Development of a psychological intervention for people with bipolar disorder in rural Ethiopia

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Background
Evidence from high- and middle-income countries indicates that psychological interventions (PSIs) can improve the well-being of people with bipolar disorder. However, there is no evidence from low-income countries. Cultural and contextual adaptation is recommended to ensure that PSIs are feasible and acceptable when transferred to new settings, and to maximise effectiveness.

Aims
To develop a manualised PSI for people with bipolar disorder in rural Ethiopia.

Method
We used the Medical Research Council framework for the development and evaluation of complex interventions and integrated a participatory theory-of-change (ToC) approach. We conducted a mental health expert workshop (n = 12), four independent ToC workshops and a final workshop with all participants. The four independent ToC workshops comprised people with bipolar disorder and caregivers (n = 19), male community leaders (n = 8), female community leaders (n = 11) and primary care workers (n = 21).

Results
During the workshops, participants collaborated on the development of a ToC roadmap to achieve the shared goal of improved quality of life and reduced family burden for people with bipolar disorder. The developed PSI had five sessions: needs assessment and goal-setting; psychoeducation about bipolar disorder and its causes; treatment; promotion of well-being; and educational techniques to reduce anxiety and prevent relapse. Participants suggested that the intervention sessions be linked with patients’ monthly scheduled healthcare follow-ups, to reduce economic barriers to access.

Conclusions
We developed a contextually appropriate PSI for people with bipolar disorder in rural Ethiopia. This intervention will now be piloted for feasibility and acceptability before its wider implementation.

Keywords
Psychoeducation; behavioural intervention; relapse prevention; individual therapy; theory of change approach.

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Burden
Bipolar disorder is a severe mental illness with an estimated global prevalence ranging from 0.4 to 2.4%. In the 2017 Global Burden of Disease Study, bipolar disorder accounted for 9.3 million disability-adjusted life-years. In low- and middle-income countries (LMICs), the burden of bipolar disorder is exacerbated by a high treatment gap, ranging from 76 to 90%, which contributes to a risk of premature mortality double that of the general population. In Ethiopia, the lifetime prevalence of bipolar disorder ranges from 0.5 to 1.8%. Studies conducted in different settings in Ethiopia have found that people with bipolar disorder have multiple unmet needs, including a high relapse rate, premature mortality and verbal and physical abuse. In addition, bipolar disorder in Ethiopia is associated with substantial social, physical and functional role restrictions. Studies conducted in mental and general hospitals in Ethiopia have also reported a higher risk for hospital admission and length of hospital stay among people with bipolar disorder compared with other patients, which is associated with higher healthcare costs and insufficient use of limited mental health resources.

The unmet psychosocial needs in LMICs
Studies conducted globally have identified potential mediators and moderators of bipolar disorder treatment outcomes, such as treatment adherence, knowledge about the disorder and sleep hygiene. Moreover, social factors, including stigma and discrimination, stressful life events and substance use, may influence the course and outcome of the disorder. In LMICS, inadequate care for people with bipolar disorder contributes to functional impairment, stigma, discrimination, human rights violence and premature death. Therefore, to reduce the risk of relapse and improve the well-being of people with bipolar disorder, these factors must be addressed.

The Mental Health Gap Action Programme intervention guide (mhGAP-IG) lists mood stabilisers as the main treatment for bipolar disorder. However, in many LMICs, these medications are either unavailable or their supplies are unreliable. As a result, people with bipolar disorder in rural Ethiopia are treated with typical antipsychotic medications, which are more likely to cause adverse effects. Studies conducted in Ethiopia have also shown that people with bipolar disorder have unmet psychological, social and treatment-related needs, and people with mental illness need information about their illness and treatment.

Studies conducted mainly in high-income countries indicate the efficacy of psychological interventions for reducing relapse, hospital admission and symptom severity. Evidence-based, contextually adapted psychological interventions for people with mental illness are scarce in LMICs, including Ethiopia. Additionally, LMICs typically lack the specialised mental health professionals who could deliver psychological interventions. In response to this, the World Health Organization recommends task-sharing delivery of mental healthcare with available and affordable non-specialist health professionals, and integrating the service into primary healthcare (PHC). In Ethiopia, in line with the National Mental
Health Strategy, there have been efforts to scale up primary care-based mental healthcare. As a demonstration project, the Programme for Improving Mental Health Care (PRIME project) has developed and implemented a scalable mental healthcare plan for bipolar disorder based in PHC. According to a systematic review of non-specialist-delivered mental health interventions in LMICs, psychological intervention have positive effects on depression – another mood disorder – yet few psychological interventions have been developed for bipolar disorder in LMICs.

A systematic review that included studies from LMICs showed the effectiveness of psychological intervention in improving the outcomes of bipolar disorder. The review included 18 studies, but none of them were from low-income countries and only a single study was found from Africa. The review also reported that only a few of the included studies reported how the interventions were developed or adapted. The meta-analysis of 76 interventions reported that the interventions that were targeted at a specific cultural group were four times more effective than interventions provided to groups consisting of clients from a variety of cultural backgrounds. The adaptation of psychological intervention to the target population’s culture and social context also plays a critical role in improving the feasibility and acceptability of an intervention.

Psychological interventions that can be delivered by non-specialists may play a particularly important role in settings where there is inadequate access to mood stabilisers and mental health specialists. Therefore, the aim of this study was to develop a contextualised, scalable and manualised psychological intervention for people with bipolar disorder that could be delivered by PHC workers in rural Ethiopia.

Method

We used the Medical Research Council (MRC) Framework for the Development and Evaluation of Complex Interventions, integrated with a theory-of-change (ToC) approach. The MRC framework has four phases – intervention development, feasibility and piloting, evaluation and implementation – all of which take place as an iterative rather than a linear process. We followed four steps to develop the intervention: (a) a systematic review, (b) a qualitative study with people with bipolar disorder and their caregivers, (c) a mental health expert workshop and (d) ToC workshops with various stakeholders (Fig. 1). The findings of the systematic review and qualitative study were published previously, and the key findings are summarised in Table 2 and Supplementary File 1 available at https://doi.org/10.1192/bjo.2021.999.

ToC has been defined as a ‘theory of how and why an initiative works’. A ToC roadmap is developed using feedback from stakeholders, and is amenable to change throughout the intervention development and evaluation process. ToC can be incorporated into, and provide practical guidance for, the different phases of the MRC framework. The ToC approach has been used to develop, implement, monitor and evaluate complex mental health interventions in Ethiopia.

Setting

The qualitative study and ToC workshops were carried out at two adjacent sites: the Sodo and Butajira districts of the Gurage Zone, Ethiopia. Sodo district is located 100 km from the capital city of Addis Ababa, and had an estimated total population of 173,185 in 2014. Sodo Gurage is the largest ethnic group (85.3%), followed by Oromo (11.6%). Most of its population are followers of Orthodox Christianity (97%). Butajira district is located 130 km from Addis Ababa and had an estimated total population of 350,297 in 2017, with most of the population following Islam. The town of Butajira is a Health and Demographic Surveillance Site that has been functioning since 1987.

The Ethiopian healthcare system comprises three levels. The first level, which is the focus of this intervention, consists of PHC, which includes primary hospitals, health centres and health posts. Health centres are staffed with health officers, nurses and midwives. Health posts are staffed with health extension workers (HEWs), high school graduates with 1 year of training in disease prevention and health promotion activities at the community level. Sodo district has eight health centres and one primary hospital; Butajira district has one district hospital and 13 health centers. PHC workers in both districts have been trained and
supported to deliver mental healthcare through the PRIME project in Sodo district and the Task-Sharing for the Care of Severe Mental Illness in a low-income country (TaSCS) project, which aims to test the effectiveness and cost-effectiveness of task-sharing the care of people with a severe mental illness within the PHC setting in Butajira.

Participants and data collection methods

Mental health expert workshop

Twelve (three female and nine male) health experts and health professionals from diverse professional backgrounds (two psychiatrists, three public health professionals, five clinical psychologists, one pharmacist and one social worker) participated in this workshop. Findings from the systematic review and the qualitative study (stages 1 and 2) were presented and discussed. The experts were then asked to give their suggestions and recommendations on the content and delivery of the intervention based on the systematic review, the qualitative findings and their clinical and research experience. The workshop was conducted in Amharic and English in Addis Ababa, and lasted for 3 h. A.F., a psychiatrist, facilitated the discussion. The discussion was audio-recorded and notes were taken by the first author.

ToC approach

To reduce power imbalances among ToC workshop participants, we initially conducted separate workshops with groups of stakeholders with the lower difference among them. Additionally, we engaged a balanced number of participants from each stakeholder group to ensure the representation of various stakeholders’ voices: (a) people with bipolar disorder and their caregivers, (b) women community leaders, (c) male community and religious leaders, and (d) PHC workers and district-level government office personnel. Even within these broad categories, power imbalances exist, e.g. between people with bipolar disorder and caregivers or between PHC workers and district-level government office personnel. In this setting, people with bipolar disorder commonly rely on caregivers to support them to attend meetings, and so the presence of both caregivers and people with bipolar disorder was necessary. To address this concern, within workshops, the facilitators paid particular attention to ensuring that all voices were heard. We grouped PHC workers and government officials in one ToC workshop, while the officials were health professionals and had experience working in a PHC setting. Additionally, PHC workers and district-level officials have a culture of working together for a common purpose. The final ToC workshop included all participants from the stakeholder groups to ensure that each group could hear the others’ voices, and to discuss issues that needed consensus.

The ToC workshop participants were selected purposively based on their experience in mental healthcare service delivery or roles in traditional or social associations in the communities. The first four ToC workshops were conducted in the Sodo district in August 2019, and the last ToC workshop was held in Butajira town in September 2019. All ToC workshops were co-facilitated by M.D. and S.A., both of whom are PhD students. S.A. has previous experience in facilitating ToC workshops with various groups in the study site. All participants were given an opportunity to express their opinions, and were encouraged to identify challenges and suggest possible solutions for each topic area. The facilitators summarised the discussions, recorded key points on a flip chart and asked for confirmation. All ToC workshops except the final one, had two sections: (a) exploring the feasibility and acceptability of a psychological intervention; and (b) developing a ToC map that indicated the causal pathway through which the proposed psychological intervention was expected to achieve consensus in its short-, medium- and long-term effects, identification of preconditions for achieving the effect, possible barriers and facilitators and indicators of success.

In the first section, findings from the systematic review and qualitative study were presented, participants were introduced to the objectives of the ToC workshop, and their expected roles were outlined in a Microsoft PowerPoint for Windows presentation prepared in Amharic. Participants then discussed the findings, the potential benefits of psychological intervention, and the feasibility and acceptability of this approach. The participants were asked to consider anticipated or experienced responses to the intervention in relation to the culture and religion of the society, health system resources; the impact of the socioeconomic status of people with bipolar disorder and their caregivers; and the community, transportation availability, affordability, accessibility of the healthcare service, the PHC workers’ time and any other relevant considerations.

During the second section, we used farming metaphors to explain the ToC concepts, procedures and avoid technical terms. For example, we asked question like: What did the farmer want to achieve (effect)? What do farmers do to prepare the land for farming (interventions/pre-conditions)? Which activities should be done first and last, and why? The participant responses were used to explain how a similar way of thinking can help us to plan the development and testing of psychological intervention.

The actual ToC workshop then started by asking the participants what they wanted to see in the long run for people with bipolar disorder. Short-, medium- and long-term outcomes and wider effects were agreed upon, and then the pathways, interventions, preconditions, assumptions and indicators of success were mapped using sticky notes posted on the wall. An integrated ToC map was drafted by reviewing the ToC maps arising from each of the four workshops alongside the minutes and the recorded discussions. The goal of the fifth and final ToC workshop was to bring all stakeholder groups to a consensus on the content, timing, duration and number of sessions of the intervention, including implementation strategies to overcome potential barriers, in the context of broader care for people with bipolar disorder. In an initial presentation, the shared and divergent ideas from the preceding workshops were summarised and used to prioritise discussion points.

All ToC workshops were conducted in Amharic, lasted an average of 5 h, were audio-recorded and minutes were taken. The minutes, drafted ToC maps and recorded ToC workshops were reviewed by M.D. and A.F. to refine the ToC map and finalise the content of the psychological intervention. The draft manual was translated into the local language, and PHC workers reviewed and approved the content for pilot testing.

Analysis

All audio recordings were transcribed verbatim in Amharic and then translated into English. The transcripts were imported to OpenCode version 4.03 for Windows (Umeå University, Umeå, Sweden; see https://www.umu.se/en/department-of-epidemiology-and-global-health/research/open-code2/) to facilitate data management and assist analysis. We used thematic analysis procedures. First, MD conducted line-by-line coding of all five ToC workshop transcripts and shared them with the second author (C.H.) for review. M.D. and C.H. mapped codes onto themes deductively based on key components of the ToC map, including key tasks, intervention, preconditions, assumptions and indicators, as well as acceptability and feasibility (Table 3). Finally, we summarised the findings in the tables and text, and identified illustrative quotes.

In each ToC workshop, four draft ToC maps were developed through discussion and consensus, and then combined by the authors to develop a single ToC map. Finally, this final draft ToC map was refined and approved in the fifth ToC workshop with all ToC workshop participant groups.
We triangulated the findings with different information sources (Table 2) to increase trustworthiness. Furthermore, M.D. and S.A. were engaged for an extended time in the field. The involvement of co-authors with multidisciplinary backgrounds improved data interpretation.

Quality of reporting
We used the Guidance for Reporting Intervention Development (GUIDED) checklist35 to report the intervention development process.

Ethical approval
The Institutional Review Board of the College of Health Sciences of Addis Ababa University approved the study (reference number 043/17/Psy), and written informed consent was obtained from each participant.

Results

Mental health expert workshop
Mental health experts suggested two intervention components: (a) components that could be used to improve the PHC workers’ skills in establishing therapeutic rapport and competence in needs assessment and goal-setting; and (b) the ‘active ingredients’ of the intervention, such as psychoeducation, development of relapse prevention plans and behavioural techniques such as muscle relaxation and breathing exercises, to help people with bipolar disorder to control their overarousal, aggression and anxiety symptoms. Experts recommended four intervention sessions for the following reasons: in our systematic review, most of the included studies included people with bipolar disorder and their caregivers described the varying nature and intensity of symptoms over time. Because of the episodic nature of the illness, bipolar disorder was perceived by many people with bipolar disorder and their caregivers to be caused by evil spirits or other supernatural acts, leading them to try various religious or traditional treatments. They also noted the chronicity of the illness and the need for long-term support:

‘… Mental illness is not like tuberculosis, which gets cured just by giving medication. Mental illness requires long-term support and effort from doctors, caregivers and the surrounding societies …’

People with bipolar disorder and caregivers reported that people with bipolar disorder are sensitive; simple stressors can be enough to trigger their illness. When other people speak of their own social affairs, they may be suspicious and assume that they are the focus of discussion, which may hurt them psychologically. Community leaders also noted that medications are important to people with bipolar disorder, and they believe that caregivers had a responsibility to support access. People with bipolar disorder and their caregivers reported experiencing stigma because of having a mental illness or having a relative with mental illness. One caregiver said:

‘… At the coffee shop, at a wedding, there are people who treat [the person with bipolar disorder] as if she is a different person. In such situations, there are times that she would return to home because her feelings get hurt …’

The intervention was perceived as important because it would provide information about bipolar disorder, its causes and treatments, and would decrease misconceptions. One participant said:

‘… People take patients to different traditional places because of lack of awareness. As long as society is well-informed about the intervention and where they can access it, they will go to the health facility as soon as they feel sick. For instance, if someone gets malaria the society is well-informed about where to get treatment and the same is true in this case’.

The health professionals also expected that the intervention would be acceptable for PHC workers because it would help them develop their skills and would improve the acceptability of the service. This, in turn, was predicted to improve the mental health knowledge of people with bipolar disorder, their families and the community, and increase treatment adherence and improve outcomes. Health professionals reflected that, often, people with bipolar disorder visit health facilities only after the illness become severe. They emphasised that early detection of relapse should be addressed in the intervention.

Participants in all groups considered the health centre as the ideal place for the intervention because this is where people with bipolar disorder receive their regular follow-ups and fill their prescriptions. Additionally, a quiet and private place was preferred, but without segregating people with bipolar disorder from other

Results of the ToC workshops

Four independent ToC workshops and one ToC workshop that included all participants were conducted, with a total of 59 participants (Table 1).

Feasibility and acceptability of psychological intervention
Participants perceived that PSI was needed for people with bipolar disorder. However, they also argued that the developed intervention must be feasible and acceptable to be implemented. The group that

| Table 1: Theory-of-change workshop participants |
|-----------------------------------------------|
| Stakeholder group                            | Female | Male | Total |
| ToC with patients and caregivers             |        |      |       |
| People with bipolar disorder                 | 4      | 4    | 8     |
| Caregivers                                  | 6      | 5    | 11    |
| ToC with male community leaders              |        | 8    | 8     |
| ToC with female community leaders            | 11     |      | 11    |
| ToC with professionals                       |        |      |       |
| Primary healthcare workers                   | 5      | 11   | 16    |
| District-level government office representative | 0    | 5    | 5     |
| Final ToC workshop participants              | 26     | 33   | 59    |
| Total                                        | 59     | 59   | 118   |

ToC, theory of change.
health centre attendees, to avoid stigma and discrimination. Some participants from the community and health professionals suggested that the intervention should be located at the health post to increase accessibility, and it should be delivered by the health centre staff as part of outreach activity. Finally, participants in the final ToC workshop agreed that the intervention should be delivered at the health centre by PHC workers because PHC clinicians are in a better position to know the mental health history and current health status of the person with bipolar disorder, and this will improve trust because the clinician is likely to be known to them from their routine care. Participants also mentioned the importance of HEWs creating awareness in the community, in the form of a campaign or through another mechanism, as an important supportive activity.

The participants came to a consensus that a one-to-one consultation format would be better than a group format. Among the reasons, people with bipolar disorder may not want to talk about their social, economic, and personal lives in front of others. Furthermore, in rural areas, people may struggle to attend group interventions at a specific time. Similar to the mental health experts, participants also suggested the option of a common session for people with bipolar disorder and their caregivers as long as the patients are willing and it does not interfere with their privacy.

Regarding the session, people with bipolar disorder and their caregivers and community groups suggested that the number, duration and frequency of intervention sessions should be determined based on the content and advice of professionals. Additionally, they underlined the importance of aligning the monthly intervention sessions with regular appointment dates, to encourage attendance by minimising transportation costs and time. PHC workers provided different suggestions for the duration of session (from 20 to 45 min). Finally, considering the workload of PHC workers, they reached a consensus to reduce the intervention content per session to be covered in a maximum of 20 min and to increase the number of sessions from four to five. They also suggested working in collaboration with HEWs, especially to help people with bipolar disorder with their treatment adherence. The PHC workers raised the issue of workload and expressed concerns about people with bipolar disorder and their caregivers being made to wait for a long time while they delivered the intervention.

All participants agreed on the importance of preparing an information leaflet to facilitate the sessions and encouraging the participants to share the information with their entire families and neighbours. The key findings and contributions of various methods to the development of the intervention are summarised in Table 2.

ToC Map

Factors identified as necessary to the development and implementation of a psychological intervention for people with bipolar disorder are summarised in the ToC map (Fig. 2) and described below.

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### Table 2 Summary of contribution of various methods to the development of a psychological intervention manual

| Methods                          | Findings                                                                 | Contribution to the psychological intervention development               |
|----------------------------------|--------------------------------------------------------------------------|--------------------------------------------------------------------------|
| Systematic review                | • Identified psychological intervention: psychoeducation, family therapy,  | Defined the type of intervention                                          |
|                                  |   cognitive–behavioural therapy and mindfulness-based cognitive therapy  | • Defined the intervention content                                       |
|                                  |   • The number of sessions ranged from 1 to 18                           | • The studies were used to identify the intervention manual              |
|                                  |   • The content of the intervention includes education about signs and  |                                                                         |
|                                  |   symptoms of bipolar disorder, the causes and prognosis of bipolar    |                                                                         |
|                                  |   disorder, treatment adherence and side-effects of medication, early   |                                                                         |
|                                  |   identification of symptoms of relapse, triggering factors, substance   |                                                                         |
|                                  |   use, regular habits and management plans or prevention strategies     |                                                                         |
|                                  |   • Intervention providers were mental health specialists or practitioners|                                                                         |
| Qualitative study                | • People with bipolar disorder and their caregivers reported perceiving | Define problems from the people with bipolar disorder and caregivers’ lived |
|                                  |   early signs and symptoms of relapse                                   |   experience                                                                  |
|                                  |   • A major concern for people with bipolar disorder and their caregivers | Identify psychosocial factors that could be addressed in current psychological intervention|
|                                  |   related to the patients’ illness being identified                     |                                                                         |
|                                  |   • Perceived factors that precipitate or worsen the illness were        |                                                                         |
|                                  |   explored                                                              |                                                                         |
|                                  |   • Coping mechanisms used by people with bipolar disorder to cope       |                                                                         |
|                                  |   with stressful life events were explored                              |                                                                         |
|                                  |   • Bipolar disorder has a negative effect on the social, functional    |                                                                         |
|                                  |   and economic status of people with bipolar disorder and their families|                                                                         |
| Mental health expert workshop    | • Possible components of the intervention were suggested to address the  | Experts suggested intervention components based on their clinical and research experience as well as findings of qualitative and systematic review |
| Theory-of-change workshops       |   concerns of people with bipolar disorder and improve their health and  | • Explored the feasibility and acceptability of psychological intervention   |
|                                  |   treatment outcome                                                     | • Defined the necessary resources to give the intervention                 |
|                                  |   • Stigma and financial problems                                       | • Support the patients to use the existing supporting platforms like the safety net programme |
|                                  |   • Need for psychological intervention                                 | • Suggested the intervention content, frequency of sessions, format, and providers |
|                                  |   • The necessary condition for improving the acceptability and          | • Defined the desired outcome                                              |
|                                  |   feasibility of psychological intervention                             | • Defined indicators for success                                            |
|                                  |   • Developed theory-of-change map                                      |                                                                         |
|                                  |   • Need for training in communication skills for intervention providers |                                                                         |
|                                  |   • Need to improve community awareness                                  |                                                                         |

‘People do not come alone and will have someone with them, those that came will also get an education on the subject that they will later transfer to other family members and improve the support they provide to the patient’.
Outcomes and effects

People with bipolar disorder and their caregivers mentioned improved social and psychological well-being and reduced family burden, hospital admission and school drop-out as the desired long-term outcomes of the intervention, with reduced mortality as a potential broader effect of the intervention. Community leaders focused on stigma reduction and improved physical, social and functional well-being as the preferred long-term outcome. PHC workers and district health office managers emphasised the improved quality of life of people with bipolar disorder and reduced family burden as a long-term outcome. Participants also mentioned reduced mortality and disability related to the illness as a desired effect, but recognised that these require multisectoral changes and are not expected to be achieved just through the psychological intervention alone. In the final ToC workshop, participants discussed the feasibility of the identified long-term outcomes and reached a consensus that reduced hospital admissions, reduced caregiver burden and improved quality of life would serve as the long-term outcomes. Participants also discussed and agreed that the reduction of mortality and school drop-out needs the involvement of various stakeholders beyond the delivery of psychological intervention. As a result, they reached a consensus that reduced mortality and school drop-out would serve as an effect.

Preconditions for intervention

Participants were asked to list the interventions needed, preconditions, assumptions and indicators. Participants mentioned that there should be interventions for people with bipolar disorder and their caregivers, implemented at the community and health facility level. Likewise, the preconditions, assumptions and indicators were also identified to achieve an agreed-upon outcome were also identified, as illustrated in Table 3.

Description of the newly developed intervention manual

The findings from the formative qualitative study and ToC workshops were triangulated to identify the unmet needs and priorities of people with bipolar disorder. These inputs were then used to select the intervention components and to decide on the number, frequency and duration of sessions, as well as the facility where the intervention should be provided. During the design of the intervention, the identified needs and priorities were linked to the intervention components (Table 4).

In general, the intervention manual was structured in five sessions: (a) needs assessment and goal-setting; (b) psychoeducation about bipolar disorder, its causes and influencing factors; (c) treatment and treatment adherence; (d) sleep hygiene and...
problem-solving techniques to promote well-being and; (e) behavioural techniques to target anxiety and relapse prevention, and closing session (Table 4). Each session was intended to last for 20 min and be delivered every month, aligned with the person’s attendance for routine care. The intervention was designed to be given by PHC workers who had been trained in the mhGAP-IG and had received 1 week of theoretical and 1 week of practical training.
The manuals and leaflets were translated into Amharic by two clinical psychologists with experience of working with people with mental illness. Mental health experts and PHC workers involved in the ToC workshop reviewed the translated manual and gave feedback that helped to simplify the manual’s structure and readability. They recommended that illustrations in the manual and leaflet be prepared based on local realities; for example, to include false banana trees, which are very common in the study area, as well as pictures representing people from different religions and genders. Case stories were also prepared and annexed to enable PHC workers to engage better and use them as illustrations as needed.

### Discussion

This is the first manualised psychological intervention guide to be deployed in an integrated care context for people with bipolar disorder. We used qualitative exploration to understand the unmet needs and priorities of people with bipolar disorder and their caregivers that could potentially be addressed by psychological interventions. Priorities identified by primary beneficiaries are important because psychological interventions work through common factors, such as the therapeutic alliance, positive expectations and a convincing treatment rationale, as well as through treatment-specific components. Therefore, the components of psychological intervention and the cultural adaptation of the intervention to the local context are vital for improving an intervention’s effectiveness.

We used ToC approaches involving different stakeholders, including people with bipolar disorder and their caregivers, community leaders and health professionals. This participatory approach was useful to understand the context and make decisions that reflect scientific evidence the views of patients/caregivers and service providers, to develop and implement the intervention. Therefore, the ToC approach worked as a bridge between the evidence and the local context, helping to ensure ownership, acceptability and support for the intervention, which are key to its implementation. The participatory approach also helped to build trust, encouraging the pooling of resources and knowledge.

In our mental health expert and ToC workshops, psychoeducation about bipolar disorder, its causes, treatment and the course of the illness were considered essential by all groups of participants.
This was seen as the key to improving the knowledge and attitudes of people with bipolar disorder, and their caregivers helping them to understand the illness and its treatment. In this rural setting, literacy levels and access to formal education (beyond primary) are low, and most people lack access to the internet, underscoring the value of including consistent, relevant and evidence-based information within the intervention.

In the ToC workshop, participants spoke of the importance of caregivers’ support and endorsed the importance of involving them in the intervention. Previous studies also mentioned that family members are the primary source for the physical, psychological and treatment-related support for people with mental illness in many low-income countries. The positive effect of family interventions on clinical and functional outcomes of people with bipolar disorder may be even greater in this setting. However, previous work from Ethiopia has also highlighted the differing priorities of people with mental health conditions and their caregivers, underlining the need to ensure that the person with bipolar disorder remains at the centre of care.

People with bipolar disorder and their caregivers, community leaders and health professionals had different perspectives for improving long-term outcomes. People with bipolar disorder and their caregivers prioritised social and functional outcomes, such as educational impact, stigma and productivity, as the most important long-term outcome. However, community leaders acknowledged the difficulties of social engagement related to public stigma and emphasised stigma reduction as a long term-outcome, as they viewed these as important barriers to reintegration into the community. Health professionals identified the improved quality of life of people with bipolar disorder and reduced caregiver burden as long-term outcomes. This may also reflect the view of health professionals with limited expertise regarding the longer-term outcome of bipolar disorder. These different perspectives are relevant and point to the need for a multi-layered intervention package beyond a health facility-based intervention to address multidimensional needs. Further development work to address these multisectoral and multidimensional issues is essential.

In LMICs like Ethiopia, the treatment gap for mental illness is around 90%. The World Health Organization has recommended the integration of mental health services within PHC settings to address unmet mental health needs. In our study, participants supported the delivery of the intervention by PHC workers to facilitate its future integration within routine care. Although the participants were concerned about the possible work burden on PHC workers, they considered that training would enhance PHC providers’ skills, interest and confidence in providing the intervention, which could in turn reduce the feeling of work burden. Additionally, group intervention was noted to be less feasible for this rural setting, where there is inadequate local transportation and it is difficult to identify a convenient time for group intervention.

### Implications of the study

This intervention was developed based on previous evidence and by involving mental health specialists with clinical and research experience, PHC workers, people with bipolar disorder and their caregivers, and community leaders. The approach focused on intervention content, manual and leaflet preparation, language and delivery strategies. This improved stakeholders buy-in, ensuring that this intervention will be feasible and acceptable. A pilot test to assess the feasibility, fidelity and acceptability in routine clinical settings, and to ensure the scalability and preliminary efficacy of the developed psychological intervention, is warranted.

### Strengths and limitations

The main strength of this study is that we began the intervention development by synthesising evidence on the efficacy of the psychological intervention in LMICs and conducting formative work. Our study involved diverse stakeholder groups, which can ensure the intervention’s local appropriateness through stakeholder buy-in and direct inputs. Although we sought to reduce the impact of power imbalances in the ToC workshops by conducting separate workshops with groups of similar stakeholders, a residual power imbalance (e.g. between caregivers and people with bipolar disorder) may still have affected the content of what participants felt comfortable to expressing. The skilled facilitator sought to address this by actively seeking out the views of people with bipolar disorder. However, even skilled facilitation did not fully address the power imbalance; therefore, future studies may consider capacity-building training to enhance participants’ capacity before conducting ToC interventions. Finally, we brought all stakeholder groups together at the end of the study, which allowed us to ensure that the views of all participants were incorporated. However, some participants in the group of people with bipolar disorder, their caregivers and the community, struggled to understand the visual presentation of the ToC map, especially the final ToC map that included the merged ToC map. This could be because of the low literacy rate in a rural community, the lack of experience with intervention development and the technical elements of the ToC map. Regarding reviewing the manual, people with bipolar disorder and their caregivers were not involved in reviewing the manual, unlike PHC workers. However, in the final ToC workshop, the intervention content and the number and frequency of the sessions were discussed and approved by all ToC participants, including people with bipolar disorder and their caregivers. Additionally, we plan to evaluate the feasibility and acceptability of the actual implementation of the intervention and address any gaps that are identified in the next step.

Although financial problems were repeatedly reported in our qualitative study and ToC workshops, economic problems were not directly targeted with our intervention. However, we do anticipate indirect benefits to financial status through the problem-solving techniques and change to the anticipated outcomes, like reduced symptom severity and caregiver burden, improved well-being of people with bipolar disorder and reduced stigma. However, further studies are needed to determine better ways to reduce financial problems.

In conclusion, the mixed approach that we have used to develop the intervention, including a systematic review, qualitative study, expert workshop and ToC workshops, enabled us to understand the needs and priorities of people with bipolar disorder and their caregivers, and identify intervention components. The ToC workshop helped us to develop the ToC map, which includes an intervention component, underlying assumptions and preconditions for its effective implementation. Finally, the methods enabled us to develop a culturally appropriate, individual psychosocial intervention that can be delivered in five sessions in the PHC setting. This intervention needs to be tested for feasibility, acceptability and effectiveness before wider implementation.

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Data availability
The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials.

Author contributions
M.D., A.F. and C.H. designed the study. M.D. led the study, and drafted and revised the manuscript with supervision from A.F., C.H., R.M. and L.N. The mental health experts workshop was led by M.D. and M.D. and A.F. The ToC workshops were run by M.D. and S.A. M.D. and C.H. conducted the analysis. A.F., C.H., R.M., S.A. and L.N. edited the paper. All authors read and approved the final manuscript.

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Declaration of interest
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