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Adapting and piloting a social contact-based intervention to reduce mental health stigma among primary care providers

Protocol for a multi-site feasibility study

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Adapting and piloting a social contact-based intervention to reduce mental health stigma among primary care providers: Protocol for a multi-site feasibility study

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ABSTRACT

Stigma among primary care providers (PCPs) is a barrier to successful integration of mental health services in primary healthcare settings globally. Therefore, cross-culturally adaptable and feasible strategies are needed to reduce stigma among PCPs. This protocol is for a multi-site pilot study that aims to adapt and evaluate crosscultural feasibility and acceptability of a social contact-based primary healthcare intervention in 7 sites in 5 low-and-middle-income countries. A mixed methods pilot study using an uncontrolled before-after study design will be conducted in China (Beijing, Guangzhou), Ethiopia (Sodo), India (Bengaluru, Delhi), Nepal (Syangja), and Tunisia (Testour). The intervention, entitled REducing Stigma among HealthcAre ProvidErs (RESHAPE), is a collaboration with people with lived experience of mental health conditions (PWLE), their family members, and aspirational figures (who are PCPs who have demonstrated high motivation to integrate mental health services). PWLE and their family members are trained in a participatory technique, PhotoVoice, to visually depict and narrate recovery stories. Aspirational figures conduct myth busting exercises and share their experiences treating PWLE. Outcomes among PCPs will include stigma knowledge, explicit and implicit attitudes, and mental healthcare competencies. To understand the feasibility, and acceptability of the intervention, qualitative interviews will be carried out with PWLE, family members, and aspirational figures, PhotoVoice trainers, mental health specialists co-leading the primary care trainings, and PCPs receiving mental health training. The sites will also generate evidence regarding feasibility, acceptability, recruitment, retention, fidelity, safety, and usefulness of the intervention to make further adaptations and modifications. The results will inform cross-cultural guidelines for collaboration with PWLE when conducting mental health training of primary healthcare

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1. Background

The recent World Mental Health Report (World Health Organization, 2022) calls for reform of health services to put greater emphasis on the delivery of mental health services in primary care settings. This is consistent with nearly two decades of efforts to expand primary care based mental health services, including initiatives such as the mental health Gap Action Programme (mhGAP) (World Health Organization, 2016). These task-sharing approaches in which care traditionally delivered by mental health specialists, such as diagnosis and treatment of mental health conditions, is taken on by primary care providers (PCPs) including doctors, nurses, and healthcare auxiliary workers. There is now a strong body of evidence that mental health interventions can effectively be delivered by PCPs and other non-specialists in lowand middle-income countries (LMICs) in the context of research studies (Hanlon et al., 2022; Keynejad et al., 2022; van Ginneken et al., 2021). However, there continues to be lack of large-scale benefit of these initiatives when delivered under real-world conditions; for example, even after mhGAP trainings of PCPs, there continues to be low rates of detection of mental health conditions in primary care settings (Fekadu et al., 2022; Jordans et al., 2019; Kauye et al., 2014).

One of the barriers to success of primary-care based initiatives is that PCPs, similarly to other healthcare workers and members of the general public, share negative stereotypes about people with lived experience of mental health conditions (PWLE) (Koschorke et al., 2021; Thornicroft et al., 2022; Vistorte et al., 2018). Stigma and discrimination against PWLE contribute to poorer quality of health services, including both physical and mental health care, thus contributing to earlier mortality among PWLE (Druss et al., 2010; Fekadu et al., 2015; Henderson et al., 2014; Thornicroft, 2013). The recent Lancet Commission on Ending Stigma and Discrimination in Mental Health includes multiple strategies to tackle the originators and facilitators of stigma, with one of the key advocacy points focusing on partnership with PWLE (Thornicroft et al., 2022).

Given that scaling-up of mental health integration into primary care is often done within government health programs, typically without the input of PWLE regarding how these services should be delivered, there is an opportunity to develop new scalable implementation strategies for collaboration with PWLE and ultimately improve the quality of mental health services in primary care. Greater engagement with PWLE to shape primary care-based mental health services has multiple potential benefits. First, social contact with PWLE is associated with positive changes in attitudes as well as improved behavior towards PWLE (Thornicroft et al., 2022). In addition, when primary healthcare workers are trained by PWLE, they learn not only the clinical criteria for diagnosis and treatment, they also learn what matters most to PWLE and their family members (Kohrt et al., 2020, 2021). This can lead to more person-centered care and redefining of recovery that reflects what PWLE want (Gurung et al., 2022), rather the reductionism to changes in symptom checklists distributed by pharmaceutical companies (Crawford et al., 2011).

For strategies of collaborating with PWLE to improve primary care services, the approaches need to be feasible, acceptable, and perceived as beneficial across a range of healthcare systems around the world. Strategies that are highly tailored to one country or setting may not be feasible or effective when delivered in another context. Given that mental health and attitudes toward mental health are strongly influenced by culture, there is a need for evidence-based and also culturally adaptable strategies (Javed et al., 2021; Kirmayer and Swartz, 2014; Kirmayer and Ryder, 2015). Therefore, our goal was to adapt and pilot test a strategy, in partnership with PWLE, for reducing stigma among PCPs in diverse global settings. In this protocol, we describe the

multi-site collaboration, strategies for adaptation, and procedures for pilot testing in order to modify the implementation strategy for worldwide use and to enable future multi-site hybrid implementation-effectiveness trials of the strategy.

2. Methods

2.1. Multi-site study collaboration: INDIGO

This multi-country adaptation and pilot study of a strategy, in collaboration with PWLE, to reduce stigma among PCPs was conducted within the International Study of Discrimination and Stigma Outcomes (INDIGO) Partnership (Gronholm et al., 2023). INDIGO was founded on the idea of more global solutions to reduce stigma and discrimination (Thornicroft et al., 2019). With the broader global collaborations of the INDIGO Network, the INDIGO Partnership is a 5-year multi-country initiative funded by the United Kingdom Medical Research Council to pilot strategies to reduce stigma at different levels of the healthcare system (specialist care, primary care, and community settings). This includes developing common guidance on cultural adaptation of interventions, the development and adaptation of measurement strategies to attitudes and behavior that can be used across diverse settings, and the piloting of interventions at different health systems levels across LMICs to identify what are feasible and acceptable strategies for scaling up common framework of evidence supported, culturally adaptable stigma reduction (Gronholm et al., 2023). This domain of stigma reduction among PCPs by collaborating with PWLE is the focus of the current protocol.

2.2. Settings

The INDIGO Partnership includes 7 sites across five LMICs: China (Beijing and Guangzhou), Ethiopia (Sodo), India (Bengaluru and Delhi National Capital Region), Nepal (Syangja), and Tunisia (Testour). The details of the study sites, including their primary health care systems and types of mental health training for primary healthcare workers, are described in Table 1. Of note, even though aspects of this intervention were already piloted in Nepal (Kohrt et al., 2018a, 2021), the original piloting was done in the southern semi-urban area of Nepal when mhGAP was integrated within the government healthcare system. The INDIGO current study will be implemented in remote hilly region of Western Nepal (a more rural and resource poor area) in the context of integrated mental health training provided by the government.

2.3. Intervention: RESHAPE

The anti-stigma intervention for PCPs piloted in the 7 sites is "REducing Stigma among HealthcAre ProvidErs" (RESHAPE). RESHAPE was developed in Nepal and is based on principles of social contact to reduce stigma (Kohrt et al., 2020). RESHAPE is an implementation strategy to modify how mental health trainings of PCPs, such as mhGAP, are conducted. In standard mhGAP and similar trainings, psychiatrists and other mental health clinical specialists conduct the training. However, in RESHAPE, the training includes recovery testimonials and social contact with PWLE, as well as testimonials from aspirational figures, who are PCPs who have already taken on delivery of mental health services. In RESHAPE, PWLE and their caregivers are trained using a participatory visual technique known as PhotoVoice. These trainings are approximately 6–8 sessions (typically 1 session over the course of a day, and one session per week). The PhotoVoice training is used to teach PWLE basic photography techniques, presentation skills, stress

Table 1
Study site and settings.

Site	Description of Location	Primary healthcare system details	Type of existing standard mental health training for primary healthcare workers in site prior to INDIGO
Beijing, China	INDIGO will be implemented by Peking University Sixth Hospital, also known as Peking University Institute of Mental Health, which is the base of clinical treatment, practitioner training, and scientific research in psychiatry and mental health at Peking University. Located in Haidian District in Beijing, which has a population of 3 million, Peking University Sixth Hospital serves patients from all over the country.	The primary healthcare system in Beijing consists of general practitioners, nurses, public health workers, management staff and physician assistants. Primary healthcare facilities provide basic clinical services, epidemic prevention services (vaccination for children, COVID-19 vaccination, etc.), and chronic disease management (follow-up management of people with serious mental health conditions, hypertension, and diabetes).	The mental health training for primary healthcare workers is a community mental health prevention and treatment training, lasting 1 or 2 days. This is carried out in Beijing by psychiatrists and management staff. The site teams integrated RESHAPE intervention within this standard training.
Guangzhou, China	INDIGO will be jointly implemented by the Affiliated Brain Hospital of Guangzhou Medical University and the Qiwei Mental Social Work Service Center in Tianhe District, Guangzhou. Implementation will be done in the Tianhe District of Guangzhou, Guangdong Province, China. Tianhe District is one of the 11 districts of Guangzhou, with a population of 2.2 million.	Primary health care is provided by more than 20 community health service centers in this district. There are 20 primary mental health care staff such as public doctors, psychiatrists and nurses.	Mental health training for primary health care staff in this district is delivered by psychiatrists in Guangzhou. The training content includes recognition, diagnosis and management of mental health conditions. The site teams integrated RESHAPE intervention within this standard training.
Sodo district, Ethiopia	INDIGO will be implemented in Sodo district of the Southern Nation, Nationalities and Peoples region of Ethiopia, located approximately 100 km from Addis Ababa. The district has an estimated population of 181,407, of which 90% live in rural areas. 85% of the population are from the Gurage ethnic group.	The district has 8 health centers and 58 health posts. There are 116 health extension workers or community health workers in the health posts. There is 1 primary hospital which has a psychiatric nurse-led outpatient clinic. Most of the mental health services are provided by primary healthcare workers.	The district had been a pilot area for mhGAP training of primary healthcare workers and so mental health services at primary healthcare level have been ongoing in the district. A referral system has been established in the district to psychiatric nurse-led care in the primary hospital or to Addis Ababa for psychiatric admission. Site teams followed the mhGAP training modules to training new primary health care workers in the district and integrated the
Bengaluru, India	INDIGO will be implemented in Ramanagara district, in the southern state of Karnataka. It covers 4 taluks with a total population of about 10 lakhs with 80% residing in rural areas. The major occupations are industry, sericulture, and agricultural farming.	Primary healthcare exists in both urban and rural areas which are an integral part of India's government healthcare system. A total of 65 PHC's are located in various taluks of Ramanagara. Mental health services are delivered at various levels which include PHC's, community hospitals, and district hospitals.	RESHAPE intervention in the mhGAP training. The District Mental Health Programme (DMHP) comprising a multidisciplinary team provides mental health services in PHC's and carries out mental health camps at community hospitals. Yearly, a one- day training on mental health is provided to the primary health care providers by the DMHP team. Site teams integrated RESHAPE intervention within the 1-day training provided by DMHP team for the INDIGO project.
Delhi, India	INDIGO will be implemented at two Urban Primary Health Centers (UPHCs) were purposively selected located in Faridabad district in Haryana (a state in Northern India). Faridabad is the largest and most populous district in state of Haryana. It is also situated in the National Capital Region bordering New Delhi. This district has a combination of rural, urban and semi-urban areas with the majority being urban populations.	There are 16 Primary Health Care Centers, one Government District Hospital and one sub-district level community outreach hospital in Faridabad. Mental health professionals are available only at the hospital level.	Prior to INDIGO, there were no standard training for primary healthcare workers as mental health services were not integrated and available in the district. Site teams had to design a 1-day training for primary healthcare workers for the INDIGO project and integrate the RESHAPE intervention within that training.
Syangja district, Nepal	INDIGO will be implemented by Transcultural Psychosocial Organization (TPO) Nepal, which is a non-profit mental health organization working in Nepal. Implementation will be conducted in the Arjunchaupari Municipality of the Syangja District, Gandaki Province in Nepal. The municipality is one among 744 local units in Nepal and has population of 16,176. The Municipality consists of 4 primary healthcare facilities with average catchment population of 3327.	The primary healthcare system in Nepal consists of prescribers (medical officers, health assistants, and auxiliary health workers) who are able to prescribe medications for common conditions; and non-prescribers (staff nurses, auxiliary nurses, and midwives) who do not have the right to prescribe medications but provide other medical services. These healthcare cadres provide free and emergency basic healthcare services from the primary healthcare facilities (health posts, primary healthcare centers, and primary hospitals).	The national mental health training for primary healthcare workers (referred to as Module 2) is adapted from mhGAP. The trainings are delivered by Nepali psychiatrists, with some trainings also including a psychosocial expert. In the site, no healthworkers had received the module 2 training and so the site teams integrated the RESHAPE intervention within the module 2 training for the primary healthcare workers.
Testour, Tunisia	INDIGO will be implemented in the municipality of Testour, Beja Governorate, which has a population of 13,331 habitants and lies 77 km southwest of the capital of Tunis.	The public primary HC system in Tunisia consists of a network of PHC centers and primary care and district hospitals in easy reach (<5 km) of 98% of the Tunisian population. Medical doctors and nurses as well as other healthcare staff provide basic health care for acute and chronic conditions as well as preventive activities such as regular health checkups and vaccination. This includes the detection, diagnosis and if necessary, referral for mental health conditions as well as follow up	There are variations in the types of training received by primary healthcare workers in the field site. Family doctors work 3 months in a psychiatric service during their specialty training, and nurses receive basic, mostly theoretical training as part of their initial training. Some primary care doctors receive mhGAP training as part of the continued medical education. Nurses, auxiliary nurses and other health workers rarely receive mental health training refresher sessions. For the INDIGO project.

(continued on next page)

training refresher sessions. For the INDIGO project,

site teams adapted the mhGAP training and integrated the RESHAPE intervention within the

training in the INDIGO project.

for mental health conditions as well as follow up mental health care (mainly prescribing). Testour has one primary health care centre and is also

home to the district hospital. There are 6 primary

care medical doctors who work at the hospital and at all the primary care centers of the district of

Table 1 (continued)

Site	Description of Location	Primary healthcare system details	Type of existing standard mental health training for primary healthcare workers in site prior to INDIGO
		Testour (in shifts). At the primary health care centre of Testour, there are 11 primary care workers and at the District Hospital of Testour, there are 15 primary care workers.	

management, and self-care. The core of the training being participatory photography narrative techniques. PWLE are taught to use digital cameras or mobile phones to take pictures, and they take photographs to capture 3 acts of recovery stories: i) photos representing pre-treatment; ii) photos to explain treatment; and iii) photos illustrating life after treatment. By the end of PhotoVoice, PWLE have produced a series of photographs that they show during a 7–10-min recovery story during the PCP training.

For each site, the standard mental health training may vary based on their health systems and government mandates. For example, the Ethiopia and Nepal sites will provide mhGAP style trainings courses that have been scaled up by the government, while the Bengaluru site will provide 2-days mhGAP based training, modifying content and method to the requirement (about 12 h over 2 days). As an example of modification, in the Nepal site, the standard mental health training for primary healthcare workers consists of mhGAP training for 6 days. The psychiatrists may spend 2 h describing the diagnosis and treatment of depression on day 4 of the training in the standard training. However, in the RESHAPE adaptation, the psychiatrist's didactic session of 90 min on depression will be followed by a 30-min presentation by a PWLE of depression followed by a question-and-answer session.

In addition to engagement with PWLE, social contact interventions often include a bridge between the person living with mental health conditions and the intervention beneficiaries. In health care, this is typically a PCP who already has engaged with persons with mental health conditions. Therefore, the role of "aspirational figures" who are respected primary care workers already providing mental health care was created. The "aspirational figures" will be trained in mental health-related stigma faced by patients at healthcare facilities, myth busting exercises, and narrating their experiences of providing treatment/services to people with mental health conditions at primary healthcare facilities. The aspirational figures are trained over 2–3 sessions. The myths are culturally adapted in each setting to match local common negative beliefs related to mental health conditions.

2.4. Study design

This is a mixed-methods (quantitative and qualitative) proof-of-principle study using a before-after study design. In this feasibility, PCPs from primary health facilities will receive mental health training where social contact of PhotoVoice-trained PWEL (RESHAPE intervention) will be incorporated. Stigma attitudes and competency data will be collected from the primary care providers immediately before and after the training with some site including follow-up data collection will take place at follow-up points 3-months post-training.

2.5. Participants and recruitment

The target population for this component of INDIGO is PCPs who may be involved in one or more of the following responsibilities: (i) recognition of mental health conditions; (ii) diagnosis of mental health conditions; (iii) management of mental health conditions; (iv) referral to specialty services; (iv) physical healthcare of patients with mental health conditions. The type of primary healthcare or frontline workers may vary for each site depending on the type of health systems and PCPs available. The inclusion criteria and targeted number for the study for PCP training along with PWLE and caregivers for PhotoVoice training

and aspirational figures are described in Table 2.

At each site, the sample size will be determined by the number of PCPs available and feasible to include in the mental health training. The expected sample ranges from 2 to 3 in the Delhi to 36 in Bengaluru. The PCPs will be contacted by the local site implementation institution to participate in the training. Written informed consent will be sought prior to the first session of the training and before pre-training data collection. Any queries or additional information sought by the PCPs will be clarified by the research team. It will be made clear by the research team that their participation in the training and any future supervision sessions will not be penalized by their non-participation in the research.

2.6. Data collection

For the primary healthcare workers, various tools and data collection methods will be used to measure their stigma attitude, knowledge, and competency. Stigma related mental health knowledge will be measured using the Mental Health Knowledge Scale (MAKS) tool (Evans-Lacko et al., 2010). This is a brief, 12-item scale with a 5-point response scale ranging from strongly agree to strongly disagree to assess and track stigma-related mental health knowledge. Primary care provider's explicit attitudes will be measured using Reported and Intended Behavior Scale (RIBS) and Social Distance Scale (SDS). RIBS is an 8-item scale to measure the reported and intended behavior towards people with mental health problems (Evans-Lacko et al., 2011). SDS is an explicit stigmatizing attitudes questionnaire widely used in mental health in global stigma comparisons (Link, 1987). This is a 12-item measure with a 6-point response scale. This tool has been used as a primary measure in sites such as Nepal and Ethiopia, to measure the explicit attitudes (Kohrt et al., 2018b).

Primary care provider's implicit attitudes with be measured with the *Implicit Association Test (IAT)*. The IAT avoids problems of social desirability because it is a timed computer-administered test assessing implicit associations between concepts and attributes. It has been used to evaluate the implicit bias of mental vs. physical illness with harmfulness and burdensomeness attributes in Nepal (Tergesen, 2018). Similar attributes have been developed to suit the cultural context in all sites.

Clinical competency of primary care providers will be measured through an observed structured clinical exam called *Enhancing Assessment of Common Therapeutic factors (ENACT)* where primary care providers conduct a 10-min role-play with standardized actors/raters acting as patients (Kohrt et al., 2015).

For the PWLE and caregivers involved in PhotoVoice training, a Service User Collaboration Checklist will be implemented immediately after the PhotoVoice training and after their participation in health worker training to assess if they have faced any difficulties or received any benefits related to the training and intervention. This is a 13-item checklist with 4-point response scale and qualitative response options developed to assess whether the participants have experienced worsened or improved symptoms, increased or reduced stigma, and other barriers and facilitators due to their participation in the intervention.

The use of measures by sites and their assessment points are shown in Table 3. All the measures for the PCPs will be used at baseline immediately before the training session, immediately after the training session, and optionally at 3- months after completion of the training. In most sites, the data collection will be carried out in paper-pen format while (where feasible) and they will be stored in digital format with the

Table 2Participant selection criteria and sample size by site.

Training groups	Sites	Selection criteria	Targeted participant sample
People with lived experience of mental health conditions (PWLE) and family members	Beijing, China	Diagnosed with schizophrenia or bipolar disorder; showing stable signs of improvement; 18–50 years old; minimum education: junior high school; planning to reside in Beijing for at least one year	11
	Guangzhou, China	Diagnosed with schizophrenia, bipolar disorder, depression, anxiety; showing stable signs of improvement; 18–50 years old; planning to reside in Guangzhou for at least one year	10
	Sodo, Ethiopia	Diagnosed with psychosis, depression, or alcohol use condition from health centers or primary hospital; diagnosis confirmed by psychiatric nurse	16
	Bengaluru, India	Diagnosed with schizophrenia, depression, and substance use conditions; hailing from local community, educated, and motivated individuals; recruited from local outpatient clinics and mental health camps	20
	New Delhi, India	Adults (18+ years old) who have been diagnosed and are being treated for depression, anxiety, or suicide risk by doctors trained in mhGAP at primary health centers or by a psychiatrist at the district hospital	7
	Syangja, Nepal	Adults (18+ years old) diagnosed with depression, anxiety, psychosis, and alcohol use condition by primary healthcare facilities; diagnosis confirmed by structured interview with a psychiatrist	12–14
	Testour, Tunisia	Adults (18–65 years old) with a diagnosis of psychosis or mood disorders who are clinically stable; receiving mental health care at Razi Hospital	6
Aspirational figures	Beijing, China	Mental health workers in prevention and management, working at primary medical facilities; have completed the mental health training and supervision; consent to participate in the training	6–8
	Guangzhou, China	Mental health workers recommended by Qiwei Mental Social Service Work Centre to provide community rehabilitation for PWLE in Tianhe District, Guangzhou; have completed the mental health training and supervision; consent to participate in the training	6
	Sodo, Ethiopia	Medical doctors, health officers or nurses who have received mhGAP training and are working at the primary level of Ethiopian health care trier will be selected by site teams	2–4
	Bengaluru, India	Due to clinical demands on local healthcare facilities, aspirational figures will not be recruited at this site	NA
	New Delhi, India	Medical officers of primary health centers who were part of another mental health study and trained in mhGAP from neighboring locations	1
	Syangja, Nepal	Primary healthcare workers trained in mhGAP adapted national mental health training and who have been providing mental health services from primary healthcare facilities will be selected	3–4
	Testour, Tunisia	General nurse who has experience in mental health care through several years of work in the mental hospital and outpatient care for mental patients	1
Primary Care Providers (PCPs) being trained in mental healthcare	Beijing, China	Primary healthcare workers involved in management of mental health conditions or physical healthcare of patients with mental health conditions	20
	Guangzhou, China	Primary healthcare workers who may be involved in one or more of the following responsibilities: recognition of mental health conditions; diagnosis of mental health conditions; management of mental health conditions; referral to specialty services; physical healthcare of patients with mental health conditions	20
	Sodo, Ethiopia	Primary healthcare workers identifying, diagnosing, treating and referring people with mental health conditions.	18
	Bengaluru, India	Primary healthcare providers (Medical officers) identifying, diagnosing, treating, and referring people with mental health conditions. We also trained pharmacists who dispense medication and nurses who also manage people with mental health conditions	36
	New Delhi, India	Primary healthcare workers, i.e., Medical Officers in charge of Urban Primary Health Centers (UPHCs) of Aitmadpur and Mewla Maharajpur in Faridabad district of Haryana State.	2
	Syangja, Nepal	All primary healthcare workers who are licensed as health assistants or auxiliary health workers and working in healthcare facilities (health posts or Primary healthcare centers) in Arjunchaupari Municipality.	10
	Testour, Tunisia	Primary healthcare workers who are involved in recognition, diagnosis and management of mental conditions as well as in the physical care of people with mental conditions and who work in primary health care centers or the primary care hospital of Testour municipality	17

use of REDCap database (Harris et al., 2019).

In addition to these quantitative measures, qualitative data will be gathered from all sites using semi-structured interviews and/or focus group discussions to explore the feasibility, acceptability, and effectiveness of the intervention after the 3-month follow-up outcome assessment. The topic guide will cover pre-training knowledge, attitude, and competency related to mental health conditions and its treatment of the primary healthcare workers; changes in such knowledge, attitude, and competency and barriers and facilitators to providing care at primary healthcare facilities after the RESHAPE training.

Qualitative interviews will also be carried out with PWLE and caregivers after the PhotoVoice training after the completion of the healthcare worker's training. Qualitative interviews will also be

conducted with the aspirational figures after their involvement in health worker's training. These qualitative interviews with PWLE, caregivers, and aspirational figures will focus on feasibility and acceptability of the intervention, barriers and facilitators for collaboration, and recommendations for adaptation.

All sites will also complete a site-specific Ecological Validity Model (Sangraula et al., 2020) to log modifications, adaptations, and process indicators such as who, what, how much, when and where for the PhotoVoice, aspirational figure, and primary healthcare worker training courses.

2.7. Data analysis

The quantitative outcomes of interest will be summarized descriptively using appropriate summary statistics (mean and standard deviation for continuous outcomes and numbers and proportions for categorical outcomes) over time for the primary care providers. The impact of the intervention on outcome measures will be analyzed comparing the MAKS, RIBS/SDS, ENACT, and IAT scores at baseline, post-training, and 3-months follow-up with the use of linear or logistic mixed regression models to take into account the repeated measures in the study. The trends over time for each score will be plotted to examine between- and within-person differences and to determine the plausible pattern (e.g., linearity) of those trends.

Qualitative data analysis will be using thematic approach (Guest et al., 2011). The local site teams fluent in local and English language will transcribe and translate the audio-recorded interviews. Each site team will then perform inductive coding of at least 2 anonymized transcripts to generate initial codes. The initial codes generated from each site along with a-a priori codes based on literature will be used to generate a coding framework. A coder from each site will be assigned to code full transcripts using Dedoose or NVIVO 12. Inter-coder agreement will be achieved between the coders (Kappa >0.75) before full indexing and charting of the information. After the completion of coding, code summaries for each theme will be generated.

3. Discussion

The results from this study will help inform the research teams whether a full trial of effectiveness and cost-effectiveness can be carried out. The sites will also have qualitative and quantitative information on problems related to feasibility, acceptability, barriers and facilitators to recruitment, retention, fidelity, safety, and usefulness of the intervention to make further adaptations and modifications. Additionally, the study may also provide cross-country comparative understanding of specific contextual issues on stigma related to mental health conditions at primary healthcare level and adaptations necessary based on cultural contexts. Key limitations of the study are the inability to quantitatively assess effectiveness of the intervention at this stage. However, the study will generate data on feasibility and acceptability of the intervention that might be transferable to other similar settings.

The planned study has numerous strengths. The RESHAPE intervention was designed using active ingredients drawn from theories from social psychology and medical anthropology where a social-contact strategy is developed using the 'what matters most' framework (Kohrt et al., 2020). The use of social contact, which is proven to be effective in various low-, middle-, and high-income settings is the key ingredient as recommended by the Lancet Commission on Ending Stigma in Mental Health, where sites are able to adapt the intervention based on 'what matters most' to their local culture and healthcare settings that sites have explored in their situational analyses (Gronholm et al., 2023; Thornicroft et al., 2022). The content, delivery methods, duration and intensity of training (for PWLE, aspirational figures, and PCPs) are determined by the sites from the beginning while still retaining the key ingredients of the intervention. The existing evidence on stigma tends to be focused on knowledge and explicit attitude that can be subjected to reporting biases due to social desirability. The evaluation in our proposed study uses a mixed methods design and explores all aspects of mental health stigma: knowledge, both explicit and implicit attitudes, and behavior (competency) of the health workers. As PCPs are the first point of contact of PWLE seeking mental healthcare, a successful intervention to reduce stigma in such setting may help improve their health-seeking and health-care experiences. The intervention also promotes the principle of active participation and inclusion of PWLE in the improvement of mental healthcare.

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CRediT authorship contribution statement

Dristy Gurung: designed the protocol, drafted the manuscript. Brandon A. Kohrt: designed the protocol, drafted the manuscript, supervised the study. Syed Shabab Wahid: drafted the manuscript. Kalpana Bhattarai: Reviewed, revised, and provided final approval for the manuscript. Binita Acharya: Reviewed, revised, and provided final approval for the manuscript. Feryel Askri: Reviewed, revised, and provided final approval for the manuscript, for the manuscript. Bethel Ayele: Reviewed, revised, and provided final approval for the manuscript. Ioannis Bakolis: Reviewed, revised, and provided final approval for the manuscript. Anish Cherian: Reviewed, revised, and provided final approval for the manuscript. Mercian Daniel: Reviewed, revised, and provided final approval for the manuscript. Kamal Gautam: Reviewed, revised, and provided final approval for the manuscript. Eshetu Girma: Reviewed, revised, and provided final approval for the manuscript. Petra C. Gronholm: Reviewed, revised, and provided final approval for the manuscript. Charlotte Hanlon: Reviewed, revised, and provided final approval for the manuscript. Sudha Kallakuri: Reviewed, revised, and provided final approval for the manuscript. Bezawit Ketema: Reviewed, revised, and provided final approval for the manuscript. Heidi Lempp: Reviewed, revised, and provided final approval for the manuscript. Jie Li: Reviewed, revised, and provided final approval for the manuscript. Santosh Loganathan: Reviewed,

Study Period					
	Pre- PhotoVoice Training	Post-PhotoVoice Training	Pre-Primary Care Worker Training	Post-Primary Care Worker Training	3-months Post-Primary Care Worker Training
TIMEPOINT	t ₀	t_1	t ₂	t ₃	t ₄
Month	1	2	3	3	6
ACTIVITIES:					
PhotoVoice training for PWLE and	<		->		
family members					
Mental health training of primary care workers	e		<	·	
ASSESSMENTS:					
People with lived experience of me	ental health conditions (PWLE) and	their family members – trained in Phot	oVoice to facilitate delivery of recovery stories	and other components of the primary care me	ental health training
Service User Collaboration Checklist	All sites	All sites	•	All sites	_
Qualitative interviews All sites				All sites	
Aspirational figures - Primary health	hcare workers who have previously be	en trained in integration of mental healt	h services and have shown high levels of motiv	ation to provide mental health care	
Qualitative interviews				All sites	
Primary Healthcare Providers – trai	ined by mental health specialists and I	PWLE in order to provide mental health s	ervices in primary care		
Mental Health Knowledge Scale (MAKS))		All sites	All sites	All sites
Reported and Intended Behavior Scale			All sites	All sites	All sites
(RIBS)					
Social Distance Scale (SDS)			All except Tunisia ^a	All except Tunisia ^a	All except Tunisia ^a
Implicit Association Test (IAT)			All except Bengaluru, Guangzhou,	All except Bengaluru, Guangzhou,	All except Bengaluru,
			Tunisia ^a	Tunisia ^a	Guangzhou, Tunisia ^a
Observed competency (Enhancing			All except Bengaluru and Guangzhou ^a	All except Bengaluru and Guangzhou ^a	All except Bengaluru
Assessment of Common Therapeutic					and Guangzhou ^a
Factors, ENACT)					
Qualitative interviews					All sites

^a Sites had tested feasibility and acceptability of the tools in their setting during the formative stages and so sites opted out of the use of these tools if it was perceived as not feasible or acceptable during the formative stage.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. B. Kohrt is a co-editor-in-chief for *SSM-Mental Health*.

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