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A study to investigate the concordance of smartphone-based self-monitoring, imaging, and blood-based biomarkers with clinical disability in participants with multiple sclerosis

Submission date
25/10/2021

Recruitment status
No longer recruiting

Registration date
27/10/2021

Overall study status
Completed

Last Edited
02/01/2026

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is a lifelong condition that affects the brain and nerves. Common symptoms include tiredness, vision problems and problems with walking or balance. The main purpose of the study is to assess how the Floodlight (FL) MS App helps and/or improves the portrayal of neurological (nervous system) disability in patients with MS. FL MS is a smartphone application that informs users of various conversations and health care provider decisions by collecting information on patient function in between clinic visits. This app also helps collect data regarding patient symptoms and neurological function such as gait, balance while moving, hand function and cognition (mental abilities such as learning, thinking, problem-solving etc) over a period of time. The study will look at:
1. The ease of using the FL MS App to describe domain-specific (cognition, hand function, gait and balance) neurological disabilities
2. The ease of using the FL MS App to describe the overall neurological disability
3. The ease of using the FL MS App to describe the course of the disease
4. The ease of using the FL MS App to describe a relapse (worsening of the disease after a temporary improvement)
5. The ease of using the FL MS App to describe participant and disease characteristics collected using patient-reported outcome measures (PROMs) - a questionnaire to track daily mood, physical abilities and symptoms
6. The participant's user experience with the FL MS App which helps them to report outcome measures digitally regularly and also the risks they feel are associated with it
7. The ease with which the risk score obtained from the FL MS App can be used to predict the progression of disability
8. The features of participants with slow and fast disease progression according to the outcome measures and PROMs
9. The convenience of using the FL MS App to describe biomarkers (signs of certain medical conditions that can be measured) of neurological impairment and the course of the disease

Who can participate?
Patients with MS who are over 18 years of age and have a smartphone

What does the study involve?
Participants may be asked to be in the study for up to 4 years. Participants will be assessed for eligibility to participate in the study and their ability to use a smartphone. Eligible participants will be given access to the FL MS App and will be enrolled in the study the same day. There will be a run-in period of 8 weeks to help participants learn how to use the FL MS App, followed by an observational period where participants will be followed up for at least 3 years with one check-up at the clinic every year. Participants who have been selected for biomarker assessments will be followed up for one additional year (a total of 4 years).
The FL MS App will prompt the participants to perform various tests to assess cognition, hand function (drawing a shape test and pinching test) and gait and balance (2-minute walk test and U-turn test). The participants can also record any other symptoms in a journal within FL MS. Participants can also provide feedback, following a clinic visit, through the app using a questionnaire. During each annual clinic visit information regarding disability, performance, PROMs, clinical MS data such as relapses and changes in treatment will be collected.

What are the possible benefits and risks of participating?
There is no direct medical benefit from being in this study, but participants will be able to see the information recorded on the App. The information gained from this study may help researchers and doctors to learn more about MS in general and other people who have a similar medical condition may benefit from the results of such research in the future. There are no risks from participating in the study.

Where is the study run from?
F. Hoffmann-La Roche (USA)

When is the study starting and how long is it expected to run for?
October 2021 to December 2024

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
MN43238

Study information

Scientific Title
A prospective investigation of the concordance of smartphone-based self-monitoring, imaging, and blood-based biomarkers with clinical disability in patients with multiple sclerosis within the TONiC program

Study objectives
The aim of this study is to evaluate the feasibility of using the Floodlight multiple sclerosis (FL MS) application to characterize neurological impairment in patients with MS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective longitudinal (primary data collection non-interventional) study

Primary study design
Observational

Study type(s)
Other

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

Interventions
1000 subjects with multiple sclerosis actively enrolled in the TONiC observational study at participating UK-based TONiC site(s) will be prospectively evaluated for correlations between digital outcome measures on the FL MS App and clinical outcome measures over 3 years. Participants with clinical change at Year 3 will receive an additional confirmatory clinical assessment at Year 4. Correlations between digital outcome measures and select TONiC patient-

reported outcome measures (PROMs) will also be assessed during the study period. Lastly, a biomarker sub-study will evaluate correlations between digital outcome measures and fluid biomarkers and magnetic resonance imaging (MRI) characteristics over 4 years of observation (n=300).

Intervention Type
Other

Primary outcome(s)
1. Digital outcomes measured using the Floodlight MS App at baseline and Years 1, 2, and 3
2. Upper limb function measured using the 9-hole Peg Test (9HPT) at baseline and years 1, 2, and 3
3. Lower limb function measured using the Timed 25-foot Walk Test (T25FWT) at baseline and years 1, 2, and 3
4. Neurocognitive function measured using the Symbol Digit Modalities Test (SDMT) at baseline and years 1, 2, and 3

Key secondary outcome(s))
1. Longitudinal digital outcomes measured weekly using the Floodlight MS App from baseline to Year 3
2. Neurologic impairment measured using the Expanded Disability Status Scale (EDSS) at baseline and years 1, 2, and 3
3. Visual function measured using the low-contrast visual acuity (LCVA) at baseline and years 1, 2, and 3. LCVA is scored as the total number of correct letters on a 2.5% contrast Sloan chart positioned at a 2-metre distance from the patient's eyes.
4. Time to onset of Confirmed Disability Progression (CDP) for at least 48 weeks during the study period (time frame: 4 years). Disability progression is defined as an increase in the EDSS score of ≥1.5 points if the initial EDSS is 0, an increase of ≥1.0 point if the initial EDSS is >0 to ≤ 5.5, or an increase of ≥0.5 points if the initial EDSS is >5.5.
5. Time to onset of Confirmed Disability Improvement (CDI) for at least 48 weeks during the study period (time frame: 4 years). Disability improvement is defined as a decrease of ≥1.0 point if the initial EDSS is 2.0–5.5, or a decrease of ≥0.5 points if the initial EDSS is >5.5.
6. Time to onset of confirmed worsening of upper limb function for at least 48 weeks (time frame: 4 years). Worsening of upper limb function is defined as a 20% increase on the 9HPT.
7. Time to onset of confirmed improvement of upper limb function for at least 48 weeks (time frame: 4 years). Improvement of upper limb function is defined as a 20% decrease on the 9HPT.
8. Time to onset of confirmed worsening of lower limb function for at least 48 weeks (time frame: 4 years). Worsening of upper limb function is defined as a 20% increase on the T25FWT
9. Time to onset of confirmed improvement of lower limb function for at least 48 weeks (time frame: 4 years). Improvement of upper limb function is defined as a 20% decrease on the T25FWT.
10. Time to onset of confirmed worsening of neurocognitive function for at least 48 weeks (time frame: 4 years). Worsening of neurocognitive function is defined as a 4-point reduction on the SDMT.
11. Time to onset of confirmed improvement of neurocognitive function for at least 48 weeks (time frame: 4 years). Improvement of neurocognitive function is defined as a 4-point increase on the SDMT.
12. Time to onset of Progression Independent of Relapse Activity (PIRA) for at least 48 weeks (time frame: 4 years). PIRA is defined as EDSS worsening in the absence of Protocol Defined Relapse (PDR)
13. Time to onset of Composite Progression Independent of Relapse Activity (PIRA) for at least

48 weeks (time frame: 4 years). Composite PIRA is defined as a worsening on EDSS (an increase of ≥1.5 points if the initial EDSS is 0, an increase of ≥1.0 points if the initial EDSS is >0 to ≤ 5.5, or an increase of ≥0.5 points if the initial EDSS is >5.5), 9HPT (20% increase), T25FW (20% increase), SDMT (4-point decrease), or LCVA (7-point decrease) in the absence of PDR
14. Time to onset of Composite Disability Accumulation (CDA) for at least 48 weeks (time frame: 4 years). CDA is defined as worsening on the EDSS (an increase of ≥1.5 points if the initial EDSS is 0, an increase of ≥1.0 points if the initial EDSS is >0 to ≤ 5.5, or an increase of ≥0.5 points if the initial EDSS is >5.5), 9HPT (20% increase), T25FW (20% increase), SDMT (4-point decrease), or LCVA (7-point decrease)
15. Time to onset of Protocol-Defined Relapse (PDR) from baseline to year 3
16. Spasticity measured by the 88-item Multiple Sclerosis Spasticity Scale (MSSS-88; three subdomains of pain, spasms, and stiffness) at baseline and years 1, 2, and 3
17. Quality of life measured by EuroQoL 5 Dimensions 5 Levels (EQ-5D-5L) at baseline and years 1, 2, and 3
18. Fatigue measured by the Neurological Fatigue Index (NFI)-MS at baseline and years 1, 2, and 3
19. Anxiety and depression measured by the Hospital Anxiety and Depression Scale (HADS) at baseline and years 1, 2, and 3
20. Physical and psychological impact of MS measured by the Multiple Sclerosis Impact Scale (29-item scale; MSIS-29) at baseline and years 1, 2, and 3
21. Quality of life measured by the World Health Organization Quality of Life: Abbreviated Version (WHOQOL-BREF) at baseline and years 1, 2, and 3
22. Subjective disability measured by the World Health Organization Disability Assessment Schedule-2 (WHODAS-2) at baseline and years 1, 2, and 3
23. Pain measured by the Neuropathic Pain Scale (NPS) at baseline and years 1, 2, and 3
24. Walking impairment measured by the Multiple Sclerosis Walking Scale (MSWS-12) at baseline and years 1, 2, and 3
25. Upper limb impairment measured by the ABILHAND-56 and Quality of Life in Neurologic Disorders (Neuro-QoL)-Upper Extremity (UE) at baseline and years 1, 2, and 3
26. Perceived benefit of FL MS measured using the In-App Post-Appointment Questionnaire at years 1, 2, and 3
27. FL MS usability measured using the health App Usability Questionnaire (MAUQ) at years 1, 2, and 3
28. FL MS adherence measured by the number of FL MS assessments completed from baseline to year 3
29. Percentage of participants with adverse events (AEs) from baseline up to year 3. AEs include adverse events related to usage of the FL MS App
30. Brain volume detected by brain magnetic resonance imaging (MRI) at baseline and at years 2 and 4
31. Thalamic volume detected by brain magnetic resonance imaging (MRI) at baseline and at years 2 and 4
32. Cervical cord area detected by cervical spinal cord magnetic resonance imaging (MRI) at baseline and at years 2 and 4
33. Rate of neuroaxonal injury measured using Serum Neurofilament Light Chain (NfL) concentration at baseline and years 1, 2, and 4

Completion date
06/12/2024

Eligibility

Key inclusion criteria

1. Participant in the TONiC study (with two or more completed TONiC PROM packs)
2. Have a definite diagnosis of MS, confirmed as per the revised McDonald 2017 criteria
3. EDSS of 0.0 to 8.5, inclusive
4. Have a compatible smartphone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
703

Key exclusion criteria
1. Severely ill and unstable participants as per investigator's discretion
2. Participant incapable of using an app due to neurological impairment as per the investigator's discretion (i.e. visual impairment, bilateral impaired hand function)
3. For the subset of participants having MRI assessments: unable or unwilling to complete regular MRI
4. For the subset of participants having both biomarker and genetic analysis: unable or unwilling to provide blood samples

Date of first enrolment
13/05/2022

Date of final enrolment
10/04/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Walton Centre NHS Foundation Trust
Lower Ln
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Study participating centre
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Study participating centre
Greater Manchester Neuroscience Centre
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Sponsor information

Organisation
Roche (United States)

ROR
https://ror.org/011qkaj49

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?
Basic results		02/01/2026	02/01/2026	No	No
Study website		11/11/2025	11/11/2025	No	Yes