

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The impact of implementation of educationl package on quality of life of cervical cancer women

Protocol summary

Summary

This medical research has been done for the analysis of the effects of the educational package on the quality of life of women who suffer from cervical cancer .This research consists of a selected sample of seventy two cervical cancer patients who are selected randomly according to the criteria of Iranian nationality and stages 1,2 & 3 of this disease .This group is randomly divided in to intervention and control group. After the completion of a pretest or preliminary questionnaire, these two groups are separated, then during four sessions and ninety minutes per week, a researcher and a psychologist present the content of the educational package for the intervention group. The main focus of the first session is on the definition of this disease, subtypes, age of infection, risk factors and the quality of life. And, finally all of the patients receive booklets .In the second session, the patients are asked to brainstorm as many solutions as possible for the problems ,anxieties and the negative effects of the disease on their lives. In the third session,which is called group therapy, both patients and their attendants try to deal with the above mentioned problems . In the fourth session, with the presence of a psychologist many questions related to stress management, depression, disappointment and relaxation techniques are answered. In addition to these arrangements, some inspiring and spiritual slide shows are presented .In the end, the patients are invited to come for the further completion of the questionnaire after twelve weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207039463N4**

Registration date: **2012-07-15, 1391/04/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-15, 1391/04/25

Registrant information

Name

Zahra Behboodi Moghadam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6692 7171

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behboodi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences , vice chancellor for research

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of implementation of educationl package on quality of life of cervical cancer women

Public title

The impact of implementation of educationl package on quality of life of cervical cancer women

Purpose

Supportive

Inclusion/Exclusion criteria
inclusion criteria: Iranian nationality; cervical cancer
affliction in stage 1 , 2 & 3 that diagnosed with biopsy;
absence of psychologic or known cognitive disease;
absence of another cancers exclusion criteria: refuse
from continuance of participation in study; complete
faulty of questionnaires

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 72

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

Tehran University of Medical Sciences

Street address

floor6,central organization of university, qods street,
keshavarz blv.

City

Tehran

Postal code

Approval date

2012-04-08, 1391/01/20

Ethics committee reference number

130/2575/90/3

Health conditions studied

1

Description of health condition studied

quality of life in women with cervical cancer

ICD-10 code

C53.9

ICD-10 code description

malignant neoplasms of female genital organs

Primary outcomes

1

Description

quality of life

Timepoint

before intervention and 12 weeks after intervention

Method of measurement

adjusted questionnaire of quality of life in women with
cervical cancer

Secondary outcomes

1

Description

physical domain of quality of life

Timepoint

before intervention and 12 weeks after intervention

Method of measurement

physical domain of adjusted questionnaire of quality of
life in women with cervical cancer

2

Description

social - family domain of quality of life

Timepoint

before intervention and 12 weeks after intervention

Method of measurement

social - family domain of adjusted questionnaire of
quality of life in women with cervical cancer

3

Description

emotional domain of quality of life

Timepoint

before intervention and 12 weeks after intervention

Method of measurement

emotional domain of adjusted questionnaire of quality of
life in women with cervical cancer

4

Description

functional domain of quality of life

Timepoint

before intervention and 12 weeks after intervention

Method of measurement

functional domain of adjusted questionnaire of quality of
life in women with cervical cancer

5

Description

sexual domain of quality of life

Timepoint

before intervention and 12 weeks after intervention

Method of measurement

sexual domain of adjusted questionnaire of quality of life in women with cervical cancer

Intervention groups

1

Description

control group : This group are received their routine cares and cures and are not received educational package.

Category

Other

2

Description

The content of educational package will be presented during four , 90 minutes sessions and per week. The first session is on the definition of cervical cancer and concept of quality of life ,its different aspects and impressive factors on it . finally all of the patients will be received booklets .The second session, the patients will discuss to brainstorm about their problems and anxieties. Third session,in next week , patients and their attendants group therapy will be done, patients will be invited to groups 3-5persons and each group and their attendants try to deal with the above mentioned problems. In this session , educational film will be displayed. The fourth session, with questions related to stress management, depression, disappointment and relaxation techniques are answered. In addition to these arrangements, some inspiring and spiritual , slide shows are presented in 15 minutes.The questionnaires after 12 weeks will be completed in this group, again.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Institute of Imam Khomeini hospital in Tehran

Full name of responsible person

Razie Chahardehi- Master student of midwifery

Street address

Tohid square , East nusrat str, school of Nursing & midwifery Tehran University of Medical Sciences

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences, vice chancellor for research

Full name of responsible person

Dr Akbar Fotuhi-

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floor 6 , central organization of University , quds street , Keshavarz blv

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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

Tehran University of Medical Sciences, vice chancellor for research

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

Tehran University of Medical Sciences

Full name of responsible person

Dr Zahra Behboodi Moghaddam

Position

PhD in Reproductive Health/ Manager of Reproductive Health

Other areas of specialty/work

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Tehran University of Medical Sciences

Full name of responsible person

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Master student of Midwifery

Other areas of specialty/work**Street address**

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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