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Validating digital mobility assessment using wearable technology

Submission date
04/11/2019

Recruitment status
No longer recruiting

Registration date
24/03/2020

Overall study status
Completed

Last Edited
22/01/2024

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The ability to move is important for physical, mental and social well-being. Aging and chronic diseases can lead to a loss of mobility and a loss of independence. In order to target and treat mobility loss, we need tools that can detect and measure mobility. Existing measures of mobility (based on self-reporting and one-off assessments) are highly limited. A new approach is needed that is low cost, simple, accurate and capable of use in the home and the community. Wearable digital technology (a small device worn on the body to measure movement) has the potential for measuring and monitoring mobility to predict clinical outcomes. Over a period of five years, the Mobilise-D project aims to revolutionise the assessment of mobility loss using digital technology. This study is the first phase of the Mobilise-D project. The researchers are developing a method of measuring how people move and walk in their usual daily lives based on data that can be derived from small wearable devices. To do this, they will use a variety of different measurement tools to track walking and other activities of daily living (such as getting in and out of a chair) in a gait laboratory and in the home. These measurement tools will include small wearable motion sensors, foot insoles (to measure foot pressure on the ground) and camera-based motion capture systems. Data from these measurement systems will be used to evaluate the accuracy of an algorithm (the mathematical process used to transform the signal from the device to a measure of movement) designed to measure different characteristics of mobility. This algorithm will be used in the second phase of the Mobilise-D project. This is a larger clinical study which will use wearable digital technology and the algorithm to identify outcome measures that can accurately monitor and assess mobility in multiple diseases. This validated assessment of mobility will then be used in clinical trials to investigate the effects of new drugs on mobility and disability.

Who can participate?
Older adults without any neurological, respiratory, cardiac or musculoskeletal condition affecting their ability to walk, and adults diagnosed with one of the following five conditions: Parkinson’s disease, congestive heart failure, multiple sclerosis, proximal femoral fracture, or chronic obstructive pulmonary disease

What does the study involve?
Participants undertake three different assessments over the course of approximately nine days (gait laboratory assessment, unsupervised free-living assessment and home-based assessment).

Gait laboratory assessment:
Participants complete a brief cognitive test and some additional questionnaires to measure their disease progression. They are asked to complete a number of walking and functional tasks. The walking tasks will include standing, walking and turning at different speeds (i.e. preferred, slow and fast speed). The functional tasks will be similar to the typical daily activities you do at home. These tasks include sitting down, setting the table and moving a chair from one place to another. Whilst performing these tasks their movement will be recorded using a set of movement tracking cameras. The face and any distinguishing features will not be recorded. In addition, participants will be asked to wear a number of different wearable sensors. These will be;
- pressure insoles inserted into each of their shoes
- two small distance sensors attached to each of their ankles
- two activity monitors attached to their shoes
- one activity monitor attached to their non-dominant wrist
- one activity monitor worn on their lower back

Unsupervised free-living assessment:
At the end of the gait laboratory assessment participants will be asked to continue wearing the activity monitor on their lower back for the next 9 days. For this they will be provided with an elasticated strap and instructions on how the monitor should be worn. During this part of the study participants continue with their normal daily activities. The monitor should be worn at all times, except when swimming or taking a shower/bath. Participants are provided with a mobile phone which will track their movement during this assessment. A sensor will also be attached to any walking aids that they normally use.

Home assessment:
At the end of the unsupervised free-living assessment, a member of the research team will visit the participants at home. During this assessment, they will be asked to complete some questionnaires looking at their opinions of the wearable device. They may also be asked to complete an audio-recorded interview about their experiences during the week, their experiences of using digital technology both in their day to day life and in the management of their health condition, and their opinions on how technology may be used in healthcare. They are then set up with the same six sensors as in the gait laboratory assessment and they will be asked to wear these for a period of 2.5 hours whilst they go about their usual daily activities.

What are the possible benefits and risks of participating?
There will be no direct benefit of participating in this study. There should be no major disadvantages or risks in taking part in this study. The sensors are non-invasive and operate on very low power. It is possible that participants will feel tired during and after the assessments, but they will be given as much time to rest as they require.

Where is the study run from?
This study is being conducted across five different sites in Europe. Within the UK there are two sites: The Newcastle upon Tyne Hospitals NHS Foundation Trust and Sheffield Teaching Hospitals NHS Foundation Trust. There are also two sites in Germany and one in Israel.

When is the study starting and how long is it expected to run for?
April 2019 to December 2021 (updated 22/03/2022, previously: April 2022) (updated 27/09/2021, previously: October 2021) (updated 19/07/2021, previously: April 2021)

Who is funding the study?
The study is funded by the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 820820. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

Who is the main contact?
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Study website
https://mobilise-d.eu/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
270519

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 43318, IRAS 270519

Study information

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

Acronym
Mobilise-D

Study objectives
The Mobilise-D Technical Validation Study is part of the EU-funded IMI project Mobilise-D. This project aims to link digital assessments of mobility to clinical outcomes for regulatory and clinical endorsement. This study comprises the first phase of this project and aims to carry out a technical validation of a device/algorithm pair to measure real-world walking speed and other digital mobility outcomes. The study is an observational design that will compare free-living gait speed and other digital outcomes against reference standards. The usability and acceptability of the device from the perspective of participants and researchers will also be evaluated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/11/2019, London - Bloomsbury Research Ethics Committee (HRA RES Centre Manchester, Barlow House 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; Tel: +44 (0)207 104 8196; Email: nrescommittee.london-bloomsbury@nhs.net), REC ref: 19/LO/1507

Study design
Observational; Design type: Validation of outcome measures

Primary study design
Observational

Secondary study design
Cohort 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
Chronic obstructive pulmonary disease (COPD), Parkinson’s disease (PD), multiple sclerosis (MS), proximal femoral fracture (PFF), congestive heart failure (CHF)

Interventions

120 participants representing the disease cohorts of interest to MOBILISE-D partners will be recruited from six different groups: chronic obstructive pulmonary disease (COPD), Parkinson's disease (PD), multiple sclerosis (MS), proximal femoral fracture (PFF), congestive heart failure (CHF) and healthy older adults (HA). Participants will be recruited from five clinical sites who have access to the populations of interest and have the capability to conduct technical studies and recruit the participants.

Condition 1: Walking-related activities in a movement analysis laboratory (Day 1)
Participants are recorded during two separate experimental sessions and will take up to 5 hours. Participants can have breaks between the screening and the two sessions, where they are provided with a small meal and/or coffee. For both parts, the following data will be collected simultaneously:
1. An optoelectronic stereo-photogrammetric system consisting of multiple infrared cameras that reconstruct the trajectories of non-invasive markers
2. A multi-sensor wearable system (INDIP) which includes two pressure insoles inserted into each of the participants shoes, two small distance sensors with one attached to each of the participants ankles, and four additional inertial sensors, two of which will be secured to the participant's shoes, one attached to the non-dominant wrist by an elastic strap and one secured on the lower back

Part A - The first part is a pre-set sequence of specific gait activities under strictly controlled conditions (outlined in the protocol):
1. Walk back and forth (preferred gait speed) along a straight walkway
2. Walk back and forth (slow gait speed) along a straight walkway
3. Walk back and forth (fast gait speed) along a straight walkway
4. Complete a circuit by walking (preferred gait speed) over a carpeted mat (2 m in length) and turning around two cones (4 m apart along a straight walkway)
5. Walk (preferred gait speed) around the outline of the square marked out on the floor by cones.
6. While walking back and forth (preferred gait speed), step up and down a box (stair height, placed in the middle of the capture area and clearly highlighted to avoid tripping)
7. Perform the Timed Up and Go test (3 meters back/forth at preferred gait speed)
8. Perform the L-test back and forth (to ensure turning 90 degrees left and right)

Part B - The second part is a simulated daily activity session. The daily-life assessments will contain activities such as replacing objects, setting the table, drinking a glass of water and eating a cookie (outlined in the protocol). These daily-life activities will mimic movements performed at home. To ensure patient safety and comfort, two variations of the simulated daily activity session have been created. Level One is a simplified version accommodating the participants who may find some of the tasks in Level Two too physically demanding or uncomfortable. Level Two consists of some complex movements that may not be suitable for all participants but will be crucial for the development and validation of the single sensor system/algorithm pair.

Condition 2: Seven days free-living activities (Day 1-9, to ensure at least seven consecutive days of monitoring).
There are two parts to this condition. Firstly participants wear a device to capture everyday activities over seven days (Part A) and secondly participants and the assessor will be asked their opinions on how user friendly they found the experience (Part B).
Part A. Monitoring free-living for a week
At the end of day 1, participants will return home wearing the single Dynaport device. The participants are asked to "Do what you usually do during a week", without any further instructions. Participants will be provided with a mobile phone which will track their geolocation

during the monitoring period. The phones will be provided with internal SIMs to avoid using Wi-Fi networks. A beacon sensor will also be attached to any walking aids normally used by the participants to detect if and when these are being used. Beacon data will be collected automatically and stored on the mobile phone (when in the proximity of the device).
Part B - On day 9, participants will complete an interview/questionnaire to assess participant acceptability and compliance (usability and human factors). In addition, a sub-group of participants will be asked to complete a semi-structured interview which will be audio-recorded.

Condition 3: Daily free-living activities (Day 9)
The final day of assessment will be completed in the participant's home environment wearing the INDIP system described above for a 2.5-hour session. The protocol is free-living and unsupervised, but participants are provided with a written list that describes activities that they should try to include during the 2.5 hour-session (outlined in the protocol).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
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Primary outcome measure
Current primary outcome measure as of 01/11/2022:

Walking speed data in the real-world measured using a single sensor in comparison to walking speed data collected using multi-sensor reference systems in the lab and in the home. The laboratory tasks (45 minutes) and the home environment measurement (2.5 hours unsupervised) take place within 9 days of each other.

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Previous primary outcome measure:

Walking speed in real-world settings, collected via the sensor during a 7-day continual recording of free-living activities in the home environment

Secondary outcome measures
Current secondary outcome measures as of 01/11/2022:

Right and left step, stride, turning angle, cadence, distance walked, gait variability and symmetry, and other gait-related outcomes relevant in the real-world measured using a single sensor in comparison to multi-sensor reference systems in the lab and in the home. The laboratory tasks (45 minutes) and the home environment measurement (2.5 hours unsupervised) take place within 9 days of each other.

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Previous secondary outcome measures:

Right and left step, stride, turning angle, cadence, distance walked, gait variability and symmetry, and other gait-related outcomes relevant for assessments in real-world settings, collected via the sensor during a 7-day continual recording of free-living activities in the home environment

Overall study start date
01/04/2019

Completion date
14/12/2021

Eligibility

Key inclusion criteria
All groups:
1. Able to walk 4 meters independently with or without walking aids
2. Able to give informed consent
3. Willingness to wear the sensor set-ups during the study
4. Shoe size 36 (3 UK) or above
5. Able to read and write in first language in the respective country
6. MoCA >154
7. Available for home visit/office during study period

Each disease cohort has specific inclusion criteria:

COPD:
1. ≥45 years of age
2. Diagnosis of COPD (post-bronchodilator forced expiratory volume in the first second (FEV1) to forced vital capacity (FVC) ratio <0.70)
3. Clinical stability, defined as at least 4 weeks without antibiotics and/or oral corticosteroids to treat either a moderate or severe exacerbation
4. 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)

PD:
1. Aged 18+ years
2. Diagnosis of PD according to the Movement Disorders Society criteria

MS:
1. Aged 18+ years
2. Diagnosis of MS based on the revised McDonald’s criteria

PFF:
1. 65+ years of age
2. 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 within last 12 months

CHF:
1. ≥45 years of age
2. Diagnosis of chronic heart failure NYHA class II-IV

HA:
1. 65+ years of age

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
112

Total final enrolment
111

Key exclusion criteria
All groups:
1. The occurrence of any of the following with 3 months prior to inclusion: myocardial infarction, hospitalization for unstable angina, stroke, coronary artery bypass graft (CABG), percutaneous coronary intervention (PCI), implantation of a cardiac resynchronization therapy device (CRTD)
2. Current medical condition that could interfere with the patient's compliance

COPD:
1. Having undergone major lung surgery (e.g. lung volume reduction, lung transplant)
2. Having a lung tumor
3. Primary respiratory diseases other than COPD
4. Impaired mobility related to non-COPD causes, as judged by the investigator

PD:
1. Impaired mobility related to non-PD causes, as judged by the investigator

MS:
1. Impaired mobility related to non-MS causes, as judged by the investigator

PFF:
1. Impaired mobility related to non-PFF causes, as judged by the investigator

CHF:
1. History of COPD ≥GOLD III
2. Impaired mobility related to non-CHF causes, as judged by the investigator

HA:
1. Neurological, respiratory, cardiac or musculoskeletal conditions affecting the ability to walk independently without a walking aid

Date of first enrolment
01/07/2020

Date of final enrolment
22/03/2022

Locations

Countries of recruitment
England

Germany

Israel

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
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
Robert Bosch Gesellschaft Fur Medizinische Forschung MBH
Auerbachstrasse 112
Stuttgart
Germany
70376

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
European Commission; Grant Codes: 820820

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website

Intention to publish date
01/04/2023

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be stored in a non-publically available repository for the duration of the project (5 years) and thereafter on a publically available repository indefinitely. The current platform is e-Science Central (e-SC) and the public repository for long-term storage and access for the wider research community will be selected by the consortium during the course of the project. The following types of de-identifiable participant data will be collected: clinical & demographic data, motion data, clinician/patient-reported outcomes, geolocation and beacon data, usability/acceptability questionnaire data and transcriptions from semi-structured interviews. All data loaded to the e-SC platform will be de-identified at source and the associated study key code will be maintained at the relevant sites. During the 5-year term of the project, the data will be available to researchers within the consortium only and access will be tightly controlled. Access to data is role-based and each role is assigned the minimum amount of access for that role. Platform manager has full access to the platform, analysts have access to all datasets, clinicians have access to cohort dataset and assessors have access to the patient dataset. Analyses will combine descriptive statistics, technical validation, wearability and compliance combining a qualitative and quantitative approach. A fully anonymised dataset will become available at the end of the study post-publication and will be available indefinitely in a public repository as part of the researchers' commitment to adhere to the open data policy. This anonymised dataset will be made available

to the wider research community for secondary research purposes. Participants must give explicit consent for this use.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		02/12/2021	06/12/2021	Yes	No
Basic results			29/11/2022	No	No
Other publications	Protocol validation	16/12/2022	16/12/2022	Yes	No
Preprint results	Gait sequence detection, foot initial contact detection, cadence and stride length results	21/09/2022	16/01/2023	No	No
Results article		14/06/2023	15/06/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article		19/01/2024	22/01/2024	Yes	No