

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### The effect of group therapy based on coping strategies on mental adjustment of the women with gynecological cancer that referred to urmia education- research and treatment centers

#### Protocol summary

##### Study aim

This study was carried out to determine the effect of group therapy based on coping strategies in the mental adjustment of women with Gynaecological cancer referring to Urmia educational centers in 1395-1396.

##### Design

In this survey, 70 women with gynecologic cancer who are referred to Urmia treatment-educational centers will be selected by simple random sampling method. Samples will be assigned randomly to intervention and control groups and will be assigned a code for each participant.

##### Settings and conduct

The present study was conducted in Urmia In this way, Individuals were randomly assigned into two groups of 35 subjects intervention and control. The experimental group was divided into three subgroups of 11-12-12 people and during eight sessions of 1.5-2 hours that held weekly in one session was subjected to group therapy interventions based on coping strategies. But for control group no treatment was applied. After the end of the sessions, a three-month deadline was given to the team to carry out coping skills working in the group, in their daily lives. Assessment form of mental adaptation in cancer before the intervention; after intervention; one month after the intervention; and three months after the intervention was completed by patients.

##### Participants/Inclusion and exclusion criteria

Major inclusion criteria include knowledge of disease; willingness to participate in research; having Literacy reading and writing; passing at least 6 months of illness and Major exclusion criteria include participating in psychiatric intervention at the same time as intervention; having another chronic disease; Incidencing an important stressful factor in life.

##### Intervention groups

70 eligible women were randomly divided into two

groups of 35 controls and intervention. The intervention group was divided into three subgroups of 11-12-12 people and Based on group therapy interventions with coping strategies.

##### Main outcome variables

The main variable is the outcome of assessment form of mental adaptation in cancer.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140212016564N6**

Registration date: **2018-01-12, 1396/10/22**

Registration timing: **prospective**

Last update: **2018-01-12, 1396/10/22**

Update count: **0**

##### Registration date

2018-01-12, 1396/10/22

##### Registrant information

##### Name

Molood Radfar

##### Name of organization / entity

Urmia University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 1275 4961

##### Email address

radfar.m@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Urmia University of Medical Sciences, Vice Chancellor of Research

**Expected recruitment start date**

2018-01-20, 1396/10/30

**Expected recruitment end date**

2018-08-20, 1397/05/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of group therapy based on coping strategies on mental adjustment of the women with gynecological cancer that referred to urmia education- research and treatment centers

**Public title**

The effect of group therapy on mental adjustment of the women with gynecological cancer

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women with gynecological cancer lack of participation in group therapy programs in the last three months having Literacy reading and writing ability to communicate Passed at least six months after the onset of the disease lack of distant metastases Awareness of own illness The desire to participate in the study

**Exclusion criteria:**

History of using Psychiatric drug concurrent suffering with another chronic illness Participation in psychiatric interventions simultaneously with research implementation The emergence of an important stressful factor in life A prominent history of mental illness

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**Target sample size: **70**Actual sample size reached: **70****Randomization (investigator's opinion)**

Randomized

**Randomization description**

150 women with gynecological cancer who were referred to treatment centers in the years 1395 and 1396 were selected. After reviewing the records of these patients and considering the inclusion and exclusion criteria and other criteria, 100 eligible patients were enrolled in the study. Considering that 70 patients were needed for intervention. A total of 70 individuals were randomly selected (random numbers). The method of assignment to groups was done in this way That: We put 35 A cards and 35 B cards in the envelope and mixed them thoroughly(Card A represents the intervention group and

the B card index represents the control group), Then the cards are randomly arranged in a row. Anyone who entered the study was able to take one of the cards and enter the study, respectively. In this way, the intervention group and the control group were identified.

**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 Sciences

**Street address**

Urmia alley, Resalat Blvd, Urmia, Iran

**City**

urmia

**Province**

West Azarbaijan

**Postal code**

5756115111

**Approval date**

2016-12-09, 1395/09/19

**Ethics committee reference number**

ir.umsu.rec.1395.380

**Health conditions studied****1****Description of health condition studied**

Gynecologic cancer

**ICD-10 code**

C51-C58

**ICD-10 code description**

Malignant neoplasms of female genital organs

**Primary outcomes****1****Description**

The effect of intervention (group therapy based on coping strategies) on mental adjustment of participants was assessed using the mental adjustment questionnaire in cancer in four stages before intervention, after intervention, one month after intervention and three months after intervention. And compared to the control group.

**Timepoint**

Before the intervention immediately after the intervention one month later and three months after the intervention

**Method of measurement**

Mini-Menta IAadjustment to Cancer scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

To implement the group therapy, the intervention group was divided into three small groups of 11-12-12 people, Each subgroup underwent a group therapy based on coping strategie which was held in eight sessions of 2 hours and one day per week. The group's force was used to create new methods and to have a positive impact on each other and learning from each other. At the end of each meeting, a homework assignment was provided for patients. Which was reviewed and rated at the next meeting at the end of the work, those who received more points were ewarded. The titles of the meetings were as follows: The First meeting included introduction and familiarity of the group members with each other and explaining the principles of the group, the definition of cancer and the causes of cancerous cell and the presentation of an educational booklet prepared by the researcher for study, which included the knowledge that help to alleviate patient anxiety.The second meeting included discussions about the fighting spirit, acceptance of their role, belief in their ability, and negative self-change. Third session included physical care such as: healthy eating, physical activity, changing the style of life, accepting responsibility and seeking social support.The fourth session included a search for treatment, such as: Participation with the treatment team and follow-up therapy. The fifth session included psychological care such as: religious beliefs, valuing your interests, modifying negative beliefs, gaining emotional support, self-control and do not follow the culprit. The sixth session included the use of sedative techniques such as slow and deep breathing, mental imagery, thought leadership, realism, and complementary therapies such as laughter therapy and the use of relaxed speech.The seventh session included anti recurrence strategies, such as providing information on the recurrence of disease, the importance of pursuing health care and maintaining the fighting spirit.The Eighth session Scores recorded from each patient were reviewed and awarded to the highest score. one of the Cancer who were victorious in curing cancer, talked to patients. After the end of the sessions, a three month deadline was given to the team to carry out coping skills working in the group, in their daily lives. Assessment form of mental adaptation in cancer before the intervention; after intervention; one month after the intervention; and three months after the intervention

was completed by patients.

**Category**

Behavior

**2****Description**

During the intervention, the control group did not receive any coping skills and in terms of data entry was about control.

**Category**

Behavior

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

Omid hospital-Urmia

**Full name of responsible person**

Moloud Radfar

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

Oroumia University of Medical Sciences

**Full name of responsible person**

Mohebbie Erag

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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**

Oroumia 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

Faculty of Nursing and Midwifery, Urmia University of Medical Sciences, Urmia, Iran

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

Oroumia University of Medical Sciences

**Full name of responsible person**

Smaeilzadeh khangah Sepideh

**Position**

The Master Science student of nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

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**Position**

The Master Science student of nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Radfar Moloud

**Position**

Nursing PhD

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

File Title: Mental Adjustment Data The whole data will be shared after being unidentified.

**When the data will become available and for how long**

Start the access period 6 months after printing the results

**To whom data/document is available**

Researchers working in academia

**Under which criteria data/document could be used**

The data will be available to other researchers in the

form of a printed article. Other researchers are allowed from the research team to use the data.

**From where data/document is obtainable**

Radfar moloud Email:mrادfar1343@gmail.com

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

You will submit your application to Mrs. Radfar, who will send you the requested application within ten days after reviewing your request.

**Comments**