


# BMJ Open Evaluation of the Friendship Bench' Circle Kubatana Tose (CKT): an add-on support group intervention – a mixed-methods pilot interventional cohort study protocol

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## ABSTRACT

**Introduction** Mental disorders are endemic. However, the mental health treatment gap remains high, especially in low-resource settings. Task-shifting is a universally recommended strategy to mitigate the care gap. The Friendship Bench (FB), a task-shifting, low-intensity psychotherapy programme founded in Zimbabwe, is effective in managing anxiety and depression. The FB programme offers clients the choice of joining add-on mental health support groups known as Circle Kubatana Tose (CKT). These groups offer an opportunity for continued psychoeducation, social support and economic strengthening. However, the evidence base for the effectiveness of add-on support groups is sparse. We hypothesise that participation in CKT is associated with increased adherence to treatment regimens, social support and well-being. This mixed-methods prospective cohort study seeks to evaluate the intermediate effects (6-month follow-up) of CKT groups, including process outcome evaluation.

**Methods and analysis** We will recruit participants (N=178) receiving mental healthcare from the FB in Harare primary care clinics. Follow-up assessments will occur at enrolment, 6 weeks, 3 months and 6 months, assessing changes in common mental disorders (depression and anxiety), social support, positive psychological indices (hope and resilience), health-related quality of life, working alliance, economic outcomes (net income) and implementation outcome (feasibility, acceptability/satisfaction and uptake of services). Quantitative data will be analysed using descriptive analysis, bivariate statistics, Cox proportional hazard models and generalised mixed models (maximum likelihood estimation). Qualitative data will be analysed using thematic analysis.

**Dissemination and ethics** Ethical approval was granted by the Medical Research Council of Zimbabwe (MRCZ/A/2427). The findings will inform the potential utility of add-on support groups in the management of anxiety and depression using task-shifting. Dissemination study outcomes will be disseminated in academic journals, social media, conferences and policy briefs.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ We will collect data on multiple constructs, including both negative (eg, depression) and positive (eg, hope) psychological constructs; this enables a holistic evaluation of mental health.
- ⇒ Use of mixed methods, quantitative and qualitative methods, to holistically understand the clinical, economic and implementation outcomes.
- ⇒ This is one of few studies evaluating the intermediate effects of group-based, task-shifted intervention.
- ⇒ The study was cocreated through the involvement of multiple stakeholders, including service users and counsellors.
- ⇒ The risk of loss to follow-up due to the long follow-up period may lead to measurement bias.

## BACKGROUND/RATIONALE

Mental disorders contribute significantly to the global disease burden and are a leading cause of disability.<sup>1</sup> For example, the Global Burden of Disease 2019 estimates showed an exponential increase in disability-adjusted life-years (DALYs) due to mental disorders, that is, an increase from 80.8 to 125.3 million DALYs.<sup>2</sup> Importantly, the burden of mental disorders has been compounded by global epidemics and natural disasters, including climate-related changes and droughts. For instance, the COVID-19 pandemic has led to an exponential increase in the burden of mental disorders, with the global prevalence of depression and anxiety increasing by 27.2% and 25.2%, respectively.<sup>3</sup> Despite the high burden of mental disorders, approximately 55% of persons needing treatment for common mental disorders (CMDs), particularly major depression and generalised anxiety disorders, have no access to services worldwide.<sup>4</sup> The mental health treatment gap



is even worse in low-resource settings, with only 15%–25% of persons needing mental healthcare receiving support.<sup>5,6</sup> The care gap in low-resource settings is hugely driven by a lack of financial investment in mental healthcare and is further compounded by a high burden of infectious and non-communicable diseases.<sup>7</sup> For instance, the sub-Saharan region shoulders the highest burden of HIV/AIDS, with up to 40% of people living with HIV suffering from comorbid mental disorders.<sup>8</sup> Also, protracted socio-economic challenges have further exacerbated the care gap. Fortunately, there is a growing recognition of the need to close the vast mental health treatment gap.

The WHO recommends task-shifting to mitigate the care gap in the face of resource limitations.<sup>9</sup> Systematic reviews have demonstrated the effectiveness of task-shifting approaches in managing mental disorders,<sup>10–11</sup> with Friendship Bench (FB) evolving as a leading global mental health innovation.<sup>10</sup> Founded in Zimbabwe, the FB is task-shifted low-intensity psychotherapy based on problem-solving therapy and behavioural activation.<sup>12</sup> The strength of the FB model lies in using lay health workers, primarily grandmothers, to offer a culturally adapted, cost-effective and evidence-based mental healthcare solution.<sup>12</sup> Zimbabwe has undergone decades of socioeconomic challenges that have strained the healthcare system. Chronic healthcare financing, brain drain and low prioritisation of mental health services have negatively impacted mental healthcare delivery/coverage.<sup>7,12</sup> For example, Zimbabwe has only 8 psychiatrists and 16 clinical psychologists to serve a population of 16 million people.<sup>7</sup> Moreover, the lifetime prevalence of CMDs in the Zimbabwean adult population is estimated at 25%; the high burden of CMDs strains the fragile mental healthcare system further.<sup>7</sup> Consequently, it is necessary to explore ways of leveraging existing resources to close the care gap. FB has been adopted as a national healthcare strategy. As part of its scale-up efforts, the FB is harnessing add-on support groups to increase mental health coverage further. Group therapies are clinically and cost-effective as they optimise resource usage by increasing treatment coverage per available delivery agent, an essential consideration for low-resourced settings.<sup>13–15</sup>

Under the current FB model, clients ideally receive up to six sessions; the number of sessions depends on individual client needs. On completing the second session, clients are offered a chance to join peer-led mental health support groups known as Circle Kubatana Tose (CKT); participation in CKT groups is not obligatory. CKT groups offer an opportunity for continued psychoeducation, social support and economic strengthening through a variety of activities, for example, gardening. The group is facilitated by the lay health worker during the formative stages of the group, after which management is transferred to the group members, with lay counsellors offering ongoing support, including providing additional therapy and linkage to additional care. The CKT concept is modelled around the notion of social determinants of mental health by offering income-generation

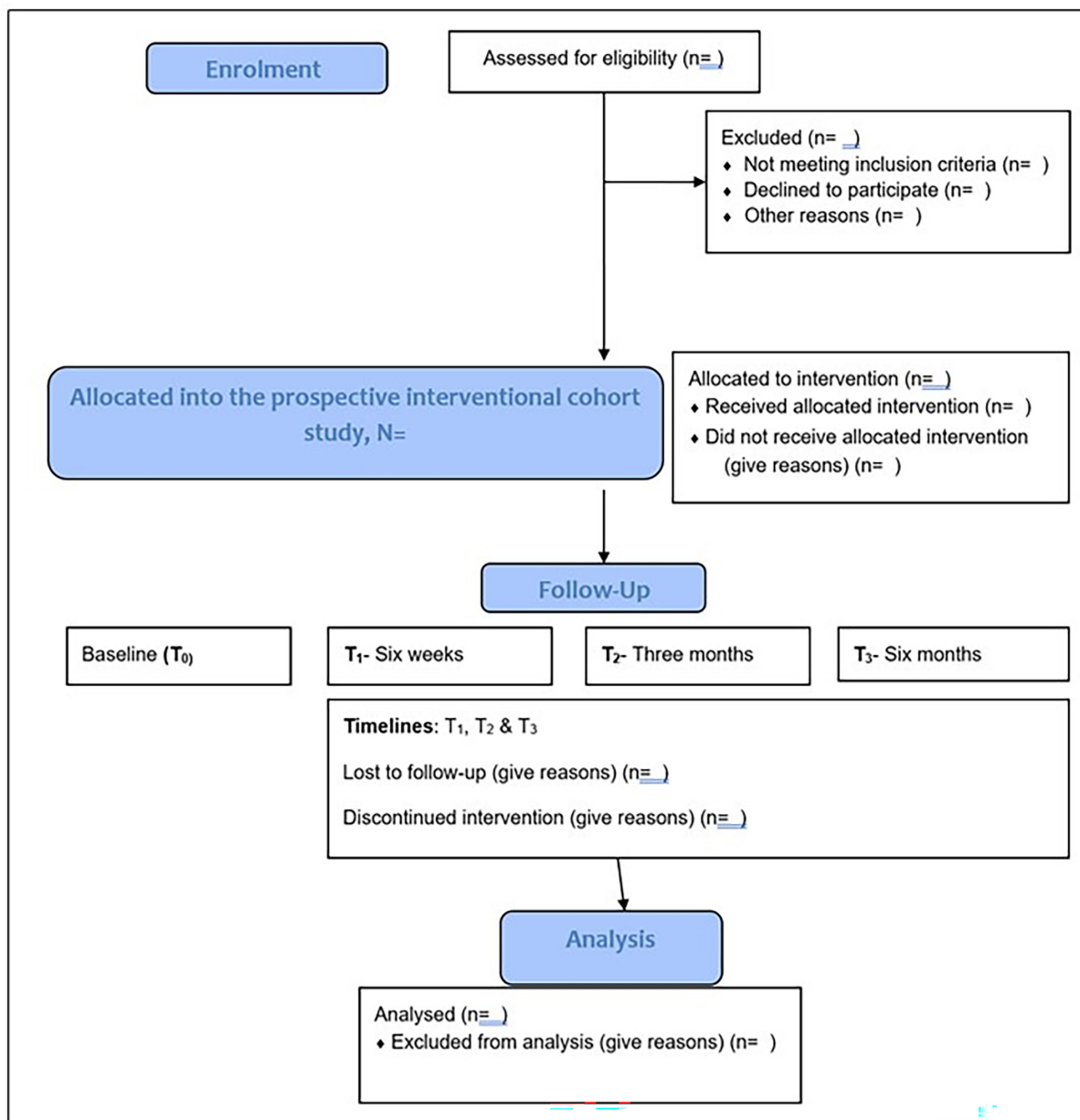
opportunities using the asset-based community development (ABCD) model.<sup>16</sup> The ABCD model trains clients how to collectively identify, mobilise and use readily available resources to address their challenges.<sup>16</sup> Besides the seed starter pack from the FB, the CKT groups also receive additional support from the government through the Ministry of Women Affairs, Community, Small and Medium Enterprises Development, including basic skills training in entrepreneurship and marketing. Exposure to CKT groups potentially optimises treatment outcomes. Previous studies have demonstrated that group therapies are linked with increased treatment adherence, social support and well-being when compared with individual therapies.<sup>13–15</sup> Also, most of the evidence of the effectiveness of task-shifting is from one-on-one psychotherapies; the evidence base for the effectiveness of add-on support groups is sparse.<sup>17–18</sup> Importantly, there is a paucity of longitudinal data on the effectiveness of task-shifted therapies.<sup>13–15</sup> We hypothesise that participation in CKT is associated with increased adherence to treatment regimens and social support. Further, the linked economic strengthening activities will likely improve mental well-being and health-related quality of life (HRQoL). This mixed-methods prospective cohort study seeks to evaluate the intermediate-term effects (6-month follow-up) of CKT groups, including process outcome evaluation. The study will specifically glean data on the intermediate effects of CKT groups on changes in CMDs (depression and anxiety), social support, positive psychological indices (hope and resilience), HRQoL, working alliance, economic outcomes (net income/profitability) and implementation outcome (feasibility, acceptability/satisfaction and uptake of services). Outcomes from this pilot study will provide data to inform the design of a definitive future implementation trial, including providing data to inform the optimisation of the CKT groups.

## STUDY DESIGN

This pilot interventional prospective cohort study (see figure 1) is designed and reported per Strengthening the Reporting of Observational Studies in Epidemiology statement guidelines.<sup>19</sup> The qualitative outcome evaluation is designed per Consolidated criteria for Reporting Qualitative research checklist guidelines.<sup>20</sup>

## SETTING

Participants will be recruited from 10 randomly selected primary healthcare facilities in Harare using a computer-generated list. FB services are available in all primary healthcare facilities in Harare, the capital city of Zimbabwe. Of note is that one facility may have more than one CKT group. In such a scenario, we will recruit all CKT groups linked to the randomly selected facility. Participants will be recruited from November 2023 and followed up for 6 months. We anticipate a recruitment



**Figure 1** The study processes from enrolment, intervention allocation, participants' follow-up and analysis.

rate of 40 clients/month; thus, the study is likely to run till November 2024.

### INTERVENTION

This prospective pilot interventional cohort will recruit participants receiving mental healthcare from the FB. The FB is lay-delivered psychotherapy. Ideally, clients undergo six therapy sessions that are based on problem-solving therapy and behavioural activation. Therapy sessions are conducted on a one-on-one basis, with a choice of involvement add-on group-based activities to increase the effectiveness of therapeutic activities. The first session mainly focuses on psychoeducation, that is, introduces the client to the notion of PST and sets out treatment goals and expectations, including an orientation of the probable therapeutic

processes. It is during the first session that clients are introduced to the CKT support group concept. Subsequent participation in CKT groups is optional; clients can join the nearest CKT group from the second session onwards. CKT groups are created by FB delivering agents/community healthworkers (CHWs) and facilitated by the clients to encourage peer support and further empowerment. The CKT groups comprise 10–15 participants who meet once every week for an hour. Each meeting starts and ends with a prayer while group members take turns to lead sessions. For subsequent sessions, group members decide on their own any topics they want to discuss to promote their well-being. For easy facilitation of the groups, they are given guiding and supporting documents such as a CKT Handbook, register, constitution and asset inventory. Besides

the peer support, clients in CKT groups are also involved in economic strengthening activities such as gardening, poultry, confectionary and detergent manufacture, among other activities agreed on by the group members. The FB provides a financial starter pack; the groups are expected to self-sustain from the project earnings. Last, clients can choose to continue with CKT activities beyond remission. In such cases, clients who have entered remission can act as 'champions', that is, provide peer support to future clients.

## PARTICIPANTS

### Eligibility criteria

To be included, participants should meet all the following criteria:

1. Have received a service from FB. Here, we define service as having a documented interaction with a lay counsellor; this can range from a psychoeducation, booking of a prospective appointment to completion of the first session therapy session.
2. Aged  $\geq 18$  years. FB services are provided for adolescents, young adults and adults. This cohort study primarily focuses on outcomes in adults.
3. Willingness to provide written consent and contact details for follow-up purposes.
4. A permanent resident within the primary healthcare facility catchment area.

5. Intention to reside within the catchment area for up to 6 months from the baseline data collection.

### Follow-up methods

We will identify all newly enrolled clients from the FB digital database. Clients are assigned unique identification codes based on site and date of enrolment. From the database, we will contact the clients by telephone or physically through the delivery agent. On contact, we will explain the study rationale and procedures. Clients will be given the opportunity to ask any pertinent questions before making an informed decision; participation will not be obligatory neither affect the client's ability to access FB services. On consent, we will collect baseline data and create a dedicated database on REDCap of all consenting clients; the database will be linked to the main FB database. We will document the number of sessions completed as this will determine the administration of subsequent follow-up measures (see [table 1](#)).

## VARIABLES

### Data sources/measurement

[Table 1](#) shows the exposures, outcome measures and frequency of measurement.

**Table 1** Outcome assessment

Category	Outcome	Outcome measure	Baseline (T <sub>0</sub> )	6 weeks (T <sub>1</sub> )	3 months (T <sub>2</sub> )	6 months (T <sub>3</sub> )
Primary clinical outcomes	CMDs	SSQ-14	√	√	√	√
Secondary clinical outcomes	Depression	PHQ-9	√	√	√	√
	Anxiety	GAD-7	√	√	√	√
	Social support	MSPSS	√	√	√	√
	Functioning	WHODAS	√	√	√	√
	HRQoL	EQ-5D-5L	√	√	√	√
	Hope	Herth Hope Index	√	√	√	√
	Resilience	Davison Connor Resilience Scale	√	√	√	√
Implementation outcomes	Feasibility	Number of scheduled sessions	√	√	√	√
		Number of sessions completed		√	√	√
	Uptake	Number of clients joining CKT groups		√	√	√
		Number of CKT sessions/activities completed		√	√	√
	Impact and sustainability	Ad hoc costing questionnaire	√	√	√	√
Exploratory–implementation	Satisfaction with services/acceptability	Ad hoc questionnaire		√	√	√
Exploratory–clinical	Therapeutic alliance	Working Alliance Inventory-Short Revised	√	√	√	√

CKT, Circle Kubatana Tose; CMDs, common mental disorders; EQ-5D-5L, EuroQol 5 Dimensions 5 Level; GAD-7, Generalised Anxiety Disorder Assessment; HRQoL, health-related quality of life; MSPSS, Multidimensional Scale of Perceived Social Support; PHQ-9, Patient Health Questionnaire; SSQ-14, Shona Symptom Questionnaire; WHODAS, WHO Disability Assessment Schedule.

## INSTRUMENTATION

### Patient Health Questionnaire (PHQ-9)

The PHQ-9 is a multipurpose instrument for screening, diagnosing, monitoring and measuring the severity of depression. The PHQ-9, which derives its scoring system from the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria for depressive disorders, asks about symptoms over the past 2 weeks.<sup>21</sup> Each of the nine items is scored from 0 (not at all) to 3 (nearly every day).<sup>22</sup> The total score for the questionnaire ranges from 0 to 27 and can be further classified into Minor depression (cut-off: 0–9), moderate/moderately severe depression (cut-off: 10–19) and severe depression (cut-off: 20–27).<sup>21 22</sup> The PHQ-9 has been validated in an urban Zimbabwean population, and it has been found to have a good validity with a sensitivity of 85%, specificity of 69% for the set cut point ( $\geq 11$ ), and reliability with a Cronbach's  $\alpha=0.86$ .<sup>22</sup>

### The Generalised Anxiety Disorder Assessment (GAD-7)

The Generalised Anxiety Disorder (GAD-7) is a 7-item Likert scale which measures severity of anxiety symptoms according to reported responses with a maximum possible score of 21.<sup>23</sup> The questionnaire enquires about symptoms experienced in the last 2 weeks and responses range from not at all=0, several days=1, more than half the days=2, nearly every day=3. Scores on the GAD-7 are categorised as follows: 0–4—minimal anxiety, 5–9—mild anxiety, 10–14—moderate anxiety, and greater than 15 as severe anxiety. The GAD-7 has been validated in an urban Zimbabwean population, and it has been found to have a good validity, with a sensitivity of 89%, specificity of 73% and reliable with a Cronbach's  $\alpha=0.87$  at a cut-off of  $\geq 10$ .<sup>22</sup>

### Shona Symptom Questionnaire (SSQ-14)

The Shona Symptom Questionnaire (SSQ-14) was developed and validated in Zimbabwe. This instrument is a screening tool for people at risk for developing CMDs, used in both research and clinical assessments. The questionnaire has two responses, yes or no for each question. Scoring ranges from 0 (best/not at risk of having CMDs) to 14 (at risk of having CMDs), with a cut-point of  $\geq 9$ .<sup>22</sup> The tool has been validated in the local setting and found to have a good reliability (Cronbach's  $\alpha=0.74$ ).<sup>22</sup>

### The Multidimensional Scale of Perceived Social Support (MSPSS)

The Multidimensional Scale of Perceived Social Support (MSPSS) is a brief measure of social support designed to measure the respondent's perception of the adequacy of the support received.<sup>24</sup> The original version of the MSPSS is a 12-item scale with 7 possible responses to each statement (scored 0–6), giving a score out of a maximum of 72, with a higher score indicating greater perceived social support. The 12-item MSPSS was designed to measure the perceived adequacy from the following three sources: family, friends and significant others.<sup>25</sup> The MSPSS has been translated to Shona, validated in an urban

Zimbabwean setting and found to be valid and reliable with Cronbach's  $\alpha=0.91$ .<sup>26</sup>

### EuroQol 5 Dimensions 5 Level (EQ-5D-5L)

The EQ-5D-5L is a generic HRQoL outcome measure that includes mobility, personal care, usual activities, pain/discomfort and anxiety/depression domains. Respondents indicate that they either experience no problems, slight problems, moderate problems, severe problems or extreme problems. The instrument also includes a 100-point vertical Visual Analogue Scale where 0 (0 cm) and 100 (20 cm) are represented by the worst and best imaginable health states, respectively.<sup>27</sup> Responses from the five domains can be converted to a single summary score (known as multiattribute utility) where death and full health are represented by 0.00 and 1.00, respectively. Utility scores for Zimbabwean adults are available.<sup>27</sup>

### WHO Disability Assessment Schedule (WHODAS 2.0)

The WHO Disability Assessment Schedule (WHODAS 2.0) is a practical, generic assessment instrument that can measure health and disability at the population level or in clinical practice. WHODAS 2.0 captures the level of functioning in six domains of life: cognition, mobility, self-care, getting along, life activities, participation.<sup>28</sup> Scores for the WHODAS can be calculated using 'simple scoring', where the scores assigned to each of the items—'none' (1), 'mild' (2) 'moderate' (3), 'severe' (4) and 'extreme' (5). Scores can be summed, that is, total scores range from 0 to 100 (where 0=no disability; 100=full disability). Cronbach's alpha levels were generally very high (0.94–0.96 for domains and 0.97 for total score).<sup>28</sup>

### Herth Hope Index (HHI)

The Herth Hope Index (HHI) is a 12-item Likert scale, arranged with scores from 1 to 4, where 1 is 'strongly disagree' and 4 is 'strongly agree'.<sup>29</sup> Negative items should be reversed, and the scores may range from 12 to 48; the higher the score, the higher the level of hope.<sup>29 30</sup> The psychometric properties of the HHI, tested in a Rwandan population, are considered satisfactory with the Cronbach alpha coefficient of 0.85.<sup>31</sup> We have translated and validated the Hope Index into Shona (article in press).

### Connor-Davidson Resilience Scale-10 (CD-RISC10)

The Connor-Davidson Resilience Scale 10 (CD-RISC10)<sup>32</sup> is a short version of the original CD-RISC.<sup>33</sup> It is a self-report measure of resilience with 10 items. Respondents rate items on a scale from 0 (not true at all) to 4 (true nearly all the time). The possible score ranges from 0 (minimum resilience) to 40 (maximum resilience). The CD-RISC10 has been validated in a South Africa population (almost similar to the current research setting) and has been found to be valid and reliable with Cronbach's  $\alpha=0.80$ .<sup>34</sup>

### Working Alliance Inventory-Short Revised (WAI-SR)

Consisting of 12 items, the Working Alliance Inventory-Short Revised is a brief and most extensively applied

**Table 2** Bias mitigation strategies

Bias classification	Bias type	Mitigation strategy
Information bias	Over surveillance	Use equal surveillance that is, evaluate both groups equally
	Knowledge of the exposure	▶ For the interviewer—blind the interviewer to the hypothesis so their recording will not be influenced
Selection Bias	Confounding	▶ Limit participation in study to individuals who are similar with respect to confounders. ▶ During analysis apply stratification to classify participants according to confounder or use multivariate regression analysis
	Participation of subjects	Using a regression model including several covariates
	Selection of subjects	Using a computer-generated random selection list for selecting CKT groups and clinics
	Loss to follow-up	▶ Recruitment of participants within primary healthcare catchment area ▶ Verification of contact details at recruitment ▶ Request alternative contact details and possible permission for lay health workers to perform follow-up home visits

CKT, Circle Kubatana Tose.

therapeutic measure. It measures therapeutic alliance in three domains, that is, agreement of tasks, agreement on therapeutic goals and bond creation. It is a widely used and psychometric robust therapeutic alliance measure.<sup>35</sup>

### Economic/cost outcomes

We will use an ad-hoc questionnaire to document the income and profitability of the income generation projects. For instance, we will document the capital, production, marketing and transportation costs. Additionally, we will also document the dietary diversity scores as a proxy indicator of socioeconomic well-being.

### BIAS

**Table 2** outlines the anticipated biases and corresponding mitigation strategies.

### SAMPLE SIZE CALCULATION

Based on our implementation data (publication in preparation), we assume that 60% of the participants will have SSQ scores  $\geq 9$  at enrolment ( $p_0=0.6$ ) and the proportion to drop to 40% on session completion ( $P_1=0.4$ ). The minimum sample size required is 178 at  $\alpha=0.95$ ,  $\beta=0.80$  and anticipated 30% loss to follow-up. The sample size was calculated using STATA (V.17.0).

### QUALITATIVE METHODS

We will apply qualitative methods to understand the implementability (feasibility, acceptability and uptake) of the CKT groups. Participants will be purposively selected to represent diverse characteristics such as gender, duration (recent vs participants who have participated in CKTs for a greater duration), adherence (completers, defined as completing at least half of the scheduled sessions vs non-completers), age, among other pertinent salient

characteristics that may influence participation and study outcomes. Data will be collected using semistructured interview guides. Additionally, we will also interview the lay counsellors and administrators who assist with the establishment and monitoring of the CKT groups, to understand the barriers and facilitators, including ways of optimising the CKT groups. We aim to interview at least 15 participants and 10 lay counsellors and administrators. Recruitment will be done until theoretical saturation is achieved.

### STATISTICAL ANALYSIS

#### General analysis plan

Descriptive statistics such as means, frequencies and proportions will be used to describe participants' characteristics and clinical outcomes. Missing data will be imputed. The Shapiro-Wilks test will be used to test for the normality of all data before deciding to use either parametric tests (eg, t-tests) or non-parametric tests (eg, Mann-Whitney U). We will use the  $\chi^2$  test for binary outcomes and the t-test for continuous outcomes.

#### Clinical and implementation outcomes analysis

We will evaluate the extent of selection bias by assessing the comparability of the two groups (CKT users vs non-CKT users). For instance, t-tests will be used to evaluate differences in continuous scores, for example, mean differences in baseline SSQ-14 scores. We will compare mean/proportion differences and associated CIs between baseline and endpoints (end of sessions). ORs will be used to evaluate differences in binary data. A one-way, repeated measures analysis of Variance will be used to compare mean differences in continuous scores from baseline through follow-up, that is,  $T_1$ ,  $T_2$  and  $T_3$ . A Kruskal-Wallis test will compare proportion differences at the three time points (**table 3**). We will use Cox proportional hazard

**Table 3** Statistical plan

Construct-outcome measure	Assessment point				Data type	Effect measure	Tests
	T <sub>0</sub>	T <sub>1</sub>	T <sub>2</sub>	T <sub>3</sub>			
Screening: (1) Demographic data	x				<ul style="list-style-type: none"> <li>▶ Continuous</li> <li>▶ Nominal</li> <li>▶ Ordinal</li> </ul>	<ul style="list-style-type: none"> <li>▶ Means</li> <li>▶ Proportions</li> <li>▶ Median</li> <li>▶ Range</li> </ul>	<ul style="list-style-type: none"> <li>▶ Continuous- t-tests</li> <li>▶ Binary/categorical-<math>\chi^2</math></li> </ul>
Primary clinical outcomes: (1) CMDs-SSQ-14	x	x	x	x	<ul style="list-style-type: none"> <li>▶ Numeric–summative scores</li> <li>▶ Binary–classifications per cut-off points</li> </ul>	<ul style="list-style-type: none"> <li>▶ Mean differences</li> <li>▶ Differences in proportions</li> </ul>	<ul style="list-style-type: none"> <li>▶ One-way ANOVA repeated measures</li> <li>▶ Kruskal-Wallis</li> </ul>
Secondary clinical outcomes: (1) Depression–PHQ-9, (2) Anxiety–GAD-7, (3) Social support–MPSS, (4) Functioning–WHODAS, (5) HRQoL–EQ-5D-5L, (6) Hope– Herth Hope Index, (7) Resilience–Davison Connor Resilience Scale, (8) therapeutic alliance- WAI-SR	x	x	x	x	Numeric–summative scores	Mean differences	One-way ANOVA repeated measures
Implementation outcomes: (1) feasibility, (2) uptake/reach, (3) satisfaction, (4) economic/cost		x	x	x	Numeric–summative scores Qualitative	<ul style="list-style-type: none"> <li>▶ Mean differences</li> <li>▶ Thematic analysis</li> </ul>	t-tests

ANOVA, analysis of Variance; CMDs, common mental disorders; EQ-5D-5L, EuroQoL 5 Dimensions 5 Level; GAD-7, Generalised Anxiety Disorder Assessment; HRQoL, health-related quality of life; PHQ-9, Patient Health Questionnaire; SSQ-14, Shona Symptom Questionnaire; WAI-SR, Working Alliance Inventory-Short Revised (WAI-SR); WHODAS, WHO Disability Assessment Schedule.

models and generalised mixed models (maximum likelihood estimation) adjusting for baseline scores and covariates (eg, sex, age) to estimate treatment differences and associated 95% CIs. Mediation hypotheses (exploratory analyses) will be evaluated using structural equation modelling to include potential confounders of mediator and outcome relationships, making causal inferences more plausible. All tests will be performed at  $\alpha=0.05$  using STATA V.17. Qualitative implementation data will be analysed using thematic analysis in NVivo. Potential cobenefits or unintended consequences of the implementation will be assessed qualitatively.

### PATIENT INVOLVEMENT AND ENGAGEMENT

We cocreated this study with lay counsellors and expert clients. For instance, the research questions for the present study we formulated through a priority-setting exercise. The study advisory board will consist of lay workers and CKT group representatives. The representatives will also be involved in interpreting the qualitative findings and dissemination of the study findings.

### ETHICS AND DISSEMINATION

Ethical approval was granted by the Medical Research Council of Zimbabwe, Ref- MRCZ/A/2427. The findings will inform the application of add-on support groups in the management of CMDs. Dissemination of the outcomes of the study is expected via publications in peer-reviewed

journals, presentations at conferences, social media and policy briefs.

### DISCUSSION

The proposed study will provide insights on the preliminary effectiveness of an add-on group-based and peer-led task-shifted interventions. The study can potentially inform the design of large-scale clinical trial to assess the clinical and cost-effectiveness of the intervention. Such evidence is necessary given the large mental healthcare gap. The study outcomes have potential external validity, thus contributing to the global mental health body of knowledge.

### Strengths and limitations

The study strengths include the following: (1) We will collect data on multiple constructs, including both negative (eg, depression) and positive (eg, hope) psychological constructs; this enables a holistic evaluation of mental health. (2) The use of mixed methods, quantitative and qualitative methods, to holistically understand the clinical, economic and implementation outcomes. (3) This is one of few studies evaluating the intermediate effects of group-based, task-shifted intervention. Information gathered will contribute to the evidence base of task-shifting. (4) The study was cocreated through the involvement of multiple stakeholders, including service users and counsellors. However, the study has its own inherent weakness. First, the risk of loss to follow-up due to the intermediate follow-up period may lead to measurement bias. However,

we have put several measures to mitigate against loss to follow-up. Second, the lack of a comparison group limits our inference of the possible impact of the CKT groups. However, this pilot study will provide preliminary data for the design of a definitive trial.

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**Contributors** JD and BKS were primarily responsible for writing the protocol first draft. JD, BKS, TDT, CC, TT and TM were involved in conceptualising the study and editing all protocol manuscript versions. LD worked on the first draft of the revised manuscript, including providing a more nuanced description of the interventions. DC will provide overall supervision, mentoring and guidance. JD is the guarantor.

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not applicable.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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