

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of family-based education on level of depression in Stomach cancer patients

Protocol summary

Summary

Objective: Determining the effect of Family-Oriented training on level of depression between patients with Stomach Cancer. The studied group include the patients with Stomach Cancer. The sample size is 40 patients in every group. The samples were selected with using random sampling method and divided into control and test groups randomly. The training course includes five , thirty minutes session in several successive days. The phone follow up continues until the post-test implementation two months after the intervention. The inclusion criterion for this study is: The patients with Stomach Cancer: The exclusion criterion is : The absence of the patient and his family from one of the training sessions. The training curriculum includes five successive sessions with the patient and one of his family members in the test group and the patient himself alone in the control group. To compare the test and control groups after two months, then with using post-test the effect of training courses on depression level of the patients will be investigated . The primary outcome is the patient's level of depression.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014020716513N1**

Registration date: **2014-12-15, 1393/09/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-15, 1393/09/24

Registrant information

Name

Yaqob Mahmodi

Name of organization / entity

Tehran University Medical Sceince, Faculty of Nursing

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

Expected recruitment start date

2014-07-11, 1393/04/20

Expected recruitment end date

2014-08-11, 1393/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of family-based education on level of depression in Stomach cancer patients

Public title

Effect of family-based education on level of depression in Stomach Cancer patients

Purpose

Other

Inclusion/Exclusion criteria

The inclusion criteria: The doctor and the diagnostic tests' results should confirm the disease diagnosis: The patient or one of his family members should be educated: They should understand Persian language: The patient or his family members should not have received any formal

education: The minimum age of the patient should be 18 years old. The exclusion criteria: The patient and his family do not want to cooperate anymore: The patient and his family do not attend one of the training sessions: The patient and his family have attended other organizations' formal training.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

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 Science

Street address

Tums Center, Ghods st, Keshavarz blv, Tehran

City

Tehran

Postal code

146164745

Approval date

2014-05-25, 1393/03/04

Ethics committee reference number

9011196049-1

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

stomach cancer

ICD-10 code

(C16)

ICD-10 code description

Malignant neoplasm of stomach

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

level of depression

Timepoint

Before and two months after intervention

Method of measurement

depression Beck questionnaire

Secondary outcomes

empty

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

In the control group, the training course includes five successive sessions with the patient. The formulated content would be taught in five and thirty minutes sessions in several successive days and at the beginning of the first session pretest and at the end the post test would be taken from the topics of interest to confirm the effect of the presented training. The training content includes explaining the disease and its implications and the importance of being informed(first session), acceptance and cure(second session), importance of observance and correct use drug(third session), psychological complication and depression and the ways of opposition fourth and fifth). Afterwards, phone follow up would continue every two weeks.

Category

Other

2**Description**

The training course consists of five successive sessions with the patient and one of his family members in the test group . The formulated content would be taught in five , thirty minutes sessions in several successive days and at the beginning of the first session pretest and at the end the posttest would be taken from the topics of interest to confirm the effect of the presented training. The training content includes explaining the disease and its implications and the importance of being informed(first session), acceptance and cure(second session), importance of observance and correct use drug(third session), psychological complication and depression and the ways of opposition fourth and fifth). Afterwards, phone follow up would continue every two weeks.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Daryadokht Masror Rudsary

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Fax

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Tehran University of
Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Sixth Floor, Central Organization of TUMS, Keshavarz
Blvd, 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

Vice Chancellor for research, Tehran University of
Medical Sciences

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

Faculty of Nursing and Midwifery, Tehran University of
Medical Sciences

Full name of responsible person

Daryadokht Masror Rodsari

Position

Faculty member of Nursing and Midwifery

Other areas of specialty/work

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**Person responsible for scientific
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Master of Science

Other areas of specialty/work

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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