

# The medical device Mindlenses for cognitive rehabilitation in stroke

<b>Submission date</b> 02/02/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 07/02/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/06/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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](mailto:massimiliano.oliveri@restorativeneurotechnologies.com)

## Contact information

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Scientific

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## 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.hsriglio.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.digarbo@restorativeneurotechnologies.com).

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>			20/06/2024	No	No