Adaptation of the WHO e-mhGAP-Intervention Guide app for mobile devices in Nepal and Nigeria: Protocol for a feasibility study

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Abstract

Background: There is growing global need for scalable approaches to training and supervising primary care workers to deliver mental health services. Over the past decade, the World Health Organization mental health Gap Action Programme Implementation Guide (mhGAP-IG) and associated training and implementation guidance have been disseminated to more than 100 countries. Drawing upon the opportunities provided by mobile technology, an updated electronic version of the mhGAP-IG (e-mhGAP-IG) is now being developed along with a clinical dashboard and guidance for use of mobile technology in supervision.

Objectives: This study will assess the feasibility, acceptability, adoption, and other implementation parameters of the e-mhGAP-IG for diagnosis and management of depression in two low- and middle-income countries (Nepal and Nigeria), as well as conduct a feasibility cluster randomised control trial (cRCT) to evaluate trial procedures for a subsequent fully-powered trial comparing the clinical and cost-effectiveness of e-mhGAP-IG and remote supervision with standard mhGAP implementation.

Methods: A feasibility cRCT will be conducted in Nepal and Nigeria to evaluate the feasibility of the e-mhGAP-IG for use in depression diagnosis and treatment. In each country, an estimated 20 primary health clinics (PHCs) in Nepal and 6 PHCs in Nigeria will be randomized to have their staff trained in e-mhGAP-IG or the paper version of mhGAP-IG v2.0. The PHC will be the unit of clustering. All primary care workers (PCWs) within a facility will receive the same training (e-mhGAP-IG vs. paper mhGAP-IG). Approximately 2-5 PCWs, depending on staffing, will be recruited per clinic (estimated n=20 health workers per arm in Nepal and 15 per arm in Nigeria). The primary outcomes of interest will be the feasibility and acceptability of training, supervision, and care delivery using e-mhGAP-IG. Secondary implementation outcomes include adoption of the e-mhGAP-IG and feasibility of trial procedures. The secondary intervention outcome—and primary outcome for a subsequent fully-powered trial—will be the accurate identification of depression by PCWs. Detection rates before and after training will be compared in each arm.

Results: To date, qualitative formative work has been conducted in both sites to prepare for the pilot cRCT, and the e-mhGAP-IG and remote supervision guidance have been developed.

Conclusions: Incorporation of mobile digital technology has the potential to improve the scalability of mental health services in primary care and enhance the quality and accuracy of care.

Trial Registration: Clinicaltrials.gov NCT04522453,
https://clinicaltrials.gov/ct2/show/NCT04522453

Keywords: Mental health; Community mental health; Digital technology; Primary health care; Intervention; eHealth; mHealth; LMIC; Remote supervision; Training

Introduction

Mental illnesses are common, affecting one in every three people during their lifetimes [1]. Globally, mental illnesses are the leading contributor of years lived with a disability [2]. Despite the prevalence and impact of mental illness, a large difference between true and treated prevalence rates of mental disorders, also known as the mental health treatment gap, exists. It is estimated that more than 80% of people with severe mental illness in low- and middle-income countries (LMICs) receive no treatment [3]. Only 16.5% of people with depression living in LMICs have access to minimally adequate treatment [4]. The consequences of this treatment gap include symptom persistence and deterioration, social exclusion, and long-term disability of people who could be economically productive and socially included. Globally, there is growing recognition of the importance of mental health as evidenced by its incorporation in the United Nations 2030 Agenda for Sustainable Development and extension of the World Health Organization (WHO) Comprehensive Mental Health Action Plan to 2030 by the World Health Assembly [5].

Limited numbers of mental health specialists and the concentration of care in hospital settings in urban rather rural areas limits the availability and accessibility of care [6]. Low treatment rates in LMICs are related to poor demand and supply-side forces. High levels of stigma associated with mental illness manifest in low rates of help-seeking among those who would benefit from care [7-10]. The WHO recommends a task-shifting approach to strengthen the generalist workforce and improve access to health care, including mental health care [11]. However, this method requires the availability of evidence-based tools and appropriate training, supervision, and support.

In recent years there has been an exponential rise in global access to mobile technologies in LMICs. In 2012 there were 287 million unique mobile phone subscribers across sub-Saharan Africa covering 32% of the population [12]. Six years later, that number rose to 465 million representing 44% of the population. In Nepal, the number of mobile contracts (27.85 million) surpasses the total population (26.49 million) [13]. The increased application of mobile technology to health care arena, known as mobile health (mHealth), aims to provide a powerful platform to improve the quality of interventions employing a task-shifting approach and reduce the treatment gap. Mobile health refers to the use of mobile technology in health interventions and service provision [14]. In a recent WHO survey, 87% of responding countries reported at least one government sponsored mHealth programme in their country [14]. However, only 14% of countries reported an evaluation of these programmes, raising concerns about insufficient evidence of impact.

A systematic review of smartphone use in clinical decision making by health care professionals identified seven randomised control trials conducted in high-income settings, which demonstrated improved knowledge, diagnosis, treatment decisions and documentation using mHealth technology [15]. Studies on mHealth tools in LMICs have had more mixed results [16]. Qualitative data does, however, suggest the intervention facilitated task shifting and improved health workers' morale.

In 2010, the WHO launched the Mental Health Gap Action Programme Intervention Guide (mhGAP-IG) [17], an evidence-based assessment and management guide for mental, neurological and substance use (MNS) conditions designed for use by primary and community health staff in LMICs [18]. The first edition of the mhGAP-IG (v1.0) has been implemented in over 100 countries. An updated version (v2.0) was launched in 2016 with new sections and updated evidence-based guidance [17], along with a first version of a smartphone app available for both Android and iOS devices in 2017. The mhGAP-IG v2.0 consists of eight modules addressing priority conditions (i.e. depression, psychoses, epilepsy, child and adolescent mental and behavioural disorders, dementia, disorders due to substance use, self-harm/suicide and other significant mental health complaints that impair daily functioning or lead to help-seeking). It provides an overview of common presentations for each condition followed by detailed guidance for assessment, management (including referral to specialist care) and follow-up.

The *E-mhGAP Intervention guide in Low- and middle-income countries: proof-of-concept for Impact and Acceptability* (Emilia) project seeks to re-address the treatment gap by developing a potentially practicable way for primary care workers (PCWs) to diagnose and treat people with mental illness according to evidence-based guidelines.

Aims and objectives

Emilia aims to test the feasibility of an updated electronic version of the mhGAP-IG v2.0 (e-mhGAP-IG) and trial procedures for the future conduct of a large-scale trial, which would evaluate differences in depression detection between facilities using e-mhGAP vs. paper mhGAP. The objectives of this feasibility study, in preparation for a future trial, include the following:

1. To evaluate the feasibility and overall implementability of primary care mental health services utilizing the e-mhGAP-IG for training, supervision, and delivery of care [primary objective];
2. To determine recruitment and retention rates for primary care workers (PCWs) and patients;
3. To establish the acceptability and feasibility of assessing PCW and patient outcomes;
4. To assess ethics and safety procedures using adverse event reporting;
5. To describe depression detection rates in primary health clinics (PHCs); and
6. To describe depression treatment outcomes in PHCs.

Methods

Settings

The study will take place within the administrative districts in Nepal (Jhapa Administrative District) and Nigeria (Ibadan North, Ibadan North West, Ona Ara and Akinyele Local Government Areas). In each country, a minimum of six PHCs will be recruited for the study to represent a range of urban and rural settings.

Nepal is classified as a lower-middle-income country with an estimated population of 28.1 million [19]. In a recent survey, 16.8% of individuals attending primary care facilities met the criteria for depression [20]. However, only 8.1% had sought care for their mental health [21]. Primary care facilities includePHCs, health posts, urban health centres, community health units, and primary health care outreach clinics. In these facilities service is delivered by medical officers, health assistants, staff nurses, auxiliary health workers and auxiliary nurse midwives. However, medical officers and staff nurses are available only in PHCs [22]. Availability of mental health care in the country is limited with services largely provided through hospitals located in the larger cities [22]. The Jhapa Administrative district has a total population of 812,650. Medical care is provided through one zonal hospital, six PHCs, 44 health posts and six urban health centers [23]. Specialist outpatient mental health services are located in two private hospitals within the district. The mhGAP-IG was adopted by the government of Nepal and implemented in several districts after the major earthquake of 2015. The government has allocated a budget for district level mental health care services to include the addition of six psychotropic drugs to those already freely available within health facilities and stregnthening of community mental health care services [24].

Nigeria is Africa's biggest economy and classified as a lower-middle-income country. In addition, it is home to the largest national population in Africa [195.9 million in 2018; 25]. Recent research in the country estimates a prevalence of depression of 5.5% [26]. However, like other LMIC, 85% of individuals living with a mental disorder receive no treatment [27]. Ibadan metropolis has 11 local government areas and a population of approximately 3.5 million people. Mental health services in Ibadan are primarily provided by two large general hospitals. There are 186 PHCs each serving a population of approximately 10,000. The study will be conducted in two urban and two rural local government areas. PHCs in Nigeria are staffed by non-physician health workers (nurses, community health officers and community health extension workers) who provide treatment for common disorders (including depression) presenting in primary care. The country adopted the mhGAP as a national program for expanding mental health services in 2013 and the PHCs are among those where providers have received training in the use mhGAP-IG. In Ibadan, PCWs are provided with unstructured supervision by a supervisory general practitioner who typically oversees a group of 6-8 PHCs within a local government area.

The use of digital technology in both Nepal and Nigeria has seen exponential growth in recent years with the trend expected to continue. In Nepal, mobile penetration was 133% in 2018; the number is greater than 100% because most Nepalis have multiple mobile phone provider contracts [28]. In the same year, mobile penetration was estimated at 49% in Nigeria, with a projected increase to 55% in 2025 [29]. Thirty-six percent of mobile phone connections in Nigeria are linked to a smartphone.

Technology

A 2015 WHO consultation on the five-year impact of the mhGAP-IG v1.0 highlighted the demand for an electronic version (e-version). Respondents identified increased utility and coverage of an electronic guide as reasons for its development. An e-version also creates new opportunities for quality improvement (e.g. in remote supervision).

A year later, a privately developed e-version of the mhGAP-IG for use in Afghanistan was used for 3,000 screenings and 600 referrals [30]. Community health workers reported good acceptability of the mobile app. An e-version of the mhGAP-IG v2.0 was launched by the WHO in October 2017 for Apple and Android smartphones and tablets.

The Emilia project is comprised of three phases: (1) development of an adapted e-mhGAP intervention guide, (2) feasibility testing, and (3) knowledge transfer and future work. In Phase 1, an updated version of the WHO's electronic intervention guide was developed using a human-centred design approach. Human-centred design is an approach which actively engages stakeholders in the design process using cutting-edge methods to ensure interventions are optimised for both front-line use and local and national implementation [31]. The approach includes qualitative research with key stakeholders to identify motivations, an iterative process of intervention development and prototyping, and intervention evaluation. The updating of the electronic version of the mhGAP-IG v2.0 (e-mhGAP-IG) includeded individual and group interviews with primary care workers in Nepal and Nigeria to understand the accessibility of technology by health workers and their usage patterns as well as preferences for the design of the e-mhGAP-IG. Findings showed that most health workers had access to a personal smartphone, were familiar with use of various smartphone apps and valued the idea of an electronic version of mhGAP. Requested features included decision support functions, ability to be used offline mode and an easy to use design that limited text entry. The formative work also highlighted the importance of recording patient information for review and use in supervision through a clinical dashboard. The resulting updated app features a "reference mode" for training and exploration, and a "patient mode" for completing an assessment or management visit with an individual. Health workers, can access a brief description of possible conditions through the "Master Chart" (a feature of mhGAP 2.0) and then select modules for further assessment (see Multimedia Appendix 1: [Updated e-mhGAP-IG screenshots]). The mhGAP algorithms are presented in a single page series of yes/no questions with a "proceed" button indicating when the end of an algorithm has been reached. Health workers are then presented with an assessment summary, including any additional information to consider such as if the individual belongs to a "special population" that may affect treatment decisions. Within the app, health workers can complete additional information for a patient's record including measures of severity, functioning and information for follow-up visits. All information is accessible in a clinical dashboard which summarises key information for each visit as well as aggregate information to help supervisors identify any issues that can be addressed in supervision (e.g. overmedication or inaccurate diagnosis). The process of intervention delivery and supervision is described in Multimedia Appendix 2: [Description of e-mhGAP-IG implementation]. The e-mhGAP-IG will be available in both English and Nepali. Prototypes of the app have been tested with health workers in Nepal (five iterations) and Nigeria (four iterations) who have found the app to have an intuitive design which is appropriate and feasible for use in clinical work.

Study design

A feasibility cluster randomised control trial (cRCT) will be conducted to evaluate and compare the implementation outcomes [32] and clinical outcomes of the adapted e-mhGAP-IG v2.0 and the paper version of the mhGAP-IG v2.0. Ten PHCs in each country (Nepal and Nigeria) will be randomised to training, supervision, and care delivery using the paper mhGAP-IG (control arm) or e-mhGAP-IG (experimental arm), and primay care worker and patient outcomes will be collected over a 9-month period (see Figure 1.). Data collected through the feasibility study will be used to further refine the intervention (e.g. acceptability/feasibility for randomisation and recruitment) and power a subsequent cRCT.

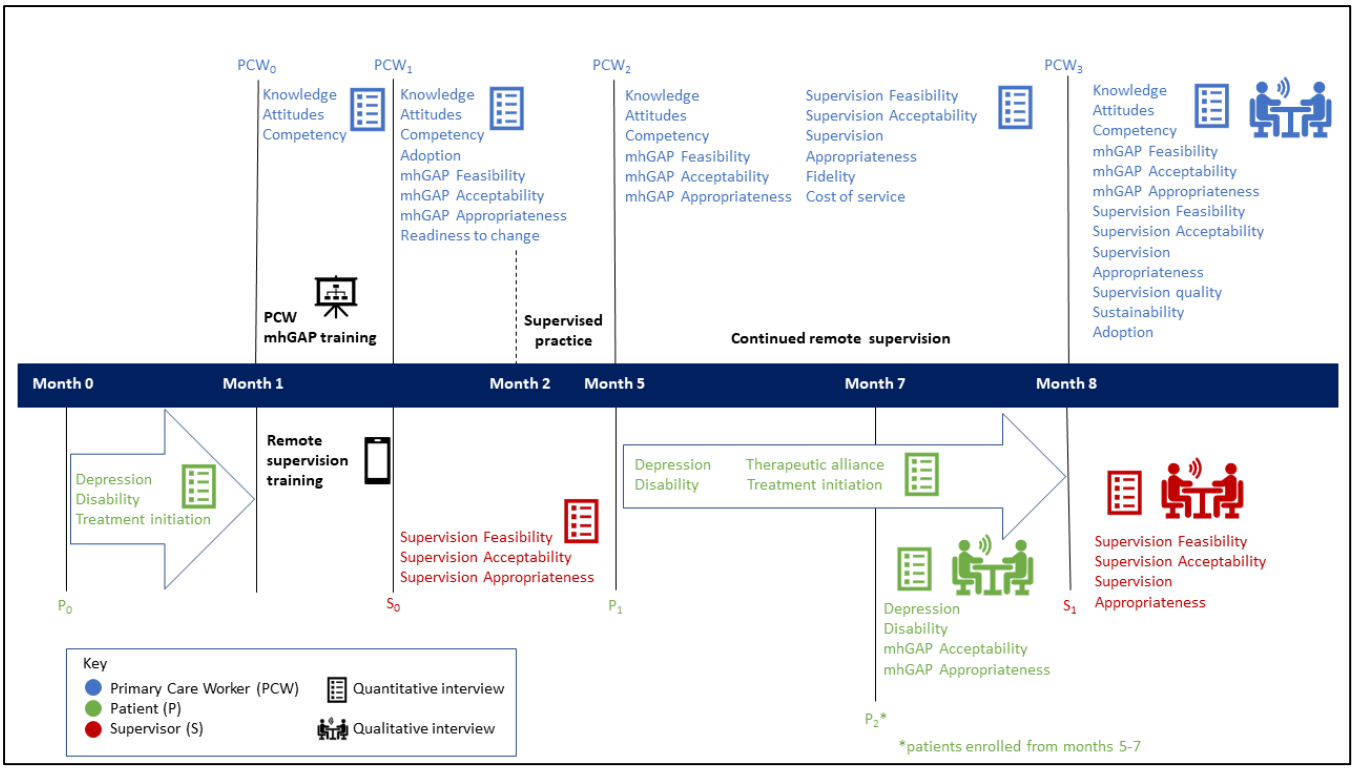

Figure 1. Feasibility study patient and provider data collection procedure

Participants

An estimated 20 PHCs in Nepal and six PHCs in Nigeria will be identified by local partners. Clinic managers and PCWs will be approached by local research staff with invitations to take part in the study. Based on the staffing of PHCs, we estimate 2-5 PCWs per PHC will participate, equivalent to 40 PCWs in Nepal and 30 PCWs in Nigeria, approximately 15-20 health workers per arm per country (see Figure 2.Figure **2**. Emilia flow chart).

Primary care workers will be eligible to participate if they are employed by the PHC or government and have roles and responsibilities that relate to the use of the mhGAP-IG (e.g. direct clinical use or supervision). All relevant primary care workers, regardless of individual study participation, will receive training in the mhGAP-IG v2.0 (electronic

or paper version) and have ongoing remote support and supervision by Health care providers with enhanced mental health knowledge.

Patients presenting to primary care will be enrolled in the study to evaluate their perceptions of services, and to obtain descriptive information on detection rates and treatment impact to inform a subsequent fully-powered cRCT. There will be two periods of patient enrolment: 'pre-training', which is prior to primary care workers receiving mhGAP training, and 'post-training', which after primary care workers have received mhGAP training. For the one-month prior to mhGAP training, a random selection of adults presenting to primary care will be screened by research assistants to determine depression status, which will be compared to documented diagnoses by the primary care workers. Similarly, beginning at 3-months post-training, a random selection of patients will be screened by research assistants for depression status. This post training patient enrolment will last a minimum of three months.

Based on prior data on primary care service use and screening depression rates, we anticipate being able to screen approximately 50% of adult patients presenting to primary care, with a possibility for screening a higher percentage depending on patient flow in the facility [33]. Therefore, we anticipate screening approximately 200 patients per arm per country per month (i.e. 400 patients per country in the 1-month pre-training patient enrolment period and 1,200 patients per country in the minimum of 3-months post-training patient enrolment period).

Inclusion criteria for patients to be screened includes the following requirements:

- Attending PHC for treatment of a new case at recruitment;
- Reached the age of adulthood (i.e. ≥18 years); and
- Fluent in Nepali language (Nepal only) or English or Yoruba (Nigeria only).

Adult attendees will be deemed ineligible for the study if they are unable to understand or complete study assessment (e.g. individuals with severe learning disability or dementia), unable give informed consent, or have a medical emergency requiring immediate intervention.

All patients who meet eligibility criteria and choose to enroll in the study will then be screened by a research assistant to determine depression status. Following this screening, patients will be evaluated by a PCW who will make an independent diagnosis without speaking to the research assistant or reviewing screening results. Administration of screening tools may occur before or after the patient meets the health worker based on work flow of the clinics. After patients meet with the primary care workers, a research assistant will review the provider's case notes to document whether or not a depression diagnosis was made.

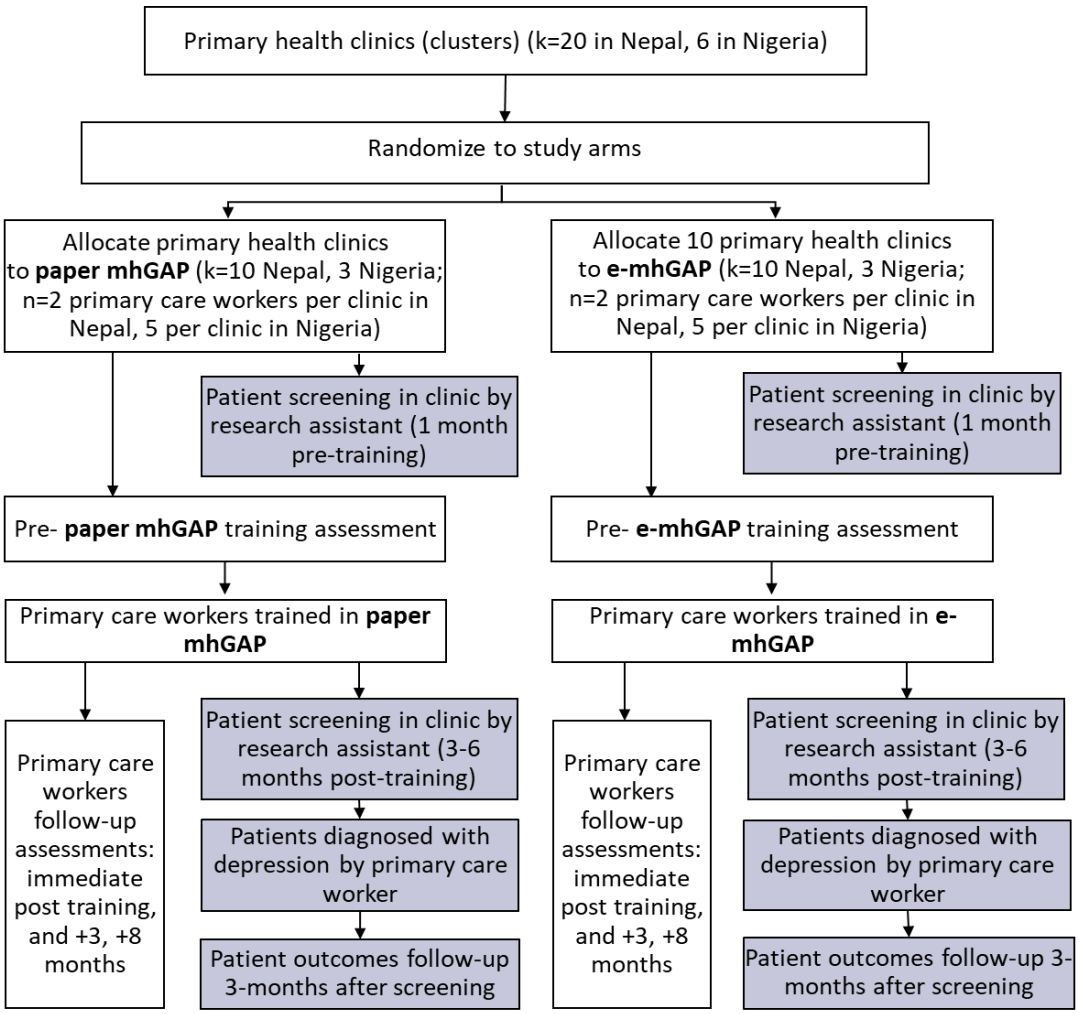

Figure 2. Emilia flow chart

Study arms

Intervention condition

The intervention will consist of: (i) availability of the adapted e-mhGAP-IG for use on a clinic tablet; (ii) participation in remote supervision and support module developed within Phase 1 for implementation in Nepal and Nigeria; and (iii) training to all relevant primary care workers and supervisors in the use of the adapted e-mhGAP-IG and clinical dashboard (see). Health care providers with enhanced mental health knowledge who have attended Training of Trainers Workshops for the e-mhGAP-IG and supervision from distance will act as supervisors for the purpose of the study. These might include, but are not limited to psychiatrists, mental health nurses, general physicians, senior primary care workers and counsellors.

Table 1. Feasibility study arm components

Component	Intervention condition	Control condition
e-mhGAP-IG v2.0	X	
Paper mhGAP-IG v2.0[a]	X	X
Remote supervision and support module	X	X
Primary care workers training in use and administration of relevant mhGAP-IG v2.0	X	X
Primary care workers training in clinical dashboard	X	
Supervisor training in relevant mhGAP and remote supervision and support	X	X
Supervisor training in clinical dashboard	X	

[a] The paper mhGAP-IG 2.0 will be used in intervention condition training and available for use as a resource throughout the study.

Control condition

The control condition will consist of: (i) availability of the paper version of the mhGAP-IG v2.0 adapted for use in Nepal and Nigeria; (ii) participation in remote supervision and support module developed within Phase 1 for implementation in Nepal and Nigeria; and (iii) training to all relevant primary care workers and supervisors in the use of the paper version of the mhGAP-IG v2.0 and supervision from distance (see Table 1). Trained specialists in the research teams within each study sites will act as supervisors for the purpose of the study. Supervisors are intended to be health care providers with enhanced mental health knowledge who have attended Training of Trainers Workshops for the paper mhGAP-IG v2.0. These might include, but are not limited to, psychiatrists, mental health nurses, general physicians, senior primary care workers and counsellors.

Remote supervision

In both study arms remote supervision will comprise an initial face-to-face meeting (where possible) and subsequent contact by voice and/or messaging to discuss implementation of the mhGAP-IG (paper or electronic version) and any case queries. Supervision format (e.g. voice calls, video calls, messaging, group, individual) will be agreed by each supervision dyad. Supervisors will be provided with training on how to set up and run supervision remotely using telephone and other common communication platforms such as WhatsApp groups prior to the start of the study. Training will cover issues such as: (a) building rapport; (b) format for running supervision over a telephone; (c) format for clinically supportive WhatsApp groups; and d) ensuring patient confidentiality when using remote supervision methods. Primary care workers will receive training on how to make the most of remote supervision during mhGAP-IG training. Primary care workers will have access to project mobile phones to facilitate remote supervision. Both primary care workers and supervisors will be provided with data packages.

Randomisation and allocation concealment

Clinics will be randomised to the control or intervention conditions, with equal numbers of clinics in either group (1:1). Randomisation will be carried out independently (to ensure concealment), by the trial statistician via a computer-generated random sequence before participants are recruited or the intervention is initiated. PCW selection will be done according to health staffing levels prior to randomisation of clinics to a study arm. Blinding/masking of participants, clinicians and fieldworkers will not be possible as it will be clear which conditions clinics/municipalities are assigned to during implementation and data collection. However, the senior and junior trial statistician who carries out the randomization will not know the characteristics of the clinics being randomised, and the primary statistical analysis will also be blinded to allocation status.

Statistical power and sample size calculation

The study will take place in one government administrative region in Nepal and four in Nigeria. Within Nepal we shall identify an estimated 20 PHCs and within Nigeria six PHCs. In each country, half of the PHCs will be randomly allocated to either (i) the e-version, or (ii) the paper version of the mhGAP-IG. As the clinics vary in size, we shall assess at least two staff members in each clinic, with an estimated 2-5 health workers per facility and overall enrolment of 40 PCWs in Nepal and 30 PCWs in Nigeria. Regarding patient numbers, on the basis of the sample size for Sangha et al.'s [34] smartphone app study of improve cognitive to improve case detection, we will conduct within-arm comparison detection rates if at least 40 patients screen positive on the PHQ-9 in the research assistant interview in the 1-month pre-training period and in first month of the post-training patient enrolment period, which begins after three months of intensive supervision. This will allow us to detect a within-arm increase in the clinical case identification rate of 43% for the e-mhGAP-IG after the implementation of the electronic version with 90% power at the 5% level of significance, assuming an intra-class correlation coefficient of 0.02. For example, with a 10% detection rate pre-training, two patients would receive a health worker depression diagnosis out of 20 patients screening positive. Then, after training, the detection rate would increase to 53%, which equates to 11 patients diagnosed by a health worker out of 20 screening positive.

Data collection

In line with current best practice in implementation research [32], the research team shall evaluate implementation processes and outcomes (e.g. acceptability and feasibility) and factors that influence effectiveness implementation (e.g. organisational readiness to change) across multiple stakeholder groups, including patients, primary care workers, and supervisors, and at different stages of implementation stages [32, 35]. This offers a 360-degree implementation evaluation, which considers needs and perspectives that typically differ between stakeholder groups and can vary over time. Data collection procedures are outlined in Figure 1. and presented in Multimedia Appendix 3: [Schedule of enrollment, intervention and assessments]**Error! Reference source not found.**.

Implementation data

Primary care workers

Primary care workers will be interviewed by a member of the research team during a one-week period at each PHC clinic at four timepoints: (1) prior to mhGAP training (PCW_0), (2) immediately post-training (PCW_1), (3) three-months post-training (PCW_2), and (4) eight-months post-training (PCW_3, see Multimedia Appendix 3: [Schedule of enrollment, intervention and assessments]). During research interviews all primary care workers will complete quantitative assessments, assessing seven variables relating to the implementation of the intervention.

1. Implementation readiness: Health worker resolve and capability to implement the e-mhGAP-IG (i.e. readiness to change) will be assessed using the Organisational Readiness for Implementing Change (ORIC) scale [36]. ORIC is a 12-item, theory-based measure assessing health workers commitment towards and ability to implement change.
2. Acceptability, appropriateness and feasibility: Acceptability, appropriateness and feasibility of the mhGAP-IG and remote supervision will be assessed using the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM) and Feasibility of Intervention Measure (FIM), respectively [37]. These brief, four-item instruments have been developed by implementation scientists and mental health professionals and display good psychometric properties. Cultural and linguistic adaptation and further psychometric evaluation will be undertaken prior to deployment of the meaures within this study. Appropriateness, feasibility and acceptability of the mhGAP-IG and remote supervision will also be assessed through qualitative interviews with health workers at the last data collection timepoint (PCW_3).
3. Fidelity: Patient records and app usage, as recorded electronically through the e-mhGAP-IG v2.0 or patient records as recorded on paper in clinics randomised to provide the paper version mhGAP-IG v2.0 and supervision notes, will be assessed by members of the research team to determine fidelity to the training manuals for the paper mhGAP-IG v2.0 and the adapted e-mhGAP-IG v2.0.
4. Adoption: Health workers' intention to adopt mhGAP, will be assessed by using two study-specific questions regarding provider intended use within the study and after the study has ended. Intention to adopt at the provider-level will also be assessed through qualitative interviews with health worker.
5. Integration and sustainability: The potential for long-term integration of the mhGAP-IG v2.0 within standard health services will be assessed using the Normalization Measure Development (NoMAD) scale [38, 39]. NoMAD is a 23-item instrument that assesses staff perceptions of factors relevant to embedding interventions in health care. NoMAD consists of 4 theoretical constructs: (1) Coherence; (2) Collective Action; (3) Cognitive Participation; and (4) Reflexive Monitoring.
6. Operating costs: The time taken to be trained and to use the paper and electronic tools, and remote supervision will be estimated from information collected from staff and this, combined with information on staff wages, will be used to derive operating costs for the economic modelling.

During the last data collection timepoint (PCW_3), 15 primary care workers in each country will be randomly selected and invited to participate in an additional qualitative interview with a member of the research team to gain further insight into their views on the implementation of the mhGAP-IG v2.0 and remote supervision. We will aim to conduct focus group discussions (FDGs) in the first instance. However, where this is not possible, individual interviews will be conducted. Individual interviews and FDGs will be audio recorded and last no longer than 30 and 60 minutes, respectively. Interviews will be transcribed and anonymised prior to analysis.

Supervisors

mhGAP supervisors will be interviewed by a member of the research team during a one-week period at two timepoints: (1) immediately post-training (S_0) and (2) eight months post-training (S_1, see Figure 1.). Interviews will focus on perceived acceptability, appropriateness and feasibility of remote supervision using the quantitative assessments described above (i.e. AIM, IAM, and FIM, see Multimedia Appendix 3: [Schedule of enrollment, intervention and assessments]). All supervisors will be invited to participate in a qualitative interview eight months post-training (S_1) to gain further insight into their experiences of remote supervision. Focus group discussions will be conducted where possible with the remaining selected participants completing individual interviews. All qualitative interviews will be audio recorded and last between 30 (for individual interviews) and 60 minutes (for FGDs). Interviews will be transcribed and anonymised prior to analysis.

Patients

We estimate screening a minimum of 400 patients in each site during the pre-training enrolment period and 1200 patients in the post-training enrolment period (starting three months after the mhGAP trainings). In the post-training period, we will include a subset of patients who have received a health worker depression diagnosis to follow-up for treatment outcomes (see Multimedia Appendix 3: [Schedule of enrollment, intervention and assessments]). We will follow-up with them at approximately three months after they are screened to measure their treatment outcomes. A subset of patients will also participate in FGDs to assess their perspectives of the acceptability (AIM) and appropriateness (IAM) of the intervention three months after their baseline health care appointment (P_2).

Outcome data

Primary care workers

Primary care workers will be interviewed by a member of the research team during a one-week period at each PHC clinic at four timepoints: (1) prior to mhGAP training (PCW_0), (2) immediately post-training (PCW_1), (3) three-months post-training (PCW_2), and (4) eight-months post-training (PCW_3, see Multimedia Appendix 3: [Schedule of enrollment, intervention and assessments]).

1. mhGAP Knowledge Scale: In the mhGAP training, knowledge is assessed by a standardised set of 30 questions in the multiple-choice question (MCQ) format, the mhGAP Knowledge Scale. These are administered prior to the training and after the training to measure the change in knowledge.

2. Depression Attitude Questionnaire (R-DAQ): Previously used in both Nepal and Nigeria, the R-DAQ [40] assess clinician's views and understanding of depression. This 22-item scale asks clinicians to rate each item as "strongly disagree", "disagree", "neither disagree nor agree", "agree" or "strongly agree". Examples of items include "depression is a disease like any other (e.g. asthma, diabetes", "psychological therapy tends to be unsuccessful with people who are depressed" and "becoming depressed is a natural part of being old".
3. Social Distance Scale (SDS): The SDS was designed by Bogardus [41] to measure the level of acceptability of various types of social relationships between Americans and members of common ethnic groups [42, 43]. The modified SDS has been widely used to measure mental health-related stigma and to understand the importance of labels attached to people with former mental illnesses [42, 44]. The modified version consists of 12 items that represent social contact with different degrees of distance. The SDS measures the acceptability of different degrees of social distance and thus, by inference, the attitude of the respondent to the person with the condition [45]. The SDS sum score represents the attitude of the respondent towards the condition. The SDS has been used in global mental health research. Among stigma measures, it has been shown to most strongly associate with health worker competence [46].
4. The Enhancing Assessment of Common Therapeutic Factors (ENACT)-clinician version: The ENACT-clinician version [47] is a measure of therapist competence that has been developed for use in training and supervision across settings varied by culture and access to mental health resources. It is an 18-item scale which rates items on a 4-point scale from potentially harmful to done well, with good reliability (α=0.89). Examples of items include "non-verbal communication, active listening", "assessment of functioning & impact on life" and "explanation and promotion of confidentiality", among others.
5. Perceptions of Supervisory Support Scale (PSS): Supervision quality will be assessed using the PSS [48]. The PSS is a 19-item scale which assesses perceived support. Sub-scales include: (1) emotional support; (2) support for client goal achievement; and (3) professional development support. Each item is rate using a five-point Likert Scale. Additional information about supervision quality will be collected through qualitative interviews with health workers at the last data collection timepoint (PCW_3).

Patients

In the month prior to mhGAP-IG training, the research team will collect depression diagnosis and treatment initiation data from patient baseline interviews and clinical notes at participating clinics (see Multimedia Appendix 3: [Schedule of enrolment, intervention and assessments]). This data will be used as a baseline assessment of accuracy of diagnosis and adequacy of treatment initiation. Patients attending PHC three- to eight-months following primary care worker mhGAP-IG training will be interviewed by a trained member of the research team either immediately before or following their clinic appointment. Quantitative measures will be used to assess

depression, disability, intervention acceptability, and therapeutic alliance during individual interviews with a member of the research team. Confirmation of diagnosis and treatment initiation will be collected from clinical notes by primary care workers.

1. Depression: The Patient Health Questionnaire [PHQ-9; 49] is a self-administered diagnostic instrument for depressive disorder. DSM-IV criteria for depression are scored as "0" (not at all) to "3" (nearly every day). A PHQ-9 score ≥10 had a sensitivity of 94% and 85% a specificity of 80% and 99 % for major depression in Nepal [50] and Nigeria [51], respectively.
2. Disability: Data on socio-demographic information (sex, age, education, marital status and work status) will be collected through questions A1-A5 of the WHO Disability Assessment Schedule 2.0 [WHODAS 2.0; 52]. The WHODAS 2.0 is a generic assessment instrument assessing health and disability across six domains (cognition, mobility, self-care, getting along, life activities, and participation). The research team will use the 12-item interviewer administered version. WHODAS has been adapted and validated for use in Nepal [53-55] and Nigeria [56].
3. Treatment initiation: Treatment details will be extracted by the research team from patient records to document how diagnosis matches up with treatment, and treatment modifications during care.
4. Therapeutic alliance: The ENACT-Service user version [47] is a 15-item measure of patient experience of care and perception of therapeutic engagement. Example items include clear explanations, name for health problem, understanding and empathy, and expectation for recovery.
5. Suicidal ideation and behaviour: Suicidal ideation and behaviour will be assessed, in Nepal only, using suicidality questions adapted from the Composite International Diagnostic Interview (CIDI) suicidality module [57]. This tool has widely been used in Nepal [58]. We will ask participants about whether in the past 12 months they had thoughts of taking their own life. Those who will respond affirmatively to the ideation question will be asked if they had made a plan to take their own life. In Nepal, Those who meet the criteria for current suicidal thoughts or those attempted suicide in the past 3 months will be immediately referred to a trained psychosocial counsellor. In Nigeria, patients endorsing the suicidal ideation item from the PHQ-9 will receive further assessment of suicide risk in line with local protocols.

Patients interviewed in the first three months of data collection who screen positive for depression will be invited to participate in a follow-up interview three months after their first appointment. The interview will consist of quantitative assessments of depression (PHQ-9), disability (WHODAS 2.0), therapeutic alliance (the ENACT-Service user version) and suicide ideation and action (CIDI). Treatment details will be extracted by the research team from patient records to document treatment retention.

Measure translation and adaptation

All standardised measures, except for the AIM, IAM, FIM, ORIC, NoMAD and PSS (Nigeria only), have been translated and culturally adapted in Nepal and Nigeria. Psychometrics for translated and validated (when appropriate) measures are provided within descriptions above. Within each site, where measures have not yet been adapted and validated, the International Test Commission Guidelines for Translating and Adapting Tests [59] will be followed, including cognitive interviewing [60, 61] and the assessment of content validity.

Analysis

Implementation outcome analysis

Quantitative data will be assessed using generalised linear mixed models depending on the distribution of the outcome (continuous, binary, count). Descriptive statistics of implementation survey data (FIM, AIM, IAM) will be provided. The association between the primary outcome (changes in the PHQ-9 detection rate) and implementation survey data will be analysed using linear mixed models at 3- and 8-months post training. A two-level hierarchical model will be employed and all time points will be included as repeated measures in the model at baseline, 3-months post training and 8-months post training to improve power and account for clustering of observations at patient and PCW level. These models utilise maximum likelihood estimation and thus allow for missing outcome data under the missing at random assumption. Associations between secondary outcomes (e.g. knowledge, attitudes and competency) and implementation survey data will be assessed with a similar methodology for the primary outcomes, using generalized linear mixed models depending on the type of outcome (e.g. normal, binary, count). All analyses will be conducted in STATA V.15.1.

Qualitative data will be assessed using thematic analysis [62]. Thematic analysis consists of five stages: familiarisation, generating codes, constructing themes, revising themes and defining themes [63]. Draft codebooks for each participant group (e.g. primary care workers, supervisors, and patients) will be developed on an initial sub-set of transcripts by two researchers in each site. Following refinement based on researcher consensus, the final codebooks will be used to code each transcript independently by two researchers in each site. Sub-categories will be assessed for the number of occurrences across all transcripts and themes and categories relevant to the data identified. Findings will be triangulated with quantitative data on implementation and provider and patient outcomes to assess the feasibility and impact of the e-mhGAP-IG.

Primary care worker and patient outcome analysis

The primary outcome will be accuracy of depression diagnosis. The research team will define screening positive according to a research assistant in which the PHQ-9 is administered either immediately before or after the patient sees the primary care worker. “Screening positive” will be defined as scoring at or above 10 on the PHQ-9. The research team will also assess sensitivity to change, for change in both the PHQ-9 and WHODAS 2.0 scores from baseline and 3-months after initiation of treatment.

"Positive diagnosis" will be defined as a clinical diagnosis of depression documented by the health worker in the clinical notes. "Accurate detection" will be defined as PHQ-9≥10 and a health worker depression clinical diagnosis. We will also report findings in terms of sensitivity and specificity of health worker diagnoses. 'Sensitivity' will be defined as the proportion of health worker diagnosed patients who had PHQ-9 above the cut off, out of to all patients who scored above the PHQ-9 cut off. 'Specificity' will be defined as the proportion of patients who did not receive a health worker depression diagnosis and scored below the PHQ-9 cut off, out of all patients scoring below the PHQ-9 cut-off.

Features of the cRCT design will be accommodated in all analyses and an intention-to-treat approach will be used. The principles of analysis will be: (1) the PHC-level accuracy outcome is binomial (i.e. number accurate diagnoses out of all diagnoses based on patient-level data) and therefore a generalized linear mixed model (will be used (specifically a log-binomial regression to obtain probability ratios), (2) accuracy is a cumulative measure and therefore there are no repeated measures over time, and, (3) missing data can occur at either the health worker or patient-level.

Differences in detection rates will be assessed using patient outcome data at 3-months after enrolment only in identified depression cases within each arm (i.e. scoring at or above 10 on the PHQ-9) and the health worker clinical diagnosis. A three-level hierarchical model will be employed when all time points will be included as repeated measures in the model to improve power and take into account clustering of the observation at patient and PHC levels. The three-level linear mixed model will be used to estimate a 95% confidence interval (CI) for the comparison of clinical diagnosis compared to PHQ-9 screening positive rates (as well as a sub-analysis with PHQ-9 plus WHODAS 2.0 criteria) within electronic and paper mhGAP-IG versions. Secondary outcomes (e.g. knowledge, attitudes) will be assessed within each arm with a similar methodology for the primary outcomes, using generalized linear mixed models depending on the type of outcome (normal, binary, count). Clinical feasibility will also be triangulated with penetration and costing data.

Health economic analysis

We will develop a simulation model to assess the potential cost-effectiveness of the e-mhGAP-IG compared to the paper-based tool. We are not measuring patient outcomes within the study and hence costs of services and impacts on patienst will be taken from other sources. The model will take the form of a decision tree which maps out key events following use of either tool and outcomes that are achieved. A simple form of the model will have cases detected or not as key events and whether or not outcome improves as a result of detection (the latter information coming from previous research). The cost of providing care for people detected will be included as will the reduction in disability-adjusted life years (DALYs) following treatment. Some of the data will be obtained from within the study (costs of using the tools based on staff time, rate of detection of depression) while other data (costs of treatment, DALYs) will be obtained from the wider literature and from expert opinion. The model will be subject to sensitivity analyses to address uncertainty that there will be around

model parameters. The model will enable us to generate a cost per DALY avoided by using the tool.

Feasibility criteria for progression to full trial

The primary objective is to evaluate feasibility and acceptability of the intervention, its implementation and trial procedures for the subsequent cRCT. We must establish indicators on what procedures to carry on to the full trial and where modifications should be made to study design or content. Overall feasibility and acceptability will be determined in the intervention arm by the following criteria at endline to determine progression to the full trial:

a) identification of qualitative themes reporting that both primary care workers and clients perceive group primary care mental health services as being acceptable, feasible, and appropriateness;
b) retention of at least 67% of primary care workers and patients through endline assessments;
c) fewer than 15% missing items on outcome measures across all assessments or fewer than 15% (for each questionnaire with more than 10 items) or 50% (for each measure with 10 items or less) of missing items on an individual assessment; and
d) presence of adverse events among fewer than 10% of participants and any serious adverse events.

In domains where criteria are met, we will retain the procedure for the full trial. In domains where criteria are not met, we will modify procedures for the full trial guided by data collected during interviews. The presence of any adverse events and/or serious adverse events will be addressed by the trial team to identify alternative strategies for the full trial and Data Safety Monitoring Committee. The number of feasibility and acceptability criteria that are not met will determine the extent of intervention and trial design modification.

Results

The Emilia project was funded by the UK Medical Research Council in July 2018. Ethical approval for this feasibility study was obtained from all collaborating institutions. These include:

- Psychiatry, Nursing and Midwifery Research Ethics Committee, King's College London, United Kingdom (May 2020);
- University of Ibadan/University College Hospital Joint Ethics Committee, University of Ibadan, Nigeria (December 2018);
- Nepal Health Research Council for the Transcultural Psychosocial Organization Nepal (October 2020); and
- World Health Organization Ethics Review Committee, World Health Organization, Geneva (May 2020).

Data collection is projected to begin in November 2020 and end in August 2021. As of October 2020 no participants have been recruited.

Discussion

The mhGAP-IG enables greater access to evidence-based mental health care by targeting non-mental health specialists (e.g. primary care doctors, nurses, community health workers) as providers. Despite its use in more than 100 countries, a WHO consultation process identified the paper format to be a hindrance to its uptake, due to burden on primary care workers to carry it with them during appointments, and limited mental health specialists to provide support and supervision. The Emilia project aims to address these barriers to scale. The existing WHO developed electronic mhGAP-IG v2.0 has been adapted and refined for use in Nepal and Nigeria. Through a feasibility cRCT, its impact on detection and treatment initiation for depression, one of the most common mental conditions, will be tested along with stakeholder perceptions of its implementation and suitability for scale. While we believe the availability of the e-mhGAP-IG will improve demand and usability of the mhGAP-IG, the paper version will still serve a vital role in settings where access to electronic technology and/or the internet is limited. The inclusion of a new remote supervision module for ongoing support of health workers made available in both trial arms will allow us to assess its feasibility, appropriateness, and acceptability, in addition to its potential impact on the success of both the paper and electronic mhGAP-IG versions.

This feasibility trial will provide initial evidence of the utility and impact of the e-mhGAP-IG and remote supervision. The study takes advantage of the availability and potential of electronic technology and will advance work to reduce the mental health treatment gap around the world.

Trial status to date

Formative qualitative research has been conducted in both countries, and the e-mhGAP-IG app has been developed. Activities have been delayed in both countries due to COVID-19.

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Authors' contributions

GT, TTS, IB, BAK, MJ, LH, OG, NL, NS and PMcC were involved in designing the study. KC, NC, TD, HL, OG, NL, LK, PP, EPG adapted the intervention for electronic use. IB will oversee quantitative data analysis. HL will oversee qualitative data analysis. All authors will be involved in the interpretation of the results. TTS wrote the first draft of the manuscript. All authors have contributed to, read and approved the final manuscript.

Conflicts of Interest

NS is the director of the London Safety and Training Solutions Ltd, which offers training in patient safety, implementation solutions and human factors to health care organisations. No additional conflicts of interest are declared.

Abbreviations

AIM: Acceptability of Intervention Measure
FIM: Feasibility of Intervention Measure
CIDI: Composite International Diagnostic Interview
COVID-19: Coronavirus disease
cRCT: Cluster randomized controlled trial
DALY: disability-adjusted life year
ENACT: Enhancing Assessment of Common Therapeutic Factors
Emilia: The E-mhGAP Intervention guide in Low and middle-income countries: proof-of-concept for Impact and Acceptability
e-mhGAP-IG: Electronic mental health Gap Action Program Intervention Guide
e-version: Electronic version
IAM: Intervention Appropriateness Measure
LMICs: Low and middle-income countries
mhealth: Mobile health
mhGAP-IG: mental health Gap Action Programme Implementation Guide
MNS: Mental, neurological and substance use
NoMAD: Normalization Measure Development
ORIC: Organisational Readiness for Implementation Change
P: Patient
PCW: primary care worker
PHC: Primary health clinic
PHQ-9: Patient Health Questionnaire
PSS: Perceptions of Supervisory Support Scale

R-DAQ: Depression Attitude Questionnaire
S: Supervisor
SDS: Social Distance Scale
WHO: World Health Organization
WHODAS 2.0: WHO Disability Assessment Schedule 2.0

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