Technical Validation Study: Study Summary

What we knew:

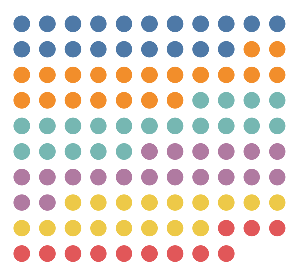
The ability to move is important for well being. Ageing and chronic disease can lead to a loss of mobility and independence. In order to treat, diagnose and monitor mobility loss, we need tools that can detect and measure mobility. Existing measures (based on self-reporting and one-off tests) are limited as they do not sufficiently reflect real-life. A new approach is needed to accurately measure how people move in their usual daily lives. Wearable technology (body worn sensors) has the potential to revolutionise how we assess mobility.

What we planned to do:

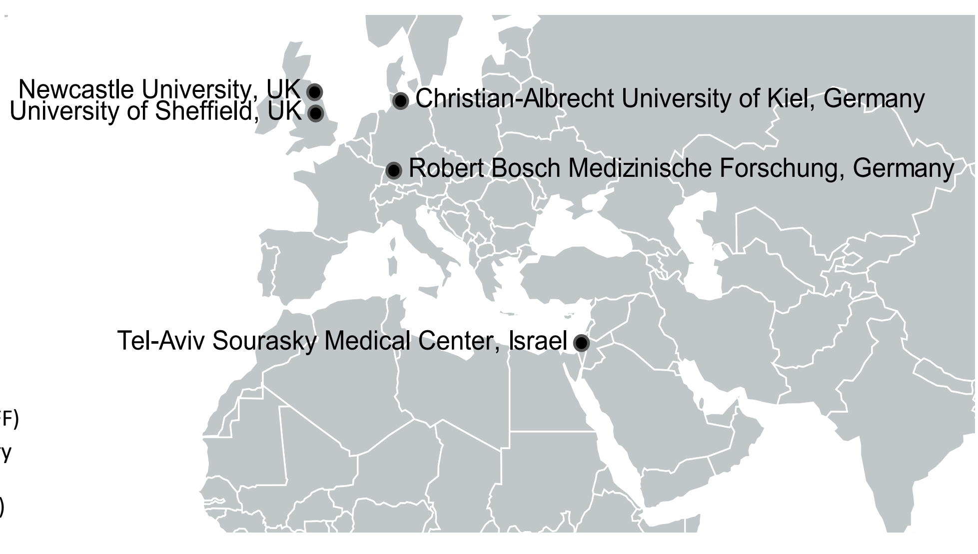
This study aimed to develop an accurate assessment of mobility using body worn sensors. This required the development of an algorithm which can transform signals from a sensor into a meaningful measure of mobility. We also aimed to understand participant views of this assessment.

Who we included:

The study recruited healthy older adults, as well as adults diagnosed with five conditions where mobility may be altered. A total of 111 participants were recruited from five clinical sites across Europe (in UK, Germany and Israel).



- Healthy Older Adults (HOA)
- Multiple Sclerosis (MS)
- Parkinson's Disease (PD)
- Proximal Femoral Fracture (PFF)
- Chronic Obstructive Pulmonary Disease (COPD)
- Congestive Heart Failure (CHF)



Included conditions: each dot represents an enrolled participant

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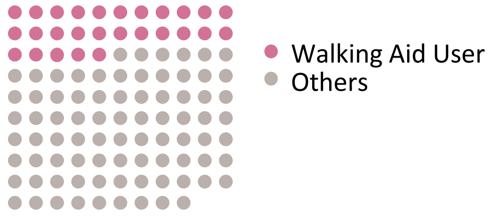
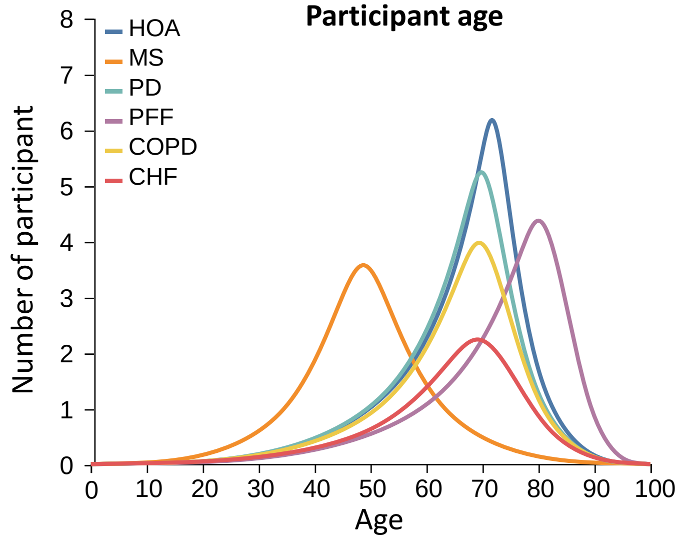
Participants with varying ages and levels of mobility were included in the study.

Gender: each dot represents a participant



Walking aid use : each dot represents a participant

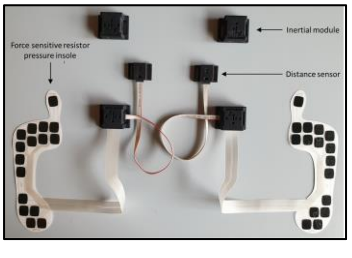


What was done: Each participant completed three steps of data collection:

Step One (Laboratory): Participants completed a range of walking tasks in a clinical laboratory. During these tasks, participants wore a single sensor and a multi-component system of sensors attached to their body and shoes. Their movement was recorded using motion capture cameras (laboratory reference system).

Step Two (Real-world): Participants were instructed to undertake their usual daily activities while wearing the single sensor on their lower back for nine days. A mobile phone was provided to track their location.

Single waist worn sensor



Multi-component sensor system consisting of a range of body and shoe worm sensors

Step Three (Home): Participants were asked to complete a 2.5 hour measurement of unsupervised activities in the home (at a time when they would be active). During this time, participants wore the single sensor and the same multi-component sensor system (home reference system) that was used in the laboratory. Participants were asked about their experience of wearing the single sensor and their use of wearable technology.

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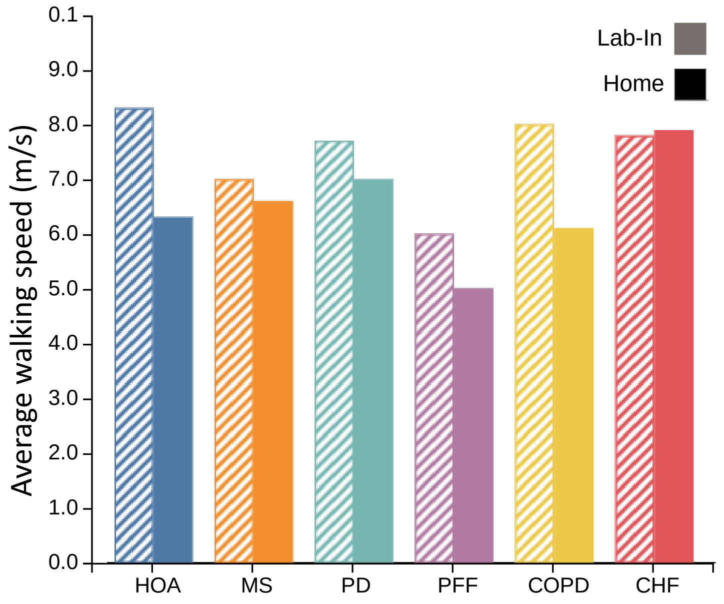
What we found:

As expected, the data collected showed differences in the way people move in the laboratory compared to the real-world. This confirms the limitation of existing methods of measuring mobility, and highlights the need for a real-world assessment of mobility. The graph shows that participants walk slower in the home than in the laboratory.



The data collected in this study included a large number of distinct walking periods and a wide range of walking speeds across all participant groups. This is what we expect to see in the real-world, and therefore the data could be used to test our algorithms.

In this study, data collected from the laboratory and the home reference systems were compared against the data from the single sensor. Walking speed data (our primary outcome measure) was investigated to identify the best performing algorithm with the lowest error in real-life conditions.

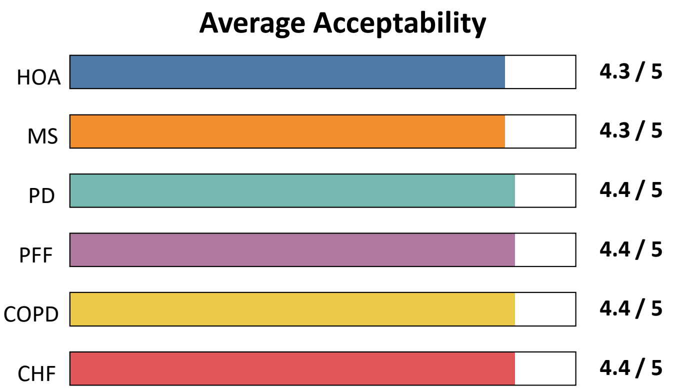
We also tested algorithms looking at other measures of mobility (e.g. rhythm) which are clinically important to the specific patient groups involved.

As the algorithm showed very promising results, with an acceptable level of error when compared to the reference systems, this can now be used with the single sensor to confidently detect and measure mobility in the real-world. This will allow further exploration of how we move in everyday life, and is the focus in the next stage of the project.

How patients found it:

An important aspect of this study was to understand whether this method of measuring mobility is acceptable to patients. Participants spoke about their experiences, and completed questionnaires about the comfort and acceptability of the device.

Participants reported that the sensor was comfortable. Specifically, using the Comfort Rating Scale Questionnaire, they reported low levels of discomfort with an average score of 1.4 out of 20.



Acceptability levels were high with an average score of 4.3 out 5 using the Rabinovich Questionnaire. Participants said they didn't realise the device was on them once they put it on.

Some participants were initially concerned that it might be intrusive to wear due to its size, but once they put it on, they didn't notice it during their daily activities. They were very open to the idea of using a wearable sensor to monitor their condition and felt that any tool which would help their clinician to understand more about their condition would be useful. However, they were not yet sure exactly how it might help yet, as this is still a new method. There were very few fears relating to privacy as participants trusted both researchers and clinicians to manage their information safely.

What's next:

This algorithm developed in this study is now being used in the second phase of the Mobilise-D project – the Clinical Validation Study. This is a larger clinical study (2400 participants) which is investigating the ability of the sensor and algorithm to measure and predict relevant clinical outcomes. These include a general measure of disability, as well as condition-specific outcomes: fall frequency (Parkinson's Disease and Multiple Sclerosis), occurrence of exacerbation (Chronic Obstructive Pulmonary Disease), and admission to care home (hip fracture).

The next stage of the project will be to obtain regulatory approval to use our assessment of mobility in clinical trials and in clinical practice. For more information about the wider Mobilise-D project and what we aim to achieve, please visit our website: https://www.mobilise-d.eu

Thanks to:

We are very grateful to the clinical staff at the study centres and to all participants who donated their time to the study

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Glossary of terms for this study:

Assessment: Action of measuring mobility
Sensor: Device which detects and records mobility
HOA: Healthy Older Adults
PD: Parkinson's Disease
MS: Multiple Sclerosis
COPD: Chronic Obstructive Pulmonary Disease
PFF: Proximal Femoral Fracture
CHF: Congestive Heart Failure