Evaluating the effects of a virtual communication environment for people with aphasia

Submission date	Recruitment status	[] Prospectiv	
17/02/2016	No longer recruiting	[X] Protocol	
Registration date	Overall study status	[] Statistical	
23/02/2016	Completed	[X] Results	
Last Edited 15/03/2023	Condition category Signs and Symptoms	[X] Individual	

-] Prospectively registered
- Statistical analysis plan
- K] Individual participant data

Plain English summary of protocol

Background and study aims

Aphasia, or loss of language, is one of the most devastating consequences of stroke. While symptoms may be alleviated by speech and language therapy, many people are left with long term communication problems that profoundly affect their family, social and working lives. Loss of friends and feeling isolated are common. New online virtual technologies have exciting potential for people with aphasia. These are simulated environments, on the internet, where people can meet and talk. They offer a novel way for developing verbal communication (talking) skills, and can simulate social contexts in which to practice those skills. They also have the potential to reduce social isolation. Eva Park is a virtual environment developed by the researchers containing a number of simulated locations including houses, restaurants, a tropical bar, a health centre and a disco. Users are represented by avatars (moving images of people on the screen) and communicate using speech. Several people can use Eva Park at the same time, making it a place for social contact and communication. This study aims to find out if treatment delivered in this tailor made virtual environment benefits the communication skills of people with aphasia, increases their confidence in communication and reduces feelings of social isolation. It also explores ease of access to the environment and what the participants think about it.

Who can participate?

Adults diagnosed with aphasia following a stroke which happened at least 4 months before the start of the study.

What does the study involve?

Participants are recruited into the study in one of four groups. Those participants in the first and third recruitment groups (or cohorts) are allocated to the immediate group. Those participants in recruitment cohort 2 and 4 are allocated to the waitlist group. Participants are assigned to each group in order of recruitment – that is, the first five participants are assigned to cohort one, the next five to cohort two and so on. This means that there are four treatment (intervention) periods, one for each cohort. Participants in the immediate group receive the intervention between weeks 2 and 6, and then no further treatment between weeks 7 and 13. Participants in

the waitlist group receive no treatment between weeks 1 and 7, but do receive it between weeks 8 and 12. The intervention involves five weeks (25 hours) of access to Eva Park in order to help develop participants verbal communication skills. They receive daily sessions with support workers and they work on communication goals. For example, they might target asking questions or improving their vocabulary. Some people might want to improve particular communication tasks, such as enquiring about swimming classes. Activities in Eva Park include role plays, conversation and group discussions. The effects of the intervention are assessed using a measure of everyday communication, a confidence rating scale and a measure of social isolation. Word retrieval (or "finding" a word) is also assessed in a category naming task, during conversation and in storytelling. Each participant is assessed three times in week 1,7 and 13 following their recruitment. They are also interviewed, to explore their views about the intervention and are observed using Eva Park. The waitlist is used so that assessment scores can be compared between those who have and have not (yet) received the Eva Park treatment.

What are the possible benefits and risks of participating?

Participation may improve communication skills and confidence and reduce feelings of isolation. However, such benefits cannot be assured. Even if there are benefits across the group, individual responses may vary. Possible risks are very low. There are no medical risks; e.g. drugs are not being administered. Participants have to give up some of their time and may find sessions in Eva Park tiring.

Where is the study run from? City University London (UK)

When is the study starting and how long is it expected to run for? September 2012 to March 2016

Who is funding the study? The Stroke Association (UK)

Who is the main contact? Professor Jane Marshall J.marshall@city.ac.uk

Study website http://smcse.city.ac.uk/eva/

Contact information

Type(s) Public

Contact name Prof Jane Marshall

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers TSA2011/2010

Study information

Scientific Title

Evaluating the effects of a virtual communication environment for people with aphasia: a single centre quasi randomised controlled trial

Study objectives

Will access to a virtual communication environment improve communication skills in people with aphasia? Will access improve confidence and reduce feelings of social isolation? Will effects be maintained? What are participants' views about the virtual environment and its accessibility?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the School of Health Sciences, City University London, 21/12/2012, ref: LCS /PR/Staff/12-13/05

Study design

Single centre quasi randomised controlled design

Primary study design Interventional

incervencional

Secondary study design Quasi randomised controlled trial

Study setting(s) Community

Study type(s) Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Aphasia

Interventions

Participants were recruited in 4 cohorts. Two cohorts (1 and 4) were randomly allocated to the immediate group and two (2 and 3) to the waitlist control group. Assignment of the cohorts was determined at the outset of the study, before any recruitment took place. Participants were assigned to the cohorts in order of recruitment; i.e. the first five recruits were assigned to cohort one, the next five to cohort two and so on. This meant that there were four periods of intervention, one for each cohort. Testing occurred at three time points following participant recruitment: week 1, week 7 and week 13. Participants in the immediate group received the intervention between week 2 and week 6, and no further intervention between week 7 and week 7; but received the intervention between week 8 and week 12. The intervention consisted of five weeks (25 hours) of language stimulation provided in a bespoke virtual communication environment called Eva Park. Treatment was provided by trained support workers. All participants received the same protocol of intervention, either immediately or after a delay.

Intervention Type

Behavioural

Primary outcome measure

1. Functional communication, assessed by the Communication Activities of Daily Living - 2 Test (CADL-2, Holland et al, 1999)

2. Communicative confidence, assessed by the Communication Confidence Rating Scale for Aphasia (CCRSA, Babbitt & Cherney, 2010)

3. Feelings of social isolation, assessed by the Friendship Scale (Hawthorn, 2006) Measures were administered at three time points post participant recruitment: week 1, week 7 and week 13

Secondary outcome measures

1. Verbal fluency, using a category naming task

2. Word retrieval in conversation, using indices from the Profile of Word Errors and Retrieval in Speech (POWERS, Herbert et al, 2013)

3. Word production in narrative, using indices from the Quantitative Production Analysis, Berndt et al, 2000)

4. The Social Network Analysis (Antonucci & Akiyama, 1987) examined whether participants' social contacts expanded as a result of the intervention

All measures were administered at week 1, week 7 and week 13

Participants' views about the intervention were also probed with post intervention interviews Human Computer Interaction assessments, involving structured observations during intervention, explored their use of Eva Park

Overall study start date

10/09/2012

Completion date

31/03/2016

Eligibility

Key inclusion criteria

1. Diagnosis of aphasia following a stroke that occurred at least 4 months prior to the study

2. Fluent users of English prior to their stroke

3. Some spoken output (scoring at least 20% correct on the picture naming subtest of the Comprehensive Aphasia Test (Swinburn et al, 2004)

4. Impaired functional communication

Participant type(s) Patient

Age group Adult

Sex Both

Target number of participants 20

Key exclusion criteria

1. No uncorrected visual impairment

2. No hearing loss above 40Db

3. No severe impairments of speech comprehension (scoring above 70% correct on the CAT test of Spoken Word to Picture Matching; and above chance on the CAT test of Sentence to Picture Matching).

Date of first enrolment

01/02/2013

Date of final enrolment 31/12/2014

Locations

Countries of recruitment England

United Kingdom

Study participating centre City University London Northampton Square London United Kingdom EC1V 0HB

Sponsor information

Organisation City University London

Sponsor details Northampton Square London England United Kingdom EC1V 0HB

Sponsor type University/education

ROR https://ror.org/04489at23

Funder(s)

Funder type Charity

Funder Name Stroke Association

Alternative Name(s)

Funding Body Type Private sector organisation

Funding Body Subtype Associations and societies (private and public)

Location United Kingdom

Results and Publications

Publication and dissemination plan

1. Four publications are planned from the study. The first two have been published (see below). The third will report the results of the human computer interaction assessments and will be submitted by Summer 2017. The fourth will report the results of the participant interviews and will be submitted by August 2017.

2. Dissemination events at our University and off site will communicate the results to our participants and other people with aphasia. One event was held in June 2015 and a second (at Woburn Abbey Safari Park) is planned for February 2016. We are also visiting Stroke groups in London and beyond to demonstrate Eva Park and disseminate our findings, and have published on user group websites.

3. Dissemination activities are also targeting the computing design community. For example Eva Park was entered for the Tech4Good 2015 awards and won the people's prize.

4. Conference presentations have included: the British Aphasiology Society Biennial conference (London 2015), the 10th Saffran Memorial Conference (Philadelphia USA, 2015), the Danish Speech-Language-Hearing Association (Nyborg, Denmark, 2015).

Intention to publish date

01/08/2017

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are provided as supporting information with the results publication: https://doi.org/10.1371/journal.pone.0160381.s002

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	intervention design	02/01/2015		Yes	No
Results article	results	12/08/2016		Yes	No
<u>Dataset</u> Protocol (other)		12/08/2016 12/08/2016	15/03/2023 15/03/2023	No No	No No
<u>Protocol (other)</u>		12/00/2010	13/03/2023	NO	NO