

# 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 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

##### Phone

+92 41 87509715

##### Email address

2022-ms-pt-014@tuf.edu.pk

##### 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, uprightnes 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, uprightnes 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

#### Street address

GC university, Jhang road, New Campus Dr,  
Faisalabad

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+92 41 9203065

#### Email

2022-ms-pt-014@tuf.edu.pk

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

The University of Faisalabad

#### Full name of responsible person

Syed Saqlain Babar

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Faisal Town, West Canal Road, Faisalabad, Punjab

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#### Phone

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syedsaqlain264@gmail.com

### 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**

Physiotherapy

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

Dr. Warda Jabbar

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Dr. Gulraiz Ayub

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**Latest degree**

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**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