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Training CHWs to Support Re-Engagement in TB/HIV Care in the Context of Depression and Substance Use

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Training CHWs to Support Re-engagement in TB/HIV Care in the Context of Depression and Substance Use

SIYAKHANA – C

South African Medical Research Council Protocol Number: EC039-10/2021

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Authorized By:

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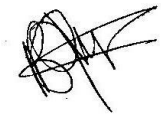

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Date:
29 August 2021

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Role: Principal Investigator
Date:
29 August 2021

Key Words: community health workers, lay health workers, trainings, mental health stigma, substance use stigma, depression, substance-related disorders, HIV, tuberculosis

GENERAL INFORMATION

FUNDER

National Institute of Mental Health (NIMH), Division of the National Institutes of Health (NIH)
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AUTHORIZATION

The study will be authorized by Drs Bronwyn Myers and Jessica Magidson.

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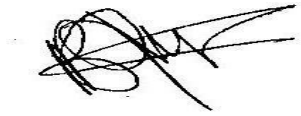
DECLARATION

We, **Bronwyn Myers and Jessica Magidson,** have read the Department of Health: *Ethics in health research: principles, processes and structures, second edition,* 2015, the *Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa,* Second Edition, 2006, Department of Health, Pretoria, South Africa (where applicable), and the Declaration of Helsinki (2013) and have prepared this proposal with due cognizance of its content. Furthermore, we will adhere to the principles expressed when conducting this proposed research project.

Signed:



Bronwyn Myers, PhD	29 August 2021 *Date*
Jessica Magidson, PhD	29 Aug 2022 *Date*

TABLE OF CONTENTS

Table of Contents

LIST OF ABBREVIATIONS

AE	Adverse Event
ART	Antiretroviral Therapy
CFIR	Consolidated Framework for Implementation Research
CHW	Community Health Worker
Co-I	Co-Investigator
DoH	Department of Health
HREC	Human Research Ethics Committee
ID	Identification
LMIC	Low and Middle-Income Countries
LTFU	Lost to Follow-Up
MD	Maryland
MDR-TB	Multidrug-Resistant Tuberculosis
MH	Mental Health
MI	Motivational Interviewing
MPI	Multi-Principal Investigator
NGO	Non-Governmental Organization
NIH	National Institutes of Health
NIMH	National Institutes of Mental Health
PI	Principal Investigator
PLWH	People Living With HIV
PST	Problem Solving Therapy
SA	South Africa
SAMRC	South African Medical Research Council
SDS	Social Distance Scale
sIMB-CIM	Situated Information Motivation Behavioral Skills Model of Care Initiation and Maintenance
SSA	Sub-Saharan Africa
SU	Substance Use
TAU	Treatment As Usual
TB	Tuberculosis
UMD	University of Maryland
US	United States

1. OVERALL AIM AND SPECIFIC OBJECTIVES

1.1 Overall Aim

The overall aim of this study is to test the feasibility, acceptability, fidelity, and preliminary effectiveness of a community health worker (CHW) training programme. The goal of this program is to reduce stigma on the part of CHWs towards patients living with HIV/tuberculosis (TB) and with depression or substance use (SU) in order to better help these patients re-engage in TB/HIV care. The training we propose to test was informed by formative interviews conducted with CHWs, other stakeholders, and patients in South African Medical Research Council (SAMRC) Protocol #EC039-9/2020.

We wish to extend our initial feasibility test of the training into a larger, stepped-wedge pilot trial. Findings will inform future iterations of this training at a larger scale.

1.2 Specific Objectives

1.2.1. Initial Pilot Training

To test the feasibility, acceptability, and fidelity of this CHW training program, we will:

a. Train CHWs in the adapted training program (*n* = 25)
b. Conduct assessments with the CHWs (*n* = 25) to obtain feedback on the perceived appropriateness, acceptability, and feasibility of the adapted training. We will also assess a representative sample of patients seen by the CHWs following the training (*n* = 75). Patients will be asked about the presence or absence of stigmatizing behaviours from each of the CHWs.
c. Code a subset of audiotaped CHW visits and/or behavioural role plays (n=25) to assess fidelity to the training
d. Adapt the implementation strategy and content (if needed) of the CHW training program based on findings from objectives b and c.

1.2.2 Stepped-Wedge Pilot Trial

To further evaluate the implementation (feasibility, acceptability, fidelity) and preliminary effectiveness of this CHW training program to reduce CHW stigma towards depression and SU in order to promote re-engagement in TB/HIV care, we will conduct a Type 2, hybrid effectiveness-implementation trial.[1] This will be guided by Proctor's implementation model.[2] Using a stepped-wedge design with multiple NGO/clinic sites (*N* = 60 CHWs total), we will randomly allocate the timing of the CHW training (versus treatment as usual; TAU) over six months. The following multi-level outcomes will be evaluated:

a. Feasibility, acceptability and fidelity of the CHW training (primary implementation outcomes). This will be assessed through both quantitative and qualitative methods so that qualitative data can add key context to quantitative findings and will include both CHWs and stakeholders (e.g., NGO leaders, policymakers focused on CHW training, supervisors of CHWs) to identify potential organizational barriers and facilitators to implementation of the training beyond the course of this study.
b. CHW stigma towards depression and SU in TB/HIV patients (primary; effectiveness outcome)
c. Patient re-engagement in TB/HIV care over six months via chart review (secondary effectiveness outcome)

2. INTRODUCTION

2.1 Background and Rationale

Globally, South Africa (SA) is in the top three countries with the highest burdens of HIV and TB.[3] With approximately 7.7 million people living with HIV (PLWH), SA has the most HIV cases in the world,[3,4] and PLWH are over 20 times more likely to develop TB than HIV-uninfected individuals.[5] TB is a leading cause of death in SA, and PLWH have the highest burden of TB.[6]

Poor engagement in care contributes to HIV and TB morbidity and mortality in SA, and depression and SU contribute to poor engagement in TB/HIV care. In SA, 62% of PLWH are on HIV medication[3] – called antiretroviral therapy (ART) – and over 70% of individuals with TB are diagnosed and initiated on treatment.[7] However, nearly half of PLWH have not achieved viral suppression,[3] and only about half of people with TB successfully complete treatment (29% are LTFU between TB diagnosis and treatment completion).[7] Individuals with depression and/or SU are particularly susceptible to poor engagement in TB/HIV care, including missed visits and greater likelihood as being LTFU.[8,9] Approximately one-third of PLWH have hazardous alcohol use,[10] over half have elevated depressive symptoms,[9,11] and rates are even higher among TB/HIV co-infected patients.[8,12] In previous studies, our team has shown a 42% lower odds of HIV treatment adherence among PLWH with depressive symptoms versus those without elevated depressive symptoms, and that depressive symptoms are associated with poorer engagement in HIV care.[9] Further, our team has also shown that alcohol use is associated with 2 times greater odds of poor TB outcomes, including treatment failure and LTFU, and poor HIV adherence.[13,14]

CHWs are frontline workers in SA who play a central role in re-engaging patients who are LTFU in TB/HIV care. As part of SA's national strategy for HIV and TB care,[15] CHWs are deployed in communities to provide active support for patients, including finding PLWH and TB-infected individuals who have been LTFU. Community-based, CHW-delivered interventions show promising outcomes, including improved engagement in care and treatment completion for patients with TB/HIV co-infection.[16–19] However, barriers continue to remain for TB/HIV re-engagement.

CHWs need additional support and training to manage patients with depression and/or SU in TB/HIV care. Despite the prevalence of depression and SU in TB/HIV co-infected individuals[8] and the impact on engagement in care, CHWs receive little, if any, training on how to respond and re-engage people with depression and/or SU in care. In fact, although CHWs form an integral part of SA's response to the HIV epidemic, CHW training programs in SA do not routinely provide training in mental health (MH) comorbidities such as depression or SU. In our team's pilot data with CHWs in SA *(n*=66), 63% reported not having prior training on depression or SU, although over 90% were 'very interested' in learning how to support these clients.[20]

High levels of MH and SU stigma exist among CHWs, which is a central barrier to patient re-engagement in care. Our team's pilot data also demonstrated high levels of stigma towards SU and depression among CHWs (*n*=66). Using the Social Distance Scale (SDS), 79% of CHWs had moderate to high stigma towards patients with SU, and 53% had moderate to high stigma towards patients with depression.[20] These findings are aligned with other research on stigma and CHWs in sub-Saharan Africa (SSA).[21] Additionally, our team has found extensive qualitative evidence that CHW SU stigma is a major barrier to care engagement, with patients describing feeling "scolded", "judged" and disrespected for SU,[22–24] resulting in reluctance to both access

and continue HIV and TB care.[25] Other work by our team has also shown that PLWH with depression and/or SU[26] report lack of respect and stigma from CHWs as a barrier to accessing care.[27] There is also quantitative evidence that PLWH experience high levels of stigma related to MH – and particularly to SU – that contributes to delays in seeking or re-starting care.[28] Further, there is evidence that when CHWs have negative attitudes towards patients with depression or SU, they spend less time with these patients, are less likely to implement evidence-based practices, and deliver less patient-centred care.[29] At the same time, it is well documented that MH and SU stigma lead to negative health outcomes among patients including patient delays in seeking treatment, lower treatment continuation rates, and poorer physical health.[30–32] In SA specifically, patients have been found to stop seeking TB/HIV care or terminate prematurely due to stigmatisation of MH-related symptoms.[33] Yet, to date, few studies have explored how to reduce CHW stigma as a means to improve re-engagement in TB/HIV care.

There is evidence that MH-related stigma reduction interventions in low and middle-income countries (LMICs) can reduce discrimination and improve patient outcomes. In SSA, stigma reduction strategies for TB and HIV stigma have demonstrated efficacy for reducing discriminatory practices among health workers and improve patient-level outcomes, including engagement in TB and HIV care.[34–37] However, compared to TB- and HIV-related stigma, there is much less research on how to shift MH and SU-related stigma in LMICs, particularly in the context of TB/HIV care. The limited evidence available indicates that the most effective MH-related stigma reduction interventions among healthcare workers include social contact with peers or service users.[36,38] However, this research is still in early phases[36,38] with the impact of these interventions on patient-level care outcomes rarely examined.[36]

The proposed training integrates two conceptual models: the Link and Phelan stigma framework[39] and the Situated Information Motivation Behavioural Skills Model of Care Initiation and Maintenance (sIMB-CIM).[40] According to the Link and Phelan stigma framework, stigma may occur among providers (including lay health workers, such as CHWs) when (1) individuals label differences and attach negative stereotypes to others and (2) the 'us' and 'them' are separated leading to status loss, discrimination, and conditional access to care. The sIMB-CIM model guides the identification of relevant contextual variables that may affect patients' re-engagement in care and suggests that engagement and maintenance in care is determined by (1) accurate information about one's illness; (2) intrapersonal and interpersonal motivation; and (3) behavioural skills, including systems navigation and organizational/planning skills, all of which may be affected by depression and SU.

Guided by the conceptual models, our proposed CHW training integrates two-evidence based CHW training approaches that have not previously been integrated *with* information from qualitative interviews in SAMRC Protocol #EC039-9/2020. The proposed training integrates:
(1) a CHW-training developed in SA[41] to increase awareness and understanding of depression and SU and reduce stigma—which addresses the *Information* element of sIMB-CIM; and
(2) evidence-based skills for promoting re-engagement in care (i.e., problem solving therapy; PST) and motivational interviewing (MI), previously adapted for CHW delivery in SA[42]—which addresses the *Motivation and Behaviour* elements of sIMB-CIM.

2.2 Adapting Training for the Initial Pilot Trial

We previously conducted a rapid analysis of Phase 1 interviews (#EC039-9/2020) to guide adaptations to the training in three domains: (1) training content; (2) training structure; and (3) the implementation strategy. Through this, we identified the need for ongoing supervision, monitoring, and consultation with CHWs; the need to consider how to incorporate cultural beliefs and

practices into the training; and the need to consider how to incorporate lived experience into the training to reduce stigma.

Based on these qualitative interviews, we determined that:

- The training should be at least three days long
- The training should cover basic information about depression and substance use along with information about stigma
- The training should focus on empowering CHWs to work with patients who have depression or are struggling with SU, as currently many CHWs feel underprepared to help such patients.

2.3 Adapting Training for the Stepped-Wedge Pilot Trial

Based on the findings of the initial training, we will adapt the training for a larger pilot test. We will use a randomized, hybrid Type 2 effectiveness-implementation design[1] to compare the adapted CHW training to usual CHW training (treatment as usual; TAU) in this setting. This type of design builds evidence for the effectiveness of an intervention in a real-world context, while also supporting the transition to implementation for subsequent, larger trials, with an equal emphasis on effectiveness and implementation.

This hybrid Type 2 effectiveness-implementation study will utilize a stepped wedge design to maximize power and ethically ensure that all clinics receive the CHW training, while also including a rigorous comparison condition. In this pilot trial, all clinics will receive the CHW training; each clinic will be randomized to the timing in which their CHWs receive the training.

Before CHWs receive this adapted training, they will receive TAU. In TAU, a CHW is typically deployed to a patient's home who has TB/HIV and has been LTFU for TB and/or HIV treatment with the central goal for supporting re-engagement in TB/HIV care. The CHW Typically goes to the patient's home twice per week for one month, or until the patient has re-engaged in care (if less than one month). CHWs typically meet with supervisors weekly for monitoring, which is limited to target review and does not include additional skills training or psychosocial debriefing. CHWs typically routinely document their visits to facilitate supervision and monitoring, and as part of efforts to roll out screening for depression and SU.

3. RESEARCH WORK PLAN

Aims: The aims of this study are to test the implementation (feasibility, acceptability, fidelity) and preliminary effectiveness of a CHW training programme. The goal of this program is to reduce stigma on the part of CHWs towards patients living with TB/HIV and with depression or substance use (SU) in order to better help these patients re-engage in TB/HIV care. We have adapted this training first based on interviews with patients and stakeholders in SAMRC Protocol #EC039-9/2020.

We are initially piloting this training with a small group (up to *n*=25) CHWs. Based on the feedback from these CHWs and our study team running the training, we are making small adaptations to the training. We will pilot this updated training with a larger group of CHWs (*n*=60) using a stepped-wedge design.

3.1 Study Sites

3.1.1 Initial Pilot Training

For the initial training, we are recruiting CHWs from NGOs employing CHWs at clinics in the Western Cape, for instance TB/HIV Care, ANOVA, Kheth'Impilo, and Courage to Care. More information about these sites is detailed in the table below.

NGO	Description of Work	Locations	Contact Info
TB/HIV Care	TB HIV Care is a registered non-profit organisation that puts integrated care at the heart of responding to TB, HIV and other major diseases. They work to prevent, find and treat TB and HIV in South Africa as well as targeting interventions to address the needs of populations at risk, such as inmates, sex workers and people who inject drugs.	Atlantis DuNoon Hout Bay Khayelitsha Philippi	Head Office 7th Floor, 11th Adderly St Cape Town City Centre Cape Town 800 #: 021 424 0500 Wynberg Office Wynberg Main Road Cape Town #: 021 699 8866
ANOVA (APACE Western Cape)	The Anova Health Institute is an NGO that empowers people and changes lives. With a specific focus on HIV, their work is built on a foundation of research to ensure that funds are focused where they can make the most difference. They have teams throughout South Africa that are also actively involved in community outreach, support, engagement and awareness, and educational campaigns.	Khayelitsha	Head Office 3rd Floor, Tijger Park 2, Bellville Cape Town #: 012 824 0052 / 083 253 7161
Kheth'Impilo	Kheth'Impilo is an NGO that has provided innovative approaches to clinical care and treatment services, health and community systems strengthening with social facilitation through program implementation at all levels of health and social service delivery.	Gugulethu Khayelitsha Phillipi	Head Office Uitvlugt, 20 Howard Drive, Pinelands 7405 #: 021 410 4300
Courage to Care	Courage to Care offers community development and set out to establish additional programmes funded by the Department of Health, Western Cape. Courage to Care's Community Wellness Centres opened in the Eersteriver and Kuilsriver area, serving both communities with Intergraded Home and Community Based Care Services. This include but not limited to family planning; support groups, wound care; bereavement counselling and child health, TB	Eersteriver Kuilsriver Mfuleni	Head Office Unit 15 Tainan Centre, Gordon St, Eerste River Cape Town #: 072 599 7063

	screening, HIV/AIDS testing, and medication distribution.		

3.1.2 Stepped-Wedge Trial of the Training

We will recruit CHWs employed by our partner NGOs (see above) who work at one of the clinics this study has partnered with. The exact clinics will be determined based on ongoing conversations with the Western Cape Department of Health, the City of Cape Town, and the NGO's. We expect the majority of clinics – if not all – to be based in Khayelitsha.

3.2 Study Design

3.2.1 Initial Training

We will invite up to 25 CHWs to participate in a pilot training. As the purpose of this activity is to gather feedback from the CHWs about their experiences with the brief training—rather than to test the effectiveness of the training—all enrolled CHWs will receive the training.

3.2.2 Stepped-Wedge Trial

We will use a stepped-wedge design.

CHWs will be clustered based on the site at which they work. When recruiting participants, we will aim to recruit approximately 20 CHWs per cluster.

CHWs across all clusters will be recruited and complete a baseline assessment at approximately the same time. In stepped-wedge trials, all groups have different intervals of a baseline period in which they are not exposed to an intervention (which we refer to as "treatment as usual" or "TAU"). Following this, at measurable intervals (steps), one group at a time will receive the training intervention. This process continues until all clusters have received the intervention. Then, at least one more follow-up assessment occurs after all clusters have received the intervention.

In this study, when a cluster receives the intervention (versus continues TAU) depends on whether they are randomized to Training Time #1, Training Time #2, or Training Time #3. Each training time will occur at a measurable intervention (compared to when the baseline assessment was conducted) so that the doses of TAU are discernable.

During data analysis, outcome variables will be compared between people before taking the intervention (TAU only; timepoints are baseline assessment (t1) and pre-training assessment (t2)) and with the same group of people after the intervention (TAU+Training; additional timepoints are 3-month follow-up (t3) and 6-month follow-up (t4)) after adjusting for individual random effect and time effect.

Randomization will not affect any other TB/HIV-related clinic services or mental health training.

3.3 Participants and Eligibility

The below table shows who will be recruited and consented.

Participants in study

	CHWs	Patients

Initial Pilot Training	Up to *n* = 25	Up to *n* = 75
Stepped-Wedge Trial	Approximately *n* = 60	0

3.3.1 Initial Training

3.3.1a CHW Participants

CHW participants will be 25 CHWs from TB/HIV Care, Kheth'Impilo, Courage to Care, and ANOVA. CHWs from any of these NGOs will be eligible.

Rationale for enrolment numbers.
Based on previous trainings and interventions our team has piloted, we believe 25 CHWs will allow us to get a good sense of the preliminary acceptability, feasibility, and fidelity of the intervention and provide enough information to help us refine the training programme for future implementation.

Eligibility.
To be eligible for the training, CHWs must meet all of the following eligibility criteria: (1) be at least 18 years old; (2) previously completed CHW training approved by the Western Cape Department of Health; (3) be employed by one of the NGOs listed above as a CHW; (4) work with patients who have HIV and TB and struggle with depression or SU, or supervise CHWs who work with such patients; (5) be able to complete informed consent and study procedures in English, Afrikaans or isiXhosa; (6) be able to complete training in English.

3.3.1b Patient Participants

Patient participants will be up to 75 patients (up to three patients/ CHW) who receive care from a CHW who attended the training.

Rationale for enrolment numbers.
The number of patients (*n* = 75) was based on the number of CHWs in the study; each CHW will be asked to try to identify at least one and up to three patient who may be eligible for the study.

Eligibility.
To be eligible for the study, patients must meet the eligibility criteria below. These criteria were chosen to reflect patients with life experiences that are relevant to the content of the training programme. These criteria are identical to those used in our formative work.

Please note that the purpose of this pilot study is to focus on CHWs learning skills taught in the training/ the feasibility of the training, and not patient outcomes.

Patient Eligibility Criteria

Inclusion	Exclusion
1. Be a patient of one of the CHWs enrolled in the study	1. Currently pregnant (due to receiving more intensive adherence support and treatment plan)
2. Have or have had a history of TB/HIV co-infection	
3. The CHW believes the patient is struggling with substance use (alcohol or other drug use) or depression	2. Having multi-drug resistant TB (MDR- TB; due to receiving more intensive adherence support and treatment plan)
4. Age 18 or older	
5. Able to complete informed consent and study procedures in a language spoken by research team (isiXhosa, Afrikaans, or English)	

3.3.1 Stepped-Wedge Trial

3.3.2a CHW Participants

Participants will be 60 CHWs who are employed by one of the NGOs listed above. Please see Section 3.1.2 (above) for more information on these NGOs.

Rationale for enrolment numbers.

The number of CHWs to enroll (*N*=60) was determined through power calculations based on the primary effectiveness outcome (i.e., CHW stigma measured with the SDS.[20,43,44]

A linear mixed model will be used for the primary outcome, considering both the within clinic correlation (i.e., multiple CHWs working at the same clinic) and the within person correlation (i.e., repeated measures on CHW stigma over time). In the power analysis, anticipated standardized effect sizes were defined from (1) a meta-analysis of 13 randomized clinical trials of mental health stigma reduction interventions that shows a standardized effect size of 0.63 on measures of stigma [121], and (2) prior work in sub-Saharan Africa using the SDS to test changes in mental health stigma among community mental health volunteers that had an effect size of 0.75.[44] Assuming similar baseline characteristics from a prior study using SDS among community health workers,[44] and an intra-class correlation of 0.1 within clinic and 0.3 within person, with 60 CHWs, our study can achieve a power of 86% at a significance level of 0.05 and a CHW training effect of 0.63, and 96% power at a training effect of 0.75.

A subset of these CHWs (up to *n*=20) will then participate in qualitative interviews. We will select CHWs for these further interviews by classifying CHWs based on level of change in stigma during the training. We intend to include CHWs who had reduced stigma following the training, no change in stigma following the training, and increased stigma following the training. We will also ensure that recruited CHWs represent the multiple NGOs that participated in the training. Only CHWs who attended the training will be eligible. We anticipate that this number of participants will allow us to reach theoretical saturation for qualitative analysis.[47]

Eligibility.

To be eligible, CHWs must meet all of the criteria in the below table.

CHW Eligibility Criteria

Inclusion	Exclusion
1. At least 18 years old	1. Unable to complete informed consent or study procedures in English or isiXhosa
2. Be employed as a CHW through a partner NGO that provides HIV/TB CHW services	2. Unable to complete training in English
3. Work with patients who have HIV and TB and struggling with depression or SU	3. Participated in the initial trial(s) of this training.

3.3.2b Stakeholder participants

Participants will be up to n=28 NGO leaders as well as policymakers and other stakeholders working with these NGOs. Please see Section 3.1.2 (above) for more information on these NGOs.

Rationale for enrolment numbers.

This number of participants will allow us to represent a wide range of perspectives. As in Phase I of this study, we will identify stakeholders by asking health care system leadership to refer us to stakeholders involved in NGO-managed CHW services. NGO stakeholders that participated in formative work for this stepped-wedge training will be also be recruited. We anticipate this number will also allow us to reach theoretical saturation for qualitative analysis.[47]

Eligibility

To be eligible, stakeholders must meet all of the criteria in the below table. Stakeholders that participated in formative work for this stepped-wedge training will be eligible to be enrolled, however prior participation is not required.

Stakeholder Eligibility Criteria

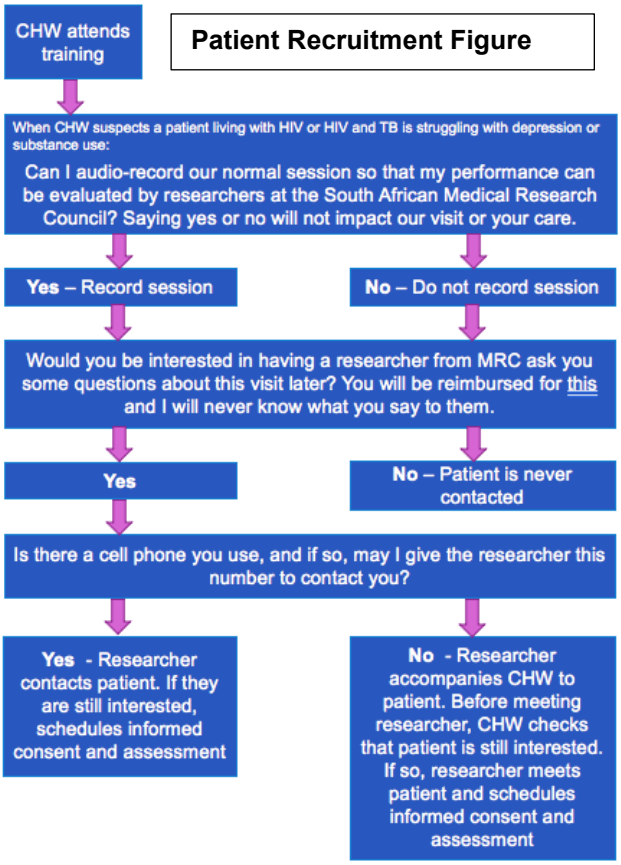
Inclusion	Exclusion
4. At least 18 years old	1. Unable to complete informed consent or study procedures in English or isiXhosa
5. Be employed by or referred by a partner NGO that provides HIV/TB CHW services	2. Unable to complete training in English
6. Work with patients who have HIV and TB and struggling with depression or SU	

3.4 Recruitment

3.4.1 Initial Training

3.4.1a CHW Recruitment

CHWs (*n* = 25) will be recruited from the NGOs we are working with (please see above). Specifically, study team members will consult with supervisors at these NGOs to determine which CHWs may be able to participate in the training and incorporate the training content into their current job. Trained study team members will approach these CHWs, tell them about the training and study procedures, and ask if they would be interested in participating in the training. Participation (or lack thereof) will not affect the CHW's employment.



3.4.1b Patient Recruitment

At the training, CHWs will be asked to identify at least one and up to three patients with a history of HIV/TB co-infection who they suspect is depressed or struggling with substance use. CHWs will be asked to follow the scripts below with such patients:

1. <u>Before the visit:</u> Is it okay with you if I audio-record this session? This recording will be used by researchers at the SAMRC to help assess how I am doing my job, not to collect information about you. You may say yes or no—it will not affect your care. *If the patient says yes, the CHW will audio-record his/her interaction with the patient. If the patient says no, the CHW will continue with the session as usual. The patient will continue to receive their usual care from the CHW.*
2. <u>At the end of the visit:</u> Would you be willing to talk to a researcher from the SAMRC about your experience with this visit? This researcher will contact you and you will be compensated for your time spent answering these questions. *If the patient says no, the CHW will end the session as usual. If the patient says yes, the CHW will ask:* Can I give the researcher your contact information? *If the patient says yes, the CHW will pass on any relevant contact information (e.g., a phone number) to the study team. If the patient says no they do not want to have their details passed on but is willing to participate in the study, a researcher and the CHW will arrange to visit this patient together.*

Patients who agree to be contacted by a researcher and have a phone number, will be called by a researcher in the team. During this call, the researcher will

perform informed consent procedures with the patient and ask them some brief questions about themselves and the CHW visit.

For patients who agree to be asked questions by a researcher but do not agree for their contact details to be passed on or do not have a phone number to allow them to be interviewed telephonically, we will ask the CHW to arrange a suitable date and place for the researcher to meet the patient for a follow up interview. This will be a place where the patient feels comfortable and that can maintain confidentiality. If COVID-19 permits, we will offer patients the option of being transported to our project site in Delft where they can complete the interview. All procedures will follow usual CHW care processes and ways of engaging with particular patients so that their HIV status is not inadvertently disclosed to family members or others. Before the researcher meets the patient, the CHW will ask the patient if they are still interested in talking to the researcher and if now is a good time. If it is, the researcher will complete informed consent processes with the patient and ask them questions about themselves and the CHW visit. The CHW will be waiting away from the researcher and patient at this time so they cannot overhear what the patient says. If it is not a good time to complete these questions, the researcher will set a suitable time directly with the patient (should they still wish to participate in the study).

The patient recruitment process is illustrated in the Patient Recruitment figure.

3.4.2 Stepped-Wedge Trial

3.4.1. CHW Recruitment.

CHWs (*n*=60) will be recruited from the NGOs we are working with (please see Section 3.1.2 above). Specifically, study team members will consult with supervisors at our partner NGOs—who employ the CHWs—to determine which CHWs may be eligible to participate in the training and incorporate the training content into their current job (i.e., CHWs to see patients living with HIV/TB and may be struggling with depression and/or substance use). Trained study team members will approach these CHWs, tell them about the training and study procedures, and ask if they would be interested in participating in training. Participation (or lack thereof) will not affect the CHW's employment.

For qualitative interviews, a subset of CHWs (up to n=20) will be contacted from the organizations that participated in the training. Only CHWs who attended the training will be recruited for these interviews. CHW will be recruited across organizations and across change in stigma levels (improvement in stigma, no change in stigma, increase in stigma). Trained study team members will approach CHWs, tell them about the further study procedures, and ask if they would be interested in participating in the interview. Participation (or lack thereof) will not affect the CHW's employment.

3.4.2. Stakeholder recruitment

NGO leaders, policy makers and other stakeholders (up to n=28) will also be recruited. These stakeholders will be recruited after referral from health system leadership. Additionally, stakeholders who participated in Phase 1 interviews may be re-enrolled to participate in these follow-up interviews. Trained study team

members will approach stakeholders, tell them about the study procedures, and ask if they would be interested in participating.

3.5 Study Procedures

3.5.1 Initial Training

3.5.1a CHW Screening and Consent

Potentially eligible CHWs—referred to us by staff at partner NGOs—will be screened for eligibility. If they are eligible and interested in participating, they will undergo informed consent procedures. As part of this process, participants will be informed of all the potential risks and benefits to taking part in the study. Participants will be reminded that participation is voluntary, that they can decline to answer questions they are not comfortable answering, they are able to leave the study at any point, and that their decision to participate in the study will not impact their job. As part of signing the consent form, they will also consent to the Protection of Personal Information Act 4 of 2013. Upon giving willing, informed consent, they will then be invited to attend the training.

3.5.1b Training

Eligible and interested CHWs (*n* = 25) will be invited to attend a training on mental health and substance use. This training was adapted for this setting based on qualitative feedback collected from providers, stakeholders, and patients in our formative work, described in SAMRC Protocol #EC039-9/2020. It integrates two evidence-based training approaches: (1) information, defined as training to increase awareness and understanding of depression and SU in order to reduce stigma; and (2) motivation and behavior, defined as problem-solving therapy and motivational-interviewing for promoting re-engagement in care. More information on the specific training is provided in the training outline.

Training will be conducted in English, as the business language of the healthcare system. All CHW trainings offered by the Western Cape Department of Health that are required as part of their certification occur in English. Our training team, however, consist of isiXhosa and Afrikaans mother-tongue speakers and therefore will be able to address questions in these languages and facilitate roleplays in multiple languages should the need arise.

3.5.1c CHW Assessments

Pre-Assessment. Before the training begins, CHWs will complete a brief assessment. This assessment will include questions around demographics and stigma. It will also contain a brief roleplay vignette (approximately 10 minutes long) to assess pre-training competencies in psychological care, based on the ENACT stigma training,[45–47] which will give us an estimate of how CHWs currently work with patients before attending our training. Finally, the assessment will include some questions to assess what CHWs already know about HIV, TB, depression, SU and stigma. We anticipate that this assessment will take about 40 minutes to complete.

Post-Assessment. On the last day of training, CHWs will complete another assessment with questions around stigma and knowledge of HIV, TB, depression, SU, and stigma. They will also complete another roleplay vignette based on the ENACT[45,46] to assess competencies in psychological care and how they will work

with their patients after the training. Finally, they will self-complete surveys[48] to assess the training's feasibility and acceptability.

1-Month Follow-Up. Approximately one-month after the training—and one-month into receiving supervision—the CHWs will be asked to complete a final brief assessment. This assessment will contain the same questions around stigma, knowledge of HIV, TB, depression, SU, and stigma. It will also contain questions to assess the feasibility and acceptability of the supervision component of the training package.

3.5.1d Patient Recruitment

After the training, CHWs will return to their normal jobs and will be provided with the patient study eligibility criteria. CHWs will be asked to identify at least one patient and up to three patients who they believe fit eligibility criteria and that they think might be interested in (1) having their normal session audio-recorded and (2) if they would be interested in talking to a researcher at the MRC about the visit (for which they will be compensated). CHWs will be reminded of this in ongoing supervision. Please see the Patient Recruitment section for more details on this process.

3.5.1e Patient Assessment

Patients who agree to be contacted by a researcher and complete informed consent will be given a brief assessment where they are asked about demographic information, their HIV and/or TB, depression, and substance use. They will also be asked about their thoughts on their most recent CHW visit. Please note that informed consent will including consenting to the Protection of Personal Information Act 4 of 2013.

3.5.1f CHW Fidelity

CHW fidelity to the training will be measured in either or both of the following ways: through audio-recordings with real patients and through role-playing after the training.

a) Audio-recordings with patients. Audio-recordings obtained by the CHWs will be assessed for fidelity to the training (i.e., skills taught that the CHW uses, correct information, and non-judgmental language). If a CHW obtains multiple audio-recordings, one audio-recording will be randomly selected to be assessed for fidelity.
b) Roleplays. The roleplays in the post-assessment training will be videorecorded and will also be rated for fidelity to the training (i.e., skills taught that the CHW uses, correct information, and non-judgmental language, including non-judgmental nonverbal communication). Using roleplay information will (1) allow us to assess fidelity immediately after the training and (2) allow us to assess fidelity to the training even if CHWs are unable to later obtain audio-recordings of their actual sessions with patients.

3.5.1g CHW Supervision

Once a week for about a month, each CHW will have the opportunity to receive weekly small group supervision (n=5) with a registered psychological counselor. Supervision sessions will include feedback from fidelity checks, reminders from the three-day training, and role-playing of challenging patient interactions. There

will also be opportunities for clinical debriefing and psychosocial support for challenging patient interactions with a focus on problem solving. Role-plays may also be recorded at the end of some supervision sessions.

3.5.2 Stepped Wedge Trial

3.5.2a CHW Screening & Consent

Potentially eligible CHWs—referred to us by NGO staff will be screened for eligibility. If eligible and interested in participating, they will undergo informed consent procedures. As part of this process, participants will be informed of all the potential risks and benefits to taking part in the study. Participants will be reminded that participation is voluntary, that they can decline to answer any questions they are not comfortable answering, they can leave the study at any point, and their decision to participate in the study will not impact their job. As part of signing the consent form, they will also consent to the Protection of Personal Information Act 4 of 2013.

3.5.2b CHW Baseline and Pre-Training Assessments

Baseline Assessment. Upon giving willing, informed consent, CHWs will complete a baseline assessment with study staff. The baseline assessment will consist of self-report questions around CHWs' demographic characteristics and job, personal mental health questions, questions around knowledge of HIV, TB, depression and substance use, and questions around stigma.

Pre-Treatment Assessment. Immediately before their training, participants will complete a pre-training assessment. At this visit, participants will be asked to answer the same self-report questionnaires and as they did at baseline (with the exception of demographic and job information, which will not be asked again). All CHWs will also complete a brief (~10 minutes) role-play vignette with a staff member who is minimally involved in delivering the training, which will be videotaped and later coded for stigma using the ENACT.

3.5.2c CHW Training

After the baseline assessment all groups will receive at least one dose of TAU. Based on the training time to which their cluster was randomized, CHWs will then be invited to participate in a training on mental health and substance use. Clusters randomized to Training Time #1 will receive the training first (while the other training times continue to receive TAU), followed by Training Time #2 (while the final training time continues to receive TAU), and finally, Training Time #3.

The training in the stepped-wedge trial will be the as the initial training, with minimal adaptations based on participant feedback (e.g., potentially an additional day, allocating more or less time to specific concepts, etc.). It will still be conducted in English, as all CHW trainings offered by the Western Cape Department of Health are required as part of the CHW certification occur in English. Roleplays will be conducted in English (training language) or isiXhosa (patients' language). Additionally, our training team consists of English, isiXhosa, and Afrikaans mother-tongue speakers; therefore, our team will be able to address questions and further explain concepts in these languages if needed.

3.5.2d CHW Post-Training Assessments

In addition to the Baseline and Pre-Treatment Assessments (which both occur before the training, and therefore, measure TAU), CHWs will also be required to complete two additional assessments after the training:

3-Month Follow-Up Assessment (3MFU): All participants will be invited to complete a follow-up assessment approximately 3-months after their training (3MFU). At this visit, participants will answer the same self-report questions they answered at the Pre-Training Assessment, answer additional questions about their perceived feasibility/acceptability of the training, and complete a roleplay for later ENACT coding.

6-Month Follow-Up Assessment (6MFU): All participants will also be invited to complete another follow-up assessment approximately 6-months after their training (6MFU). At this visit, participants will answer the same self-report questions they answered at the 3MFU and complete a roleplay for later ENACT coding. A subset of CHWs will also participate in semi-structured individual interviews in which they answer open-ended questions about their perceived feasibility/acceptability of the training.

3.5.2e Additional CHW Self-Report Measures

CHWs will complete the same measures during the stepped-wedge trial as they did in the initial training. In addition, they will also complete an integrated measure that assesses stigmas related to HIV and TB, which has been previously validated among health workers in South Africa.[49,50] Additionally, the personal questions around personal mental health/ substance use will be slightly expanded upon (i.e., asking about self and friends in addition to family). Although there is not an immediate post-training assessment, participants will additionally do another roleplay on their last day of training, which will be rated using the ENACT.[45,46] Please see Initial Training Procedures (above) for more information on the roleplay.

Based on feedback from the initial training, measures used in the initial training may also be shortened or slightly reframed (e.g., only asking the feasibility and acceptability subscales of the D&I measure).

3.5.2f Stakeholder Screening and Consent

Potentially eligible NGO leaders and stakeholders will be screened for eligibility. If eligible and interested in participating, they will undergo informed consent procedures. As part of this process, participants will be informed of all the potential risks and benefits to taking part in the study. Participants will be reminded that participation is voluntary, that they can decline to answer any questions they are not comfortable answering, they can leave the study at any point, and their decision to participate in the study will not impact their job. As part of signing the consent form, they will also consent to the Protection of Personal Information Act 4 of 2013.

3.5.2g Additional Measurements

Training Feasibility. CHW attendance in the training (less than one-week) and will be assessed as one measure of training feasibility. Over 75% of training sessions attending across all CHWs will be used as a benchmark for assessing whether the training is feasible.[2]

CHW Fidelity. To assess the fidelity of CHW delivery of training components (e.g., using non-judgmental communication, implementing MI/PST skills), 20% of the 3MFU roleplays will be randomly selected and rated using a fidelity assessment rating form in addition to being rated on the ENACT. A fidelity score will be calculated based on the proportion of key intervention components delivered as intended across the interactions based on these ratings.

NGO leader and stakeholder perceptions of feasibility and acceptability: Following the 6MFU assessment timepoint and collection of mixed-methods feasibility and acceptability data from CHWs, we will conduct qualitative interviews with leadership staff from NGOs, as well as policymakers and other stakeholders. These interviews will explore their perceptions of the feasibility and acceptability of the stepped-wedge training and aid in interpretation of data from CHWs themselves. Further, understanding organizational and systems barriers and facilitators to this training has important implications for longer term sustainment.

Patient Re-Engagement.
Chart Extraction. Chart extraction will be used to examine the rate of patient re-engagement in TB/HIV care. Specifically, data will be extracted from a centralized database of routinely collected data *(the Western Cape Province's Health Data Center),* which is hosted within the Western Cape Department of Health. The database includes information pertaining to demographic information, TB and HIV status, including whether TB and/or HIV treatment was initiated, date of initial diagnosis, lost-to-follow-up for TB and/or HIV care (i.e., missed treatment for two consecutive months), and date of TB and/or HIV treatment visits. This data is available by site and by unique patient health identification number (PHIN).

Around the time of a group's training, trained study researchers will receive a list of PHINs assigned to each CHW in the group in the past six-months from CHW supervisors/ workers overseeing CHWs. Aggregating data by CHW, and only viewing patients' PHIN and TB/HIV attendance data, we will extract whether patients re-engage, the time to re-engagement among those who return to care, and where patient re-engage in the six-months before the training.

Approximately six-months after a group's training, trained study researchers will receive a list of PHINs assigned to each CHW in the group since the training. Aggregating data by CHW, and only viewing patients' PHIN and TB/HIV attendance data, we will extract whether patients re-engage, the time to re-engagement among those who return to care, and where patient re-engage in the six-months before the training.

As only aggregate, de-identified data will be extracted from a centralized database, patients will not need to give informed consent.

3.6 COVID-19 Modifications

If any assessments or participant contacts take place over the phone:

- The informed consent process will occur over the phone or virtual platform. The study staff will offer to email the informed consent form to the participant so that they can follow along/ have the form for their records. Documented verbal informed consent will be received before any study procedures can occur.
- All survey questions will be read to participants over the phone by a study team member. The study team member will enter the answers to these questions on REDCap on behalf of the participant.
- Training may occur over video platforms, such as Microsoft Teams- this is aligned with current strategies being used to train CHWs during COVID, delivered through the Western Cape Department of Health's People Development Centre.
- At the beginning and the end of the training we will set up a secure video call so that we may complete the pre-training and post-training role-play vignettes and adjust our scoring of these vignettes to account for this modality using an approach used in other studies using this measure and conducted during the pandemic.
- Qualitative interviews may take place in person or remotely over video platform such as Microsoft teams. Likewise, they may take place individually or in group formats to align with current guidance on social distancing.

3.7 Participant Reimbursement

3.6.1a CHW Reimbursement (Initial Pilot & Stepped-Wedge Training)

CHWs will not receive monetary compensation for the training because participation in trainings are normal and required part of their professional development for CHWs. Participation in this training as part of usual working hours will be negotiated with their NGO employers. However, attendees will be provided with meals during training and will receive reimbursement for travel when training is in-person.

The subset of CHWs participating in semi-structured qualitative interviews will receive a 150 Rand gift voucher for being consented and completing questions about their perceptions of the feasibility and acceptability of the stepped-wedge training with researchers conducted during a separate study visit with members of the research team.

3.6.1b Patient Reimbursement (Initial Pilot Only)

Patients will not receive monetary compensation for the recording of their sessions with the CHW, as these sessions are part of their normal care and evaluation of the training. Further the purpose of these recordings is for quality improvement of training rather than data collection. Patient participants will receive a 150 Rand gift voucher for being consented and completing questions about themselves and their visit with the CHW with researchers conducted during a separate study visit with members of the research team. No data will be directly collected from participants in the stepped-wedge pilot trial of the training.

3.6.1c Stakeholder Reimbursement (Stepped-Wedge Trial only)

Stakeholder participants will receive a 150 Rand gift voucher for being consented and completing questions about their perceptions of the feasibility and acceptability of the stepped-wedge training with researchers conducted during a separate study visit with members of the research team.

4. Data Analysis

4.1 Type and purpose of Data

4.1.1 Initial Pilot Training

As this is a pilot of our training, the main purpose of data collection is for us to collect sufficient information that will allow us to adapt the training for the next phase (implementation of training across six clinics). The aim of the study is not to generate effect sizes or statistical significance but rather pilot procedures including data collection procedures with patients who interact with CHWs) and gather feedback on how well these procedures worked and how they might need to be refined for the future.

This study will collect quantitative and video data from assessments with CHWs (*n* = 25) and brief assessments with their patients (*n* = 75). CHW fidelity to training will also be generated by having an independent team member listen to a subset of sessions and/or roleplays and rate the sessions on a pre-determined fidelity checklist.

Conducting roleplays both at the assessments before and after the training will also allow us to measure improvements in competencies we teach in the training (i.e., non-judgmental communication, confidentiality). If the roleplay is conducted in English, the independent rater will rate the video as they watch the video. If the session is not conducted in English, it will be translated into English and then rated along with the non-verbal communication from the video. A final competency score[45,46] will be calculated for both pre-training and post-training roleplays for comparison.

4.1.2 Stepped Wedge Trial

The purpose of this stepped wedge trial is to examine the preliminary effectiveness and implementation of the proposed training. This study will collect the same quantitative and video data from assessments with CHWs (*n* = 60). An independent team member will rate the roleplays for both fidelity to the training using a predetermined fidelity checklist, and for stigma using the ENACT[45,46] checklist. The fidelity rating will yield a final fidelity score, and the ENACT checklist will yield a final stigma score.

4.2 Primary Implementation Outcomes

4.2.1 –Initial Pilot Training

Fidelity. At least one session or roleplay per CHW (*n* = 25) will be rated for fidelity using the fidelity monitoring tool. If a CHW recorded more than one session with a patient, the recording to be assessed for fidelity will be randomly selected. If the session or roleplay to be rated is conducted in English, the independent fidelity rater will rate the session as they listen to the audio. If the session is not conducted in English, it will be translated into English and then rated for fidelity using the checklist. Fidelity monitoring will focus on the presence of stigmatizing language and behaviors, adherence and competence in delivering skills learned in training, correct information, and the presence of positive, supportive interactions (i.e., use of positive affirmations in steps towards change). A final fidelity score will be calculated for each rated session/roleplay based on the proportion of key intervention components delivered as attended across interactions based upon these ratings.

4.1.2 Stepped-Wedge Trial

Fidelity. ENACT roleplays at the 3MFU will be rated for fidelity using a predetermined fidelity checklist. If the roleplay to be rated is conducted in English, an English-speaking

independent fidelity rater will rate the session as they listen to the audio. If the session is conducted in isiXhosa, an isiXhosa-speaking independent fidelity rater will rate the session using the same checklist (translated into isiXhosa). Fidelity monitoring will focus on the presence of stigmatizing language and behaviors, adherence and competence in delivering skills learned in training, correct information, and the presence of positive, supportive interactions (i.e., use of positive affirmations in steps towards change). A final fidelity score will be calculated for each rated session/roleplay based on the proportion of key intervention components delivered as attended across interactions based upon these ratings.

Feasibility. Feasibility will be assessed by assessing CHW attendance in the training. Over 75% of training sessions attended across all CHWs will be used a threshold for determining feasibility based on our prior work. Feasibility will additionally be assessed using the Feasibility subscale of the D&I tool.[48] CHWs will complete this measure at the 3MFU (primary) and 6MFU (secondary). Further, we will convergently analyze the quantitative measure of feasibility collected from CHWs with the qualitative exploration of feasibility among CHWs. The coding process will be aided by the CFIR codebook and coding tool (available at http://cfirguide.org). After coding the individual transcripts, we will create case memos, which summarize, aggregate, and prioritize the barriers by CFIR construct and implementation outcomes for each participant. This will identify the most prevalent implementation barriers that require implementation strategy prioritization. Key themes from qualitative interviews with CHWs will then be compared for discrepancies and areas of alignment with the quantitative measure from CHWs. Lastly, key themes from qualitative interviews with stakeholders will also be compared to findings from CHWs for areas of discrepancy and alignment and for further organizational context.

Acceptability. Acceptability will be assessed using the Acceptability subscale of the D&I Tool,[48] which measures the perceived satisfaction, relevance, usefulness, comprehension, and comfort level of the training to the CHWs. Acceptability will be assessed at both the 3MFU (primary) and 6MFU (secondary). We will also convergently analyze the quantitative acceptability measure collected from CHWs with qualitative data on acceptability from CHWs, using the same methods as for feasibility. Again, we will also compare and contextualize the mixed-methods data from CHWs with qualitative data from stakeholders.

4.3 Primary Preliminary Effectiveness Outcomes (Stepped-Wedge Trial Only)

4.3.1 –Stepped Wedge Trial

CHW Stigma. The primary measure of CHW stigma is the Social Distance Scale (SDS),[20,43,44] a well-validated measure of stigma used to capture health-related stigma across conditions and has been recommended for assessing mental health stigma among healthcare providers. A total SDS score will be calculated to represent CHW stigma towards the target population at each timepoint, with high scores indicating greater desire for social distance. First, we will conduct descriptive analyses (e.g., mean, standard deviation) to summarize the CHW stigma, using the continuous SDS score. The data distribution will be assessed to see whether the underlying assumptions are met (e.g., normality). To account for the stepped wedge study design, we will fit a linear mixed model (LMM). This analytic approach will allow us to account for both random effects of the clinic and CHW, and fixed effects of time and the effect of the training. We will analyze the within- and between-group effects. Specifically, the within group effect will evaluate changes in stigma before and after receiving the training with CHWs from the same clinic,

and the between group effect will compare the CHW training to assessments before the CHW training. An F-test will be used to test the between and within clinic intervention effects. Covariates (i.e, CHW demographic and job-related characteristics) will be included in the model. The model accounts for any baseline differences in CHW stigma between clinics and individual CHWs. Secondary measures of CHW stigma will include behavioral coding to stigmatizing responses in a role play based on vignettes using the ENACT scale.[45,46,51] Specifically, we will examine whether specific ENACT items (interpersonal skills sub-scale) at the pre-training timepoint predict other ENACT items (clinical skills sub-scale) at the later timepoints using multivariate linear models. This will allow us to begin to explore whether pre-training ENACT roleplays could be helpful for pre-training screening of CHWs in future research. We will also examine improvement in individual ENACT items across the data collection timepoints to examine the effect of the training and supervision on CHW helping skills and the durability of CHW helping skills over time. Additionally, analyses will be conducted on the an integrated HIV and TB stigma scale to measure intersectional HIV and TB stigmas. This scale has previously been validated among health workers in SA.[49,50]

4.4 Secondary Prelminary Effectiveness Outcomes (Stepped-Wedge Trial Only)

4.4.1 Stepped-Wedge Trial

Re-engagement in TB/HIV care. The rate of patient re-engagement at the CHW level and time to re-engagement in TB/HIV care at the patient level in the six months prior to the CHW training compared to six-months following the CHW training will be evaluated using chart extraction. We will apply a Poisson regression model to compare rates of patient re-engagement at the CHW level, accounting for both clinic random effect and the fixed effect of time in the stepped wedge design. Pre-intervention patient re-engagement rates will be collected during the TAU phase for each clinic over the six months prior to the first CHW training, and post-intervention rates will be collected six months after the CHW training is complete via chart review. A Wald test will be used to test the effect of the CHW training intervention on the rates of patient re-engagement.

Time to re-engagement. To further investigate whether the CHW training intervention decreases patient time to re-engagement in TB/HIV care over six months, we will use a Cox Proportional Hazard survival model to model the patient-level outcome of time of re-engagement. Right censoring (those who do not re-engage within six months) is handled in the Cox model. A frailty model includes the random effect of clinics to account for unobserved heterogeneity. If the proportional hazard assumption is not met, the parametric accelerated failure time model can be used instead. We will control for amount of CHW contact with the patient (i.e., whether the CHW makes contact with the patient and the number of times the CHW visits the patient before the patient re-engages) and the patient's screening results (i.e., whether they screen positive for depression, hazardous alcohol use, and/or other drug use).

4.5 Missing Data (Stepped Wedge Trial Only)

Intent-to-treat (ITT) analysis will be conducted so all participants are analyzed based on their initial randomization assignments. All data will be included, regardless of subsequent participant dropout or missing data. For observed missing data, we will follow guidelines for handling clinical trial missing data. Specifically, data are assumed missing at random (MAR) for ITT analysis, but subsequent sensitivity analyses will be conducted where data are assumed not missing at random (MNAR) using multiple imputation to assess the robustness of the MAR assumption.

5. Ethical Considerations

5.1 Potential Risks to Participants

There is minimal risk from the research procedures in the present study. However, the following risks are still possible:

5.1.1 Breach to Confidentiality

As with any study, breach of confidentiality is a potential risk. Ways to minimize this risk are described below.

5.1.2 Psychological or Mental Discomfort

It is possible that participants will feel uncomfortable discussing certain topics in the interviews. For instance, patient participants may feel uncomfortable discussing their SU, feelings of depression, or experiences feeling stigmatised, and CHW participants may feel uncomfortable talking about their stigmatising behaviours.

5.1.3 COVID-19 Transmission

Due to the current COVID-19 pandemic, there is a potential risk for COVID-19 transmission between project staff and participants. Efforts to minimize these risks are described below.

5.2 Protections Against Risks

Every effort will be made to minimize all study-related risks. These efforts include:

5.2.1 Informed Consent

All CHWs and patients who are asked questions will complete informed consent procedures. To join the study, these participants must fully understand and sign the consent. All participants will have as much time as they want to review the consent form and ask questions. A study team member will also review the form with each participant. The consent form will include all study procedures, information about potential risks and benefits of participation, and information regarding whom they can contact for further questions. It will also state that participation is voluntary, that participants can refuse to answer any question, that participants can withdraw from the study at any time, and that participation (or lack thereof) is in no way related to their employment or care. All procedures and protocols will be approved by the South African Medical Research Council's (SAMRC) Human Research Ethics Committee (HREC) before study initiation.

Ensuring capacity to provide consent if a person has depression or uses substances.
Depression is considered a common mental disorder, and unlike severe mental illnesses such as schizophrenia, is unlikely to impact on a person's capacity to provide consent. The majority of people who screen positive on the screening tools we propose using will have mild to moderate psychological distress. In and of itself, this is unlikely to impact on capacity to provide consent. Ensuring that people are not intoxicated at the time of providing consent is important. If a potential participant appears acutely intoxicated, that person will not be consented into the study. We include a question about alcohol and other drug use in the past four hours, which would cause acute intoxication. Individuals who respond positively to this question will not be enrolled. Likewise, individuals who respond positively to this question before the interview will not be interviewed at that time. The

study team will also be trained by Drs Myers and Magidson on how to detect simple signs of intoxication, such as impaired or slurred speech, smelling of alcohol, impaired co-ordination or balance—if any of these signs are present we will not enrol a participant or continue with any research activities at subsequent appointments with those already enrolled in the study. To increase our confidence in potential participant's capacity to consent, we include a simple assessment of capacity to provide consent in our consent form, that has been used in other studies with populations of patients who use alcohol and local studies with people with severe mental illness. These procedures were approved and used in the formative work to develop the training programme (#EC039-9/2020).

5.2.2 Preventing Breaches to Confidentiality

The confidentiality of each participant will be respected and maintained. Participant confidentiality will be ensured at all stages of the study.

All data will be kept confidential and only accessible to study staff. Participants' data will be identified by a study identification (ID) number only and a link between the names and ID numbers will be kept separately on a secure server and in a password protected document. This link will be destroyed after the study, including data analysis, has ended. The only individuals who have access to the link are the trained research staff in South Africa. Participant documents which include personal identifiers (such as signed consent forms) will be kept in locked files at SAMRC with restricted access. All other de-identified study documents will be kept in a secure location (such as UMD Box) and only study team members will have access to this location.

As part of the informed consent process, all participants will be advised that they may decline to answer any study questions. All study personnel working on the project will receive training about strictly adhering to study protocols regarding participant confidentiality.

Roleplays (and patient sessions in the Initial Pilot Training) will be recorded for analysis. The purpose of recording roleplays will be explained to all CHW participants in the informed consent process and authorization for recording will be obtained. Digital recordings will be uploaded to a secure database using the study computer immediately following the session and the audio file will be deleted from the digital recorder. Computer audio and video files will be saved in a secure location that only study-staff can access (i.e., UMD Box) and saved with a study ID. Any potentially identifying information will be removed or anonymized in the body of the written transcripts (e.g., the names of people). Following the South African good clinical practice (GCP) guidelines and guidelines set by the American Psychological Association (APA; APA Record Keeping Guidelines, Guideline #7), recordings will be maintained until seven years after the publication of the study. We will keep recordings even after transcription has occurred as a back-up and to allow for more nuanced coding if needed (e.g., of tone in addition to language). The ethics committee will review study procedures at least annually to review procedures pertaining to participant confidentiality.

English audio files may be transcribed to written text using Otter.ai by AISense. All audio files sent to Otter.ai will be de-identified and saved only using participant ID numbers in order to protect participants' confidentiality. Team members will only use Otter.ai for assistance; they will still check and correct any errors in the transcripts from the service. Otter.ai uses artificial intelligence technology and syncs data over an encrypted

connection and stores it in a secure data centre that has both physical and electronic security. When the user deletes the recording, there will be no record retained by AISense.

5.2.3 Protections against psychological or mental discomfort

All interviewers will be trained to recognize signs of discomfort, distress, or anxiety. Interviewers will carefully monitor the participant's response, which will allow the interviews to be completed with minimum discomfort. Participants will take breaks when necessary to help alleviate any discomfort. Participants will also be reminded that they can refuse to answer any question that makes them uncomfortable and may take breaks whenever they are needed. They will also be informed that they have the right to decline participation in the study, or to withdraw consent at any time without adverse consequences. At the end of the interview, participants will be offered referrals to local mental health and substance use services. We have a network of referral resources in Khayelitsha, established through previous studies in this area.

There is a study protocol for managing distressed participants that all study staff will receive training in as well as regular supervision and debriefing. This protocol was developed by Dr. Myers and has been used across multiple studies with highly vulnerable populations, including traumatized women who use substances, people living with HIV, depression and problem alcohol use, and adolescents with alcohol and depression. In all her studies, Dr. Myers has successfully managed all incident cases of distressed participants and there have been no serious adverse or adverse events related to mental health or substance use harms. For participants who are distressed and at risk of harm, we will actively refer and link them to appropriate resources to help them cope with and deal with their distress. Dr. Myers is a registered clinical psychologist (PS 007 1935) and given the size of this study, will be able to provide active and daily clinical oversight to determine the level of care needed for each distressed participant. Our strategies to actively link distressed participants to care include debriefing with the participant. Our study team includes registered psychological counsellors who are trained and have the correct competencies to do this debriefing and Dr Myers will be available to provide supervision and guidance. Strategies will include making (and fast-tracking appointments) at the appropriate agency and accompanying the distressed participant to the agency for their appointment to ensure that they receive the recommended services. Dr Myers has worked in the target communities for more than 15 years and has an established network of mental health and substance use providers to whom we can refer participants should the need arise. Again, it is important to note that our patient participants are unlikely to require medical management of depression.

For both distressed participants and other participants with known difficulties relating to possible depression and substance use, we will provide individuals with active referrals to mental health and substance use (or other health services) on request. Active referral involves a discussion with the individual about the benefits of additional services, obtaining the participant's consent for release of information, identifying a suitable service to which the individual can be referred, allowing the individual to use a telephone to contact the service (or contacting the service on the individual's behalf) to make an appointment, writing a formal referral letter and providing this to the individual, and in some instances, transporting the individual to the service for their first appointment. As part of managing this process, we follow up with participants to see whether they were able to access the service, and if there were barriers to help them address these. We also follow up to assess whether there has been any improvement to their mental health status.

5.2.3 Health and Safety: COVID-19

To reduce the likelihood of COVID-19 transmission, the following precautions will be taken.

Vaccines. First, all study staff who are eligible to receive the COVID-19 vaccine will be encouraged to do so. All of our research staff currently working on this project are vaccinated and have agreed to share their vaccination status in this protocol.

Telephonic Interviews. To reduce contact with study participants, if possible, assessments with patient participants be conducted telephonically. Depending on the status of COVID-19, ongoing supervision and parts of the training may be held in-person or telephonically/ over video.

In-Person Procedures. All staff members will be trained in COVID-19 safety protocols and the SAMRC standard operation procedures for the conduct of research during COVID-19. Staff members will have access to personal protective equipment (PPE) which will include sanitiser, masks, gloves, and face shield and Perspex dividers. Social distancing between staff member and the participant will be practiced, and all surfaces used will be disinfected before and after any interviews are held.

Assessments with patients will be conducted at the patient's home or over the phone. Assessments with CHWs will be conducted over the phone, at the location or the training, or where CHWs already work, so transportation should not be an issue for participation in assessments. However, we are aware that transport may be an issue for CHWs attending the training. If CHWs need to utilize public transport for the training, we will make sure that they feel safe to travel using this method, that it is their usual mode of transport for daily activities, and we will advise them to use masks while on public transport.

5.3 Potential Benefits of Proposed Research to Human Subjects

5.3.1 Participants

It is possible that participants will not directly benefit from this study. However, CHWs may find that they benefit from the additional information and skills that they learn in the training. Their patients also may benefit from them utilizing these new skills. CHW (in the initial and stepped-wedge trial), and patient participants (in the initial training), may also enjoy the opportunity to share their feedback on the CHW training.

5.3.2 Importance of the Knowledge to be Gained

From a broader perspective, the current study will likely have important implications for identifying how to optimally adapt and implement this CHW training program to promote re-engagement in care for patients co-infected with HIV and TB.

Initial Pilot Training

Findings from this formative study will inform the next iteration of this CHW training program, that we will implement in several clinics. We will seek approval for this next phase of the research in a separate submission.

Stepped Wedge Trial

CHWs are employed at every community health centre in South Africa, either through NGOs or the Department of Health. If this training program proves successful in reducing CHW stigma towards depression and substance use and promoting patient re-engagement in TB/HIV Care, it offers the potential for scale-

up. This research will also allow us to further understand barriers and facilitators to such scale-up.

6. Data Management

5.2 Data Storage

6.1.1 Data Acquisition and Transmission

Data collection occurs in South Africa at the specified data collection sites. All quantitative data will be entered into an electronic REDCap database (described below). All participants will be given a study ID. Personal identifying information of study participants will be kept entirely separate from their coded data.

Data Integrity. All interviews, measures, and observation notes will be conducted by a trained member of the study staff who will be supervised throughout the study.

Recordings. With the permission patients, some CHW sessions will be audio recorded for analysis. Please note that because CHWs—not patients—are the focus of these recordings, patients will not be enrolled in the study if their session is audio recorded. They will only be enrolled in the study if they choose to participate in a brief assessment about themselves and their CHW's visit. Roleplays with CHWs and either another CHW or staff member will be videorecorded. Qualitative interviews will be audio-recorded. If a roleplay, interview, or session is translated (e.g., because it is conducted in a non-English language), the translator will be a member of the study team and will leave out any potentially identifying data (e.g., names, locations). Roleplays will be recorded at the time of the training and saved in a secure location that only study-staff can access (i.e., UMD Box) and saved with the CHW's study ID. Qualitative interview recordings will also be stored in a secure location that only study-staff can access (i.e., UMD Box) and saved with the participant's study ID. CHWs will receive verbal consent from their patients before recording a normal session. If the patient does not want their session recorded, the visit will continue as usual. During training and supervision we will stress to CHWs that it is okay if none of their patients want to be recorded. If a session is recorded, the CHW will be asked to let the study team know. The study team will pick up the recording device as soon as possible and upload it to a secure database using the study computer. The audio file will then be deleted from the digital recorder. Computer audio files will be saved in a secure location that only study-staff can access (i.e., UMD Box) and saved with the CHW's study ID. Following the South African good clinical practice (GCP) guidelines and guidelines set by the American Psychological Association (APA; APA Record Keeping Guidelines, Guideline #7), recordings will be maintained until seven years after the publication of the study.). The ethics committee will review study procedures at least annually to review procedures pertaining to participant confidentiality.

Identifiable Data. Consent forms and any other documents with identifiable information will be kept in a separate, secure filing cabinet at the secure SAMRC study site.

De-Identified Data. De-identified data will be kept in a secure electronic system, such as Box through UMD. Only authorized study staff will have access to this data.

Link. The link between the names and ID numbers of participants will be kept separate from all other data on a secure server at SAMRC and in a password protected document. The link will be destroyed after data analysis for the study has ended. Only trained study staff in South Africa will have access to this link.

6.1.2 Data Entry Methods

Fidelity Analysis. Roleplays and sessions with patients and roleplays will be analysed for fidelity. If done in English, team members will review the recording in English on UMD box. If not done in English, study team members who speak isiXhosa will review the recording in isiXhosa on UMD box and complete the rating using an isiXhosa version of the measure.

Quantitative Assessments. Data entry will occur as close to real time as possible to facilitate data management and monitoring of study operations. If assessments are done on paper, they will be scanned by a research assistant as soon as possible and sent to the study's secure server. The paper assessment will then be filed away at a secure location at the MRC and the scanned assessment will be entered on REDCap.

REDCap. Demographic and measure data will utilize REDCap through UMD, a secure software toolset and workflow methodology for electronic collection and management of research and clinical trial data in real-time. SAMRC also uses REDCap for data collection. REDCap provides a web-based application with an intuitive interface for users to enter data and have real time validation rules (with automated data type and range checks) at the time of entry. REDCap data collection projects data on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team with planning assistance from UMD. All information entered on REDCap will be de-identified in order to protect participants' identities.

6.1.3 Quality Assurance

Data Completeness. To ensure the usability of self-report data, a member of the research team will review all self-report measures to ensure their completeness. Using an electronic data capture system such as REDCap is meant to reduce errors in the data entry and management process. Using REDCap, missing data can be reduced by making items required to answer before moving on to the next item and effort and error associated with data entry can be reduced because there is no manual entering of data at a later timepoint by research assistants.

Confidentiality. Data from all participants will be identified on study materials (including electronic study materials saved on a secure study drive such as Box) will be identified only by participant number and date of visit. By recording the study data in this manner, the information can be considered 'de-identified.'

5.3 Data Safety and Monitoring Plan

6.2.1 Regulatory Issues

The procedures laid out in this document will be followed, in compliance with NIH requirements as well as South African good clinical practice guidelines, to ensure the safety of study participants and the validity and integrity of data.

Before initiation of this study, the protocol, informed consent, and all other materials used with participants in this study will be reviewed and approved by SAMRC ethics committee. The study team will additionally submit a report to SAMRC ethics committee on an annual basis.

6.2.2 Amendments

Any changes to the protocol or amendments will be submitted to the SAMRC ethics committee before they are implemented.

6.2.3 Reporting Definitions

Unanticipated problems are any incidents/ experiences/ outcomes that are (1) unexpected (in terms of nature, severity, or frequency), (2) related or possibly related to participation in the research, AND (3) suggest that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously recognized.

Adverse events (AEs) are any untoward or unfavourable medical occurrences in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Serious adverse events (SAEs) are any adverse events that meet any of the following criteria: (1) results in death; (2) is life-threatening; (3) requires inpatient hospitalization or prolongation of existing hospitalization; (4) results in a persistent or significant disability/ incapacity; (5) results in a congenital anomaly/ birth defect; OR (6) may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

Labelling of AEs and SAEs.

Severity. AEs and SAEs will be labelled according to severity by one or both of the PIs, based on their impact on the patient. An AE will be termed "mild" if it does not have a major impact on the patient, "moderate" if it causes the patient some minor inconvenience, and "severe" if it causes a substantial disruption to the patient's well-being.

Likelihood. AEs will also be categorized according to the likelihood that they are related to participating in the study. Specifically, they will be labelled "definitely unrelated", "possibly related", "probably related", or "definitely related".

6.2.4 Protocol violations

Study staff will inform the Principal Investigators (PI) as soon as they are aware of any violations to the protocol. The South African PI will report any violations and the corrective actions taken to prevent further violations within 7 days to the SAMRC ethics committee.

6.2.5 Adverse events and unanticipated problems

As this study consists of low-risk one-time visits, we do not anticipate having any AEs, SAEs, or unanticipated problems. However, the plan for monitoring and reporting AEs, SAEs, and unanticipated problems is below.

Monitoring. Participants in semi-structured interviews will be monitored for AEs, SAEs, and unanticipated problems during the one-time interview session.

Reporting to SAMRC HREC.

AEs. If any AEs occur, they will be reported to the SAMRC HREC during the yearly progress report.

SAEs. All SAEs will be reported to SAMRC HREC within 48 hours of the team discovering the SAE, regardless of whether or not the SAE is related.

6.2.6 Additional review bodies

US National Institute of Mental Health (NIMH). The following events will be reported to the NIMH, this study's sponsor, as follows:

Event	Details	Reported By
IRB Suspension or Termination	If ethics approval is suspended or termination, a statement of reason(s) for the action must be reported to the NIMH Program Officer (PO) within **3 business days of suspension/ termination receipt.**	PIs and SAMRC ethics board
Deaths *related* to study participation	Within 48 hours of **PIs becoming aware** of death.	PIs
Unexpected SAEs *related* to study participation	Reported to the NIMH PO within **10 business days of the study team becoming aware** of the SAE.	PIs
Unanticipated Problems *involving* risks to subjects or others	Reported to the NIMH PO within **10 business days of the PI becoming aware** of event.	PIs
Serious or Continuing Noncompliance	Reported to the NIMH PO within **10 business days of ethics determination.**	SAMRC ethics board
AEs and SAEs	A summary of all AEs and SAEs that are deemed expected and/or unrelated to the study should be submitted to the NIMH PO and the SAMRC ethics board with the **annual progress report.**	PIs
Protocol Violations	**Annual progress report.**	PIs

6.3 Responsibility

The Multi-PIs (MPIs) are ultimately responsible for data and safety monitoring. The processes described above ensure that the MPIs will be aware of important study related issues on a regular basis.

6.4 Disclosure of any conflict of interest

Each investigator will complete a conflict of interest statement which will be kept on file by the study team. Any new investigators or key study staff will complete these forms, which will be stored and kept on record. At this time, there are no conflicts of interests in this study.

7. Timeline

Initial Training:

Week	Task	Amount of Time
Week 1 Week 2 Week 3 Week 4	Finalize training manual, set training date, and recruit CHWs	1 month
Week 5	Training (including pre-training and post-training assessment)	3 – 5 days
Week 6 Week 7 Week 8 Week 9	Weekly supervision, roleplays, audio-recordings, and patient consents/ assessments	1-month
Week 10	1-Month Follow-Up Assessment	~30min per CHW

Upon receiving ethics approval for stepped-wedge trial, approximate timeline:

Month	**Group 1** ***~20 CHWs***	**Group 2** ***~20 CHWs***	**Group 3** ***~20 CHWs***
1	Finalize minor adaptions to training manual, work with NGOs and Western Cape Department of Health, recruit CHWs		
2			
3	**Baseline Assessment** + TAU	**Baseline Assessment** + TAU	**Baseline Assessment** + TAU
4	TAU	TAU	TAU
5	**Pre-Treatment Assessment** **+ Training** *+ Supervision*	TAU	TAU
6	*Supervision*	**Pre-Treatment Assessment** **+ Training** *+ Supervision*	TAU
7	*Supervision*	*Supervision*	**Pre-Treatment Assessment** **+ Training** *+ Supervision*
9	**3MFU**	*Supervision*	*Supervision*
10		**3MFU**	*Supervision*
11			**3MFU**
12	**6MFU**		
13	Stakeholder (CHW and providers) interviews	**6MFU**	
14		Stakeholder (CHW and providers) interviews	**6MFU**
15			Stakeholder (CHW and providers) interviews

TAU = treatment as usual

8. Management Details

8.1 Management Approach

The present study will be led by the two PIs: Dr Bronwyn Myers and Dr Jessica Magidson.

8.1.1 SAMRC

Dr Myers (MPI) will take primary responsibility for SAMRC ethics protocols, training materials, staff training and management, and quality assurance. They will also oversee data collection.

8.1.2 UMD

Dr Magidson will oversee data management and the US based team who will support administrative coordination, oversight on regulatory issues and compliance, and all data management and cleaning.

8.3.1 Both Sites

Dissemination & Implementation. Drs Myers and Magidson will work collaboratively on the dissemination of findings. Specifically, each PI will take responsibility for gathering and coordinating resources and ensuring outputs for each area of primary responsibility. Leadership will be shared, as will responsibilities, authority, data, and credit. All final scientific and study implementation decisions will be made collaboratively between PIs, with inputs from the project team.

Communication. The PIs will communicate on a regular basis regarding study implementation and progress by telephone or video, in additional to regular email communication. Depending on travel guidelines (due to COVID-19 or other events), team members who are not located in South Africa will travel to Cape Town to support study training and implementation.

Conflict Resolution. All final decisions will be made collaboratively between Drs Myers and Magidson. In the case of conflicts, the two PIs will work diligently to resolve any issues and will draw on the expertise and inputs of the Co-Is and study collaborators to reach consensus. In the unlikely case that the two PIs cannot come to a consensus, they will seek out a third-party mediator (Dr John Joska at the University of Cape Town) to help resolve this conflict.

8.2 Staff and Scientific Collaboration

Dr Bronwyn Myers (MPI) will have the overall responsibility of ensuring procedural and scientific integrity of the SA-based study operations, including overseeing the team at the SAMRC. This will include supporting training and supervising research staff on study measures and assisting with regulatory requirements.

Dr Jessica Magidson (United States PI) will have the overall responsibility of ensuring the procedural and scientific integrity of the US-based study operations, including data management and oversight. She will lead the team at UMD in coordinating research meetings, maintaining a study timeline, creating reports on study projects, handling ethics committee issues, and ensuring clear communication between all study members.

8.3 Facilities

8.3.1 Field Site

The present study team will be based on the SAMRC premises in Delft. This site has all the privileges of SAMRC office space and is the base for several studies located within the community. Project staff will be housed at this facility.

Please note that due to COVID-19, staff may work remotely. If working remotely, staff will still have access to SAMRC resources.

8.3.2 Data Management Site

Data management will primarily occur in the Global Mental Health and Addiction Program (Director: Dr Magidson) at UMD. The office space consists of shared office space, a conference room, individual offices, and locked file storage rooms. Data files will be saved to a secure network running the PI's laboratory.

Please note that due to COVID-19, staff may work remotely. If working remotely, staff will still have access to UMD resources including access to the secure network.

9. Additional Details

9.1 Research Translation

9.1.1 Manuscripts.

We plan to publish the findings of this study in peer-reviewed journals. At a minimum we hope to publish a mixed-methods report of the implementation (i.e., acceptability and feasibility) findings of this pilot study. At a minimum we will publish a report of the implementation and preliminary effectiveness findings of the study.

9.1.2 Scientific Conferences.

We plan to present findings from this study at scientific conferences, including Addiction Health Services Research (AHSR) annual meeting, the Dissemination & Implementation Science Annual Conference, and the College of Problems on Drug Dependence (CPDD).

9.1.3 Training Materials.

This study will allow for the final adaptation of our training program for CHWs. We will use this final adaption in the next phase of the study with more CHWs (for which we will receive separate ethics approval). If at the end of this future study the approach proves to be effective, feasible, and acceptable, we will offer capacity-building workshops to train CHWs in the adapted manual, using a version that incorporates stakeholder feedback of feasibility and acceptability.

9.1.4. Data Sharing Plan.

We will make de-identified transcripts, codebooks, and quantitative data available to interested individuals (with appropriate training and approvals) after publication of the main outcome paper(s). Data will be released directly by the investigators providing evidence of their institution's ethics approval for planned analyses of the data. Our team will be available to address queries.

9.1.5. Clinical Trial Registration

In line with the requirements of the US National Institutes of Health (NIH), Part II of this study (Stepped Wedge Design) will be registered on ClinicalTrials.gov within 21 days of enrolment of the first participant.

9.2 Scientific Validity

This study has been peer-reviewed and approved by the US National Institute of Mental Health, a division of the United States' NIH.

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Appendix 1: Budget Documents

Please see attached budget documents.

Appendix 2: Procedures for Distressed Participants

Procedures for Distressed Participants and Mandatory Reporting

Given the nature of this study, there may be instances, where you as a researcher are faced with a distressed participant who you are concerned needs additional or immediate mental health support. For the most part, you can address this by talking to the participant and providing them with a referral to see the mental health nurse or for additional substance abuse services.

1. What is a distressed participant?

By "distressed" we mean that a participant shows signs of experiencing negative emotions and by his/her words, expressions, or other nonverbal behaviors or body language indicates that s/he is emotionally upset.

Possible signs or indications of distress:

- A participant who is tearful and/or reports that s/he feels badly or is sad
- A participant who shows signs of being considerably more nervous or anxious (e.g., very nervous speech, increased sweating, difficulty sitting still during the appointment) than would be expected during an appointment.
- A participant who seems agitated or aggressive and that you cannot easily calm down.

1.1 Steps to follow with mildly distressed participants who need additional services

In most cases of distress, participants may talk about feeling badly but you will be able to manage or contain these feelings and continue with the appointment. They may however, need additional services or support once the counselling intervention has been completed.

In these cases, complete the following steps at the end of the study appointment:

- Indicate to the person that they seem upset or anxious
- Discuss with the participant the importance of additional support
- Ask if they would like to receive additional services to talk more about feelings that came up during the course of the study
- If the participant indicates s/he would like to talk with someone further, ask if they would like you to refer them to an organization
- Complete the referral and release form
- With the participant's permission, call the agency or the clinic nurse to make an appointment
- Provide the patient with a copy of the referral letter in an envelope and keep one in the participant's file
- Provide the participant with a copy of the resource guide for additional services
- If the participant indicates that s/he does not want you to make a direct referral, suggest various organizations for him/her to contact on her own and give them a copy of the resource guide.
- At the end of the appointment, document this referral in the Participant's file

These steps should only be followed if the participant shows signs of distress or expresses a need for more counselling- but ***no suicidal intent or imminent harm is disclosed or suspected***.

If the person expresses any desire to end their life or hurt themselves or others, follow the steps described in 1.2 and the mandatory reporting procedures described in section 2.

1.2 Steps to follow with very distressed participants

There may be instances where participants are so distressed that you are concerned for their safety and may not be able to continue with the appointment. Remember that we have made it clear in the consent form that there are exceptions to our promise of confidentiality. If participants express the intent to harm themselves or others, or ongoing abuse and/or neglect of children, then we have a duty to report this matter to the proper authorities, e.g. the police, courts or social workers. Field staff will provide information on toll-free hotlines that people can call to talk to someone and seek assistance, as well as local resource information.

If during the course of the study you are concerned that a participant intends to harm him/herself or others, then mandatory reporting procedures need to be followed on completion of the appointment. Immediately inform the project manager and the principal investigator (PI) who will report the incident to the various ethics committees and our project officer within 72 hours.

In these instances, please follow the following steps:

- As far as possible, complete the study appointment
- Indicate to the person that they seem upset or anxious
- Remind the person of the limits of confidentiality as expressed in the consent form, and your duty to report
- Follow the mandatory reporting procedures described below
- Complete the referral and release form
- Call the agency to make an immediate appointment
- Provide the patients with a copy of the referral letter in an envelope and keep one in the participants folder
- Provide the patient with a copy of the resource guide for additional services
- At the end of the appointment, document this referral in the Participant's file
- Complete an incident report form and immediately send to the project manager and PI who will both keep copies on file and will report the incident to the relevant regulatory bodies.

2. Mandatory reporting procedures

It is possible that a participant will indicate during the course of a discussion that s/he is in immediate danger of harm or poses a threat to the safety of others. We want you to feel that you can handle this situation with confidence.

There are essentially three situations in which there may be immediate danger of harm:

1) **Suicidal Intent:** The participant expresses a desire to hurt or kill themselves.
2) **Hurtful Intent to Others:** The participant expresses an interest in hurting or killing someone else (not necessarily someone living in the household).
3) **Child Abuse and Neglect:** Ongoing abuse and/or neglect of children.

The rest of this protocol describes what to do in each of these cases. For each of these cases, you must follow compulsory or mandatory reporting procedures.

These procedures are important to follow because they take away the responsibility of you having to decide what to do. These procedures are in your best interest and in the best interest of the participant- they are to keep the participant safe and unharmed.

2.1 Suicidal Intent

If a participant expresses an interest in harming or killing him/herself, assess whether the risk is immediate or not immediate by following this procedure:

Ask the following questions:

	In The Past Month	
Answer Questions 1 and 2	**YES**	**NO**
1) ***Have you wished you were dead or wished you could go to sleep and not wake up?***		
2) ***Have you actually had any thoughts about killing yourself?***		
If **YES** to 2, answer questions 3, 4, 5, and 6. If **NO** to 2, go directly to question 6		
3) ***Have you thought about how you might do this?***		
4) ***Have you had any intention of acting on these thoughts of killing yourself, as opposed to you have the thoughts but you definitely would not act on them?***		
5) ***Have you started to work out or worked out the details of how to kill yourself?*** ***Do you intend to carry out this plan?***		
	In the Past 3 Months	
6) ***Have you done anything, started to do anything, or prepared to do anything to end your life?*** Examples: Collected pills, obtained a gun, gave away valuables, wrote a will or suicide note, took out pills but didn't swallow any, held a gun but changed your mind or it was grabbed from your hand, went to the roof but		

	In The Past Month
didn't jump; or actually took pills, tried to shoot yourself, cut yourself, tried to hang yourself, etc. ***In your entire lifetime, how many times have you done any of these things?***	

If the person answers YES to either questions 4, 5, or 6, this is a red flag and you should consider them at high risk for suicide. Risk is not immediate if the person is expressing some suicidal thoughts to describe how badly they feel but they do not have a plan. In the instance of high risk, follow the script below:

2.1.1 Procedure: IMMEDIATE or HIGH RISK of SUICIDE

If you assess that the participant is at **immediate risk** to him/herself, read the following script to the participant:

Script: Risk of participant suicide or self-injury (immediate danger of harm)

Team member reads:

"When you agreed to participate in this study, I promised that I would tell someone what you told me only if it was necessary to protect you or other people. You told me earlier that you were thinking of harming yourself. I suggest we contact an organization called LifeLine or SADAG and let them know so they can talk to you about how you feel. LifeLine and SADAG offers counseling. You can discuss your problem with one of their counsellors and they may be able to help you. Do you want to call them or should I call them for you?"

Willing participant:

- If the participant agrees to contact Lifeline or SADAG, use the project phone to make the call for the participant, hand them the phone and go to another room to give them privacy during the call.
- If the participant asks you to make the call on their behalf, use the project phone to make the call for the participant, and follow the script when speaking to the counsellor
- After the script has been read, hand the phone to the participant and go to another room to give them privacy in the call.

Script: Risk of participant suicide or self-injury (immediate danger of harm)

Team member reads to telephone counsellor

"We are conducting a research study and during an appointment, the participant expressed s/he was thinking of killing or harming him/herself. The participant has requested that we make this call for him/her.

Please note that this information was obtained through their participation in this research study. We went through appropriate informed consent, including telling the participant that a report might be made if the information s/he provided raised concerns about his/her well-being. I can give you additional information about the research study, if you would like. I can also provide you with the participant's name." Would you talk with him/her?

Unwilling participant

- If the participant is unwilling to contact the crisis hotline and doesn't want you to contact them, then you should immediately contact the project manager who should immediately contact a registered psychological counsellor who can assess the situation (e.g., determine reasons why the participant is unwilling to contact the hotline so these issues can be addressed) and who can contact one of the psychologists or the medical doctor in the investigative team for further inputs.
- In the meantime, do not leave the participant by him/herself nor let them leave on their own, as they pose a risk to themselves.
- Ask the participant if s/he has a close family member or friend who can come to sit with them until you receive clear instructions about what to do.
- If the participant remains unwilling to contact the hotline, provide the participant with the referral guide as well as the counselling hotline numbers.

- Make sure you document who you spoke to and the advice provided on the incident form

Script: Risk of participant suicide or self-injury (immediate danger of harm - unwilling to contact hotline)

Read to participant

"You told me earlier that you had thought about harming yourself, and this concerns me. I have to report this information to the appropriate authorities. I can also take you to the mental health nurse, refer you to the family physician or call LifeLine or SADAG on your behalf. I strongly suggest that you contact LifeLine or SADAG or go and speak to a doctor. Here is information about the telephone hotline that you could call to discuss your problem with a counselor. If you feel that this is an emergency now or later, you should go to a hospital emergency room right away. If you are unable to get to an emergency room without help, you should call the police for assistance."

After giving this information to the participant, immediately contact the hotline and adhere to the following script. The hotline will advise you on next steps.

Script: Risk of participant suicide or self-injury– to hotline

"During an appointment for a research project project, a participant expressed s/he was thinking of killing or harming themselves. The participant was encouraged to call LifeLine or SADAG and seek further professional assistance, but we also informed the participant that we have to report the situation. The participant was unwilling to contact anyone for help nor allow us to contact anyone on his/her behalf. S/he is with us now, but we are concerned about her safety.

Please note that this information was obtained through their participation in the study. We went through appropriate informed consent procedures, including telling the participant that a report might be made if the information s/he provided raised concerns about his/her well-being. I can provide you with the participant's name and residential area. Please can you advise us as to next steps to follow.

2.2. Hurtful Intent to Others

It is unlikely, but someone may spontaneously tell you that they are planning to seriously hurt or kill someone else. If a participant expresses an interest in harming or killing someone else, you should take the following steps.

- As far as possible, complete the study appointment
- Indicate to the person that they seem upset
- If they are expressing a desire to hurt someone else, explore whether there is an immediate risk (i.e. they have a plan and the means to do it)
- If there is immediacy and a plan, remind the person of the limits of confidentiality as expressed in the consent form, and your duty to report.
- Follow the mandatory reporting procedures described below
- Follow the reporting procedures - complete an incident report form and immediately send to the project manager and PI who will both keep copies on file.

2.2.1 NO IMMEDIATE RISK

If no immediate danger is perceived, advise the project manager and the PI immediately who will evaluate the seriousness of the issue and give advice on what to do. If the danger of harm is definitely credible, then the authorities will be called to report the incident. If the danger of harm is believed to definitely be credible, you may be advised to contact the police. In this case, please follow the script below.

Script: Risk of someone being harmed or killed revealed by participant

Team member to read to police

"We are conducting a research study, and during an appointment, a participant expressed an interest in harming or killing someone. I have discussed this situation with my supervisors and we have decided that this person might pose a real threat, so we are alerting you.

Please note that this information was obtained during an appointment that was conducted for this research study. We went through appropriate informed consent procedures, including telling the participant that a report might be made if the information s/he provided indicated that s/he might harm him/herself or others. I can give you additional information about this research study, if you would like. I can also provide you with the contact information for the participant."

2.2.2 IMMEDIATE RISK

If immediate danger is perceived please alert the project manager and the PI immediately and they will report the incident to the authorities. Do not let the participant leave before you have instructions from the police or the trial manager as to next steps to take. Please follow each of these steps.

Script: Risk of someone being harmed or killed revealed by participant during the appointment

Project manager or PI to read to the authorities

"We are conducting a research study, and during an appointment, a participant expressed that s/he intended to harm or kill someone, so we are alerting you.

Please note that this information was obtained during an appointment that was conducted for this research study. We went through appropriate informed consent procedures, including telling the participant that a report might be made if the information s/he provided indicated that s/he might harm themselves or others. I can give you additional information about the research study, if you would like. The participant is here at the moment."

It is unlikely that you will be faced with this situation!

2.3 Child Abuse/Neglect

Someone may tell you that s/he has abused or neglected a child or has been/is being abused, if a minor. If a participant reports this, you must report the incident to the authorities i.e Police (if sexual abuse) and Social Services/Childline (if any other type of abuse) after completing the appointment.
Note that, if an adult or even a person over the age of sixteen (in some cases where the age gap is more than two years above the other minor[1]) is having sex with a minor aged 12 to 15 years, even if it is consensual, it must be reported to the police.
Follow these steps:

- As far as possible, complete the study appointment
- Indicate to the person that they seem upset
- If they are reporting abusing a child or is a minor reporting that they or another minor a being abused, remind the person of the limits of confidentiality as expressed in the consent form, and your duty to report
- Follow the mandatory reporting procedures described below
- Follow the reporting procedures - complete an incident report form and immediately send to the project manager and PI who will both keep copies on file.

2.3.1. PARTICIPANT (UNDER 18) BEING ABUSED OR NEGLECTED

[1] A person aged 12 can consent to sex with someone who is 14 years old, but not someone who is 16. A minor below the age of 16 having sex with a minor below the age of 12 is also a reportable offence.

- **<u>Script</u>: Minor participant being abused or neglected revealed during the appointment**

  Team member to read to authorities:

  "*We are conducting a research study, and during an appointment with a participant, who is a minor, certain indications were made that the participant has possibly been physically or sexually abused or neglected. This led us to conclude that it was necessary to contact you to alert you of our concerns.*

  Please note that this information was obtained through the participant's participation in this research study, with appropriate informed consent procedures which included telling the participant that a report might be made if the data raised concerns about a her well-being. I can give you additional information about this research study, if you would like. I can also provide you with the contact information for the participant."

2.3.2. PARTICIPANT ABUSING OR NEGLECTING A CHILD

<u>Script</u>: Child being abused or neglected by participant revealed

Read to authorities:

"We are conducting a research study, and during an appointment with a participant, certain indications were made that the participant has possibly physically or sexually abused or neglected a minor. This led us to conclude that it was necessary to contact you to alert you of our concerns.

Please note that this information was obtained through the participant's participation in this research study, with appropriate informed consent procedures which included telling the participant that a report might be made if the data raised concerns about a child's well-being. I can give you additional information about this research study, if you would like. I can also provide you with the contact information for the participant."