Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effectiveness of family based group therapy and self help group therapy on quality of life and sense of coherence in women with breast cancer after chemotherapy

Protocol summary

Study aim
Determining the effect of group intervention with the patient's main caregiver compared to self-asserting groups on quality of life and sense of coherence in women with breast cancer

Design
A community-based & pragmatic, double blind, randomized clinical trial with a control group

Settings and conduct
A study was conducted on 80 women with breast cancer stage 3&4 at Entekhab Center affiliated to Isfahan University of Medical Sciences. Patients were selected by simple non-random sampling and were randomly assigned to one of the two intervention and control groups. Randomization was done using random numbers table. The staff responsible for collecting questionnaires and analyzing the data did not know the educational package content and the method of assignment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women with Breast Cancer Stage 3 and 4; Obtain informed consent; Have reading and writing skills; Being at the age of 18 - 60 years old Non-Inclusion criteria: Presence of psychiatric disorders such as psychosis and personality disorders by taking history; Having another physical illness that prevents the person from participating in the research program Participate in spiritual therapy sessions or therapies.

Intervention groups
Patients in the intervention group participated in family-based group intervention sessions organized by the psychotherapist 2 months after chemotherapy in 10 sessions of 90 minutes with their spouse or primary caregiver. Before and after the 10-session intervention, quality of life questionnaires or QOL-BR 23 and sense of autonomic integrity were filled in by patients with breast cancer. In the control group, the mentioned intervention was performed only for the patient (not for his/her caregiver).

Main outcome variables
Sense of coherence; quality of life.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171105037237N2**
Registration date: **2018-12-21, 1397/09/30**
Registration timing: **retrospective**

Last update: **2018-12-21, 1397/09/30**
Update count: **0**

Registration date
2018-12-21, 1397/09/30

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3668 4827

Email address
p.shirani@resident.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-08-23, 1396/06/01

Expected recruitment end date
2018-05-20, 1397/02/30

Actual recruitment start date
2017-09-23, 1396/07/01

Actual recruitment end date

2018-06-20, 1397/03/30

Trial completion date

2018-06-20, 1397/03/30

Scientific title

Comparison of the effectiveness of family based group therapy and self help group therapy on quality of life and sense of coherence in women with breast cancer after chemotherapy

Public title

The effect of group intervention based on the family (spouse or patient's primary caregiver) on quality of life and sense of coherence

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Women with Breast Cancer Stage 3 and 4 Obtain informed consent Have reading and writing skills Patients at the age of 18-60 years old

Exclusion criteria:

Having diagnostic criteria for psychiatric disorders such as psychosis and personality disorders by taking a history Having another physical illness that prevents a person from participating in the research program Participate in spiritual therapy sessions or therapies

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

1-2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

80 patients after chemotherapy and after obtaining informed consent were selected non randomly and easily among patients referring to the Isfahan Entekhab treatment center, and then randomly assigned to intervention and control groups using the random numbers table.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person responsible for collecting the questionnaires was not informed about which person was in the intervention group and who was in the control group, as well as the data was analyzed by the data analyst after the anonymity. The analyst did not know how the patients were allocated to the groups and the groups were name with an abbreviation name.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences & Health Services,Hezar Jerib St.

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2017-06-20, 1396/03/30

Ethics committee reference number

IR.MUI.REC.1396.3.030

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Quality of life

Timepoint

At three periods including before the intervention, immediately after the end of the 10th training session and 3 months after the end of the intervention (after the tenth session)

Method of measurement

EORTC-QLO-BR 23 Quality of Life Questionnaire

2

Description

Sense of coherence

Timepoint

At three periods including before the intervention, immediately after the end of the 10th training session and 3 months after the end of the intervention (after the

tenth session)

Method of measurement

Antonovsky Sense of Sensitivity Questionnaire (SOC-13)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: family based group therapy.Patients in the intervention group participated in family-based group intervention sessions organized by the psychotherapist 2 months after chemotherapy in 10 90-minute sessions with their spouse or primary caregiver. Before and after the 10-session intervention, quality of life questionnaires or QOL-BR 23 and sense of autonomic integrity were filled in by patients with breast cancer.

Category

Treatment - Other

2

Description

Control group: Self help group therapy in which patients participated in the family-based group intervention sessions administered by the psychotherapist 2 months after chemotherapy in 10 sessions of 90 minutes without their primary caregiver. Before and after the 10-session intervention, quality of life questionnaires or QOL-BR 23 and sense of autonomic integrity were filled in by patients with breast cancer.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Entekhab center

Full name of responsible person

Farzad Goli

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Shahid Motahari Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Farzad Goli

Street address

Vice chancellor for Research, Isfahan University of Medical Sciences and Health Services, Hezar Jarib Street.

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Parinaz Shirani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Public Health/Community Medicine

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Province

Isfehan

Postal code
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Email
Parinazshirani@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Parinaz Shirani

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
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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
Information will be available after obtaining permission from the research deputy of the Isfahan University of Medical Sciences, two years after the publication of the article.

When the data will become available and for how long
Information will be available after obtaining permission from the research deputy of the Isfahan University of Medical Sciences, two years after the publication of the article.

To whom data/document is available
Cancer researchers, counselors, psychologists and physicians, and especially community health researchers

Under which criteria data/document could be used
In order to compare the present studies with other similar studies or perform other statistical calculations, after coordination and permission from the vice chancellor of research of the Faculty of Medicine, Isfahan University of Medical Sciences, as well as sending a request to the email Parinazshirani@yahoo.com, information after the inescapable Identification is available to other researchers.

From where data/document is obtainable
Send your email to Parinazshirani@yahoo.com with a clear and concise statement after coordinating and obtaining permission from the research deputy of the Faculty of Medicine, Isfahan University of Medical Sciences.

What processes are involved for a request to access data/document
Send your email to Parinazshirani@yahoo.com with a clear and concise statement after coordinating and obtaining permission from the research deputy of the Faculty of Medicine, Isfahan University of Medical Sciences.

Comments