

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

<b>Submission date</b> 22/10/2024	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/01/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/10/2024	<b>Condition category</b> 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 November 2025

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

Who is the main contact?  
Prof. Ioannis Vogiatzis, [ioannis.vogiatzis@northumbria.ac.uk](mailto:ioannis.vogiatzis@northumbria.ac.uk).

## Contact information

### Type(s)

Public, Principal Investigator

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Scientific

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## Additional identifiers

EudraCT/CTIS number

IRAS number

340676

ClinicalTrials.gov number

NCT06473168

Secondary identifying numbers

## 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

### Secondary study design

Case series

### Study setting(s)

Laboratory

### Study type(s)

Prevention

### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

### 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

### **Pharmaceutical study type(s)**

Not Applicable

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

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### **Primary outcome measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

01/03/2024

### **Completion date**

01/11/2025

## **Eligibility**

**Key inclusion criteria**

1. Adults  $\geq 65$  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

**Age group**

Adult

**Lower age limit**

65 Years

**Upper age limit**

85 Years

**Sex**

Both

**Target number of participants**

55

**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**

England

United Kingdom

**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  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

## Sponsor information

**Organisation**  
Northumbria University

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**Sponsor type**  
University/education

**Website**  
<https://www.northumbria.ac.uk/>

**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**

**Publication and dissemination plan**

Planned publications in peer-reviewed journals

**Intention to publish date**

31/12/2025

**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