Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of psycho-educational intervention on anxiety, embarrassment and concern in female patients referred to general male surgeon for colorectal examinations

Protocol summary

Study aim
The comparison of psycho-educational intervention with placebo on anxiety, embarrassment and concern in female patients referred to a male general surgeon for colorectal examinations

Design
A clinical trial with control group, parallel group randomized trial and single blind

Settings and conduct
The setting of this study would be Imam Hassan Mojtaba Hospital in Darab city. In this study, a person who collects the outcomes of the study as well as a statistician and physician will be blind until the end of the study and completion of the data analysis and reporting.

Participants/Inclusion and exclusion criteria
The inclusion criteria were female patients with age range 18-60 years, and possibility to attend the sessions in person, in the training group patients. Having known mental illnesses such as chronic depression, psychosis and anxiety. The subjects who participate in the same training sessions along or 3 months ago, not attend in more than two sessions, and patients who will be trained but will not examined would be excluded. 1.

Intervention groups
Firstly, the researcher find the patients who refer to general surgeon for colorectal problems. The subjects in intervention group would be asked to be present in clinic one hour before physician visit. The subjects would receive 30 min education and 30 min psychological intervention. However, the subjects in control group would refer 15 min before visit and they would not receive intervention and receive the same program that is provided to the intervention group.

Main outcome variables
Anxiety, embarrassment, concern about judgment

General information

Reason for update

Acronym
does not have

IRCT registration information
IRCT registration number: **IRCT20170928036465N2**
Registration date: **2018-02-27, 1396/12/08**
Registration timing: **prospective**

Last update: **2018-12-15, 1397/09/24**
Update count: **1**

Registration date
2018-02-27, 1396/12/08

Registrant information

Name
zinat akade

Name of organization / entity
Shiraz university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Shiraz university of medical sciences

Expected recruitment start date
2018-02-28, 1396/12/09

Expected recruitment end date
2018-04-29, 1397/02/09

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of psycho-educational intervention on anxiety, embarrassment and concern in female patients referred to general male surgeon for colorectal examinations

Public title

The effect of psycho-educational intervention on anxiety, embarrassment and concern of judgment in female patients referring to general male surgeon

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age range of 18-60 years Tendency to participate in research Possibility to attend the sessions in person, in the training group patients

Exclusion criteria:

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Sample selection: the method of selecting admission days of this surgeon for the intervention and control group will be randomly and by using random number table in block method. Visitation days for the mentioned surgeon will be done by randomized block design, and weekdays will be allocated to two groups through block method. First, the researcher constitutes different permutations of A (indicating the visitation date of intervention group) and B (indicating the visitation date of control group) which consist of 6 different modes: for example (1-AABB, 2-ABAB… 6-ABAB). Then to select specific days for control group and intervention group from the table, randomly moves his finger from a point in the random number table in a row or column direction. If a number between one and six is observed, its permutation will be noted. For example, if the number 6 appears, we note ABAB's permutation. In this way, the examination days will be allocated by the surgeon to intervention group (receiving training) and control group (without training). The method of sample selection in this research is done randomly using a random number table; so the researcher selects 10 people randomly from the list of people who have taken appointment for colorectal examinations on the mentioned surgeon visitation day. The researcher trains those 10 people in two rounds and two groups of five before being visited. Selection method in the control group will be the same. The control group members without training will complete the questionnaire 15 minutes before the visit.

Blinding (investigator's opinion)

Single blinded

Blinding description

The blinding technique is like that those who give the questionnaires to patients and collect them, and the statistician who performs the data analysis do not know the groups, also a visitation day is assigned separately to the test group and another day is dedicated to the control group. Patients in the training group are asked to not talk about the information given in the training sessions with other people. Similarly, the necessary samples are collected.

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz, Zand Avenue, opposite the Palestine Street, Central Building of Shiraz University of Medical Sciences

City

shiraz

Province

Fars

Postal code

71348-14336

Approval date

2017-11-21, 1396/08/30

Ethics committee reference number

IR.SUMS.REC.1396.166

Health conditions studied

1

Description of health condition studied

colorectal disease

ICD-10 code

k59 , c18

ICD-10 code description

Other functional intestinal Benign neoplasm of colon, rectum, anus and anal canalMalignant neoplasm of colon

Primary outcomes

1

Description
anexiety_ embarrassment_ concern about judgment
Timepoint
Before intervention and after intervention
Method of measurement
Measurement of Beck's Anxiety Scale and measurement of embarrassment and concern are judgments of the medical embarrassment questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
The intervention is a face-to-face educational psychoanalysis program.Intervention group:Intervention method: Training groups will be 4 to 6 people and the training is done in a classroom formed at the infirmary, the training class includes:A: Educational pamphlet provided to the learner at the beginning of the classB: PowerPoint using a computer and monitorThe training time will be 60 minutes. At the beginning of the session and before the training, the researcher gives the questionnaires to patients and asks them to complete those questionnaires, then the training begins by the researcher. According to the educational pamphlet, the researcher first outlines the importance of conducting these examinations and notes the dangers of non-timely examinations and its non-adherence. Then explains the examination method with the help of images that represent how the examination will be performed. These images are available on Pamphlet and PowerPoint; Images and explanations will be based on how to make such examinations scientifically as well as the special procedure of the surgeon. Through these images and descriptions, we help the patients to learn how to prepare themselves for examinations. We explain to patients the cause of each question doctor asks and they will be asked to answer the questions correctly and tell the doctor real signs and symptoms in order to help the doctor identify the actual diagnosis. The duration of this training phase is estimated 30 minutes. After the training stage, the psychological preparation of patients begins. Fellow psychologist who is already coordinated with the research project, talks with patients and makes them mentally prepared to accept such examinations. The duration of this psychological counseling will be 30 minutes. During this psychological consultation, the group therapy will be used to solve the psychological aspect of this study. In such a way that in each session a group of 5 to 6 people will be settled under the college psychologist leadership and patients are asked to express all the negative emotions and thoughts, vague points, religious beliefs and their fears about these types of examinations and talk about the reason of these thoughts invasion and this kind of attitude toward this examination type. Then everyone in the group suggests a strategy and approach that considers as an appropriate solution to this problem and at the end, the best decision to solve the problem and accept these types of examinations will be provided by the group members under the management and leadership of fellow psychologist. In each session, the proposed solutions can be different with regard to the problems of the group members. Because decisions are made due to the members attitude and feelings in the same session. Also, there is a possibility that the proposed solution is different for each member of the same group. At the end of the class, the patient's questions are answered and they wait for visitation. Immediately after the patients in the test group were examined by a doctor, they are requested again.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hasan Mojtaba Hospital in Darab
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
jamshid eslami
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Fars, Shiraz. Zand Avenue, next to the Red Crescent Building, Shiraz University of Medical Sciences. Floor 7
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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
Shiraz 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
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Full name of responsible person
masoomeh rambod
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Doctor of Nursing Education
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Person responsible for updating data

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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available