Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 gunya. 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
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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
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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

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
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Person responsible for scientific inquiries

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Name of organization / entity
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Position
Doctorate in Internal Surgery, Nursing
Latest degree
Ph.D.
Other areas of specialty/work
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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
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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