Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The impact of educational support programe on anxiety and stress of women suffer from endometrial cancer

Protocol summary

Summary

Main objective of the study is The impact of educational support programe on anxiety and stress of women suffer from endometrial cancer. This study is a randomized control trial. Inclusion criteria include patients with endometrial cancer(histopathologic report),below 65 years old and literated, no known mental disease and disability and refractory chronic diseases,history of using antidepressant and relaxant agents. Exclusion criterias are: taking antidepressant and relaxant agents during 2 first weeks of interventionand and accurance of stressful events during study.140 patients using randomized form are divided into intervention and control groups.Thus,70 cases are in each group. Intervention includes 3 sesession in 3 weeks. Every sessen lasts 40-60 minutes. control group will receive routines care. Just after third session, 1 and 2 months later,questionnaires will filled again by patients.In this study we use 3 questionnaires:demographic,Harri`s stress and bek`s enxiety.At the end, anxiety and stress will compared between control group and intensive group. In this study,the main outcomes variable are anxiety and stress.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013120515668N1**
Registration date: **2014-02-03, 1392/11/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-02-03, 1392/11/14

Registrant information

Name

Soudabeh Niroomand

Name of organization / entity

Tehran University

Country

Iran (Islamic Republic of)

Phone

+98 21 4444 4955

Email address

s.niroomand.1984@gmail.com

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of educational support programe on anxiety and stress of women suffer from endometrial cancer

Public title

The impact of educational support programe on anxiety and stress of women suffer from endometrial cancer

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria:age below 65 years old;literate;Have an endometrial malignancies histopathologic report; no known mental disease and disability and refractory chronic diseases ;no taking antidepressant and relaxant agents ;any stressful events since 3 month ago; All of treatment of cancer must be done in study settings

exclusion criteria: taking antidepressant and relaxant agents during 2 first weeks of intervention;accurance of stressful events during study

Age

From **15 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

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

ethic reserch of Tehran medical sciences university

Street address

Tehran keshavarz bulv at the croner of ghods st.

City

Tehran

Postal code

1419733171

Approval date

2013-08-20, 1392/05/29

Ethics committee reference number

1142 /130/92 /ص

Health conditions studied

1

Description of health condition studied

steress and anxiety and endometrial cancer

ICD-10 code

C54.1, F41

ICD-10 code description

endometrium,generalized anxiety disorder, other reactions to sever stress

Primary outcomes

1

Description

stress

Timepoint

before.immediatly.after 1 and 2 months after intervension

Method of measurement

selfreporting by Harri`s stress

2

Description

anxiety

Timepoint

before Intervention, just after Intervention, 1 month and 2 month after Intervention

Method of measurement

selfreporting by Bek`s anxiety questionnaire

Secondary outcomes

1

Description

need to take antidepresant agents after 2 weeks of intervention

Timepoint

2 weaks

Method of measurement

selfreport

2

Description

need to take relaxant agents after 2 weeks of intervention

Timepoint

2 weaks

Method of measurement

selfreport

Intervention groups

1

Description

Intervention includes 3 sesession in 3 weeks. Every sessen lasts 40-60 minutes. Before,just after third session, 1 and 2 months later questionnaires will filled by patients

Category

Other

2

Description

Control group will receive routines care. Before,just after third session, 1 and 2 months later questionnaires will filled by patients.

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Complex hospital center of Emam Khomeini
Full name of responsible person
Soudabeh Niroomand
Street address
Tohid square, school of nursing and midwifery,Tehran,Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences/school of nursing and midwifery
Full name of responsible person
Tehran University of Medical Sciences/school of nursing and midwifery
Street address
Tohid square,School of nursing and midwifery,Tehran,Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences/school of nursing and midwifery
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
School of nursing and midwifery
Full name of responsible person
Leila Neisani Samani
Position
MS/faculty of university
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty