Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

Investigating the effectiveness of the Verbal Working Memory-Balance (VWM-B) robotic training program on executive functions in children with developmental dyslexia

Protocol summary

Study aim

Investigating the short-term effectiveness of the Verbal Working Memory-Balance (VWM-B) robotic training program on executive functions (phonemic and semantic verbal fluency, trail-making, response inhibition, verbal working memory, and text comprehension) in Persian children with developmental dyslexia

Design

A randomized quasi-double-blinded clinical trial study with a between-within-subjects design.

Settings and conduct

Participants are children with dyslexia who are studying in public elementary schools located in District 20, Tehran, Iran. After receiving informed consent to participate in the study from the parents, they will be divided into two groups by block randomization method. Two groups will be adjusted to age, gender, IQ level, and attention level. Children will participate in the screening and pre-intervention assessments. Following 5 weeks of training (15 sessions), participants will participate in the post-intervention assessments. Participants and assessor(s) (out of research team members) are blinded in the current study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Normal IQ and attention levels, normal or corrected vision/hearing conditions, right-handedness, native- Persian language, and average socio-economic status. Exclusion criteria: History of neurological or psychiatric disorders, history of taking drugs affecting the central nervous system, not partaking in the after-intervention assessments, and failing to complete a minimum of 75% of the training sessions (4 out of 15)

Intervention groups

Experiment and control groups: The experiment group received 15 sessions of training by the VWM-B program, and the control group received 15 sessions of training by the VWM program.

Main outcome variables

Verbal semantic and phonemic fluency; trail-making; response inhibition; verbal working memory; and text comprehension

General information

Reason for update

Acronym

VWM-B

IRCT registration information

IRCT registration number: **IRCT20171219037953N2**
Registration date: **2023-10-18, 1402/07/26**
Registration timing: **retrospective**

Last update: **2023-10-18, 1402/07/26**
Update count: **0**

Registration date

2023-10-18, 1402/07/26

Registrant information

Name

Mehdi Ramezani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-03, 1402/01/14

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date
2023-04-03, 1402/01/14
Actual recruitment end date
2023-07-13, 1402/04/22
Trial completion date
2023-07-13, 1402/04/22

Scientific title
Investigating the effectiveness of the Verbal Working Memory-Balance (VWM-B) robotic training program on executive functions in children with developmental dyslexia

Public title
VWM-B program and executive functions in Dyslexia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Normal IQ level Normal attention level Normal or corrected vision/hearing conditions Right-handedness using the short form of Edinburgh handedness inventory Native-Persian language Average socio-economic status as reported by the family
Exclusion criteria:
History of taking drugs affecting the central nervous system History of neurological or psychiatric disorders Not partaking in after-treatment assessments Failing to complete a minimum of 75% of the training sessions (being absent in more than 4 out of 15 sessions)
Age
From **8 years** old to **10 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Using Excel software, we employed a block randomization method that divided our participants (N=30) into two equal groups. In Excel, the entire participants are encoded in a column with numbers from 1 to 30. At first, participants' names are written on separate pieces of paper. These papers are then seal, place in a bag, and randomly draw to assign each person a number from 1 to 30. Next to this column, another column is made. The participants are divided into five blocks of six people, and each block is assigned a number. From top to down, the first six people are numbered by block 1. The second six people are numbered by block 2 and so forth the last six people are numbered by block 5. Using the Randbetween function in Excel, three participants from each block randomly assign to the control group and the remaining three to the experiment group. This lottery process repeats for all five blocks, resulting in 15 participants in each group.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, all participants and an assessor who is not part of the research group will be blinded. Parents will be informed, but participants will not know which group they have been assigned to (the experiment group will receive verbal working memory-balance program training, while the control group will receive verbal working memory program training). Data will be collected before and after the treatment by a blinded assessor who will not know which group each participant belongs to. However, participants may become aware of the differences in training types through their parents or other means, making this a quasi-double-blinding study. This quasi-double-blinding approach is consistent with two previously reports that used the same training programs and the same grouping. Ramezani M, Behzadipour S, Fawcett AJ, Joghataei MT. Verbal Working Memory-Balance program training alters the left fusiform gyrus resting-state functional connectivity: A randomized clinical trial study on children with dyslexia. Dyslexia. 2023 Jun 19. Ramezani M, Behzadipour S, Pourghayoomi E, Joghataei MT, Shirazi E, Fawcett AJ. Evaluating a new verbal working memory-balance program: a double-blind, randomized controlled trial study on Iranian children with dyslexia. BMC neuroscience. 2021 Dec;22:1-7
Placebo
Not used
Assignment
Parallel
Other design features
As mentioned, participants may become aware of the differences in training types through their parents or other means, making this a quasi-double-blinding study.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Shahid Hemmat Highway
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Province
Tehran
Postal code
1449614535
Approval date
2023-02-22, 1401/12/03
Ethics committee reference number
IR.IUMS.REC.1401.987

Health conditions studied

1

Description of health condition studied
Developmental Dyslexia
ICD-10 code
R48.0
ICD-10 code description
Dyslexia and alexia

Primary outcomes

1

Description
Executive functions including verbal semantic and phonemic fluency, trail making, response inhibition, verbal working memory, and text comprehension
Timepoint
Before and after the intervention
Method of measurement
Questionnaires

Secondary outcomes

1

Description
Reading skills
Timepoint
Before and after the intervention
Method of measurement
Questionnaires

Intervention groups

1

Description
Experiment group: The newly designed VWM-B program has been performed using the robotic device. Like the VWM program, each training trial in the VWM-B program includes all three sub-processes of working memory (WM). The difference is that balance movements have been combined with the maintenance and retrieval steps of WM. Participants' standing condition was controlled for uniformity among subjects. The feet position on the platform was the same for all participants, with an approximate distance of 10 cm between the feet. Also, the monitor was located at eye level, with a distance of approximately 50 cm. For the encoding step, similar to the VWM program, a trial began 3 s after touching the start button on the monitor, and the main target box appeared on the monitor for 10 s. Then, the component boxes appeared on the screen. In addition to the component boxes, a red circle (CoP marker) also appeared on the screen. This circle represented the position of the subject's center of pressure and was used to introduce balance tasks to the program. As a new method, training the maintenance and manipulation of information was performed in two forms: passive and active balance. In the passive state, the motorized moving platform underneath the subject's feet was tilted and the CoP marker was correspondingly moved toward the component boxes implying a passive exercise. After the component box was hit by the CoP marker, the participant had 10 s to recite the word inside the box. Then, the platform and the CoP marker returned to the start position. This procedure was repeated for all component boxes in the correct order. In the active state, the platform had no tilting motion, and the subject had to actively move his CoP toward the component boxes using ankle/hip strategies. After hitting each component box, the participant attempted to read the word aloud without time limitation. Following reading the word, he returned to the start position and repeated the procedure for all component boxes. For the retrieval step in the VWM program, the target is shown and the user should accept or reject recalling the target. However, in the VWM-B program's retrieval step, the subject has to move his CoP to select the target. These texts are referenced by: Ramezani M, Behzadipour S, Pourghayoomi E, Joghataei MT, Shirazi E, Fawcett AJ. Evaluating a new verbal working memory-balance program: a double-blind, randomized controlled trial study on Iranian children with dyslexia. BMC Neurosci. 2021 Sep 15;22(1):55. doi 10.1186/s12868-021-00660-1. PMID: 34525977; PMCID: PMC8442443.
Category
Treatment - Devices

2

Description
Control group: While training with the VWM program, the subject sat on a chair in a relaxed mood with arms resting on the table. A 19-inch touchscreen monitor ran the software, which was specially designed for the proposed training program, and a speaker was used to recite the words. As mentioned above, each training trial of the VWM program includes all three sub-processes (encoding, maintenance, and retrieval steps) of the working memory (WM). Each trial began 3 seconds after touching the start button on the monitor. For the encoding step, the target, which could be a word, a series of words, or a statement, written inside a box (target box), was shown on the monitor for 10 s. At the same time, the target was recited by playing a pre-recorded voice on the computer. For the maintenance step, the target was decomposed into its components (sentence to its words or word to its letters) and shown on the monitor inside separate boxes (component boxes) for 10 s. Finally, for the retrieval step, twice as many boxes, which included the practiced components and new ones appeared on the monitor. The participant had 10 s to select and touch the boxes, which had appeared and been recited as a component of the target. These texts are referenced by: Ramezani M, Behzadipour S, Pourghayoomi E, Joghataei MT, Shirazi E, Fawcett AJ. Evaluating a new verbal working memory-balance program: a double-blind, randomized controlled trial study on Iranian children with dyslexia. BMC Neurosci. 2021 Sep 15;22(1):55. doi 10.1186/s12868-021-00660-1.

PMID: 34525977; PMCID: PMC8442443.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
learning disability centers in Shahr Rey (Tehran metropolis District 20)

Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Nurse and Midwifery Research Center

Grant code / Reference number
1401-3-25-24158

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

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Iran University of Medical Sciences

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available