

Project Title: EDUCAT: An Assistive Powered Wheelchair. Stage 2. Powered Wheelchair User Evaluation of an Obstacle Alerting System.

NCT Number: NCT05292690

Document Date: 14/07/2020





**An Assistive Powered Wheelchair:
Stage 2 Trial
Powered Wheelchair User Evaluation of an Obstacle
Alerting System.
A non-interventional study
IRAS Project ID: 257062**

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1 Abstract

Title	An Assistive Powered Wheelchair. Stage 2: Powered Wheelchair User Evaluation of an Obstacle Alerting System. <i>A non-interventional study</i>
Sponsor	East Kent Hospitals University NHS Foundation Trust
Chief Investigator	Dr Mohamed Sakel
Participant Population	Non wheelchair users
Nature of the evaluated material	Powered Wheelchair [PWC] equipped with bus data recording system; object detection sensors; audio, haptic and/or visual feedback; anonymised data transmission via the internet. Participant questionnaires.
Main Objective	Preliminary evaluation of an obstacle alerting system that may enhance user's independent mobility by improving their confidence to drive and their safety in driving a powered wheelchair.
Number of study centres	3
Number of participants	10 .
Inclusion Criteria	1. Adults who are not wheelchair users. 2. Willing and able to provide a valid consent. 3. Able to participate in interviews aided or unaided using preferred method of communication. 4. Willing to drive a powered chair. 5.
Exclusion Criteria	1. Lacks capacity to consent
Evaluation Criteria	Evaluation of obstacle alerting system by; <ul style="list-style-type: none">• Adults who are not wheelchair users• Comparative analysis of driving patterns with and without the obstacle alerting system.• Analysis of driving patterns through smoothness movement, joystick deflection, positional mapping and daily usage. Searching for correlation between these patterns and user well-being, medication and location/environment.• Analysis of pre and post-trial interviews.
Participation duration	Typically up to 5 days
Duration of the study	9 months

2 Background

NOTE: Powered chair users will have underlying conditions which will make them more vulnerable to the impact of COVID-19. Therefore this revised protocol has been developed where adults who are not wheelchair users will carry out a preliminary evaluation of the Obstacle Alerting System.

2.1 Introduction

The goal of the project, “Empowerment of Disabled people through the User Coproduction of Assistive Technology” ([EDUCAT](#)), is to work with all stakeholders – including powered wheelchair users, carers, academics, healthcare professionals, user groups and industry - to develop an Assistive Powered Wheelchair. It is hoped that this Assistive Powered Wheelchair will include the following potential benefits to the user:

- Monitoring of changes in user wellbeing
- Monitoring the effect of medication
- Providing driving assistance to increase user confidence and safety in driving
- Enabling access to independent mobility for those not meeting current PWC prescription criteria

The EDUCAT project began with the development of a prototype driving assistance system [obstacle detection and avoidance] which was part of a three year European Union project, [SYSIASS](#)¹⁻⁷ by partners at the East Kent Hospitals University NHS Foundation Trust [EKHUFT], the University of Kent, University of Essex and ISEN University, Lille.

The goal of this prototype system was to improve the confidence and safety with which users can drive powered wheelchairs [PWC] by reducing the probability of collisions, especially when passing through doorways or down narrow corridors. The system achieved this by detecting the presence of obstacles and then modifying the PWC trajectory to avoid collision with those objects.

A further 12 month EU project, Empowerment of Disabled People through Ethics in Care and Technology [[EDECT](#)] then trialled this system with 12 PWC users recruited from the UK [REC reference: 14/EE/0164, Minor Amendment 2, Amendment date: 11 February 2015, IRAS project ID:141444], France, Belgium and the Netherlands. The system was further developed to include a prototype system to record and analyse the user’s joystick movements and to provide basic tactile/haptic feedback to alert the user that an obstacle is being approached and that the driving assistance system is beginning to modify the wheelchair trajectory.

The goal was to use pre and post-trial interviews to collect user specifications for the development of the PWC with Driving Assistance and their evaluation of their experience of driving the PWC with the collision avoidance system. These trials took place under carefully controlled conditions. The initial analysis of user joystick movement provided evidence to support the hypothesis that user state and driving confidence might be indicated by their individual driving patterns. The user feedback on the haptic feedback made it evident that a range of feedback options were required.

Building on the outcomes of these projects, the EDUCAT project has been funded for four years through the Interreg Va 2 Seas programme [10/2016 – 09/2020].

This project is broken down into three stages.

Stage 1: The goal of this stage was threefold.

Firstly to collect demographic information about the carers and users volunteering to take part in this stage.

Secondly questionnaires to obtain carer and user input to the criteria for the design and development of an assistive powered wheelchair.

Thirdly to further evaluate the hypothesis that the user’s driving patterns can provide diagnostic information about their condition and how confidently they are driving the powered chair.

To do this a recording system has been developed to collect data from;

- the powered chair data bus, including the user’s joystick movements.

- an inertial measurement unit (IMU)
- a Global Positioning Satellite (GPS) unit.

The IMU unit records acceleration, rate of turn and magnetic field. The data from the IMU will be used to identify any physical events e.g. collisions, passing over dropped kerbs etc. The GPS data will help to identify when the user is out of doors.

The hypothesis is being evaluated through analysis of the user's joystick movements, IMU and GPS data which will be correlated with the user's daily record of their perceived well-being, medication and the environments in which they are using the chair.

This stage is currently being run by East Kent Hospitals and Sussex Community NHS Foundation Trust [IRAS ID 235049].

Stage 2 Develop the Stage 1 system to include obstacle alerting. This system includes obstacle detection sensors e.g. infra-red, ultrasound and cameras, and a feedback system. The feedback system will have the options of auditory, haptic and visual information. This feedback will provide the user with information about the location and proximity of nearby objects. The hypothesis is that this information could help the user to drive more safely and confidently by being made aware of these objects.

The user is to evaluate this system.

Questionnaires will be used to collect user feedback before, during and after the each trial.

The anonymised data collected throughout the trial will be stored in local memory and also securely transmitted via the internet to the cloud.

The analysis of this data will be used to inform the on-going development of an obstacle alerting system which will help the user to drive more safely and confidently; thus enhancing the user's independent mobility and quality of life.

Stage 3: The Stage 2 system will be developed to use the information from the sensors to provide driving assistance by modifying the PWC trajectory to avoid collisions.

The efficacy of the system will be measured through analysis of the user's driving patterns, coupled with user interviews. This analysis will help to assess the effectiveness of this driving assistance system and provide feedback for the development of a user acceptable driving assistance system.

It is anticipated that the system developed by the end of Stage 3 will provide a basis for an assistive PWC that can be used for a range of tasks for PWC users including; improving user's access to independent powered mobility, monitoring changes in wellbeing and the effect of medication, monitoring progress during rehabilitation, training prospective users who may, with a driving assistance system, now be able to drive a PWC more safely and confidently.

The goal is to enhance the user's independent mobility and quality of life.

Because of the challenging nature of this project Ethics and HRA approval are being applied for stage by Stage.

Stage 1 is now underway [IRAS ID 235049].

This study protocol relates to **Stage 2** where, because of the impact of COVID-19, the participants will no longer be powered chair users but adults who are not wheelchair users.

As the project technology is developed it is planned to submit an application for Stage 3.

2.2 Object Alerting System (OAS)

In order to alert the user to the presence of objects three components are added to the Stage 1 Trial system.

- Object detecting sensors
- Feedback to the user about the location and proximity of those objects.

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- Transmission of pseudonymised data to the project partner servers [The Cloud].

The system [Fig 1.] will consist of a Data Management Unit, using the propriety PWC data bus interface, a Communication and Control Unit [Android Tablet], Haptic feedback system, Reversing Camera and sensor nodes.

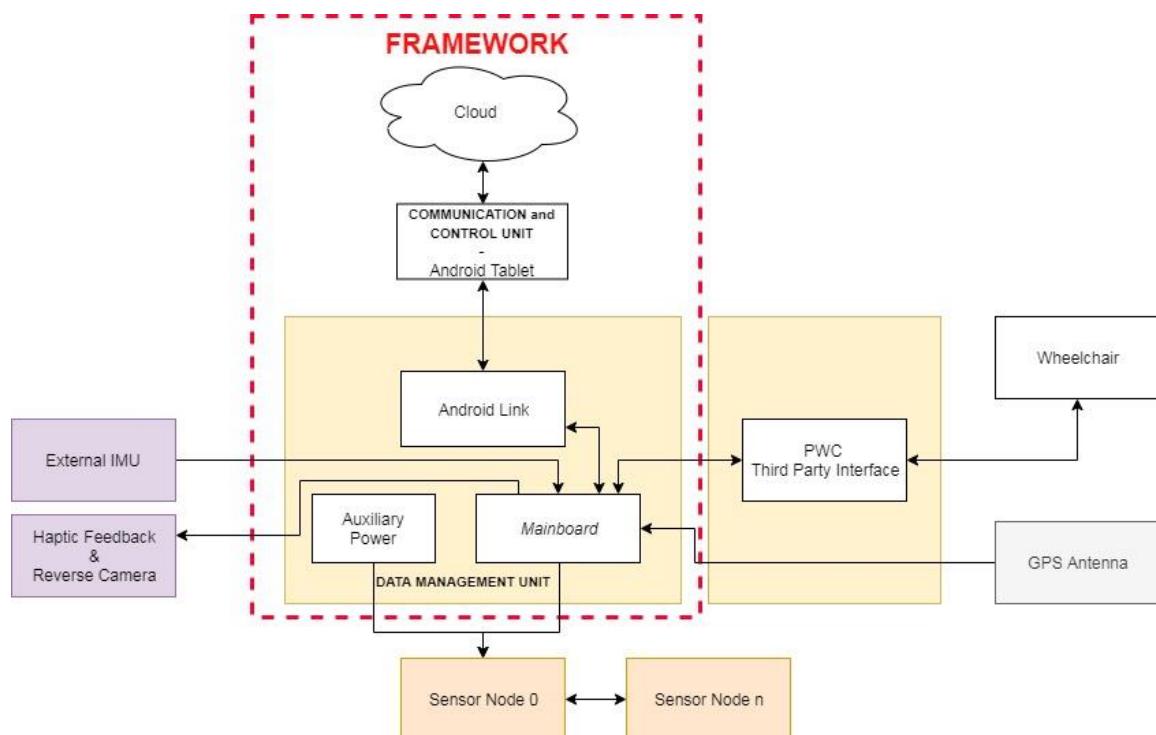


Figure 1: Obstacle Alerting System Block Diagram

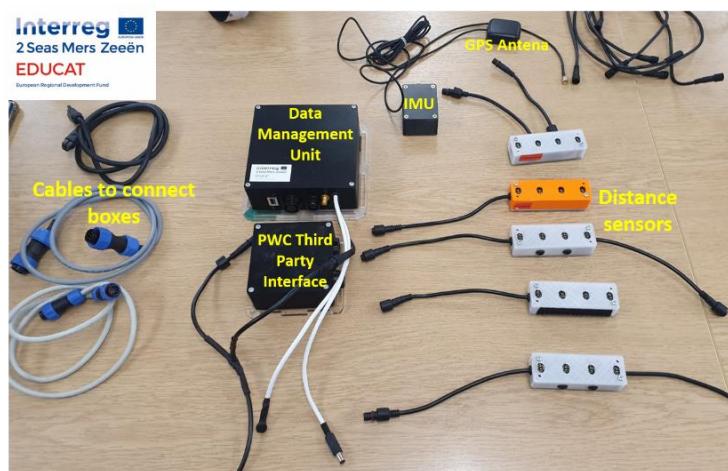


Figure 2: Obstacle Alerting System Components

The sensors, control unit and display unit will be attached to the wheelchair in a manner which will not mark or damage the wheelchair or inadvertently affect wheelchair stability.

In this modified trial the research team's powered chairs will be used.

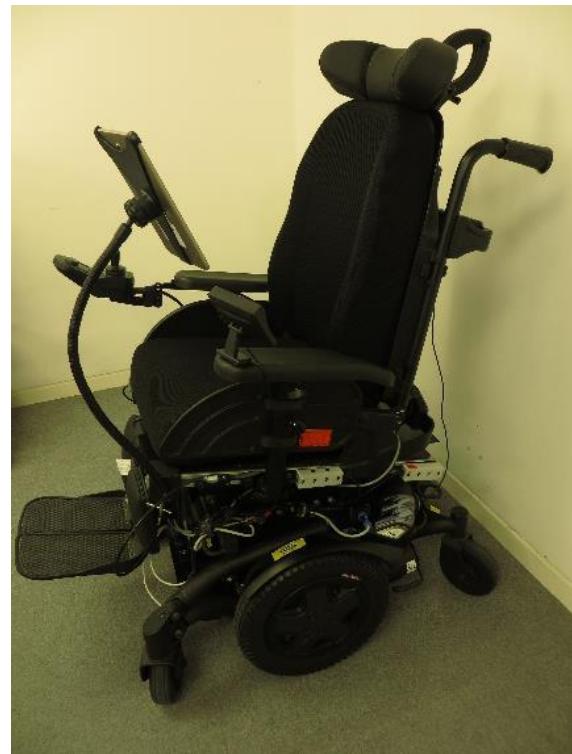


Figure 3: Example of a Powered Chair with Sensors and Display Units

2.2.1 The Data Management Unit

The Data Management Unit [DMU] collects data from the powered chair data bus and the sensors. It will also control the reversing camera and haptic feedback.

The Data Management Unit is connected to an Inertial Measurement Unit, a GPS unit, the proprietary Third Party Interface, the PWC data bus, the sensors and to the Communication and Control Unit.

The DMU can record:

- Time and date
- User Joystick Movements
- Powered Chair User profiles
- Whether actuators are being used
- Which controller is active – user or attendant
- GPS location – dependent on user consent
- Inertial Measurement Unit data
- Processed sensor data.

The DMU will transfer the data to the Communication Control Unit and display.

All data will be pseudonymised.

2.2.2 Powered Wheelchair Third Party Interface

In order to develop these systems it is necessary to safely extract data from the PWC data bus about the user's joystick activity and other control information made available by the manufacturer on the PWC.

[Dynamic Controls](#)¹⁰ have provided the bus interfaces for their DX and LiNX control systems. [Penny & Giles](#)¹¹ have made available the bus interface for their R-Net control system.

Dynamic and P&G estimate that they cover 95% of the powered chair control market worldwide.

2.2.3 Sensors and Data Recording

The sensors will be based on ultrasound, infrared, thermal and visible (camera) devices. The data from these sensors will be processed to provide the user with information about the location and proximity of objects close to the chair (within 2 metres).

The processing of any video data will ensure that it is not possible to identify any persons in the images, but only their presence and proximity.

The technology will be similar to that currently used to provide driving assistance in cars.

The sensor system also includes;

- **GPS Unit:** so that the location of the chair is known – whether outdoor or indoor. This information will help identify the impact of location on driving characteristics and of the efficacy of the OAS.
- **Inertial Measurement Unit:** The unit can be used to identify any physical events experienced by the chair. These events can be intended events e.g. climbing or descending kerbs, running over rough surfaces or potholes, docking against a bed. Or accidental events e.g. striking a door frame or wall. Data is to be analysed to try and identify signatures for these events.

2.2.4 The Communication and Control Unit

The Communication and Control Unit (CCU), a tablet computer, will process the data from the DMU and transmit pseudonymised data to the partners' secure server via the internet/mobile phone network.

The CCU also provides an interface to enable the:

- Researcher to configure the OAS before each trial
- Participant to configure feedback options
- Participant to enter data into questionnaires
- Participant to enter data into the Daily Diary throughout the trial
- Provision of Audio and visual feedback about object location and proximity (2.2.5).

2.2.5 Feedback to the Participant

The participant will be asked to evaluate a range of feedback options as follows:

Visual Feedback: Initially the participant will be provided with a display with minimal information to identify where objects are in relation to the wheelchair. Eventually a display with fuller data presentation, including an image of the surroundings and an indication of the proximity of that object, will be developed.

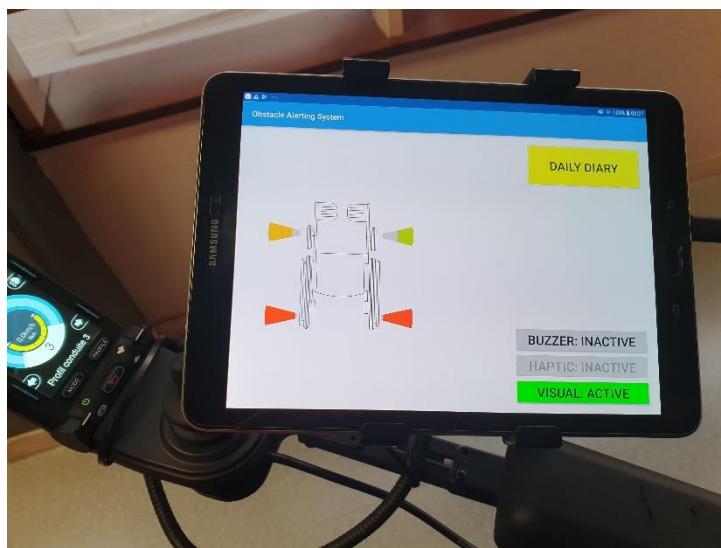


Figure 4: Visual Alert of Objects

Auditory Feedback: The participant will be provided with a range of options to evaluate. For example a basic beep with increasing pitch and/or volume or a spoken message giving information about the location and proximity of the nearest object. The auditory feedback can be used on its own or in combination with the visual feedback.

Haptic Feedback: Vibration of the joystick to alert the participant to the presence of objects in the vicinity of the powered chair. The strength and frequency of the vibration can be modulated to give some indication of object proximity. This feedback can be combined with the visual data such that the vibration alerts the participant who then inspects the display for additional information.

Reversing Camera: Users have identified reversing as a challenge and requested a reversing camera. This will use the same technology as that in a car. Initially the camera output will be connected directly to a separate display. The visual data will include marker lines to indicate the proximity of any objects and in the future an indication of the chair turning circle.

2.3 Project Partners

A multidisciplinary team of six partners are committed to EDUCAT.

- ISEN-Lille – Technical University and lead partner¹²
- School of Engineering and Digital Arts, University of Kent¹³.
- East Kent Hospitals University NHS Foundation Trust¹⁴
- Sussex Community NHS Foundation Trust
- Catholic University Leuven - KU Leuven¹⁶
- VOKA – Chamber of Commerce of East Flanders¹⁷

2.4 Stakeholders

One of the key factors underpinning EDUCAT is the involvement of all stakeholders. These stakeholders will be involved in the development and evaluation of the system from project start to conclusion.

The stakeholders include wheelchair users, carers, service providers, clinicians, observer groups and industry.

The stakeholders committed to EDUCAT team are:

France:

CRN-T APF Association des Paralysés de France¹⁸

The Eurosanté Development Agency¹⁹

ESIGELEG University Rouen²⁰

United Kingdom:

Dynamic Controls²¹

Penny & Giles²²

Kent Brain Injury Forum (KBIF)²³

Sir William Beveridge Foundation (SWBF)²⁴

Belgium:

DSP Valley (a SME cluster)²⁵

3 Objectives

3.1 Stage 2 Main Objectives

The main objective is to obtain feedback from the participants on the value and efficacy of the obstacle alerting system. This feedback will be used to inform the ongoing development and specifications for the OAS.

This feedback will be obtained as follows.

Demographic Information: A brief questionnaire will be used to collect demographic information about the participants volunteering to take part in this stage.

Design and Development: Interviews using questionnaires will be conducted before and after the trial to obtain participant input to the specifications for the design and development of an assistive powered wheelchair, with special focus on the obstacle alerting system.

Evaluate Participant Driving Patterns with and without Obstacle Alerting: The impact of the presence of an obstacle alerting system will be investigated. Building on the initial experience from the Stage 1 trial the recorded data will be correlated with the participant's Daily Diary and their feedback on the value of the alerting system.

Typical parameters will be the frequency of use of the chair, the number of collisions, the participant's selection of feedback options and their satisfaction with those options.

For example the measurement of frequency of use of powered chairs and the speeds at which chairs are driven has been investigated by Cooper et al³⁴. This research focused on usage patterns rather than on how the user was driving the PWC. However, even knowledge of the environment in which the chair is driven, the way in which a chair is driven and the frequency with which it is driven can inform the clinician whether the user is confident in driving the chair. Lack of confidence and/or increased number of collisions can arise because the chair has not been set up to match the user's driving ability and/or that the user requires some driving assistance to mitigate these difficulties.

Monitoring driving patterns with and without the obstacle alerting system could provide evidence of the efficacy of that system. In turn this will help to develop a system that will help to improve user confidence and their level of independent mobility and quality of life.

Therefore the goal of Stage 2 is to use participant feedback to help develop a configurable obstacle alerting system which will help improve user independent mobility by enhancing their confidence and safety in driving a powered wheelchair.

Once the risks presented by COVID-19 are managed then the system can be evaluated by wheelchair users and their carers.

3.2 Secondary Objectives

Stage 1 and Stage 2 will also provide the foundation for:

- Stage 3 of the project. To assess:
 - the impact of driving assistance [Obstacle Avoidance] on the user's ability to drive more safely and with greater confidence.
 - whether the level of driving assistance provided by the PWC should be modified as the user's condition changes.

4 Study Design and Evaluation

4.1 Participants/Sample Size

10 adult non wheelchair users from staff of East Kent Hospitals NHS Foundation Trust [EKHUFT], Sussex Community Foundation Trust [SCFT] and the University of Kent

4.2 Location

The primary location for the trial will be the participant's place of work.

4.3 User Inclusion and Exclusion Criteria

Inclusion Criteria:

1. Adults who are not wheelchair users.
2. Willing and able to provide a valid consent
3. Able to participate in interviews aided or unaided using preferred method of communication.
4. Willing to drive a powered chair.
- 5.

Exclusion Criteria:

1. Lacks capacity to consent.

4.4 Length of User Involvement

Participants will drive one of the project teams PWC which have been fitted with the OAS.

Participants will have two options.

1. Drive the chair several time over a prescribed course with and without the Obstacle Alerting System active.

The whole process from familiarisation to the end of trial could take up to one day. The participant will have the option of spreading the trial over shorter periods of testing. This will depend on their work environment and work commitments.

2. Drive the chair over a period of up to 5 days.

Half the time with the system off and half with it on.

In practice this period may be a day or two shorter or longer dependent on the occurrence of weekends, the availability of participants and on their working patterns..

4.5 Recruitment:

Participants will primarily be recruited from within EKHUFT, SCFT and the University of Kent. All potential participants will be given the study Participant Information Sheet. They will then be contacted by the local research team to ask if they are interested. If they are interested a meeting will be arranged at a time and place suitable for the potential participant where consent will be received to participate. Optional consent to have photographs and video taken will also be received.

4.6 Participant Anonymity

Participant identification will be pseudonymised.

Personal information will be kept on secure servers within the relevant NHS organisation.

Pseudonymised information will be kept on the secure servers of EKHUFT, the University of Kent, SCFT and of the French and Belgian partners.

4.7 Information and consent sheets

Participants will be issued with information and consent sheets.

- Participant Information Sheet
- Participant Consent Form
- Participant Image Consent Form

4.8 Questionnaires:

4.8.1 Enrolment Forms

The purpose of this form is to obtain or check demographic information. The participants will be issued unique ID code for use in the pseudonymised questionnaires.

These forms will be paper based and stored in a secure location at the relevant NHS partner organisation.

4.8.2 Pre-trial Questionnaires

The purpose is to obtain or verify the wheelchair user's medical information and to obtain their views on the possible configuration and value of an OAS. The questionnaire includes open ended questions to elicit preferences for the configuration of the system for their use during the trial.

Experience from Stage 1 shows that wheelchair users who are engaged in the project want to discuss in detail their experiences and ideas. Therefore the time to complete the interview can be approximately 1 hour.

4.8.3 Daily Diary

The participant will be asked to fill out the Daily Diary for the time periods that they are using the powered chair. The information from this diary will be used to correlate participant opinion of the OAS, their driving patterns and any changes due to those patterns with their:

- Feeling of wellbeing
- Level of Pain
- Taking of medication
- Environment in which they are using the PWC
- Opinion of the powered wheelchair
- Evaluation of the OAS – deficits and areas for improvement.

The diary will be completed using the CCU tablet. A paper version will be available as a backup. It is hoped that the use of an electronic diary will facilitate/encourage the entry of data by the participant and aid the analysis of the data from the OAS.

4.8.4 Post-Trial Questionnaire

At the end of the stage 2 trial the participant will be asked to provide their feedback on the obstacle alerting system and on the trial design.

This questionnaire will be face to face and conducted by the project team staff.. This should take less than 60 minutes.

4.8.5 Study Design

The trial will take place at the partner sites [EKHUFT, SCFT and the University of Kent]. The PWC will be provided by the study team and configured to suit the participant.

4.8.5.1 Pre-trial Enrolment Form

The enrolment form (4.7.1 & 2) will be completed.

4.8.5.2 Driving Training

The participant will take part in a familiarisation session so that they can learn to drive the PWC.

4.8.5.3 Familiarisation with the Obstacle Alerting System

The participant will be familiarised with the OAS. This will include:

- Overview of the system
- Training on how to enable and disable audio, visual and haptic feedback options
- Driving the chair with feedback provided around a prescribed course
- Configuration of the feedback options to suit the wheelchair user
- Reminder of how to adjust this configuration during the trial to suit their environment and preferences
- Operation of the data input device to access the Daily Diary.

The participant will use this familiarisation to inform the team of their preferences for setting up the OAS in terms of sensitivity to objects and the preferred feedback mode.

The participant will be provided with a user manual and an information sheet telling them what to do and who to contact in case of faults with the system or any other questions.

4.7.6.3 Data Recording

The participant will have the choice of which study protocol they wish to follow. Data will be recorded with the OAS feedback turned off and turned on.

This allows the collection of comparative data on how the obstacle alerting system may influence and affect aspects of driving, including confidence in different environments.

4.9 Outcome Measures

4.9.1 Analysis of Questionnaires

The main goal of this stage is to obtain participant feedback on the design and value of the OAS.

This information will be fed into the ongoing refinement of Stage 2 and the development of Stage 3 of the project.

Participant feedback will also be used to refine the information sheets, questionnaires and Daily Diary.

4.9.2 Driving Data Analysis

The recorded data will be analysed to examine the correlations between:

- Time and Date
- Joystick Movement Smoothness²⁶⁻²⁸
- Joystick Displacement patterns
- PWC collisions
- Time spent driving the chair
- Use of Actuators
- Location of the chair

- Daily Diary information [4.8.3]

4.9.3 Driving data Analysis Correlation with Daily Diary Information

This driving analysis data will be correlated with the information recorded in the Daily Diary - reported wheelchair participant wellbeing, medication, location in which the PWC is being driven and impact/usefulness of the OAS - over the intervals of morning, afternoon, evening and night. This information will be used for future trials with wheelchair users. The data analysis software developed with normal participants will be used in the on-going evaluation of the hypothesis that:

- each wheelchair user has their own driving characteristics which also depend on wheelchair user
 - wellbeing
 - medication
 - environment/location

and that these characteristics and changes in these characteristics can

- identify the wheelchair user
- inform the wheelchair user and clinician about wheelchair user health and changes in health
- monitor the effect of medication – if any
- monitor the impact of the OAS

4.10 Stage 2 Trial Study Duration

The study duration is 9 months.

The duration for the participant is estimated to be a maximum of two hours for enrolment and the pre and post Stage 2 trial interviews. This duration will depend on the level of engagement of the participant.

It is estimated that the participant will spend 10 minutes a day filling out the Daily Diary.

The participant will drive the chair for up to 5 days dependent on the protocol chosen. Of this time, half will be with the system inactive and half with the system active.

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