

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of mentalization-based treatment on impulsive behaviors in cancer patients undergoing treatment

Protocol summary

Study aim

Determining the effect of treatment based on mentalization on impulsive behaviors in cancer patients treated at Amir Oncology Hospital, Shiraz University of Medical Sciences in 1401

Design

The clinical trial has a control group, a blind strain, randomized, the sample size is 54 people, and the intervention will be done on 27 people. Random software is used for randomization.

Settings and conduct

Outpatient Chemotherapy Department of Amir Hospital, random sampling and allocation of 27 people to the intervention group, holding 12 treatment sessions based on Fonagy mentalization in one and a half hour sessions, single-blinding for the outcome evaluator and people who pre-test and post-test The test is taken from the participants

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with gastrointestinal cancer in the outpatient department of Amir Hospital; moderate to high impulsivity score; Willingness to participate in the study. Exclusion criteria: history of participating in similar meetings; Suffering from chronic mental and cognitive diseases

Intervention groups

Holding 12 sessions of one and a half hour treatment based on mentalization according to the Fonagy protocol for the intervention group on a weekly basis, re-giving the questionnaires to both groups after the end of the intervention, receiving educational content after the end of the intervention by the control group

Main outcome variables

Knowing the levels of impulsive behaviors of cancer patients and its relationship with mentalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230929059548N1**

Registration date: **2023-10-24, 1402/08/02**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-24, 1402/08/02**

Update count: **0**

Registration date

2023-10-24, 1402/08/02

Registrant information

Name

Hanieh Edalati

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3730 7889

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2023-11-01, 1402/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of mentalization-based treatment on impulsive behaviors in cancer patients undergoing treatment

Public title

Investigation the effect of mentalization - based treatment on the impulsive behaviors in cancer patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with gastrointestinal cancer Patients admitted to the outpatient department of Amir Shiraz Oncology Hospital Willingness to participate in the study Moderate to high impulsive behavior based on the Barrett Impulsivity Scale Failure to participate in similar treatment sessions

Exclusion criteria:

Suffering from chronic mental and cognitive diseases

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be allocated to two control and intervention groups by randomization method of permutation blocks. Finally, the sample size was considered to be 54, and for proportionality and equality of allocation, the samples will be placed in 9 blocks of 6. The random allocation list will be prepared by Random Allocation software. Randomization will be done individually. Concealment will also be one-way blind. In this way, the people who analyze the results and the people who take the pre-test and post-test from the participants are unaware of the intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding is performed in such a way that the people who analyze the results (outcome evaluator) and the people who take the pre-test and post-test from the participants are unaware of the intervention.

Placebo

Not used

Assignment

Parallel

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

Salman Farsi Blvd., Javanmardi Street, Eram Residential Complex, Block 2/6, Unit 131

City

Shiraz

Province

Fars

Postal code

7145834538

Approval date

2023-08-26, 1402/06/04

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1402.058

Health conditions studied

1

Description of health condition studied

Cancer patients

ICD-10 code

Malignant

ICD-10 code description

Malignant neoplasms

Primary outcomes

1

Description

Score of impulsive behaviors in cancer patients based on Barrett's impulsivity scale

Timepoint

Measuring the level of impulsive behaviors at the beginning and end of the study

Method of measurement

Barrett impulsivity questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mentalization-based therapy (MBT) is a special type of psychodynamic psychotherapy invented by Bateman and Fonagy. MBT is based on two main concepts: Balbi's attachment theory and mentalization. The main focus of MBT is to help the client bring their subjective experiences to the level of consciousness and facilitate a coherent and full sense of psychological agency. The goal of treatment is to grow and strengthen the mentalizing capacity through therapeutic

relationships and increase the capacity of the patient to recognize the thoughts and feelings he experiences. Batman and Fonagy treatment protocol includes two parts: preliminary MBT and individual and group MBT. Preliminary MBT consists of 12 group therapy sessions, which are held weekly and each session lasts 1.5 hours, and after these sessions, individual and group sessions are offered to people, which are held in a period of 18 months. But according to Batman and Fonagy's conclusion; Evidence that this arrangement is optimal is lacking, suggesting that MBT should now be offered for shorter durations as well as as group or individual therapy. Therefore, in this study, only 12 preliminary MBT sessions will be conducted in person for the intervention group. After completing the interventions, the questionnaires will be given to both groups again. In each session, according to the protocol, they are taught about topics that include; The first session (what is mentalization and a mentalizing stance?), the second session (what does it mean to have a problem with mentalizing?), the third session (why do we have emotions and what are the basic types?), the fourth session (mentalizing emotions), the fifth session (the significance of attachment relationships), the sixth session (attachment and mentalizing), the seventh session (what is meant by impulsive behavior?), the eighth and ninth sessions(mentalization-based treatment), the tenth session (anxiety, attachment and mentalizing), the session It is the eleventh (depression, attachment and mentalizing) and the twelfth session (summary and conclusion). In each meeting, the objectives of the same meeting along with assignments are presented to the participants.

Category

Other

2

Description

Control group: The control group will receive the educational content after the end of the intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Oncology Hospital

Full name of responsible person

Ali Amanati

Street address

Farhang Shahr Street, 11th Station, Amir Oncology Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Zand St., Central Building, Shiraz University of Medical Sciences, 7th floor, Research and Technology Vice-Chancellor

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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

Shiraz University of Medical Sciences

Full name of responsible person

Hanieh Edalati

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Ladan Zarshenas

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Person responsible for updating data

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Other areas of specialty/work

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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