Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Studying the Effectiveness of Group Logotherapy on the Care Burden and Quality of life of Cancer Patients' Caregivers

Protocol summary

Study aim

The aim of this study is to determine the effectiveness of group logotherapy on caregiving burden and quality of life among caregivers of patients with cancer.

Design

A randomized controlled clinical trial with parallel groups, single-blind, with a sample size of 60 participants. Randomization is conducted using a random numbers table.

Settings and conduct

This study will be conducted at Motahari Clinic. After obtaining written informed consent, participants will be randomly allocated to the intervention or control group. The intervention group will receive group logotherapy, while the control group will receive usual care. Outcome assessment will be performed by a blinded assessor.

Participants/Inclusion and exclusion criteria

Inclusion: Primary caregivers of patients with cancer; more than 18 years old; able to attend group logotherapy; willing to participate; provided written consent, Severe psychiatric disorder Exclusion: individual or family conditions at entry preventing attendance.

Intervention groups

Intervention Group:Participants in the intervention group receive group logotherapy based on Viktor Frankl's approach, following a structured protocol and established references.The intervention is delivered in 8 weekly group sessions, each lasting 90 minutes, over a total period of 8 weeks. Session content focuses on meaning-centered exploration, responsibility and attitudes toward suffering. Control Group:Participants in the control group receive no logotherapy or structured psychological intervention during the study period and continue to receive routine care and standard services of the clinic as usual.

Main outcome variables

Caregiving burden; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251229068482N1**
Registration date: **2026-02-16, 1404/11/27**
Registration timing: **retrospective**

Last update: **2026-02-16, 1404/11/27**
Update count: **0**

Registration date

2026-02-16, 1404/11/27

Registrant information

Name

Mohammad Hadi Owjfard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3620 3478

Email address

mhadiog@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-15, 1404/10/25

Expected recruitment end date

2026-02-14, 1404/11/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the Effectiveness of Group Logotherapy on the Care Burden and Quality of life of Cancer Patients' Caregivers

Public title
The Effects of logo therapy on the cancer patients' caregivers
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Voluntary Willingness to Participate in the Study and Signing the Informed Consent Form Membership in the Patient's Family and Direct Responsibility for Daily Care A Minimum History of Three Months of Direct Caregiving With an Average of at Least Two Hours per Day for a Patient With Cancer (Based on Self-Report in the Demographic Form) Aged eighteen years or older. No Receipt of Payment or Salary for Caregiving Ability to Read and Write in the Persian Language No History of Severe Psychiatric Disorders or Cognitive Impairment Based on Self-Report or Medical Records
Exclusion criteria:
History of substance abuse or current use of psychoactive medications at the time of study entry. Inability to plan for attendance at group logotherapy sessions at the time of study entry.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, after confirming eligibility criteria and obtaining written informed consent, participants were allocated to the intervention and control groups using simple randomization with a 1:1 allocation ratio. The unit of randomization was the individual, and neither cluster randomization nor stratified randomization was applied. The random allocation sequence was generated prior to participant recruitment by an independent researcher using a random numbers table. Group assignment was determined based on whether the generated numbers were odd or even, and a complete allocation list was prepared in advance. This researcher was not involved in participant recruitment or intervention implementation. To ensure allocation concealment, the prepared random sequence was placed in sequentially numbered, opaque, sealed, and impermeable envelopes. The envelopes were opened in order of participants' entry into the study, ensuring that group assignment was not predictable for either the researcher or the participants prior to allocation.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the intervention, which involved group logotherapy, blinding of participants and health care providers delivering the intervention was not feasible. Participants were aware of whether they received the intervention, and the therapist was directly involved in delivering the sessions. The principal investigator was also aware of group allocation because of involvement in the design and implementation of the study. To minimize potential bias in outcome assessment, the outcome assessor responsible for collecting questionnaires and evaluating outcome variables was kept blinded to group allocation. Data were provided to the assessor without any indication of the participants' group assignment. Data analysis was performed after completion of data collection, and the data analyst was aware of the original group allocation. Given the academic nature and limited scale of the study, no Data Safety and Monitoring Committee was established. All participants provided written informed consent after receiving complete information about the study objectives and procedures.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Schools of Nursing and Midwifery, Management & Medical Information Sciences
Street address
Seventh Floor, Central Building, Shiraz University of Medical Sciences, Adjacent to the Red Crescent, Zand Street, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2025-11-01, 1404/08/10
Ethics committee reference number
IR.SUMS.NUMIMG.REC.1404.095

Health conditions studied

1

Description of health condition studied

Cancer

ICD-10 code

C00-C97

ICD-10 code description

Malignant neoplasms

Primary outcomes

1

Description

Caregiving burden score among caregivers of patients with cancer measured using the Zarit Burden Interview.

Timepoint

Caregiving burden will be measured at two time points; at baseline before the start of the group logotherapy intervention; and at the end of the intervention period immediately after completion of the group logotherapy sessions.

Method of measurement

Caregiving burden among caregivers of patients with cancer will be measured using the Zarit Burden Interview questionnaire.

2

Description

Quality of life score among caregivers of patients with cancer measured using the World Health Organization Quality of Life Brief questionnaire.

Timepoint

Quality of life will be measured at two time points; at baseline before the start of the group logotherapy intervention; and at the end of the intervention period immediately after completion of all group logotherapy sessions.

Method of measurement

Quality of life among caregivers of patients with cancer will be measured using the World Health Organization Quality of Life Brief questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group:Participants in this group receive group logotherapy through a structured 8-session weekly program, each session lasting 90 minutes, based on Viktor Frankl’s logotherapy principles. Session content includes:Introduction to logotherapy conceptsIdentifying personal values and sources of meaningReviewing caregiving burden and attitude toward sufferingTransforming suffering into growth opportunitiesEnhancing hope and psychological resilienceClarifying caregiving roleIntegrating meaning into daily lifeAll sessions are conducted by a trained therapist, and participants receive identical content throughout the intervention period.Control Group:Participants in this group receive no structured logotherapy intervention and continue with routine care and standard clinic services.

Category

Behavior

2

Description

Control group: Participants in the control group will not receive any group logotherapy intervention during the study period and will receive only the usual care and services routinely provided at Shahid Motahari Clinic. No additional educational or psychological intervention will be provided to this group during the study period.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Specialized and Subspecialized Clinic

Full name of responsible person

Shahrzad YektaTalab

Street address

Shahid Motahari Specialized and Subspecialty Clinic, Beside Namazi Hospital, Namazi Square, Shiraz, Iran

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Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Hamid mohhamadi

Street address

Seventh Floor, Research and Technology Vice Chancellorship, Shiraz University of Medical Sciences Main Building, Zand Street, Shiraz, Iran

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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

Mohammad Hadi Owjfard

Position

Student of MSN

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Mohammad Hadi Owjfard

Position

Student of MSN

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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City

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no plan to share individual participant data from this study. No further information is available.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available