

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of virtual reality on trunk control and gross motor function in children with developmental delays

Protocol summary

Study aim

This study investigates the effect of virtual reality on trunk control and gross motor function in children with developmental delays

Design

Randomized controlled, parallel group trial with blinded outcome assessors. It will be lottery method where numbers will be computer generated.

Settings and conduct

The place of the study: The children hospital & institute of Faisalabad; the study population: children with developmental delays; type of the blinding: single blind (outcome assessors kept blind)

Participants/Inclusion and exclusion criteria

Inclusion criteria; Willing to give consent; Age limit 3-8 years; Ability 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) Malignancies and Infectious disorders (encephalitis, meningitis, malignancy, tumors); Patients having musculoskeletal problems (fracture, congenital hip dysplasia); Spastic CP with Ashworth scale 2+; Any surgery within last 6 months; A diagnosis of Autism or attention deficit disorders; Psychiatric disorder

Intervention groups

Active control group will receive neurodevelopmental treatment (NDT) focusing on trunk control through dynamic co-activation, weight shift facilitation, and trunk rotation induction for half an hour 3 times a week for 6 weeks. Intervention group undergoes 24 sessions combining NDT with immersive VR protocol targeting trunk control and gross motor function over 6 weeks. Sessions include 15 minutes of NDT followed by 15 minutes of VR gameplay with dynamic adaptations for motor learning including rest period of 1 minute.

Main outcome variables

The trunk control measurement scale score; gross motor function scale-88 score, HINE performance section 3

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240307061203N2**

Registration date: **2024-05-14, 1403/02/25**

Registration timing: **retrospective**

Last update: **2024-05-14, 1403/02/25**

Update count: **0**

Registration date

2024-05-14, 1403/02/25

Registrant information

Name

Gulraiz Ayub

Name of organization / entity

The University of Faisalabad

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-17, 1402/11/28

Expected recruitment end date

2024-04-17, 1403/01/29

Actual recruitment start date

2024-02-17, 1402/11/28

Actual recruitment end date

2024-04-30, 1403/02/11

Trial completion date
2024-04-30, 1403/02/11

Scientific title
Effect of virtual reality on trunk control and gross motor function in children with developmental delays

Public title
virtual reality on trunk control and gross motor function in children with developmental delays

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Willing to participate and giving consent Both genders male/female Age limit of 3-8 years of children Being 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) Malignancies and Infectious disorders (encephalitis, meningitis, malignancy, tumors) Patients having musculoskeletal problems (fracture, congenital hip dyspepsia) Spastic CP with Ashworth scale 2 + Any surgery within last 6 months A diagnosis of Autism or attention deficit disorders Psychiatric disorder or any cardiac anomalies affecting exercise intolerance Less than 4 months after undergoing surgery

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

Gender
Both

Phase
2

Groups that have been masked

- Outcome assessor

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

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization process will utilize a lottery method, where numbers generated by a computer will be drawn based on the sample size. The numbers will then be allocated to different groups in the poll, ensuring an effective distribution.

Blinding (investigator's opinion)
Single blinded

Blinding description
In single blinded outcome assessors will kept unaware of which participants received the experimental treatment and which received the control 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, gross motor functions, trunk measurement scale, virtual reality

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
gross motor developmental delays
ICD-10 code
R62.0
ICD-10 code description
Delayed milestone in childhood

Primary outcomes

1

Description
Trunk control
Timepoint
Before and after 6 weeks of intervention
Method of measurement
Trunk control measurement scale

2

Description
Gross motor function
Timepoint
Before and after 6 weeks of intervention
Method of measurement
Gross motor functional scale-88

Secondary outcomes

1

Description

Tone

Timepoint

Before and after 6 weeks of intervention

Method of measurement

Modified Ashworth Scale

2

Description

Cognition

Timepoint

Before and after 6 weeks of intervention

Method of measurement

HINE performa section 3

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 sagittal plane children will be asked to play with toys in front 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 18 sessions in alternating three days a week for 6 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 focuses 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

The University of Faisalabad

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

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

Wardah.jabbar5@gmail.com

Contact

Name of organization / entity

The University of Faisalabad

Full name of responsible person

The University of Faisalabad

Position

consultant clinical physiotherapist

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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