Non-CTIMP Study Protocol

The impact of environmental controls on mental health

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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
ECS	Environmental Control Service
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

Within the UK there are over 15 million people who live with at least one long term condition. Of these people, over 4 million suffer from mental health problems (Naylor C. 2012). A study by Emerson et al (2009) found that people with disabilities have poorer mental health than their counterparts.

Environmental control systems are a type of assistive technology that can be controlled by a wide variety of different access methods (e.g. switches) and can assist people with physical disabilities to control various electronic devices in the home environment. The systems are designed to provide independence, removing the requirement to be reliant on other people (for the operation of the controlled devices) and potentially could have a positive effect on mental health and quality of life.

A systematic review carried out by Brandt et al. (2010) concluded that there was not enough evidence to conclusively say that environmental control systems improve outcomes for patients. Whilst the review did not specifically investigate mental health outcomes it did look at quality of life and user satisfaction. There is a paucity of studies specifically focusing on mental health outcomes. A study by Squires et al. (2021) did include some mental health outcome measures. However, it was a case study with one participant and it is therefore not possible to draw any conclusions for a wider population. This project aims to address the issues above by determining the impact of environmental control systems on mental health by recording outcome measures pre and post intervention.

1.2 RATIONALE FOR STUDY

The research question for this study is to determine impact of environmental controls on mental health. It is hypothesised that there will be a positive impact on mental health of the participants.

This study will contribute to an evidence base for the importance and value of environmental control systems. This evidence base can be used as part of a review of the NHS Scotland service provision of environmental controls and writing and implementing a national service specification for environmental controls in Scotland.

2 STUDY OBJECTIVES

2.1 OBJECTIVES

2.1.1 Primary Objective

To explore the impact of environmental controls on the user's mental health and quality of life.

2.2 ENDPOINTS

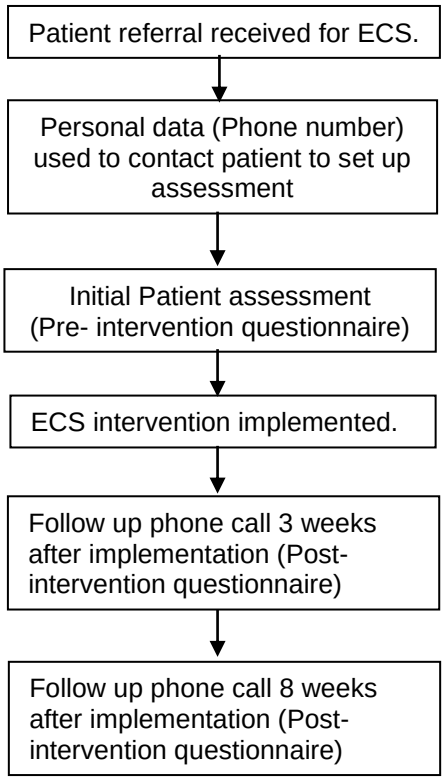
2.2.1 Primary Endpoint

The co-primary endpoints are the PROMIS Global10 and PIADS-10 measures.

NB due to predicted low participant numbers this study has not been powered to assess these endpoints. Instead the data will be analysed with descriptive methods with a focus on clinical significance.

3 STUDY DESIGN

Case series (follow-up) design. Participants will be involved from their assessment until 8 weeks after device provision. The full duration of involvement will vary depending on assessment wait times and availability of required intervention. The study will take place in the participant's home.



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 <10. 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. Eligible for an environmental control system (age 18-80).
ii. New user (no previous intervention).
iii. Neurological condition.
iv. Cognitive ability to answer the questions and to give consent.

4.3 EXCLUSION CRITERIA

i. Previous environmental control intervention
ii. Patients requiring equipment not supplied by NHS Lothian's ECS (e.g. door interface)
iii. Patient recently diagnosed (within 6 months)
iv. 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 working in NHS Lothian's Environmental Control Service (ECS). The patient will be contacted by a Clinical Scientist via telephone, to arrange an environmental control assessment, at which point they will be approached to join the study.

5.2 CONSENTING PARTICIPANTS

Informed consent will be collected by a Clinical Scientist at the assessment appointment in the form of a consent form. The participants will be sent the information sheet at least 1 week in advance of the assessment 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 trial but continued use of data collected up to that point. To safeguard data protection and confidentiality, the minimum personally-identifiable information possible will be collected.

6 STUDY ASSESSMENTS

6.1 STUDY ASSESSMENTS

The intervention provided will be dependent on the patients' needs however it will comprise of an electronic environmental control system which will help them to access devices around their home independently. An example system would consist of a controller (e.g. Qwayo 2) with a switch and mounting system and any additional peripherals (e.g. remote controlled sockets). The assessment for the system will take place first and can take between 30-60 minutes. Questionnaires will be completed afterwards and will take approximately 30 minutes to complete.

Assessment	Screening	Baseline (Assessment)	3 weeks following provision	8 weeks following provision
Assessment of Eligibility Criteria	☒			
Written informed consent		☒		
Demographic data (name, age, address) contact details	☒	☒		
Questionnaire		☒	☒	☒

6.2 LONG TERM FOLLOW UP ASSESSMENTS

The longest follow up will be 8 weeks.

7 DATA COLLECTION

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

1. Participant will complete pre-intervention questionnaire **PROMIS Global10- score, PIADS-10 and study specific questions** (completed in person at assessment)
2. Intervention with environmental control equipment (prescription dependant on patient requirements)
3. Participant will complete post intervention questionnaire **PROMIS Global10-score, PIADS-10 and study specific questions** (3 weeks) (follow up over phone)
4. Participant will complete post intervention questionnaire **PROMIS Global10-score, PIADS-10 and study specific questions** (8 weeks) (follow up over phone)

7.1 Source Data Documentation

1. PIADS10 Questionnaire.
2. PROMIS Global 10 Questionnaire.
3. Study Specific Questions Questionnaire.

7.2 Case Report Forms

Collect data on structured form – will be transcribed onto database (spreadsheet). Handwritten forms will be kept locked in cabinet.

8 DATA MANAGEMENT

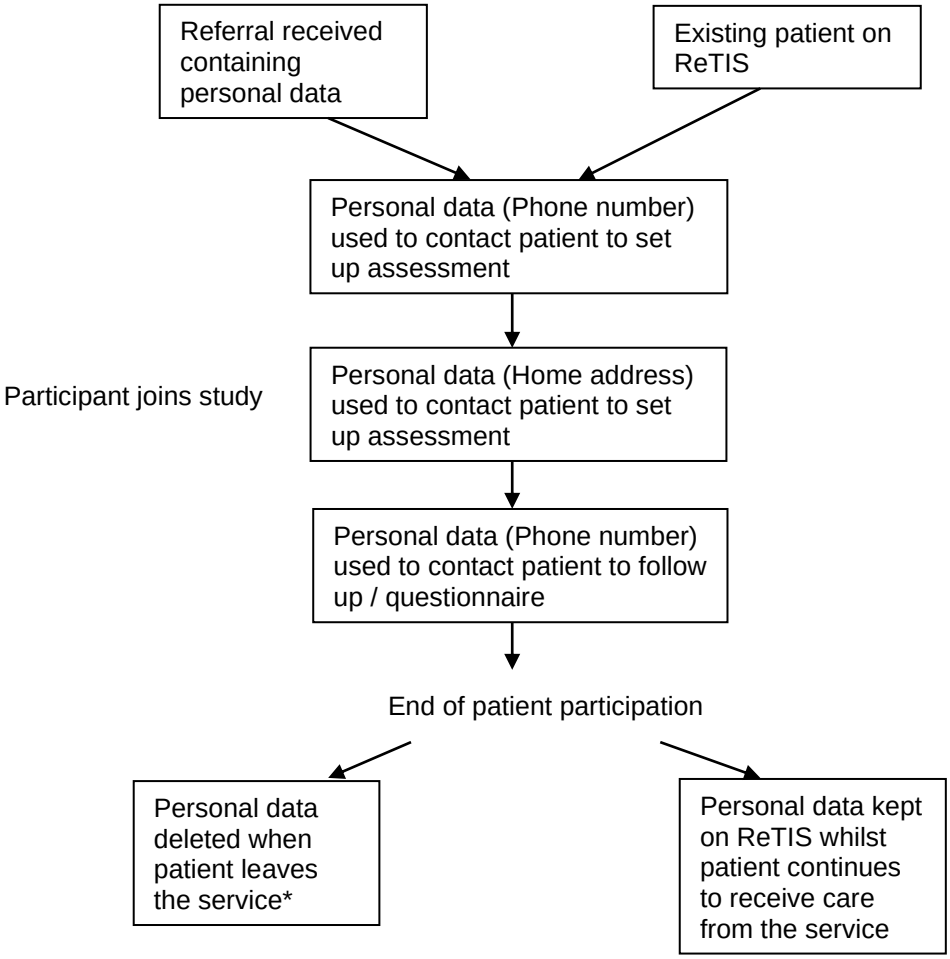
8.1.1 Personal Data

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 patient's referral form.

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.

8.1.2 Data Information Flow



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

8.1.3 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).

8.1.4 Data Controller

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

NHS Lothian are data controller 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)

8.1.5 Data Breaches

Any data breaches will be reported to the NHS Lothian Data Protection Officer 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 data will analysed with descriptive methods 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 mental health outcome measures.

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

Spearman Rank Correlation Coefficient will be used to test the significance of the relationship between variables.

10 OVERSIGHT ARRANGEMENTS

10.1 INSPECTION OF RECORDS

Investigators and institutions involved in the study will permit trial 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.

10.2 STUDY MONITORING AND AUDIT

The ACCORD Sponsor Representative will assess the study to determine if an independent risk assessment is required. If required, the independent risk assessment will be carried out by the ACCORD Quality Assurance Group to determine if an audit should be performed before/during/after the study and, if so, at what frequency.

Risk assessment, if required, will determine if audit by the ACCORD QA group is required. Should audit be required, details will be captured in an audit plan. Audit of Investigator sites, study management activities and study collaborative units, facilities and 3rd parties may be performed.

11 GOOD CLINICAL PRACTICE

11.1 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 required approvals will be obtained and any conditions of approvals will be met.

11.2 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.

11.2.1 Informed Consent

The Investigator is responsible for ensuring informed consent is obtained before any protocol 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 Investigator or delegated member of the trial team and the participant will sign and date the Informed Consent Form(s) to confirm that consent has been obtained. The participant will receive a copy of this document and a copy filed in the Investigator Site File (ISF) and participant's medical notes (if applicable).

11.2.2 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 trial related duties.

11.2.3 Data Recording

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

11.2.4 Investigator Documentation

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

11.2.5 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. However, 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.

11.2.6 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.

11.2.7 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 and be of a form where individuals are not identified and re-identification is not likely to take place.

STUDY CONDUCT RESPONSIBILITIES

11.3 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.

Amendments will be submitted to a sponsor representative for review and authorisation before being submitted in writing to the appropriate REC, and local R&D for approval prior to participants being enrolled into an amended protocol.

11.4 MANAGEMENT OF PROTOCOL NON COMPLIANCE

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.

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. All protocol deviation logs and violation forms should be emailed to QA@accord.scot

Deviations and violations are non-compliance events discovered after the event has occurred. Deviation logs will be maintained for each site in multi-centre studies. An alternative frequency of deviation log submission to the sponsors may be agreed in writing with the sponsors.

11.5 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 trial; or

(b) the scientific value of the trial.

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

11.6 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 not be destroyed without permission from the sponsor.

11.7 END OF STUDY

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

The Investigators or the co-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 co-sponsors 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 co-sponsors via email to resgov@accord.scot

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

11.8 CONTINUATION OF TREATMENT FOLLOWING THE END OF STUDY

Detail if intervention will be continued to be provided following the end of the study. If not provide justification

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

11.9 INSURANCE AND INDEMNITY

The Sponsor is 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 Sponsors' responsibilities:

- 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 co-sponsors 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.
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12 REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

12.1 AUTHORSHIP POLICY

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

13 REFERENCES

Brandt A, Samuelsso K, Toytari O, Salminen A-L. 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 2011:6;189-206

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