Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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 .Fatemeh Moghaddam Tabrizi

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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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Resalat blv,next to the emergency center,Urmia University of Medical Sciences

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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 .Fatemeh Moghaddam Tabrizi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Position

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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 -itspublication 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