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Can a computer game designed to rehabilitate young people with visual field loss improve functional vision?

Submission date
09/12/2013

Recruitment status
No longer recruiting

Registration date
29/01/2014

Overall study status
Completed

Last Edited
11/03/2019

Condition category
Eye Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The visual field is the portion of the space around a person that can be seen at any one time without moving the eyes. Damage or disease to areas of the brain which process vision can result in a loss of part of the usual field of vision. Recent research has shown that certain rehabilitation approaches can be used to improve the functional vision of adult stroke patients with visual field loss. One particular method has been to use specialised computer software that requires visually scanning the images displayed on a monitor. However, these tools are typically too boring and often unable to engage young people for the long periods required for training to be effective. We are carrying out a feasibility study to pilot a computer game designed to rehabilitate young people with visual field loss. Our goal is to determine whether this training is effective in improving functional vision and to explore the potential of computer games technology to increase engagement with rehabilitation programmes.

Who can participate?
Young people between the ages of 7 and 25 years old can participate if they have a visual field loss due to damage or disease of the visual pathway in the brain. Potential participants must be able to perform a standard automated visual field assessment and have the capability of using a mouse, keyboard or touch screen to play the computer game.

What does the study involve?
All participants will receive the rehabilitation programme. The study involves a 6-week rehabilitation programme where participants are invited to play a computer game at home. Each session takes about half an hour to complete and participants will be asked to complete 30 sessions over the 6-week period (about 5 sessions per week). Participants will be asked to take part in four assessments of their vision one month before the programme, immediately before and after the programme, and one month after the programme.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement in functional vision as part of the rehabilitation programme, and information obtained from this study may benefit future vision rehabilitation

programmes by helping us to develop strategies that are more engaging for young people. Repetitive strain injuries have been associated with excessive use of computer games so the rehabilitation programme only allows the player to complete one session per day. Very rarely young people with epilepsy may be photosensitive, which means that flashing lights or certain colour sequences can trigger seizures. To minimise these risks we will be excluding potential participants with photosensitive epilepsy from this study.

Where is the study run from?
The study has been set up by the University of Lincoln and the WESC Foundation in Exeter. Vision assessments will be performed at the WESC Foundation or at Bristol Eye Hospital.

When is the study starting and how long is it expected to run for?
The study is expected to start in April 2014 and is expected to run until November 2014 or until the required number of participants have been recruited and assessed.

Who is funding the study?
The study is being jointly funded by the Technology Strategy Board, Medical Research Council and the WESC Foundation, UK.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
KTP 008989

Study information

Scientific Title
Can a computer game designed to rehabilitate young people with visual field loss improve functional vision? A case series intervention and feasibility study

Study objectives
Visual field loss is a visual impairment caused by damage to the visual pathway or areas of the brain that process vision, which results in missing areas of vision. This study will assess whether a computer game that has been designed to rehabilitate young people with visual field loss can improve their functional vision.

Current study hypothesis as of 18/07/2018:
Hypothesis 1: We anticipate that rehabilitation using the computer game will lead to improvements in the speed and efficiency of day-to-day activities that require visual search, and improvements in patient-reported outcome measures of functional vision and quality of life.

Previous study hypothesis:
Hypothesis 1: We anticipate that rehabilitation using the computer game will lead to improvements in the speed and efficiency of day-to-day activities that require visual search, and improvements in patient-reported outcome measures of functional vision and quality of life.
Hypothesis 2: We do not anticipate a significant improvement in the border of the visual field.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East Newcastle & North Tyneside 1, 30/05/2014, ref: 14/NE/0097

Study design
Case series intervention and feasibility study (interrupted time series design)

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

See additional files

Health condition(s) or problem(s) studied
Visual field loss

Interventions
All participants will receive training that will consist of playing the computer game for approximately 20-30 minutes to complete one session, and completing five sessions per week for 6 weeks (30 training sessions in total).

Four assessments of functional vision will be undertaken: one month before the rehabilitation programme begins, immediately before and immediately after the rehabilitation, and one month after the rehabilitation ends.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The speed at which participants perform 'activities of daily living' (ADLs), measured one month before the rehabilitation programme begins, immediately before and immediately after the rehabilitation, and one month after the rehabilitation ends.

Secondary outcome measures
Current secondary outcome measures as of 18/07/2018:
1. Scores on two patient-reported outcome questionnaires:
1.1. The Impact of Vision Impairment for Children (IVI_C) and
1.2. The Cardiff Visual Ability Questionnaire for Children (CVAQC)
Measured one month before the rehabilitation programme begins, immediately before and immediately after the rehabilitation, and one month after the rehabilitation ends.

Previous secondary outcome measures:
1. Perimeter and size of the visual field border
2. Scores on two patient-reported outcome questionnaires:
2.1. The Impact of Vision Impairment for Children (IVI_C) and
2.2. The Cardiff Visual Ability Questionnaire for Children (CVAQC)
3. Speed at which participants perform a mobility course and the percentage of brightly coloured cards found that are placed along the route.
Measured one month before the rehabilitation programme begins, immediately before and immediately after the rehabilitation, and one month after the rehabilitation ends.

Overall study start date
01/02/2013

Completion date
31/01/2017

Eligibility

Key inclusion criteria
Current inclusion criteria as of 18/07/2018:
Young people (7-25 years old, male and female) with bilateral visual field loss caused by a lesion of the post-geniculate optic pathway or visual cortex

Previous inclusion criteria:
Young people (8-25 years old, male and female) with bilateral visual field loss caused by a lesion of the post-geniculate optic pathway or visual cortex

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
10

Total final enrolment
9

Key exclusion criteria
1. Cognitive or physical impairments which cause a formal assessment of the visual field (standard automated perimetry) to be impractical
2. The inability to use either a mouse, keyboard or touch screen to access the game

Date of first enrolment
01/07/2014

Date of final enrolment
31/07/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
WESC Foundation
Topsham Road
Exeter
United Kingdom
EX2 6HA

Study participating centre
University of Lincoln
Brayford Pool
Lincoln
United Kingdom
LN6 7TS

Study participating centre
Bristol Eye Hospital
Lower Maudlin Street
Bristol
United Kingdom
BS1 2LX

Study participating centre
Torbay Hospital
Lowes Bridge
Torquay
United Kingdom
TQ2 7AA

Study participating centre
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
University of Lincoln (UK)

Sponsor details
c/o Professor Sara Owen
Brayford Pool
Lincoln
England
United Kingdom
LN6 7TS

Sponsor type
University/education

Website
http://www.lincoln.ac.uk

ROR
https://ror.org/03yeq9x20

Funder(s)

Funder type
Research council

Funder Name
Technology Strategy Board

Alternative Name(s)
TSB

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
WESC Foundation (UK)

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
30/09/2018

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study are available upon request from jwaddington@wescfoundation.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V5	17/03/2015	02/06/2017	No	Yes
Participant information sheet	version V6	17/03/2015	02/06/2017	No	Yes
Participant information sheet	version V6	17/03/2015	02/06/2017	No	Yes
Participant information sheet	version V6	17/03/2015	02/06/2017	No	Yes
Basic results	results	12/07/2018	18/07/2018	No	No
Results article		01/11/2018		Yes	No
HRA research summary			28/06/2023	No	No