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An inconspicuous, non-invasive, mobile sensor device for real-time control of assistive technologies through facial expression

Submission date
15/10/2018

Recruitment status
No longer recruiting

Registration date
20/11/2018

Overall study status
Completed

Last Edited
06/09/2022

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
This study aims to investigate a new sensor technology, FRAME, integrated into a regular pair of glasses. FRAME has been designed to allow facial expressions and emotional responses to be measured and tracked over time. The aim of this technology is to measure the progression of diseases, such as facial palsy, via facial expressions and emotional responses. To help in the development process, the aim of this study is to analyse the faces of people living with facial palsy and to check whether FRAME can accurately track their facial expressions.

Who can participate?
Healthy volunteers and patients with facial palsy or Parkinson's disease, all aged 18-75

What does the study involve?
In the first part of the study all participants are asked to watch a series of selected video clips designed to elicit emotional responses such as happiness, sadness, fear and anxiety. Whilst watching the videos, their facial expressions are recorded in a range of commonly used ways, including videos and measurement of facial muscle movements using electromyography (EMG; electrodes attached to the skin) which is a highly sensitive method to pick up tiny muscle signals from the muscles. The FRAME glasses are used to record the facial movements and vocal responses, to compare the performance of the FRAME sensor technology to the commonly used ways and to compare the emotional responses of people who live with conditions such as facial palsy. In the second part of the study participants are asked to wear FRAME for up to 8 hours a day during weekdays for up to 4 weeks. Participants complete various questionnaires at the start and end of the study and at three-daily intervals, prompted by automated calls to their smartphone, for each day they wear FRAME.

What are the possible benefits and risks of participating?
There is no direct benefit for any of the participants as an immediate outcome from the trial. As the aims of the trial are to collect data for the development of the FRAME sensor technology for use with facial palsy and Parkinson’s disease patients, this data will have no immediate non-research-based benefit. However, the data will enable development of such a system which,

when fully functional, could significantly improve future patient outcomes and quality of life. EMG electrodes will be attached to the surface of the skin on the face. The measurement will be performed with entirely non-invasive methods. Low stress is anticipated when watching the videos. However, a member of the research team will be present with the participants during this part of the study and the videos can be halted at any time should the participant decide they are too stressful. No significant stress, burden or discomfort is expected when wearing the FRAME glasses beyond that of wearing ordinary glasses. However, participants will have weekly conversations with a member of the research team where any issues can be raised. In addition, participants will be completing daily dairies, which will be regularly monitored by the research team, where issues can also be raised. Finally, one of the research questions is to assess the feasibility of wearing the FRAME glasses, so the experiences of participants, the issues they raise and how long they are happy to wear them, will all be measured. Participants wear them for up to 8 hours a day for up to 4 weeks - if participants choose to wear them for less time, then this is of interest.

Where is the study run from?
Queen Victoria Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2017 to September 2020

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Mr Charles Nduka
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
38092

Study information

Scientific Title
Ambulatory measurement of facial expressions in health and disease

Acronym
FRAME (facial remote activity monitoring eyewear)

Study objectives
The primary hypothesis is that measurable differences in facial expressions can be captured using a wearable device in both healthy volunteers and patient groups (facial palsy and Parkinson's disease).
The secondary hypothesis is that users are willing to use the technology at home to enable future treatment monitoring in future.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Edgbaston Research Ethics Committee, 14/09/2018, ref: 18/WM/0205

Primary study design
Interventional

Study design
Non-randomised; Both; Design type: Treatment, Device, Management of Care, Active Monitoring, Validation of outcome measures

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Parkinson's disease, facial palsy

Interventions
The study is divided into two parts.

Part one will include 50 participants with Parkinson's disease, 50 participants with facial palsy and 50 healthy control participants. Participants will first have EMG skin surface electrodes attached (10 minutes) and wear a pair of FRAME glasses. They will then watch a series of short video clips, ranging from 20-33 seconds in length. These video clips come from a validated video library for affective scientists and have been used in numerous research studies. Videos are divided into those of either positive or negative valence and of either high or low arousal, making four categories. Participants will watch a series of these video clips, including a number from each category, for a total length of approximately 20 minutes whilst their facial activity is being monitored by EMG, FRAME and video recording of their face and any vocalisations. Following the videos, the EMG electrodes and FRAME glasses will be removed (5 minutes). Finally, participants will complete a series of questionnaires, which should take approximately 20

minutes to complete. The total study duration will be approximately 1 hour. Participants with Parkinson's and participants with facial palsy will also complete additional questionnaires specific for their conditions.

The trialists will examine associations between facial muscle activity, as measured by EMG, FRAME and the video recordings, and the valence (positive or negative) and arousal level (high or low) of individual video clips being observed. Data from these 3 sensor modalities will be converted into muscle activations analogous to the Facial Activation Coding System. This gives an output of muscle activation in terms of activation intensity, activation duration and symmetry of activation. Associations between these aspects will be investigated.

Part two will include 20 participants with Parkinson's disease, 20 participants with facial palsy and 20 healthy control participants. This is an exploratory study to observe and investigate how facial muscle reactions change during the course of a normal day in participants from the various participant groups. It is known that conditions fluctuate during the day, depending on factors such as time of day, time since medication/therapy, mood state, etc, and the trialists want to investigate the impact of daily life on responses measured by FRAME in participants of the different groups.

FRAME glasses are designed to be lightweight and worn instead of, or over, a normal pair of glasses. The trialists will ask participants to wear FRAME for up to 8 hours a day during weekdays for up to 4 weeks. Participants will be asked to complete various questionnaire measures at different time points - at the baseline, upon study completion and at three-daily intervals, prompted by automated calls to their smart phone, for each day the participants are wearing FRAME.

The outcomes of this study will be recruitment rate and retention rate for a study of this kind. In addition, the trialists will be assessing the usability of FRAME, for how long participants are prepared to wear them each day and for how many days in succession. Finally, the trialists will be investigating associations between FRAME measures of facial activation and different times of day, events, and between various questionnaire measures.

Participants will be supported by the research team throughout this study. Participants will receive an initial fitting and training session about how to use FRAME. They will then receive a weekly call from a member of the research team to ensure there are no problems or concerns from participants during the study. Furthermore, the software will alert research team if there are issues with the technology itself.

Intervention Type
Device

Primary outcome(s)
The range of facial expressions in response to emotional stimuli, as measured by facial muscle activity by EMG and FRAME sensors in a single visit

Key secondary outcome(s)
Measured at baseline, upon study completion, and at three-daily intervals, prompted by automated calls to their smartphone, for each day the participants are wearing FRAME:
1. Personality, assessed using OCEAN
2. Presence of any existing mental health issues, assessed using CORE-10. Participants who reveal potential mental health issues will be advised that we will write to their GP informing

them of the results of the questionnaire
3. Quality of life, assessed using SF36
4. Current mood at time of assessment, assessed using Self-Assessment Mannikin (SAM)
5. Disease-specific issues, assessed using UPDRS & SAQ

Completion date
30/09/2020

Eligibility

Key inclusion criteria
All participants:
1. Aged 18-75 years
2. ASA I (normal, healthy) or II (mild systemic disease, no functional limitation, e.g. smoker with well-controlled hypertension)
3. Ability to read and understand English
4. Use of both hands
5. Ambulatory (able to walk around own home (walking aids are allowed))

Additional inclusion criteria for participants with facial palsy:
1. Unilateral facial palsy (i.e. one side effected)
2. A facial grading score, using the House-Brackmann scale, of less than 6
3. A facial grading score, using the Sunnybrook Facial Grading System, of less than 100

Additional inclusion criteria for participants with Parkinson's disease:
1. Clinical diagnosis of Parkinson’s disease
2. Stable medication for at least 6 weeks

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Key exclusion criteria
All participants:
1. Evidence of neuro-muscular dysfunction

Additional exclusion criteria for participants with facial palsy:
1. History of facial surgery (except eye lid surgery)

Additional exclusion criteria for participants with Parkinson's disease:
1. Unable to walk

Date of first enrolment
21/11/2018

Date of final enrolment
01/09/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Victoria Hospital
Holtye Road
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Sponsor information

Organisation
Queen Victoria Hospital NHS Foundation Trust

ROR
https://ror.org/03bs2yy11

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: II-LA-0814-20008

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Plain English results			06/09/2022	No	Yes