Feasibility trial of a low-intensity preventive intervention delivered at community doorsteps by frontline workers in rural Pakistan: mPareshan Study protocol

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Abstract

Background: There is a dearth of specialized mental health workforce in low- and middle-income countries. In the presence of huge treatment gaps, the feasibility of utilizing frontline community workers to promote mental well-being needs to be explored.

Objective: To assess the feasibility, acceptability, and usefulness of an app-based counselling intervention delivered by Lady Health Workers (LHWs) to reduce anxiety and depression at the community level in Pakistan.

Methods: This is a single-arm, pre- and post-test feasibility trial using mixed methods of data collection in a rural district of Sindh, Pakistan. After a baseline screening survey using PHQ-9 and GAD-7, individuals with mild and moderate symptoms of anxiety and depression are invited to take part in face-to-face, home-based, counselling sessions. The counselling sessions are delivered by LHWs through the mPareshan app (intervention). Each 20-minute session imparts psychoeducation through audio and video clips, breathing exercises and promotes coping skills. WHO mhGAP guide 2.0 is used to improve mental health literacy of LHWs and LHSs. Change in mean symptomatic scores of anxiety and depression will be assessed for intervention effectiveness. Feasibility will be measured by participant recruitment, retention, and adherence to the intervention. Knowledge and skills of health workers in identification of symptoms, counselling techniques and appropriate referrals, will be determined.

Results: This paper describes the protocol of the mPareshan feasibility trial. The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) on 14th August 2022. Ethical clearance was obtained in December 2021, and an extension granted in 2022. Data collection started in 2022. Data analysis is ongoing and study results will be disseminated in early 2024.

Conclusions: Marginalized rural communities do not seek mental health care due to fear of stigmatization, lack of resources and specialized mental health workforce. This low-intensity preventive intervention will promote mental well-being at community doorsteps through early identification and prompt referrals. This study marks the first instance of utilizing frontline healthcare workers at the primary care level to promote mental well-being through a technology-assisted intervention. Clinical Trial: ACTRN12622000989741

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Protocol

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Abstract

Background: There is a dearth of specialized mental health workforce in low- and middle-income countries. In the presence of huge treatment gaps, the feasibility of utilizing frontline community workers to promote mental well-being needs to be explored.
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Results: This paper describes the protocol of the mPareshan feasibility trial. The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) on 14th August 2022. Ethical clearance was obtained in December 2021, and an extension granted in 2022. Data collection started in 2022. Data analysis is ongoing and study results will be disseminated in early 2024.
Conclusions: Marginalized rural communities do not seek mental health care due to fear of stigmatization, lack of resources and specialized mental health workforce. This low-intensity preventive intervention will promote mental well-being at community doorsteps through early identification and prompt referrals. This study marks the first instance of utilizing frontline healthcare workers at the primary care level to promote mental well-being through a technology-assisted intervention.
Trial Registration: ACTRN12622000989741

Keywords: Anxiety; Depression; Feasibility; mHealth intervention; Lady Health Workers; Primary Healthcare; Frontline workers

Introduction

Mental disorders account for 14% of the global burden of disease [1]. Globally, 322 million (4.4%) and 264 million (3.6%) people suffer from depression and anxiety, respectively [2]. The data from World Mental Health Surveys (WMHS) concluded that people with mental disorders sought treatment in a very small proportion, particularly in low-and-middle income countries (LMICs) [3]. Barriers to accessing mental-healthcare facilities in LMICs include the cost of mental-health care, poor distribution of available resources, and the distance to reach a mental health facility [4,5].

Pakistan has a sizable burden of psychiatric morbidity, particularly depression and anxiety. It is a LMIC with a population of 220 million, with almost 60% residing in rural areas [6,7]. Pakistan has the highest depression rates in contrast to other developing countries which can be attributed to factors such as poverty, political turmoil, insecurity, stressful conditions for workers, economic challenges, gender inequality, natural disasters, and social disturbances [1,5,7,8]. The COVID-19 pandemic has worsened the mental health crisis with a rise in depression, anxiety, and stress [9]. The number of suicides being committed have also increased since the pandemic [10].

Community Health Workers (CHWs) are the first contact for individuals seeking health care in the developing world [11]. A well-structured CHW program has already been established in Pakistan, known as the Lady Health Worker Program (LHW-P) [12]. Lady Health Workers (LHWs) and Lady Health Supervisors (LHSs) will be collectively referred to as CHWs in this protocol. The LHW-P covers 85% of the rural population in Pakistan through 115,000 LHWs. They act as "focal points of care" for their individual catchment areas [13]. An LHW typically serves between 100 and 150 houses (1,000 people) monthly [14] and provides health promotion and disease prevention counselling and monitoring for vaccinations, family planning and maternal and child health care along with appropriate referrals to specialists where needed [15]. Typically, each LHS oversees 20–25 LHWs and provides them with the required mentorship and supervision. In Pakistan, LHWs can be utilized to be the first responders to screen, counsel and make suitable referrals, thus integrating mental health into primary care. Mental health interventions offered by LHWs can provide cost-effective health promotion preventive options for communities with limited resources [16]. The stigma associated with seeking mental ill-health can be reduced if LHWs are tasked to provide mental health care at community doorsteps. Previously, engaging CHWs has shown to improve health outcomes for heavily stigmatized disorders such as schizophrenia [17].

The role of mobile and wireless technologies has an immense capacity to promote and strengthen healthcare through CHWs. These innovations utilize the ubiquity of cell phones to enhance the functionality of the health systems [18]. Mobile penetration being greater than 90% in LMICs has strengthened the viability of mHealth programs, especially in remote areas [19].

Besides being cost-effective, mobile technology has better potential for extensive population-based outreach given its higher penetration and accessibility [20,21]. App-based interventions offer early detection of symptoms, decrease barriers associated with traditional in-person interventions and offer efficient use of time by minimizing delays in initiating contact with healthcare system and self-pacing. It no longer remains limited by proximity to available psychotherapists [22–24].

The promising role of mHealth in screening symptoms of depression and anxiety and halting progression towards severity has been highlighted in previous work [25]. Usefulness of mobile apps for making mental health referrals was highlighted by a quasi-experimental study from India in 2020, in which CHWs were trained to screen the community participants through a mobile app for depression and anxiety using Patient Health Questionnaire-9 (PHQ-

9) and Generalized Anxiety Disorder-7 (GAD-7) scales and make referrals with help of psychiatrists. The study reported a significant reduction in the depression and anxiety scores of 900 participants and this task-sharing was found useful for increasing access to mental health care in rural areas [25].

Like other developing countries, Pakistan has also given less consideration to mental health at the policy level [26]. Hence, instead of initiating a parallel mental health system, the most convincing strategy would be the horizontal integration of mental health services within current primary health system [27]. This would require integration of primary health care work force into the agenda of the governments, NGOs, and global mental health stakeholders [28].

The general objective of this study is to assess the feasibility, acceptability, and usefulness of a digital app-based mental health intervention (mPareshan) delivered by LHWs at community doorsteps to screen/track symptoms of anxiety and depression, offer supportive counselling to halt disease progression, and provide appropriate referrals to next level of care.

Aims and Objectives

- Assess the feasibility, acceptability, and usefulness of a digital app-based intervention (mPareshan) delivered by LHWs to adult men and women in District Badin, Sind, Pakistan.
- Examine the effect of mPareshan intervention on screen positive participants' mean anxiety and depression scores.
- Observe the effect of a contextually adapted mhGAP training on mental health literacy (knowledge) and skills of LHWs and LHSs working in District Badin.

Methods

Study Procedure

Project mPareshan is a prospective, single-district, pre- and post-test feasibility trial, employing mixed methods (qualitative and quantitative) of data collection. In a baseline survey, residents of District Badin were screened by trained data collectors for symptoms of anxiety and depression using standardized psychometric scales of PHQ-9 and GAD-7, respectively. Individuals screening positive (SPs) for symptoms of mild and moderate anxiety and/or depression are recruited to receive mental health counselling sessions at community doorstep via mPareshan app. An endline assessment of the SPs is done after intervention to assess reduction in anxiety and depression scores. Pre-and-post intervention in-depth interviews and focus group discussions with community participants and community health workers (LHWS and LHSs) have been built-in to determine feasibility, acceptability, and usefulness of delivering mental health counselling via the mHealth application. Before the intervention, CHWs (LHWs/LHSs) are trained to improve their mental health literacy using a contextually adapted version of WHO mhGAP guide for non-specialist setting [29]. A schematic diagram of the study procedures and expected outcomes is presented in Table 1. This study has been prospectively registered by Australian New Zealand Clinical Trial Registry (ACTRN12622000989741).

Table 1: Summary of mPareshan study phases, data collection methods and expected outcomes.

Project Phase	**Phase 1: Pre-intervention**			**Phase 2: Intervention**	**Phase 3: Post-intervention**	
Data collection	**Qualitative data**	**Quantitative data**		**Intervention Rollout**	**Qualitative data**	**Quantitative data**
	FGDs & KIIs	HH Survey	mhGAP based	Regular feedback received through	FGDs & KIIs	Endline survey PHQ-

	PHQ-9, GAD-7	training	mPareshan App	9, GAD-7	
Research Questions					**Expected outcome**
1. What is the point prevalence of anxiety & depression amongst a sample of rural households?	✓				**Establishing prevalence of mild, moderate, and severe symptoms of anxiety & depression in District Badin.**
2. Is it feasible to implement an mHealth-based mental health intervention through LHWs at community doorsteps?	✓			✓	**Acceptability of LHW/LHS for using mPareshan app in managing anxiety & depression. Perceived barriers & facilitators in using the mPareshan App.**
3. Is there a change in LHW knowledge & skills in assessing, diagnosing, & managing anxiety & depression because of mPareshan mhGAP-based training?		✓			**Capacity building of LHS & LHWs through mPareshan training**
4. Is there any change in anxiety & depression scores of SPs because of mPareshan intervention?	✓			✓	**Change in anxiety & depression scores of SPs. Operability, usefulness, & task-technology fitness of mPareshan App to the end-users**

HH: Household

Study Site

Badin is a coastal district in Pakistan's southern province of Sindh with a population of 1.8 million. There are 5 Talukas (administrative units) and 49 union councils. Badin has an average literacy rate (ability to read and write) of 24% with an approximate household size of 6 persons [30]. The district has one of the highest suicide rates in the province with a poor mental health care infrastructure [31]. Badin has a functional national LHW-P with 1100 LHWs working under the supervision of 36 LHSs.

Eligibility Criteria

Inclusion Criteria

Residents that are 18 years of age and older, who exhibit "mild" or "moderate" symptoms of anxiety or depression as determined by the GAD-7 and PHQ-9 scales, are included in the research.

Exclusion Criteria

Individuals receiving therapy or pharmacological treatment for mental health issues and exhibiting severe anxiety/depression with danger signs (self-harm, harm to others and suicidal ideation) are not included in the study.

Intervention Package

Training to build CHW's Mental Health Literacy

A manual is designed to train LHSs and LHWs in identification of symptoms of anxiety and depression, counselling techniques, and making appropriate referrals. The brief outline of this modular training curriculum is given in Figure 1. Curriculum content is an adaptation of WHO Mental Health Gap Action Program-Intervention Guide V2.0 (mhGAP-IG 2.0) [29].
Figure 1

Main intervention: mPareshan Digital App

The mPareshan app has been designed after a formal feasibility assessment using qualitative research methods (explained in next section). The app has three segments: tracking, counselling, and referral. The tracking segment records information on participant recruitment/retention, consent and has interfaces for LHS, LHW, and study coordinator (SC) to access and record their feedback. Based on a two-week recall, the referral segment identifies danger signs related to suicidal ideation, self-harm and harm to others and then suggests appropriate referrals to the nearest mental health facility. In the absence of danger signs, the LHW is guided to the counselling segment for those who have been screened positive (SPs) for mild and moderate anxiety and depression based on standard psychometric scales. This segment of the app has features of psychoeducation delivered through audio and video clips, breathing exercises and imparts skills to cope with symptoms of anxiety and depression. This segment has different content for each of the 6 sessions.
Completion of counselling segment redirects the LHW to the section on feedback where she checks all activities that are performed in the session and records her written comments. Once submitted to the server by the LHW, the session gets locked and is passed on to her LHS for review as part of supportive supervision. LHS logs in from her portal to review all the feedback provided by LHW and submits it through her portal to the SC for a final check. The subsequent session gets unlocked for the LHW after 15 days of completion and submission of feedback of the preceding session.
These sessions coincide with LHWs' scheduled monthly household visits in their catchment area. A summary of the app layout and a workflow are presented in Figure 2 and 3, respectively.
Figure 2
Figure 3

Quantitative Assessments

Pre-intervention, a baseline survey is conducted in 5 Talukas of District Badin, Sind to identify individuals having symptoms of anxiety and depression. Trained data collectors visit households (HH) for data collection. Data collectors are recruited from the district and

provided training on administering GAD-7 and PHQ-9 tools. They are trained in entering data electronically using REDCap software on a tablet.

Psychometric Instruments

The GAD-7 scale is used to screen symptoms of anxiety disorders. This scale has 7 items, and the score is calculated by assigning scores of 0 to "not at all", 1 to "several days", 2 to "more than half of the days" and 3 to "nearly every day" category, and then adding the score of each question results in the overall anxiety score. The maximum score is 21 and the minimum score is 0. Scores of 5, 10, and 15 are taken as the cut-off points for mild, moderate, and severe anxiety, respectively. The GAD-7 has 89% sensitivity and 82% specificity for generalized anxiety disorder by using the cut-off score of 10 [32].
The PHQ-9 scale is used to screen for symptoms of depression. There are 9 items, and the score is calculated, like GAD-7, by assigning scores from 0 to 3. The maximum score is 27 and the minimum score is 0. Scores of 5, 10, 15, and 20 represent cut-off points for mild, moderate, moderately severe, and severe depression, respectively. The PHQ-9 has 88% sensitivity and 88% specificity for major depression by using the cutoff score of 10 [33].

Sample size calculations

For baseline screening survey, sample size is calculated using OpenEpi version 3.01. Assuming 30% prevalence of depression and anxiety symptoms among adults, at 5% level of significance and 80% power, 323 people are required to assess point prevalence of depression and anxiety [34]. Catering to 10% refusals, the final sample size is 366 people. Participants who screen positive (SPs) for signs of anxiety or depression receive 6 mPareshan app-based counselling sessions. REDCap based endline survey is repeated post-intervention with SPs to assess a change in their anxiety and depression scores.
To assess change in knowledge and skills scores of health workers pre- and post-training, another quantitative assessment is carried out. 72 health care workers are required to detect a mean difference of 1.5 (SD 3.9) in pre- and post-training knowledge and skills score, assuming 5% significance level and 80% study power [35]. All 36 LHSs will be selected and each LHS will randomly select one LHW among her most committed LHWs.
For receiving mPareshan app-based intervention, the sample size for recruitment of SPs is calculated using Medcalculator version 19.8 (MedCalc Software, Ostend, Belgium). Assuming a mean difference between pre- and post-intervention of PHQ-9 scores of 1.5 (SD 5.6) (mean score at baseline=11.61, and post-intervention=10.1), the minimum sample size required at a 5% level of significance and 80% power is 112. Considering 10% attrition rate, with some oversampling, the expected sample size is 123 for recruiting participants for the mPareshan intervention [36].

Qualitative Assessments

Pre-intervention qualitative assessments through Focus Group Discussions (FGDs) and Key Informant Interviews (KIIs) are done with LHSs, LHWs, community participants (CP) and LHW-P stakeholders to assess the acceptability, appropriateness, and feasibility of executing the digital intervention through the LHWs at the household level. For postintervention, same assessments are repeated to ascertain the task technology shift, acceptance, and uptake of the mHealth based intervention. Enablers and barriers in implementing the intervention are simultaneously ascertained.
All FGDs and KIIs are developed according to a semi-structured guide with a pre-set list of open-ended questions, organized in a logical pattern with relevant probes. The latter focuses on acceptability and appropriateness of technology, task shifting to LHWs, facilitators and barriers for intervention roll-out and implementation scale-up. These semi-structured guides

are translated into the local language, Sindhi, and then translated back into English.

Execution of Implementation Strategy

The health workers assigned to the households of SPs are trained to use configured Samsung Galaxy Tab A7 (4G) on which the mPareshan app is downloaded. The training facilitators demonstrate how health workers are to operate tracking, referral, counselling, and feedback segments of the mobile application. SPs having mild and moderate anxiety and depression scores are recruited to receive the intervention.

Prior to commencement of the 20-minutes counselling session, the LHW requests the SP to be seated in a comfortable, preferably isolated place in the house. At the end, the participant is instructed to practice breathing exercises until the next session. LHW ensures that the participant feels comfortable and consents to receiving the intervention. In the unlikely event of the participant feeling uncomfortable at any point while receiving the intervention, the LHW/LHS concludes the session immediately.

Data Analysis

Baseline and endline data collected from respondents will be exported from REDCap to Statistical Package for the Social Sciences (SPSS) Version 21 (IBM Corp). Frequency and proportion will be used to report categorical variables. Depending on the distribution of GAD-7 and PHQ-9 scores, and knowledge and skill scores of CHWs, a paired t-test/McNemar's Chi Square test will be used to evaluate the change in outcome from baseline to post-intervention. Mean difference with 95% confidence intervals will be reported. A p-value of <0.05 will be considered statistically significant.

All interviews will be transcribed in English. Using QSR NVivo, content analysis will be conducted on all KII and FGD transcripts, and codes will be organized into either emergent or pre-determined categories by the researchers. Commonalities and differences across the data will be identified and clustered around thematic sections. Verbatim quotes will be added to complement the themes. RE-AIM framework will be used to describe the feasibility outcomes [37].

Ethical Approval

This study protocol has been approved by the Ethical Review Committee of Aga Khan University (ERC# 2021-6570-20015). This is a behavior modification intervention with app-based counselling being provided by peer frontline health workers at community doorsteps and is not a clinical/drug trial. No adverse events are anticipated because of this intervention. Any participants exhibiting (the a priori defined) danger signs will be immediately referred during subject recruitment or counselling phases.

Results

Ethical clearance (ERC#2021-6570-20015) for this study was obtained in December 2021, and further extension received in December 2022. Data collection was done in 2022. Final data cleaning and data analysis is ongoing, and the results will be disseminated through peer-reviewed publications in 2024.

Discussion

Project mPareshan will introduce a novel modality for provision of mental healthcare, by empowering frontline health workers to identify symptoms of anxiety and depression, offer early referrals and provide preventive psychosocial counselling at community doorsteps. The community will ultimately benefit as the mental well-being of the population improves. This

study will be the first to introduce delivery of mental health counselling by CHWs with the help of a mobile application. Previous studies utilizing mHealth modalities have used cellular devices for the purpose of making referrals and record keeping [25]. Despite the high reported suicide rate there is lack of awareness about mental health and availability of specialized mental health services is suboptimal in district Badin. The novel approach being tested in our project is expected to prove effective in improving mental health of rural population where access to healthcare is limited and difficult. Results from this study will be important in initiating policy dialogue for horizontal integration of basic mental health counselling initiatives in the current primary health system of low-resource settings.
Through the modified mhGAP training provided by the project, frontline CHW's capacity to identify signs of mental illness, provide counselling and give appropriate referrals will improve. Based on the results of this pilot project, mental health can be introduced as part of the LHW training and curriculum and scaling up at the provincial level can be planned. This policy decision can help to promote mental well-being of communities in a resource-constrained setting such as Pakistan.

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Conflict of Interest

None declared.

Abbreviations

CHW: Community Health Worker

FGD: Focus Group Discussion

GAD-7: Generalized Anxiety Disorder 7

HH: Household

KII: Key Informant Interviews

LHS: Lady Health Supervisor

LHW: Lady Health Worker

LHW-P: Lady Health Worker Programme

LMIC: Low- and Middle-Income Country

mhGAP: Mental Health Gap Action Programme

PHQ-9: Patient Health Questionnaire 9

SC: Study Coordinator

SD: Standard Deviation

SP: Screen Positive

WHO: World Health Organization

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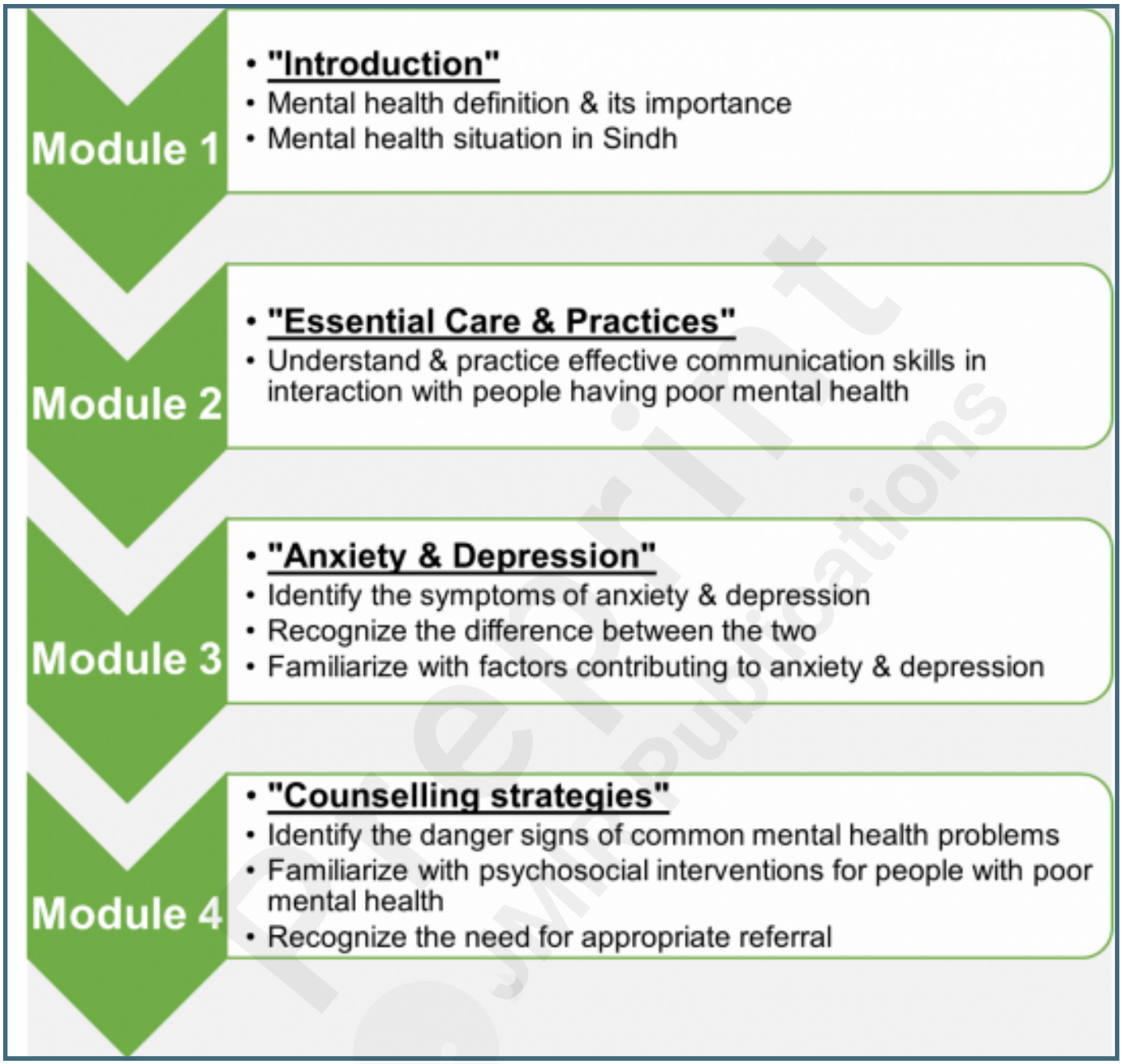
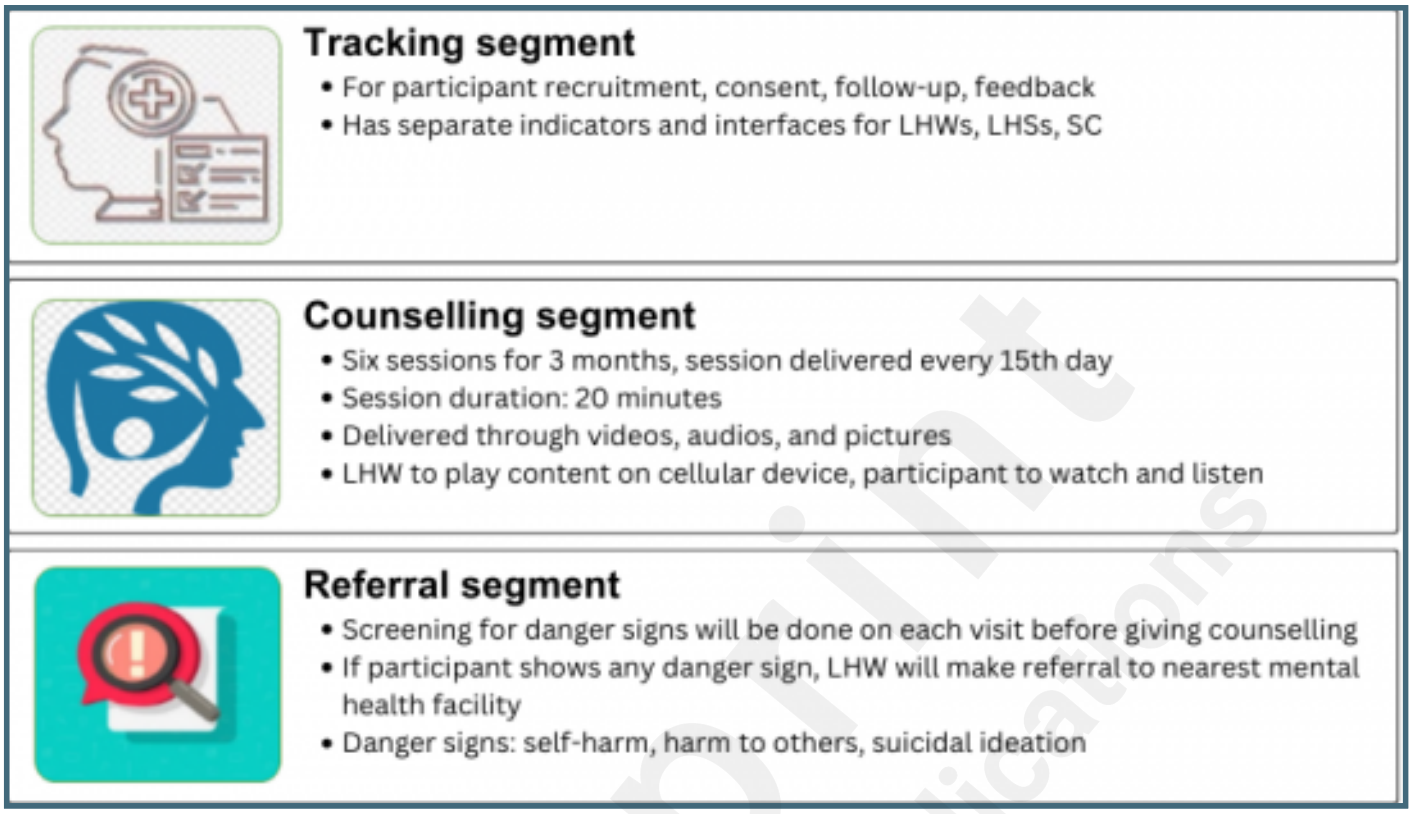
Supplementary Files

Figures

Outline of mPareshan training curriculum.



Outline of mPareshan app segments and active ingredients.



mPareshan workflow.