ISRCTN12243194 https://doi.org/10.1186/ISRCTN12243194

The medical device Mindlenses for cognitive rehabilitation in stroke

Submission date
02/02/2024

Recruitment status
No longer recruiting

Registration date
07/02/2024

Overall study status
Completed

Last Edited
20/06/2024

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
Prism adaptation is a technique that involves wearing prismatic glasses to shift how a person sees the world. Studies have suggested that prism adaptation can change the activity of the brain hemisphere on the same side as the visual field change caused by the prisms. Stroke patients often experience changes in the activity of their brains on both the affected and unaffected sides. A necessary quality for a rehabilitation method is the ability to encourage changes in the activity of both sides of the brain in stroke patients with damage on one side. The aim of this study is to test the effectiveness of the medical device Mindlenses. Mindlenses combine prism adaptation with digital cognitive training through serious games to rehabilitate various cognitive functions in individuals who have had their first stroke.

Who can participate?
Patients aged 30-90 years with first-ever stroke

What does the study involve?
Patients are randomly assigned to an experimental group treated with Mindlenses or to a control group treated with standard rehabilitation. Patients wearing prismatic goggles are asked to make pointing movements towards visual stimuli presented on a tablet until adaptation to the visual distortion is reached. Immediately following this phase, the goggles are removed and the patients of the experimental group perform seven games on a tablet targeting attention, decision-making, planning and other cognitive functions.

What are the possible benefits and risks of participating?
There are no risks for participants. The expected benefits are an acceleration of improvement of cognitive abilities.

Where is the study run from?
Fondazione Istituto G. Giglio di Cefalù (Italy)

When is the study starting and how long is it expected to run for?
March 2019 to June 2022

Who is funding the study?
Restorative Neurotechnologies srl (Italy)

Who is the main contact?
Prof. Massimiliano Oliveri, massimiliano.oliveri@restorativeneurotechnologies.com

Contact information

Type(s)
Scientific

Contact name
Prof Massimiliano Oliveri

Contact details
Via Trinacria 23
Palermo
Italy
90144
+39 (0)3398857299
massimiliano.oliveri@restorativeneurotechnologies.com

Type(s)
Public, Principal Investigator

Contact name
Dr Sergio Bagnato

Contact details
Ospedale G Giglio
Cefalu
Italy
90015
+39 (0)921 920111
sergiobagnato@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Comparison of the efficacy of the combination of digital prism adaptation and serious games with standard rehabilitation for cognitive deficits in stroke patients

Acronym
StrokeMind

Study objectives
The medical device Mindlenses is at least comparable to standard cognitive training for the rehabilitation of cognitive deficits in stroke patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/06/2019, Comitato Etico Palermo 1 (Azienda Ospedaliera Universitaria Policlinico Paolo Giaccone, Via del Vespro, 129, Palermo, 90127, Italy; +39 (0)91 6551111; urp@policlinico.pa.it), ref: 06/2019

Study design
Interventional double-arm randomized non-inferiority 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
Cognitive deficits in stroke

Interventions
Experimental treatment with the medical device Mindlenses, combining prism adaptation with serious games in 10 days. Control treatment with standard cognitive training

Patients are randomly assigned by a simple randomization method to an experimental group treated with Mindlenses or to a control group treated with standard rehabilitation. Patients wearing prismatic goggles are asked to make pointing movements towards visual stimuli

presented on a tablet until adaptation to the visual distortion is reached. Immediately following this phase, the goggles are removed and the patients of the experimental group perform seven games on a tablet targeting attention, decision-making, planning and other cognitive functions.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Mindlenses

Primary outcome measure
All measured at baseline and immediately after the end of treatment:
1. General cognitive functioning will be measured using the Oxford Cognitive Screen
2. General intelligence and abstract thinking will be measured using the Ravens' Progressive Matrices
3. Verbal short-term and working memory will be assessed using Digit Span Forward and Backward Tests
4. Spatial short-term and working memory will be assessed using Spatial Span Forward and Backward Tests
5. Verbal long-term memory will be assessed using the Rey Auditory Verbal Learning Test, Immediate and Delayed Recall
6. Constructional apraxia will be measured using the Rey Complex Figure Copy, the Freehand Copy of Drawings and The Copy of Drawings with Landmarks Tests
7. Attention will be measured using the Attentive Matrices and The Line Bisection Tests
8. Inhibition abilities will be measured using the Stroop Test
9. Language production abilities will be measured using the Name and Verb Naming Tests
10. Lexical semantic abilities will be measured using the Semantic Fluency Test
11. Visuospatial perception abilities will be measured using the Visual Object and Space Perception Battery (VOSP)
12. Buccofacial apraxia will be measured using the Buccofacial Apraxia Test

Removed 13/06/2024:
13. Functional activities of daily living will be measured using the Barthel Index

Secondary outcome measures
All measured at baseline and immediately after the end of treatment:
1. Anxiety will be measured using the Beck Anxiety Inventory
2. Depression will be measured using the Hamilton Depression Scale

Added 13/06/2024:
13. Functional activities of daily living will be measured using the Barthel Index

Overall study start date
01/03/2019

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. First ever unilateral stroke
2. Aged 30-90 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
30 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. Bilateral stroke
2. Other neurological disease

Date of first enrolment
05/12/2019

Date of final enrolment
30/03/2022

Locations

Countries of recruitment
Italy

Study participating centre
Fondazione G Giglio
Cefalù

Italy
90015

Sponsor information

Organisation
Fondazione Istituto G. Giglio di Cefalù

Sponsor details
Contrada Pietrapollastra
Cefalù
Italy
90015
+39 (0)921 920111
protocollo@pec.hsrgiglio.it

Sponsor type
Hospital/treatment centre

Website
https://www.ospedalegiglio.it/sito/index.php

ROR
https://ror.org/03dykc861

Funder(s)

Funder type
Industry

Funder Name
Restorative Neurotechnologies srl

Funder Name
EIT Health

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer-reviewed journals

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request. Not sensitive data concerning the clinical characteristics of the recruited patients could be available.
Type of data: Excel files summarizing clinical and neuropsychological data of all tests at baseline and post-therapy sessions.
Consent forms are required and obtained by the hospital that conducted the trial.
The data sets could be requested from Prof. Massimiliano Oliveri (massimiliano.oliveri@restorativeneurotechnologies.com) or to Dr Agnese Di Garbo (agnese.digarborestorativeneurotechnologies.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			20/06/2024	No	No