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IMPACT: Innovations using mHealth for people with dementia and comorbidities and their caregivers in Peru

Submission date
15/10/2025

Recruitment status
No longer recruiting

Registration date
23/10/2025

Overall study status
Ongoing

Last Edited
17/10/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Dementia is a major public health challenge in Peru and across Latin America, affecting both people living with dementia (PwD) and their family caregivers. Most caregiver support interventions have been developed in high-income countries, and there is limited evidence about how they can be adapted and implemented in low- and middle-income settings. This study aims to test the feasibility of implementing an adapted version of the Care Ecosystem (CE) intervention — a phone- and digital-based program that provides structured support to dementia caregivers. The goal is to understand whether this intervention can be delivered effectively in Peru and to prepare for a future large-scale trial.

Who can participate?
The study will include dyads made up of a person with dementia aged 60 years or older, previously identified through the IMPACT screening phase or with a clinical diagnosis of dementia issued by a healthcare professional in facilities previously contacted in each region, and their primary informal caregiver aged 18 years or older who provides unpaid daily support and has access to a mobile phone. Both participants must live in one of the study cities (Lima, Huancayo, Iquitos, or Tumbes) and plan to remain there for at least nine months.

What does the study involve?
This is a two-arm randomized controlled feasibility trial involving 96 dyads, assigned in a 2:1 ratio to the intervention and control groups. In the intervention group, caregivers will receive monthly phone calls from trained Care Team Navigators (CTNs) and have access to a chatbot for everyday support. The CTNs will provide guidance, emotional support, and referrals to community and health services following standardized care protocols. The control group will receive enhanced usual care, consisting of structured dementia information materials. Assessments will be conducted at baseline, 4.5 months, and 9 months to evaluate caregiver burden, depressive symptoms, and quality of life.

What are the possible benefits and risks of participating?
Caregivers may feel more supported, less stressed, and more confident in managing daily

challenges, while PwD may experience improved quality of life and fewer emergency visits. Risks are minimal. Some questions about emotional well-being or caregiving stress may cause mild discomfort. Fieldworkers are trained to handle these situations with empathy, and participants may pause or withdraw at any time. All data are coded and stored securely to ensure confidentiality.

Where is the study run from?
The study is coordinated by Imperial College London (UK) and implemented in Peru by the CRONICAS Center of Excellence in Chronic Diseases at Universidad Peruana Cayetano Heredia (UPCH). Recruitment and delivery take place in four Peruvian cities: Lima, Huancayo, Iquitos, and Tumbes.

When is the study starting and how long is it expected to run for?
The study is expected to start in September 2025 and run until October 2026, with each participant involved for approximately nine months.

Who is funding the study?
The study is funded by the UK National Institute for Health and Care Research (NIHR) under the Global Health Research Programme (grant 17/63/130) through UK Research and Innovation (UKRI).

Who is the main contact?
Dr Christopher Butler, Department of Primary Care and Public Health, Imperial College London.
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Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
6647445, NIHR150287

Study information

Scientific Title
IMPACT Dementia: Feasibility of an Intervention to Support People with Dementia and their Caregivers in Peru

Acronym
IMPACT

Study objectives
Primary objective: Assess the feasibility of implementing the adapted Care Ecosystem (CE) intervention for caregivers of people with dementia (PwD) across four Peruvian cities (fidelity, engagement, usability, and implementation barriers/facilitators).

Secondary objective: Assess the feasibility of conducting a future randomized controlled trial of the adapted CE intervention (consent rates, retention at 4.5 and 9 months, ability to collect proposed clinical and economic outcomes, and variation over time/by site).

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 05/06/2025, Imperial College Research Ethics Committee (ICREC) (Level 5, Sherfield Building, South Kensington Campus, London, SW7 2AZ, United Kingdom; +44 (0) 2075949456; rgitcoordinator@imperial.ac.uk), ref: 7714369

2. approved 28/02/2025, Comité Institucional de Ética en Investigación (CIEI) de la Universidad Peruana Cayetano Heredia (Av. Honorio Delgado 430 - San Martín de Porres, Lima, 4314, Peru; +51 3190000; orvei.ciei@oficinas-upch.pe), ref: 209080

Study design
Interventional two-arm parallel-group pilot randomized controlled feasibility trial

Primary study design
Interventional

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Dementia, hypertension and diabetes mellitus (common physical comorbidities among PwD)

Interventions
Care Ecosystem (CE) Peru – Adapted Intervention
A 9-month, telephone- and mHealth-based person-centred care navigation program for informal caregivers of PwD. The intervention provides structured counselling, emotional support, and problem-solving guidance through regular calls from trained Care Team Navigators (CTNs), supervised by a nurse coordinator and supported by a chatbot for asynchronous communication. CTNs follow standardized Care Protocols and generate individualized Care Plans updated after each interaction. The intervention aims to improve caregiver well-being, reduce emergency visits, and enhance home-based dementia management.

Caregiver/PwD dyads are assigned in a 2:1 ratio to the intervention and control groups.

In the intervention group, caregivers will receive monthly phone calls from trained Care Team Navigators (CTNs) and have access to a chatbot for everyday support as above.

The control group will receive enhanced usual care, consisting of structured dementia information materials. Assessments will be conducted at baseline, 4.5 months, and 9 months to evaluate caregiver burden, depressive symptoms, and quality of life.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility outcomes measured using study records at one timepoint:
1. Recruitment rate (% dyads consenting out of those invited)
2. Retention rate at 4.5 and 9 months
3. Fidelity of intervention delivery (proportion of CTN calls and protocols completed as planned)
4. Engagement metrics (number of caregiver–CTN and caregiver–chatbot interactions)
5. Data completeness and usability of the digital platform for data collection

Key secondary outcome(s))
The following secondary outcome measures are assessed at baseline, 4.5 months and 9 months:
Caregiver:
1. Burden measured using the Zarit Caregiver Burden Questionnaire
2. Depressive symptoms measured using the PHQ-9
3. Self-efficacy in caregiving measured using an ad-hoc CE questionnaire
4. Quality of life measured using the EuroQol EQ-5D-5L questionnaire

Person with dementia (PwD):
1. Quality of life measured using the EuroQol EQ-5D-5L
2. Clinical measures assessed via blood pressure measured using a sphygmomanometer through a trained fieldworker and blood glucose through an external laboratory
3. Medication adherence measured using the Morisky Medication Adherence Scale (MMAS-4)
4. Use of emergency and hospital services measured using an ad-hoc questionnaire

Economic:
1. Health resource utilization and implementation cost measured using economic cost measures through interviews at the end of the intervention

Completion date
31/10/2026

Eligibility

Key inclusion criteria
For People with Dementia (PwD):
1. Classified as a "dementia case" in WP2 of IMPACT (positive results on RUDAS-PE and CDR scales) or people with a clinical diagnosis of dementia issued by a healthcare professional in facilities previously contacted in each region.
2. Resides in the study city ≥6 months and plans to remain for 9 months.
3. Provides informed consent or assent (if possible), with legal representative consent from the caregiver when applicable.

For Caregivers:
1. ≥18 years old.
2. Primary unpaid caregiver (family or close person).
3. In caregiving role ≥3 months (shorter periods accepted when roles recently changed).
4. Resides in the study city ≥6 months and plans to remain for 9 months.
5. Able to provide informed consent.
6. Has access to a mobile phone.

Participant type(s)
Patient, Carer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
For caregivers:
1. Inability to communicate with study staff due to language or severe cognitive barriers.

For PwD:
1. Active objection to participation or refusal to provide assent.

General:
1. Any condition that, in the investigator's opinion, prevents safe participation or comprehension of study procedures.

Date of first enrolment
20/10/2025

Date of final enrolment
15/12/2025

Locations

Countries of recruitment
Peru

Study participating centre
Universidad Peruana Cayetano Heredia
Av. Honorio Delgado 430, San Martín de Porres
Lima
Peru
15102

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

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
The datasets generated and/or analysed during the current study will be made available upon reasonable request to the Principal Investigator (Dr Christopher Butler, christopher.butler@imperial.ac.uk). Data will be anonymised before sharing, and requests will be evaluated by the study's research governance and ethics committees to ensure compliance with ethical and legal requirements.

All data will be stored securely in UPCH/REDCap servers, following confidentiality regulations under Peruvian law and GDPR. Metadata will include study identifiers, variables, and de-identification methods. Shared data will include participant-level quantitative measures (such as caregiver burden, quality of life, and clinical indicators) and aggregated qualitative summaries from the process-evaluation interviews.

Data retention will follow the requirements of the research sponsor and UPCH, with a minimum retention period of ten (10) years after study completion. Any data sharing will occur only under a controlled-access agreement specifying permitted use, anonymisation, and confidentiality obligations.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes