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Formative impact evaluation of a clinical trial for implementing Digitally Integrated Care Pathway (DICP) for multiple long-term conditions in primary care — Sri Lanka

Submission date 23/04/2026	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 18/05/2026	**Overall study status** Ongoing	
Last Edited 15/05/2026	**Condition category** Other	

Plain English summary of protocol

Background and study aims

In Sri Lanka, about one in three people aged 50 years and older live with more than one long-term health condition. This finding comes from a large household survey of 10,000 households that was recently carried out in the Northern Province, that asked about 19 common health conditions. Common examples include diabetes, high blood pressure (hypertension), ischaemic heart disease (reduced blood supply to the heart), chronic kidney disease, anxiety and depression. Managing these conditions together can be complex, especially in busy primary care clinics.

As the number of people living with multiple long-term conditions increases, health services need better ways to provide coordinated and consistent care. In Sri Lanka, most patients with long-term conditions receive treatment in Primary Medical Care Units (PMCUs) and Divisional Hospitals (DHs). Although clinical guidelines are available, they are not always fully integrated into daily practice. Treatment decisions and referrals to specialists may vary between clinics. Electronic Health Records (EHRs) are used in some settings, but the information recorded is not always used to improve care quality.

To address this, a Digitally Integrated Care Pathway (DICP) was developed. A care pathway is a structured plan that guides treatment and follow-up. A digital care pathway uses computer-based tools within an electronic health record system to support healthcare staff in making evidence-based decisions during routine consultations.

This study tests and improves the digitally integrated care pathway before a larger study can be conducted in the future. The main aim is to assess whether the system can be successfully introduced and used in three primary care units in Sri Lanka.

The specific objectives are:

1. To introduce the digitally integrated care pathway in three primary care units.
2. To assess whether the digitally integrated care pathway (DICP) can be successfully introduced and used in primary care units in Sri Lanka.

3. To assess whether routine electronic health record data can be used to evaluate how well the pathway works.
The findings will help refine the system and guide the design of a future larger study.

Who can participate?
This study mainly involves healthcare staff working in three selected primary care units in Sri Lanka (two Divisional Hospitals and one Primary Medical Care Unit), including doctors, nurses, support staff, and administrative staff. Staff must be involved in delivering care or using the digital system.

What does the study involve?
For the electronic record analysis, the study will review routine anonymised clinical data from patients who attend these clinics and have multiple long-term conditions. This includes patients who have diabetes and/or high blood pressure together with at least one of the following conditions: ischaemic heart disease, chronic kidney disease, anxiety or depression. Patients are not directly recruited into the study and will not be asked to attend extra appointments.
The study does not test a new medicine or treatment. It tests a digital system designed to support healthcare staff during routine care.

The Digitally Integrated Care Pathway (DICP) has three main components:
1. Digital treatment guidelines
The electronic system includes computer-based clinical guidelines to support staff in managing diabetes and high blood pressure alongside related conditions. These recommendations appear during patient consultations.
2. Digital referral guidance
The system provides guidance on when patients should be referred to specialist services or community-based care for further tests or treatment.
3. Automated audits
The system automatically reviews whether care follows clinical guidelines and whether data are recorded accurately. This helps improve both clinical practice and data quality.

The study will collect information in three ways:
- Structured observations of clinical consultations
- Focus Group Discussions with healthcare staff
- Analysis of routine electronic health record data collected during normal care
The study will assess whether the system fits within normal clinic workflows, whether staff find it useful, and whether it supports high-quality care.

What are the possible benefits and risks of participating?
Possible benefits
This study aims to find out whether digital tools can be used to improve care in Sri Lanka for people with multiple long-term conditions (MLTCs). The findings will help design and develop a future randomised controlled trial (RCT) to test a Digitally Integrated Care Pathway (DICP). The goal of that future study would be to improve how MLTCs are managed, including improving health outcomes, wellbeing, and the efficiency of care.
Healthcare professionals and research teams will gain a better understanding of how digital clinical support tools can be used in primary care. The study will also help improve clinical support tools that are based on evidence-based guidelines for managing patients with MLTCs.

Possible risks
There are minimal risks associated with participation.
No additional medical treatments are given as part of this study. Patients continue to receive

their usual care.
The information collected from participants during observations and focus group discussions, together with anonymised electronic health record (EHR) data, will only be used for the purposes described in this study protocol.
All data collected during this feasibility study will be stored securely at the Centre for Digital Epidemiology (CoDE), Faculty of Medicine, University of Jaffna. All patient data analysed are anonymised. No names or identifying details are used. Data is stored securely in password-protected systems in line with data protection regulations. Information received from the participants will not be shared or published with any personal information (e.g. name, address etc.). All required steps will be taken to ensure the confidentiality of the data collected, by preventing access to people other than the small research team where necessary. Only the research team and supervisors of this study will handle the anonymised raw data from the FGDs. Further the quality of data collection and entry will be ensured by the investigators.

Where is the study run from?
The study is conducted in two Divisional Hospitals and one Primary Medical Care Unit in Sri Lanka (totally in three Primary Care Units). The study is coordinated by the lead research team responsible for developing and implementing the digitally integrated care pathway.

When is the study starting and how long is it expected to run for?
The study will run from June 2026 to 30 June 2027, with data collection between June 2026 and February 2027.

Who is funding the study?
The National Institute for Health and Care Research (NIHR), UK.

Who is the main contact?
Prof. Kumaran Subaschandren (Principal Investigator), s.kumaran@univ.jfn.ac.lk

Contact information

Type(s)
Principal investigator, Public, Scientific

Contact name
Prof Kumaran Subaschandren

ORCID ID
https://orcid.org/0000-0002-5923-2573

Contact details
Faculty of Medicine, University of Jaffna, Adiyapatham Rd
Jaffna
Sri Lanka
40000
+94 077 3777446
s.kumaran@univ.jfn.ac.lk

Additional identifiers

Study information

Scientific Title
Formative impact evaluation of a Digitally Integrated Care Pathway (DICP) for multiple long-term conditions in primary care: Sri Lanka04

Acronym
DIGIPATHS

Study objectives
1. To implement a DICP in three primary care units (PCUs).
2. To assess the feasibility of implementing the DICP in primary care units in Sri Lanka.
3. To assess the feasibility of evaluating the DICP through the collection of implementation and intervention effectiveness outcomes from existing electronic health records (EHRs).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/11/2025, Ethical review Committee of the Faculty of Medicine, University of Jaffna (Adiyapatham Road, Kokuvil, Jaffna, 40000, Sri Lanka; +94212222073; ercmed@univ.jfn.ac.lk), ref: J/ERC/25/176/NDR/0357

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Implementation of a Digitally Integrated Care Pathway (DCIP).

Study type(s)

Health condition(s) or problem(s) studied
Multiple Long-term Conditions: Diabetes and/or hypertension, plus at least one of: ischemic heart disease, chronic kidney disease, anxiety, or depression.

Interventions
The complexity of interactions between the treatments for separate chronic diseases is often neglected in standalone clinical guidelines, and a more integrated and dynamic approach is

required. Key factors influencing successful implementation of Digitally Integrated Carpathways (DICP) indude technological simplicity, human perspective (specifically intention to use, and acceptability), organizational readiness (eg leadership, communication and training), and macroenvironmental factors (eg tersion for change, management support and alignment of the DICP with wider policy guidance). Combined these factors influence success (or failure) of implementation, adoption, optimal use, and medium to long term maintenance. Given these complex factors, it is imperative to assess the feasibility of implementing the DICP and identify opportunities to adapt both the DICP and the proposed approach to implementation (stakeholder engagement, training, monitoring) prior to the Randomized Control Trial (RCT). Additionally, assessing the feasibility of the design and of collecting proposed outcomes prior to a trial is important for future successful evidence generation. Existing digital data collection tools are often designed to help healthcare providers access and manage clinical data rather than for research purposes. This formative feasibility study aims to assess the feasibility of using healthcare data to evaluate the future RCT.

Materials
Electronic Health Record (EHR) Platform: A system implemented in primary care units to record patient demographics, physiology (eg., BP, HR), risk assessments, and biomarkers.

Computer-Executable Integrated Guidelines: Real-time, evidence-based prompts embedded within the EHIR for the management of diabetes, hypertension, ischemic heart disease, chronic kidney disease, and anxiety/depression.

Digital Referral Criteria: Standardized digital logic based on national and international guidelines for timely referral to specialist and multidisciplinary care.

Automated Audit Tools: A "double-loop" digital audit mechanism designed to monitor and enhance clinical practice and data quality.

Procedures
DICP to be implemented in the formative impact evaluation will comprise the following three components

1. Digital guidelines: Implementation of computer executable integrated clinical guidelines for evidence-based practice for the management of diabetes and hypertension with comorbid ischaemic heart disease, chronic kidney disease and anxiety or depression.

2. Digital referral criteria: Based on guidelines for timely referral to multidisciplinary community care and specialist care for early diagnosis, investigations, and treatment.

3. Automated audit: A double loop audit to improve 1) clinical practice and 2) data quality

Intervention Providers
The DICP is utlized by a multidisciplinary Primary Care Team, which includes:
Primary care doctors Medical Officers)
Qualified nurs
Health service assistants who use or interact with the DICP system in their daily work.

Mode of Delivery
The intervention is delivered via a digitally integrated care pathway interface.

Location
The intervention is implemented in the three primary care units in Sri Lanka. These sites have been purposefully selected to represent variation in organizational and environmental contexts.

1. Divisional Hospital Kondavil
2. Divisional Hospital Chankanal
3. Primary Medical Care Unit Kokuvill

Schedule and Duration
The DICP is utilized during all eligible encounters for patients with MLTC throughout the study period. For this formative evaluation, data regarding the intervention's use will be collected from 1st June 2006 to 28th February 2027.

Tailoring and Adaptation
The intervention is inherently tailored to the individual patient's comorbidity profile, offering personalized clinical guidance. Furthermore, as a formative evaluation, the implementation process and the DICP itself may be adapted iteratively based on stakeholder feedback from Focus Group Discussions (FGDs) and structured observations to optimize local usability, acceptability, and adoption.

Intervention Type
Other

Primary outcome(s)
1. Reach, defined as the proportion of patients eligible for the DICP during our study period who received care via the DICP, measured using data [stored on the DCIP?], which has been collected for the duration of the study period of 9 months at a single time point

2. Fidelity measured using Fidelity is defined as the DICP pathway (assessment and screening, Initiation of therapy, Titration of therapy, Referral) being followed as intended. at During the study period, 9 months.

3. Adoption measured using Adoption is defined as acceptability of the DICP as perceived by the stakeholders. Perceptions will inform likely future adoption, and sustainability of the DICP beyond the RCT duration. at During the study period, 9 months.

Key secondary outcome(s)

Completion date
30/06/2027

Eligibility

Key inclusion criteria
For Staff Participants:
The study population includes healthcare staff directly involved in patient care or support activities within each participating PCU. This will include primary care doctors, nurses, and health service assistants who use or interact with the DICP system in their daily work. Clinical, support, and administrative staff working within the selected PCUs who are involving with the implementation and use of the Digitally Integrated Care Pathway (DICP).

For EHR Data :
De-identified clinician-patient encounters involving patients with multiple long-term conditions (MLTCs) such as : Diabetes and/or hypertension, plus at least one of: ischemic heart disease, chronic kidney disease, anxiety, or depression.

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
1 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Participants who decline or withdraw informed consent.

Date of first enrolment
01/06/2026

Date of final enrolment
28/02/2027

Locations

Countries of recruitment
Sri Lanka

Sponsor information

Organisation
University of Jaffna

ROR
https://ror.org/02fwjgw17

Funder(s)

Funder type

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			15/05/2026	No	No