Non-CTIMP Study Protocol

The impact of smart glasses on the usability and satisfaction of operating an environmental control system or communication aid

Co-Sponsors	The University of Edinburgh and/or Lothian Health Board ACCORD The Queen's Medical Research Institute 47 Little France Crescent Edinburgh EH16 4TJ
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LIST OF ABBREVIATIONS

ACCORD	Academic and Clinical Central Office for Research & Development - Joint office for The University of Edinburgh and Lothian Health Board
CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
PI	Principal Investigator
QA	Quality Assurance
REC	Research Ethics Committee
SOP	Standard Operating Procedure

1 INTRODUCTION

1.1 BACKGROUND

Upper limb mobility impairments are a common problem for people with neurological conditions. These impairments can have a detrimental effect of individual's lives and can limit access to everyday technology within the home environment. Consequently, environmental control systems (ECS) have been developed to facilitate access to a range of devices in the home including televisions, alarm systems, and telephones. These systems consist of an access method for example a switch or eye gaze, the controller itself which houses the electronics to control various devices and the output devices themselves. Due to the development of tablet based ECS the software that is used for environmental controls can also be used for the purposes of communication.

A previous study has demonstrated that ECS tend to increase independence and increase the ability of individuals to carry out ADL, socialise and increase quality of life (Brandt et al. 2011). There are however concerns over their design and ease of use (Etinger et al. 2018, Myburg et al. 2017). One particular problem is that the majority of communication aid and environmental control systems aimed at high end users require a screen to be mounted in front of the user. The limitations with this are that the user is only able to control their environment or speak when they are in front of the screen and it is difficult to achieve independent access to the device when the user has been driving their wheelchair, or is moving between a wheelchair and another chair/bed.

Smart glasses technology has been developed in the last decade with Google unveiling their first Google Glass edition in 2012 and subsequently companies such as Epson, Microsoft and Sony also releasing devices (Kim and Choi 2021). Smart glasses consist of a pair of glasses which are equipped with a see-through optical display that enables the user to see both their environment and also a virtual display (Lee and Hui 2018). By using smart glasses, displays are accessible to the user in any location in their environment and this could provide an effective solution for increasing the independent use of communicate aids and environmental control systems.

The existing NHS Lothian environmental control service (https://www.smart.scot.nhs.uk/service/environmental-control/) has approximately 100 service users. Smart glasses potentially have the benefit of allowing users who would not be able to use environmental controls to access one. There are no significant risks of harm to users identified.

1.2 RATIONALE FOR STUDY

The research question for this study is - what are the impact of smart glasses on the usability and satisfaction of operating an ECS or communication aid.

The outcomes from the study could lead to new ECS/communication aids being developed that incorporate smart glasses as a user display. If this is realised then it could lead to a reduction in the barriers to smart glasses by removing the mounting requirement for a screen. It could also improve how users interact with others by removing a visible screen displaying what the user is writing ahead of it being spoken and therefore increasing privacy. There is also a potential cost benefit to NHS services due to the high costs of specialist mounting bracketry.

2 STUDY OBJECTIVES

2.1 OBJECTIVES

2.1.1 Primary Objective

To explore the impact of smart glasses on the usability and satisfaction of operating ECS and communication aids.

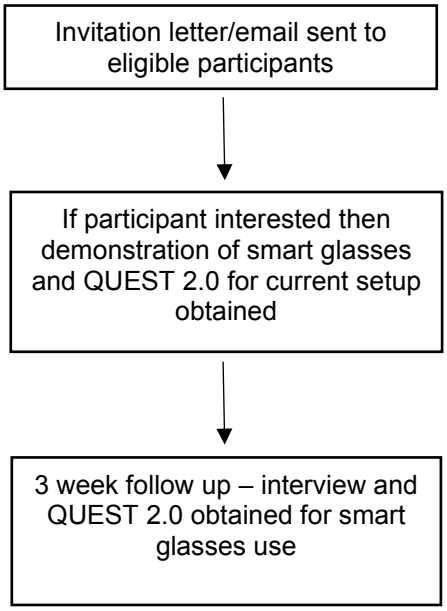
2.2 ENDPOINTS

2.2.1 Primary Endpoint

Quest 2.0

3 STUDY DESIGN

The evaluation is to be conducted by a UK based NHS Rehabilitation Engineering department. Individuals who currently have an ECS or communication aid on long term loan will trial the device and provide feedback. Questionnaires and interviews will evaluate the usability and the satisfaction that smart glasses provide.



The QUEST 2.0 questionnaire will be used to explore the user's satisfaction both with their existing setup and with the use of the smart glasses.
A semi-structured interview will be used to explore the usability of the smart glasses.

At the end of study participants will not be able to keep the smart glasses. The service will review the results from the study to inform future provision.

4 STUDY POPULATION

4.1 NUMBER OF PARTICIPANTS

The participants will be recruited from the population served by NHS Lothian's Environmental Control Service. The number of participants will be determined by how many participants it is possible to recruit within 12 months – it is expected to be <20. The participants will be referred to service as normal and the clinical intervention (supply of an environmental control system) will proceed irrespective of their participation or otherwise in the study. The only difference to the normal service provision and pathway is the application of the baseline and follow up questionnaires.

4.2 INCLUSION CRITERIA

i. Existing environmental control system user (age 18-80).
ii. Neurological condition.
iii. Cognitive ability to answer the questions and to give consent.
iv. Current environmental control system is compatible with smart glasses display.

4.3 EXCLUSION CRITERIA

i. Current environmental control system or communication aid is not compatible with smart glasses display.
ii. Rapidly deteriorating condition

4.4 CO-ENROLMENT

Co-enrolment will not be allowed in any circumstances.

5 PARTICIPANT SELECTION AND ENROLMENT

5.1 IDENTIFYING PARTICIPANTS

Participants will be identified by Clinical Scientists (who are in the patient's direct care team) working in NHS Lothian's Environmental Control Service (ECS) from a database of existing patients. The patient will be contacted by a Clinical Scientist via telephone, to ask if they wish to take part in the study.

5.2 CONSENTING PARTICIPANTS

Informed consent will be collected by a Clinical Scientist at the initial setup in the form of a consent form. The participants will be sent the information sheet at least 1 week in advance of the initial setup appointment.

5.2.1 Withdrawal of Study Participants

Participants are free to withdraw from the study at any point or a participant can be withdrawn by the Investigator. If withdrawal occurs, the primary reason for withdrawal will be documented in the participant's case report form if possible. The participant will have the option of withdrawal from:

(i) all aspects of the study but continued use of data collected up to that point. To safeguard rights, the minimum personally-identifiable information possible will be collected.

6 STUDY ASSESSMENTS

6.1 STUDY ASSESSMENTS

The participant will be provided with a set of smart glasses as an alternative display for their existing environmental control system. Training will be provided on how to operate the smart glasses. The initial setup and questionnaire will take between 2-3 hours. Further questionnaires will be completed at a second appointment and will take approximately 1 hour to complete.

Assessment	Screening	Baseline	3 weeks following loan of smart glasses
Assessment of Eligibility Criteria	☒	☐	☐
Written informed consent	☐	☒	☐
Demographic data, contact details	☒	☐	☐
Questionnaire	☐	☒	☒
Interview	☐	☐	☒

6.2 LONG TERM FOLLOW UP ASSESSMENTS

The longest follow up will be 3 weeks.

6.3 STORAGE AND ANALYSIS OF SAMPLES

N/A

7 DATA COLLECTION

All data will be collected by a Clinical Scientist within NHS Lothian's Environmental Control Service.

1. Participant will complete initial questionnaire **QUEST 2.0** (completed in person at initial appointment)
2. Participant will complete follow up questionnaire **QUEST 2.0 and study specific semi-structured interview** (completed in person at follow up appointment)

7.1 Source Data Documentation

Source data is defined as all information in original records and certified copies of original records or clinical findings, observations, or other activities in a clinical study necessary for the reconstruction and evaluation of the study. Source data are contained in source documents.

Source documents are original documents, data and records where source data are recorded for the first time.

1. QUEST 2.0
2. Study specific semi-structured interview

7.2 Case Report Forms

Data will be collected on a structured form. –

8 DATA MANAGEMENT

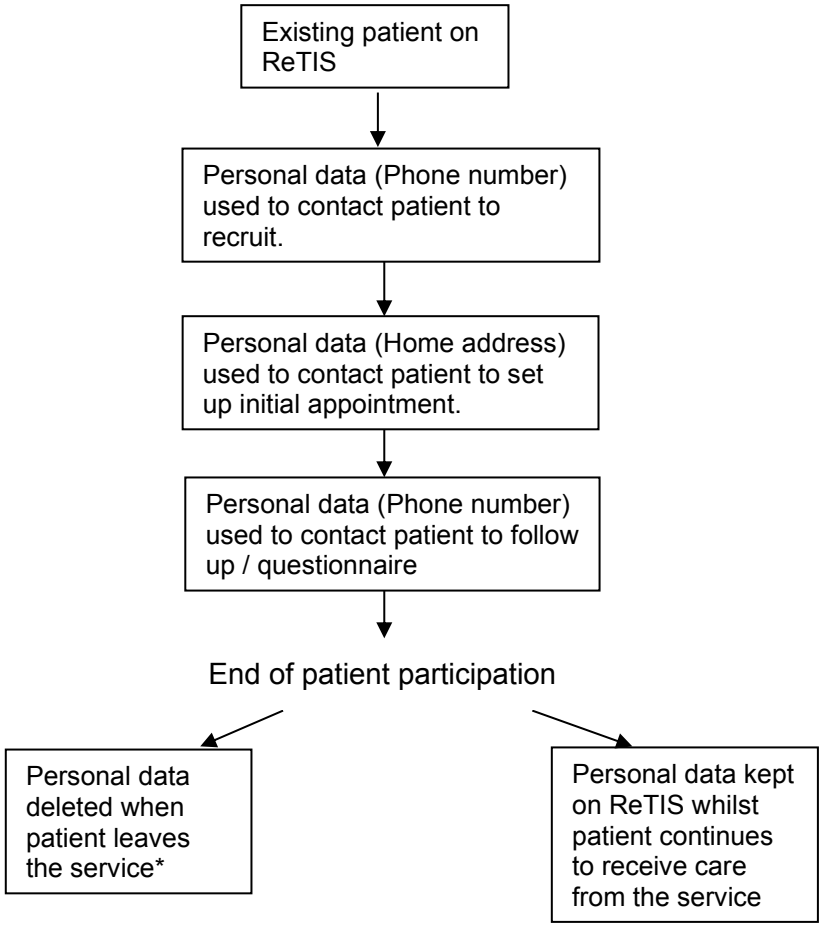
8.1 Personal Data

The following personal data will be collected as part of the research:

- Name, ReTIS number (this is 6 digit identifier used by the ReTIS database – the system used for patient management within the SMART Centre for issuing wheelchairs and environmental control systems etc.), Phone number, Home address, health conditions. This information is collected from the ReTIS database record.

Personal data will be stored by the research team on ReTIS (Local data management software) which is password protected. A mapping spreadsheet will be created to map between the ReTIS number and the participant's study specific code. Personal data will be stored for as long as they are a patient of the Environmental Control Service.

8.2 Data Information Flow



* After a fixed period in accordance with the retention of health records requirements.

8.3 Data Storage

The results of the QUEST 2.0 scores will be recorded on handwritten forms. The results from the semi-structured interview will be recorded on a secure NHS approved device.

A study spreadsheet will be created for saving the results of the QUEST 2.0 scores and the semi-structured interview. This will be on secured NHS Lothian network shared drive accessible only to the study investigators. Handwritten forms will be kept locked in cabinet in the lead investigators office – once transcribed they will be destroyed using the confidential waste.

The semi-structured interview data will be transcribed by the lead researcher onto the spreadsheet. After this the recordings will be deleted from the device.

8.4 Data Retention

Personal data will be stored for the duration of the study and for additional time for the study to be written up – this will be 3 years from the end of the study.

8.5 Disposal of Data

Data will be deleted from the shared drive.

Handwritten forms will be destroyed using the confidential waste.

8.6 External Transfer of Data

Data collected or generated by the study (including personal data) will not be transferred to any external individuals or organisations outside of the Sponsoring organisation(s).

8.7 Data Controller

A data controller is an organisation that determines the purposes for which, and the manner in which, any personal data are processed.

The University of Edinburgh and NHS Lothian are joint data controllers along with any other entities involved in delivering the study that may be a data controller in accordance with applicable laws (e.g. the site).

8.8 Data Breaches

Any data breaches will be reported to the University of Edinburgh (dpo@ed.ac.uk) and NHS Lothian (Lothian.DPO@nhslothian.scot.nhs.uk) Data Protection Officers who will onward report to the relevant authority according to the appropriate timelines if required.

9 STATISTICS AND DATA ANALYSIS

9.1 SAMPLE SIZE CALCULATION

Due to the small number of participants expected, data will be analysed with descriptive methods and therefore no sample size calculations are required.

9.2 PROPOSED ANALYSES

Incomplete datasets will be removed before undertaking the analysis.

The data will be analysed with descriptive methods with a focus on clinical significance.

Correlation analysis will be conducted to determine relationships between the device use and social context and the satisfaction outcome measures.

For all of the outcome measures the following data will be reported: mean, change in mean between intervals and standard deviation.

Statistical tests will be used to analyse the significance of the relationship between variables.

10 ADVERSE EVENTS

The NHS Lothian Adverse Event Management Policy and Operational Procedure will be followed for recording and dealing with adverse incidents.

11 OVERSIGHT ARRANGEMENTS

11.1 INSPECTION OF RECORDS

Investigators and institutions involved in the study will permit study related monitoring and audits on behalf of the Sponsor, REC review, and regulatory inspection(s). In the event of audit or monitoring, the Investigator agrees to allow the representatives of the Sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation.

11.2 STUDY MONITORING AND AUDIT

The ACCORD Sponsor Representative will assess the study to determine if a study specific risk assessment is required.

If required, a study specific risk assessment will be performed by representatives of the Sponsor(s), ACCORD monitors and the QA group, in accordance with ACCORD governance and sponsorship SOPs. Input will be sought from the Chief Investigator or designee. The outcomes of the risk assessment will form the basis of the monitoring plans and audit plans.

If considered necessary, ACCORD clinical trial monitors, or designees, will perform monitoring activities in accordance with the study monitoring plan. This will involve on-site visits and remote monitoring activities as necessary. ACCORD QA personnel, or designees, will perform study audits in accordance with the study audit plan. This will involve investigator site audits, study management audits and facility (including 3rd parties) audits as necessary (delete where not required).

12 GOOD CLINICAL PRACTICE

12.1 ETHICAL CONDUCT

The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP).

Before the study can commence, all necessary approvals will be obtained and any conditions of approvals will be met.

12.2 INVESTIGATOR RESPONSIBILITIES

The Investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments. In accordance with the principles of ICH GCP, the following areas listed in this section are also the responsibility of the Investigator. Responsibilities may be delegated to an appropriate member of study site staff.

Delegated tasks must be documented on a Delegation Log and signed by all those named on the list prior to undertaking applicable study-related procedures.

12.2.1 Informed Consent

The Investigator is responsible for ensuring informed consent is obtained before any study specific procedures are carried out. The decision of a participant to participate in clinical research is voluntary and should be based on a clear understanding of what is involved.

Participants must receive adequate oral and written information – appropriate Participant Information and Informed Consent Forms will be provided. The oral explanation to the participant will be performed by the Investigator or qualified delegated person, and must cover all the elements specified in the Participant Information Sheet and Consent Form.

The participant must be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information. The participant must be given sufficient time to consider the information provided. It should be emphasised that the participant may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled.

The participant will be informed and agree to their medical records being inspected by regulatory authorities and representatives of the Sponsor(s).

The Investigator or delegated member of the study team and the participant will sign and date the Informed Consent Form(s) to confirm that consent has been obtained. The original will be signed in the Investigator Site File (ISF). The participant will receive a copy of the signed consent form and a copy will be filed in the participant's medical notes.

12.2.2 Study Site Staff

The Investigator must be familiar with the protocol and the study requirements. It is the Investigator's responsibility to ensure that all staff assisting with the study are adequately informed about the protocol and their study related duties.

12.2.3 Data Recording

The Principal Investigator is responsible for the quality of the data recorded in the CRF at each Investigator Site.

12.2.4 Investigator Documentation

The Principal Investigator will ensure that the required documentation is available in local Investigator Site files (ISFs).

12.2.5 GCP Training

For non-CTIMP (i.e. non-drug) studies all researchers are encouraged to undertake GCP training in order to understand the principles of GCP. This is not a mandatory requirement unless deemed so by the Sponsor. GCP training status for all investigators should be indicated in their respective CVs.

12.2.6 Data Protection Training

All University of Edinburgh employed researchers and study staff will complete the Data Protection Training through Learn.

NHS Lothian employed researchers and study staff will comply with NHS Lothian mandatory Information Governance Data Protection training through LearnPro.

Non-NHS Lothian staff that have access to NHS Lothian systems will familiarise themselves and abide by all NHS Lothian IT policies, as well as employer policies

12.2.7 Information Security Training

All University of Edinburgh employed researchers, students and study staff will complete the Information Security Essentials modules through Learn and will have read the minimum and required reading setting out ground rules to be complied with.

NHS Lothian employed researchers and study staff will comply with NHS Lothian mandatory Information Governance IT Security training through LearnPro.

Non-NHS Lothian staff that have access to NHS Lothian systems will familiarise themselves and abide by all NHS Lothian IT policies, as well as employer policies

12.2.8 Confidentiality

All laboratory specimens, evaluation forms, reports, and other records must be identified in a manner designed to maintain participant confidentiality. All records must be kept in a secure storage area with limited access. Clinical information will not be released without the written permission of the participant. The Investigator and study site staff involved with this study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished information, which is confidential or identifiable, and has been disclosed to those individuals for the purpose of the study. Prior written agreement from the Sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.

12.2.9 Data Protection

All Investigators and study site staff involved with this study must comply with the requirements of the appropriate data protection legislation (including the General Data Protection Regulation and Data Protection Act) with regard to the collection, storage, processing and disclosure of personal information.

Computers used to collate the data will have limited access measures via user names and passwords.

Published results will not contain any personal data that could allow identification of individual participants.

13 STUDY CONDUCT RESPONSIBILITIES

13.1 PROTOCOL AMENDMENTS

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant in the case of an urgent safety measure, must be reviewed and approved by the Chief Investigator.

Proposed amendments will be submitted to the Sponsor for classification, review and authorisation.

Amendments to the protocol must be submitted in writing to the appropriate REC and local R&D for approval prior to implementation and prior to participants being enrolled into the amended protocol.

13.2 MANAGEMENT OF PROTOCOL NON COMPLIANCE

13.2.1 Protocol Waivers

Prospective protocol deviations, i.e. protocol waivers, will not be approved by the Sponsors and therefore will not be implemented, except where necessary to eliminate an immediate hazard to study participants. If this necessitates a subsequent protocol amendment, this should be submitted to the REC and local R&D for review and approval if appropriate.

13.2.2 Management of Deviations and Violations

Deviations and violations are non-compliance events discovered after the event has occurred. Protocol deviations will be recorded in a protocol deviation log and logs will be submitted to the Sponsors every 3 months. Each protocol violation will be reported to the Sponsor within 3 days of becoming aware of the violation.

Deviation logs will be maintained for each site in multi-centre studies.

Deviation logs/violation forms will be transmitted via email to QA@accord.scot. Only forms in a pdf format will be accepted by ACCORD via email. Forms may also be submitted by hand to the office. Where missing information has not been sent to ACCORD after an initial report, ACCORD will contact the Investigator and request the missing information. The Investigator must respond to these requests in a timely manner.

13.3 SERIOUS BREACH REQUIREMENTS

A serious breach is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the study; or

(b) the scientific value of the study.

If a potential serious breach is identified by the Chief investigator, Principal Investigator or delegates, the Sponsor(s) (qa@accord.scot) must be notified within 24 hours. It is the responsibility of the Sponsor(s) to assess the impact of the breach on the scientific value of the study, to determine whether the incident constitutes a serious breach and report to research ethics committees as necessary.

13.4 STUDY RECORD RETENTION

All study documentation will be kept for a minimum of 3 years from the protocol defined end of study point. When the minimum retention period has elapsed, study documentation will be destroyed with permission from the Sponsor.

13.5 END OF STUDY

The end of study is defined as the last participant's last visit.

The Investigators and/or the Sponsor(s) have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the REC, and R&D Office(s) and Sponsor(s) within 90 days, or 15 days if the study is terminated prematurely. The Investigators will inform participants of the premature study closure and ensure that the appropriate follow up is arranged for all participants involved. End of study notification will be reported to the Sponsor(s) via email to researchgovernance@ed.ac.uk.

A summary report of the study will be provided to the REC within 1 year of the end of the study.

13.6 CONTINUATION OF TREATMENT FOLLOWING THE END OF STUDY

The participant will continue to be provided their environmental control device in line with NHS Lothian's service provision.

13.7 INSURANCE AND INDEMNITY

The Sponsor(s) are responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and staff.

The following arrangements are in place to fulfil the Sponsor(s)' responsibilities:

- The Protocol has been designed by the Chief Investigator and researchers employed by the University and collaborators. The University has insurance in place (which includes no-fault compensation) for negligent harm caused by poor protocol design by the Chief Investigator and researchers employed by the University.

- Sites participating in the study will be liable for clinical negligence and other negligent harm to individuals taking part in the study and covered by the duty of care owed to them by the sites concerned. The Sponsor(s) require individual sites participating in the study to arrange for their own insurance or indemnity in respect of these liabilities.
- Sites which are part of the United Kingdom's National Health Service will have the benefit of NHS Indemnity.
- Sites out with the United Kingdom will be responsible for arranging their own indemnity or insurance for their participation in the study, as well as for compliance with local law applicable to their participation in the study.

14 AUTHORSHIP POLICY

Ownership of the data arising from this study resides with the study team.

15 REFERENCES

Brandt, A. et al. (2011). Activity and participation, quality of life and user satisfaction outcomes of environmental control systems and smart home technology: a systematic review. *Disability and Rehabilitation: Assistive Technology*, 6(3), pp.189–206.

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