

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

AgeFrom **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

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Fax

+98 51 3859 7313

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 addressAzadi 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

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

PositionMaster's student in nursing majoring in internal
surgery**Latest degree**

Bachelor

Other areas of specialty/work

Nursery

Street addressAzadi 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

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 addressAzadi 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 ProtocolUndecided - 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 ReportUndecided - 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

