ISRCTN11241743 https://doi.org/10.1186/ISRCTN11241743

Assessment of dementia diagnosis using 3D facial mapping technology

Submission date
29/07/2020

Recruitment status
No longer recruiting

Registration date
14/08/2020

Overall study status
Stopped

Last Edited
05/12/2024

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Dementia is a neurological dysfunction that occurs in the brain and is commonly diagnosed in individuals over the age of 65 years. It's a form of disease which results in greater loss of neurons in the brain that progresses over the course of a number of years. Dementia has different subtypes such as Alzheimer's disease, vascular dementia, dementia of Lewy body, Parkinson's disease dementia and frontal-temporal dementia. In order to diagnose and identify subtypes of dementia, currently neuropsychological tests as well as neuroimaging such as brain scans are used and these methods generally take a long time and are also expensive. The latest research suggests changes within the brain secondary to dementia can be detected with changes in faces and ears. This is screened using a new technique called 'facial recognition', which is also shown to detect subtle changes in facial expressions. The aim of this study is to further examine this technique for the detection of subtypes of dementia that are listed above.

Who can participate?
Patients who have a diagnosis of dementia and similar age group healthy volunteers

What does the study involve?
Participants undergo a non-invasive 3D facial mapping technique that involves facial photographs being taken, followed by a 20-second' video recording of participants' faces presenting different facial expressions such as frowning or smiling. Additionally, participants will be asked to follow a dot on the computer/iPad screen from left to right as part of an eye examination.

What are the possible benefits and risks of participating?
There are no identified risks of participation.

Where is the study run from?
Chelsea and Westminster Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2020 to October 2022

Who is funding the study?
Strong Room Technology Pty Ltd (Australia)

Who is the main contact?
Dr Ruth Mizoguchi
ruth.mizoguchi@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Ruth Mizoguchi

ORCID ID
https://orcid.org/0000-0001-8938-5477

Contact details
Chelsea and Westminster Hospital
London
United Kingdom
SW10 9NH
+44 (0)203 315 8000
ruth.mizoguchi@nhs.net

Type(s)
Public

Contact name
Mr Max Mito

Contact details
Strong Room Technology Pty Ltd,
58 The Blvd, Malvern East VIC
Melbourne
Australia
3145
+61 (0)468 336 360
max.mito@strongroom.ai

Additional identifiers

Integrated Research Application System (IRAS)
263501

Study information

Scientific Title

Investigating the use of 3D facial mapping technology as an effective screening tool to detect dementia-related diseases

Study objectives
The detection of unique facial features with non-invasive 3D facial mapping technology will reliably differentiate between healthy participants and individuals with dementia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/03/2020, London - City & East Research Ethics Committee (Bristol Research Ethics Committee Centre, Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0) 2071048033/53; cityandeast.rec@hra.nhs.uk), REC ref: 20/LO/0280

Primary study design
Observational

Study design
Observational case-control study

Study type(s)
Diagnostic, Other

Health condition(s) or problem(s) studied
Alzheimer’s disease (AD), vascular dementia (VD), dementia with Lewy body (DLB), Parkinson’s disease dementia (PDD), frontal-temporal dementia (bvFTD)

Interventions
This project aims to engineer an innovative AI facial recognition solution to remedy the current weaknesses in the detection of different types of dementia. If successful, this would provide a quick, cost-effective, non-invasive, and objective new methodology to diagnose dementia and differentiate subtypes. 50 patients with dementia fulfilling the DSM-5 criteria (schedule 2) will be recruited from the memory clinic of the Chelsea and Westminster Hospital NHS Trust. 25 healthy age-matched controls will be recruited within the Chelsea and Westminster Hospital NHS Trust. Initially, participants will be invited to participate in the study by the clinician and information sheet will be provided. At the beginning of the facial mapping protocol, each participant will have three photographs taken, from the front as well as both sides of the face. A video of each participant frowning and smiling for 20 seconds will be captured. Finally, each participant will be asked to follow a dot on the screen from left to right as part of the eye examination. This does not form part of the standard diagnostic protocol; however, it is routinely used to assess saccades. Follow-up of patient’s data can last up to 1 year after the first visit and will be continuously collected. The GPs whom the patients are assigned to will be informed of their participation.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome(s)
All outcome measures will be collected at baseline and at follow up 1 year later:
1. Cognitive decline measured using Montreal Cognitive Assessment (MOCA) Assessment
2. Cognitive decline measured using Addenbrooke's Cognitive Examination (ACE 3) Assessment
3. Facial mapping photographs from the front, the right side and the left side of the face

The neuropsychological assessments will include:
1. Estimated premorbid intellectual function assessed using National Adult Reading Task (NART)
2. Current cognitive status assessed using Mini-Mental State Exam (MMSE)
3. Learning, memory recall and recognition memory assessed using Hopkins Verbal Learning Task (HVLT)
4. Memory recall for complex verbal material assessed using Weschler Memory Scale (WMS)
5. Featural and holistic visuospatial perceptual processing assessed using Rey Complex Figure Task (RCFT)
6. Phonemic and semantic verbal fluency and executive function assessed using Verbal fluency tasks (VF)
7. Processing speed, attentional switching and Executive function assessed using trail-making task (TMT)
8. Levels of anxiety and depression assessed using Hospital and Anxiety Scale (HADS)
Qualitative observations of processing style, impulsivity, metacognition, fatigue and self-monitoring difficulties are made throughout the assessment and recorded separately by the assessor

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
01/10/2024

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. A diagnosis of dementia under the DSM-5 Criteria for Dementia for the dementia cohort using:
1.1. Medical history
1.2. Neuroimaging
1.3. Neuropsychological assessment
2. At least 8 years of education
3. Normal cognition under standardised testing for the age-matched healthy controls

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
109

Key exclusion criteria
1. Any significant facial deterioration through another disease or aetiology that could influence facial mapping or imaging
2. Patient diagnosed with Mild-Cognitive Impairment (MCI)
3. Patients diagnosed with mild memory impairment
4. Patients diagnosed with psychiatric conditions such as schizophrenia (due to presence of cataracts, lens opacities or corneal pigmentation) Smith et al., 1997 aggravated by poor performance on visual tasks (Hess et al., 1997 and Silverstein et al., 2000; 2009, 2012)
5. Patient diagnosed with neurological lesions such as cerebellar lesions as seen in Huntington's, Wilson's and Whipple Disease – can produce similar ocular hypometric, prolonged saccade latencies as seen in some types of dementia
6. Patients with underlying dermatological conditions such as dermatomyositis – as important facial landmarks and anatomy can be altered

Date of first enrolment
01/10/2020

Date of final enrolment
01/10/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Chelsea and Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Sponsor information

Organisation
Strong Room Technology Pty Ltd

Funder(s)

Funder type
Industry

Funder Name
Strong Room Technology Pty Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No