ISRCTN71500761 https://doi.org/10.1186/ISRCTN71500761

Efficacy of computerized cognitive retraining in cognitive impairment after stroke

Submission date
03/07/2024

Recruitment status
No longer recruiting

Registration date
08/07/2024

Overall study status
Completed

Last Edited
22/01/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Vascular cognitive impairment (VCI) is a spectrum of cognitive disorders ranging from mild cognitive impairment to dementia caused by cerebrovascular disease. According to the World Health Organization (WHO), cerebrovascular accidents, commonly known as strokes, are the second leading cause of death globally, after ischemic heart disease. Those who survive strokes often face multiple disabilities, including motor, sensory, and cognitive impairments. Approximately 72% of stroke survivors experience some form of cognitive impairment, with about 30% developing severe conditions such as vascular dementia. The high prevalence of VCI underscores the need for effective treatment options aimed at improving cognitive functions and daily life activities. Existing cognitive retraining programs have shown improvements in neuropsychological test performances but have struggled to generalize these improvements to everyday functioning. This study aims to develop a Computer-adaptive Cognitive Remediation Program (CCRP) tailored to the needs of patients with VCI to enhance their cognitive functions and overall daily living abilities.

Who can participate?
Male patients aged between 18 and 60 years old diagnosed with vascular cognitive impairment

What does the study involve?
Participants will be randomly assigned to either the experimental group receiving the CCRP or the control group receiving Treatment As Usual (TAU). The CCRP will consist of daily sessions lasting one to one and a half hours for four weeks. The program includes tasks designed to improve various cognitive functions such as attention, working memory, information processing, mental speed, fluency, and visuospatial construction. The tasks will be adapted based on participants' performance levels to ensure optimal engagement and improvement.

What are the possible benefits and risks of participating?
The primary benefit of participating in this study is the potential improvement in cognitive functioning and overall daily living abilities. By participating in the CCRP, patients with VCI may experience enhanced cognitive functions that could translate to better performance in daily tasks and an improved quality of life.

There are minimal risks associated with this study. The main risk is the possibility of fatigue or frustration during the cognitive training sessions. Measures will be taken to minimize these risks, such as adjusting the difficulty of tasks and providing breaks as needed.

Where is the study run from?
The School of Social Science, Devi Ahilya University, Indore, Madhya Pradesh, India

When is the study starting and how long is it expected to run for?
January 2021 to December 2023

Who is funding the study?
The School of Social Science, Devi Ahilya University, Indore, Madhya Pradesh, India

Who is the main contact?
Amit Kumar Soni (Assistant Professor of Psychology), amit.soni7@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
CCRP-201924

Study information

Scientific Title
Effectiveness of Computer-adaptive Cognitive Remediation Program for Vascular Cognitive Impairment (CCRP-VCI)

Acronym
CCRP-VCI

Study objectives

1. There will be a significant improvement in the treatment group of the Computer-Adaptive Cognitive Remediation Program (CCRP) in the pre and post-assessment of cognitive function
2. There will be no significant difference between the pre and post-assessment of functional outcomes in the treatment group of CCRP
3. There will be no significant difference between the CCRP group and the Treatment As Usual (TAU) group on pre and post-assessment of cognitive functions
4. There will be no significant difference between the CCRP group and the TAU group on pre and post-assessment of functional outcomes

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/08/2021, Doctoral Research Committee, Devi Ahilya University (RNT Marg, Indore, 452001, India; Telephone number not provided; registrar.davv@dauniv.ac.in), ref: Acm/XI/Ph.D /Psychology/21/1932

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Intervention targeting cognitive functioning in vascular cognitive impairment

Interventions
This study will assess a cognitive retraining method called a Computer-adaptive Cognitive Retraining Program (CCRP) as compared to Treatment as Usual (TAU). CCRP will be a 4-week home-based use of computer adaptive cognitive training tasks similar to everyday life situations. Sessions are 30-45 minutes long, every day for at least 5 days a week. Every week, participants will be given 3-5 tasks of 5 to 7 minutes which tend to target specific cognitive functions. The randomization process will use a random number generator in Microsoft Excel. Each participant receives a random number: those from 0.00 to 0.49 were assigned to the Experimental group, and from 0.50 to 1.00 to the Control group. Participants will be given multiple tasks targeting the same function over four weeks. The control group will be given paper-pencil-based cognitive retraining which is similar to standard care for vascular cognitive impairment.

Intervention Type
Behavioural

Primary outcome(s)
The following cognitive functioning tests will be assessed pre and post-intervention as suggested by the National Institute of Neurological Disorders and Stroke (NINDS):
1. Animal Naming Test
2. Controlled Oral Word Association Test
3. WAIS III Digit Symbol Coding
4. Trail Making Test

5. Boston Naming Test
6. Auditory Verbal Learning Test
7. Ray O Complex Figure Test
8. Neuropsychiatric Inventory, Questionnaire Version
9. Center for Epidemiologic Studies Depression Scale (CES-D)
10. Informant Questionnaire for Cognitive Decline in the Elderly

Key secondary outcome(s)
Activities of Daily Living Function measured using the Barthel index (BI) and Lowton Instrument for Activities of Daily Living pre and post-intervention

Completion date
15/12/2023

Eligibility

Key inclusion criteria
1. Those who fulfill the diagnostic criteria for vascular cognitive impairment
2. Right handedness
3. Minimum education of 8th standard
4. Hindi/English speaking

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Male

Total final enrolment
100

Key exclusion criteria
1. Presence of severe aphasia/ dysphasia, right side hemiplegia
2. Presence of substance dependence other than tobacco
3. Presence of Major psychiatric disorder or mental retardation or other co-morbid neurological disorder
4. Co-morbid neurological disorders

Date of first enrolment
12/10/2021

Date of final enrolment
25/10/2023

Locations

Countries of recruitment
India

Study participating centre
School of social sciences, Devi Ahliya University
Davv Takshila Parisar, Indore
Indore, Madhya Pradesh
India
452001

Sponsor information

Organisation
Devi Ahilya Vishwavidyalaya

ROR
https://ror.org/05c2p1f98

Funder(s)

Funder type
University/education

Funder Name
Devi Ahilya Vishwavidyalaya

Alternative Name(s)
DAVV

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
India

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Amit Kumar Soni (Assistant Professor of Psychology), amit.ksoni@mp.gov.in. Shared data will be individual participant data underlining the results reported in the article, after deidentification (including text, tables, figures, and appendices). Data will be available beginning 3 months and ending 3 years following article publication. Consent was obtained from participants, agreeing that the data collected would be preserved and made available in anonymized form for consultation and reuse. There are no ethical or legal restrictions.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/01/2025	22/01/2025	Yes	No