Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Clinical trial of evaluating and comparing the effectiveness of cognitive-behavioral and psychoeducation intervention on quality of life in patients with colon cancer

Protocol summary

Study aim

This study aims to evaluate and compare the effectiveness of cognitive-behavioral intervention and psychological training on quality of life in patients with colorectal cancer.

Design

Patients will be included in the study after obtaining informed consent with admission and admission criteria. Then 20 subjects with colorectal cancer will be assigned randomly to the study groups (parallel groups) (intervention group 1, cognitive behavioral therapy group, intervention group 2, psychiatric training). Patients and therapists, Are aware of the study.

Settings and conduct

Meetings will be held in both groups by a specialist and psychiatrist assistant at the Shafa hospital. All participants in the baseline period, after the intervention, and one month later, are evaluated by psychological examinations. Blinding is not done in this study.

Participants/Inclusion and exclusion criteria

The study population included 20 colorectal cancer patients referring to the specialized clinic of Razi hospital, recently diagnosed by the gastroenterologist. Inclusion criteria: Diagnosis of colorectal cancer by specialist, Age, education, Consent to participate in the study. Exclusion criteria: Having neurological diseases, Third stage of disease and above, Getting Beck depression and anxiety questioners score higher than 28, Having psychiatric disorders

Intervention groups

Intervention group1: Individuals in intervention group1 will receive cognitive-behavioral group therapy. The process of treatments will be set up during 6sessions of 90 minutes. Intervention group2: Individuals in intervention group1 will receive psychoeducation group therapy . The process of treatments will be set up during 6sessions of 90 minutes.

Main outcome variables

Quality of life in patients with colorectal cancer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150427021965N10**
Registration date: **2019-07-31, 1398/05/09**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-31, 1398/05/09**
Update count: **0**

Registration date

2019-07-31, 1398/05/09

Registrant information

Name

Homa Zarrabi

Name of organization / entity

Guilan University of Medical Sceinces,«Kavosh » Cognitive Behaviour Sciences and Addiction Researc

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of evaluating and comparing the effectiveness of cognitive-behavioral and psychoeducation intervention on quality of life in patients with colon cancer

Public title

The effect of cognitive-behavioral intervention and psycho educational training in patients with colorectal cancer

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of colorectal cancer by specialist Age between 20 and 65 years old Minimum five primary educations Consent to participate in the study

Exclusion criteria:

Having neurological diseases Third stage of disease and above Getting Beck depression and anxiety questioners score higher than 28 Having psychiatric disorders

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

After the convenience sampling method, the resident of psychiatry will randomly divide them into two intervention groups. Samples will be assigned by block randomization method one by one samples by using closed envelopes in two groups of 10 (With cognitive-behavioral intervention and psycho educational training). Given that the total number of samples is 20, people will be divided into 5 blocks of 4. Then assistant assigns patients to each group by closed envelopes. The first group is subjected to a cognitive-behavioral group for 6 weeks per week for a 1.5 hour session. The second group is subjected to a group of psycho educational training in six sessions per week, one 1.5 hour session.

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

Ethics committee of Guilan University of Medical Sciences

Street address

Old Building of School of Health, In front of the 17th Shahrivar Hospital, Shahid Siadati Avenue, Namjoo St.

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2019-06-26, 1398/04/05

Ethics committee reference number

IR.GUMS.REC.1398.134

Health conditions studied

1

Description of health condition studied

Colorectal cancer

ICD-10 code

C19

ICD-10 code description

Malignant neoplasm of rectosigmoid junction

Primary outcomes

1

Description

Quality of Life

Timepoint

At baseline, after the intervention and one month later, they will be evaluated by the WHOQOL quality of life test.

Method of measurement

All participants are assessed by WHOQOL Quality of Life Test.

Secondary outcomes

1

Description

Depression

Timepoint

All participants in the baseline period, after the intervention, and one month later, are evaluated by Beck Depression Psychology Test.

Method of measurement

All participants are evaluated by Beck Depression Psychology Test.

2

Description

Anxiety

Timepoint

All participants at baseline, after intervention, and one month later, are evaluated by Beck Anxiety Test.

Method of measurement

All participants are evaluated by Beck Anxiety Test.

Intervention groups

1

Description

Intervention group: People in the first intervention group will receive cognitive-behavioral group therapy/ First session: Running pre-test, introduction, discussing the importance of non-pharmacological treatments, introducing the cognitive-behavioral pattern. Second session: Reviewing the tasks of the previous session, teaching behavioral techniques to control the severity of complications from cancer, teaching some ways to cope with fatigue, teaching relaxation, teaching cognitive-behavioral techniques, expressing negative emotions (such as avoiding absolutism and generalization, Analysis of profits and losses and expressing feelings along with expressing expectations) and presentation of tasks. Third Session: Reviewing the tasks of the previous session, getting to know ways to deal with problems such as denial, projection, zoom Out, magnification, catastrophizing and Intellectual ruminations , Familiarity with problem solving techniques, regular planning for activity and planning for positive affairs on a daily basis and the presentation of tasks. Fourth session: Reviewing the tasks of the previous session, familiarizing with negative thoughts including negative thinking, mind Reading and negative predictive, preparing a list of negative thoughts. Fifth session: Reviewing the tasks of the previous session, familiarizing with How to deal with negative thoughts, presenting tasks for coping with negative thoughts in everyday life. Sixth session: Reviewing to use of problem-solving interventions on everyday issues, Reviewing the past contents and summaries, providing feedback on progress and receiving feedback from the patient about successful and unsuccessful aspects of treatment, post-test implementation, and appreciation of participants. The treatment process will be 6 sessions per 90 minutes.

Category

Rehabilitation

2

Description

Intervention group: People in the second group of intervention will receive group therapy for psychoeducational training. The process of treatments will be set up during 6 sessions of 90 minutes./ First session: Running pre-test , introduction, general description about the psycho educational training model, presentation of medical explanations for colorectal cancer, treatments and follow-up, presentation of educational pamphlet to patients. Second session: Reviewing the previous session, Teaching on how to be aware of stress and recognizing the sources of stress and recognizing personal responses to it including physical, psychological, and behavioral responses. Third session: Reviewing the previous session, practical training of stress management Includes: changing attitudes toward existing stress and then changing physical responses to it through relaxation methods. Fourth session: Reviewing the previous session, training key components of coping methods includes: optimism, ability to do, flexibility, adding information and awareness. Familiarity with the three common coping strategies: Behavioral - Active, Cognitive - Active, avoidance. Fifth session: Review of previous sessions, Training five steps of problem solving, including of relaxation, problem identification, thinking about possible solutions , choosing an appropriate solution to the circumstances, evaluation and action. Sixth session: Reviewing the previous session, explaining the importance of mental support and help patients to express their emotions and excitements (Positive or Negative) and sharing it with other members of the group, Summing up the sessions and answers to patient questions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Siamak Rimaz

Street address

Sardar Jangal St, Razi Research and Therapeutic Research Center

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Rasht

Province

Guilan

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

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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
Rasht University of Medical Sciences
Proportion provided by this source
50
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
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Full name of responsible person
Aida Yahyazadeh
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Person responsible for updating data

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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

All data will be coded and unidentifiable, will be shared.

When the data will become available and for how long

Start the access period 3-6 months after printing the results

To whom data/document is available

All physicians and paramedics in the field of psychology

Under which criteria data/document could be used

For further information on rehabilitation methods for patients with severe medical conditions, such as cancer

From where data/document is obtainable

Email address

What processes are involved for a request to access data/document

The demandant will be responded to by the moderator after 3-5 days.

Comments