Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Adaptation and Feasibility of Managing Cancer and Living Meaningfully (CALM) Intervention for Patients with Advanced Cancer in Iran: Investigating Its Cognitive and Psychological Impacts

Protocol summary

Study aim

Adaptability and feasibility of Cancer Management and Meaningful Life (CALM) intervention for patients with advanced cancer in Iran and investigating its cognitive and psychological effects.

Design

A pretest-post-test clinical trial with the control group and follow-up. Phase 2-3 on 50 patients. Randomized using random sequence generation software.

Settings and conduct

In the first stage, the intervention will be performed on 3 to 5 eligible patients referred to the oncology services of Imam Khomeini Hospital in Tehran. Program deficiencies will be identified and improved based on patients' feedback and professors' comments. Then, 50 people will be selected, randomly divided, and received interventions. All participants will complete all questionnaires at baseline (T0), month 3 (T1), and month 4 (T2).

Participants/Inclusion and exclusion criteria

Eligible patients are greater than18 years; fluent in Persian; with a diagnosis of malignant solid tumor (UICC III or IV); average life expectancies between 12 and 18 months; and have a score greater than or equal to 10 on the PHQ-9 and/or greater than 5 on PCL-5 and/or greater than or equal to 20 on DADDS and/or lesser than 27 on MMSE. Exclusion criteria are inability to commit to the required sessions; concomitant psychotherapy; severe sensorimotor disability or brain damage; reported suicidal ideas and/or criteria of psychosis.

Intervention groups

Patients are divided into two groups. A group receives CALM and the control group receives routine palliative treatment. CALM is a brief, manual supportive-expressive therapy, done individually or by inviting a family member depending on the patient's needs and wishes; three to six 45-60 minute sessions will be delivered twice monthly over three months.

Main outcome variables

Depression symptoms; post-traumatic stress symptoms; death stress; quality of life ;and retrospective-prospective memory

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230627058602N1**
Registration date: **2023-07-22, 1402/04/31**
Registration timing: **prospective**

Last update: **2023-07-22, 1402/04/31**
Update count: **0**

Registration date

2023-07-22, 1402/04/31

Registrant information

Name

Sanaz Nabipour

Name of organization / entity

The University of Kharazmi

Country

Iran (Islamic Republic of)

Phone

+98 21 2220 8653

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nabipour.sanaz@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Adaptation and Feasibility of Managing Cancer and Living Meaningfully (CALM) Intervention for Patients with Advanced Cancer in Iran: Investigating Its Cognitive and Psychological Impacts

Public title

Adaptation, feasibility, and investigation of CALM on cognitive and psychological problems of patients with advanced cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Fluency in Persian language Diploma or higher level of education and living in Tehran Diagnosis of the metastatic solid tumor as follows: stage III B or IV lung cancer; any stage of pancreatic cancer, stage III or IV ovarian and fallopian tube cancers, or stage IV of other gynecological cancers; and stage IV breast, genitourinary, gastrointestinal, melanoma, sarcoma, or endocrine cancers Life expectancy 12 to 18 months A score greater than or equal10 on the Patient Health Questionnaire (PHQ9) A score greater than 5 on the Post-traumatic Stress Disorder Checklist (PCL-5) A score greater than or equal to 20 on the Death and Dying Distress Scale (DADDS) A score lesser than 27 on Mini-Mental State Examination (MMSE)

Exclusion criteria:

Language or communication barriers hindering psychotherapy Consciousness problems or inability to participate in assessment and intervention sessions Disorder and features of acute psychosis Suicidal thoughts and attempts Severe sensorimotor disabilities Brain damage or any medical condition that better explains the cognitive and psychological problems of patients with advanced cancer Concomitant psychotherapy

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

We will use simple stratified randomization with 1:1 allocation between arms. Computerized randomization will be created, administered, and password protected by a researcher at Razi University independent of the research team. After obtaining written informed consent and completing the initial steps, the research assistant contacts the center via email to receive the subject and inform the patients about the therapist they will be seeing. No member of the research team will have access to the randomization list.

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

Research Ethics Committees of Imam Khomeini Hosp

Street address

Management of Research and Technology Affairs of the University, 6th Floor, Central Building of Tehran University of Medical Sciences, Intersection of Keshavarz Blvd and Qods Street, Tehran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2023-06-20, 1402/03/30

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.117

Health conditions studied

1

Description of health condition studied

Malignant solid tumor as follows: stage III B or IV lung cancer; any stage of pancreatic cancer, stage III or IV ovarian and fallopian tube cancers, or other stage IV gynecological cancer; and stage IV breast, genitourinary, gastrointestinal, melanoma, sarcoma, or endocrine cancers

ICD-10 code

C00-C80

ICD-10 code description

Malignant neoplasms, of specified sites, except of lymphoid, haematopoietic and related tissue

Primary outcomes

1

Description
The score of depression symptoms in the Patient Health Questionnaire (PHQ-9)
Timepoint
Before starting the intervention, the third month for evaluation and the 4th month for follow-up
Method of measurement
Using the Patient Health Questionnaire (PHQ-9)

2

Description
The score of death distress in the Death And Dying Distress Scale (DADDS)
Timepoint
Before starting the intervention, the third month for evaluation and the 4th month for follow-up
Method of measurement
Using Death And Dying Distress Scale (DADDS)

3

Description
The score of post-traumatic stress symptoms in Posttraumatic Stress Disorder Checklist (PCL-5)
Timepoint
Before starting the intervention, the third month for evaluation and the 4th month for follow-up
Method of measurement
Using Posttraumatic Stress Disorder Checklist (PCL-5)

4

Description
The quality of life score in the quality-of-life scale of patients with advanced cancer (QUAL-EC)
Timepoint
Before starting the intervention, the third month for evaluation and the 4th month for follow-up
Method of measurement
Using Quality of life scale of patients with advanced cancer (QUAL-EC)

5

Description
The memory score in the Prospective and Retrospective Memory Questionnaire (PRMQ)
Timepoint
Before starting the intervention, the third month for evaluation and the 4th month for follow-up
Method of measurement
Using Prospective and Retrospective Memory Questionnaire (PRMQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Managing Cancer and Living Meaningfully (CALM) is a brief, semi structured and manualized psychotherapeutic intervention intended to treat and prevent depression and end-of-life distress in patients with advanced cancer. It consists of three to six sessions, usually of 45 minutes, delivered across 3 to 6 months, and addresses 4 main domains: symptom control and communication with health care providers; changes in self and relations with close others; spiritual well-being and sense of meaning and purpose; and preparing for the future, sustaining hope, and facing mortality. The timing of sessions and content explored are guided by the patient’s interests and priorities. Interventions are adapted to patient and caregiver needs by using supportive approaches, such as education and validation, and expressive approaches, including facilitation of reflection and creation of meaning. So the therapist facilitates exploration of four broad domains, while also attuning to and helping to regulate the patient’s emotional state. Control group: They are referred to the palliative clinic to receive common treatment. Their therapeutic approach is based on an integrative approach consisting of psycho-oncological counseling, provision of information, crisis intervention as well as supportive individual therapy. As for the intervention arm, patients randomized to the control arm will receive up to six, 50-min sessions delivered over 3 months.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Sanaz Nabipour
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Akbar Fotuhi

Street address
No 605, 6th Floor, Central Organization of the University, Corner of Quds St., Keshavarz Blvd.

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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
The University of Kharazmi

Full name of responsible person
Sanaz Nabipour

Position
PhD candidate

Latest degree
Medical doctor

Other areas of specialty/work
Psychology

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

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Demographic information, excluding personally identifiable information, medical information, and primary outcome information, may be shared. Also, the information obtained from the analysis of tests and questionnaires and the result of the research will be available to those interested in the form of an article.

When the data will become available and for how long
The start of the access period will be after the publication of the results in the form of an article, and will be for a maximum period of one year.

To whom data/document is available
Researchers working in academic and scientific institutions can request to send data.

Under which criteria data/document could be used
The information contained in the data will be provided to the applicant for study purposes only.

From where data/document is obtainable
Applicants can send their application through the email below: nabipour.sanaz@gmail.com

What processes are involved for a request to access data/document
In case of request via email, they will be answered within 48 working hours.

Comments