

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of self-management of pain with self-care on nature of pain and quality of life in patients with sickle cell disease

Protocol summary

Study aim

The effect of self-management of pain with self-care on nature of pain and quality of life in patients with sickle cell disease

Design

The clinical trial study has a control group with three groups of pain and control self-care-self-management groups. Samples are three groups of 25 people randomly grouped using random number table.

Settings and conduct

The study was performed at Shahid Baqai Hospital in Ahvaz and Shahid Beheshti Hospital in Abadan. Random sampling, then self-care training for patients in the first group, self-management of pain in the second and third groups are also observed. Questionnaires will be completed before and after the intervention.

Participants/Inclusion and exclusion criteria

Entry Criteria: Be willing to participate in the study. - Be able to read and write. Be in the age range of 18-65 years. Criteria for non-entry: non-cooperation of the patient to continue participating in the study (two consecutive or intermittent absenteeism sessions) - concurrent complications of other chronic diseases - any acute mental disorder and acute physical illness

Intervention groups

Group 1: Teaching self-care techniques to self-care group. Group 2: Teaching pain management techniques to the pain management group. Group 3: The group with no training.

Main outcome variables

quality of life of sickle cell patients, pain of sickle cell patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160726029086N5**

Registration date: **2020-04-15, 1399/01/27**

Registration timing: **retrospective**

Last update: **2020-04-15, 1399/01/27**

Update count: **0**

Registration date

2020-04-15, 1399/01/27

Registrant information

Name

Nasrin Elahi

Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 3373 8071

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elahi-n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-16, 1398/04/25

Expected recruitment end date

2019-10-09, 1398/07/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-management of pain with self-care on nature of pain and quality of life in patients with sickle cell disease

Public title

effect of pain management with self-care on pain and quality of life in patients with sickle cell disease

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The desire to participate in the study Be able to communicate in the context of transferring experiences Aged 18 years and up

Exclusion criteria:

Concurrent with complications from other chronic diseases Affected by any acute mental disorder and acute physical illness

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of individuals to each study group is done using a random number table and a simple random method. The number zero was removed from the table of random numbers, and the numbers 1, 2, and 3 were considered for the self-care group, the numbers 4, 5, and 6 for the pain self-management group, and the numbers 7, 8, and 9 for the control group.

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

The Ethics committee of ahvaz university of medical sciences

Street address

College Of Nursing, Golestan highway, Ahvaz

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Approval date

2019-04-13, 1398/01/24

Ethics committee reference number

IR.AJUMS.REC.1398.017

Health conditions studied

1

Description of health condition studied

Sickle Cell Disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Quality of life

Timepoint

Measurement of quality of life 1,2 and 3 months after intervention.

Method of measurement

Quality of life questionnaire for sickle cell patients

2

Description

The Nature of Pain

Timepoint

Measuring the nature of pain 1, 2 and 3 months after the intervention.

Method of measurement

McGill Pain Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The self-care group is a 25-person group that provides necessary education about self-care, such as nutrition, medication, and so on. Pain and quality of life questionnaires were administered to patients after intervention. In the self-care group, patients will be divided into 5-person groups and will be taught in 4 sessions, basic information about the disease, how to use the medication, physical activity, pain exacerbations and The method of training will be like a pain management group.

Category

Lifestyle

2

Description

Intervention group 2: The self-management group

consisted of 25 patients who were trained on pharmacological and non-pharmacological methods of pain reduction and quality of life questionnaire and McGill pain questionnaire before and after the intervention. The pain self-management program will be administered over 4 sessions for 12 weeks in which patients will be divided into 5 groups. After the intervention phase, patients will be followed up in individual weeks, in-person follow-up, and in paired follow-up weeks. At the end of the training session, one, two, and three months after the training, the questionnaires will be completed by the sample units. The process of group training is as follows.

Category

Lifestyle

3

Description

Control group: There are 25 people in the group with no intervention. But at the end of the study they will be given the necessary training in groups one and two.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Baqaei Hospital of Ahvaz

Full name of responsible person

seyyedeh azadeh moosapour

Street address

College Of Nursing, Golestan Highway, Ahvaz

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2

Recruitment center

Name of recruitment center

Abadan Shahid Beheshti Hospital

Full name of responsible person

Seyyedeh Azadeh Moosapour

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Ahmad abad Avenue-Shahid Beheshti Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad badvi

Street address

Ground Floor, Vice Chancellor for Research and Technology of Ahvaz University of Medical Sciences, Shahr Daneshghahi

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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

Seyyedeh Azadeh Moosapour

Position

Master

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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