ISRCTN17035495 https://doi.org/10.1186/ISRCTN17035495

A study to evaluate the feasibility of smartphone-based assessments in individuals with mild memory problems, early Alzheimer's disease, and healthy controls

Submission date
25/07/2020

Recruitment status
No longer recruiting

Registration date
10/11/2020

Overall study status
Completed

Last Edited
03/01/2024

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Alzheimer's disease (AD) is the most common cause of dementia. Dementia is a syndrome (a group of related symptoms) associated with an ongoing decline of brain functioning. It can affect memory, thinking skills and other mental abilities. Detection of cognitive decline is important for early diagnosis of AD. Currently, detecting cognitive decline is based on in-clinic assessments, typically carried out on an annual basis.
Smartphone-assisted functional testing of brain function, movement ability, and behavior would provide the ability to assess symptoms of dementia in a real-world setting. This study aims to investigate the feasibility of performing smartphone-based cognitive and functioning assessments

Who can participate?
This study is open to men and women ages 65 and up, who have previous experience with smartphone or tablet technology and willingness and ability to complete all aspects of the study (including brain MRI and PET imaging, if applicable). All participants will use study smartphones to continuously collect data during daily activities in order to capture subtle changes in cognition, function and behavior.

What does the study involve?
Participants will do a number of brain function tests and movement tests (including brain imaging) at the first study visit and again after the period of study using the smartphone. Participants will be issued a smartphone with the assessment software which they are required to use daily (around 8 minutes per day) for 30 days. The total length of participation is around 10 weeks.

What are the possible benefits and risks of participating?
This study is low-risk, and there is no clinical benefit from participation.

Where is the study run from?
The study is run by Roche (Switzerland) and takes place at:
1. Fundación ACE; Servicio de Neurología (Spain)
2. Stanford Neuroscience Health Center (USA)

When is the study starting and how long is it expected to run for?
June 2019 to October 2021

Who is funding the study?
Roche (Switzerland)

Who is the main contact?
global-roche-genentech-trials@gene.com

Contact information

Type(s)
Scientific

Contact name
Mr Trial Information Support Line

Contact details
1 DNA Way
San Francisco
United States of America
CH-4070
+1 888-662-6728
global-roche-genentech-trials@gene.com

Additional identifiers

Protocol serial number
MN40655

Study information

Scientific Title
A prospective pilot study to evaluate the feasibility of conducting smartphone-based remote self-assessments of cognition, function, and behavior in individuals with subjective cognitive decline, early Alzheimer's disease, and healthy controls

Study objectives
This study aims to evaluate the feasibility of smartphone-based cognitive, functional, and behavioral assessments in individuals with subjective cognitive decline, early Alzheimer's Disease, and healthy controls. The analysis of the study will be hypothesis-generating and have exploratory rather than confirmatory objectives.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/09/2020 Comite D'Etica d'Investigacio amb medicaments, Universitat Internacional de Catalunya (Carrer de la Immaculada, 22, 08017 Barcelona, Spain; +34 93 504 20 00; ceim@uic.es), ref: MN40655-MED-FACE-2019

Primary study design
Interventional

Study design
Interventional multi-centre single-group assignment

Study type(s)
Screening

Health condition(s) or problem(s) studied
Subjective cognitive decline, early Alzheimer's Disease

Interventions
This is a prospective pilot study to assess the feasibility of conducting smartphone-based remote self-assessments of cognition, function and behavior in participants with SCD (subjective cognitive decline), eAD (defined as prodromal to mild Alzheimer’s disease), and healthy controls (HC).
The study will consist of a screening period of up to 6 weeks followed by a baseline visit at the clinic (study site); a 30-day smartphone-based remote self-assessment period; and an end-of study visit at the clinic.
It is planned to recruit 60 SCD, 30 eAD participants, and 30 healthy controls.

Screening visit:
The following key assessments will be performed at the screening visit:
• Clinical dementia rating (CDR) Scale
• Mini-Mental State Examination (MMSE)
• Cognitive Change Index (CCI) tool
• Free and Cued Selective Reminding Test (FCSRT)
• Trail-Making Test (TMT; Parts A & B)
• Category Fluency Test (Animals)
• Digit Symbol Coding Test
• Boston Naming Test
• Amsterdam instrumental activities of daily living questionnaire short version (A-IADL-Q-SV)
• Neuropsychiatric inventory (NPI)
• Hospital Anxiety and Depression Scale (HADS)
• Medical history and demographic data
• Physical examination including body weight and height measurement
• Vital signs
• Magnetic resonance imaging (MRI) read centrally
• Amyloid positron emission tomography (PET) scan read centrally
• Adverse events assessment and medication review

Baseline visit (Day 1):
Eligible participants will be enrolled in the study at the baseline visit and will receive a preconfigured study smartphone with installed software for the self-assessments to

perform all the 9 different “Active Tasks” and 4 different “Diary Questionnaires” in the study smartphone. If opted, an additional software application will be installed on their personal smartphone for “Phone usage tracking”.
Participants will also perform the following assessments at the clinic:
• Vital signs
• Social Network Index (SNI)
• Revised University of California, Los Angeles (UCLA) Loneliness Scale
• Pittsburgh Sleep Quality Index (PSQI)
• Gait and balance tests (Timed 25-foot walk test [T25WT] and Timed Up and Go [TUG] test)

Remote monitoring:
Enrolled participants will take part in the study for a period of 32 days (including baseline and end of study/early termination on site visits). Outside of the clinic visits, participants will be asked to perform a selection of “Active Tasks” and diary questionnaires daily, keeping their participation burden to be on an average under 8 min per day. Participants are encouraged to always carry their study smartphone, and their personal smartphone for Passive Monitoring, if they opted for “Phone usage tracking”. Participants can pause location monitoring or “Phone usage tacker” app monitoring whenever they need.

End of study visit or early termination visit as applicable:
The study smartphone must be returned to the study site at the end of the study, or upon early termination. The “Phone usage tracker” app will be removed from the participant’s personal smartphone, if installed, by the site staff. At the end of the study, or at early termination as applicable, participants will be asked to complete a paper satisfaction survey. In addition to the survey, vital signs, adverse event assessment and medications review will be performed at the end of study visit or early termination visit as applicable. The study partners will be asked at the end of study visit or early termination visit to complete a survey on the level of support they might have provided to the participant during the remote monitoring period.

Length of Study:
Approximately 10 to 12 months. For an individual participant the study will take a maximum of 10 weeks.

Data collection:
Study participants are asked to perform daily active tasks on a preconfigured smartphone. They also carry the smartphone for passive monitoring during the course of the study. During active tasks and passive monitoring, the smartphone will record movement and location data, as well as data on the technical status and connectivity of the smartphone. For selected active tasks, touch and sound interactions are also recorded. For a subset of participants who have consented to take part in the optional phone usage tracking part of the study, an additional app will be installed on their personal smartphone to collect information on app usage behavior, movement, location, and ambient sound data. These raw data will then be proposed to relevant outcome measures.

Intervention Type
Behavioural

Primary outcome(s)
Adherence level defined as the fraction of days the participants have completed the digital assessments during the observation period of 30 days measured using the smartphone software

Key secondary outcome(s)

1. Sensor data (movement and location data) collected using smartphone sensor metrics throughout the duration of the study
2. Vital signs measured by the researcher at baseline and end of study/termination visit
3. Social network measured using the Social Network Index (SNI) at baseline and end of study /termination visit
4. Loneliness measured using the revised University of California, Los Angeles (UCLA) Loneliness Scale at baseline and end of study/termination visit
5. Sleep quality measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline and end of study/termination visit
6. Gait and balance (Timed 25-foot walk test [T25WT] and Timed Up and Go [TUG] test) at baseline and end of study/termination visit
7. Brain imaging (MRI) at baseline and end of study/termination visit
8. Adverse events measured by self-report at end of study/termination visit

Completion date
16/10/2021

Eligibility

Key inclusion criteria
1. Signed informed consent form
2. Age 65 years or above
3. Previous experience with smartphone or tablet technology
4. Fluency in the language of the tests used at the study site
5. Adequate visual and auditory acuity, in the investigator’s judgment, sufficient to perform the neuropsychological testing
6. Willingness and ability to complete all aspects of the study (including brain MRI and PET imaging [if applicable])
7. Availability of a study partner throughout the study and which agrees to provide information and to complete all aspects of the study at clinic visits

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Unable to comply with the study protocol, in the investigator’s judgment
2. History or known presence of any significant neurological disorders such as Parkinson’s disease, multiple sclerosis, traumatic head injury, territorial infarct or brain tumor with cognitive sequelae
3. History or known presence of any significant psychiatric disorder such as schizophrenia, bipolar disorder, substance use disorders
4. Current active clinically significant anxiety or depressive disorder (moderate anxiety or depression as judged by the investigator) that is likely to impede a participant's ability to participate in the study

5. Current use of any medication that could affect cognitive performance (e.g. benzodiazepines, etc.)
6. Participation in any interventional AD clinical study including studies with digital assessments within the past 6 months at the time of screening
7. Any significant cerebral abnormalities or significant MRI finding such as ischemic or hemorrhagic strokes as confirmed by the central reader.
8. Inability to tolerate MRI procedures or contraindication to MRI, including but not limited to, presence of pacemakers not compatible with MRI, aneurysm clips, artificial heart valves, ear implants, or foreign metal objects in the eyes, skin, or body that would contraindicate an MRI scan, or any other clinical history or examination finding that, in the judgment of the investigator, would pose a potential hazard in combination with MRI
9. In addition, for participants with SCD and healthy controls: Prior diagnosis and/or treatment for a memory disorder

Date of first enrolment
07/10/2020

Date of final enrolment
15/09/2021

Locations

Countries of recruitment
Spain

United States of America

Study participating centre
Fundación ACE; Servicio de Neurología
Gran Via de Carles III, 85 bis
Barcelona
Spain
08028

Study participating centre
Stanford Neuroscience Health Center (SNHC)
213 Quarry Road, Rm 2726A M/C 5963
Palo Alto
United States of America
94304

Sponsor information

Organisation

Roche (United States)

ROR
https://ror.org/011qkaj49

Funder(s)

Funder type
Industry

Funder Name
Roche

Alternative Name(s)
F. Hoffmann-La Roche Ltd, F. Hoffmann-La Roche & Co, F. Hoffmann-La Roche AG, Roche Holding AG, Roche Holding Ltd, Roche Holding, Roche Holding A.G., Roche Holding, Limited, F. Hoffmann-La Roche & Co., Roche Holdings, Inc.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	P150, P152, P153, P209	01/12/2022	03/01/2024	No	No