Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Self-care education on the severity of pain and quality of life in patients with metastatic cancer

Protocol summary

Study aim
Determining the effect of self-management training on pain intensity and quality of life in metastatic cancer patients
Design
A clinical trial with a control group, randomized
Settings and conduct
The intervention group uses 8 weeks of self-administered pain management techniques that are taught and recorded on the checklist. At first and 3 months later, quality of life is also measured. The control group does not receive the training. But the pamphlet Educational is given to both groups. This study is done in Oncology Clinic of Ahvaz Golestan Hospital.
Participants/Inclusion and exclusion criteria
Entry requirements: 1- The age of the patients is between 18 and 80 years 2- People whose score is based on scale of 10-3 Non-arrival condition: 1. Persons who are physically capable of managing self-management pain 2.People who can not communicate
Intervention groups
The intervention group uses 8 weeks of self-administered pain management techniques that are taught and recorded on the checklist. At first and 3 months later, quality of life is also measured. The control group does not receive the training. But the pamphlet Educational is given to both groups.
Main outcome variables
pain, Quality of Life

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190418043314N1**
Registration date: **2019-07-14, 1398/04/23**
Registration timing: **registered_while_recruiting**
Last update: **2019-07-14, 1398/04/23**
Update count: **0**
Registration date
2019-07-14, 1398/04/23

Registrant information
Name
Mahsa Mousavi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 61 3292 4622
Email address
mousavi.m@ajums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-05-10, 1398/02/20
Expected recruitment end date
2019-08-11, 1398/05/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Self-care education on the severity of pain and quality of life in patients with metastatic cancer

Public title
Investigating the effect of self-care in Cancer
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The age of the Patients is between 18 and 80 years old

Individuals whose scores are based on a scale of 3-10 Persons who are physically capable of self-management People who have the ability to communicate People who have read and write literacy People who have not had a history of using complementary therapies in the past and now

Exclusion criteria:

People who are physically unable to manage self-management People who can not communicate People who are not literate to read and write

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were selected based on entry criteria and then assigned randomly into intervention and control groups. The method of assigning intervention to individuals is randomized and random blocked blocks with block size 4 (using the table for random permutations). The randomization list is provided by a statistic specialist. The intervention used in this research according to a randomized list is provided by a person outside the study who is not aware of the research objectives and will be assigned a different code to the closed envelopes and will be allocated to any disease that is included in the study.

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 Ahvaz University of Medical Sciences

Street address

No.7,Shamkhani Ave., Azadegan Blvd

City

Ahvaz

Province

Khouzestan

Postal code

6193763331

Approval date

2018-11-17, 1397/08/26

Ethics committee reference number

IR.AJUMS.REC.1397.606

Health conditions studied

1

Description of health condition studied

Metastatic cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

Before intervention and every day for 8 weeks after intervention

Method of measurement

Visual Analogue Scale

2

Description

Quality of Life

Timepoint

Before intervention and 3 months after intervention

Method of measurement

Questionnaire on 30 questions for assessing the quality of life of patients with cancer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the test group, after completing the questionnaires, patients received routine care, self-management training for pain (respiratory and respiratory compression, and visual therapy), and for 8 weeks, daily pain intensity and method used in the check The relevant list is recorded and after 3 months the quality of life is measured again.

Category

Rehabilitation

2

Description

Control group: In the control group, demographic questionnaires, needs assessment and quality of life and

daily checklist were distributed and received routine care. At the end of the study, educational pamphlets were also distributed.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Mahsa Mousavi

Street address

No.7,Shamkhani Ave.,Azadegan Blvd

City

Ahvaz

Province

Khouzestan

Postal code

6193763331

Phone

+98 61 3292 4622

Email

mousavi.m@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr majid karandish

Street address

No.7,Shamkhani Ave.,Azadegan Blvd

City

Ahvaz

Province

Khouzestan

Postal code

6193763331

Phone

+98 61 3292 4622

Email

mousavi.m@ajums.ac.ir

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

Mahsa mousavi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 7.,Shamkhani Ave., Azadegan Blvd

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Province

Khouzestan

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Phone

+98 61 3292 4622

Email

mousavi.m@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mahsa Mousavi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No.7.Shamkhani Ave,Azadegan Blvd,Ahvaz Town

City

Ahvaz

Province

Khouzestan

Postal code

6193763331

Phone

+98 61 3292 4622

Fax

Email

mousavi.m@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mahsa Mousavi

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+98 61 3292 4622

Fax

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