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

Submission date	Recruitment status	[ ] Prospectively registered
22/10/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/01/2025	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/10/2025	Other	[X] 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

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Public, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
340676

ClinicalTrials.gov (NCT)
NCT06473168

Protocol serial number
CPMS 61049, IRAS 340676

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)
-

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
Adult

Lower age limit
65 years

Upper age limit
85 years

Sex
All

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
United Kingdom
NE1 8ST

Study participating centre
NIHR Newcastle Clinical Ageing Research Unit (CARU)
Freeman Hospital
Freeman Road
High Heaton
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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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Stored in non-publicly available repository, Data sharing statement to be made available at a later date

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