Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of family participatory dignity therapy on the some psychological outcomes of family caregivers and patients with gastrointestinal cancers undergoing chemotherapy

Protocol summary

Study aim
Determining the effect of family participatory dignity therapy on depression and hope of patients with gastrointestinal cancers and psychological distress, and family adaptation and cohesion of their family caregivers.

Design
A clinical trial with a control group, single-blinded , non-randomized.

Settings and conduct
The research will be conducted in the Cancer Institute of Imam Khomeini Hospital. Questionnaires will be completed in two shifts, at the beginning of the study by the control group and then one month after receiving usual care in the control group and one month after receiving the intervention in the test group. After completing the questionnaires, family participatory dignity therapy protocol will be implemented for the intervention group. Blinding will be done for the data analyst.

Participants/Inclusion and exclusion criteria
The criteria for entering the study related to patients: 1- Having a medical file with the diagnosis of gastrointestinal cancers confirmed by the attending physician, 2- Age range of 18 to 65 years, 3- Listening, speaking and writing ability to participate in the study, 4- Awareness of Illness and being interested in participating in the study, 5- not having cognitive impairment 6- presence of a caregiver next to the patient during hospitalization and entry criteria related to family members including: 1- family members or close relatives of the patient 2- main responsibility for patient care 3- To have the ability to provide informed consent and feedback regarding family participatory dignity therapy Exclusion criteria : 1-deterioration of the patient's condition, 2-disinclination to continue the study, 3-research sample size, 4-discharge earlier than 4 days.

Intervention groups
The experimental group receives family participatory dignity therapy intervention. The control group received only usual ward care.

Main outcome variables
depression; Hope

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240313061275N1**
Registration date: **2024-04-12, 1403/01/24**
Registration timing: **prospective**

Last update: **2024-04-12, 1403/01/24**
Update count: **0**

Registration date
2024-04-12, 1403/01/24

Registrant information

Name
Ehsan Jalalabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 4261 3751

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-21, 1403/03/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of family participatory dignity therapy on the some psychological outcomes of family caregivers and patients with gastrointestinal cancers undergoing chemotherapy

Public title

Effect of family participatory dignity therapy on the some psychological outcomes of family caregivers and patients with gastrointestinal cancers undergoing chemotherapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having a medical file with the diagnosis of gastrointestinal cancers, confirmed by the attending physician Age range from 18 to 65 years Listening, speaking and writing ability to participate in the study Being aware of the disease and being interested in participating in the study Not having cognitive impairment The presence of a caregiver next to the patient during hospitalization

Exclusion criteria:

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **148**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding will be done for data analysts

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tohid square- Nursing & Midwifery faculty

City

Tehran

Province

Tehran

Postal code

7887990

Approval date

2024-03-10, 1402/12/20

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.518

Health conditions studied

1

Description of health condition studied

سرطان های گوارشی

ICD-10 code

C26.9

ICD-10 code description

Malignant neoplasm: Ill-defined sites within the digestive system

Primary outcomes

1

Description

Depression score in Beck questionnaire

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Beck's standard depression questionnaire, second version (BDI-II)

2

Description

Hope score in Snyder 12-item hope questionnaire

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Snyder 12-item hope questionnaire

Secondary outcomes

1

Description

Psychological distress score in Kessler questionnaire

Timepoint

Before the intervention and one month after the

intervention

Method of measurement

Kessler psychological distress questionnaire

2

Description

The score of family adaptation and cohesion in Elson et al.'s questionnaire

Timepoint

Before the intervention and one month after the intervention

Method of measurement

family adaptation and cohesion Elson et al.'s questionnaire

Intervention groups

1

Description

Intervention group: In order to implement family participatory dignity therapy, four sessions of 45-60 minutes will be considered. The patient and the patient's companion are present in the sessions at the same time. In the first session, the researcher will introduce dignity therapy with family participation to the patient-family couples and will receive their written informed consent. Also, the optimal time and place will be planned according to the patient's condition and the family caregiver's schedule. In the second session, that is, 24 to 48 hours later, two or three interviews, which are adjusted to the needs of the participants, will be conducted based on the framework of questions of the family participatory dignity therapy method and will be recorded using a digital audio recorder. The therapist also facilitates conversations, disclosure of real feelings and concerns, and encourages caregivers to think positively. In the third session, the interview will be transcribed verbatim and cleaned by the therapist to obtain a coherent text using an editing process. In this stage, the therapist reads the text to the patient and his companion and asks them to express the parts that need to be corrected. It will be collected from virtual space software, and at the end of this stage, the therapist will check that the edited text matches the participants' statements. In the final session, the final and edited product will be provided to the participants and it will be read in full by the therapist, the patient and the patient's companion, and the participants' opinion will be asked about the final product. In this meeting, the patient and the family can share the final product, which includes the images sent and the texts expressed, with anyone who wishes. After the intervention, the questionnaires mentioned above will be completed again one month after the completion of the treatment for the intervention group. During the study period, the control group will receive the center's routine treatments.The content of the meetingsThe main activity in family-centered participatory dignity therapy intervention is that the patient's couple and family talk about the important incidents and events in the patient's life, and finally the stated items are rewritten and given to friends and acquaintances. The patient and family can share the final version of the retold memories with friends and acquaintances. In this intervention, education is not given to the patient, and the patient himself has an active and main role in this intervention, and by doing it, the focus of the patient and the family is focused on the previous life activities and important events in the patient's life. By remembering and sharing the bright and important points of life, the patient will find a sense of purpose in life.Session 1: Introduction to family participatory dignity therapy The therapist introduces the method to the patient-family pairs and receives their written informed consent: in this part, the activities that will be performed in this intervention are fully explained to the patient and family, which include 1- Interview sessions (in which the patient's memories and past activities are asked in these sessions) 2- Sessions related to reviewing the expressed memories and correcting them 3- Session to share the final file with friends and acquaintancesThe questions of patients and their families are answeredThe optimal time of the interviews is planned according to the patient's condition and the family caregiver's scheduleSession 2: InterviewsQuestions related to family participatory dignity therapy are asked to patients and their families, which can be asked to family and patient couples in two or three interviews according to the conditions of the participants.(Questions related to the intervention are given in full in the attached files)Questions and answers of patients and family members are recorded with a tape recorderSession 3: Examining transcripts and collecting imagesThe recorded audio files have been fully transcribed and in this session the transcribed files will be shown to the patient and the caregiver, and the patient and the caregiver will identify the parts that need to be corrected by reading the file and checking it.Collecting photos: The patient and the caregiver are asked to provide the researcher with the photos and images related to the memories expressed in the previous session. Photos that evoke memories for family members and patients are collected by virtual space softwareSession 4: SharingThe final electronic file and product (which includes the collected memories and photos) can be shared with anyone the patient-family couple wishes.At this stage, the file and the final product are read by the patient couple and family and their opinion is asked about it

Category

Other

2

Description

Control group: The patients of the control group receive the usual care of the hospital and their caregivers do not receive any intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
Pegah Matouypour

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Deputy of research and technology, Tehran University of Medical Sciences

Street address
6th floor of Research and Technology Vice-Chancellor,, Central Organization of the University, corner of Quds St,Keshavarz Blvd. Tehran Town

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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

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
Tehran University of Medical Sciences

Full name of responsible person
Pegah Matouypour

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Position
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Latest degree
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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