ForPatients
by Roche

Multiple Sclerosis (MS)

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)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	0 Countries	MN42134

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

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)

F. Hoffman La Roche (Switzerland)
Sponsor

MN42134
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	18 years or older	No

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, and risks associated 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

10. Assessing the influence of FL MS in clinical decision-making

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 (Run-in) Period: Following the baseline visit, participants will be asked to perform the following test during the 6-weeks run-in 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 run-in 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 run-in period, participants will enter the observational period for approximately 2 years. Participants will continue to have the usual routine visits with their neurologist, approximately 6-monthly, 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, 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 before the first two weeks of FL MS testing 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 May 2025

Who is funding the study?

F. Hoffman La Roche (Switzerland)

Who is the main contact?

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