

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The Effect of Non Pharmacological Palliative Methods Education on the Severity of Pain and Referring Rate of Adolescences with Sickle cell Anemia

#### Protocol summary

##### Study aim

determining the Effect of Non-pharmacological Palliative Method Education on Pain Severity and the Rate of Referring in Adolescents with Sickle cell Anemia

##### Design

Parallel Group Trial, one-blinded with Intervention and Control Group Which Randomly Assigned to Six Blocks .

##### Settings and conduct

The study will be carried out at The Ahvaz shafa Hospital and the use of Non-pharmacological Pain Relief Methods at the time of the onset of pain. Clients will enter the study according to entry criteria and provide them with the necessary Training During 4 sessions, and They will be asked to repeat and practice techniques at home and use them at the time of pain.

##### Participants/Inclusion and exclusion criteria

-Aged 12-18 years -Repeat visits to the clinic or admission to the hospital due to pain (at least once a year) -They have not received any pain care education. - Members use only oral Analgesics such as acetaminophen or Ibuprofen.

##### Intervention groups

60 adolescents With Sickle cell Anemia will be divided into two groups of intervention and control.

##### Main outcome variables

severity of pain; number of visits

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180128038531N1**

Registration date: **2018-04-21, 1397/02/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-04-21, 1397/02/01**

Update count: **0**

##### Registration date

2018-04-21, 1397/02/01

##### Registrant information

###### Name

fatemeh maniavi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3443 3787

###### Email address

fatimanurse@yahoo.com

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-02-20, 1396/12/01

##### Expected recruitment end date

2018-05-21, 1397/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Non Pharmacological Palliative Methods Education on the Severity of Pain and Referring Rate of Adolescences with Sickle cell Anemia

##### Public title

study of The effect non-pharmacological Palliative Method on severity of pain and the rate of referral to the clinic in Adolescences with sickle cell

##### Purpose

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Non-acute and chronic physical and mental illness Not having mental-emotional disturbances A history of frequent visits to the clinic or admission to the hospital due to pain (at least once a year) Failure to receive Pain Care Education in advance Use only oral hygiene drugs such as acetaminophen or profen.

**Exclusion criteria:**

**Age**  
From **12 years** old to **21 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant

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

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

**Randomization description**  
Random Block Method using six Blocks

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

**Blinding description**  
The Study is one-sided type so that the person evaluating the results of the study is kept unaware of the type of treatment group in each patient.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

##### Street address

Department of Research and Technology Development, Academic City, Jundishapur University of Medical Sciences

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

61357-15794

#### Approval date

2018-01-16, 1396/10/26

## Ethics committee reference number

879.IR.AJUMS.REC.1396

## Health conditions studied

### 1

#### Description of health condition studied

Sickle Cell Anemia

#### ICD-10 code

D57

#### ICD-10 code description

Sickle-cell disorders

## Primary outcomes

### 1

#### Description

pain severity

#### Timepoint

4 Weeks before Training

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

Reduce referring

#### Timepoint

4 and 8 weeks after training

#### Method of measurement

Patient report

## Intervention groups

### 1

#### Description

In the intervention group, there were 30 adolescents with sickle cell disease who have been trained in non-pharmacological palliative care and who are required to apply the methods for 8 weeks, during which time they recorded the severity of pain and referral to the clinic or hospital for pain. Finally, the effect of applying these methods on the severity of pain and the number of referrals due to pain is evaluated by the researcher.

#### Category

Prevention

### 2

#### Description

Control group: In the Control group, there were 30 adolescents suffering from sickle cell Disease, who do not receive any pain relief training in the field of non-pharmacological methods, record only the severity of pain and the cases of referral to the clinic or hospital due to pain, and care is routinely done.

**Category**

Other

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Shafa Hospital

**Full name of responsible person**

Rostami Shahnaz

**Street address**

University of Medical Sciences, Jundishapur University of Medical Sciences, Faculty of Nursing, Midwifery

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**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammad Badawi

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Development Assistant Development Dept. of Jundishapur University of Medical Sciences, Academic City.

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Badavim@yahoo.com

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

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Rostami Shahnaz

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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

Ahvaz University of Medical Sciences

**Full name of responsible person**

Keikhaei Dehdezi bijan

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

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**Person responsible for updating data****Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Fatemeh Maniavi

**Position**

MSc student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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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