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Can playing Neuro-World mobile games improve cognitive function in people who have had a stroke 2 years or more previously?

Submission date
22/03/2019

Recruitment status
No longer recruiting

Registration date
30/03/2019

Overall study status
Completed

Last Edited
08/01/2020

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Rehabilitation games have the potential to enable stroke survivors to repeatedly practice and improve their cognitive function. However, there are no mobile game solutions that are specifically developed for cognitive rehabilitation and clinically tested. The aim of this study is to test Neuro-World, six mobile games developed for cognitive rehabilitation.

Who can participate?
Stroke survivors with mild cognitive function in their chronic stage (1 year or longer since their last onset)

What does the study involve?
Participants are randomly allocated to one of two groups. One group play Neuro-World games for 30 minutes (5 minutes for each game) a day, 2 days a week for 12 weeks in addition to their medical care, while the other group receive only medical care. Participants are assessed before and after the treatment (12 weeks).

What are the possible benefits and risks of participating?
Study subjects may improve their cognitive function by participating in the study. Playing the games may cause eye and mental fatigue.

Where is the study run from?
Heeyeon Rehabilitation Hospital (South Korea)

When is the study starting and how long is it expected to run for?
September 2017 to October 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2018-4728

Study information

Scientific Title
Effectiveness of self-administered cognitive rehabilitation games in chronic stroke survivors with mild-to-moderate cognitive impairment: a randomized controlled trial

Acronym
Neuro-World Clinical Study

Study objectives

Self-administration of Neuro-World, mobile cognitive rehabilitation games, can improve cognitive function of chronic-stage stroke patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/05/2018, University of Massachusetts Amherst Institutional Review Board (Research Compliance Human Research Protection Office (HRPO), 108 Research Administration Building, 70 Butterfield Terrace, Amherst, MA 01003-9242; Tel: +1 (0)413-545-3428; Email: ncswett@ora.umass.edu), Protocol ID: 2018-4728

Study design
Single-center randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Stroke survivors with mild-to-moderate cognitive impairment (18 points or greater in K-MMSE) in their chronic stage (2 years or longer since their last onset)

Interventions
Participants were randomized using a random number generator. An experimental group self-administered 24 30-minute sessions of Neuro-World, six mobile games for cognitive rehabilitation, twice a week for 12 weeks in addition to their medical care while the control group received only medical care.

Intervention Type
Device

Phase
Phase II

Primary outcome measure
Overall cognitive function and impairment level measured using Korean Mini-Mental State Examination (K-MMSE) assessed before (baseline) and after the treatment (12 weeks)

Secondary outcome measures
Assessed before (baseline) and after the treatment (12 weeks):
1. Overall cognitive function and impairment level measured using Digit Forward Span (DFS), Digit Backward Span (DBS)
2. Overall depression level measured using Geriatric Depression Scale (GDS)

Overall study start date
15/09/2017

Completion date
30/10/2018

Eligibility

Key inclusion criteria
Current inclusion criteria as of 06/01/2020:
Stroke survivors with mild-to-moderate cognitive impairment (18 points or greater in K-MMSE) in their chronic stage (2 years or longer since their last onset)

Previous inclusion criteria:
Stroke survivors with mild cognitive function (18 points or greater in K-MMSE) in their chronic stage (1 year or longer since their last onset)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50 in 2 clusters (1 experimental group, 1 passive control group), and 25 participants for each cluster

Key exclusion criteria
Visual neglect

Date of first enrolment
05/06/2018

Date of final enrolment
05/07/2018

Locations

Countries of recruitment
Korea, South

Study participating centre
Heeyeon Rehabilitation Hospital
25 Woni-daero, Gyeongsangnam-do
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Korea, South
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Sponsor information

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University of Massachusetts Amherst

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Sponsor type
University/education

ROR
https://ror.org/0072zz521

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The analyzed results will be submitted to a clinical journal by the end of March 2019.

Intention to publish date
31/03/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available sharing the data was not part of the study plan, not approved by UMass IRB nor the study participants. Also, it was planned that the raw data would be removed completely once the analyzed results are published in academic journals. The data is currently stored in the secure online storage provided by UMass Amherst. The data is accessible only by researchers with valid authority.

IPD sharing plan summary
Not expected to be made available