1/27/2026

NIHR Global Health Research Centre for Multiple Long-Term Conditions Pilot Study to Assess the Acceptability, Feasibility, Fidelity and Usability of a Co-designed Intervention to Improve Management of Multiple Long-term Conditions

NCT number

NOT AVAILBLE

Background:

India is witnessing a rapid rise in the prevalence of multiple long-term conditions (MLTC), defined as the co-existence of two or more chronic diseases in an individual (1,2). Despite this growing burden, the current healthcare system remains largely oriented toward single-disease management, resulting in fragmented care pathways (3). This approach poses significant challenges for patients, caregivers, and healthcare providers alike, often leading to poor health outcomes and increased out-of-pocket expenditures (3). In response to this evolving landscape, the National Institute for Health and Care Research (NIHR) Global Health Research Centre (GHRC) for MLTC has been established. The Centre aims to co-design, implement, and evaluate integrated, technology-enabled interventions that strengthen MLTC care across diverse health system settings in India. Through collaborative research and innovation, GHRC seeks to support scalable solutions that align with national priorities and improve the quality of life for individuals living with chronic conditions.

The Centre's objectives span three phases. In the short term, we aim to conduct health system and case-mix assessments and identify challenges faced by patients with MLTC, their caregivers, and healthcare providers. The mid-term goals include co-designing an integrated, technology-enabled, patient-centered intervention comprising an Electronic Decision Support System (EDSS), assisted telemedicine models, patient-facing application and community champions. Three of these interventions will be pilot tested to assess the retention and recruitment rates, acceptability, feasibility, fidelity, and costs. Our long-term vision is to establish a fully functional Global Centre for improving MLTC-related health outcomes and research, closely aligned with the Government of India as a strategic partner.

Between March 2024 and May 2025, we completed the formative phase to address our short-term objectives. We have estimated the prevalence and clustering of MLTC through a cross-sectional survey of 600 patients aged 40 years and above attending 20 primary health centers. Health system readiness was assessed at 20 PHCs and 40 sub-centers using the Indian Public Health Standards (IPHS, 2022) framework. Additionally, in-depth interviews with 60 patients and caregivers, 40 healthcare professionals, and 10 state and district health officials revealed critical barriers, including fragmented care pathways, lack of provider training, insufficient digital support, and gaps in continuity of care. Additionally, out of 10 we have completed 4 co-design workshops to co-develop the integrated, technology enabled, health system interventions.

Technology enabled platforms for intervention delivery

Expansion of DigiSetu EDSS module: DigiSetu, developed by the BRIDGE Centre for Digital Health at the Centre for Chronic Disease Control (CCDC), is a digital health and telemedicine platform designed to improve access to chronic disease care in underserved communities. Currently, it includes EDSS modules for hypertension, diabetes, and cardiovascular disease. Based on case-mix findings from the formative phase, the platform is being expanded to incorporate conditions such as asthma, depression, anxiety, substance use disorders, vision and hearing impairments, and osteoarthritis. These upgraded modules will deliver tailored, algorithm-2018driven decision support while systematically tracking clinical outcomes.

Upgrade of Ai.m Healthy mobile application: The Ai.m Healthy application, developed and maintained by ClinAlly, will be deployed as the patient-facing tool to strengthen self-management and adherence. Core features include ABHA Health ID creation, secure storage of health records, and personalized health assessments through scorecards. The upgraded version integrates medication and visits reminders, symptom tracking, and multilingual educational content to promote awareness and lifestyle modification. Interactive functions are designed to enhance patient–provider communication and complement EDSS and telemedicine interventions.

Objectives of the pilot study:

1. To explore the acceptability of the intervention components among enrolled study participants and healthcare providers.
2. To assess the usability, feasibility, and fidelity of integrating digital health interventions into routine service delivery at Primary Health.

Methodology:

1. **Study design:** We will conduct a cluster non-randomized pilot study to evaluate the feasibility, acceptability, usability, and fidelity of three digital health interventions in rural Primary Health Centres (PHCs). The study is designed to inform the development of a future large-scale trial.
2. **Study setting and duration:** The pilot will be implemented across four purposively selected rural PHCs: two in Jodhpur, Rajasthan and two in Anakapalli, Andhra Pradesh. The pilot duration will be six months.

Figure 1: Study area for pilot

3. **Study Participants:** Two participant groups will be recruited
    a. *Intervention recipients:* The recipients will include all individuals visiting the selected PHCs, will be screened for eligibility using a standardized screening tool. Eligible participants will include adults aged 40 years and above diagnosed with two or more of the following conditions: hypertension, diabetes mellitus, depression, anxiety, chronic obstructive pulmonary disease (COPD), asthma, vision impairment, hearing difficulties, osteoarthritis, and chronic back pain.
    b. *Intervention implementers*: Medical officer (MO) and staff nurse at each PHC who will implement the EDSS and assisted telemedicine components of the intervention.
4. **Intervention components:**
    1. Electronic Decision Support System (EDSS): To integrate guideline-based decision making into PHC workflows.
    2. Assisted telemedicine models (full and backpack): To expand access to specialist input at both facility and community levels.
    3. Patient facing mobile application: To support self-management, adherence, and patient provider communication.

Table 1: Intervention components and core activities

Setting	Intervention	Providers/Recipients	Core activities
PHC	Electronic Decision Support System (EDSS)	MO, staff nurse	1. Capture symptoms, vitals, history, and lab results through structured digital forms. 2. EDSS will develop generates individualized treatment plans and determine need for up referral and follow up.
PHC	Assisted telemedicine	MO, staff nurse	Expands specialist access through structured teleconsultations at both facility and community levels.
Community	Patient facing app	Enrolled participants or care givers	1. Support enrolled individuals with personalized reminders, education. 2. PHC linkage-enhancing self-management, adherence, and continuity of care.

5. **Study procedure:** A total of 30 participants will be enrolled per PHC.

Training for intervention implementers: Medical officers and staff nurses of participating PHCs will undergo three days structured training on the use of the EDSS and assisted telemedicine protocols and procedures. Delivered through in person workshops the sessions will cover, standard operating procedures, system navigation, clinical workflows, patient documentation, and ethical data use. Facilitated by experts from NIHR GHRC, the training will include hands-on practice, case simulations, and pre/post assessments.

PHC level implementation:

Visit 1: Trained health personnel affiliated with the NIHR GHRC Centre will conduct preliminary screening of all individuals aged 40 years and above attending the primary health center, using a standardized screening tool. Individuals identified with two or more specified chronic conditions listed above will be considered eligible for study participation. Those meeting the eligibility criteria will be provided with a detailed participant information sheet and informed consent form. Health worker will explain the objectives, procedures, and expectations. Participants will be given up to seven days to review the materials and make an informed decision regarding their enrollment.

Visit 2: Upon consent, health workers will enroll the participant and conduct baseline assessments. Data related to sociodemographic, quality of life [SF-12, EQ-5D, WHOQOL], and cost of illness will be collected in REDCap and generates unique ID

for enrolled participant. Subsequently, staff nurses will capture detailed patient history including past medical conditions, family history and perform clinical examinations. Patient records and clinical findings will be entered in a structured manner into the DigiSetu EDSS platform. The participant will be referred to the Medical Officer, who will review the recorded inputs, conduct additional assessments if require, and utilize the EDSS to generate a treatment plan. The MO may exercise clinical judgment to approve, modify, or reject the proposed treatment plan by EDSS. All decisions, along with the rationale for any modifications or disagreements, will be documented within the application.

In cases requiring specialist input, assisted telemedicine services will be initiated by either the MO or the nurse. Two telemedicine models will be piloted: (i) a facility-based full model, providing comprehensive, integrated specialist consultations within the PHC, and (ii) a backpack model, a portable, outreach ready telemedicine kit for community setting.

Following the consultation, the EDSS will be updated and the treatment plan revised to ensure continuity and clinical appropriateness. The nurse will then document the MO's final decisions and deliver health education and counselling, covering both pharmacological and non-pharmacological recommendations generated by the EDSS. A structured follow-up plan will also be provided to guide subsequent clinic visits.

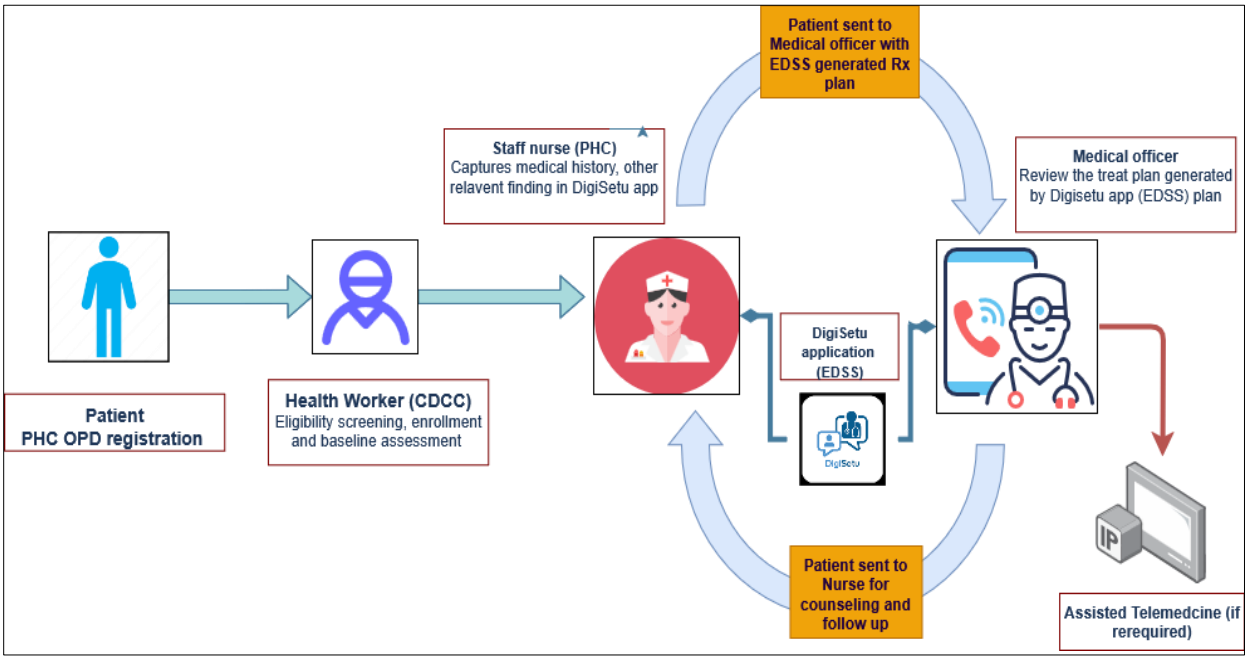

Figure 2: Workflow at the Primary health care centres during the intervention

Community level Implementation:

A patient-facing mobile application will be deployed to support intervention recipients or their care givers. This application is intended to promote self-management,

strengthen treatment adherence, and facilitate continuity of care by providing personalized reminders, educational resources, and linkage with primary health care services.

6. **Pilot study outcomes:**
    - **a.** Acceptability: Perceived relevance, satisfaction, and willingness to adopt interventions among providers and participants.
    - **b.** Usability: Ease of use, navigation, and workflow integration of EDSS, telemedicine, and patient app.
    - **c.** Feasibility: Practicality of implementation within PHC settings, including time, resources, and workflow fit.
    - **d.** Fidelity: Delivery as intended, protocol adherence, and completeness of data entry.

7. **Pilot study evaluation:**

    The EDSS and assisted telemedicine interventions will be evaluated for their acceptability, usability, and feasibility within Primary Health Centre (PHC) workflows.

    Acceptability will be explored among medical officers and staff nurses using the *Theoretical Framework of Acceptability (TFA) frame work.* This will include think-aloud sessions, where participants verbalize their thoughts while interacting with the digital tools. The evaluation will explore key TFA domains such as:

    - Affective attitude – how providers feel about using the intervention
    - Burden – perceived effort required to use the system
    - Ethicality – alignment with professional values and norms
    - Intervention coherence – understanding of how the intervention works
    - Perceived effectiveness – belief in the intervention's ability to improve care
    - Self-efficacy – confidence in using the system effectively

    Usability will be evaluated among the same provider group using the *System Usability Scale (SUS)*, it's a validated 10-item questionnaire scored on a 0–100 scale, with scores ≥70 considered satisfactory and end of recruitment.

    Feasibility of the interventions will be assessed by the research team through a combination of backend analytics, direct monitoring, and structured checklists. Key operational indicators will include medical officer usage logs, number of log-ins, average screening time, consultation completion rates, system stability (e.g., app crashes), and portal update frequency, teleconsultation setup duration, tele-referral success rates. All metrics will be tracked continuously throughout implementation to guide iterative improvements and inform scalability.

The assisted telemedicine component will undergo a further evaluation to assess its operational feasibility and effectiveness in enhancing specialist access.

Teleconsultation logs: Researchers will analyse provider–patient teleconsultation records to generate indicators including (i) success rate of completed sessions, (ii) average consultation duration, (iii) dropout or termination rates, (iv) frequency and nature of technical issues, and (v) proportion of consultations missed due to technical problems. These data will enable estimation of the percentage of successful teleconsultations relative to scheduled sessions.

Table 2: Evaluation framework for EDSS and assisted telemedicine

Outcome	Method	Study Tool	Target Group	Time Period
Acceptability	Qualitative (Think-aloud)	TFA-based interviews & think-aloud sessions	Medical Officers, Staff Nurses	End of recruitment
Usability	Quantitative	System Usability Scale (SUS), Validated 10-item	Medical Officers, Staff Nurses	End of recruitment
Feasibility	Qualitative (backend data + monitoring checklists)	Usage logs, backend analytics, structured feasibility checklist	Researchers (observing provider use)	Continuous; summarized at (3M) & (6M)
Operational feasibility (Telemedicine)	Quantitative log analysis	Teleconsultation logs	Researchers (provider-patient sessions)	Continuous; summarized at (3M) & (6M)

The patient-facing app will be evaluated for their acceptability, usability, and feasibility with enrolled participants.

Acceptability: In-Depth Interviews (IDIs) will be conducted with enrolled partcipants and/or caregivers at endline to explore user experiences, perceived benefits, and barriers/facilitators of app engagement.

Usability: Will be quantitatively assessed using the **mHealth App Usability Questionnaire (MAUQ)**, a validated 18-item tool specifically designed for mobile health applications. The MAUQ covers three subscales: *Ease of Use and Satisfaction* (7 items), *System Information Arrangement* (4 items), and *Usefulness* (7 items). Each item is scored on a **7-point Likert scale** (1 = strongly disagree to 7 = strongly agree), with higher scores indicating better usability. A mean score of **≥5.0** is considered acceptable usability.

Feasibility: Researchers will use backend data and usage logs to evaluate patient engagement patterns, including (i) number of log-ins per week, (ii) response rates to reminders, (iii) proportion of educational content accessed, and (iv) navigation patterns.

Table 3: Evaluation framework for patient facing application

Outcome	Method	Study Tool	Target Group	Time Period
Acceptability	Qualitative	In-Depth Interviews (IDIs)	Participants and/or Caregivers	End of recruitment
Usability	Quantitative	mHealth App Usability Questionnaire (MAUQ)	Participants and/or Caregivers	End of recruitment
Feasibility	Quantitative (app analytics)	Backend data and usage logs	Researchers (based on patient use)	Continuous; summarized at (3M) & (6M)

The fidelity of all interventions (EDSS, assisted telemedicine, and patient-facing app) will be evaluated using the Carroll et al. (2007) conceptual framework for implementation fidelity, with refinements by Hasson (2010). This framework emphasizes four key domains of fidelity: adherence to protocol, dose/exposure, quality of delivery, and participant responsiveness.

a. **Adherence to protocol**: Adherence refers to the extent to which intervention components are delivered as designed. For EDSS, this will include whether all required fields (symptoms, vitals, history, laboratory results) are completed and whether treatment plans are reviewed by medical officers. For telemedicine, adherence includes compliance with referral and consultation protocols. For the patient-facing app, adherence refers to consistent delivery of reminders and educational modules.
   - *Tools:* Structured fidelity checklists, backend audit trails, supervisor observations.
   - *Indicators:* ≥80% of required steps completed per encounter.

b. Dose/Exposure: This domain assesses the amount of intervention actually received by participants. For EDSS, this will be the proportion of eligible participants managed using the system. For telemedicine, it includes the proportion of eligible cases successfully referred and completed. For the app, dose will be reflected in the proportion of participants actively engaging (log-ins, reminders responded to, content viewed).
   - *Tools:* Usage logs, referral records, app analytics.
   - *Indicators:* ≥80% of eligible participants exposed to intervention as planned.

c. Quality of delivery: Quality refers to the competence and consistency of how interventions are delivered. For EDSS, this will assess whether medical officer modifications of treatment plans are appropriate and whether rationale is

documented. For telemedicine, it includes the clarity and completeness of referral documentation and the quality of specialist responses. For the app, it assesses whether educational content and reminders are delivered accurately and consistently with the protocol.

- *Tools:* Supervisor review checklists, random record audits, qualitative interviews.
- *Indicators:* ≥75% of sampled encounters rated as high-quality delivery.

d. **Participant response:** Responsiveness captures the engagement and receptiveness of both providers and participants. Providers will be asked about tool relevance, usability, and integration into workflow. Participants will be assessed for engagement with the app (e.g., reminder responses, navigation patterns) and satisfaction with teleconsultations.

- *Tools:* SUS, MAUQ, Acceptability of Intervention Measure (AIM), in-depth interviews, focus groups.
- *Indicators:* ≥70% of users reporting positive engagement (Likert ≥4/5).

Domain	Key Indicators
Adherence to protocol	1. % of eligible participants who received consent and were registered in EDSS by staff nurses. 2. % of EDSS-registered participants whose treatment plans were reviewed by Medical Officers. 3. % EDSS treatment plans accepted by Medical Officers 4. % of EDSS treatment plans rejected with documented rationale 5. % of enrolled participants who returned for follow-up visits 6. % EDSS encounters with all mandatory fields completed (symptoms, vitals, labs) 7. % telemedicine referrals following protocol 8. % patient facing app users receiving scheduled reminders 9. % receipts installed patient facing app
Exposure	1. % of screened individuals found eligible for the study 2. % of eligible participants who were consented 3. % of consented participants who were initiated into EDSS workflow 4. % eligible participants managed via EDSS

	5. % eligible cases referred and completed via telemedicine 6. % app users with ≥1 login and ≥1 module viewed
Quality of delivery	1. % EDSS treatment plans modified by MO 2. % tele-referrals with complete documentation and specialist response 3. % app messages delivered accurately and on time and screening time
Participant responsiveness	1. % providers rating tools as usable and relevant (SUS ≥70) 2. % receipts responding to app reminders or engaging with content

Data analysis:

Quantitative

The results of the pilot study i.e., usability, feasibility, and fidelity from provider's and patient's perspectives will be reported as number (percentages). Descriptive statistics about the baseline characteristics of the participants will also be reported as number (percentages). To assess the usability across all the three interventions, total score will be evaluated per intervention and categorized as number(percentages). Response obtained from SUS and MAUQ will be reported as median (IQR) under Likert scales. Spearman's rank correlation will be used to measure the relationships between ordinal variables used in the respective scales, and ordinal logistic regression can help us to model the relationship between the Likert scale response and other independent variables.

Feasibility of the interventions will be assessed based on number of logins, average screening time, and estimate proportions namely for consultation completion, navigation pattern on app, response rate to reminders, and frequency to access educational content for the participants respectively. Further, feasibility of the application/patient app will be observed in terms of system stability by reporting the frequency of the participant visits to the portal, number of tele-referrals and average duration of teleconsultation. The operational feasibility will also be measured with respect to teleconsultation i.e., to measure the number of complete sessions, number of dropouts or termination due to technical issues.

Fidelity across all the interventions will be assessed in terms of adherence, response and exposure by the participants. Adherence with respect to interventions such as EDSS and telemedicine will be measured in terms of proportions of participants with completion of registration, history and advised treatment plans which will be accepted or rejected by the providers. It will also measure the percentage of enrolled participants in terms of follow-ups, referrals and frequency of reminders from application/app. The exposure under fidelity will be

measured in terms of proportions of eligible participants, consented participants, under treatment via EDSS, cases referred and treatment via telemedicine.

Response of the provider will be measured in terms of usability of the tool (SUS score ≥70) and participant response will be measured with respect to response to the reminders on app as well as pattern of navigation while using app. Further, fidelity will also be assessed in terms of consistency and competence of the intervention delivered to the participants. This will be measured under quality of delivery as proportions of treatment plans modified by providers; number of tele-referrals and proportion of apps messages delivered within screening time of the participants.

Qualitative Analysis:

The qualitative component of the pilot study will focus primarily on assessing the acceptability of the three intervention components i.e., Electronic Decision Support System (EDSS), assisted telemedicine (full and backpack models), and the patient-facing mobile application. The qualitative data collected from the Think-Aloud sessions with healthcare providers (medical officers and staff nurses) as they engage with EDSS and assisted telemedicine platforms. The participants will be encouraged to verbalize their thoughts, expectations, and decision-making processes in real time. These sessions will be audio recorded with participant consent, supplemented by researcher field notes documenting pauses, difficulties, and contextual factors. In-depth interviews (IDIs) with patients, their caregivers, and healthcare providers to explore reflective perceptions of intervention use, perceived benefits, and associated barriers/facilitators. Logbooks and process observations maintained by field researchers to record workflow integration, fidelity, user engagement, and contextual challenges documenting real-time observations during intervention delivery.

This data in from of audio recordings with participant permission and observation notes will be transcribed verbatim and translated from local language to English and imported into NVivo software for analysis. The coding will follow a framework analysis approach using TFA domains as the primary deductive coding frame, while also allowing inductive codes to capture additional emergent themes using the thematic analysis framework by *Braun & Clarke*. This will be done by applying line-by-line coding allowing multiple codes per data segment and iteratively adding inductive codes as new findings emerge, the related codes will be grouped into a single theme and be reviewed for coherence, distinctiveness, and alignment with the data set. These themes will be then mapped to the acceptability framework by TFA. These themes will be compared and triangulated across intervention components and stakeholder groups (healthcare providers, patients, caregivers) and across sites using anonymized quotes to illustrate findings. To ensure coherence in data interpretation around 20% of transcripts will be independently double coded by two researchers, with differences resolved through discussions and eventually reviewed by a third researcher. Qualitative findings will be

integrated with the quantitative data to inform the acceptability outcome of the pilot study by using an explanatory approach that will guide refinement of intervention components prior to the full-scale cRCT.

Data Management

All participant data will be stored in secure, password-protected digital systems with role-based access. A data dictionary defines all variables, coding structures, and permissible ranges. Data synchronization procedures ensure secure transfer from field devices to central servers. Identifiable information will be stored separately from analytical datasets.