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A study to investigate the feasibility of smartphone-based self-monitoring to characterise cognitive and neurological impairment in participants with multiple sclerosis (Floodlight MS_More Active)

Submission date
02/03/2022

Recruitment status
No longer recruiting

Registration date
11/03/2022

Overall study status
Completed

Last Edited
05/11/2025

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 chronic (long-lasting), inflammatory, demyelinating (causing damage to the myelin sheath (protective covering) surrounding nerve fibers in the brain), and degenerative disease (characterized by progressive deterioration and loss of function) of the central nervous system (CNS). Symptoms of MS are very different between people but can commonly include tiredness, vision problems, and problems with walking or balance. The main purpose of this study is to analyse how a combination of the information collected during the participant's routine clinic visits (including MS history and magnetic resonance imaging (MRI) scans), along with other information about participants' movement, brain function, hand function, speech and quality of life collected using smartphone applications (App), can be used to improve the way change in function is monitored in people with MS. The study will mainly focus on:
1. The ease of using Floodlight MS (FL MS) cognitive test to identify cognitive (mental processes like thinking, learning, etc.) impairment in participants with MS (pwMS)
2. The ease of using FL MS cognitive test to characterise cognitive trajectories in pwMS
3. Exploring the effect of different frequencies of administration for the FL MS cognitive test on learning and practice effects in pwMS
4. Evaluating the ease of using FL MS gait and hand function tests to characterise neurological impairment and trajectories in pwMS
5. Evaluating the ease of using FL MS digital outcomes to predict future disability progression in pwMS
6. Assessing participant adherence to self-monitoring tasks
7. Assessing participant's user experience with regular digital outcome measures with FL MS
8. Assessing the learning effect for each measure of FL MS in pwMS
9. Assessing the ease of using self-monitoring tasks to characterize clinical relapses in pwMS

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

What does the study involve?
Participants will be asked to be a part of this study for at least 2 years, and information about participants' MS may be accessed for up to 3 years. The participants taking part in this study will also have to agree to participate in the MSBase Registry study. MSBase is a large, ongoing, long-term study that collects information from over 70,000 people with MS in over 34 countries. The participants will have to perform the following tests while they participate in the study:
- FL MS smartphone application tests: This test includes-
1. Completing a survey on how the participant is feeling and assessing their MS symptoms
2. Drawing a shape on the smartphone screen
3. Pinching a shape on the smartphone screen
4. Walking for 2 minutes and as fast as possible but safely (Two-minute walk test)
5. Walking safely and performing at least 5 successive U-turns (U-Turn test)
6. Cognitive test (measuring how fast participants are thinking or processing information)
These tests will take 5-10 minutes to complete
- Expanded Disability Status Scale (EDSS) exams: It is based on a standard neurological examination used for the determination of disability in a participant. The scores of the neurological examination are then used in conjunction with observations and information concerning ambulation (ability to walk) and the use of assistive devices by a participant to determine the EDSS score.
- MSReactor tests: This test is designed to measure changes in the participant's reaction time and memory (cognition), and so may provide slightly different information than the FL MS application tests. At the end of the MSReactor tests, participants will be presented with some questionnaires that measure the quality of life, work productivity, worry, and depression. This will take 10-15 minutes to complete
- Redenlab tests: This measures changes in the participant's speech and consists of five reading aloud and speaking tasks that will take less than 5 minutes to complete.
- Audio Recorded Cognitive Screen (ARCS) test: Participants will be asked to sit in a quiet area with no distractions, unsupervised, and listen to an audio file on headphones and record their responses in the booklet provided. The test will be completed in 35-40 minutes, after which it is scored by a trained person.

The study will consist of 4 periods:
1. Screening Period: Participants will be screened for enrollment in this study by the Investigator.

2. Baseline Visit: The first study visit, during which the investigator/coordinator will assist participants in installing and registering the FL MS, Redenlab, and MSReactor App on their smartphones. This process may be completed through a virtual visit using available video-calling software. After installation of these apps, participants will be asked to complete the following tests:
- FL MS smartphone application tests: Will be performed in-person during the baseline visit
- Redenlab tests: Will be performed in-person during the baseline visit
- Participant's most recent (within 6 months) MRI scans will be collected

3. Familiarisation Period: Following the baseline visit, participants will be asked to perform the following test during the 6-weeks familiarisation period:
- FL MS tests 1 to 5 using the FL MS App: Every other day or at least 3 times per week (18 to 21 times in total). Participants will also need to perform the cognitive test (test 6 in the list above) weekly using the FL MS App
- MSReactor tests: Once per week (or at a minimum, 4 times in total)

- Redenlab tests: Once a week (or at a minimum 4 tests in total)
The purpose of the familiarisation period is for the participants to learn how to use the Apps and to ensure that they are conducting the tests as per the instructions. All the tests will be performed by the participants at their homes.

4. Observational Period: After the familiarisation period, participants will enter the observational period for approximately 2 years. Participants will continue to have the usual routine visits with their neurologist, for approximately 6 months, and will need to attend a study-only visit once during Month 12 and once during Month 24. Participants will have to perform the following tests during the observational period:
- FL MS App Tests: Tests 1-5: For the first 2 weeks, will be performed every other day except the cognitive test (to be performed once weekly) to establish baseline data. After 2 weeks of the observation period, FL MS tests 1-5 will be performed at least twice a month; and test 6 once a week, once in two weeks, or once a month (depending on the participant's study group) for the remainder of the 2-year study period.
- EDSS: A telephonic EDSS (tele-EDS) assessment conducted over the telephone within a ±2-week time around the first two weeks of FL MS testing (from Day 29 to Day 70) in the observational period to ensure that a baseline tele-EDSS measurement is available for all participants
- MSReactor tests: At least once a month for the remainder of the 2-year study period. Participants who have done MSReactor tests on a tablet or desktop before may be approached to perform the test twice, once on a tablet computer and once on the smartphone
- Redenlab tests: At least once a month for the remainder of the 2-year study period
- ARCS test: Once a year at a study clinic visit i.e., once during Month 12 and once during Month 24
- Participant's MRI scans performed as part of the routine clinical care will be collected during the 2-year study period

Participants will be divided into three cohorts based on the frequency at which they will perform the FL MS cognitive test. All other tests mentioned above will be performed at the same frequency by all the participants.
- Participants in Cohort 1 will perform the FL MS cognitive test once every week.
- Participants in Cohort 2 will perform the FL MS cognitive test once in two weeks
- Participants in Cohort 3 will perform the FL MS cognitive test once a month

For participants who were a part of the Floodlight Open study (Study MN39878):
1. Participants will complete the final test for the Floodlight Open study at the first visit for this study (Baseline visit).
2. Participants will uninstall the Floodlight Open study application and install the new FL MS software application to be used in this study

What are the possible benefits and risks of participating?
Participants will receive no clear benefit from participating in this research. The results of this study may provide valuable information to the researchers and doctors that may help improve the treatment or care of people with MS as a group. There may be unknown or unforeseen risks, including privacy risks, associated with participating in this study.

Where is the study run from?
F. Hoffman La Roche (Switzerland)

When is the study starting and how long is it expected to run for?
January 2022 to July 2024

Who is funding the study?
F. Hoffman La Roche (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific

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Additional identifiers

Protocol serial number
MN42134

Study information

Scientific Title
A prospective investigation of the feasibility of smartphone-based self-monitoring to characterize cognitive and neurological impairment in patients with multiple sclerosis (Floodlight MS_More Active)

Study objectives
The primary purpose of this study is to evaluate the feasibility of using the Floodlight Multiple Sclerosis (FL MS) Cognitive Test to characterize cognitive impairment in participants with MS (pwMS).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/07/2022, The Alfred (PO Box 315, , Prahran, VIC 3181, Australia; +61 (03) 9076 2000; research@alfred.org.au), ref: Project 612/21

Primary study design
Observational

Study design
Prospective non-interventional primary data collection study

Study type(s)
Other

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

Interventions
- Cohort 1: Participants in Cohort 1 will perform the FL MS Cognitive Test once every week and all other FL MS tests every 2 weeks, MSReactor tests, and Redenlab tests at least once a month and Audio Recorded Cognitive Screen (ARCS) test once a year up to Month 24.
- Cohort 2: Participants in Cohort 2 will perform the FL MS Cognitive Test and all other FL MS tests every 2 weeks, MSReactor tests, and Redenlab tests at least once a month, and ARCS test once a year up to Month 24.
- Cohort 3: Participants in Cohort 3 will perform the FL MS Cognitive Test every 4 weeks and all other FL MS tests every 2 weeks, MSReactor tests, and Redenlab tests at least once a month, and ARCS test once a year up to Month 24.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 05/11/2025:
Cross-sectional correlation between FL MS Cognitive Test vs. ARCS at Baseline and Month 12

Previous primary outcome measure:
Cross-sectional correlation between FL MS Cognitive Test outcome and ARCS total outcome measured using Spearman’s Rank-order Correlation at baseline, Month 12, and Month 24

Key secondary outcome(s)
Current secondary outcome measures as of 05/11/2025:
1. Longitudinal Correlation Between Change From Baseline to Month 12 on FL MS Cognitive Test vs. ARCS from Baseline up to Month 12
2. Cross-sectional Correlation Between Composite Digital Cognition Outcome vs. ARCS at

Baseline and Month 12
3. Longitudinal Correlation Between Change From Baseline to Month 12 in Composite Digital Cognition Outcome vs. ARCS from Baseline up to Month 12
4. FL MS Cognitive Feature Differences at Month 6, Month 12, and Month 18
5. Cross-sectional Hand/Gait vs Expanded Disability Status Scale (EDSS) Assessed Using Spearman Rank-order Correlation at Baseline, Month 6, Month 12, and Month 18
6. Correlation Between FL MS Digital Outcomes (Calculated from Baseline to Month 12) and Subsequent Changes in EDSS
7. In-app FL MS Post-appointment Questionnaire Assessed During Study Period at Baseline, Month 6, and Month 12
8. FL MS Usability Score From mHealth Usability Questionnaire Assessed During Study Period at Baseline, Month 6, Month 12, Month 18, and Month 24
9. Association Between FL MS Digital Outcome and Clinical Relapses up to Month 24

Previous secondary outcome measures as of 21/12/2023:
1. Cross-sectional correlation between composite digital cognition outcome with FL MS and ARCS total score measured using Spearman's Rank-order Correlation at baseline, Month 12, and Month 24
2. Cross-sectional correlation between FL MS digital cognition outcome and Expanded Disability Status Scale (EDSS) measured using Spearman's Rank-order Correlation at Months 6, 12, 18 and 24
3. Cross-sectional correlation between digital outcome measures with FL MS and Redenlab score measured using Spearman's Rank-order Correlation at Months 6, 12, 18 and 24
4. Cross-sectional correlation between digital outcome measures with FL MS and MSReactor Cognitive score measured using Spearman's Rank-order Correlation at Months 6, 12, 18 and 24
5. Cross-sectional correlation between FL MS digital outcome measures (MS gait and hand function test) and Patient-reported outcome measures (PROMs)- Multiple Sclerosis International Quality of Life (MusiQoL) assessed using Spearman's Rank-order Correlation at baseline, Months 12 and 24
6. Cross-sectional correlation between FL MS digital outcome measures (MS gait and hand function test) and PROMs- Work Productivity and Activity Impairment Questionnaire: General Health (WPAI:GH) assessed using Spearman's Rank-order Correlation at baseline, Months 12 and 24
7. Cross-sectional correlation between FL MS digital outcome measures (MS gait and hand function test) and PROMs- Patient Health Questionnaire-9 (PHQ-9) assessed using Spearman's Rank-order Correlation at baseline, Months 12 and 24
8. Cross-sectional correlation between FL MS digital outcome measures (MS gait and hand function test) and PROMs- Penn State Worry Questionnaire (PSWQ-15) assessed using Spearman' s Rank-order Correlation at baseline, Months 12 and 24
9. Cross-sectional correlation between FL MS digital outcome measures (MS gait and hand function test) and PROMs- Patient Global Impression of Severity Questionnaire (PGIS) assessed using Spearman's Rank-order Correlation at Months 12 and 24
10. Cross-sectional correlation between digital outcome measures with FL MS and MRI parameters assessed using Spearman's Rank-order Correlation at Months 6, 12, 18 and 24
11. Longitudinal correlation between composite digital cognition outcome with FL MS and ARCS total score measured using Spearman's Rank-order Correlation at baseline, Month 12, and Month 24
12. Longitudinal correlation between digital cognition outcome measures with FL MS and EDSS measured using Spearman's Rank-order Correlation at Months 6, 12, 18 and 24
13. Longitudinal correlation between digital cognition outcome measures with FL MS and Redenlab score measured using Spearman's Rank-order Correlation at Months 6, 12, 18 and 24
14. Longitudinal correlation between digital cognition outcome measures with FL MS and

MSReactor Cognitive score measured using Spearman's Rank-order Correlation at Months 6, 12, 18 and 24
15. Longitudinal correlation between FL MS digital outcome measures (MS gait and hand function test) and PROMs (MusiQoL) assessed using Spearman's Rank-order Correlation over 24 months
16. Longitudinal correlation between FL MS digital outcome measures (MS gait and hand function test) and PROMs (WPAI:GH) assessed using Spearman's Rank-order Correlation over 24 months
17. Longitudinal correlation between FL MS digital outcome measures (MS gait and hand function test) and PROMs (PHQ-9) assessed using Spearman's Rank-order Correlation over 24 months
18. Longitudinal correlation between FL MS digital outcome measures (MS gait and hand function test) and PROMs (PSWQ-15) assessed using Spearman's Rank-order Correlation over 24 months
19. Longitudinal correlation between FL MS digital outcome measures (MS gait and hand function test) and PROMs (PGIC) assessed using Spearman's Rank-order Correlation at Months 12 and 24
20. Longitudinal correlation between FL MS digital outcomes (MS gait and hand function test) and PROMs (PGIS) assessed using Spearman's Rank-order Correlation over 24 months
21. Longitudinal correlation between digital outcome measures with FL MS and MRI parameters assessed using Spearman's Rank-order Correlation at Months 6, 12, 18 and 24
22. Correlation between FL MS Digital Outcomes and subsequent changes in EDSS assessed using Spearman's Rank-order correlation calculated from baseline to Month 12 and Month 12 to 24
23. Cognitive phenotypes identified using a joint latent profile analysis (LPA) on the baseline FL MS Cognitive Test outcome, ARCS Global Score, and MSReactor Cognitive score at baseline (Day 1)
24. Difference in trajectories of FL MS Cognitive Test outcome between participants performing cognitive test every week versus every 2 weeks versus every 4 weeks, measured using a Piecewise Linear Regression Method over the first 6 and 12 months
25. Participant engagement patterns in the first 3 months of usage of FL MS
26. Participant engagement patterns in the first 24 months of usage of FL MS
27. Factors influencing participants engagement (demographics and disease factors) on FL MS, Redenlab, and MSReactor Apps usage recorded from baseline to Month 24
28. Factors influencing participant's adherence (physician-driven factors i.e., phone calls) to self-monitoring recorded from baseline to Month 24
29. In-app FL MS Post-appointment Questionnaire assessed at Month 12 and Month 24
30. FL MS usability score from mHealth Usability Questionnaire assessed at Month 12 and Month 24
31. Number of assessments or familiarisation period duration required to minimize the impact of learning effect assessed using FL MS to ensure stable FL MS baseline performance measured from baseline to Week 6
32. Changes in digital outcome measures with FL MS and the presence of protocol-defined relapse measured from baseline to Month 24
33. Longitudinal correlation between composite digital outcome and ARCS total score measured using Spearman's Rank-order Correlation over 24 months
34. Differences between participants with different learning patterns on FL MS Cognitive Test outcome identified using practice effect trajectories from baseline to Months 6, or 12
35. Differences between participants with different learning patterns on ARCS score identified using practice effect trajectories from baseline to Months 6, or 12
36. Differences between participants with different learning patterns on EDSS scale score identified using practice effect trajectories from baseline to Month 6, or 12

37. Differences between participants with different learning patterns on MRI outcome measures identified using practice effect trajectories from Months 6 or 12 to Month 24
38. Cross-sectional correlation between FL MS digital outcomes (MS gait and hand function test) and EDSS assessed using Spearman's Rank-order Correlation at baseline, Months 6, 12, 18 and 24
39. Longitudinal correlation between FL MS digital outcomes (MS gait and hand function test) and EDSS assessed using Spearman's Rank-order Correlation over 24 months

Previous secondary outcome measures:
1. Cross-sectional correlation between supervised digital outcome measures with FL MS and unsupervised digital outcome measures with FL MS measured using Spearman's Rank-order Correlation at Months 6, 12, 18, and 24
2. Cross-sectional correlation between composite digital cognition outcome with FL MS and ARCS total score measured using Spearman's Rank-order Correlation at baseline, Month 12, and Month 24
3. Cross-sectional correlation between digital cognition outcome with FL MS and Expanded Disability Status Scale (EDSS) measured using Spearman's Rank-order Correlation at Months 6, 12, 18 and 24
4. Cross-sectional correlation between digital cognition outcome with FL MS and Redenlab score measured using Spearman's Rank-order Correlation at Months 6, 12, 18 and 24
5. Cross-sectional correlation between composite digital cognition outcome with FL MS and MSReactor Cognitive score measured using Spearman's Rank-order Correlation at Months 6, 12, 18 and 24
6. Cross-sectional correlation between FL MS digital outcomes (MS gait and hand function test) and Patient-reported outcome measures (PROMs)- Multiple Sclerosis International Quality of Life (MusiQoL) assessed using Spearman's Rank-order Correlation at baseline, Months 12 and 24
7. Cross-sectional correlation between FL MS digital outcomes (MS gait and hand function test) and PROMs- Work Productivity and Activity Impairment Questionnaire: General Health (WPAI: GH) assessed using Spearman's Rank-order Correlation at baseline, Months 12 and 24
8. Cross-sectional correlation between FL MS digital outcomes (MS gait and hand function test) and PROMs- Patient Health Questionnaire-9 (PHQ-9) assessed using Spearman's Rank-order Correlation at baseline, Months 12 and 24
9. Cross-sectional correlation between FL MS digital outcomes (MS gait and hand function test) and PROMs- Penn State Worry Questionnaire (PSWQ-15) assessed using Spearman's Rank-order Correlation at baseline, Months 12 and 24
10. Cross-sectional correlation between digital outcome measures with FL MS and MRI parameters assessed using Spearman's Rank-order Correlation at Months 6, 12, 18 and 24
11. Longitudinal correlation between supervised digital outcome measures with FL MS and unsupervised digital outcome measures with FL MS measured using Spearman's Rank-order Correlation at Months 6, 12, 18, and 24
12. Longitudinal correlation between composite digital cognition outcome with FL MS and ARCS total score measured using Spearman's Rank-order Correlation at baseline, Month 12, and Month 24
13. Longitudinal correlation between digital cognition outcome with FL MS and EDSS measured using Spearman's Rank-order Correlation at Months 6, 12, 18 and 24
14. Longitudinal correlation between digital cognition outcome with FL MS and Redenlab score measured using Spearman's Rank-order Correlation at Months 6, 12, 18 and 24
15. Longitudinal correlation between digital cognition outcome with FL MS and MSReactor Cognitive score measured using Spearman's Rank-order Correlation at Months 6, 12, 18 and 24
16. Longitudinal correlation between FL MS digital outcomes (MS gait and hand function test) and PROMs (MusiQoL) assessed using Spearman's Rank-order Correlation over 24 months
17. Longitudinal correlation between FL MS digital outcomes (MS gait and hand function test) and PROMs (WPAI:GH) assessed using Spearman's Rank-order Correlation over 24 months

18. Longitudinal correlation between FL MS digital outcomes (MS gait and hand function test) and PROMs (PHQ-9) assessed using Spearman's Rank-order Correlation over 24 months
19. Longitudinal correlation between FL MS digital outcomes (MS gait and hand function test) and PROMs (PSWQ-15) assessed using Spearman's Rank-order Correlation over 24 months
20. Longitudinal correlation between digital outcome measures with FL MS and MRI parameters assessed using Spearman's Rank-order Correlation at Months 6, 12, 18 and 24
21. Time to unscheduled clinical or paraclinical (e.g., MRI) assessment measured using area under the curve (AUC) from baseline to Month 24
22. Time to first treatment (disease-modifying therapy [DMT]) switch measured using AUC from baseline to Month 24
23. Time to prescription of new MS symptomatic drugs measured using AUC from baseline to Month 24
24. Correlation between FL MS Digital Outcomes and subsequent changes in EDSS assessed using Spearman's Rank-order correlation calculated from baseline to Month 12 and Month 12 to 24
25. Cognitive phenotypes identified using a joint latent profile analysis (LPA) on the baseline FL MS Cognitive Test outcome, ARCS Global Score, and MSReactor Cognitive score at baseline (Day 1)
26. Difference in trajectories of FL MS Cognitive Test outcome between participants performing cognitive test every week versus every 2 weeks versus every 4 weeks, measured using a Piecewise Linear Regression Method over the first 6 and 12 months
27. Participant engagement patterns in the first 3 months of usage of FL MS
28. Participant engagement patterns in the first 24 months of usage of FL MS
29. Factors influencing participants engagement (demographics and disease factors) on FL MS, Redenlab, and MSReactor Apps usage recorded from baseline to Month 24
30. Factors influencing participant's adherence (physician-driven factors i.e., phone calls) to self-monitoring recorded from baseline to Month 24
31. In-app FL MS Post-appointment Questionnaire assessed at Month 12 and Month 24
32. FL MS usability score from mHealth Usability Questionnaire assessed at Month 12 and Month 24
33. Percentage of participants with FL MS-associated adverse events (spontaneously reported) assessed through the PROM questionnaire data from baseline to Month 24
34. Number of assessments or run-in period duration required to minimize the impact of learning effect assessed using FL MS to ensure stable FL MS baseline performance measured from baseline to Week 6
35. Changes in digital outcome measures with FL MS and the presence of protocol-defined relapse measured from baseline to Month 24
36. Longitudinal correlation between FL MS Cognitive Test outcome and ARCS total score measured using Spearman's Rank-order Correlation over 12 and 24 months
37. Differences between participants with different learning patterns on FL MS Cognitive Test outcome identified using practice effect trajectories from baseline to Months 6, or 12
38. Differences between participants with different learning patterns on ARCS score identified using practice effect trajectories from baseline to Months 6, or 12
39. Differences between participants with different learning patterns on EDSS scale score identified using practice effect trajectories from baseline to Month 6, or 12
40. Differences between participants with different learning patterns on MRI outcome measures identified using practice effect trajectories from Months 6 or 12 to Month 24
41. Cross-sectional correlation between FL MS digital outcomes (MS gait and hand function test) and EDSS assessed using Spearman's Rank-order Correlation at baseline, Months 6, 12, 18 and 24
42. Longitudinal correlation between FL MS digital outcomes (MS gait and hand function test) and EDSS assessed using Spearman's Rank-order Correlation over 24 months

Completion date
31/07/2024

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 21/12/2023:
1. Be able to provide informed consent to the study, and to participate in the MSBase registry and the MRI repository
2. Aged 18 years or older
3. EDSS in the range of 1.0 to 7.0 inclusive
4. Diagnosis of MS (new or revised) based on the 2017 revised McDonald criteria
5. Untreated or treated with an approved or off-label DMT, if DMT was initiated >3 months ago
6. Must have a personal smartphone
7. Willing to discontinue participation in any other Floodlight application.

Previous participant inclusion criteria:
1. Be able to provide informed consent to the study, and to participate in the MSBase registry and the MRI repository
2. Aged 18 years or older
3. EDSS in the range of 2.0 to 7.0 inclusive
4. Diagnosis of MS (new or revised) based on the 2017 revised McDonald criteria
5. Untreated or treated with an approved or off-label DMT, if DMT was initiated >3 months ago
6. Must have a personal smartphone
7. Willing to discontinue participation in any other Floodlight application.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
279

Key exclusion criteria
1. Unable to provide data to establish a minimum dataset
2. Any contraindication for use of smartphone as per the investigator’s discretion
3. Known significant cognitive impairment as per the investigator’s discretion
4. Not able to tolerate routine clinical MRI
5. Clinical relapse in the 30 days before enrolment.

Date of first enrolment
26/07/2022

Date of final enrolment
09/04/2024

Locations

Countries of recruitment
Australia

Study participating centre
The Alfred
Dept of Neurosciences Level 6
CCS, Alfred Centre
99 Commercial Road
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Study participating centre
John Hunter Hospital
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Study participating centre
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Study participating centre
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Hobart, Tas
Australia
7000

Study participating centre
Perron Institute
8 Verdun Street
Nedlands, WA
Australia
6009

Study participating centre
Monash Health
246 Clayton Rd
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Australia
3168

Sponsor information

Organisation
F. Hoffmann-La Roche Ltd

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
The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement

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			05/11/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes