

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### "Design and evaluation of the impact of active video games on joint range of motion, pain intensity, and motor function in children with burn injuries"

#### Protocol summary

##### Study aim

Design and evaluation of the impact of active video games on joint range of motion, pain intensity, and motor function in children with burn injuries

##### Design

Randomized controlled clinical trial whose statistical population will be 60 children aged 5-15 who have burns of less than 30% of the whole body and second degree burns. Stata software version 17 will be used for randomization.

##### Settings and conduct

The location of the project will be in the burn department of Imam Reza Hospital (AS) in Mashhad.

##### Participants/Inclusion and exclusion criteria

No visual impairment  
Absence of medical contraindications for doing practices (for example, epilepsy and cognitive disorders, orthopedic, cardiovascular problems, infection, hand amputation), which will be examined by a pediatrician. A child aged 5 to 15 years who has TBSA<30% and has second degree burns on the hand, wrist, elbow and shoulder. Existence of informed consent

##### Intervention groups

The intervention group will perform exercises through Xbox Kinect games based on the burn location. Children in the intervention group will play the games designed by the research team using the Xbox Kinect game console twice a day at 11 am and 5 pm. The location of the game console and TV for playing designed games will be one of the rooms of the burn department. The distance of children from the TV screen will be 1.5 to 2 meters and the duration of their exposure to the screen will be 15 to 30 minutes.

##### Main outcome variables

Range of motion (ROM) will be assessed using a gonyometer. Children's performance will be evaluated with the 30-item, 9-domain ASK (The Activities Scale for Kids) self-

report questionnaire, and children's pain intensity will be evaluated with the Wong-Baker FACES® scale. In both groups, range of motion and pain intensity score will be evaluated daily and at the time of discharge, and children's performance at the time of discharge.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230723058891N1**

Registration date: **2023-11-04, 1402/08/13**

Registration timing: **prospective**

Last update: **2023-11-04, 1402/08/13**

Update count: **0**

##### Registration date

2023-11-04, 1402/08/13

##### Registrant information

##### Name

Maryam Varzeshi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3739 3883

##### Email address

varzeshim4012@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-12-21, 1402/09/30

##### Expected recruitment end date

2024-05-19, 1403/02/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

"Design and evaluation of the impact of active video games on joint range of motion, pain intensity, and motor function in children with burn injuries"

**Public title**

"Design and evaluation of the impact of active video games on joint range of motion, pain intensity, and motor function in children with burn injuries"

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

No visual impairment  
Absence of medical contraindications for doing practices (for example, epilepsy and cognitive disorders, orthopedic, cardiovascular problems, infection, hand amputation), which will be examined by a pediatrician. A child aged 5 to 15 years who has TBSA < 30% and has second degree burns on the hand, wrist, elbow and shoulder. Informed consent  
Stabilization of the patient's hemodynamic conditions after hospitalization

**Exclusion criteria:**

Readmission of a child with burns for any reason  
Failure to participate in practicing sessions  
Leaving the child from the research project at the doctor's discretion  
Symptoms of infection

**Age**

From **5 years** old to **15 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The researcher selected the eligible patients as available and after introducing himself and providing explanations regarding the purpose of the research and the working method to them and obtaining informed consent, assigning them to the intervention and control groups randomly using the software. Stata (stata) version will be done. Then, permuted blocks with sizes 4 and 2 will be produced by a statistician with the help of Stata software version 17. To hide the allocation of each block, it will be placed in an envelope. After completing each sampling with the envelope, the envelope is discarded and the next envelope will be opened.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

**Other design features**

This research has two stages. In the first stage, by using the guidelines and applying the opinions of relevant specialists, the upper body exercises are prepared and short films are made based on them. Then these films will be used to make active video games. The second phase is a randomized controlled clinical trial, to investigate the effect of active video games on joint range of motion, pain intensity and performance of children with burns.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

**Street address**

Daneshgah Ave.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Approval date**

2023-10-17, 1402/07/25

**Ethics committee reference number**

IR.MUMS.NURSE.REC.1402.083

**Health conditions studied****1****Description of health condition studied**

Children with second degree burns on the upper limbs with total body burns less than 30%

**ICD-10 code**

T29.2

**ICD-10 code description**

Burns of multiple regions, no more than second-degree burns mentioned

**Primary outcomes****1****Description**

In the current study, motor performance is the score obtained by the subjects in the 30-question ASK (The Activities Scale for Kids) self-report questionnaire, which has 9 domains.

### **Timepoint**

upon discharge

### **Method of measurement**

The Activities Scale for Kids (ASK) is a 30-question self-report questionnaire that has 9 domains

## **2**

### **Description**

Pain intensity in the present study is the score obtained by the subjects in pain measurement. Pain intensity is measured using the Wong-Baker FACES® tool, which is in the form of 5 faces. Smiley number 5 has the most pain and smiley number 0 has no pain.

### **Timepoint**

Daily and upon discharge

### **Method of measurement**

Pain intensity is measured using the Wong-Baker FACES® tool, which is in the form of 5 faces. Smiley number 5 has the most pain and smiley number 0 has no pain.

## **3**

### **Description**

The range of motion of the joints in the present study is the score obtained by the subjects in measuring the range of motion of the joints with goniometry.

### **Timepoint**

Daily and upon discharge

### **Method of measurement**

Using goniometry

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

### **Description**

Intervention group: The intervention group will perform exercises through Xbox Kinect games based on the burn site. Children in the intervention group will play the games designed by the research team using the Xbox Kinect game console twice a day at 11 am and 5 pm. The location of the game console and TV for playing designed games will be one of the rooms of the burn department. The distance of children from the TV screen will be 1.5 to 2 meters and the duration of their exposure to the screen will be 15 to 30 minutes.

### **Category**

Rehabilitation

### **2**

### **Description**

Control group: The control group will receive standard exercises based on the location of the burn (equal to the number of sessions of the test group). Children in the control group will receive standard physical therapy that includes daily targeted therapy aimed at maintaining

normal ROM and muscle strength, preventing contracture formation and facilitating normal activities of daily living (ADLs) and activity according to protocols set in It is the burn part. In the control group, after warming up for 15 minutes, children play games like the one designed in Xbox Kinect for 15 to 30 minutes in the playroom with game equipment.

### **Category**

Rehabilitation

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Imam Reza Hospital

##### **Full name of responsible person**

Razie Froutan

##### **Street address**

on the edge of Imam Reza Square, Ibn Sina Street,

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

9137913316

##### **Phone**

+98 51 3854 3031

##### **Email**

froutanr@mums.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Mashhad University of Medical Sciences

##### **Full name of responsible person**

Mohsen tafaghodi

##### **Street address**

Azadi Square, East Gate of Ferdowsi University of Mashhad, University Campus, Shahid Dr. Kharazmi Educational Complex

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

9137913199

##### **Phone**

+98 51 3859 1511

##### **Fax**

+98 51 3859 7313

##### **Email**

nms.pr@mums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

**Title of funding source**

Mashhad 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

**City**

Mashhad

**Province**

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**Email**

froutanr@mums.ac.ir

**Web page address****Person responsible for general inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Razie Frootan

**Position**

Doctorate in Internal Surgery, Nursing

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Azadi Square, East Gate of Ferdowsi University of  
Mashhad, University Campus, Shahid Dr. Kharazmi  
Educational Complex

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**Postal code**

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froutanr@mums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Maryam Varzeshi

**Position**

Master's student in nursing majoring in internal  
surgery

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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**Email**

varzeshim4012@mums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Razie Frootan

**Position**

Doctorate in Internal Surgery, Nursing

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Azadi Square, East Gate of Ferdowsi University of  
Mashhad, University Campus, Shahid Dr. Kharazmi  
Educational Complex

**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**

No more information.

**Study Protocol**

Undecided - It is not yet known if there will be 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**

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