ISRCTN12051706 https://doi.org/10.1186/ISRCTN12051706

Clinical validation of a mobility monitor to measure and predict health outcomes

Submission date 09/12/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/12/2020	**Overall study status** Completed	
Last Edited 25/06/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The ability to move is important for general well-being. Ageing and chronic health conditions can lead to a loss of mobility and a loss of independence. In order to treat mobility loss, tools are needed that can detect and accurately measure mobility. Existing measures of mobility (based on self-reporting and one-off tests) are highly limited. Wearable digital technology (a small device worn on the body) that can be used in the home and the community can provide a simple, accurate and low-cost measure of mobility. The researchers have validated a wearable mobility monitor which can accurately measure how well a person walks by measuring aspects of mobility such as speed and symmetry. The aim of this study is to investigate the ability of the mobility monitor to measure and predict outcomes in a variety of health conditions. The digital assessment of mobility developed in this study will be used in clinical trials and in clinical practice.

Who can participate?
People aged 18 or over who have been diagnosed with Parkinson’s disease, chronic obstructive pulmonary disease, multiple sclerosis and recent hip fracture.

What does the study involve?
Participants will attend a baseline visit and four follow up visits every 6 months (study length is 24 months). Each visit will last around 3 hours and will involve the completion of a range of questionnaires and assessments:
- Descriptive measures (i.e. height and weight, living arrangements, smoking and alcohol use and vision).
- Clinical assessments (i.e. level of function and disability, quality of life, frailty, fall and injury history, medical history, medication, blood pressure, pain, fatigue and muscle/fat mass).
- Psychological assessments (i.e. brief memory test, fear of falling and depression)
- Physical assessments (i.e. balance tests, 6-minute walk test and muscle strength)
- Disease-specific assessments measuring the severity of participant's health condition
At the end of each visit, participants will be asked to wear a mobility monitor around their waist for 7 days. The monitor will measure several aspects of mobility such as walking speed and step length.

What are the possible benefits and risks of participating?
There will be no direct benefit to participating in this study. Participants will be making a valuable contribution to the development of a digital assessment of mobility. There should be no major disadvantages or risks in taking part in this study. It is possible that participants will feel tired during and after the study visits, but opportunities to rest times will be given.

Where is the study run from?
Newcastle University (UK)

When is the study starting and how long is it expected to run for?
October 2018 to May 2024

Who is funding the study?
Innovative Medicines Initiative 2 Joint Undertaking (EU)

Who is the main contact?
Isabel Neatrour, Isabel.Neatrour@newcastle.ac.uk
Prof Lynn Rochester, lynn.rochester@newcastle.ac.uk

Study website
https://www.mobilise-d.eu/

Contact information

Type(s)
Scientific

Contact name
Miss Isabel Neatrour

Contact details
Mobilise-D Office
Room 3.27
The Catalyst
3 Science Square
Newcastle Helix
Newcastle upon Tyne
United Kingdom
NE4 5TG
+44 (0)191 2081406
isabel.neatrour@newcastle.ac.uk

Type(s)
Scientific

Contact name
Prof Lynn Rochester

Contact details
Newcastle University
Clinical Ageing Research Unit

Campus for Ageing and Vitality
Newcastle upon Tyne
United Kingdom
NE4 5PL
+44 (0)191 208 1291
lynn.rochester@newcastle.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
289543

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 289543

Study information

Scientific Title
Validating digital mobility assessment using wearable technology – the Mobilise-D Clinical Validation study

Acronym
Mobilise-D CVS

Study objectives
The Mobilise-D Project aims to link digital assessments of mobility to clinical outcomes for regulatory and clinical endorsement. The Clinical Validation Study is the second stage of this project and aims to use a technically validated device-algorithm pair to link digital mobility outcomes (DMOs) to clinical endpoints in four chronic conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/01/2021, London - Bloomsbury Research Ethics Committee (HRA RES Centre Manchester, Barlow House 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8196; nrescommittee.london-bloomsbury@nhs.net), ref: 20/PR/0792

Study design
Observational non-interventional study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Parkinson’s disease (PD), multiple sclerosis (MS), chronic obstructive pulmonary disease (COPD), proximal femoral fracture (PFF)

Interventions
Participants will attend a baseline visit and four follow up visits every 6 months (study length is 24 months). Each visit will involve the completion of questionnaires and assessments including:
1. Descriptive measures (i.e. height and weight, living arrangements, smoking and alcohol use and vision)
2. Clinical assessments (i.e. level of function and disability, quality of life, frailty, fall and injury history, medical history, medication, blood pressure, pain, fatigue and muscle/fat mass)
3. Psychological assessments (i.e. brief memory test, fear of falling and depression)
4. Physical assessments (i.e. balance tests, 6-minute walk test and muscle strength)
5. Disease-specific assessments measuring the severity of the participant's health condition
At the end of each visit, participants will be asked to wear a mobility monitor around their waist for 7 days. The monitor will measure several aspects of mobility such as walking speed and step length.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
Current primary outcome measure as of 27/10/2022:

Global primary outcome:
Change in the functional component score of the Late-Life Functional Disability Index (LLFDI) during 12-month follow-up.

There are also disease-specific primary outcomes for each cohort:
1. PD Cohort: Fall frequency during first 12 months follow-up, collected via face-to-face interview, participant-completed falls diaries and hospital records at baseline, 6 and 12 months.
2. MS Cohort: Fall frequency during first 12 months follow-up, collected via face-to-face

interview, participant-completed falls diaries and hospital records at baseline, 6 and 12 months.
3. COPD Cohort: Occurrence of moderate-to-severe COPD exacerbations during the first 12 months of follow-up, collected via face-to-face interview, participant-completed falls diaries and hospital records at baseline, 6 and 12 months.
4. PFF Cohort: Admission to a care home assessed from patient records at 6 months follow-up.

Previous primary outcome measure:

Global primary outcome:
Change in the functional component score of the Late-Life Functional Disability Index (LLFDI) during 24-month follow-up, measured at baseline, 6, 12, 18 and 24 months

There are also disease-specific primary outcomes for each cohort:
1. PD Cohort: Fall frequency during 24 months follow-up, collected via face-to-face interview, participant-completed falls diaries and hospital records at baseline, 6, 12, 18 and 24 months
2. MS Cohort: Fall frequency during 24 months follow-up, collected via face-to-face interview, participant-completed falls diaries and hospital records at baseline, 6, 12, 18 and 24 months
3. COPD Cohort: Occurrence of moderate-to-severe COPD exacerbations during the first 12 months of follow-up, collected via face-to-face interview, participant-completed falls diaries and hospital records at baseline, 6 and 12 months
4. PFF Cohort: Admission to a care home assessed from patient records at 6 months follow-up

Secondary outcome measures
Current secondary outcome measures as of 27/10/2022:

1. Assess predictive capacity of DMOs over 12 months.
2. Assess construct validity of DMOs over 12 months.
3. Assess ability of DMOs to detect change over 12 months.
4. Estimate the Minimum Important Difference of DMOs to measure change over 12 months.
5. Describe real-world walking behaviour with DMO's.

Previous secondary outcome measures:

There are no secondary outcome measures

Overall study start date
26/10/2018

Completion date
25/05/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 19/07/2021:

All participants:
1. Adults aged 18 or over
2. Able to walk 4 meters independently with or without walking aids
3. Anticipated availability for repeated study visits over 24 months
4. Ability to consent and comply with any study specific procedures.
5. Willingness to wear the McRobert's body sensor (DynaPort MoveMonitor)
6. Able to read and write in first language in the respective country

PD Cohort:
1. Patients with the clinical diagnosis of PD according to the recent criteria of the Movement Disorder Society
2. Hoehn & Yahr stage I-III.

MS Cohort:
1. A diagnosis of MS based on the revised McDonald's criteria
2. EDSS score of 3.0 - 6.5
3. Clinical evidence of disability worsening over the previous two years

COPD Cohort:
1. Diagnosis of COPD (post-bronchodilator forced expiratory volume in the first second (FEV1) to forced vital capacity (FVC) ratio <0.70
2, Clinical stability, defined as at least 4 weeks after the onset of the last exacerbation
3. Current or ex-smokers with a smoking history equivalent to at least 10 pack years (1 pack year = 20 cigarettes smoked per day for 1 year)

PFF Cohort:
1. Surgical treatment (fixation or arthroplasty) for a low-energy fracture of the proximal femur (ICD-10 diagnosis S72.0, S72.1, S72.2) as diagnosed on X-rays of the hip and pelvis. Between 3 days and 52 weeks post-surgery
2. Aged 45 years or older

———

Previous inclusion criteria:

All participants:
1. Adults aged 18 or over
2. Able to walk 4 meters independently with or without walking aids
3. Anticipated availability for repeated study visits over 24 months
4. Ability to consent and comply with any study specific procedures.
5. Willingness to wear the McRobert's body sensor (DynaPort MoveMonitor)
6. Able to read and write in first language in the respective country

PD Cohort:
1. Patients with the clinical diagnosis of PD according to the recent criteria of the Movement Disorder Society
2. Hoehn & Yahr stage I-III.

MS Cohort:
1. A diagnosis of MS based on the revised McDonald's criteria
2. EDSS score of 3.0-6.5.
3. Evidence of confirmed disability progression within the 12 months prior to screening (defined

by a 6-month
confirmed EDSS increase of 1.0-point for participants if the EDSS score was 3.0 to 5.5 and a 0.5-point if the EDSS score was 6.0 to 6.5).

COPD Cohort:
1. Diagnosis of COPD (post-bronchodilator forced expiratory volume in the first second (FEV1) to forced vital capacity (FVC) ratio <0.70
2, Clinical stability, defined as at least 4 weeks after the onset of the last exacerbation
3. Current or ex-smokers with a smoking history equivalent to at least 10 pack years (1 pack year = 20 cigarettes smoked per day for 1 year)

PFF Cohort:
1. Surgical treatment (fixation or arthroplasty) for a low-energy fracture of the proximal femur (ICD-10 diagnosis S72.0, S72.1, S72.2) as diagnosed on X-rays of the hip and pelvis. Between 3 days and 52 weeks post-surgery
2. Aged 45 years or older (added 14/04/2021)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2,400 (600 per cohort)

Total final enrolment
2388

Key exclusion criteria
All participants:
1. Occurrence of any of the following within 3 months prior to informed consent: myocardial infarction, hospitalization for unstable angina, stroke, coronary artery bypass graft (CABG), percutaneous coronary intervention (PCI), implantation of a cardiac resynchronization therapy device (CRTD), active treatment for cancer or other malignant disease, uncontrolled congestive heart disease (NYHA class >3), acute psychosis or major psychiatric disorders or continued substance abuse.

PD Cohort:
1. History consistent with Dementia with Lewy Bodies (DLB), atypical parkinsonian syndromes (including multiple system atrophy or progressive supranuclear palsy, diagnosed according to accepted criteria)
2. Repeated strokes or stepwise progression of symptoms, leading to a diagnosis of ‘vascular parkinsonism’
3. Drug-induced Parkinsonism

MS Cohort:
1. Clinical relapse within 30 days prior to screening and baseline.

COPD Cohort:
1. Having undergone major lung surgery (e.g. lung transplant)
2. Current diagnosis of lung cancer
3. Primary respiratory diseases other than COPD
4. Substantial limitations in mobility due to factors other than COPD
5. Lung volume reduction within 6 months before inclusion

PFF Cohort:
1. Not able to walk before treatment of hip fracture

Date of first enrolment
12/04/2021

Date of final enrolment
31/07/2023

Locations

Countries of recruitment
Belgium

England

France

Germany

Greece

Israel

Italy

Norway

Spain

Switzerland

United Kingdom

Study participating centre
The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton

Newcastle-upon-Tyne
United Kingdom
NE7 7DN

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Guys and St Thomas' NHS Foundation Trust
Sydney Street
London
United Kingdom
SW3 6NP

Study participating centre
The Foundation For Medical Research Infrastructural Development And Health Services
Weizmann Street 6
Tel Aviv
Israel
64239

Study participating centre
Christian-Albrechts-Universität
Olshausenstrasse 40
Kiel
Germany
24118

Study participating centre
University Hospitals Leuven
Herestraat 49
Leuven
Belgium
3000

Study participating centre
Institut De Salut Global
Calle Rosselló, 132 - Planta 7
Barcelona
Spain
08036

Study participating centre
Pneumologisches Forschungsinstitut an der LungenClinic
Wöhrendamm 80
Großhansdorf
Germany
22927

Study participating centre
Universität Zürich
Rämistrasse 71
Zürich
Switzerland
8006

Study participating centre
Thorax Foundation
3, Ploutarchou St.
2nd floor
Athens
Greece
106 75

Study participating centre
Universitätsklinikum Erlangen
Maximiliansplatz 2
Erlangen
Germany
91054

Study participating centre
St. Olavs hospital
Erling Skjalgssons G. 1

Trondheim
Norway
7030

Study participating centre
Centre Hospitalier Universitaire de Montpellier
191 Doyen Gaston Giraud Avenue
Montpellier
France
34090

Study participating centre
San Raffaele Hospital
Olgettina Street, 60
Milan
Italy
20132

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Newcastle Joint Research Office
Level 1
Regent Point
Newcastle upon Tyne
England
United Kingdom
NE3 3HD
+44 (0)1912824461
Tnu-tr.sponsormanagement@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Research organisation

Funder Name
Innovative Medicines Initiative 2 Joint Understanding under grant agreement No 820820

Results and Publications

Publication and dissemination plan
The protocol will be published at later date. There are multiple measures in place to maximise dissemination of the results of the clinical validation study, emphasising a stakeholder-driven dissemination strategy and an Open Access policy. The study will be listed on the ISRCTN registry and included on the NIHR Clinical Research Network Portfolio. Relevant stakeholders for Mobilise-D include the scientific community; patients and patient organisations; health care professionals and public health authorities; pharmaceutical and associated industries; regulatory bodies; and the general public. Scientific dissemination will take place through peer-reviewed publications in scientific journals and presentations at scientific conferences, addressing the main objectives of the study in comprehensive primary papers across all included cohorts, as well as consisting of secondary papers focusing on specific cohorts and sub-questions. Furthermore, scientific dissemination will take place through training of early career researchers through direct involvement in the clinical validation study as PhD students and post-doctoral students, as well as through a Mobilise-D summer school targeting students and young professionals in e.g. (bio-)engineering and medical sciences. The results of the clinical validation study will also be disseminated through popular-science and professional publications in a variety of trade journals and magazines. The wider audience will also be kept appraised of the study results through the Mobilise-D website, social media, newsletters, press releases and project videos. In addition, participants in the clinical validation study will receive feedback in the form of newsletters targeted expressly at them.

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan
The datasets generated from the study will be available upon request. The type of data that will be available is outlined on the study website (https://www.mobilise-d.eu/data). All data is stored in a de-identified manner and no patient identifiable data will be included in the dataset. Consent for sharing the anonymised dataset with the wider research community is obtained from all participants.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article	version 1.0	06/10/2022	27/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
Basic results			25/06/2025	No	No