Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 accessors. 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; Ablility 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, trumatic brain injury) Malignancies 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
Active control group will receives 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 performa 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

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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
2024-04-17, 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 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 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 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Faisalabad
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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

Contact

Name of organization / entity
The University of Faisalabad

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Position
consultant clinical physiotherapist

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Master

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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