

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of intervention based on constructive relationship between couples on the sense of spouse support in women with uterine and cervical cancer

Protocol summary

Study aim

Determining the effect of intervention based on constructive relationship between couples on the sense of spouse support in women with uterine and cervical cancer

Design

Clinical trial with control and intervention group, with parallel groups, non-blinded, randomized, on 60 patients. An envelope containing even and odd numbers was used for randomization. Even numbers are for the control group and odd numbers are for the intervention group.

Settings and conduct

Consulting room of Imam Khomeini Hospital in Urmia, Consulting room of Hospital in Urmia. There is no blinding in the study.

Participants/Inclusion and exclusion criteria

Age range of 30-60, being married, familiarity with Persian and Azerbaijani languages, diagnosis of uterine and cervical cancer, after more than 48 hours of chemotherapy, not having other cancers, under treatment of uterine and cervical cancer, stage I, II, III of uterine and cervical cancer according to pathobiology sheet, not experiencing any other stressful situations in the last 6 months, not attending other educational sessions, not having any depression history or hospitalization. The exclusion criteria include: having other cancers, having any life-threatening illness

Intervention groups

Intervention group: Intervention Based on Couples Constructive Communication will be done on couples in intervention group, which will include groups of 6 to 10. The designed interventions include: strengthen effective and constructive discussion skills, how to manage communication problems, repairing relationships. To evaluate the participants, a diary will be provided for each person to record her daily behavior. Control group: The control group will not receive the any

intervention. But due to ethical norms that they were in the control group, after the intervention, one or two sessions will do for them

Main outcome variables

Spouse support sense

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150125020778N22**

Registration date: **2021-02-19, 1399/12/01**

Registration timing: **retrospective**

Last update: **2021-02-19, 1399/12/01**

Update count: **0**

Registration date

2021-02-19, 1399/12/01

Registrant information

Name

Fatemeh Moghaddam Tabrizi

Name of organization / entity

Uromia University of Medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-30, 1398/02/10

Expected recruitment end date

2020-02-21, 1398/12/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of intervention based on constructive relationship between couples on the sense of spouse support in women with uterine and cervical cancer

Public title
The effect of intervention on couples on the sense of support of the spouse

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Age range of 30-60 Being married Familiarity with Persian and Azerbaijani languages Diagnosis of uterine and cervical cancer After more than 48 hours of chemotherapy Not having other cancers Under treatment of uterine and cervical cancer (chemotherapy, radiotherapy, hormone therapy) Stage I, II, III of uterine and cervical cancer according to pathobiology sheet
Exclusion criteria:
 Having any life-threatening illness: Life-threatening illness are chronic, usually incurable diseases, which have the effect of considerably limiting a person's life expectancy. These include, cancer, diabetes, neurological conditions, coronary heart disease and HIV/Aids. Having other cancers

Age
From **30 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
By taking into account the inclusion criteria and getting consent, 60 couples enter the study by availability sampling method. Using the envelope of odd and even numbers, 30 people will be selected randomly for the control group and 30 for the intervention group. 40 envelopes contain even and odd numbers from 1 to 40. Couples were asked to choose an envelope. Even numbers are for the control group and odd numbers are for the intervention 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
 Ethics committee of Urmia University of Medical science
Street address
 Resalat blv,next to the emergency center,Urmia University of Medical sciences
City
 Urmia
Province
 West Azarbaijan
Postal code
 5714783734
Approval date
 2019-04-24, 1398/02/04
Ethics committee reference number
 IR.UMSU.REC.1398.031

Health conditions studied

1

Description of health condition studied
uterine and cervical cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Spouse support sense

Timepoint
Before intervention and 6 weeks after the first session

Method of measurement
Spouse support questionnaires

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group: For the intervention group, the intervention based on constructive relationship of couples will be done, classes will be held in groups of 6 to 10. Each session will be 60-90 minutes long per week,

in 5 weeks. Sessions include: introduction, the stage of strengthening effective and constructive discussion skills and how to manage communication problems, the stage of repairing relationships, the stage of control, the stage of evaluation.

Category

Lifestyle

2**Description**

Control group: The control group will not receive the any intervention. But due to ethical norms that they were in the control group, after the intervention, one or two sessions will do for them

Category

Lifestyle

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

Imam Khomeini hospital

Full name of responsible person

Dr .Fateme Moghaddam Tabrizi

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Ershad street - Ayatollah Modarrers blvd , Khomeini

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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

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

No

Title of funding source

Urmia 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**

Oroumia University of Medical Sciences

Full name of responsible person

Dr .Fateme Moghaddam Tabrizi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

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

Title and more details about the data/document

not decided yet - its publication plan is still unclear

When the data will become available and for how long

not decided yet - its publication plan is still unclear

To whom data/document is available

not decided yet - its publication plan is still unclear

Under which criteria data/document could be used

not decided yet - its publication plan is still unclear

From where data/document is obtainable

Not decided yet - its publication plan is still unclear

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

not decided yet - its publication plan is still unclear

Comments