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Adaptation and piloting of an integrated intervention model for alcohol use disorders in primary healthcare in rural Tanzania: a study protocol

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ABSTRACT

Introduction Integration of evidence-based interventions for alcohol use disorders (AUDs) into primary healthcare has potential to increase coverage and reduce population burden. However, these interventions are rarely implemented in low- and middle-income countries and there is little existing guidance on how this could be achieved. The aim of the proposed study is to adapt and pilot an integrated model for AUDs in Tanzanian primary healthcare.

Methods and analysis The study design will include a situational analysis, a qualitative study, a series of participatory Theory of Change (ToC) workshops and pilot intervention study. The evidence-based packages of care for AUD from the WHO mental health Gap Intervention Guide will form the basis of intervention. The situation analysis will use publicly available data to identify existing resources and system functioning. In-depth interviews will be conducted with key stakeholders (people with lived experience of substance use problems, health workers, health planners and community-based organisations) to identify barriers and facilitators to integration and recommended implementation strategies. Thematic analysis will be used. Triangulation of findings will inform the ToC map for the adapted model of integrated services for AUDs. This model will then be piloted. Change in knowledge, skills and attitudes of health workers will be measured pre-implementation and post-implementation. Interrupted time series analysis will be used to identify change in the rate of identification of AUDs beyond that observed due to secular trends or by chance. The integrated model will be finalised for future implementation and larger-scale evaluation.

Ethics and dissemination Ethical approval was obtained from Addis Ababa University College of Health Science Institutional Review Board and Muhimbili University of Health and Allied Sciences Institutional Review Board. Findings will be disseminated to inform strategies for scale up of integrated interventions for people with AUDs in Tanzania and similar contexts.

BACKGROUND

Alcohol use is a major contributor to the burden of disease and injury worldwide, with a higher alcohol-attributable disease burden

Strengths and limitations of this study

▶ Innovations of the study approach include: Application of a mixed method approach that will provide a comprehensive understanding of the implementation challenges and how they can be overcome.
▶ Multidisciplinary and participatory approach, involving a broad range of mental health stakeholders, beyond the biomedical realm and across different levels of the healthcare system (community, health facility, healthcare organisation) which will enhance relevance and local buy-in.
▶ The pilot will largely be restricted to facility-based components of the Theory of Change map for an adapted model for integration of care for people with alcohol use disorders.
▶ The pilot evaluation will not have a control group.

in low-income and lower middle-income countries.[1] In 2016, harmful use of alcohol caused about 5.1% of all disability-adjusted life years and resulted in an estimated 5.3% of all deaths globally. The mortality resulting from alcohol consumption has been estimated to be higher than that caused by diseases such as HIV/AIDS, diabetes and tuberculosis.[1]

In studies from sub-Saharan African countries, the prevalence of problematic alcohol use has been found to be substantial among people attending healthcare facilities.[2–5] In previous studies from Tanzania, the prevalence of alcohol use and alcohol use disorder (AUD) has been shown to vary across populations,[6–9] with college students and women employed in food and recreation facilities reporting the highest levels of alcohol use and AUD.[6 7] The findings from these previous studies have led to recommendations to increase the accessibility of care for people with AUD.

Integration of care for people with mental, neurological and substance use disorders into primary healthcare has been recommended as an important strategy to narrow the treatment gap in low resource settings.[10] Not only is there scarcity of specialist mental health workers in most low- and middle-income countries (LMICs), but also primary healthcare is the place where people with AUDs commonly present with adverse physical and mental health effects of their condition.[11] Primary healthcare is also the entry point into the healthcare system for most people and is affordable and accessible to the majority. Therefore, primary healthcare workers are ideally placed to detect AUDs and provide first-line care.[12] To facilitate this integration, the WHO has identified packages of evidence based interventions for priority mental, neurological and substance use disorders that can be integrated into primary healthcare.[13] However, adaptation is essential to ensure that these packages of care are effective, sustainable, acceptable and feasible in different sociocultural and health system contexts. The development of a contextual plan or a model to guide the integration of interventions for mental healthcare (including AUDs) is recommended.[11 14–17] To date, there has been limited research into how evidence-based interventions for people with AUDs can be successfully integrated into primary healthcare services in LMICs.[17 18]

In the proposed study, we will use a mixed methods participatory approach to adapt and pilot a model for integration of care for people with AUD in Primary Healthcare (PHC) in rural Tanzania.

METHODS
Study design
The proposed study will use mixed qualitative and quantitative methods. The study will be conducted in two phases: phase 1 comprises a situational analysis, a series of participatory Theory of Change workshops and a qualitative study; phase 2 will be a quasi-experimental pretest–posttest pilot study, interrupted time series study and nested qualitative study. These phases will be informed by two formative studies (figure 1): a facility-based cross-sectional survey to measure the detection of AUD by primary healthcare workers and a scoping review to identify previous evidence of implementation of AUD interventions in primary healthcare settings.

Setting
The study will be conducted in Moshi rural district in Tanzania. The district is one of seven districts in the Kilimanjaro region of northern Tanzania. The Kilimanjaro region is located around 530 km from the main economic city of Dar es Salaam (the former capital city of Tanzania). Moshi rural district had 539 586 residents (262 897 male and 276 689 female) based on the 2012 census. The population is predominantly Christian. There are two district hospitals owned by the Catholic church, eight health centres and eighty dispensaries.

Moshi rural district has been selected to be the setting for this study based on the existence of previous epidemiological studies of AUDs in Tanzania. In these previous studies, the prevalence of alcohol use and AUDs was reported to be high and significantly different from other regions. On the basis of previous findings, it was recommended that access to interventions for AUD should be expanded.[6 7]

Phase 1: adaptation of an integrated intervention model for alcohol use disorders
Study population
Study participants will be selected purposively based on being a stakeholder in relation to the expansion of care for people with AUD. The sample will include representatives from the Ministry of Health, Kilimanjaro region and Moshi rural district health management team, mental health experts and researchers, health workers, people with lived experience of mental health problems and substance use disorders, representatives of organisations
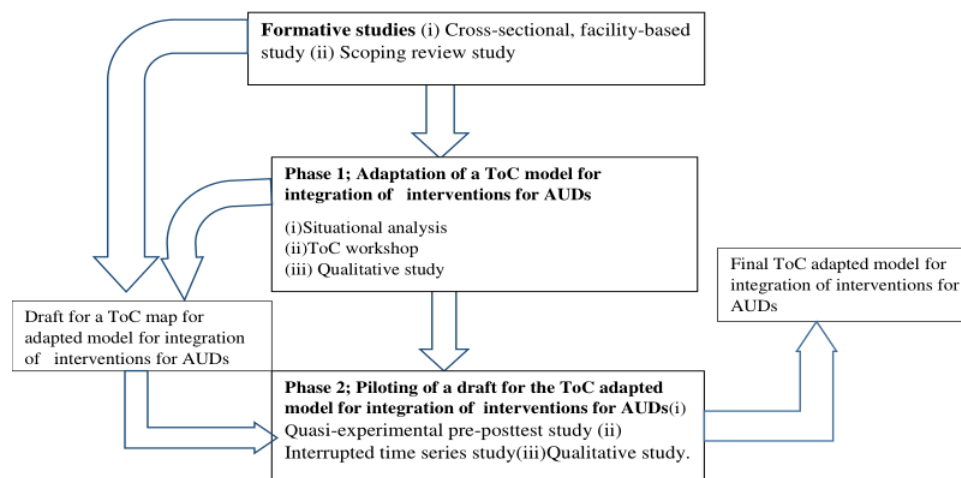

Figure 1 Diagrammatic illustration of the study phases on how two formative studies (facility-based cross-sectional survey and a scoping review) inform on the current study, and on how the study phases link to each other. AUD, alcohol use disorder; ToC, Theory of Change.

and other sectors who are working on mental health/alcohol related issues, religious and community leaders. A description on how participants will be engaged in the data collection activities is provided below.

Data collection and management

Data collection procedures for the adaption phase will involve a situational analysis, theory of change workshop and a qualitative study. Each of these elements will now be described in more detail.

Situational analysis

A situational analysis tool that was designed for district level planning of care for mental health and substance use disorders in LMICs will be adapted to collect information about resources and system functioning in relation to proposed integration of services for AUD in the study area. The tool has been applied previously at the district and subdistrict level in two other countries from East Africa.[18]

The tool provides a structured format for systematic mapping of the available resources and constraints to the integration of services for people with mental, neurological and substance use disorders, including alcohol use disorders. The tool covers the different pillars of the health system required to support a new programme, including leadership, financing, human resources, services, monitoring and evaluation and medication/psychosocial interventions. In addition, contextual information such as community resources: for example, about non-governmental organisations, faith-based organisations and mental health service user associations will be collected. The tool relies on information that is available in the public domain and consultation with key officials or public figures. The quantitative information collected from the situation analysis will be summarised descriptively (using frequencies and percentages), yielding information on: (1) the number of people with AUD in contact with services in the past year, (2) the number of mental health and non-mental health professionals and (3) the number of general and specialised healthcare facilities. A narrative report will also be prepared and used alongside the quantitative findings to inform the Theory of Change (ToC) workshops and identify areas requiring further exploration in the qualitative study.

ToC workshops

ToC is a participatory approach to mapping out how a programme (a complex intervention) can be implemented to achieve its goal. ToC provides a framework for identifying potential bottlenecks to implementation, as well as setting out indicators of success.[19]

Three ToC workshops will be conducted with a range of mental health stakeholders. The first ToC workshop will be conducted with mental health specialists and researchers who have familiarity with delivering, expanding or evaluating mental healthcare. The next two meetings will be done with mental health stakeholders

at the national, regional and district levels (including general health workers) who are responsible for policy-making, implementing and coordinating mental health services, as well as with potential service users.

The first workshop will consider potential desirable goals of integrated AUD care and work backwards to map out possible pathways to achieving these goals. Necessary pre-conditions will be identified based on the synthesised evidence, and the expertise and experience of the participants. The provisional ToC will be used as a starting point for the next two workshops, to stimulate discussion and refine particular aspects of the ToC map; however, participants will not be constrained by the draft ToC. Discussions will also focus on what types of interventions might be needed to be able to achieve the desired outcomes, the underlying assumptions and possible indicators of success.[16 17] The workshop sessions will be audio-recorded and minutes will be taken.

The main output of the ToC workshop will be a roadmap for implementation of integrated care for people with AUD in the study area. A narrative report will be drafted to complement the ToC roadmap, explaining the points of difference and how consensus was achieved. Key assumptions will be identified and explored in the qualitative study.

Qualitative study

A qualitative study will be conducted to (1) explore the feasibility and acceptability of the proposed ToC model of integrated care for AUD in PHC, and (2) identify anticipated facilitators, barriers and implementation strategies. A total of 15 to 20 in-depth interviews (IDI) is anticipated to be conducted, however, interviewing will continue until theoretical saturation is achieved. In addition, one focus group discussion (FGD) with the heads ('in charge') of PHC facilities and two FGDs with healthcare providers (HCP) will be conducted.

Selection of participants will be done purposively based on their work experience. Sampling characteristics of interest are job type, time in service, sex and age. One facility in-charge from six health centres and three HCPs from each health centre will participate in the FGD.

The focus of the IDIs and FGDs will be to explore the feasibility and acceptability of an adapted model of integrated care for AUDs in PHC; for example, what are the needed essential components, anticipated facilitators, barriers and strategies on how to overcome them. Moreover, participants will be asked to share their opinions on how the adapted model can be implemented during piloting, so that it will be acceptable and feasible. Interviews will be recorded, transcribed and translated into English. Thematic analysis for the IDIs and FGDs will be conducted based around themes aligned with the ToC map. The data will be managed using qualitative data analysis software NVivo, V.11.

Triangulation of the data from the situational analysis, ToC workshops and qualitative study will be conducted.

The final output will be a ToC map for the adapted model of integrated care for AUDs in primary healthcare.

Phase 2: piloting of an adapted model for intervention for alcohol use disorders

Piloting of an adapted model of integrated care for AUD will be conducted at the healthcare facility level. A mixed method approach will be applied, employing a quasi-experimental pretest–posttest study design and a qualitative study.

The ToC adapted model for integration of care for AUD will be used to guide the collection of process and qualitative data in the pilot evaluation. The final model of integrated care for AUD will be determined by the previous phases. However, based on the experience of previous studies, a pilot study will start with the following potential interventions for integration of services for AUD: (1) training HCPs on identification and treatment for AUDs, (2) application of a single question alcohol screening test to identify people who will need more detailed screening using the Alcohol Use Disorders Identification test (AUDIT), (3) interventions for AUDs based on a stepped care approach, (4) supportive supervision of HCPs and (5) documentation of integrated care for people with AUD. Below is a detailed description of each of these elements.

Screening for alcohol use

A single question alcohol screening test will be used to identify people who need further in-depth screening using the AUDIT. A meta-analysis study,[20] has recommended the use of a single question as a screening test for AUDs in primary care, but only when paired with longer screening tool to decide who need a brief intervention. A single question asks how many times in the past year that someone had X or more drinks in a day, whereby X is five for men and four for women. A response of more than once is considered positive. The WHO's AUDIT, has 10 items, and gives a score ranging from 4 to 40. A score of 8 or more indicates probable AUD, a score of 8 to 15 indicates hazardous drinking, a score of 16 to 19 indicates harmful drinking and a score of 20 or more indicates probable alcohol dependence. The AUDIT was developed on the basis of a cross-national study that included one country from East Africa (Kenya).[21] The AUDIT has been validated across different populations and LMIC settings.[21–23] The AUDIT has been adapted into the national language (Swahili) and used previously in Tanzania.[6–8] The Swahili version of the AUDIT has been validated and the psychometric properties found to be acceptable.[24]

Stepped care approach for the management of AUD

Stepped care is the WHO recommended approach for identification and management of AUDs. The identification of AUDs is conducted using AUDIT and, based on the scoring, the appropriate intervention will be delivered, as follows: (1) a person who scores less than 8 has no need of intervention, (2) a person who scores in the range of 8 to 15 needs brief intervention and periodic re-assessment, (3) a person scoring 16 to 19 needs a brief intervention and regular monitoring and (4) a person scoring 20 to 40 needs diagnostic assessment and, depending on the severity of physical dependence, assisted detoxification and other interventions may be required.[25]

Training for the management of AUDs

The training will seek to support healthcare providers to acquire skills for screening of alcohol use, interventions for AUDs and its associated comorbidities. The training package will contain materials from the following manuals: (1) WHO manual for AUDIT,[21] (2) WHO brief intervention package for hazardous and harmful drinking,[25] (3) WHO mhGAP intervention guide (evidence-based guidance on assessment, medication, psychosocial care and referral indications)[13] and (4) Programme for Improving Mental Healthcare (PRIME) training packages for HCPs (http://www.prime.uct.ac.za/prime-tools), including motivational interviewing techniques adapted for the primary care context. These manuals will be adapted to the Tanzanian context.

Documentation of integrated care for people with AUDs

The current clinical documentation forms and routine health information data collected in primary care are limited to general description and diagnosis. Data recording forms will be adapted in consultation with PHC staff in the study health centres to ensure a standardised and user-friendly approach. We anticipate that the following information will be documented: (1) general description, (2) number of people received screening for alcohol use and (3) number of people who received interventions for AUDs and information on referral to specialised care.

Supervision of integrated care for people with AUD

A facility supervision form will be adapted, in consultation with PHC staff in the area. This form assesses for: (1) administrative issues and (2) clinical skills in terms of diagnosis/mental state and physical health assessment, advice given, prescribing and psychosocial care. In collaboration with the district supervision team, we anticipate conducting monthly supportive supervision sessions. The goal of supervision is to provide in-service mentorship for screening, intervention and data collection for AUDs services in each health centre during the 6-month piloting phase.

Study participants will include all HCPs in the outpatient clinics in the study area (20 participants).

Evaluation of pilot intervention
Data collection and analysis

1. Pretest and posttest training assessments will be conducted to evaluate change in HCP knowledge, skills and attitudes. A pre and post training evaluation form will be adapted (http://www.prime.uct.ac.za/prime-tools). HCPs will be given an anonymised form with an

ID number that can link pre and post training assessment data. A paired-sample t-test analysis will be used to test for significant pre–post change.

2. Interrupted time series study of health worker identification of AUDs.

An interrupted time series study will be conducted using routinely recorded process data from the pilot health centres. Baseline data (pre-piloting phase) will be collected for 10 weeks before implementation of the pilot intervention. Data will be collected for a further 10 weeks during the implementation of the pilot model. The data will be recorded by the PHC workers on a customised reporting form. A primary outcome for this study is the number of people identified and recorded by PHC workers as having AUDs. Secondary outcomes will be numbers screened for AUDs, numbers who received brief intervention and numbers who were referred for more specialist care.

Interrupted time series statistical techniques, (segmented regression analysis)[26] will be used to identify a change in the rate of identification of a person with AUDs beyond that observed due to secular trends or by chance.

3. Qualitative study.

A qualitative study will be conducted to explore: (1) experience of HCPs during piloting of an adapted model of integrated care for people with AUDs, and (2) the encountered facilitators, barriers and strategies that were used to overcome them. A study team will conduct two FGDs with PHC providers who participated in the piloting phase. Thematic analysis will be used.

The pilot study findings will be used to inform finalisation of a model for integrated care for people AUDs in the study area.

Patient and public involvement

Participants were not directly engaged in the design of the study, however we will utilise participatory approaches to developing the model of care and will obtain in-depth perspectives of people with substance use disorders and community members during phase 1.

OUTCOMES

An adapted model for integrated care for people with AUDs that can be implemented and evaluated at larger scale in the Tanzanian primary healthcare system.

DISCUSSION

The study will provide comprehensive understanding of the implementation challenges, and how they can be overcome, in the integration of services for AUDs in the existing healthcare system. The multidisciplinary and participatory approach, involving a broad range of mental health stakeholders, beyond the biomedical realm and across different levels of the healthcare system, will enhance local buy-in, acceptability, feasibility and

sustainability of the integrated services. However, the pilot study will largely be restricted to the facility-based components of the ToC map for an adapted model for integration of care for people with AUDs and its evaluation will not have a control group.

ETHICS AND DISSEMINATION

Ethical approval was obtained from Addis Ababa University College of Health Science Institutional Review Board and Muhimbili University of Health and Allied Sciences Institutional Review Board. Findings will be disseminated to inform strategies for scale up of integrated interventions for people with AUDs in Tanzania and similar contexts.

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Contributors All authors DPM, CH, JMF and ST contributed to the development of a study protocol. DPM wrote the first draft, other authors read, provide inputs on and approved the final version of the manuscript.

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.

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