

Real-world gait in people with multiple long-term conditions

Submission date 22/10/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/01/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/12/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Walking difficulties are common in people with multiple long-term health conditions (MLTCs), such as diabetes, heart disease, or arthritis. These conditions can make it harder to walk, reducing mobility and overall quality of life. This study aims to develop and validate new digital mobility outcomes (DMOs) that can track walking patterns in people with MLTCs using sensors worn on the body. The main goal is to create accurate ways of measuring walking ability in real-world conditions, which could help clinicians better understand the impact of these conditions on mobility and tailor treatments accordingly.

Who can participate?

Adults aged 65 years and older with two or more long-term health conditions can participate. Both men and women are eligible to take part.

What does the study involve?

Participants will be asked to wear small sensors on their lower back and wrist during their normal daily activities. These sensors, known as Inertial Measurement Units (IMUs), will record walking-related data such as walking speed, stride length, cadence (steps per minute), and the time spent walking or being sedentary. The study has two main phases:

The first phase involves validating the accuracy of these sensors in a controlled laboratory setting.

In the second phase, participants will wear the sensors for 7 days to track their walking in real-world conditions. No medication or treatment will be provided as part of this study.

What are the possible benefits and risks of participating?

There are no direct benefits to participants. However, the information gathered may help improve monitoring of health and treatment effects in people with MLTCs. The risks of participating are minimal, as the sensors are non-invasive and pose no known health risks. Participants might experience slight discomfort wearing the sensors for extended periods, but they are designed to be lightweight and unobtrusive.

Where is the study run from?

The study is managed by Northumbria and Newcastle Universities (UK)

When is the study starting and how long is it expected to run for?
March 2024 to December 2025

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Prof. Ioannis Vogiatzis, ioannis.vogiatzis@northumbria.ac.uk.

Contact information

Type(s)

Public, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
340676

ClinicalTrials.gov (NCT)
NCT06473168

Central Portfolio Management System (CPMS)
61049

Study information

Scientific Title

Walking-related mobility assessment in older people with multimorbidity

Acronym

Multi-mobility

Study objectives

In older adults with multimorbidity, walking-related digital mobility outcomes (DMOs) derived from wearable sensors (from both lower-back and wrist-worn inertial measurement units [IMUs]), can be accurately and reliably assessed and provide accurate estimates of real-world mobility patterns. It is reasoned that these DMOs will exhibit construct validity in reflecting global and disease-specific mobility impairment, enabling the development of a robust tool for holistic health status assessment.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 11/07/2024, NHS Health Research Authority North East York Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048079; york.rec@hra.nhs.uk), ref: 24/NE/0131

Study design

Observational case series

Primary study design

Observational

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Older adults with multimorbidity, defined as having two or more coexisting long-term conditions

Interventions

The study involves laboratory-based technical validation, unsupervised real-world validation, and construct validation of walking-related digital mobility outcomes (DMOs) from both lower-back and wrist-worn wearable sensors.

The methodology consists of two main work packages that are focused on validating digital mobility outcomes (DMOs) using wearable sensors. The first work package comprises a technical validation study. Work package 1 is the laboratory-based validation, which initially tests algorithms for mobility assessment using lower-back and wrist-worn inertial measurement units (IMUs) against the gold-standard technique (stereophotogrammetry). Work package 2 includes a preliminary clinical validation, where the construct validity of the DMOs is examined by relating the sensor data with disease-specific and global health outcomes in multimorbid patients.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

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Primary outcome(s)

1. Cadence is measured in steps per minute using Inertial Measurement Units placed on the lower back and wrist during a 7-day real-world assessment
2. Stride length is measured in meters using Inertial Measurement Units placed on the lower back and wrist during a 7-day real-world assessment
3. Walking speed is measured in meters per second using Inertial Measurement Units placed on the lower back and wrist during a 7-day real-world assessment
4. Stride duration is measured in seconds using Inertial Measurement Units placed on the lower back and wrist during a 7-day real-world assessment

Key secondary outcome(s)

1. Turning angle is measured in degrees per second using Inertial Measurement Units placed on the lower back and wrist during a 7-day real-world assessment
2. Daily steps are measured in steps per day using Inertial Measurement Units placed on the lower back and wrist during a 7-day real-world assessment
3. Sedentarism is measured in minutes per day using Inertial Measurement Units placed on the lower back and wrist, capturing time spent in activities such as sitting, lying, and walking during a 7-day real-world assessment

Completion date

09/12/2025

Eligibility

Key inclusion criteria

1. Adults ≥ 65 years old
2. Able and willing to provide informed consent
3. Able to read and write in English
4. To be mobile (including the use of walking aids)
5. Two or more of the following long-term conditions: arthritis, asthma, atrial fibrillation, bronchiectasis, cancer, chronic kidney disease, chronic obstructive pulmonary disease, coronary heart disease, anxiety, depression, diabetes mellitus, heart failure, hypertension, osteoporosis, parkinson's disease, peripheral vascular disease, stroke or transient ischaemic attack

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

65 years

Upper age limit

85 years

Sex

All

Total final enrolment

50

Key exclusion criteria

1. Unable to give consent for the study
2. Severe mental health problems
3. Active malignancy (on chemotherapy/radiotherapy/planned urgent surgery)

Date of first enrolment

01/12/2024

Date of final enrolment

30/10/2025

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre**University of Northumbria at Newcastle**

Ellison Building

Newcastle upon Tyne

England

NE1 8ST

Study participating centre**NIHR Newcastle Clinical Ageing Research Unit (CARU)**

Freeman Hospital

Freeman Road

High Heaton

Newcastle upon Tyne

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NE7 7DN

Sponsor information

Organisation

Northumbria University

ROR

<https://ror.org/049e6bc10>

Funder(s)

Funder type

Government

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

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 published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication