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RESILIENT: Using predictive approaches to manage people with long-term conditions at risk of dementia.

Submission date	Recruitment status	[_] Prospectively registered
14/08/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/08/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/09/2024	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study addresses the growing demand for social care among older adults, particularly those with multi-morbidities, which significantly increase healthcare costs and hospital stays. By using advanced technologies like the Internet of Things (IoT) and wearable devices, the study aims to develop machine learning models to predict health deterioration and cognitive decline, such as dementia, in people aged 65 and over with multiple chronic conditions. The ultimate goal is to create a sustainable framework for continuous, individualised care and timely interventions.

Who can participate?
Adults aged 65 years and over who are living with two long-term conditions (multi-morbidities) are eligible to participate in this study.

What does the study involve?
Participants will use in-home monitoring devices that the data will be used to develop and test machine learning algorithms for predicting health deterioration. The study also involves health and wellbeing assessments, generating health reports for care teams, monitoring carer stress levels, and surveys to gather opinions on remote health monitoring from clinicians and the public.

What are the possible benefits and risks of participating?
Benefits:
Improved health monitoring and management through personalised care.
Potential delay in the progression of cognitive decline and dementia.
Enhanced understanding and involvement in personal health data usage.
Risks:
Privacy concerns related to continuous monitoring.
Potential technical issues with the in-home devices.
Data accuracy and reliability challenges due to varying environmental and individual factors.

Where is the study run from?
Surrey and Borders Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
November 2022 to October 2025

Who is funding the study?
Engineering and Physical Sciences Research Council (EPSRC) and National Institute for Health and Care Research (NIHR) (UK)

Who is the Main Contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
321104

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 321104, CPMS 55166

Study information

Scientific Title
PREdictive approacheS in managIng people with Long-term condItions at risk of dEmeNTia: from remote monitoring data to digital biomarkers: a feasibility study

Acronym
RESILIENT

Study objectives
To build upon our work in dementia, this feasibility study will examine the feasibility of adults aged over 65 with multi-morbidities accepting and using in-home monitoring devices. We will explore whether sufficient data can be gathered to begin the development of machine learning algorithms which could be used as the building blocks to predict health deterioration, including cognitive decline indicative of dementia, in a larger future study. This feasibility study aims to begin the development of a sustainable framework to integrate and evaluate the applicability of algorithmic and engineering developments in managing multi-morbidities such as ageing-associated conditions and how these might lead to dementia. Future work will evaluate this framework based on: performance, accuracy, generalisability, and explainability of the models. The continuous analysis of the in-home monitoring data will allow for more rapid and accurate predictive risk analysis, condition and symptom management, and timely interventions based on personalised models in healthcare.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/06/2023, London-Surrey Borders Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 207 104 8057; surreyborders.rec@hra.nhs.uk), ref: 23/LO/0443

Study design
Prospective interventional feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)

Home

Study type(s)
Prevention

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied
Predict health deterioration in people aged 65 years and over who are living with multiple morbidities.

Interventions
Intervention Arm:
Enrolment:
• Participants aged 65 and over with two or more chronic health conditions are recruited.
• Participants undergo an initial baseline visit where the study's details are explained, and informed consent is obtained.
Installation of Equipment:
• Participants receive a package of passive monitoring devices (such as smartwatches, sleep analysers, and weighing scales).
• The RESILIENT Research Assistant assists with the installation of these devices in the participants' homes, ensuring they understand how to use them.
Monitoring and Data Collection:
• Over the course of 24 months, data is continuously collected from the in-home devices.
• Participants complete health questionnaires with a research assistant at different intervals to monitor their physical and mental health.
Health Reports:
• The data collected from the devices and questionnaires is compiled into health summary reports by the RESILIENT research team.
• These reports are shared with the participants and their healthcare providers for review and potential clinical intervention.
Follow-up:
• Participants are monitored for the entire duration of the study (24 months).
• Any suspected deterioration in health, particularly in cognition or mental health, is highlighted for the participant's usual care team to address.

Survey Arm:
Enrolment:
• Participants with long term health conditions, People who support someone with a long term health conidition, or people who work as a clinical professional aged 18+
Survey:
• Anonymous online survey (~10 minutes) completed via Qualtrics

Intervention Type
Device

Pharmaceutical study type(s)
Predictive digital biomarkers

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Withings Sleep Matt for analysis, Withings Smart Watch, Withings Weighing Scales

Primary outcome measure
Feasibility of data collection from in-home devices and health assessments to inform the creation of machine learning models to predict health deterioration in people aged 65 and over who are living with multiple morbidities Measured by review of data completeness from in-home devices and health assessments throughout the 24-month study period, with continuous data collection

Secondary outcome measures
1. Health Report Feedback collected from the participant's care team regarding the health reports generated at regular intervals when reports are generated (weekly or aggregated over three months)
2. Carer Stress Levels measured using Questionnaires and data from in-home devices assessing carer stress levels continuously during the 24-month study period
3. Public and Clinician Survey on Remote Monitoring measured using an Online survey conducted with clinicians and members of the public.
It is a one off 10 minute survey at any point during the study

Overall study start date
01/11/2022

Completion date
01/10/2025

Eligibility

Key inclusion criteria
1. Age: 65 years and over
2. Have at least two long-term health conditions. This will include but is not limited to:
2.1. Arthritis
2.2. Chronic Kidney Disease
2.3. Chronic Obstructive Pulmonary Disease
2.4. Heart Disease or Failure
2.5. Depression
2.6. Diabetes
2.7. Hypertension
2.8. Liver disease
2.9. Stroke
2.10. Mental Health Disorders
3. Capacity to consent

Participant type(s)
Patient

Age group
Senior

Lower age limit
65 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
500 (public survery) 75 (intervention)

Key exclusion criteria
1. People with an unstable mental state including severe depression, severe psychosis, agitation and anxiety
2. People with severe sensory impairment
3. People who are receiving treatment for terminal illness at baseline (life expectancy less than 6 months or recognised as being in their last year of life)
4. People who lack capacity

Date of first enrolment
01/10/2023

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Surrey and Borders Partnership NHS Foundation Trust
Research and Development
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Sponsor information

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Surrey and Borders Partnership NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
https://www.sabp.nhs.uk/

ROR
https://ror.org/00f83h470

Funder(s)

Funder type
Research council

Funder Name
Engineering and Physical Sciences Research Council

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, EPSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Publication and dissemination plan
We will publish the findings, methods and approaches developed in the study in peer-reviewed conferences and journals. The intention is to create wider awareness and disseminate the findings and innovations of the study.

Intention to publish date
31/10/2026

Individual participant data (IPD) sharing plan
We plan to publish fully anonymised data available in a public repository. This is currently a plan, but in the past, we have deposited the data on Zenodo

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 4.0	19/04/2024	16/08/2024	No	Yes
Participant information sheet	Participant Information Leaflet version 1.0	12/10/2023	16/08/2024	No	Yes