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Computerized cognitive training for pediatric patients with congenital or acquired brain injury

Submission date
06/10/2017

Recruitment status
No longer recruiting

Registration date
25/10/2017

Overall study status
Completed

Last Edited
21/11/2023

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Cognitive rehabilitation is widely considered to be an important need for patients with brain injury. Traditional cognitive rehabilitation is performed at specialized centers, where face-to-face or group interventions are delivered. However, this kind of intervention presents with some limitations, since it tends to be time-limited, costly, not accessible to all patients due to distance from care centers, and it does not guarantee the same treatment across clinicians. Recently, new rehabilitation programs based on technological devices have been introduced with the aim of increasing opportunities and consistency of rehabilitation. Usage of technology for rehabilitation also allows services to be provided at a distance and out of the medical setting. The aim of this study is to investigate the feasibility of home-based computerized cognitive training in Italian pediatric patients with brain injury, both congenital and acquired.

Who can participate?
Adolescents aged 11-16 with acquired or congenital brain injury who are native Italian speakers

What does the study involve?
Participants are randomly allocated to one of two groups. Group 1 receives the cognitive training for 8 weeks, followed by a comparable time with no treatment. Group 2 is put on a waiting list for 8 weeks (no-treatment) and then receives the cognitive training for the following 8 weeks. The training selected for this study is Lumosity Cognitive Training, a web-based program developed by Lumos Labs (San Francisco, CA, USA) providing different games aimed at stimulating different cognitive domains (flexibility, memory, speed, attention and problem-solving). This training allows automatic collection of data on both adherence and performance. For this study, five games of the program are used, each stimulating one of the five different cognitive domains trained by the program. Playing the selected games does not require the use of language, as the proposed activities are based on visual-spatial but not verbal information and are considered to be easy to understand and perform.

What are the possible benefits and risks of participating?
Benefits are expected in the cognitive domains covered by the training as well as quality of life. No risks are expected. Patients with photosensitive epilepsy are excluded to avoid any remote risk of seizure.

Where is the study run from?
Neurorehabilitation Units of the Scientific Institute IRCCS E. Medea –Bosisio Parini (Lecco) (Italy)

When is the study starting and how long is it expected to run for?
January 2016 to September 2020

Who is funding the study?
Italian Ministry of Health

Who is the main contact?
Dr Renato Borgatti

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
The Italian Ministry of Health Trial 44249

Study information

Scientific Title
Computerized cognitive training for pediatric patients with congenital or acquired brain injury: a home-based randomized controlled trial using the Lumosity platform

Study objectives
The aim is to investigate the feasibility and efficacy of a 40-session Lumosity cognitive training in a sample of Italian patients aged 11-16 with an acquired or congenital brain injury. As regards to efficacy, the aim is to estimate both neurocognitive and functional adjustment outcomes. The trialists hypothesize that Lumosity cognitive training may:
1. Result feasible to a population of pediatric non-English speaking brain injured patients, after a precise selection of exercises by the research team and a provision of instructions in original

mother tongue
2. Produce benefits in ameliorating cognitive performance
3. Generate an improvement of patients' quality of life and adjustment in patients who will show cognitive improvement

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Scientific Institute (IRCCS) Eugenio Medea, 01/03/2016, ref: #284 Rev. 1

Study design
Single-center clinical stepped-wedge control trial

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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Congenital or acquired brain injury

Interventions
The study applies a stepped-wedge research design, randomly assigning patients to one of 2 groups providing different research conditions: Group 1 (G1) receives the training for 8 weeks, followed by a comparable time of no-treatment; Group 2 (G2) remains in stand-by list for 8 weeks (no-treatment) and then receives the cognitive training for the following 8 weeks. More specifically, all participants are initially evaluated through a battery of neurocognitive tests tapping all cognitive domains stimulated by the training and questionnaires on adjustment (T1). Then, they are randomized into two groups. Children of G1 immediately start the 2 month training (step 1) and are re-evaluated at T2 after the training period. Then, they enter a 2 month non-treatment period (step 2). For G2 the 2 steps are inverted: at step 1 children wait and serve as control, while at step 2 they start the training. At T3, G2 is evaluated soon after treatment, while G1 receives a short term (2 months) follow-up assessment After 6 months from the end of the treatment, a long-term follow-up assessment is performed for both G1 (T4) and G2 (T5), in order to check for the long-lasting effects of the treatment.

The training selected for this study is LumosityTM Cognitive Training, a web-based program developed by Lumos Labs (San Francisco, CA, USA) providing different games aimed at stimulating different cognitive domains (flexibility, memory, speed, attention and problem-

solving). This training allows an at a distance automatic collection of data on both adherence and performance. The rationale behind the choice of this training was motivated by the unavailability in Italy of a brain training that focuses on a wide array of cognitive functions through an intensive, but time-limited stimulation and that allows precise collection and monitoring of data at a distance. Besides these motivations, the Lumosity Cognitive TrainingTM exhibits other important features considered to be necessary for this study:
1. It is adaptive, modifying the complexity of the games based on the individual performance; this aspect is particularly relevant considering that a sample of non-selected individuals with brain injury can be very inhomogeneous with respect to cognitive functioning
2. It allows an intensive daily training of limited duration (about 20 minutes), saving patients from excessive cognitive requests at an age where everyday life demands are high in both the academic and home environment
3. It has been already studied in different populations, both healthy and clinical
For this study, five games of the program were selected, each stimulating one of the five different cognitive domains trained by the program. Playing the selected games did not require the mediation of language, as exercises proposed activities based on visual-spatial but not verbal information and were considered to be easy to understand and perform.

Intervention Type
Behavioural

Primary outcome measure
To assess training feasibility:
1. Number of dropouts: number of children who renounce to complete the 8-week training
2. Number of sessions completed per child: total number of sessions done in front of the total number proposed of 40 sessions

To assess training acceptability:
1. Acceptability questionnaire: an ad hoc questionnaire completed by participants and another one by their parents after training conclusion to assess subjective evaluation of training accessibility and efficacy.

Primary outcome measure:
Visual-spatial working memory, assessed by Corsi block tapping task. All selected exercises of the training require the manipulation of the visual-spatial information and all of them, except for the game “Lost in Migration” stimulating attention, require the intervention of working-memory competencies. Children are required to indicate a visual-spatial sequence in the same order it was presented by the examiner. A z score will be collected.

Outcome measures collected at all assessment points for both groups of participants (T1;T2; T3; T4 for Group 1 and T1; T2; T3; T5 for Group 2).

Secondary outcome measures
1. Flexibility, assessed using the Wisconsin Card Sorting Test. In this test, children are requested to identify a rule for associating cards and then to modify it on the basis of a computerized feedback. WCST measures difficulties in selecting flexible strategies and in blocking an automatic responding, abilities that are central for flexible thinking. Adjusted standard scores for number of total errors, perseverative responsive and perseverative errors will be collected.
2. Speed, assessed using the reaction time index (HRT) of Conners’ Continuous Performance Test III, measuring time response to a visual attention task. During this task, children are requested to

press as fast as possible a button on the computer board in front of the presentation of any alphabetical letters comparing on the screen, except for letter X.
3. Attention, assessed using the visual attention task of Conners' Continuous Performance Test III. This attentional task ask children to press a button on the computer board in front of the presentation of any alphabetical letters comparing on the screen, but not letter X. Omissions, commissions and perseverations at this task are automatically
counted by the program and T-scores are collected.
4. Problem-solving, assessed using the problem solving and/or the arithmetical calculation tasks of the Italian battery AC-MT are used. An age-appropriate task is provided to each subject.
5. Adjustment and psychosocial functioning, assessed using Child Behavior Checklist 6-18 (Achenbach & Rescorla, 2001; http://www.aseba.org) completed by parents; Youth Self-report (Achenbach, 1991; http://www.aseba.org) completed by children; Teacher Report (Achenbach & Rescorla, 2001; http://www.aseba.org) completed by teachers. These instruments yield scores on internalizing, externalizing and total psychological problems of children.
6. Overall functioning and quality of life, assessed using the World Health Organization Quality of Life- Brief Version (WHOQOL; http://www.who.int/mental_health/publications/whoqol/en/) that assess quality of life, health and well-being of patients. This test is completed by subjects.
7. Self-esteem, assessed using the Italian version of the Multidimensional Self-Concept Scale, tr. It., Bracken, 1993), that assesses self-concept related to the following six domains: social, competence, affect, academic, family and physical. This test is completed by subjects.

Outcome measures collected at all assessment points for both groups of participants (T1;T2; T3; T4 for Group 1 and T1; T2; T3; T5 for Group 2).

Overall study start date
01/01/2016

Completion date
27/09/2020

Eligibility

Key inclusion criteria
Participants are recruited among the adolescents with a congenital or acquired brain injury who had been referred to the Neurorehabilitation Units of the Scientific Institute IRCCS E. Medea in the last year. Patients with acquired brain injury are considered eligible for the study only if they are in a chronical phase (i.e., at least 1 year post-injury). For the whole sample, inclusion criteria for eligibility are:
1. An age between 11 and 16 years, as in this age-range cognitive requests are generally elevated and individuals are usually able to use technological devices
2. Being native Italian speakers, as in this study demonstrations and instructions on training games were provided in Italian language

Participant type(s)
Patient

Age group
Child

Lower age limit
11 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
A final sample of 60 patients is set for such a study in order to detect within-group change of moderate effect size (Cohen's d = 0.47) with a power of 0.95 and alfa level set at $p < 0.05$. The software G Power 3 was used for this estimation

Total final enrolment
68

Key exclusion criteria
1. Severe sensory or motor deficits that could not be corrected through compensatory tools and could interfere with training execution and assessment
2. Being simultaneously involved in a different cognitive rehabilitation treatment, to prevent excessive demands to children and possible interference on training adherence rates
3. A diagnosis of photosensitive epilepsy, as computer-based stimulation could produce negative health effects in these patients

Date of first enrolment
02/03/2016

Date of final enrolment
27/11/2019

Locations

Countries of recruitment
Italy

Study participating centre
Scientific Institute IRCCS Eugenio Medea
Via Don Luigi Monza 20
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Sponsor information

Organisation
Scientific Institute (IRCCS) Eugenio Medea

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Sponsor type
Research organisation

Website
http://www.emedea.it

ROR
https://ror.org/05ynr3m75

Funder(s)

Funder type
Government

Funder Name
Ministero della Salute

Alternative Name(s)
Italian Ministry of Health, Italy Ministry of Health, Ministry of Health of Italy, Ministry of Health - Italy, Ministry of Health, Italy

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Italy

Results and Publications

Publication and dissemination plan
The protocol has not been published yet and will be published as supplementary material in the manuscript reporting the feasibility of the training. The results about feasibility and efficacy will be published in international peer-review journals. The trialists intend to publish the preliminary data on feasibility within 6 months and the preliminary data on efficacy after 1 year.

Intention to publish date

30/06/2021

Individual participant data (IPD) sharing plan
Data are collected in a protected database and are anonymized, as a research member assigns to each participant an identity number that substitutes the name. Participants' parents give written informed consent to anonymized data use. The anonymized data are available at request by sending an email to Dr Renato Borgatti or Dr Claudia Corti. Preliminary data on feasibility are available since July 2017. Data on efficacy will become available from March 2017. All data will be available for five years after the relevant publication. All materials and methods regarding data collection and treatment have been analyzed and approved by the Ethics Committee of Scientific Institute (IRCCS) Eugenio Medea and all procedures are in agreement with the principles expressed in the Declaration of Helsinki.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	feasibility study results	20/06/2018		Yes	No
Protocol file			21/11/2023	No	No
Results article	preliminary results in a sample of patients	29/01/2020	21/11/2023	Yes	No
Results article	study outcome results	04/09/2023	21/11/2023	Yes	No