

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of the effect of two methods of active Distraction based on computer games and Inactive Distraction based on playing music on anxiety and physiological indicators of removing the cast in children aged 8 to 12 years

Protocol summary

Study aim

In this study, the effect of two methods of active distraction based on computer games and inactive distraction based on playing music on anxiety and physiological indicators of removing the cast in children aged 8 to 12 years is investigated.

Design

In this clinical trial study, 105 children between the ages of 8 to 12 years needed to removing the cast through a random permutation block with an equal number of members in three groups: intervention 1 (music playing), intervention 2 (do playing), and group controls, are clinically tested.

Settings and conduct

Heart rate, and children's anxiety levels are recorded before and after the intervention. The research participants are selected from children requiring cast removal at Valiasr Hospital in Arak.

Participants/Inclusion and exclusion criteria

Willingness to participant to study by parents and the child; age over 8 years and under 12 years old; having plaster on the upper or lower limbs; the ability to speak and understand Persian; not take sedative or analgesic drugs for one hour before cast removal; lack of hearing and vision problems, mental illness, speech disorders and mental retardation, hyperactivity; lack of compartment syndrome

Intervention groups

Intervention group 1: Playing children's music appropriate to the age, gender and interest of children, from 5 minutes before and 2 minutes after removing the cast through wireless headphones; Intervention group 2: selecting and performing computer games, from 5 minutes before to 2 minutes after cast removal, via tablet; Control group: no intervention

Main outcome variables

Heart rate and anxiety

General information

Reason for update

Study protocol update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180523039793N2**

Registration date: **2020-10-09, 1399/07/18**

Registration timing: **prospective**

Last update: **2025-09-30, 1404/07/08**

Update count: **2**

Registration date

2020-10-09, 1399/07/18

Registrant information

Name

Razieh Mokhtari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3277 7971

Email address

razieh.mokhtari91@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-31, 1399/08/10

Expected recruitment end date

2021-01-29, 1399/11/10

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of two methods of active
Distraction based on computer games and Inactive
Distraction based on playing music on anxiety and
physiological indicators of removing the cast in children
aged 8 to 12 years

Public title
Comparison of the effect of two methods of active
Distraction based on computer games and Inactive
Distraction based on playing music on anxiety and
physiological indicators of removing the cast in children
aged 8 to 12 years

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 8 years and under 12 years Have a upper or
lower limb plastered Willingness to participant to study
by parents and the child and signing the consent form at
the beginning of the study Able to speak and understand
Persian language Full consciousness and lack of
drowsiness Child's ability to answer the researcher's
questions and cooperate during the test
Exclusion criteria:
Hearing and vision problems (Completely not hearing
and not seeing despite the use of assistive devices)
Mental illness (According to the statement of parents)
Compartment syndrome Speech disorders and mental
retardation, hyperactivity (According to the statement of
parents) Pervasive anxiety disorders (According to the
statement of parents) Take sedative or analgesic drugs
for one hour before cast removal

Age
From **8 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
The research participants are selected using a
convenience sampling method from children requiring
cast removal at Valiasr Hospital in Arak. They are then
randomly assigned in equal numbers to three groups;
Intervention 1 (passive distraction with music),
Intervention 2 (active distraction with video games), and
the control group, using block randomization with
software. These groups undergo a clinical trial.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical
Sciences

Street address

Arak University of Medical Sciences, Sardasht, Basij
Square

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2020-07-26, 1399/05/05

Ethics committee reference number

IR.ARAKMU.REC.1399.163

Health conditions studied

1

Description of health condition studied

Orthopedics, limb fractures and joint dislocations

ICD-10 code

M96.6

ICD-10 code description

Fracture of bone following insertion of orthopedic
implant, joint prosthesis, or bone plate

2

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Anxiety

Timepoint

Before intervention and after intervention

Method of measurement

Children's Emotional Manifestation Scale (CEMS), Visual Analogue Scale

2

Description

Heart beat

Timepoint

Immediately before the intervention, after the intervention

Method of measurement

Number of beats per minute - pulse oximeter

3

Description

Anxiety

Timepoint

Before intervention and after intervention

Method of measurement

Facial Anxiety Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Inactive Distraction based on playing music; Before start removing the cast, researcher introduces the environment and equipment of cast room to the child, for to prevent the role of stress of unfamiliarity on the measurements. Then, for children in intervention group 1 (music therapy), from 5 minutes before the cast removal and during the procedure, as well as 2 minutes after the removing the cast, music appropriate to the age, sex and interest of the child is selected and played. All of the music that is used, has a beat of 80-60 beats per second and a volume of 40 to 50 decibels, and all of them have a smooth and uniform rotation melodic rhythm, and none of them are stimulating, sad or exciting. Playing the music is according to each child's situation via wireless headphones. Parents are asked not to talk to their children during the intervention. Other factors that may be used to reduce the child's stress (due to disruption of the assessment process) will also be avoided during the intervention.

Category

Treatment - Other

2

Description

Intervention group 2: Active Distraction based on computer games; Before start removing the cast, researcher introduces the environment and equipment of cast room to the child, for to prevent the role of stress of unfamiliarity on the measurements. Then, children will

play games via tablet according to their age, gender and interest from 5 minutes before and 2 minutes after cast removal.

Category

Treatment - Other

3

Description

Control group: Children in this group did not receive any intervention and cast removal will be performed routinely without intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital of Arak

Full name of responsible person

Ali Safdari

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3505

Email

asafdari.nu@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

Arak University of Medical Sciences, Sardasht, Basij Square

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3505

Email

alikalaliir@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Ali Safdari

Position

Nursing student of Arak University of Medical Sciences

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Arak University of Medical Sciences, Sardasht, Basij Square

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3505

Email

asafdari.nu@gmail.com

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

Arak University of Medical Sciences

Full name of responsible person

Razieh Mokhtari

Position

Member of Arak Nursing Faculty

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Arak University of Medical Sciences, Sardasht, Basij Square

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3505

Email

razieh.mokhtari91@gmail.com

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

Arak University of Medical Sciences

Full name of responsible person

Ali Safdari

Position

Nursing student of Arak University of Medical Sciences

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Arak University of Medical Sciences, Sardasht, Basij Square

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3505

Email

asafdari.nu@gmail.com

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