

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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

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+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

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**Email**

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**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

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**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

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**Email**

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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