The knowledge gained from the individual clinic visits was shared through 2 focus group discussions (FGD) with 12 District Health Promoters (DHPOs) representing the 12 districts of Harare. The nominal group technique (NGT) was used for the first FGD [12]. The NGT is used in situations where group consensus is needed and can include both health professionals and consumers, since it allows for the free exchange of opinions and the generation of ideas within a structured and non-hierarchical discussion forum[14]. Subsequent interaction utilized the Delphi technique [13] where information was gathered primarily through the use of electronic means.

- 2). Two assessments were conducted to determine current core competencies of 300 lay health workers, based on previous experience on the Friendship Bench [7] and core competencies developed through a meeting of stakeholders in Kampala, Uganda [15]. A guideline of core competencies that were deemed necessary to deliver the Friendship Bench intervention included the following: minimum literacy equivalent to 10 years of education; ability to read and write, use a mobile phone and send Short Message Service (SMS) [11]; and ability to recognize signs and symptoms of CMD. All LHWs (n=300) from the city health department were initially assessed for each of these components. After the first assessment, all those meeting initial competency criteria were further subjected to a face to face interview aimed at establishing their ability to recognize at least 4 signs and symptoms of CMD such as poor sleep, being withdrawn, unable to function, feeling tearful, feeling run down, suicidal ideation or deliberate self-harm, communication skills, ability to show empathy and cultural competence, basic knowledge of the etiology of depression, ability to communicate with the community about depression (kufungisisa) based on the Kampala guidelines[15]. From this assessment a final group of LHWs (n=24) were then selected and trained in the delivery of PST intervention for the RCT [11] and peer supervision. Those not selected were paired with the selected LHWs for peer support.
- 3) Consultation workshops were conducted to finalise the referral pathway based on the protocol for the RCT of the Friendship Bench [11]. Through consultations with key stakeholders during a theory of change (ToC) workshop and a review of the literature [15-17] adjustments to the referral pathway was recommended. A final workshop with all stakeholders from the community, user groups, and prison services, tertiary facilities and policy makers outlined key requirements of the referral pathway in the form of a flow diagram.
- 4) In-depth interviews and consultations were conducted with collaborating partners from both local and international institutions and NGOs, to identify funding mechanisms for specific grant applications. The focus was to ensure availability of resources and funds for scale up by September 2015.

6.4 Results

1. Needs assessment

A final list of 5 cross cutting issues was developed during the needs assessment. These included: lack of training in MH, unavailability of psychiatric drugs, depleted clinical staff levels, unavailability of time for counseling, and poor and unreliable referral systems for people suffering with depression were described as critically if a scale-up was to be successful.

Out of 48 nurses in the 60 primary care clinics, a total of 45 (93%) were available for interviews. Of these 39(81%) had been working within City Health Services for over 15 years. They were predominantly female 41(84%) with a mean age of 54 (SD 4.6). Of those interviewed 40(83%) indicated that they were too busy to provide structured psychotherapy to patients and lacked training in the use of antidepressants. Only 4(7%) had previously received training in mental health. A total of 42(92%) acknowledged the need for mental health services for depression particularly among people living with HIV. A total of 39(80%) indicated the need to provide a reliable supply of medication for depression. The need to have in place a clear referral system was mentioned by 40(93%).

The above findings were later compared with findings from the FGD with 12 DHPOs who were responsible for overseeing activities at clinic level and supervision of LHWs. The DHPOs, using the NGT reached consensus to address 4 key issues: professional support and supervision, training, availability of medication, and referral pathways. These 4 areas were later endorsed by the nursing staff as priority needs for a successful scale up strategy. Professional support was the main priority as it was felt that without this they (nurses and DHPOs) would have major challenges to support LHWs or manage depression (kufungisisa) at clinic level. Psychiatrists and psychologists were needed to provide support and supervision as both DHPOs and nurses felt that suicidal and deliberate self-harm behavior required specialist skills. Training was highlighted as key to ensure that nurses and DHPOs were able to identify those with severe symptoms and needing referral. Availability of medication such as amitriptyline, and fluoxetine including basic knowledge of appropriate dosing was needed. DHPOs supported the need to have a clear referral pathway between

clinics and tertiary facilities, including prison services since mentally ill inmates were being released from prison with no clear discharge plan to the community.

2. Competency assessment

The competency assessment of the existing 300 LHWs was carried out by district. There are 12 districts in Harare with each district having 14-25 LHWs. Of the 300 existing LHWs 230 (76%) were available for interviews. Of these a total of 187 (81%) fulfilled most of the initial criteria for core competency (Table 6.1). The 187 further received a face-to-face interview resulting in the best 24(18%) being selected and trained for the RCT while the remaining 176 were paired with the 24 for peer support.

3. Referral pathway and Supervision support

The referral pathway was finalized through the development of a consolidated algorithm aimed at addressing all 4 priorities mentioned above. All those seen by the LHWs who were identified as having a "red flag" which was defined as a score of 11 and above on the SSQ-14 or a "Yes" response to question 11 on suicidal ideation on the SSQ would immediately be referred to either the DHPO (supervisor) or to the community liaison team which consisted of a government doctor, nurse and clinical psychologist). A referral to the supervisor (DHPO) or community liaison team would result in the administration of the Patient Health Questionnaire (PHQ-9) to screen for depression. Scores above 10 on the PHQ-9 would be treated as confirmed depression and would be managed at local level with medication and the Friendship Bench or would result in further consultation through IT platform. This framework for the referral pathway was based on the developed referral plan for the RCT [11]. The supervision of the described pathway is illustrated in Figure 6.1.

Providing support to the LHWs and the nursing staff was a critical component for successful scale-up modeled along the lines of an earlier pilot of the Friendship Bench project [7] and formative work leading to the trial protocol [11]. The pool of supervisors (a) consisted of the existing LHWs' from the RCT who were peer supervisors (n=24), their supervisors (DHPOs) (n=8) and nursing staff (n=12). The

main role of the supervisors was to receive all cases identified as "red flags" by the LHWs as described above. The supervisor would assess for further referral to (d) tertiary facility via (c) the out-reach team with possible support from the IT component (g). The community liaison team (d) visits one of 12 districts to provide support and run a clinic. A key feature of the scale up is the referral of all incarcerated mentally ill offenders (e) back to the community (b,a) under the Friendship Bench where they are attached to a specific LHW who is responsible for follow up and ensuring that individuals remain stable through regular communication with supervisors (b). Such an approach has been emphasized in the National Mental Health Policy. Public tertiary facilities and universities (d) would provide support through the formalized attachment programs to the Friendship Bench initiative and by providing an outreach team consisting of hospital staff and doctors. Clinical psychologists and psychiatrists in private practice (f) would provide support to the initiative via the IT platform through a virtual communication platform previously set up for the Friendship Bench during the RCT. In return for every 5 online consultations provided by an individual in private practice points towards their Continued Professional Development (CPD) are issued. The cloud computing enables regular analysis of data and communication between the entire team but mainly between supervisors (b) and private professionals (f) and tertiary facility level staff (d)..

4.Funding

Funding of the initiative was secured through both local and 3 international funding agencies. One international agency Medecins Sans Frontieres (MSF) agreed to guarantee availability of essential drugs for depression and focus on ensuring that capacity at tertiary and primary level was built through a series of workshops and ongoing teaching programs. This will include support of an outreach team for the next 5 years, which will after the 5-year period be taken over by the local team employed by the government and city health department. The Wellcome Trust through a capacity building grant will enable the development of research excellence at masters, PhD, and postdoctoral level for the next 5 years, while the GCC will support the completion of a RCT and scale up of the Friendship Bench.

6.5 Discussion

To our knowledge this is the first description of a strategy to scale-up an existing psychological intervention delivered by lay health workers in sub-Saharan Africa. This scaled up intervention covers a population of over 1 million Earlier work in the region has justified such an approach by showing how task shifting could close mental health service gaps at primary health care level in South Africa [18, 19].

Our paper highlights the steps taken to reach consensus on a scale up strategy of the Friendship Bench which has been run as a pilot for over 8 years [7]. This study will contribute to the body of growing knowledge on how to scale up similar interventions, particularly within the context of HIV/AIDS.

Practical examples of scaling up interventions using lay health workers have largely come from the field of HIV/AIDS where results have been promising[20]. While resource mobilization for fighting HIV/AIDS in sub-Saharan Africa has in the last 20 years been successful, the huge treatment gap and lack of political buy-in to address mental neurological and substance use disorders has been a major barrier in the scale up of evidence based interventions in mental health [5]. Our approach has focused on integration into existing programs in order to improve mental health and non-mental health outcomes such as HIV/AIDS as previously recommended [21]. Through a gradual and deliberate process of systematically engaging and involving key stakeholders, policymakers including the highest offices of the ministry of health and directorate of city health department, we have managed to provide evidence highlighting the importance of structured psychological interventions within HIV care settings [22].

Further achievements that have contributed to the scale up strategy to be successfully completed include the partnerships between government, university and NGO's, plus local and international partners, resulting in the award of 4 major international grants in the last 6 years. These include the US Government's Medical Education Partnership Initiative (MEPI) linked award for Improving Mental Health Education and Research in Zimbabwe (IMHERZ www.nectar-uz.ac.zw/IMHERZ) and contributed to the establishment of an academic and research development plan for the country. The Grand Challenges Canada (GCC) grant (0087-04) that built onto

the MEPI award by focusing on strengthening community driven research. A Fogarty International Research grant that focused on building the first author's (DC) research capacity, and most recently the African Mental Health Research Initiative (AMARI) grant awarded by the Wellcome Trust as part of its DELTAS scheme which aims to Develop Excellence In Leadership Training And Science.

These funding opportunities have enabled capacity building at several levels including university, private practice, and community.

A key and novel feature of our scale up strategy is the inclusion of the private sector through the involvement of professionals in private practice as recommended by the Zimbabwe National Mental Health Policy. This has seen the involvement of the Medical and Dental Professions Council of Zimbabwe through an initiative aimed at formalizing the award of Continued Professional Development points through work in the community. By enabling professionals to provide supervision and support through the use of computer tablets, which are virtually connected to LHWs at community level, we have managed to widen our support strategy thereby increasing the likelihood of sustainability of the initiative.

The Friendship Bench model has managed to function in 3 pilot sites for over 8 years with minimal funding, thus increasing the likelihood of sustainability once scaled up [7]. Factors that have contributed to this include the integration of the intervention into existing systems within the City Health Services, the use of staff employed by the city health services, and the inclusion of tertiary facilities working under the Ministry of Health through clear referral pathways. As part of the scale up, an international NGO (MSF) will focus on capacity building in the tertiary facilities including decongestion of the prison services through the expedited release of the mentally ill offenders back into the community.

Key lessons learnt from this scale up action are the importance of early engagement with key stakeholders from government, non-governmental organisations, private sectors, and academic and research collaborating partners from external institutions both in Africa and beyond. The scale up of the Friendship Bench has further been made possible through the creation of a core Friendship Bench team consisting of local and external individuals who have continued to provide mentorship and guidance even in the absence of external funding.

There are a number of limitations to this scale up strategy. The requirement for LHWs to be literate could restrict expansion to areas of low literacy although this is not anticipated to be a major factor due to the high literacy rate in Zimbabwe. The unstable social and economic environment that is prevalent in Zimbabwe despite current support from the highest offices within both the Ministry of Health and City Health Department, could affect sustainability of the initiative. It will be important for the key drivers of the friendship Bench (DC, RV, EM) to continue with advocacy initiatives. It is encouraging to note that the Friendship Bench first started when the socio-economic environment in Zimbabwe was at it's lowest point marked by an inflation rate of over 1000% with no support from policy makers. Despite these challenges community enthusiasm managed to sustain the initiative. It is this community commitment that may hold the future of not just the Friendship Bench but for other similar interventions across sub-Saharan Africa.

Conclusion

The Friendship Bench initiative as a low cost intervention embedded in existing health care systems could be a practical model that could be replicated across the region particularly with the growing use of mobile phone technology. Key requirements for success include early buy-in from key stakeholders, extensive consultation at each point of the journey, financial support both locally and externally, and a coherent sustainability plan which is endorsed by both government and private sectors.

6.6 References

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Table 6.1. Characteristics of 187 LHWs employed by the City health department

Characteristic	Number	%
	N=187	
Years of education		
<10 years	23	10.3
≥10 years	164	87.7
Age		
<50 years	19	9.6
≥50 years	168	90.4
Mobile Phone use		
Poor	7	3.7
Fair	4	2.1
Good	176	94.1
Writing Skills		
Poor	6	3.2
Fair	10	5.3
Good	171	91.4
Reading Skills		
Poor	6	3
Fair	9	5
Good	171	93
Ability to use SMS		
Poor	85	45.5
Fair	8	4.3
Good	94	51
Knowledge of symptoms		
Good	145	77

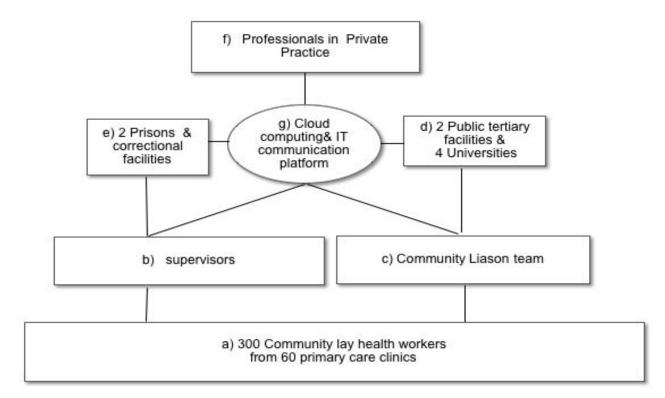


Figure 6.1. Supervision and Support structure

Chapter 7

Conclusion

With HIV increasingly becoming a chronic condition, the high incidence of non-communicable diseases associated with HIV has become a focus of interest in public health [1]. People living with HIV (PLWH) are at a greater risk than non-infected matched populations of suffering from mental, neurological and substance use disorders (MNS) [2], with common mental disorders (CMD), in particular depression being the most common [3, 4]. Addressing the burden of CMD in PLWH is particularly important as more PLWH are commenced on HAART [1]. The new World Health Organization guidelines on initiating HAART released in September 2015, recommend initiation of HAART in all HIV positive adults regardless of CD4 count (www.who.int/hiv/pub/guidelines/...arv/en/). This change in policy supported by simplified and standardized HAART regimens and monitoring [5], will see millions of PLWH being eligible for HAART. This initiative is, however, silent on CMD and other non-communicable diseases despite the growing evidence for the need to incorporate packages of care for NCDs in HIV treatment care [1, 6, 7].

The treatment gap for CMD in sub-Saharan African is estimated to be over 80% [8, 9] and is expected to grow significantly in the next 30 years with current estimates suggesting that the continent will require over 200 000 extra mental health professionals to address this treatment gap by the year 2030 [10]. This is in contrast with the ratio of approximately 1: 10 000 for both psychologists and psychiatrists disciplines in high income countries [11]. While efforts to address the treatment gap through the training of more specialized mental health care workers have in recent years produced encouraging results [12], it is estimated that it will take over 50 years to address this treatment gap unless alternative initiatives, such as the use of lay health workers through task shifting are considered [13].

This thesis highlights the manner in which the burden of CMD among PLWH and the treatment gap can be addressed through psychological interventions, which are

delivered by lay health workers. Above all it outlines the process involved in the development, evaluation and scale up of a psychological intervention for PLWH.

7.1 Summary of findings

7.1.1 A Systematic review of psychological interventions for CMD in PLWH

This thesis highlights a number of critical issues related to addressing the treatment gap for CMD among PLWH by firstly demonstrating the lack of well developed interventions from LMIC in this area. The systematic review of psychological intervention for CMD among PLWH described in chapter 2 highlights the need for more robust and adequately powered studies to evaluate such interventions. Although the few studies included in the systematic review (n=5) suggest that cognitive behavior therapy (CBT) based interventions are effective, the studies fell short of meeting the CONSORT criteria for quality[14, 15], except for one study from Iran [16].

There is a need for studies to report on actual components of psychological interventions, fidelity measurement and training, including supervision of LHWs delivering such interventions, if these are to be replicated elsewhere [17]. Although evidence supporting the use of LHWs to address the treatment gap of MNS is growing in LMIC [18], the findings of this systematic review indicate that the use of LHWs in psychological interventions for CMD in PLWH are lacking and that the few existing published trials are poorly documented [17].

7.1.2 Factors associated with CMD among PLWH utilizing primary health care facilities in Zimbabwe

Developing an appropriate intervention for CMD for PLWH requires an understanding of factors associated with CMD in this specific population. This cross sectional study revealed a strong association between negative life events and CMD. Out of a total sample size of 264 individuals, 237 (89%) of those recruited had experienced a recent negative life event. These findings supported the decision to use problem solving therapy (PST) for the trial since this approach has been recommended for CMD where negative life events appear to be prominent [19]. In

this cross sectional study, out of 165 PLWH a total of 112 (67.9%) and 107 (64.9%) met criteria for CMD and depression as measured by the SSQ-14 [20] and PHQ-9 [21] respectively. A total of 128 (85%) PLWH had been on HAART for more than 6 months prior to recruitment into the study suggesting that being on HAART may not reduce the risk of CMD in this population. This is an important observation, which will need to be explored further, in the face of the increased use of HAART in LMIC. Understanding the factors associated with CMD in this population further enabled the development of an intervention with a focus on negative life events.

7.1.3 Exploring the views and experience of lay health workers

An important part of this thesis is the description of the actual intervention as perceived by LHWs. Traditional problem solving therapy (PST) has a very specific logical sequence that it follows which involves problem listing, selection of a single problem, brainstorming for solutions followed by evaluation, and implementation of solution [19, 22]. However, this thesis highlights the use of indigenous concepts to navigate the PST process. The use of terms such as "Kuvhura Pfungwa" (Opening up the mind), "Kusimudzira" (To uplift) and "Kusimbisa" (To strengthen), appear to contribute to improved fidelity and seem to encourage continued use of this PST approach among LHWs who have been working in the pilot site of Mbare for the last 8 years [23]. The use of such local concepts has, according to the LHWs, made this intervention sustainable in the pilot sites as it is largely driven by locally derived explanatory models [24]. Knowledge derived from this qualitative study contributed to refining of the final intervention that was delivered by the 24 LHWs as part of a cluster randomized controlled trial of a brief psychological intervention that was carried out in 24 primary health care facilities in Harare [25]. The realization, for instance, that 1 session was sufficient to deliver the key components of the PST, resulted in all 3 key components (kuvhura pfungwa, kusimudzira, and kusimbisa) of the PST session being delivered in a single session. This led to a major shift in the design of the RCT. This deviation from the traditional format of delivering PST has been supported in other HIV related talk therapies [26].

7.1.4 Using a theory driven approach to develop and evaluate a complex mental health intervention: The Friendship Bench Project in Zimbabwe

Bringing together the different components of a complex intervention during the formative work is often described as the most critical phase of a trial. This thesis made use of a theory of change (ToC) model to bring together the necessary components, and to develop and evaluate the Friendship Bench program in a cluster randomized controlled trial carried out in 24 primary health care facilities in Harare [25]. The ToC map described in this thesis involved several stakeholders who collectively took part in an iterative process over 6 months to set out the causal pathway of the intervention. This included the barriers, indicators, rationale and assumptions that were needed to move from one point to the next along the causal pathway to impact. A critical take home message from this exercise is the importance of engaging stakeholders at the beginning of an initiative. There have been recent data supporting the use of this approach to develop and evaluate complex mental health interventions [27, 28]. A key feature of using this approach is that it enables all stakeholders regardless of level of education and position within an organization to participate assisted by the use of a visual map to describe the pathway.

7.1.5 Scaling up interventions for depression in sub-Saharan Africa: lessons from Zimbabwe

Through a process of early engagement with key stakeholders, planning for scale up of the Friendship Bench to over 60 clinics has been made possible. Using a mixed methods approach information was gathered from key sources to inform the team on an effective strategy for the scale up. Four specific methods identified as critical for scale-up during a stakeholders workshop, consultative meeting included: 1) Needs assessment, 2) Identifying core competencies for LHWs, 3) Consultation workshops with key stakeholders to establish referral pathways for the initiative, and 4) In-depth interviews and consultations to determine funding mechanisms for the scale up. Using this systematic and transparent approach it was possible to build consensus on a strategy for the scale up including raising the necessary funds for the scale up of the Friendship Bench to 60 primary health care clinics.

7.2 Community Involvement

A key feature of this thesis was the engagement of local communities. Unspoken rules about community norms and communication lines proved invaluable during the process of collecting both qualitative and quantitative information that informed the development of the intervention. For instance attending a funeral of one of the LHWs by the Friendship Bench team contributed significantly towards building trust and rapport with the LHWs who were present at the funeral. Participating in group prayers with both LHWs and clinic nurses during the opening of clinics each morning at clinic sites further contributed to smooth communication and a sense of mutual respect. The team's participation in activities that were not related to the thesis such as assisting in the weighing of babies during the postnatal clinic visit ensured that the nursing staff would be supportive of the research team as the team was not just seen as focusing on their specific work.

While good science is needed to deliver such a complex intervention, the examples above illustrate the importance of the human contact in all this work. It is the human contact that contributes significantly to the continued support of a programme. The researcher's ability to show empathy towards communities and particularly the nursing staff and LHWs who spend long hours interacting with the sick, is vital.

7.3 Implications for HIV and other MNS disorders

The HIV epidemic remains a major challenge for LMIC health systems due to limited resources and competing needs [29]. The human resource allocation in particular for the fight against HIV has been a challenge in sub-Saharan Africa where the greatest burden due to HIV is found [30]. In spite of these challenges HIV related mortality has been significantly reduced due to the use of HAART [31-33]. As HIV becomes a chronic condition the comorbidity of NCDs among PLWH has become the next great challenge [34, 35], with rates for MNS reported to be twice those found in non-HIV infected populations [7]. Calls to integrate services for NCD within HIV care programmes have increased in recent years [36, 37]. This thesis addresses the issue of using LHWs through task shifting to address CMD in PLWH, a concept which is not new to HIV care [38]. The use of task shifting in HIV has been described

as a major contribution to the scale up of HIV care [39]. As HIV becomes a chronic condition, retention to care has become critical, therefore ensuring that PLWH remain in treatment is a priority [1]. Lay health workers can contribute by providing the first level of care in communities and primary health care facilities. Empowering LHWs with the skills to identify and manage CMD is crucial because untreated, CMD and other MNS conditions such as alcohol use and substance use disorders may hasten HIV disease progression [40] [7]. Leveraging on the knowledge and achievements from the scale up of HIV programmes using lay health workers has been described as critical in the scale up of HAART [41] [39].

This thesis provides an evidence-based approach on how a structured low intensity psychological intervention could be integrated into existing HIV programes to improve HIV related outcomes. There is already evidence supporting the effectiveness of using LHWs in MNS care [18] and the use of problem solving therapy in PLWH to improve outcomes in resource rich settings [26]. However, this is the first detailed description of how an intervention delivered by LHWs in a resource poor setting can be developed and scaled up. The model can be replicated in similar settings as part of the new WHO policy on test and treat. Furthermore, the use of cognitive behavior therapy (CBT) with an emphasis on problem solving therapy can address challenges related to other MNS such as substance use, psychosis, and anxiety disorders [42-44]. Addressing CMD as a mental health entry point into HIV care programmes is recommended because CMD are common among other MNS conditions [7].

7.4 Implications for the National HIV Policy and Mental Health Policy

The World Health Organization (WHO) treatment guidelines for HIV released in September 2015 (www.who.int/hiv/pub/guidelines/...arv/en/) have shifted from earlier guidelines that focused on initiation of treatment based on CD4 count, to initiation of HAART regardless of CD4 count. As sub-Saharan Africa begins to prepare for the implementation of care packages based on these guidelines a key focus will be retention and adherence to care [45]. Up to 30% of PLWH on HAART have been reported to have poor adherence to treatment in a recent systematic review from sub-Saharan Africa[46]. These challenges call for a review of HIV

policies in the region to support treatment and retention to care programmes [47]. Several factors are known to contribute to poor adherence such as comorbid NCD, poverty, inequality and competing needs [7, 29, 48]. There is therefore, a need for policies to embrace a holistic approach to the challenges associated with scaling up HIV care programmes, in particular the challenge of MNS disorders as these are highly prevalent in PLWH[49]. Mental health policies need to emphasize the integration of mental health treatment care packages into HIV programmes [50, 51], with appropriate frameworks being used to evaluate these policies and plans [52]. Although the Zimbabwe National Mental Health Policy defines as one of its' key objectives, "the integration of mental health care in HIV programmes", the National HIV Policy is silent on mental health. The term "psychosocial support" is used frequently in the National HIV Policy document. While psychosocial support programmes can play a meaningful role in HIV programmes, the lack of rigorous scientific designs, use of validated tools, and indicators in these programmes often means they are difficult to measure and may not be given the seriousness they deserve. Often psychosocial packages advocated for in HIV programmes lack the ability to measure quantitative change, which often is required by stakeholders and policy makers. There is a need for scientific evidence-based approaches because using psychosocial packages without specifying the empirical evidence that underpins the interventions is problematic and may lead to the questioning of the validity of the interventions' outcomes. Psychosocial interventions need to be theoretically based with clearly defined therapeutic components. In this thesis we have described a process aimed at developing an evidence-based intervention based on cognitive behavior therapy with emphasis on problem solving therapy. Developing specific treatment packages for MNS particularly CMD can be simplified once specific categories are utilized based on either ICD-10 or DSM-V. Psychosocial packages in current use do not emphasize the use of such diagnostic categories, which emphasizes screening through the use of validated tools as a way to identify those who are most likely to benefit from an intervention. Understanding the key target population, which is highlighted in this initiative, will lead to appropriate interventions being developed to improve HIV disease outcomes.

Scaling up of such well defined interventions would be made easier when both the

National HIV Policy and the National Mental health Policy are in harmony which is not the case in Zimbabwe at present. An initial practical step would be for the National HIV Policy to recommend training in mental health for all primary care counselors attached to HIV care facilities using the Friendship Bench model (or other evidence based LHW interventions) – Friendship bench comes out of blue here?.

This thesis underscores the importance of meaningful stakeholder engagement in the process of developing and evaluating interventions (stakeholder engangement is what is described ie creating dialogue?). The process of bringing together different players should be encouraged as a way of building early consensus during the development of an initiative as this can facilitate positive policy direction. Early consensus building will contribute to the strengthening of policy decisions including the development of mental health plans and activities. The steps that have been taken in the development and implementation of this initiative can be replicated for other MNS and NCDs by focusing on bringing together the key areas highlighted in this initiative. These can be summarized as: providing a clear definition of the problem, the challenge associated with addressing the problem, possible solutions in view of the challenge, consensus building around the solution, and gaining further consensus on effective, feasible, and practical ways of realizing the solution. The theory of change workshops for instance could be a useful way of engaging policymakers and other key non-mental health groups to achieve the above highlighted areas. From the experience gained through this initiative it is reasonable to assume that the theory of change approach could also be effective in developing consensus for policy change.

7.5 Limitations of the thesis

Detailed limitations for each of the papers are described in the corresponding chapters. However, there are several general limitations that apply to all the chapters. Firstly, this thesis has focused on CMD to the exclusion of other public health priority mental, neurological and substance use (MNS) disorders such as epilepsy, psychotic illnesses and substance use (including cannabis and cough syrups) which are also prevalent in people presenting with CMD. In the systematic review more studies would have been included in the review if the criteria had been

broadened to include psychological interventions for all forms of MNS disorder in LMIC. However, the decision to focus on CMD was largely due to the need to identify CMD specific interventions as a way of ensuring that the thesis remained focused.

A second broad limitation was the absence of establishing co-morbidity with other MNS conditions among participants recruited. Furthermore, the use of a single primary care clinic for the formative work for the qualitative and quantitative components of this thesis may limit the generalizability of the findings. There are 60 primary care clinics in Harare, therefore formative work could have been spread among the clinics. However this was not possible due to lack of funding and the assumption was to strengthen an existing intervention (The Friendship Bench), which was in the chosen pilot site.

Although focus of the thesis was PLWH, the cross-sectional study included people who were not HIV positive and people who did not know their status, however, the sample size collected (n=264) provided for stratification by HIV status.

Despite these limitations this thesis has highlighted how through a process of community engagement and planning in advance it is possible to develop, evaluate and scale up a complex psychological intervention delivered by LHWs in a resource poor setting.

7.6 Key recommendations for policy

- Lay health workers can deliver psychological interventions for CMD among PLWH. There is need for urgent recognition of the role they can play in reducing the treatment gap for CMD among PLWH in Zimbabwe and beyond.
- There is need for the Department of AIDS and TB within the Ministry of Health in Zimbabwe to integrate mental health service care packages in the existing policy document. Although HIV/AIDS is included in the Mental health Policy, the inclusion of mental health in the HIV policy will further strengthen efforts of integrating mental health in HIV care programs, particularly the new test and treat initiative recommended by WHO.

- There is need to make information about mental health available at HIV clinics, in the form of pamphlets, posters on common mental health disorders and what help is available at community level through the Friendship Bench, particularly after the scale-up.
- The Friendship Bench should be integrated into existing HIV care programs particularly at primary health care level across the country.
- Ongoing training of LHWs, their supervisors, employees within government health facilities and partners in private practice should become a regular feature of the government training program and refresher course initiatives.
- The private sector is an important partner listed in the Zimbabwe National Mental Health Policy, therefore, there is need to examine ways of creating synergies with this sector for example in workplace screening and psychological intervention programmes.
- At regional level there is need to use a systematic approach to the development, evaluation, and scale up of evidence based interventions for CMD, this can be achieved through the use of a theory of change (ToC) map.

7.7 Future directions for research

There is need to look into ways of developing packages of care that not only include CMD but also include other MNS conditions such as epilepsy, psychotic disorders and substance use disorders. Epilepsy, psychosis and substance use disorders are highly prevalent within primary health care facilities and there is a need to build capacity for the management of these conditions.

There is need to consider the use of biomarkers in future research of CMD in HIV. This could come in the form of observing changes in viral load for long term adherence using dry blood spots (DBS) as these are easy to administer and can be carried out by a LHW. Other novel approaches in the area of HIV include the use of hair samples or DBS to measure HAART drug levels and infer adherence to HAART among people who are receiving psychological intervention as a way of evaluating the impact of CMD interventions to adherence of HAART. There is a need to further explore the implications of using biomarkers in relation to psychological interventions, as this is a relatively new area of research.

Future research will need to look into the use of technological support such as using mobile phone Apps, and virtual communication platforms to ensure that support and supervision of LHWs is sustainable.

7.8 Concluding remarks

This thesis has clearly demonstrated that it is possible to develop a psychological intervention based on PST, evaluate it and develop a strategy for its scale up to a large number of primary health care facilities in Harare, Zimbabwe. Above all this thesis has demonstrated that lay health workers can deliver interventions for CMD with a high level of acceptability and feasibility in this setting. There are over 10 000 registered LHWs in Zimbabwe who could contribute towards reducing the treatment gap for CMD among PLWH, thereby improving HIV and mental health related outcomes.

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Appendices

Appendix A: Informed Consent for patients

Version 2.2 English

PRINCIPAL INVESTIGATOR: Phone and Address:

Dixon Chibanda, MD +263 712 204 107 92 prince Edward Street,

Milton park, Harare, Zimbabwe

+263 772231832: University of Zimbabwe,

School of Community Medicine

INTRODUCTION:

You are being asked to take part in the research study named above. This study is part of a Phd . The doctor in charge of the study at this site is Dr Dixon Chibanda.

You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please feel free to ask us if there is anything that is not clear or if you would like more information. Once you understand the study, and if you agree to take part, you will be asked to sign this consent form or make your mark in front of someone. You will be offered a copy to keep.

Please note that:

- Your participation in this research is entirely voluntary;
- You may decide not to participate or to withdraw from the study at any time without losing the benefits of being treated at this clinic.
- If you decide not to participate in this study, you can still join another research study later, if one is available and you qualify.

PURPOSE OF THE STUDY:

Over the past 6 years we have identified a large proportion of people living with HIV who have depression and or common mental disorders in this community. The purpose of this research is to find out your views as a patient who has utilized the services of the Friendship bench; about 1) the treatment we have been using at the Friendship Bench for the last 6 years and establish what you found to be helpful. 2) If you think there are things that we can do to make the Friendship bench better, 3) If there are some concerns that you have about the services you received here.

STUDY PROCEDURES:

If you agree to join this study, you will be required to have an interview with one of the researchers. This interview will take about one and a half hours to complete and it will be audio recorded. The questions will focus on your experiences of taking part in the talking therapy for stress depression and or common mental disorders on the friendship bench, and to find out if you were able to solve any issues in your life. We will ask you about the sessions you have had with the lay health workers, how they were started and how they were terminated. We are inviting 10 people aged 18 and over to take part in these interviews.

POTENTIAL RISKS /BENEFITS:

There may be no other direct benefits to you by participating in this study though we believe this study will benefit the clinic community as a whole by increasing knowledge about treatment for depression.

You will not be subjected to any risk in this study. If you find any question posed by the interviewer is sensitive you can decline responding to that question. You will not be compelled to answer all the questions.

REIMBURSEMENT:

To thank you for taking part you will be given refreshments during the interview and your transport costs using public transport will be reimbursed at the rate of \$3.

CONFIDENTIALITY:

Your identity will be secured by assigning you a number before the meeting and only using that number through the record keeping. The only exception to this would be if you will be identified to have a serious mental health problem. In that situation, Dr Dixon Chibanda who is leading this research will discuss it with you and if needed, refer you to specialist medical care. Care will be taken to keep your situation confidential among other clinic members.

ALTERNATIVES TO PARTICIPATION:

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this form to keep and be asked to sign a consent form. If you decide to take part you are still free to not answer any question that you are not comfortable with at any point in the interview and you can withdraw at any time without giving a reason. Please note that you will not be compensated for your time in participation of this study when you withdraw

PERSONS TO CONTACT FOR PROBLEMS OR QUESTIONS:

If this study has harmed you in any way or if you have any problem or doubt about this study you may clarify from the interviewer or directly contact Dr Dixon Chibanda at the University of Zimbabwe Dept of Psychiatry, telephone +263 712 204 107 or If you ever have questions about your rights as a research participant you may call the Medical Research Council of Zimbabwe, at 04 791792 or 0712 433 164-7 (offices located corner Tongogara/Mazoe Street in Harare). You should also contact Professor Marc Blockman, University of cape Town, Human Research Ethics Committee, on telephone +27 214066338, email: shuretta.thomas@uct.ac.za.

NOTE: You are not giving up any of your legal rights by signing this informed consent document.

SIGNATURE PAGE

Version 2.2 English

STATEMENT OF CONSENT

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

•	I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw my data up within two weeks of the interview date.	or initial
•	I have read the informed consent or had it read and explained to me. I understand the information and I voluntarily agree to join this study.	
•	This page of the Informed Consent Form is stamped by the Medical Research Council of Zimbabwe to indicate it has been approved by the MRCZ.	
•	I consent to my interview being recorded.	
Partic	ipant's Statement:	
Na Date	me Signature	
Name	Signature Date	

DELETE IF NOT APPROPRIATE

Investigator's Statement:

Confirm that I have	carefully explained the nature, demands and any forese	eable
risks (where applic	ble) of the proposed research to the participant.	
Signed	Date	

Appendix B: Informed consent for survey

Version 2.2 English

PRINCIPAL INVESTIGATOR: Phone and Address:

Dixon Chibanda, MD +263 712 204 107 92 prince Edward Street,

Milton park, Harare, Zimbabwe

+263 772231832: University of Zimbabwe,

School of Community Medicine

INTRODUCTION:

You are being asked to take part in the research study named above. This study is part of a Phd. The doctor in charge of the study at this site is Dr Dixon Chibanda.

You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please feel free to ask us if there is anything that is not clear or if you would like more information. Once you understand the study, and if you agree to take part, you will be asked to sign this consent form or make your mark in front of someone. You will be offered a copy to keep.

Please note that:

- Your participation in this research is entirely voluntary;
- You may decide not to participate or to withdraw from the study at any time without losing the benefits of being treated at this clinic.
- If you decide not to participate in this study, you can still join another research study later, if one is available and you qualify.

PURPOSE OF THE STUDY:

Over the past 6 years we have identified a large proportion of people living with HIV who have depression and or common mental disorders in this community. The purpose of this research is identify people who have depression and or anxiety disorders respectively, using tools that have been validated in a previous study. These tools will enable us to identify patients who have common mental disorders and this will enable us to assist them through an intervention that is running at this clinic.

STUDY PROCEDURES:

If you agree to join this study, and if you are selected for the survey you will be asked a series of questions which will help us better understand your socio-demographic circumstances and how you are living with HIV and if depression and or common mental disorders are an issue in your life. A trained researcher will

administer these questions. These questions will take about 30-45 minutes to administer. If our study team identify you as needing further help for either severe depression or you are at risk of harming yourself or others or any other medical condition that is urgent we will refer you to the hospital. We will help you to get to the hospital by providing someone who will take you there. We are inviting people aged 18 and over to respond to these questions.

POTENTIAL RISKS /BENEFITS:

There may be no other direct benefits to you by participating in this study though we believe this study will benefit the clinic community as a whole by increasing knowledge about treatment for depression.

You will not be subjected to any risk in this study. If you find any question posed by the interviewer is sensitive you can decline responding to that question. You will not be compelled to answer all the questions.

REIMBURSEMENT:

To thank you for taking part you will be given refreshments during the interview and your transport costs using public transport will be reimbursed at the rate of \$3.

CONFIDENTIALITY:

Your identity will be secured by assigning you a number before the meeting and only using that number through the record keeping. The only exception to this would be if you will be identified to have a serious mental health problem. In that situation, Dr Dixon Chibanda who is leading this research will discuss it with you and if needed, refer you to specialist medical care. Care will be taken to keep your situation confidential among other clinic members.

ALTERNATIVES TO PARTICIPATION:

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this form to keep and be asked to sign a consent form. If you decide to take part you are still free to not answer any question that you are not comfortable with at any point in the interview and you can withdraw at any time without giving a reason. Please note that you will not be compensated for your time in participation of this study when you withdraw

PERSONS TO CONTACT FOR PROBLEMS OR QUESTIONS:

If this study has harmed you in any way or if you have any problem or doubt about this study you may clarify from the interviewer or directly contact Dr Dixon Chibanda at the University of Zimbabwe Dept of Psychiatry, telephone +263 712 204 107 or If you ever have questions about your rights as a research participant you may call the Medical Research Council of Zimbabwe, at 04 791792 or 0712 433 164-7 (offices located corner Tongogara/Mazoe Street in Harare). You should also contact Professor Marc Blockman, University of cape Town, Human Research Ethics Committee, on telephone +27 214066338, email: shuretta.thomas@uct.ac.za.

NOTE: You are not giving up any of your legal rights by signing this informed consent document.

SIGNATURE PAGE

Version 2.2 **English**

STATEMENT OF CONSENT

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

longer wisl involved ar Furthermo	n to participate in this p nd withdraw from it imn	time during the research that I no project, I can notify the researchers nediately without giving any reason. Will be able to withdraw my data up date.	or initial
		or had it read and explained to me. I voluntarily agree to join this study.	
This page of the Informed Consent Form is stamped by the Medical Research Council of Zimbabwe to indicate it has been approved by the MRCZ.			
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Participant's Stat	ement: 		
Name Date		Signature	
Name	 Signature	Date	

DELETE IF NOT APPROPRIATE

Please tick

Investigator's Stat	ement:	
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	e carefully explained the nature, demo cable) of the proposed research to the	-
Signed	Date	

Appendix C: Interview guide for lay health workers

Development of a psychological intervention for common mental disorders among people living with HIV in Zimbabwe

(Friendship Bench Formative Research Interview Guide for Health Promoters)

Information and consent form given to Health Promoter (HP) to accept and sign. Ask HP to fill in mini-demographics questionnaire.

If no objection from interviewee, continue the interview.

CHALLENGES WITH DIFFICULT SITUATIONS

- 1. In your experience as a health promoter how would you define a difficult situation with a client, partocularly a client who is HIV positive?
 - a. Can you give me an example of a time when you had to ask someone else for help when dealing with a difficult situation with a client?
 - b. Why was this particular situation difficult?

(Use the following questions as prompts if necessary)

What sorts of problems did this client have? (Prompt if necessary) Social problems? Illnesses, HIV?

How different are PLWH from your other clients? (prompts if necessary)

Why did you feel you had to ask for help?

Who did you ask for help from?

Why did you ask this person for help?

What qualities did they have that you thought might help?

Did you manage to get help? What kind of help was this?

What sort of help do you think you would need to deal with similar cases in the future?

What are your views of the current PST protocol?

Which component do you find most helpful?

Would you make suggestions on what would be good changes to this protocol?.

REFERRALS

- 2. At what point do you refer a case?
- 3. What kinds of cases have you referred?
 - a. Who do you refer these cases to and why?
 - b. How often do you refer cases of HIV and why?

(Use the following questions as prompts if necessary)

For which types of cases do you refer clients to the police?

- Can you give me an example of this?
- How often do you refer to the police?
- · What about PLWH, when would you refer them and where?

For which types of cases do you refer clients to the rape clinic?

- Can you give me an example of this?
- How often do you refer to the rape clinic?

For which types of cases do you refer clients to the nurses?

- Can you give me an example of this?
- · How often do you refer to the nurses?

For which types of cases do you refer clients to the Bench Case Manager (EM) and/or the Bench Supervisors?

- Can you give me an example of this?
- How often do you refer to the Bench Case Manager and/or the Bench Supervisors?
- How often do you refer to the bench Case Manager and /or Supervisor PLWH?

For which types of cases do you refer clients to Dr Chibanda?

- Can you give me an example of this?
- How often do you refer to Dr Chibanda?

SUICIDE

- 4. How common is suicide in this area?
- 5. What kind of clients do you think are a risk for suicide?
- 6. How often do you use the SSQ to assess whether or not a client is suicidal?
- 7. When was the last time you dealt with an HIV+ client who was suicidal? Can you tell me more about this encounter?
- 5. So what do you normally do when someone who is HIV+ answers 'Yes' to Question 11 on the SSQ? (Guide the HP through this question, asking for further information where necessary 'And then what do you do?')
- 6. From your experience, do you think clients are telling the truth when they answer Question 11 on the SSQ? Why do you think this?
- 7. Can you tell me about a specific time when you felt you dealt with a person who answered 'Yes' to Question 11 on the SSQ successfully? (Guide the HP through

- each step of this process, asking for further detail where necessary 'And then what did you do?')
- 8. Can you tell me about a specific time when you felt you did not deal with a person who answered 'Yes' to Question 11 on the SSQ successfully? (Guide the HP through each step of this process, asking for further detail where necessary 'And then what did you do?'
- 9. How do you respond when someone scores more than 12 on the SSQ, but does not answer 'Yes' to Question 11 on the SSQ? (Guide the HP through this question, asking for further information where necessary 'And then what do you do?')
- 10. How do you assess whether someone is suicidal?
 - a. Do clients ever tell you they have harmed themselves or are suicidal?
- 11. Do you feel like you know how to deal with suicidal clients?
 - a. If interviewee answered YES/NO to question 11 probe with the following:
 - Have you received training in assessing clients who have harmed themselves or who are suicidal?
 - Have you received training in dealing with clients who have harmed themselves or who are suicidal?
 - If so, what aspects of this training have you used in your work?
 - What aspects of this training have you found the least useful?
 - What training would you need to improve your ability to deal with these cases?
 - What kind of support would you like to have to deal more effectively with these cases?
- 12. Do you ever feel as though you can't handle cases where someone has harmed themselves or is suicidal? (Is it different when the person is HIV+? If yes, then How is it different?
 - a. Can you give me an example of this?
 - b. Thinking back, how do you think you could have managed it better?
- 13. Do you know of any other health or support services available for suicide in your area?
 - a. What do you think that people who are suicidal do if they do not come to the Friendship Bench?
 - b. Do suicidal clients from the Friendship Bench ever go elsewhere for care?

TEAMWORK AND SUPPORT

- 14. Can you tell me about your experience working at the friendship bench?
- 15. Can you tell me about teamwork at the Friendship Bench?
 - a. How do you interact with your peer LHWs?
 - b. How often do you communicate with them about your work on the Bench?

- c. Can you tell me about the last time when you worked with a peer LHW in the management of a case? What happened? (Guide the HP through this question, asking for further information where necessary)
- 16. How do you interact with the nurses?
 - a. How often do you communicate with them about your work on the Bench?
 - b. Can you tell me about the last time when you worked with a nurse in the management of a case? What happened? (Guide the HP through this question, asking for further information where necessary)
- 17. How do you interact with the Bench Case Manager and/or the Bench Supervisors?
 - c. How often do you communicate with them about your work on the Bench?
 - d. Can you tell me about the last time when you worked with them in the management of a case? What happened? (Guide the HP through this question, asking for further information where necessary)
- 18. How do you interact with Dr Chibanda?
 - How often do you communicate with him about your work on the Bench?
 - Can you tell me about the last time when you worked with him in the management of a case? What happened? (Guide the HP through this question, asking for further information where necessary)
- 16. How does your work on the Friendship Bench overlap with the rest of your work at the clinic?
 - a. Have you used your work on the Friendship Bench when working with people living with HIV and other conditions seen at the clinic? If so, can you give me an example of this?
 - b. What are the challenges that people with HIV present with?
 - c. Are there any differences between clients living with HIV and those not living with HIV?
 - d. How best can you get support in dealing with PLWH now that more of these clients will be utilizing the local clinics?

Interviewer to ask the respondent whether they have any questions or anything else they might like to add.

Interviewer to thank the respondent for their time and terminate the interview.

Appendix D: Interview guide for clients living with HIV

Development of a psychological intervention for common mental disorders among people living with HIV in Zimbabwe

- a) Can you tell me about depression (kufungisisa) and the treatment you got especially non-pharmacological treatment delivered through the Friendship Bench?
- b) Can you describe your experience of the Friendship Bench? What was positive about it?

What was negative about it?

c) Can you indicate the number of sessions and nature of sessions, what kind of homework if any did you get from the lay health worker?

Did the LHWs ever visit your house to talk about your kufungisisa? What kind of things happened when they came to your house?

Prompt; (What are your views about praying when the LHWs visit you?)

- d) When and how was therapy terminated and who decided when to terminate therapy?)
- e) Could you tell me about all the different areas/components you covered in the therapy? (probe by asking to list these down and come up with a priority list and solutions, homework that was done)
- f) What components of the Bench intervention do you find most useful?
- g) What components of the Bench intervention do you find least useful?
- h) What new components did you feel needed to be introduced?

Appendix E: Social Demographic questionnaire

1	PID:	Gend	er.	
2.			CI.	
	Address of Particip			
4.	Contact phone nur	mbers:	1. Name:	relationship:
	-		2. Name:	relationship:
			3. Name:	relationship:
			4. Name:	relationship:
5.	Participant's home	language	:	
	_	Shona		
	2.	English		
	3.	Ndebele		
		Other		
6.	Language of interv			
	1.	Shona		
		English		
_		Other		
	Interviewer initials Date of interview:	:		
	How old are you? What is the highes	t grade of	education you complete	d? (number of years)
	What is your religion	_		
	1	. Christian		
		a. Cath		
		b. Apo		
		c. Prot		
			en day adventists	
	•		ova's witness	
		. Muslim		
	3	. Others		
12.	Are you currently v	working?		
	1.	Not emplo	yed	
			full time permanently	
			part-time permanently	
		Do casual		
		Self emplo		
			ed and looking for work	1
			ed and not looking for wor	
	8.	Otner (Spe	ecify:)
13.	Which income am	ount best	describes the money yo	u get every month?

1. 0 US\$ 2. 1 - 50 US\$ 14. What is your main source of income? 1. My own business 2. Salary or wage 3. Partner 4. Family 5. I have no income 6. Other (Specify_____ 15. What is your marital status? 1. Married Are you legally married? Are you customary married? Was Lobola paid? 2. divorced/separated 3. widowed 4. cohabiting 5. single 16. Does your partner have other formal/informal partners? Yes 1. one other 2. two others 3. more than 2 others 4. Which partner are you? No 17. Do you have children? No Yes 1. How many biological children do you have? 2. What age(s)? 3. Do you take care of children that are not yours? No Yes a. Grandchildren b. Others 18. Are the children who live with you going to school? Yes No 19. If you have a partner, what is his/her main source of income? 1. Own business 2. Salary or wage 3. Husband or partner 4. You as his/her partner 5. He/she has no income 6. Other (Specify__

3. 51 - 100 US\$
 4. 101 - 200 US\$
 5. 201 - 500 US\$
 6. More than 500 US\$

4. No 5. Re 21. Do you own any of the 6. Ho 7. Fla	ouse at formal dwelling one efused e following kumusha (village)? ouse at formal dwelling
10. Re	
2. E 3. F 4. F	or home do you live in? Informal dwelling Backyard dwelling Formal house Flat/council house Other (Specify)
23. Including yourself, ho	w many adults live in your home?
24. How many children liv	ve in your home?
25. How many people sle	ep in the same room that you sleep in?
	me for your household per month?
2. 1 3. 5 4. 1 5. 2	0 US\$ - 50 US\$ 51 - 100 US\$ 01 - 200 US\$ 201 - 500 US\$ More than 500 US\$
1. Y 2. Y	Yes, the same every month Yes, most of the time it is the same No, it varies a lot each month
28. Do you have electrici	ity at homo?
YES NO	ity at nome:

30. What type of toilet do you have?

- 1. A flush toilet inside the dwelling
- 2. A flush toilet outside the dwelling
- 3. Communal flush toilet
- 4. Bucket system or pit latrine

31. Do you own any of the following?

- 1. Mobile phone
 - 1.1 Do you use a service like whatsapp?
 - 1.2 Are you comfortable with sending and receivinf sms?
- 2. Television
- 3. Satellite dish
- 4. Refrigerator
- 5. Bed
- 6. Bicycle

32. Have you ever suffered from TB?

No

Yes

33. How many meals do you have per day?

- 1. One meal
- 2. Two meals
- 3. More than two meals

34. Do you drink alcohol?

No

Yes

- 1. Daily
- 2. Weekly
- 3. Monthly

35. Do you smoke?

Yes

No

36. Do you suffer from a chronic physical illness?

No

Yes

- 1. Hypertension
- 2. Diabetes
- 3. TB
- 4. Arthritis
- 5. Others (Specify

37. Do you know your HIV status?

No

Yes

38. When were you last tested?

1. 1-3 months ago

)

- 2. More than 6 months
- 3. More than one year ago
- 4. More than two years ago
- 5. Can't remember
- 39. If status is positive: Your status is positive, are you on ART?

No

Yes

40. When did you start taking ART? <3months

<6months

<12months

+12months

41. Your status is positive have you received any counseling besides the post test counseling?

No

Yes

- 42. You received counseling/ support, what kind of counseling/support or therapy?
 - 1. Family counseling(systemic)
 - 2. Supportive counseling
 - 3. Church
 - 4. Friend
 - 5. Relative
 - 6. Clinic
 - 7.Others
- 43. You are postive. Have you disclosed your status to anyone?

Nο

Yes: Pastor at church

Most of my church friends

My partner

My immediate family members (sib,ings, parents)

My workmates

Others

44. Your status is negative, do you go for regular testing?

Yes

No

- 45. What family planning method do you use?
 - 1. None
 - 2. Condoms
 - 3. The pill
 - 4. The injection
 - 5. IUD
- 46. Has your family planning method been successful for you?

Yes

No

- 47. What is your reason for visiting the clinic today?
 - 1. HIV related
 - 2. Other medical condition

- 3. Kufungisisa (Depression)
- 4. Neuro-psychiatric condition (epilepsy, schizophrenia,

depression, others)

- 5. Assault/violence/rape
- 6. Routine collection of medication for chronic condition
- 7. Bringing a sick child/relative
- 8. Infertility
- 9. Antenatal clinic
- 10. Others

48. Do you know the HIV status of your partner?

No

Yes

I don't have a partner

49. You know the status of your partner

Negative

Postive

50. If positive: Your partner is HIV postive. Is he /she on medication?

No

Yes

I don't know

51. Has your partner ever suffered from TB?

No

Yes

52. Have you experienced any negative life-events in the last six months?

No

Yes. Death of partner

Death of child

Death of other family member

Illness

Loss of income/job

Loss of accommodation

Domestic upheaval

Divorce

Appendix F: Shona Symptom Screening Tool (SSQ-14)

Q No.	Question Comments	3
53	There were times in which I was thinking deeply or thinking about many things. Pane pandaimboona ndichinyanya kufungisisa kana kufunga zvakawanda	YES/NO
54	I found myself sometimes failing to concentrate Pane pandaimbotadza kuisa pfungwa dzangu pamwechete	
55	I lost my temper or got annoyed over trivial matters Pane pandaimboshatirwa kana kuita hasha zvenhando	
56	I had nightmares or bad dreams Pane pandaimborota hope dzinotyisa kana dzisina kunaka.	
57	I sometimes saw or heard things which others could not see or hear Pane pandaimboona kana kunzwa zvinhu zvaisaonekwa kana kunzwikwa nevamwe	
58	My stomach was aching Pane pandaimborwadziwa nemudumbu	
59	I was frightened by trivial things Pane pandaimbovhundutswa nezvinhu zvisina maturo	
60	I sometimes failed to sleep or lost sleep Pane pandaimbotadza kurara kana kushaya hope	
61	There were moments when I felt life was so tough that I cried or wanted to cry Pane pandaimbonzwa kuomerwa neupenyu zvekuti ndaimbochema kana kunzwa kuda kuchema	
62	I felt run down (tired) Pane pandaimbonzwa kuneta	
63	At times I felt like committing suicide Pane pandaimboita pfungwa dzekuda kuzviuraya	
64	I was generally unhappy with things that I would be doing each day Ndainzwa kusafara nezvinhu zvandaiita zuva nezuva	
65	My work was lagging behind Basa rangu rainge rava kusarira mumashure	
66	I felt I had problems in deciding what to do Ndainzwa zvichindiomera kuti ndizive kuti ndoita zvipi	

Appendix G: The Patient Health Questionnaire (PHQ-9)

any o	the LAST 2 WEEKS, how often have you been <u>bothered</u> by of the following problems? asvondo maviri apfuura makashungurudzwa kangan atambudziko anotevera	Kwete	Several days Mamwe mazuva	More than half the days Zviri pakati nepakati	Nearly every day Zuva rega rega
67	Little interest or pleasure in doing things. Kusanyatsova nechido chekuita zvinhu	0	1	2	3
68	Feeling down, depressed, or hopeless. Kusanyatsonzwa chido nezvehupenyu, kufunganya zvakapfuurikidza kana kushaya tariro muhupenyu	0	1	2	3
69	Trouble falling or staying asleep, or sleeping too much. Kutadza kuwana hope kana kurara zvakapfuurikidza	0	1	2	3
70	Feeling tired or having little energy. Kunzwa kuneta uye kuve nesimba shoma rekuita zvinhu	0	1	2	3
71	Poor appetite or overeating. Kusanyatsodya zvakakwana kana kudyisa	0	1	2	3
72	Feeling bad about yourself — or that you are a failure or have let yourself or your family down. Kuzvizvidza pachezvako-kana kuti kunzwa sekut urimukundikani muhupenyu kana kutadza kuzadzikisa zvaitarisirwa nevemhuri yako		1	2	3
73	Trouble concentrating on things, such as reading the newspaper or watching television. Kutadza kuita zvinhu zvakaita sekuverenga pepanhau nekuona chivhitivhiti pfungwa dziri pamwechete		1	2	3
74	Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual. Kufamba kana kutaura zvine kunonokera mukati zvekuti zvinogona zvakaonekwa nevamwe vakakutenderedza? Kana kuti kutadza kugarisika zvekuti wange urikufamba-famba zvakapfuurikidza zvaunofanirwa kunge uchiita		1	2	3
75	Thoughts that you would be better off dead or of hurting yourself in some way. Kuve nendangariro dzekuti zvirinani kuti dai wafa zvakodu kana kuda kuzvikuvadza neimwe nzira		1	2	3
		A11 – score/zvibo	PHQ dzwa zvab		