STUDY PROTOCOL

Feasibility of using WHO's e-mhGAP-IG Mobile Application for Child and Adolescent Mental/Behavioral Disorders and Substance Use in Indian Setting: Protocol paper

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ABSTRACT

Background: The treatment gap for people with common mental disorders is large, estimated to be 75–95% in India; the reasons are multi-factorial. It was found that 89% of the primary health centers are not providing mental health care services. Technology like the electronic-mental Health Global Action Program-Intervention Guide (e-mhGAP-IG) is necessary to fill this gap, which in turn helps to attain one of the aims of National Mental Health Program-1982. Hence, the study is planned to understand the feasibility and adaptability of WHO's e-mhGAP-IG by the primary health workers in the delivery of mental health care for child and adolescent mental/behavioral disorders (CMH) and substance use disorders (SUB).

Methods: It is an open-label randomized control trial planned to conduct at primary healthcare centers, Chittoor district. Primary health care staff working at PHCs/Sub-centers having one year experience, and being able to handle smart phones will be included in the study. Data will be collected using a self-structured case report form (CRF) and analyzed by applying per protocol analysis using JAMOVI software. The cost of intervention and the impact on disease outcomes will be taken concurrently to estimate the cost-effectiveness of the intervention.

Keywords: Digital Technology, Substance Dependence, Adolescent Health, Community Mental Health, Health care personnel, Primary health care

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INTRODUCTION

The government of India in 1982 initiated the National Mental Health Program (NMHP) with an aim to integrate mental health care with general health care and to ensure a minimum mental healthcare for all, particularly to the most vulnerable and underprivileged sections.[1]

The World Health Organization (WHO) reported that the treatment gap for people with common mental disorders is large, estimated to be 75–95% in India. The reasons for these gaps are multi-factorial including lack of awareness, stigma, limited manpower, especially in community health care settings.[2,3] To address this gap and to ensure integration of mental health services, WHO has developed an electronic model guide, consisting of interventions for prevention and management of MNS (Mental, Neurological and Substance use) conditions which can be adapted to the unique national or local situation.[4] There is an updated e-mhGAP-IG being developed for the use of mobile technology in supervision.[5] The diverse, expanding global mhGAP-IG literature demonstrates substantial impact on training, patient care, research and practice.[6]

Roxanne C Keynejad et al., (2017) reported that the mhGAP-IG literature is substantial and their review identified the importance of detailed reports of contextual challenges in the field, alongside detailed protocols, qualitative studies and randomised controlled trials.[6] An updated systematic review on the evidence and impact, published in 2021 reported the priorities for research in less-studied regions, severe mental illness and contextual adaptation of brief psychological interventions.[7]

Non-specialist health care settings in rural India needs the technology like mh-GAP intervention guide to ensure provision of care to all needy which is one of the aims of NMHP-1982.[8-11] Preliminary survey conducted by the proposed research team found that 89% of the primary health centers are not providing mental health care services which necessitates the measures to incorporate mh-GAP-IG technology which helps in easy provision of mental health care services at community health care settings which is what this study is planning to do. This study aims to address this gap by studying the feasibility and adaptability of WHO's e-mhGAP- intervention guide by the primary health workers in delivery of mental health care for child and adolescent mental/behavioral disorders (CMH) and substance use disorders (SUB).

Objectives: To evaluate the feasibility and adaptability of WHO's e-mhGAP- intervention guide by the primary health care workers (PHW) in delivery of mental health care for child and adolescent mental/behavioral disorders (CMH) and substance use disorders (SUB) living in Chittoor district, A.P, India. Besides, we will determine the challenges in adapting e-mhGAP-IG and explore the solutions to the challenges in adapting it. We will also determine the treatment outcomes of CMH and SUB disorders and estimate the cost effectiveness of adapting e-mhGAP intervention guide.

METHODOLOGY

Trial design: It will be an open-label randomized control trial with 1:1 allocation ratio for intervention and control arm. There will be no blinding.

Study setting: Primary health care centers (PHCs) within Chittoor district, A.P., India. and the sub centers linked to each of the primary health care center.

Intervention: Study includes two arms (1 intervention arm, 1 control arm). Intervention arm will be given training in using WHO's e-mhGAP-IG a mobile application which consists of interventions for prevention and management of MNS (Mental, Neurological and Substance use) conditions maily CMH and SUB which can be adapted to the unique national or local situation, especially innon-specialist health care settings.[4] This application which is available in English language will be translated into regional language (Telugu) for local use. Control arm will be given paper based mhGAP-IG in regional language and will continue with usual practice towards delivery of care for children and adolescent mental and behavioral disorders and substance use disorders.[11-16]

Outcomes: It includes condition specific outcomes, community health care setting specific outcomes, intervention specific outcomes and cost outcomes. [16]

a. Condition specific outcomes: Two conditions considered in the study are:

Substance use disorders: Disorders which affect the individual's cognitive functions and behavior due to substance use which includes both drug and alcohol use disorders and certain conditions including acute intoxication, overdose and withdrawal.

Child & Adolescent mental & behavioral disorders: Developmental (intellectual disability and autism spectrum disorders), behavioral (Attention deficit hyperactivity disorder or ADHD), conduct disorder) and emotional disorders characterized by increased levels of anxiety, depression, fear and somatic symptoms of children and adolescents.

Condition specific outcomes include the prevalence of SUB and CMH, number of screenings/referrals/psycho-education/follow-ups made, and the number of emergency cases treated, cases continuing treatment, cases recovered, cases with relapse, cases with worsened symptoms and cases dead.

b. Community health care setting specific outcomes: It includes knowledge and practices of community health care workers towards SUB and CMH.

c. Intervention specific outcomes: Feasibility and adaptability of intervention, challenges faced in adapting it and the solutions to overcome will also be reported.

d. Cost outcomes: The study reports the effectiveness of intervention both in terms of cost and health outcome.

Participant timeline: 18 months

Sampling unit: PHCs and attached sub-centers are the sampling units in the study. Those PHCs and sub-centers located within the Chittoor district, having at least one primary health care worker (PHW) are included in the study. PHW with more than 1 year of experience at PHC/Sub-center, having smart phone and able to operate them would be the prospective participants in the study.

Primary health care workers are medical officers, nursing officers/staff nurses, community health officers/mid-level health providers (CHO/MLHP), and auxiliary nurse midwifes (ANM), who are front-line public health workers who provide culturally and linguistically competent care to individuals and communities.

Eligibility criteria: We will include PHCs/Sub centers having at least one primary health care worker (PHW) with one or more than 1 year of experience at PHC/Sub-center, having smart phones and able to operate them.

Sampling technique: From the list of PHCs, centers will be allocated in intervention and control arms through simple randomization. Subcenters attached to the allotted PHC will fall under the respective arms.

Sample size: There are an estimated 64 PHCs (50 PHCs, 14 UPHCs) in Chittoor district. Each PHC is expected to have 5 to 7 sub-centers (may range up to 10 sub-centers based on the population size of the PHC) attached to it based on the population size covered. Two PHCs (One for the intervention arm, one for control) will be selected randomly and allocated in intervention and control arms. Alloted PHCs and the sub-centers attached to them (total of 10-14 approx sub-centers) will be under each arm. Primary health care workers (Medical Officers, Nursing Officers, ANMs) working at PHCs/sub-centers who ever meet the inclusion criteria will be recruited in the study.

Recruitment: Initially, a list of all the PHCs in Chittoor district is made and then divided PHCs and attached sub-centers are selected randomly and allocated into the intervention and control arm through simple randomization.

Allocation: PHCs will be allocated in intervention or control sites through simple randomization.

Sequence generation: Not applicable

Allocation concealment: Not applicable

Implementation:

After recruitment of primary health care workers working at PHCs/Subcenters, intervention arm participants will be given training on adapting electronic mhGAP intervention guide a mobile application for one week by a trained project staff. After the training, all the staff will be directed to conduct a screening survey (hospital/community based) to estimate the prevalence of CMH and SUB disorders. Those who are found with CMH and SUB disorders will be handled as per the management guidelines given in e-mhGAP-IG either by the community health care worker or by referral to tertiary care hospital based on the diagnosis and then follow up will continue as per the intervention guide. Reinforcement training sessions will be conducted every month for an initial 6 months and later once every 3 months. Interim data collection will be once every two months for a period of 18 months.

The participants working at control centers will be given training on adapting paper based mhGAP intervention guide for one week by a trained project staff. After the training, all the staff will be directed to conduct a screening survey in their respective areas to understand the prevalence of CMH and SUB disorders. Those who are found with CMH and SUB disorders will be handled as per the management guidelines given in intervention guide. There won't be any reinforcement training sessions. Interim data collection will be once every two months for a period of 18 months. (Figure 1)

Blinding (masking): It is an open label trial.

Data collection methods: We will be collecting multiple forms of data at different time points. Demographic details will be collected at baseline by applying a semi-structured case report form. The prevalence of substance use disorders will be identified by conducting a screening survey using mhGAP-IG assessment tool. A semi-structured case report form will be developed to collect the details of knowledge and practices of PHWs towards CMH and SUB disorders. The number of screenings/referrals/psychoeducation/follow-ups made, treatment outcomes of CMH will be reported as per the reporting form developed.

By interviewing health care workers, feasibility and adaptability of intervention will be elicited. Challenges faced in implementing the intervention and the solutions to overcome the challenges will be explored through focus group discussions of health care workers involved in the study. The cost of intervention (both electronic application and paper-based module) and the impact on disease outcomes will be reported concurrently to compare and estimate the cost effectiveness. Both direct and indirect costs will be considered, including training costs. The incremental cost effectiveness ratio (ICER)-willingness to pay threshold will be determined based on India's GDP at that time. (Table 1)

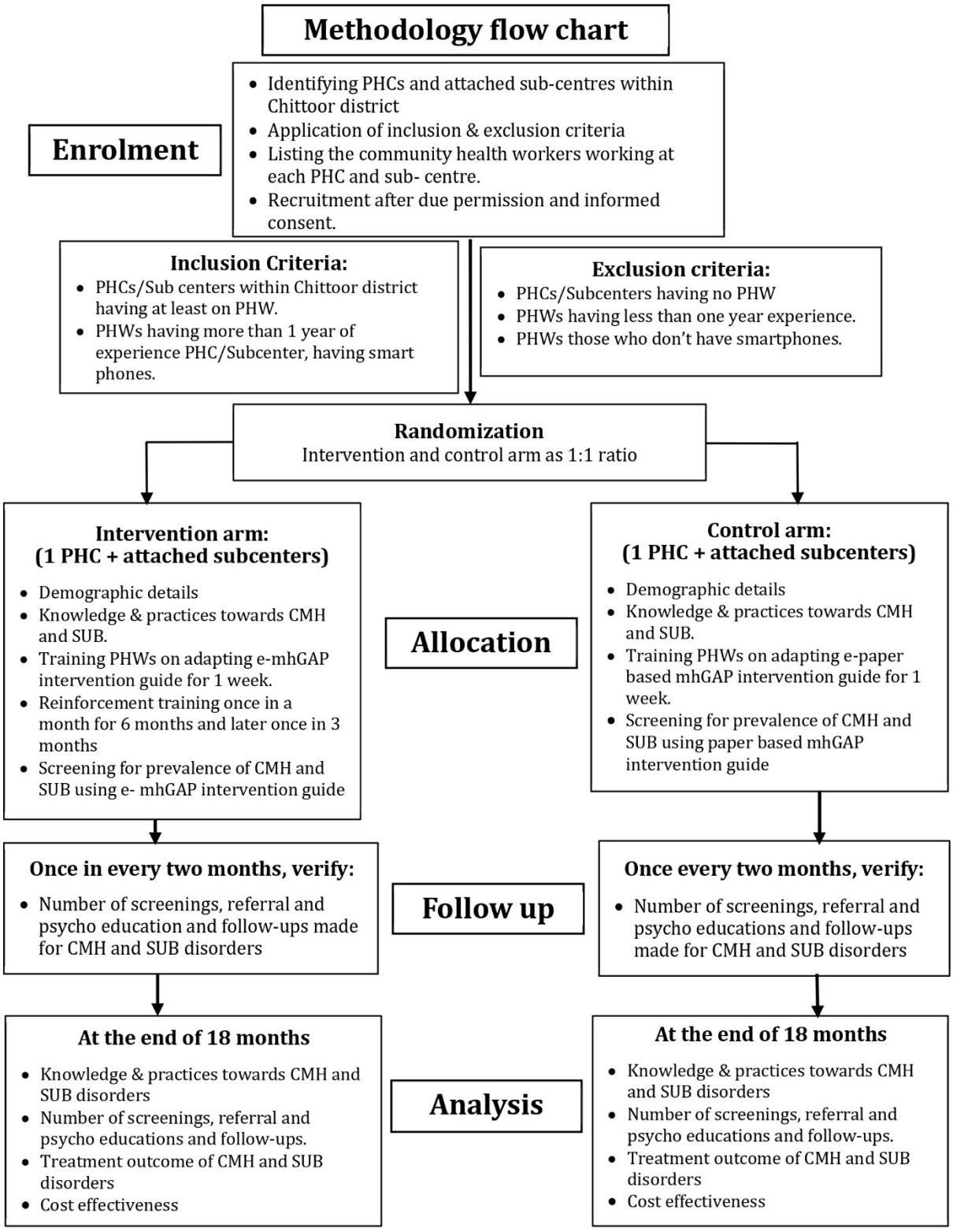

Figure 1: Methodology flow chart

Data management: Collected data will be entered electronically through an electronic case report form. All the electronic data will be stored in a secured institutional cloud server only accessible to the trial project team (PI and Co-PI). Periodic consolidation of data will be done to monitor the trial's progress.

Statistical methods: Data will be analysed using descriptive and inferential statistics. Descriptives mainly mean with standard deviation; median with interquartile range will be applied based on distribution of data. Inferential statistics, mainly the intervention effect, will be estimated as the adjusted mean difference and corresponding 95%confidence interval.

Table 1: Details of data collection

Type of data collected	Tool	Technique	Frequency
Demographic details	Semi-structured-questionnaire	Self-administered	At baseline
Knowledge & practices towards CMH and SUB disorders	Semi-structured-questionnaire	Self-administered	At baseline and end of followup
Prevalence of substance usedisorders	e-mhGAP-IG assessment tool	Interview	At the baseline
Condition specific outcomes: Number of screenings/referral/psycho-education/follow-ups	Investigator developed reporting format	Report by PHW	At baseline and once in two months for 18 months
Feasibility and adaptability of e-mhGAP IG	Semi-structured-questionnaire	Interview	At end line
Challenges faced in adapting e-mhGAP IG and solutions to overcome	Focus group discussion		At end line
Treatment outcomes of CMH and SUB disorders	Investigator developed reporting format	Report by PHW	Once in two months for 18 months
Cost effectiveness	Concurrently		

The cost of intervention (both electronic application and paper-based module) and the impact on disease outcomes will be compared to estimate the cost effectiveness. The incremental cost effectiveness ratio (ICER)-willingness to pay threshold will be determined based on India's GDP at that time.

Data monitoring: Data monitoring committee will be formed with project investigators, and other study members. This committee will monitor every step of trial implementation, namely recruitment process, collection of data at different time points, perceived risks and measures applied to overcome, data completeness, adverse events during trial conduction, withdrawal of study participants etc.

Harms: We do not expect any direct physical harm to any participants out of this study participation.

Auditing: The trial will be audited by an external agency independent of the trial team and the study sponsor.

Ethics and dissemination: Institutional ethics committee clearance was obtained for conducting the study (No.FR028/IEC/AIMSR/2023 dated 02-01-2023, Apollo Institute of Medical Sciences and Research, The Apollo Medical College, Chittoor district, Andhra Pradesh). Written informed consent from all the participants will be obtained. All the study related documents will be preserved in the department under lock and key. The soft copies of the electronic data will be preserved in password protected institutional cloud server. Besides all these, we will follow the country specific guidelines/ regulations to protect the rights of the participants.

Protocol amendments: Minor changes in the protocol (in implementation plan/in timeline) which do not bring any changes in the title and objectives and the safety of the participants will be amended with the consensus of trial/project co-coordinator. Any change in protocol which will change the title, objectives of the study will be amended after the approval of the institutional ethics committee and the funding agency.

Consent or assent: Informed written consent will be obtained from each participant before recruitment into the trial.

Confidentiality: Team ensures the confidentiality of all information which is collected during the project period and after the completion of the trial. Confidentiality protection is applicable to data obtained before trial such as eligibility assessment of prospective participants, data with personal identifiers. Data will be de-identified with unique identifiers immediately after its collection by a qualified statistician wherever required.

Declaration of interests: None of the study team members has any financial or non-financial conflict of interest.

Access to data: Access to the study data will be restricted to research team members only. Data under the above-mentioned project will be used only for the purpose of the work mentioned herein above and team members are liable to administrative action in case the data is used for any purpose beyond the scope of this work.

Ancillary and post-trial care: All the cases who ever get referred to a tertiary care facility for treatment will be followed up by the concerned ANMs / the connected health center (PHC or Subcenter) staff. Cases who are at risk for developing behavioral problems or substance abuse will be taken care as per the protocol given in the MhGAP-IG.

Dissemination policy: Findings of the study will be published through an open-access journal. A dissemination meeting will be conducted to present the findings of the study to the health care workforce and policy bodies. Anonymized data will be shared by the PI only if there is a reasonable justification.

Discussion

NMHP intended to integrate mental health care into general health care to ensure provision to all needy. Non-specialist health care settings in India needs the technology like mh-GAP intervention guide to ensure provision of mental health care to all needy which is the intent of WHO behind developing mh-GAP IG. This study aims to develop the mental health care service provision with the available resources though incorporating mh-GAP-IG technology which helps in easy provision of mental health care services at community health care settings.

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