Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of virtual reality on trunk control in children with developmental delays

Protocol summary

Study aim
To investigate the effect of virtual reality on trunk control in children with developmental delays

Design
randomized controlled trial , single blind, parallel group

Settings and conduct
The children hospital Faisalabad

Participants/Inclusion and exclusion criteria
• Willing to give consent. • Both gender male/female • Age limit 3-8 years (11) • Able to follow visual and verbal commands (16) • Gross motor function level II-IV (11) • Those with an appropriate cognitive level to understand a VR exercise program • Inability to follow instructions • Other Neurological disorders (polio, epilepsy, seizures, trumatic brain injury) • Malgnanices and Infectious disorders (encephalitis, meningitis, malignancy, tumors) • Patients having musculoskeletal problems (fracture, congenital hip dysplesia) • Spastic CP with Ashworth scale 2 + • Any surgery within last 6 months • A diagnosis of Autism or attention deficit disorders • Psychiatric disorder

Intervention groups
Group A receives baseline treatment utilizing neurodevelopmental treatment (NDT) principles, focusing on trunk control through three stages of exercises: initial stage for dynamic co-activation, second stage for weight shift facilitation, and third stage for trunk rotation induction. Group B, the study group, undergoes 24 sessions of baseline treatment combined with immersive virtual reality (VR) protocol over 8 weeks. Sessions last 30 minutes, with 15 minutes of NDT followed by 15 minutes of playing VR games targeting trunk control and gross motor function. Games involve dynamic adaptations for head and trunk movements to promote engagement and motor learning.

Main outcome variables
The trunk control measurement scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240307061203N1**
Registration date: **2024-03-24, 1403/01/05**
Registration timing: **registered_while_recruiting**

Last update: **2024-03-24, 1403/01/05**
Update count: **0**

Registration date
2024-03-24, 1403/01/05

Registrant information

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Gulraiz Ayub

Name of organization / entity
The University of Faisalabad

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-17, 1402/11/28

Expected recruitment end date
2024-03-30, 1403/01/11

Actual recruitment start date
2024-02-17, 1402/11/28

Actual recruitment end date
2024-04-30, 1403/02/11

Trial completion date
2024-05-02, 1403/02/13

Scientific title
Effect of virtual reality on trunk control in children with developmental delays

Public title
virtual reality on trunk control with developmental delays

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Willing to give consent. Both gender male/female Age limit 3-8 years Able to follow visual and verbal commands Gross motor function level II-IV Those with an appropriate cognitive level to understand a VR exercise program

Exclusion criteria:
Inability to follow instructions Other Neurological disorders (polio, epilepsy, seizures, traumatic brain injury) Malgnanices and Infectious disorders (encephalitis, meningitis, malignancy, tumors) Patients having musculoskeletal problems (fracture, congenital hip dysplesia) Spastic CP with Ashworth scale 2 + Any surgery within last 6 months A diagnosis of Autism or attention deficit disorders Psychiatric disorder

Age
From **3 years** old to **8 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **22**
Actual sample size reached: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization will be done with the help of lottery method. Lottery generated numbers will be drawn from the computer by the help of sample size. Different numbers will enter in the poll of group.

Blinding (investigator's opinion)
Single blinded

Blinding description
single blinded: outcome assessors are typically kept unaware of which participants received the experimental treatment and which received the control or comparative intervention. This blinding helps to prevent conscious or unconscious biases that could influence the assessment of study outcomes.

Placebo
Not used

Assignment
Parallel

Other design features
developmental delays, trunk control measurement scale

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research and Ethics/ technical committe for The University of Faisalabad

Street address
Faisal Town, West Canal Road, Faisalabad, Punjab

City
Faisalabad

Postal code
38000

Approval date
2024-01-05, 1402/10/15

Ethics committee reference number
TUF/Addl Reg/SB/753

Health conditions studied

1

Description of health condition studied
Delayed developmental milestone

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Trunk control

Timepoint
before and after 6 weeks of intervention

Method of measurement
Trunk control Measurement scale

Secondary outcomes

empty

Intervention groups

1

Description
Active Control group: this group will receive handling and facilitation principle of neurodevelopmental treatment approach will be utilize to encourage trunk weight bearing, uprightness and elongation. This intervention will be in three stages. In the initial stage, to stimulate flexors and extensors muscles dynamic co-activation and to maintain trunk upright without tilting body in sagital plane children will be asked to play with toys infront of them. In the second stage children will be asked to play with toys. Subsequently, toys will be placed at the child’s side to prompt weight shift, facilitating dynamic co-activation of trunk muscles and elongation of the weight-bearing side. In the third stage, elongation of the weight-bearing side will be continued by placing a toy at

approximately 45 degree to induce trunk rotation in horizontal plane. Trunk rotation will be fostering on weight bearing side in this phase.

Category

Rehabilitation

2

Description

intervention group: Patient in this group will receive handling and facilitation principle of neurodevelopment treatment approach will be utilize to encourage trunk weight bearing, uprightness and elongation. along with immersive virtual reality treatment protocol. It will involves 24 sessions in alternating three days a week for 8 weeks. this session will last for 30 minutes, starting with 15 minute of neurodevelopmental treatment followed by 15 minutes of playing immersive VR games with 1 minute rest interval. The first game involves participants features a bird's flight (bird's back), task is to collect to collect golden coins with dynamic adaptation for head and trunk movements. The second game representing planetary exploration (solar system) with head-trunk rotations, and third game entails climbing a elevator ride fouces on sitting posture, elongation and weight transfer, promoting hand and body movement.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Children Hospital & Institute of Child Health Faisalabad

Full name of responsible person
Dr. Gulraiz Ayub; PT

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

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

Title of funding source
The University of Faisalabad

Proportion provided by this source
100

Public or private sector
Private

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

Name of organization / entity
The University of Faisalabad

Full name of responsible person
Dr. Zainab Boota

Position
Consultant

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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Person responsible for scientific inquiries

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Position

Consultant clinical physiotherapist

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

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

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Effect of virtual reality on trunk control in children with developmental delays

When the data will become available and for how long
15 days after publication

To whom data/document is available
google scholar

Under which criteria data/document could be used
Access to the data will be facilitated through a specified mechanism, such as a secure online portal or data sharing platform. Requests for access will be reviewed by a designated committee or entity responsible for ensuring that they meet the established criteria and comply with relevant regulations and guidelines. Additional supporting information and documents may be provided to assist requesters

From where data/document is obtainable
The University of Faisalabad 38000 https://tuf.edu.pk/ 00924187509715

What processes are involved for a request to access data/document
To receive the documents or data files, the process typically involves the following steps: 1. Request Initiation: The applicant submits a formal request specifying the documents or data files they need. 2. Verification and Authorization: The organization verifies the request and ensures that the applicant is authorized to access the requested documents or data files. This may involve confirming the identity of the requester and checking their permissions. 3. Processing Time: The processing time varies depending on the complexity of the request, the volume of documents or data files, and any legal or regulatory requirements. It could range from a few hours to several weeks. 4. Document Retrieval or Data Extraction: Once the request is approved, the organization retrieves the documents from their archives or extracts the requested data from their databases. 5. Quality Assurance: Before releasing the documents or data files to the applicant, the organization may conduct quality checks to ensure accuracy and completeness. 6. Delivery: The documents or data files are delivered to the applicant through a secure channel, such as encrypted email, secure file transfer protocols, or a secure online portal. 7. Confirmation of Receipt: The applicant acknowledges receipt of the documents or data files, confirming that they have received the information they requested.

Comments