

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jul 2026

### Investigating the effect of digital painting on 6-12 years old children's preoperative anxiety

#### Protocol summary

##### Study aim

Investigating the effect of digital painting on preoperative anxiety in children

##### Design

A randomized controlled clinical trial on 60 patients. The rand function of Excel software is used for randomization.

##### Settings and conduct

This study will be conducted in Bo Ali Hospital, Sari. Before surgery, all children will be present with their mother for 15 minutes in a room located within the operating room. During this time, the child in both groups will not receive any medicine. According to the allocation of each person's group, the intervention is carried out. The assessment of anxiety before and after the intervention will be done by another person who is not aware of the type of intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 6 to 12 years  
Exclusion criteria: No history of previous surgery

##### Intervention groups

The software under the Android "Coloring and Learn" made by "Orange Studios Games", which is downloaded from Cafe Bazaar and installed on the tablets, and the program will be given to the child while it is running on the tablet, and from the 30 ready images in this software. First, the child will be taught how to choose and color by the researcher, and then the child will be allowed to choose as many pictures as he wants and color as he wants. The duration of coloring will be 15 minutes. No intervention is performed in the control group.

##### Main outcome variables

Child anxiety, Mother Anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110430006342N14**

Registration date: **2023-04-07, 1402/01/18**

Registration timing: **prospective**

Last update: **2023-04-07, 1402/01/18**

Update count: **0**

##### Registration date

2023-04-07, 1402/01/18

##### Registrant information

###### Name

Ali Asghar Ghods

###### Name of organization / entity

Semnan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 1335 4192

###### Email address

aaghods@sem-ums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-21, 1402/02/01

##### Expected recruitment end date

2023-10-22, 1402/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of digital painting on 6-12 years old children's preoperative anxiety

##### Public title

Investigating the effect of digital painting on anxiety

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
6 to 12 years old Ability to verbally communicate Ability to painting Informed consent of parents and children to participate in the study  
**Exclusion criteria:**  
Presence of acute and chronic pain in the child mental retardation History of previous surgery cognitive and mental illness of children, as confirmed by parents

**Age**  
From **6 years** old to **12 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Allocation of samples is done as a random block of four prepared using Excel software. A represents the test group and B represents the control group

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The evaluating nurse enters the child's room before and after the intervention and measures the child's anxiety level using the m-YPAS anxiety questionnaire. He is not aware of the type of intervention. The intervention and control groups are marked with the letters A and B so that the statistician does not know the type of intervention

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of Semnan University of Medical Sciences

##### Street address

Deputy of research and technology, Central Headquarters of Semnan University of Medical

Sciences, Basij Boulevard

##### City

Semnan

##### Province

Semnan

##### Postal code

3519899951

##### Approval date

2023-03-13, 1401/12/22

##### Ethics committee reference number

IR.SEMUMS.REC.1401.339

## Health conditions studied

### 1

#### Description of health condition studied

Anxiety

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Anxiety

#### Timepoint

before and after intervention

#### Method of measurement

Completing the Modified Yale Preoperative Anxiety Scale (m-YPAS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: the software under the Android operating system called "Coloring and Learn" made by "Orange Studios Games" which is downloaded from Cafe Bazaar and installed on the tablets and the program will be given to the child while it is running on the tablet and from 30 ready images in In this software, the first picture is selected by the researcher and the child is taught how to color, and then the child will be allowed to choose as many pictures as he wants and color as he wants. The duration of coloring will be 15 minutes.

#### Category

Other

### 2

#### Description

Control group: There is no intervention

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Bo Ali Sinai Hospital, Sari

**Full name of responsible person**

Mehrasa Mottaghi

**Street address**

Bo Ali Sinai Hospital, Sari

**City**

Sari

**Province**

Mazandaran

**Postal code**

-33556259

**Phone**

+98 935 982 5820

**Email**

mehrasa.mottaghi@gmail.com

**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Majid Mirmohammadkhani

**Street address**

Deputy of research and technology, Central  
Headquarters of Semnan University of Medical  
Sciences, Basij Boulevard

**City**

Semnan

**Province**

Semnan

**Postal code**

3519899951

**Phone**

+98 23 3105 2120

**Email**

majidmirmohammadkhani@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Semnan 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**

Semnan University of Medical Sciences

**Full name of responsible person**

Ali Asghar Ghods

**Position**

Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing, Semnan University of Medical  
Sciences, Km 6 Damghan Road,

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3513138111

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Ali Asghar Ghods

**Position**

Faculty Member

**Latest degree**

Ph.D.

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Part of the data, such as the information related to the main outcome, can be shared.

**When the data will become available and for how long**

Six months after the completion of sampling

**To whom data/document is available**

Officials of the research assistant and referees

**Under which criteria data/document could be used**

On request

**From where data/document is obtainable**

Ali Asghar Ghods aaghods@yahoo.com

**What processes are involved for a request to access data/document**

The request is reviewed and decided by the study team

**Comments**