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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
22/03/2019	No longer recruiting	<pre>Protocol</pre>
Registration date	Overall study status	<ul><li>Statistical analysis plan</li></ul>
30/03/2019	Completed	Results
Last Edited	Condition category	Individual participant data
08/01/2020	Circulatory System	<ul><li>Record updated in last year</li></ul>

## 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? Mr Hee-Tae Jung hjung@cs.umass.edu

# **Contact information**

## Type(s)

**Public** 

#### Contact name

Mr Hee-Tae Jung

#### **ORCID ID**

https://orcid.org/0000-0001-8921-570X

#### Contact details

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## Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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

## Study type(s)

Treatment

## 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(s)

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

## Key secondary outcome(s))

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)

## 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

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

#### Sex

All

## 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 Changwon Korea, South

51420

# Sponsor information

## Organisation

University of Massachusetts Amherst

#### **ROR**

https://ror.org/0072zz521

# Funder(s)

## Funder type

Other

#### **Funder Name**

Investigator initiated and funded

# **Results and Publications**

## 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

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes