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Validation of smartphone-based assessments in multiple sclerosis

Submission date	Recruitment status	[X] Prospectively registered
27/08/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/09/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/04/2026	Nervous System Diseases	

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is an immune-mediated inflammatory disease of the central nervous system (CNS). It can cause a wide range of symptoms that include weakness, spasticity, and fatigue, as well as changes in sensation, coordination, vision, cognition, and bladder function. Instrumented-based assessments can provide considerable insight into walking (gait) and balance in MS and remain a gold standard method for assessing gait and balance. However, they require trained personnel and expensive laboratory environments, making these evaluations non-feasible in a clinical setting. Moreover, these present tests present only a static snapshot of walking ability, and may have limited real-world relevance. Wearable sensors have been suggested as an alternative method to evaluate walking and postural control impairments, and these are becoming popular for assessing pwMS both in clinical settings and in the real world. Wearable sensors include intertial sensors that can measure acceleration and angular velocity of a body part using accelerometers and gyroscopes. Smartphones, also have accelerometer, gyroscope and/or magnetometer sensors. Roche developed several smartphone applications (different versions of Floodlight) which were designed to measure gait, balance, cognitive and upper extremity functions, remotely in unsupervised settings (e.g., at home). We have previously shown that a Floodlight Proof of Concept (PoC) app provides measures of moderate-to-good reliability, that correlate with standard clinical and Brain scan (MRI) measures used to quantify MS functional impairment and overall disability. We have also demonstrated that gait analysis performed on inertial sensor data harvested during a self-administered 2MWT using a single smartphone, attached to the front of the waist, provides both accurate and reliable measurements of selected spatial, temporal and spatiotemporal characteristics of gait in pwMS and HCs. This study aims to validate the Floodlight smartphone based app that aims to monitor symptoms in people with Multiple Sclerosis (MS). The app contains tests of finger coordination, cognition, walking and balance. The study will compare data obtained with the smartphone app in laboratory-based and real world environments with gold standard measures of walking and balance (3D motion analysis and posturography) and self reported outcome measures.

Who can participate?
Patients aged 18-70 years with MS and healthy volunteers

What does the study involve?
Following informed consent participants will undertake two visits interspersed with 2 weeks of home-based assessments. On the first visit clinical researchers will ask about demographics, clinical history and current medication, and undertake standardised routine clinical assessments. Participants will be shown how to use the smartphone app and also two inertial sensors that can measure walking ability when attached to the shoes. Participants will be supplied with a dedicated phone containing the app and a belt to house the smartphone during the walking and balance tests for the duration of the study.
Over the next 2 weeks participants will be asked to undertake the Floodlight app tests everyday; this will take 10-15 minutes. They will also be asked to wear their phone in a pocket while walking for at least 15 minutes in their community and complete a diary about their walking activities. At the end of this period participants will complete a booklet of questionnaires that ask about their MS symptoms and how they are affected by them, as well as a satisfaction questionnaire about the smartphone app.
On the final visit participants' walking and balance will be measured accurately using a 3D motion analysis system while also wearing six smartphones worn around the waist or legs. The 3D motion analysis system works by recording the movement of small reflective balls attached to the body. People will be asked to take a series of progressively difficult balance tests, tests of walking at various speeds on a treadmill and tests of walking overground where movement will be measured either using the 3D motion analysis system, force sensors under each foot, and/or the shoe worn sensors. Rests will be given between tests and people will wear a safety harness. In addition, participants will repeat the same smartphone-based cognition and finger coordination tests, as performed during the home-based period.

What are the possible benefits and risks of participating?
There is no direct medical benefit from taking part in this study. The information gained from this study may help researchers and health care practitioners to learn more about MS. It will also help to develop the smartphone app that could be used to monitor symptoms in people with MS. This in turn could help clinicians alike make decisions about the future management of people’s condition and allow accurate monitoring of symptoms during clinical trials. The tests of walking and balance may cause some fatigue and there is a risk of falling. To prevent any falls people will wear a safety harness for tests when they are in the laboratory.

Where is the study run from?
University of Plymouth (UK)

When is the study starting and how long is it expected to run for?
April 2021 to October 2023.

Who is funding the study?
F. Hoffmann-La Roche Ltd (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
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Protocol serial number
MN43416

Study information

Scientific Title
An observational study in patients with multiple sclerosis to assess validity and information content of smartphone-based gait and balance features and to qualitatively investigate the execution of cognition and hand motor function tests within the Floodlight program

Study objectives
This study will investigate the validity of a smartphone-based app (Floodlight) that has been developed to monitor symptoms in people with multiple sclerosis. The primary focus will be on validating walking and balance based measures using gold standard whole-body 3D motion analysis while walking and posturography.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Observational

Study design
Single-centre observational cross-sectional study

Study type(s)
Other

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
People with multiple sclerosis (n=100) and healthy controls (n=30) will attend two visits interspersed by a 2-3-week home monitoring period. Participation will occur after providing informed written consent.

Initial visit:
This will involve a visit to the clinical neurology research team. The following measures and procedures will take place. This visit will last about 120-180 minutes with rests and refreshments provided as required.

1. Demographics (e.g. age, sex); MS type and duration of condition, medical history and current medication
2. Standardised neurological examination using the Expanded Disability Status Scale
3. Assessment of hand function using the 9 hole peg test and processing speed using the symbol digit modality test (SDMT)
4. Completion of a short falls questionnaire
5. Provision of smartphones and inertial sensors and demonstration of the Floodlight app and the use of the inertial sensors to measure walking ability. This will be supplemented by a booklet outlining how to use the app and sensors at home and a research team contact number in case of queries.

Remote home assessments:
Over a 2-3 week period participants will be asked to use the Floodlight app to monitor their symptoms daily and measure real-world walking.
1. Symptom monitoring - the Floodlight app contains eight tests including questions about how people perceive their symptoms using a validated test (the MS Impact Scale) as well as standardised tests of finger coordination; cognition and walking and balance. The finger coordination tests (pinching and drawing) and cognition test for processing speed require the participants to interact with the app (e.g. undertaking a digital version of the validated symbol digit modality test). The walking and balance test requires the participant to wear the smartphone in a waistband whilst performing tests of walking (a. walk 4 m and perform U-turns at least 5 times, b. walk for 2 minutes as in a straight line and as fast as possible) or balance (standing with the feet apart). For the walking tests the start and end of the tests are indicated by the phone using vibratory and tone signals. The full battery of smartphone tests takes together 10-15 min to perform each day.
2. Real-world walking - people are asked to carry the smartphone in a pocket every day for at least 15 minutes up to a maximum time of 4 hours while undertaking their usual activities and walking in their community.
3. Gait diary - people are asked to keep a gait diary for the walking tests and the real world waking capturing e.g. where the phones was carried or whether walking was performed indoors or outdoors.
4. At the end of the 2-week period participants will be asked to complete a questionnaire booklet that contains validated questionnaires (Multiple Sclerosis Walking Scale (12-item scale); Early Mobility Impairment Questionnaire (EMIQ) (9 item questionnaire); Multiple Sclerosis Spasticity Scale (MSSS-88 [sections 1, 2 and 3]); Activities Balance and Confidence (ABC) scale;

Fatigue Scale for Motor and Cognitive Functions (FSMC) (20 item scale); Upper limb function item bank (ULF PRO); MS Impact scale MSIS-29v2; MS walking scale -12 and -41; Floodlight satisfaction questionnaire.

Final visit:
At this visit people will be asked to undertake walking and balance tasks whilst wearing a set of smartphones in different locations (two waist and four upper legs). These are attached via customised belts and adapted shorts to minimise applying excessive moments (turning forces) to the hips and spine that could impede walking. In addition, participants will be fitted with sensors (small reflective balls) on their legs, arms, and trunk. The movement of these reflective balls will be monitored using a 3D video camera system (Vicon, UK). The inertial sensors used to monitor movement remotely in the community will also be worn.

A. The following tests of walking will be taken:
1. Walking on a treadmill at normal speed (2 min); whilst performing an additional task (2 min) and walking fast (2 mins)
2. Walking overground while undertaking a U-turn test which consists of walking at least 4 m and turning five times
3. Walking in a corridor for 2 minutes as fast as possible. No reflective balls will be worn for this test, only the phones and inertial sensors
4. Performing the Timed 25 Foot Walk Test. No reflective balls will be worn for this test, only the phones and inertial sensors

B. The following tests of balance will be taken when people stand on two force plates (one under each foot) that can measure the motion of the applied forces:
1. Standing with feet together (30 s)
2. Standing with feet together eyes closed (30 s)
3. Standing with one foot in front of the other (tandem stance, 30 s)
4. Standing on one leg (preferred leg chosen, 30 s)

These balance tests are progressively harder and people will only take a test if it is deemed to be safe by the examiner. Participants can stop a test or not perform a test if they do not want to.

For the treadmill and balance tests participants will wear a harness to prevent any falls. For overground walking tests people will have a person close by to aid with balance if this is deemed necessary by the clinical researcher or the participant.

During the tests people's walking and balancing will be videoed using cameras at the side and at the back. The video images will be altered offline to pixelate the face to prevent participant identification.

Smartphone tests and clinical tests of cognition/hand function: the Floodlight app cognition and hand tests will be videoed. Here only the arms would be included in the video shot to prevent participant identification (video should not capture the face of the participant). Upper limb function would additionally be tested using the 9 hole peg test (a standardised, valid clinical test of arm function) and cognition will be tested using the Symbol Digit Mobility test) to allow an assessment of the association between these and the Floodlight app tests.

Intervention Type
Device

Phase

Not Applicable

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

Primary outcome(s)
Step intensity measured while walking using smartphone-based inertial data and 3D motion analysis at visit 3

Key secondary outcome(s)
Current secondary outcome measures as of 29/09/2021:
Walking related measures
1. Walking speed measured using smart-phone based accelerometers and inertial sensors during the 2 minute walking test and 25 foot walking test in visit 1
2. Walking speed measured using smart-phone based accelerometers, 3D motion analysis, and inertial sensors when walking at self selected and maximal walking speed and undertaking a secondary task (subtracting serial 7s, termed dual task) on a treadmill or during overground walking at visit 3 (U turn test and 25 m walking test) and during overground walking (2 minute walk test and minimum 15 mins walking) in the home based environment on 14 consecutive days
3. Cadence measured using smart-phone based accelerometers and 3D motion analysis when walking at self selected and maximal walking speed and undertaking a secondary task (subtracting serial 7s, termed dual task) on a treadmill or during overground walking (U turn test and 25 m walking test) at visit 3 and during overground walking (2 minute walk test and minimum 15 mins walking) in in the home based environment on 14 consecutive days
4. Step and stride length measured using smart-phone based accelerometers and 3D motion analysis when walking at self selected and maximal walking speed and undertaking a secondary task (subtracting serial 7s, termed dual task) on a treadmill or during overground walking (U turn test and 25 m walking test) at visit 3 and during overground walking in the home based environment (2 minute walk test and minimum 15 mins walking) in on 14 consecutive days
5. Step and stride time measured using smart-phone based accelerometers and 3D motion analysis when walking at self selected and maximal walking speed and undertaking a secondary task (subtracting serial 7s, termed dual task) on a treadmill or during overground walking (U turn test and 25 m walking test) at visit 3 and during overground walking in the home based environment (2 minute walk test and minimum 15 mins walking) in on 14 consecutive days
6. Lumbar sagittal motion length measured using smart-phone based accelerometers and 3D motion analysis when walking at self selected and maximal walking speed and undertaking a secondary task (subtracting serial 7s, termed dual task) on a treadmill or during overground walking (U turn test and 25 m walking test) at visit 3 and during overground walking in the home based environment (2 minute walk test and minimum 15 mins walking) in on 14 consecutive days
7. Perceived exertion as measured by the Borg rating of Perceived exertion during 25 m walking tests at visit 3
8. Turn speed measured using smart-phone based accelerometers and 3D motion analysis when undertaking the U turn test at visit 3

Balance related measures
9. Total sway pathlength measured using posturography and smartphone-based accelerometers whilst standing with feet together and eyes open or closed, tandem stance or in single foot stance at visit 3
10. Antero-posterior sway path measured using posturography and smartphone-based accelerometers whilst standing with feet together and eyes open or closed, tandem stance or in single foot stance at visit 3

11. Centre of pressure area measured using posturography and smartphone-based accelerometers whilst standing with feet together and eyes open or closed, tandem stance or in single foot stance at visit 3
12. Sway-jerk measured using posturography and smartphone-based based accelerometers whilst standing with feet together and eyes open or closed, tandem stance or in single foot stance at visit 3
13. Neurological function as measured by the Expanded Disability severity scale (EDSS) and Ashworth test at visit 1

Upper limb related measures
14. Upper limb function as measured by the 9 hole peg test at visit 1
15. Upper limb function as measured by the smartphone-based apps ("Pinch test" and "Draw and shape" during 14 consecutive home based assessments (visit 2) and on visit 3

Measures of Cognition
16. Processing speed as measured by the symbol digit modality test at visit 1
17. Cognition as measured by the Brief Cognitive Assessment for MS (BICAMS) at visit 1

Self reported Outcome measures
18. Falls questionnaire measure at visit 1
19. Self reported walking ability as measured by the Multiple Sclerosis walking scale 12-item and 41-item during home based assessments (visit 2)
20. Self reported spasticity as measured by the Multiple Sclerosis Spasticity scale -88 (sections 1,2 and 3) during home based assessments (visit 2)
21. Perceived balance confidence as measured by the Activities Balance and Confidence scale during home based assessments (visit 2)
22. Fatigue as measured by the Fatigue scale for motor and cognitive functions during home based assessments (visit 2)
23. Upper Limb function as measured by an upper limb item bank during home based assessments (visit 2)
24. Quality of Life as measured by the MSIS-29 version 2 during home based assessments (visit 2)
25. Falls in the previous 3 month period as measured by a falls questionnaire at visit 1
26. Walking diary detailing the main surface terrain and location of smartphone during natural walking at home recorded daily during visit 2
27. Smartphone location questionnaire recorded once during visit 1
28. Smartphone user feedback questionnaire recorded at the end of visit 2

Previous secondary outcome measures:
Walking related measures
1. Walking speed measured using smart-phone based accelerometers and inertial sensors during the 2 minute walking test and 25 foot walking test in visit 1.
2. Walking speed measured using smart-phone based accelerometers, 3D motion analysis and inertial sensors when walking at self selected and maximal walking speed and undertaking a secondary task (subtracting serial 7s, termed dual task) on a treadmill or during overground walking at visit 3 (U turn test and 25 m walking test) and during overground walking (2 minute walk test and minimum 15 mins walking) in the home based environment on 14 consecutive days.
3. Cadence measured using smart-phone based accelerometers and 3D motion analysis when walking at self selected and maximal walking speed and undertaking a secondary task (subtracting serial 7s, termed dual task) on a treadmill or during overground walking (U turn test and 25 m walking test) at visit 3 and during overground walking (2 minute walk test and minimum 15 mins walking) in in the home based environment on 14 consecutive days.
4. Step and stride length measured using smart-phone based accelerometers and 3D motion

analysis when walking at self selected and maximal walking speed and undertaking a secondary task (subtracting serial 7s, termed dual task) on a treadmill or during overground walking (U turn test and 25 m walking test) at visit 3 and during overground walking in the home based environment (2 minute walk test and minimum 15 mins walking) in on 14 consecutive days.
5. Step and stride time measured using smart-phone based accelerometers and 3D motion analysis when walking at self selected and maximal walking speed and undertaking a secondary task (subtracting serial 7s, termed dual task) on a treadmill or during overground walking (U turn test and 25 m walking test) at visit 3 and during overground walking in the home based environment (2 minute walk test and minimum 15 mins walking) in on 14 consecutive days.
6. Lumbar sagittal motion length measured using smart-phone based accelerometers and 3D motion analysis when walking at self selected and maximal walking speed and undertaking a secondary task (subtracting serial 7s, termed dual task) on a treadmill or during overground walking (U turn test and 25 m walking test) at visit 3 and during overground walking in the home based environment (2 minute walk test and minimum 15 mins walking) in on 14 consecutive days.
7. Perceived exertion as measured by the Borg rating of Perceived exertion during 25 m walking tests at visit 3.
8. Turn speed measured using smart-phone based accelerometers and 3D motion analysis when undertaking the U turn test at visit 3.

Balance related measures
9. Total sway pathlength measured using posturography and smart-phone based accelerometers whilst standing with feet together and eyes open or closed, tandem stance or in single foot stance. Measured at visit 3.
10. Antero-posterior sway path measured using posturography and smart-hone based accelerometers whilst standing with feet together and eyes open or closed, tandem stance or in single foot stance. Measured at visit 3.
11. Centre of pressure area measured using posturography and smart-hone based accelerometers whilst standing with feet together and eyes open or closed, tandem stance or in single foot stance. Measured at visit 3.
12. Sway-jerk measured using posturography and smart-hone based accelerometers whilst standing with feet together and eyes open or closed, tandem stance or in single foot stance. Measured at visit 3.
13. Neurological function as measured by the Expanded Disability severity scale (EDSS) and Ashworth test measured at visit 1.

Upper limb related measures
14. Upper limb function as measured by the 9 hole peg test at visit 1.
15. Upper limb function as measured by the smartphone based apps (“Pinch test” and “Draw and shape” during 14 consecutive home based assessments (visit 2) and on visit 3.

Measures of Cognition
16. Processing speed as measured by the symbol digit modality test at visit 1.
17. Cognition as measured by the Montreal Cognitive assessment at visit 1.

Self reported Outcome measures
18. Falls questionnaire measure at visit 1.
19. Self reported walking ability as measured by the Multiple Sclerosis walking scale 12-item and 41-item during home based assessments (visit 2).
20. Self reported spasticity as measured by the Multiple Sclerosis Spasticity scale -88 (sections 1,2 and 3) during home based assessments (visit 2).
21. Perceived balance confidence as measured by the Activities Balance and Confidence scale during home based assessments (visit 2).

22. Fatigue as measured by the Fatigue scale for motor and cognitive functions during home based assessments (visit 2).
23. Upper Limb function as measured by an upper limb item bank during home based assessments (visit 2).
24. Quality of Life as measured by the MSIS-29 version 2 during home based assessments (visit 2).
25. Falls in the previous 3 month period as measured by a falls questionnaire at visit 1.
26. Walking diary detailing the main surface terrain and location of smartphone during natural walking at home recorded daily during visit 2.
27. Smartphone location questionnaire recorded once during visit 1.
28. Smartphone user feedback questionnaire recorded at the end of visit 2.

Completion date
01/10/2023

Eligibility

Key inclusion criteria
People with multiple sclerosis must meet the following criteria for study entry:
1. Signed informed consent form
2. Able to comply with the study protocol, in the investigator's judgement
3. Confirmed diagnosis of MS, according to McDonald criteria 2010 or 2017
4. Currently untreated or treated with an approved or off-label disease-modifying treatment
5. Age 18-70 years (inclusive)
6. Body mass index (BMI) <35 kg/m²
7. Ambulatory patients with an EDSS of 0.0-6.5 (inclusive)

Patients in the healthy control group must meet the following criteria for study entry:
1. Signed informed consent form
2. Able to comply with the study protocol, in the investigator's judgement
3. Age 18-70 years (inclusive)
4. BMI <35 kg/m²
5. No ambulatory limitation, according to investigator's assessment (i.e., no use of walking aids, no musculoskeletal, vision, vestibular, cardiovascular or neurological deficits that could impair gait)

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex

All

Total final enrolment
0

Key exclusion criteria
People with Multiple Sclerosis who meet any of the following criteria will be excluded from study entry:
Clinical relapse in the past 60 days
Treatment with fampridine/dalfampridine (Fampyra®)/Ampyra®) or other symptomatic MS treatment unless on stable dose for ≥30 days prior to screening (if dose changes are expected in the course of the observation period, patient should not be enrolled)
Change in rehabilitation protocol in the previous 60 days and during the study period
Treatment initiation with a DMT expected to occur in the course of the observation period for patients who are untreated at screening
Recovering from an infection or an intercurrent illness that may interfere with balance and gait according to the investigator’s judgment
Uncorrected vision, musculoskeletal problems, marked vestibular deficits not caused by MS (e.g., benign paroxysmal positional vertigo [BPPV], Meniere's disease, previous diagnosed peripheral nerve dysfunction) or other non-MS neurological problems, that may interfere with balance and gait according to the investigator’s judgment
Pregnant women

Date of first enrolment
30/11/2021

Date of final enrolment
01/09/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Plymouth
Brain Research Imaging Centre Science Park
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PL6 8BU

Sponsor information

Organisation

Roche (Switzerland)

ROR
https://ror.org/00by1q217

Funder(s)

Funder type
Industry

Funder Name
F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		19/10/2023	23/10/2023	Yes	No
Other publications		01/04/2026	20/04/2026	Yes	No
Participant information sheet	Healthy controls version 1	27/08/2021	17/09/2021	No	Yes
Participant information sheet	Patients version 1	27/08/2021	17/09/2021	No	Yes
Preprint results		17/09/2025	12/11/2025	No	No