

Technology-assisted mental health intervention delivered by frontline workers at community doorsteps for reducing anxiety and depression in rural Pakistan: Protocol for mPareshan mixed methods implementation trial

Fauziah Rabbani, Javeria Nafis, Samina Akhtar, Muhammad Shahid Khan, Saleem Sayani, Amna Siddiqui, Sameen Siddiqi, Zul Merali

Submitted to: JMIR Research Protocols
on: November 10, 2023

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript.....	5
Supplementary Files.....	20
Figures	21
Figure 1.....	22
Figure 2.....	23
Figure 3.....	24
Figure 4.....	25
Multimedia Appendixes	26
Multimedia Appendix 1.....	27

Technology-assisted mental health intervention delivered by frontline workers at community doorsteps for reducing anxiety and depression in rural Pakistan: Protocol for mPareshan mixed methods implementation trial

Fauziah Rabbani^{1,2} PhD; Javeria Nafis² MSc; Samina Akhtar² MPhil; Muhammad Shahid Khan² MSc; Saleem Sayani³ PhD; Amna Siddiqui¹ MSc; Sameen Siddiqi² PhD; Zul Merali¹ PhD

¹Brain and Mind Institute Aga Khan University Karachi PK

²Department of Community Health Sciences Aga Khan University Karachi PK

³Digital Health Resource Centre Aga Khan Development Network Karachi PK

Corresponding Author:

Fauziah Rabbani PhD

Brain and Mind Institute

Aga Khan University

Stadium Road

Karachi

PK

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 LHSSs. 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

(JMIR Preprints 10/11/2023:54272)

DOI: <https://doi.org/10.2196/preprints.54272>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ Please make my preprint PDF available to anyone at any time (recommended).

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.

Only make the preprint title and abstract visible.

No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <http://www.jmir.org/>



Original Manuscript

Protocol

Technology-assisted mental health intervention delivered by frontline workers at community doorsteps for reducing anxiety and depression in rural Pakistan: Protocol for mPareshan mixed methods implementation trial

Fauziah Rabbani, PhD^{1,2*}, Javeria Nafis, MSc¹, Samina Akhtar, MPhil¹, Muhammad Shahid Khan, MSc¹, Saleem Sayani, PhD³, Amna Siddiqui, MSc², Sameen Siddiqi, PhD¹, Zul Merali, PhD²

¹Community Health Sciences, Aga Khan University, Karachi, Pakistan

²Brain and Mind Institute, Aga Khan University, Karachi, Pakistan

³Digital Health Resource Centre, Aga Khan Development Network, Karachi, Pakistan

Corresponding author:

Fauziah Rabbani, PhD

Chief Implementation Science and Innovation, Brain & Mind Institute and Professor Public Health,
Department of Community Health Sciences

Aga Khan University, Stadium Road, Karachi, Pakistan, 3500

Tel: (9221) 34864864, 34930051, Fax: (9221) 34934294, 3493-2095

fauziah.Rabbani@aku.edu

Abstract

Background: There is a dearth of specialized mental health workforce in low- and middle-income countries. Mobile technology in the hands of community health workers (CHWs) is exhibiting immense potential in Pakistan. However, the acceptability and do-ability of executing digital mental health services by frontline health workers for those living with mental health disorders remains uncertain. In the presence of huge treatment gaps, the feasibility of utilizing frontline CHWs 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 government Lady Health Workers (LHWs) to reduce anxiety and depression in rural Pakistan.

Methods: Project mPareshan is a single-arm, pre- and post-test implementation research trial in District Badin, Sindh employing mixed-methods of data collection executed in three phases (pre-intervention, intervention, post-intervention). In the pre-intervention phase, formative qualitative assessments through Focus Group Discussions (FGDs) and In-Depth Interviews (IDIs) assess acceptability and appropriateness of intervention through perceptions of all concerned stakeholders through a specific interview guide. A REDcap-based baseline survey using Patient Health Questionnaire-9 (PHQ-9) and Generalized Anxiety Disorder-7 (GAD-7) determines point prevalence of depression and anxiety among consenting men and women > 18 years. Individuals with mild and moderate anxiety and depression are identified as screen positives (SPs) and are eligible for mPareshan app-based intervention. Mental health literacy of health workers is improved through a customized mPareshan training adapting World Health Organization's mhGAP guide 2.0. The intervention (mPareshan App) consists of tracking, counselling, and referral segments. The tracking segment facilitates participant consent and enrolment while the referral segment guides LHWs to refer severe cases exhibiting danger signs to the next level of specialist care. Through the counselling segment, identified SPs are engaged during LHWs' routine home visits in six face-to-face, 20-minute counselling sessions over 6 months. Each session imparts psychoeducation through audio-visual aids, breathing exercises and coping skills to reduce stress. Clinical and implementation outcomes include change in mean anxiety and depression scores using the same validated instruments and qualitative assessments to determine facilitators and barriers in intervention uptake and roll out.

Results: At the time of this submission (April 2024), we are analysing results of 366 individuals who participated in the baseline prevalence survey, change in knowledge and skills of 72 health workers who took the mPareshan training, change in anxiety and depression scores of 98 SPs recruited for app-based counselling intervention, and perceptions of stakeholders pre- and post-intervention gathered through 8 FGDs and 18 IDIs.

Conclusions: This trial will assess the feasibility of early home-based mental health screening, counselling, and prompt referrals by frontline health workers to reduce anxiety and depression in the community. The study findings will set the stage for integrating mental health into primary healthcare.

Trial Registration: ACTRN12622000989741

Keywords: Anxiety; Depression; Feasibility; Mental Health; Health Workers; mPareshan App; Implementation Research

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 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 several factors such as poverty, political turmoil, gender inequality and natural disasters, to mention a few [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 deaths by suicides 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 programme has already been established in Pakistan, known as the Lady Health Worker Programme (LHW-P) [12]. Lady Health Workers (LHWs) and Lady Health Supervisors (LHSs) will be collectively referred to as CHWs or health workers 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 assigned catchment areas [13]. LHWs are required to have a minimum of 8 years of education and receives 15 months of training. They maintain health records and track basic health indicators [14]. A LHW typically serves between 100 and 150 houses (1,000 people) per month [15] and provides health promotion and disease prevention counselling and monitoring for vaccinations, family planning, maternal and child health care along with appropriate referrals to specialists where needed [16]. Each LHW is supervised by an LHS. LHSs have higher educational and competency levels as compared to LHWs and are tasked with coordination, monitoring, and supervision of the LHWs at the level of union council (smallest administrative unit of the district). Typically, each LHS oversees 20–25 LHWs and provides them with the required supervision and mentorship. LHSs report to their District Health Officer/District Coordinator [14].

In Pakistan, LHWs can be utilized to deliver mental health care by acting as the first responders to screen, counsel and make suitable referrals. Mental health interventions offered by LHWs can provide cost-effective health promotion preventive options for communities with limited resources [17]. 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 [18].

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 [19]. Mobile penetration being greater than 90% in LMICs has strengthened the viability of mHealth programs, especially in remote areas [20].

Besides being cost-effective, mobile technology has better potential for extensive population-based outreach given its higher penetration and accessibility [21,22]. 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 [23–25].

The promising role of mHealth in screening symptoms of depression and anxiety and halting progression towards severity has been highlighted in previous work [26]. 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 [26].

Like other developing countries, Pakistan has also given less consideration to mental health at the policy level [27]. 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 [28]. This would require integration of primary health care work force into the agenda of the governments, NGOs, and global mental health stakeholders [29].

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, Sindh, 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 Outline

Project mPareshan is a prospective, single-district, pre- and post-test implementation research trial, employing mixed methods (qualitative and quantitative) of data collection. All phases of the trial are described in detail in the following sections. In the pre-intervention phase, formative qualitative assessments are conducted with relevant stakeholders (community participants, LHWs, LHSs, and policy makers) to determine acceptability and appropriateness of delivering mental health counselling via a mobile application. Following this, in a baseline prevalence survey, residents of District Badin are screened by trained data collectors for symptoms of anxiety and depression using standardized psychometric scales of GAD-7 and PHQ-9, respectively. Individuals having symptoms of mild and moderate anxiety and/or depression are then identified as screen positives (SPs). Before commencing the intervention, LHWs and LHSs are trained so that their mental health literacy, communication, and counselling skills improve. The training content is contextually adapted from WHO mhGAP guide 2.0 (designed for non-specialist settings) [30]. A pre- and post-training assessment of health workers assesses improvement in their knowledge and skills. Next, the mPareshan app is developed based on stakeholder feedback acquired during the formative qualitative inquiry. The app segments and intervention contents are described below. In the intervention phase, SPs receive one home-based counselling session per month by LHWs

over a period of 6 months. After the intervention phase, a quantitative endline assessment of the SPs is done to assess change in anxiety and depression scores. Post-intervention qualitative assessments of key stakeholders determines barriers and facilitators in intervention uptake and roll out. 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). Written, informed consent is taken from all participants at each stage of the study.

Table 1: Summary of mPareshan implementation research methods: Phase-wise data collection procedures and expected outcomes in District Badin, Sindh, Pakistan (2022-2023).

Project Phase	Phase 1: Pre-intervention			Phase 2: Intervention	Phase 3: Post-intervention	
	Qualitative data	Quantitative data		Intervention Rollout*	Qualitative data	Quantitative data
Data collection	FGDs & IDIs	HH Survey	mhGAP based training	Regular feedback received through mPareshan App	FGDs & IDIs	Endline survey PHQ-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		✓				Change in anxiety & depression scores of SPs. Operability, usefulness, &

mPareshan intervention?		task- technology fitness of mPareshan App to the end-users
----------------------------	--	---

HH: Household, FGD: Focus Group Discussion, IDI: In-depth Interview.

*Intervention described in Figure 4.

Study Site

Participants for the intervention are recruited from Badin, which 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 [31]. The district has one of the highest suicide rates in the province with a poor mental health care infrastructure [32]. Badin has a functional national LHW-P with 1100 LHWs working under the supervision of 36 LHSs.

Phase 1: Pre-Intervention

Formative Qualitative Assessments

The study framework for the qualitative assessment was guided by the Reach, Effectiveness, Adoption, Implementation and Maintenance components of the RE-AIM framework [33]. The framework provides a thorough implementation research structure and focuses on several outcomes like acceptability, appropriateness, adoption, feasibility, etc. [34].

Qualitative assessments (FGDs and IDIs) in the initial formative phase are conducted in separate groups with various stakeholders comprising of LHSs, LHWs, community participants (CPs) and policy makers. The purpose is to assess stakeholder perceptions regarding the acceptability, appropriateness, and feasibility of executing the digital intervention. Permanently employed LHWs and LHSs who regularly perform household visits and report to their programme supervisors are randomly selected for the interviews. CPs are influential people of the community (religious scholars and teachers) capable of providing their viewpoint. Policy makers who are key decision-makers at the Provincial Department of Health and the Provincial Program Implementation Unit of LHW-P, Badin are selected for IDIs. Thus, information and feedback obtained before rolling out the intervention is helpful in designing the various features of the mPareshan app (the main intervention).

A semi-structured guide helps to carry out the FGDs and IDIs. The guide has a pre-set list of open-ended questions, organized in a logical pattern with relevant probes (Supplementary Table S1). The probes explore acceptability and appropriateness of involving LHWs in this technology-driven intervention. This guide is translated into the local language, Sindhi, and then translated back into English. Qualitative interviews last about 30-45 minutes, or until the point of saturation. All participants provide written consent before starting the interview.

Baseline Quantitative Assessments

Household Survey

A baseline survey is conducted in 5 Talukas of District Badin, Sindh to identify individuals having symptoms of anxiety and depression. Trained field staff visit households (HH) for data collection. Data collectors are provided training on administering GAD-7, PHQ-9 and entering data electronically using REDCap software on a tablet. Data is also collected on basic sociodemographic variables.

The GAD-7 scale is used to screen symptoms of anxiety disorders. This scale has 7 items,

and each item is rated on a sliding scale of 0-3 based on frequency of occurrence of the symptoms. The maximum possible 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. GAD-7 has 89% sensitivity and 82% specificity for detecting generalized anxiety disorder at a cut-off score of 10 [35].

The PHQ-9 scale screens for symptoms of depression. There are 9 items rated on a scale of 0 to 3. The maximum possible 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. PHQ-9 has 88% sensitivity and 88% specificity for detecting major depression at a cutoff score of 10 [36].

Participants with mild and/or moderate symptoms of anxiety and depression on the GAD7 and PHQ9 scales are identified as SPs and invited to take part in the mPareshan app-based counselling sessions.

Assessment of CHW's Mental Health Literacy

Before commencing the mental health intervention, a manual is designed to train LHSs and LHWs in identification of symptoms of anxiety and depression, counselling techniques, and making appropriate referrals [37]. 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) [30]. A pre- and post-training knowledge and skills assessment of the health workers is also carried out to determine change in their mental health literacy and awareness.

Figure 1.

Phase 2: Intervention Roll Out

Eligibility Criteria for Participant Enrolment in Intervention

Residents that are 18 years of age and older, who screen positive (SP) for “mild” or “moderate” symptoms of anxiety or depression as determined by the GAD-7 and PHQ-9 scales, are recruited for the mPareshan intervention. 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.[30]

Main intervention: mPareshan Digital App

The mPareshan app has been designed based on feedback received from stakeholders in the formative phase. 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 accordingly. In the absence of danger signs, the LHW is guided to the counselling segment of the app to deliver counselling to the SPs. This segment of the app has features of psychoeducation delivered through audio and video clips, breathing exercises and imparts skills to cope with stress. The counselling segment has different content for each of the 6 sessions, which last around 20 minutes. An outline of the content covered in the 6 sessions is provided in Figure 2.

Figure 2

Prior to commencement of the 20-minutes counselling session, the LHW requests the SP to be seated in a comfortable, preferably less crowded place in the home. At the end of each session, the participant is instructed to practice breathing exercises as homework until the next session. LHW ensures that the participant feels comfortable and consents to receiving

the counselling. If the SP feels uncomfortable at any point in time, the session is discontinued.

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. LHS logs in from her portal to review all the feedback provided by LHW and submits it to the SC for a final check. The subsequent session gets unlocked for the LHW after 15 days of completion of the previous session.

These sessions coincide with LHWs' scheduled monthly household visits in their catchment area. 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.

A summary of the app layout and project workflow (implementation steps) is presented in Figure 3 and 4, respectively.

Figure 3

Figure 4

Phase 3: Post-Intervention

Endline Quantitative Assessment

After the six mental health counselling sessions have concluded, an endline HH survey is conducted by trained data collectors using the same PHQ-9 and GAD-7 psychometric tools. This determines change in mean symptomatic scores of anxiety and depression amongst intervention recipients (SPs), indicating intervention effectiveness (clinical outcome).

Endline Qualitative Assessment

In the post-intervention phase, qualitative assessments (FGDs and IDIs) are done to ascertain the feasibility of intervention uptake and understand facilitators and barriers in implementation roll out. Key stakeholders for FGDs include those randomly selected LHSs and LHWs who took part in the delivery of the intervention. Moreover, for IDIs, community participants in the post-intervention qualitative phase also include those individuals who receive the digital counselling intervention, viz. the SPs. All participants provide written informed consent prior to their interviews.

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 [38]. Catering to 10% refusals, the final sample size is 366 individuals.

For the change in mental health literacy of CHWs, a total of 72 LHSs and LHWs are required to detect a mean difference of 1.5 (SD 3.9) in pre- and post-training knowledge and skills scores, assuming 5% significance level and 80% study power [39].

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 and demonstrating a reduction in symptoms [40].

Data Analysis

Baseline and endline data collected from respondents is being 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 anxiety/depression scores of SPs and knowledge/skills scores of health workers, paired T-tests/McNemar's Chi Square tests will be used to evaluate the change in outcomes. 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 IDI 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 [33].

Ethical Considerations

This study protocol has been approved by the Ethical Review Committee of Aga Khan University (ERC# 2021-6570-20015). mPareshan is an implementation research feasibility trial and is not a clinical/drug trial. No adverse events are therefore anticipated. Any participants exhibiting (the a priori defined) danger signs will be immediately referred during participant recruitment or counselling phases. Written, informed consent is obtained from each participant in their local language at each phase of the study. Data is anonymized and participant confidentiality is maintained. No compensation is offered to SPs for participation in the counselling sessions.

Results

Data collection was done in 2022-2023. At the time of this submission (April 2024), we are analysing results of 366 individuals who participated in the baseline prevalence survey, change in knowledge and skills of 72 health workers who took the mPareshan training, change in anxiety and depression scores of 98 SPs recruited for app-based counselling intervention, and stakeholder perceptions gathered from 8 FGDs and 18 IDIs as part of qualitative assessments. Final data cleaning and data analysis is ongoing, and the results will be disseminated through peer-reviewed publications in 2024.

Discussion

Project mPareshan will assess the feasibility of utilizing frontline workers in early home-based screening of anxiety and depression, providing app-based mental health counselling, and prompt referrals. The community will ultimately benefit as the mental well-being of the population improves by a projected decrease in mean symptomatic scores of anxiety and depression. The contextually adapted mhGAP training for health workers will also lead to an improvement in their mental health literacy thus building capacity of primary healthcare workforce in mental health service delivery.

Previous studies using mHealth modalities have used cellular devices for the purpose of making referrals and record keeping [26]. 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 this trial is expected to improve mental health of rural population where access to healthcare is limited and difficult. Results from this study will be important in initiating a policy dialogue for horizontal integration of basic mental health counselling initiatives in the current primary health system

of low-resource settings.

Implementation challenges in this trial in the field included partial disruption and delay in intervention execution attributed to natural disasters e.g. floods in 2022. Furthermore, fluctuations in internet connectivity partially compromised the delivery of the app-based counselling sessions initially. The current substantial workload of LHWs makes it difficult to add on mental health counselling as part of their routine package of service delivery. Moreover, considering the small sample size of participants enrolled for receiving the intervention, generalizability of study findings may be an issue.

Based on the anticipated results of this pilot project, mental health can be introduced as part of the LHW curriculum and service delivery package. This will set the stage for integrating mental health into primary healthcare.

Acknowledgements

This study has been funded by a grant from the Brain and Mind Institute, Aga Khan University (Grant Brain and Mind-FR-11E-mPareshan App 83000) and executed by the Department of Community Health Sciences, Aga Khan University, Karachi. We thank honourable Minister of Health, Government of Sindh, Dr. Azra Fazal Pechuho for her continuous encouragement and support throughout the implementation of the mPareshan trial. All authors contributed to this work including conceptualization and manuscript writing.

Data Availability

The data sets generated will be available from the corresponding author on request. It is to be noted that additional data pertaining to measurement of loneliness was also collected on the UCLA Loneliness Scale (LS-10) at the time of baseline and endline HH survey and will be reported separately.

Conflict of Interest

None declared.

Abbreviations

CHW: Community Health Worker

CP: Community Participant

FGD: Focus Group Discussion

GAD-7: Generalized Anxiety Disorder 7

HH: Household

IDI: In-Depth 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



References

1. Hussain SS, Khan M, Gul R, Asad N. Integration of mental health into primary healthcare: Perceptions of stakeholders in Pakistan. *East Mediterr Health J*; 2018 May; 24(2):146–153. PMID:29748943
2. World Health Organization. Depression and other common mental disorders: global health estimates. World Health Organization 2017; WHO/MSD/MER/2017.2. 2017. Available from <https://www.who.int/publications/i/item/depression-global-health-estimates>
3. Patel V. Mental health in low- and middle-income countries. *Br Med Bull* 2007 Jan 1; 81–82(1):81–96. doi: 10.1093/bmb/ldm010
4. James S, Chisholm D, Murthy RS, Kumar KK, Sekar K, Saeed K, Mubbashar M. Demand for, access to and use of community mental health care: Lessons from a demonstration project in India and Pakistan. *Int J Soc Psychiatry* 2002; 48(3). doi: 10.1177/002076402128783217
5. Trautmann S, Rehm J, Wittchen H. The economic costs of mental disorders. *EMBO Rep* 2016 Sep 4; 17(9):1245–1249. doi: 10.15252/embr.201642951
6. Iqbal Z, Murtaza G, Bashir S. Depression and Anxiety: A Snapshot of the Situation in Pakistan. *Int J Neurosci Behavior Sci* 2016 Sep 1; 4(2):32–36. doi: 10.13189/ijnbs.2016.040202
7. Mirza I, Jenkins R. Risk factors, prevalence, and treatment of anxiety and depressive disorders in Pakistan: Systematic review. *Br Med J* 2004 Apr 1; 328(7443):794–797. PMID:15070634
8. Wang PS, Angermeyer M, Borges G, Bruffaerts R, Tat Chiu W, DE Girolamo G, Fayyad J, Gureje O, Haro JM, Huang Y, Kessler RC, Kovess V, Levinson D, Nakane Y, Oakley Brown MA, Ormel JH, Posada-Villa J, Aguilar-Gaxiola S, Alonso J, Lee S, Heeringa S, Pennell B-E, Chatterji S, Ustün TB. Delay and failure in treatment seeking after first onset of mental disorders in the World Health Organization's World Mental Health Survey Initiative. *World Psychiatry* 2007; 6(3).
9. Hayat K, Haq MIU, Wang W, Khan FU, Rehman A ur, Rasool MF, Kadirhaz M, Omer S, Rasheed U, Fang Y. Impact of the COVID-19 outbreak on mental health status and associated factors among general population: a cross-sectional study from Pakistan. *Psychol Health Med* 2022; 27(1). doi: 10.1080/13548506.2021.1884274
10. Mamun MA, Ullah I. COVID-19 suicides in Pakistan, dying off not COVID-19 fear but poverty? – The forthcoming economic challenges for a developing country. *Brain Behav Immun*. 2020. doi: 10.1016/j.bbi.2020.05.028
11. Walker R. Walking beyond our borders with frontline health workers in Guatemala. *Nurs Womens Health* 2013; 17(6). doi: 10.1111/1751-486X.12082
12. Hafeez A, Mohamud BK, Shiekh MR, Shah SAI, Jooma R. Lady health workers programme in Pakistan: Challenges, achievements and the way forward. *J Pak Med Assoc* 2011; 61(3).
13. Jalal S. The lady health worker program in Pakistan - A commentary. *Eur J Public Health*. 2011. doi: 10.1093/eurpub/ckq199
14. Zhu N, Allen E, Kearns A, Caglia J, Atun R. Lady health workers in Pakistan: improving access to health care for rural women and families. Boston: Harvard School of Public Health 2014; Available from <https://www.hsph.harvard.edu/wp-content/uploads/sites/2413/2014/09/HSPH-Pakistan5.pdf>
15. Douthwaite M, Ward P. Increasing contraceptive in rural Pakistan: An evaluation of the Lady Health Worker Programme. *Health Policy Plan* 2005; 20(2). doi: 10.1093/heapol/

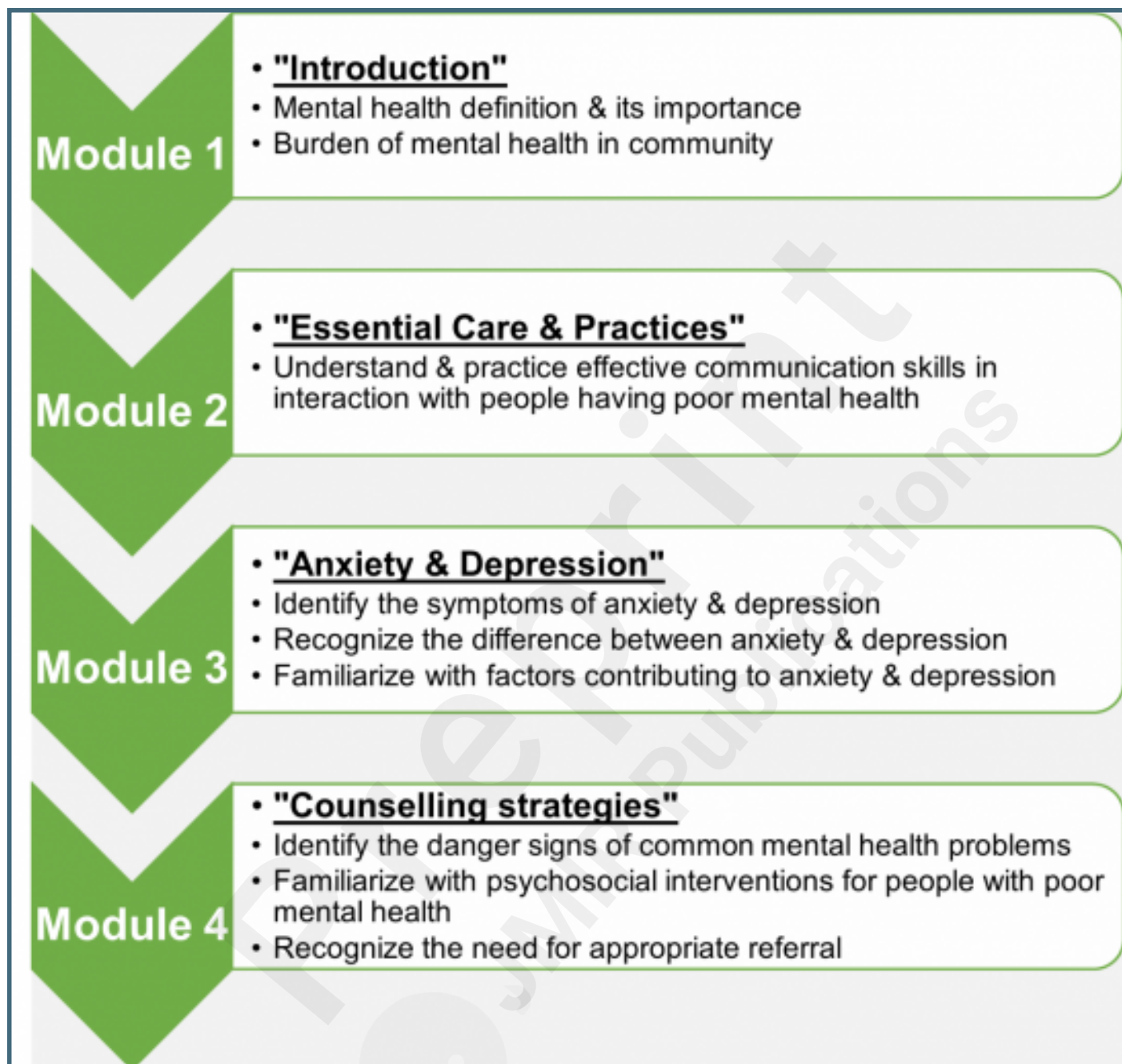
16. Folz R, Ali M. Task sharing in health workforce: An overview of community health worker programmes in Afghanistan, Egypt and Pakistan. *East Mediterr Health J* 2018; 24(9). doi: 10.26719/2018.24.9.940
17. Buttorff C, Hock R, Weiss H, Naik S, Araya R, Kirkwood B, Chisholm D, Patel V. Economic evaluation of a task-shifting intervention for common mental disorders in India. *Bull World Health Organ* 2012; 90(11). doi: 10.2471/blt.12.104133
18. Balaji M, Chatterjee S, Koschorke M, Rangaswamy T, Chavan A, Dabholkar H, Dakshin L, Kumar P, John S, Thornicroft G, Patel V. The development of a lay health worker delivered collaborative community based intervention for people with schizophrenia in India. *BMC Health Serv Res BMC Health Serv Res* 2012 Dec; 12(1). PMID:22340662
19. Braun R, Catalani C, Wimbush J, Israelski D. Community Health Workers and Mobile Technology: A Systematic Review of the Literature. *PLoS One* 2013; 8(6). doi: 10.1371/journal.pone.0065772
20. Zaidi S, Shaikh SA, Sayani S, Kazi AM, Khoja A, Hussain SS, Najmi R. Operability, acceptability, and usefulness of a mobile app to track routine immunization performance in rural Pakistan: Interview study among vaccinators and key informants. *JMIR Mhealth Uhealth* 2020; 8(2). doi: 10.2196/16081
21. Fottrell E. Commentary: The emperor's new phone. *BMJ (Online)* 2015. doi: 10.1136/bmj.h2051
22. Hall CS, Fottrell E, Wilkinson S, Byass P. Assessing the impact of mHealth interventions in low- and middle-income countries - what has been shown to work? *Glob Health Action* 2014. doi: 10.3402/gha.v7.25606
23. Bakker D, Kazantzis N, Rickwood D, Rickard N. Mental health smartphone apps: Review and evidence-based recommendations for future developments. *JMIR Ment Health* 2016. doi: 10.2196/mental.4984
24. Firth J, Torous J, Nicholas J, Carney R, Prata P, Rosenbaum S, Sarris J. The efficacy of smartphone-based mental health interventions for depressive symptoms: a meta-analysis of randomized controlled trials. *World Psychiatry* 2017; 16(3). doi: 10.1002/wps.20472
25. Mohr DC, Tomasino KN, Lattie EG, Palac HL, Kwasny MJ, Weingardt K, Karr CJ, Kaiser SM, Rossom RC, Bardsley LR, Caccamo L, Stiles-Shields C, Schueller SM. Intellicare: An eclectic, skills-based app suite for the treatment of depression and anxiety. *J Med Internet Res* 2017; 19(1). doi: 10.2196/jmir.6645
26. Maulik PK, Devarapalli S, Kallakuri S, Bhattacharya A, Peiris D, Patel A. The Systematic Medical Appraisal Referral and Treatment Mental Health Project: Quasi-Experimental Study to Evaluate a Technology-Enabled Mental Health Services Delivery Model Implemented in Rural India. *J Med Internet Res* 2020 Feb 1; 22(2). PMID:32130125
27. Karim S, Saeed K, Rana MH, Mubbashar MH, Jenkins R. Pakistan mental health country profile. *Int Review Psychiatry*. 2004. doi: 10.1080/09540260310001635131
28. Irfan M. Integration of mental health in primary care in Pakistan. *J Postgrad Med Inst* 2013; 27(4). Available from: <https://jpmi.org.pk/index.php/jpmi/article/view/1573>
29. Kok MC, Kane SS, Tulloch O, Ormel H, Theobald S, Dieleman M, Taegtmeier M, Broerse JEW, de Koning KAM. How does context influence performance of community health workers in low- and middle-income countries? Evidence from the literature. *Health Res Policy Syst* 2015; 13(1). doi: 10.1186/s12961-015-0001-3
30. World Health Organization. mhGAP training manuals for the mhGAP Intervention Guide for mental, neurological and substance use disorders in non-specialized health

- settings version 2.0 (for field testing). 2017. Available from: <https://apps.who.int/iris/bitstream/handle/10665/259161/WHO-MSD-MER-17.6-eng.pdf>
31. USAID, iMMAP. Pakistan Emergency Situation Analysis - Updated District Profile Badin, September 2014. 2014 Sep. Available from: <https://reliefweb.int/report/pakistan/pakistan-emergency-situation-analysis-updated-district-profile-badin-september-2014>
 32. Bhatti W. Incidence of suicide alarmingly high in South Asia: experts. The News International. 2022. Available from: <https://www.thenews.com.pk/print/971854-incidence-of-suicide-alarmingly-high-in-south-asia-experts>
 33. Holtrop JS, Estabrooks PA, Gaglio B, Harden SM, Kessler RS, King DK, Kwan BM, Ory MG, Rabin BA, Shelton RC, Glasgow RE. Understanding and applying the RE-AIM framework: Clarifications and resources. *J Clin Transl Sci* 2021 May 14; 5(1):e126. doi: 10.1017/cts.2021.789
 34. Proctor EK, Bunger AC, Lengnick-Hall R, Gerke DR, Martin JK, Phillips RJ, Swanson JC. Ten years of implementation outcomes research: a scoping review. *Implement Sci* 2023 Jul 25; 18(1):31. doi: 10.1186/s13012-023-01286-z
 35. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A brief measure for assessing generalized anxiety disorder: The GAD-7. *Arch Intern Med* 2006; 166(10). doi: 10.1001/archinte.166.10.1092
 36. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. *J Gen Intern Med* 2001; 16(9). doi: 10.1046/j.1525-1497.2001.016009606.x
 37. mPareshan App | Brain & Mind Institute | Aga Khan University. Available from: <https://www.aku.edu/bmi/research/Pages/mpareshan-app.aspx>
 38. Ali BS, Amanullah S. Prevalence of anxiety and depression in an urban squatter settlement of Karachi. *Journal of the College of Physicians and Surgeons Pakistan* 2000; 10(1).
 39. Bruni A. Assessing the efficacy of the Mental Health Gap Action Programme (mhGAP) training for non-specialized health workers in Ethiopia. 2014. Available from: <https://api.semanticscholar.org/CorpusID:74042721>
 40. Lüdtke T, Pult LK, Schröder J, Moritz S, Bückner L. A randomized controlled trial on a smartphone self-help application (Be Good to Yourself) to reduce depressive symptoms. *Psychiatry Res* 2018; 269. doi: 10.1016/j.psychres.2018.08.113

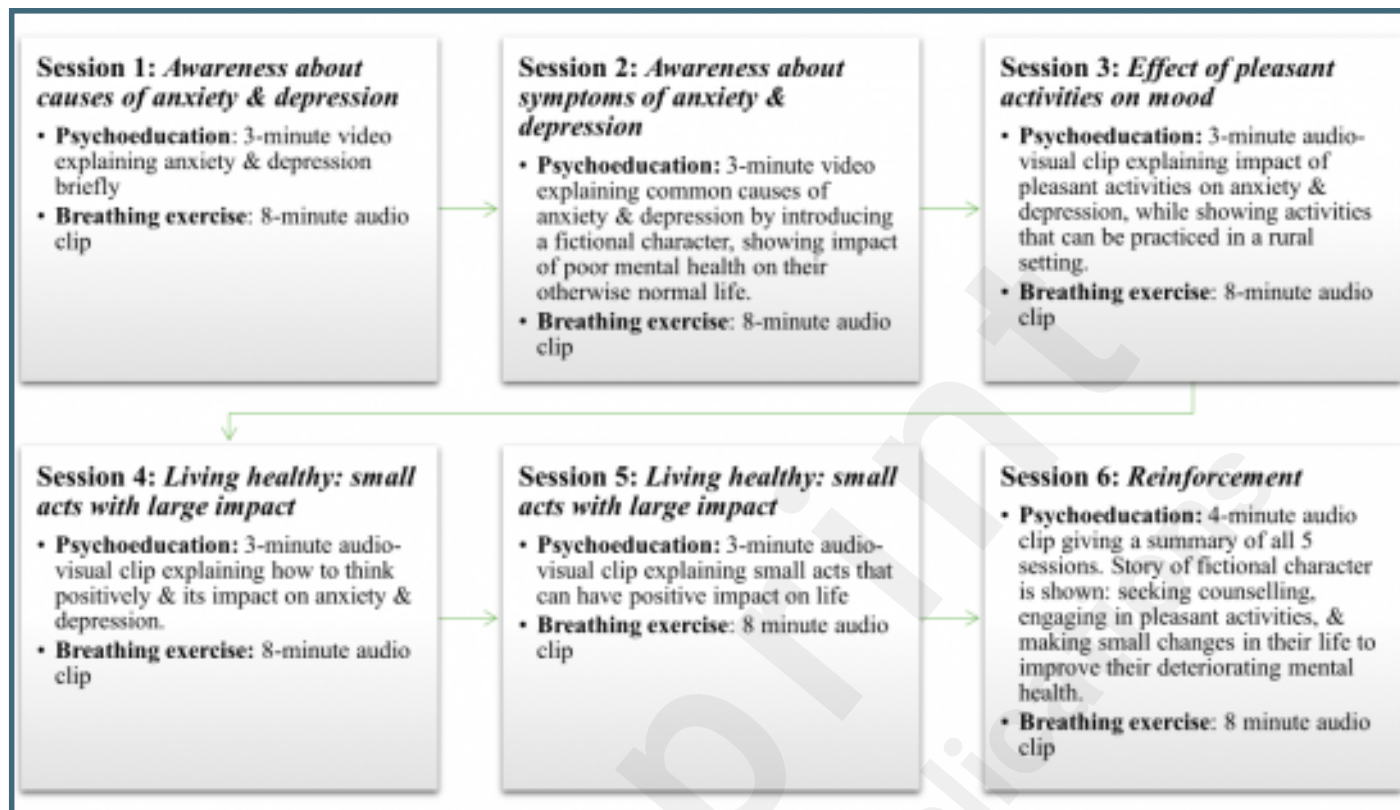
Supplementary Files

Figures



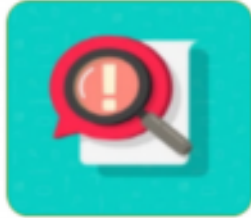
Outline of mPareshan training curriculum to improve mental health literacy of health workers.



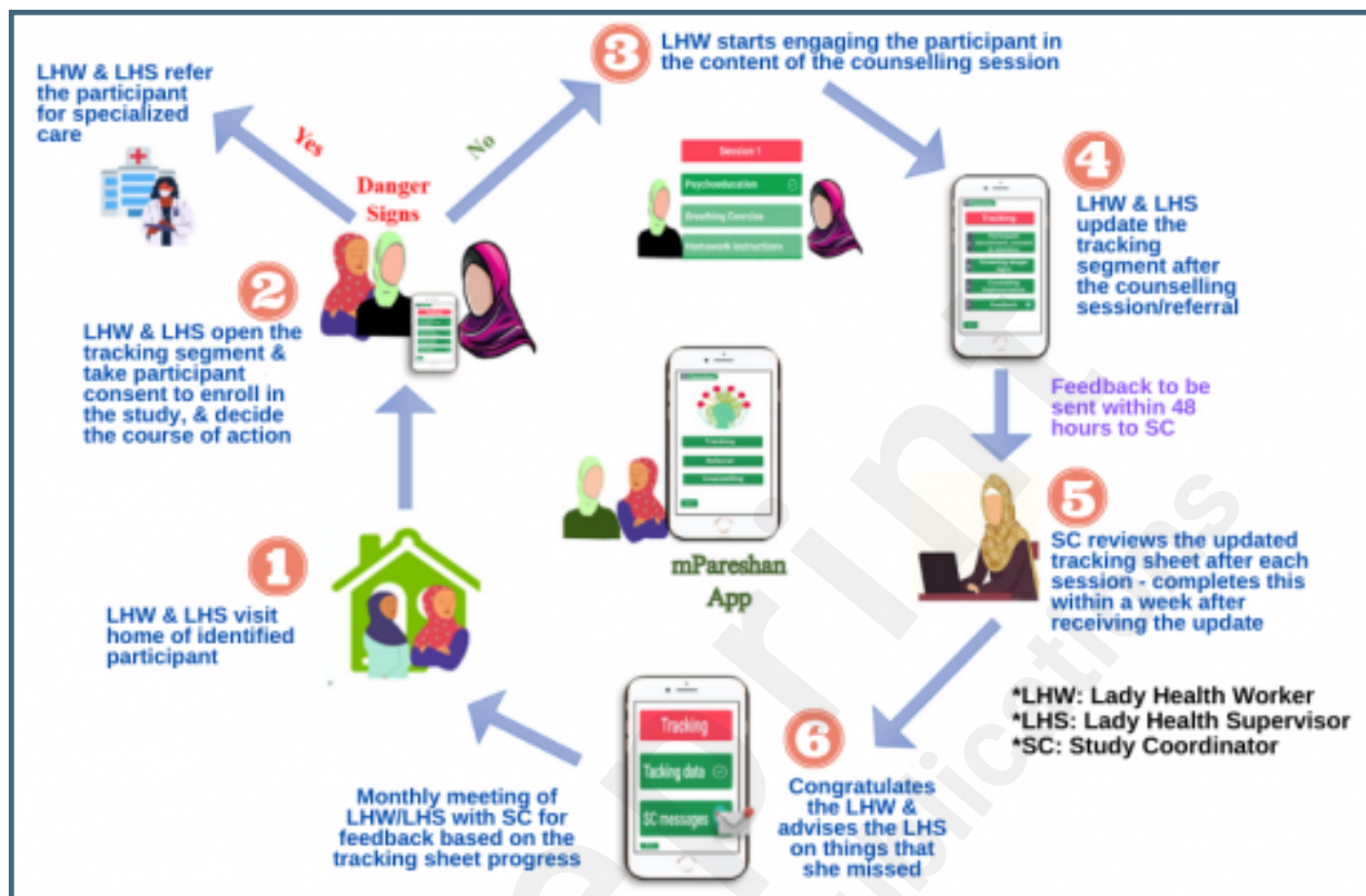
mPareshan App: Content of counselling sessions delivered by LHWs to those who screened positive for anxiety & depression. LHWs: Lady Health Workers.



Overview of mPareshan app segments.

	Tracking segment <ul style="list-style-type: none">• For participant recruitment, consent, follow-up, feedback• Has separate interfaces for LHWs, LHSs, SC interaction
	Counselling segment <ul style="list-style-type: none">• Six sessions for 6 months, session delivered during routine LHW visit• Session duration: 20 minutes• Delivered through videos, audios, and pictures• LHW to display content on cellular device, participant to watch and listen
	Referral segment <ul style="list-style-type: none">• Screening for danger signs will be done on each visit before giving counselling• If participant shows any danger sign, LHW will make referral to nearest mental health facility• Danger signs: self-harm, harm to others, suicidal ideation

mPareshan intervention workflow steps for implementation roll out.



Multimedia Appendixes

Guide for Focus Group Discussions and In-Depth Interviews used for qualitative assessments to assess feasibility and uptake of intervention.

URL: <http://asset.jmir.pub/assets/7349e22af5c2d8269fc20e0ca5a31950.docx>

