Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Dignity Therapy on the Demoralization in Patients Undergoing Chemotherapy

Protocol summary

Study aim

• Determining the effect of dignity therapy on Demoralization Syndrome in patients undergoing chemotherapy

Design

In this study, participants will be recruited using convenience sampling. Then, using simple randomization with balanced blocks, individuals will be assigned randomly to the groups. For the random assignment, due to the two-group design of the study, the randomization with balanced blocks with a block size of four will be used. In total, 84 participants (42 in each group) will be invited to participate in the study.

Settings and conduct

This will be a randomized, controlled trial, with participants randomly assigned to either the intervention group or the control group. The population for this study will be patients undergoing chemotherapy treatment in Qazvin province hospitals.

Participants/Inclusion and exclusion criteria

1. Willingness to participate in the research and complete the consent form 2. Full consciousness and the ability to communicate 3. People over 18 years old 4. Being literate in reading and writing in the Persian language 5. Starting chemotherapy at least 6 months ago 6. Access to a phone or mobile for follow-up

Intervention groups

Dignity therapy is a short-term, individual therapy in which the therapist asks a series of open-ended questions to the patient in a 30 to 60-minute session, encouraging the patient to talk about their life and significant events. The patient's speech is recorded, rewritten, and edited. After a few days, it is returned to the patient to allow the creation of necessary changes before the final version is prepared. The final version is kept as a booklet as a memento for the patient's loved ones and family members.

Main outcome variables

Improvement of Demoralization Syndrome in patients treated with chemotherapy

General information

Reason for update

The clinical trial has been completed and we are ready to update the information on IRCT.

Acronym

IRCT registration information

IRCT registration number: **IRCT20240725062542N1**
Registration date: **2024-11-28, 1403/09/08**
Registration timing: **prospective**

Last update: **2025-09-16, 1404/06/25**
Update count: **1**

Registration date

2024-11-28, 1403/09/08

Registrant information

Name
Sima Kazemi
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-31, 1403/10/11

Expected recruitment end date

2025-04-28, 1404/02/08

Actual recruitment start date

2024-12-31, 1403/10/11

Actual recruitment end date

2025-04-28, 1404/02/08

Trial completion date

2025-04-28, 1404/02/08

Scientific title

The Effect of Dignity Therapy on the Demoralization in Patients Undergoing Chemotherapy

Public title

The Effect of Dignity Therapy on the Demoralization in Patients Undergoing Chemotherapy in Qazvin City, 2024

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

1. Willingness to participate in the research and complete the consent form 2. Full consciousness and the ability to communicate 3. People over 18 years old 4. Being literate in reading and writing in the Persian language 5. Starting chemotherapy at least 6 months ago 6. Access to a phone or mobile for follow-up

Exclusion criteria:

1. Diagnosis of a psychiatric disorder and use of psychotropic drugs (as diagnosed by a physician) 2. Experience of spiritual crises in the last 6 months (self-report) 3. Use of alcohol and drugs (self-report)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Actual sample size reached: **79**

Randomization (investigator's opinion)

Randomized

Randomization description

1. Participants will be selected based on inclusion criteria and availability through a convenience sampling method. 2. After selection, they will be assigned to either group using a simple randomization with balanced blocks. 3. Given the study's two-group nature, a balanced block randomization with a block size of 4 will be employed for the randomization. 4. To determine the randomization order by a block of 4, an online tool for producing random allocation lists (https://www.sealedenvelope.com/simple-randomiser/v1/lists) will be used.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin, Iran

City

Qazvin

Province

Qazvin

Postal code

59811-34197

Approval date

2024-10-22, 1403/08/01

Ethics committee reference number

IR.QUMS.REC.1403.275

Health conditions studied

1

Description of health condition studied

Cancer, Chemotherapy

ICD-10 code

Z51.2

ICD-10 code description

Maintenance chemotherapy NOS

Primary outcomes

1

Description

This is a score that each participant will receive based on the 24-item Distress Thermometer scale developed by Kissane (2004).

Timepoint

The Demoralization Syndrome questionnaire will be administered at three different time points: before the intervention, immediately after the intervention, and three months post-intervention for follow-up.

Method of measurement

The Demoralization Syndrome (DS) is a tool designed by Kissane and colleagues (2004) to assess Demoralization Syndrome in cancer patients.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: Dignity therapy is a brief individual therapy in which the therapist asks a series of open-ended questions to the patient within a 30 to 60-minute session, encouraging them to talk about their life and significant events. The patient's speech is recorded, rewritten, and edited. After a few days, it is returned to the patient to allow the creation of necessary changes before the final version is prepared. The final version is kept as a booklet as a memento for the patient's family and loved ones.

Category
Behavior

2

Description
Control Group: In the control group, questionnaires are completed initially, immediately after the intervention, and 3 months post-intervention. At the end, a booklet containing educational points on the disease and points that should be observed during the disease is given to the patient.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Velayat Hospital, Minodar, Qazvin, Iran

Full name of responsible person
Sima Kazemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

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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
Qazvin 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
Qazvin University of Medical Sciences

Full name of responsible person
Sima Kazemi

Position
Faculty Member of Nursing

Latest degree
Master

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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 collected will potentially be shareable after the participants have been de-identified.
When the data will become available and for how long
The data will be available 6 months after the study results have been published.
To whom data/document is available
The data will only be accessible to researchers affiliated with academic and research institutions.
Under which criteria data/document could be used
The results of this study may be used by researchers for future studies, provided that they obtain permission from the project coordinators.
From where data/document is obtainable
Executors of the plan: Sima Kazemi (nurse.simakazemi@gmail.com) Mohammad Ali Soleimani (soleimany.msn@gmail.com)
What processes are involved for a request to access data/document
Please contact us via email for further communication.
Comments

Trial results

Please tick if results have been published
Yes
Summary result posting date
2025-09-16, 1404/06/25
Table of baseline comparison

Variable	Intervention (N=42)	Control (N=42)	Between-group comparison t(p)/χ^2(p)
Age (year)	53.69 (13.35)	51.57 (12.86)	0.74 (0.46)
Cancer duration (month)	29.79 (40.65)	24.79 (17.70)	0.73 (0.47)

Chemotherapy duration (month)	11.64 (11.53)	13.12 (9.07)	-0.65 (0.52)
Perceived social support (0–10 scale)	7.43 (2.49)	7.88 (1.86)	-0.94 (0.35)
Perceived religious beliefs (0–10 scale)	8.14 (1.79)	8.00 (2.25)	0.32 (0.75)
Gender	Male: 22 (52.4) Female: 20 (47.6)	Male: 18 (42.9) Female: 24 (57.1)	0.76 (0.38)
Marital status	Married: 36 (85.7) Not married: 6 (14.3)	Married: 31 (73.8) Not married: 11 (26.2)	1.84 (0.18)
Number of children	No child: 4 (9.5) 1–2 children: 18 (42.9) ≥3 children: 20 (47.6)	No child: 8 (19.0) 1–2 children: 14 (33.3) ≥3 children: 20 (47.6)	1.83 (0.40)
Educational status	Under diploma: 29 (69.0) Diploma: 9 (21.4) Academic degree: 4 (9.5)	Under diploma: 18 (42.9) Diploma: 16 (38.1) Academic degree: 8 (19.0)	5.87 (0.05)
Job	Unemployed: 16 (38.1) Employed: 14 (33.3) Retired: 12 (28.6)	Unemployed: 18 (42.9) Employed: 16 (38.1) Retired: 8 (19.0)	1.05 (0.59)
Perceived economic status	Fair: 13 (31.0) Good: 25 (59.5) Very good: 4 (9.5)	Fair: 5 (11.9) Good: 27 (64.3) Very good: 10 (23.8)	6.20 (0.045)
Family history of cancer	No: 24 (57.1) Yes: 18 (42.9)	No: 22 (52.4) Yes: 20 (47.6)	0.19 (0.66)
Insurance	No: 2 (4.8) Yes: 40 (95.2)	No: 0 (0) Yes: 42 (100)	2.05 (0.15)
Chronic disease history	No: 28 (66.7) Yes: 14 (33.3)	No: 31 (73.8) Yes: 11 (26.2)	0.51 (0.47)
Admission history	No: 11 (26.2) Yes: 31 (73.8)	No: 14 (33.3) Yes: 28 (66.7)	0.51 (0.47)
Physical activity	Fair: 10 (23.8) Good: 24 (57.1) Very good: 8 (19.0)	Fair: 5 (11.9) Good: 31 (73.8) Very good: 6 (14.3)	3.45 (0.33)

Participant flow diagram

https://www.sciencedirect.com/science/article/abs/pii/S1462388925001589

Table of variable outcomes' results

Variable	Measurement time	Groups	Between-group comparison t(p)	Mean Difference (95% CI)	Standardized Mean Difference (95% CI)	Repeated measures ANOVA F(p)	Partial η²
Loss of meaning	Baseline	Intervention: 7.06 (5.06) Control: 6.66 (5.04)	0.77 (0.44)	0.81 (-1.29; 2.90)	0.17 (-0.26; 0.60)	Time: 8.89 (0.001)	0.110
	Follow-up 1	2.68 (3.17) 6.34 (3.22)	23.98 (<0.001)	-3.67 (-5.17; -2.18)	-1.15 (-1.63; -0.66)	Group: 7.90 (0.006)	0.099
	Follow-up 2	2.39 (3.21) 5.76 (3.22)	19.94 (<0.001)	-3.38 (-4.88; -1.87)	-1.05 (-1.53; -0.57)	Time*Group: 14.17 (<0.001)	0.164

Disheartenment	Baseline	11.18 (5.62) 11.50 (5.70)	0.14 (0.89)	0.17 (-2.23; 2.57)	0.03 (-0.40; 0.46)	Time: 16.12 (<0.001)	0.183
	Follow-up 1	5.82 (3.44) 10.28 (3.44)	30.48 (<0.001)	-4.45 (-6.06; -2.85)	-1.30 (-1.79; -0.80)	Group: 14.58 (<0.001)	0.168
	Follow-up 2	5.39 (3.08) 9.42 (3.04)	31.34 (<0.001)	-4.02 (-5.46; -2.59)	-1.32 (-1.81; -0.82)	Time*Group: 14.59 (<0.001)	0.168
Dysphoria	Baseline	9.93 (4.30) 9.83 (4.32)	0.11 (0.91)	0.10 (-1.75; 1.95)	0.02 (-0.41; 0.45)	Time: 1.70 (0.19)	0.023
	Follow-up 1	7.57 (2.70) 9.94 (2.66)	14.21 (<0.001)	-2.37 (-3.62; -1.12)	-0.88 (-1.36; -0.41)	Group: 7.59 (0.007)	0.095
	Follow-up 2	7.24 (2.67) 9.82 (2.60)	17.38 (<0.001)	-2.58 (-3.82; -1.35)	-0.98 (-1.46; -0.50)	Time*Group: 7.05 (0.003)	0.089
Helplessness	Baseline	7.30 (3.79) 6.89 (3.78)	0.66 (0.51)	0.52 (-1.06; 2.11)	0.14 (-0.29; 0.57)	Time: 0.07 (0.88)	0.001
	Follow-up 1	5.77 (2.28) 8.30 (2.27)	22.63 (<0.001)	-2.54 (-3.60; -1.48)	-1.11 (-1.60; -0.63)	Group: 8.14 (0.006)	0.102
	Follow-up 2	5.82 (2.29) 8.15 (2.26)	18.96 (<0.001)	-2.33 (-3.39; -1.26)	-1.02 (-1.50; -0.55)	Time*Group: 12.31 (<0.001)	0.146
Sense of failure	Baseline	7.01 (2.84) 6.07 (2.82)	1.61 (0.11)	0.98 (-0.23; 2.18)	0.35 (-0.08; 0.78)	Time: 15.54 (<0.001)	0.178
	Follow-up 1	2.15 (2.28) 5.91 (2.28)	49.20 (<0.001)	-3.77 (-4.84; -2.70)	-1.65 (-2.17; -1.13)	Group: 16.35 (<0.001)	0.185
	Follow-up 2	2.30 (2.03) 5.20 (2.01)	36.86 (<0.001)	-2.90 (-3.85; -1.95)	-1.44 (-1.94; -0.93)	Time*Group: 40.15 (<0.001)	0.358
Demoralization (total score)	Baseline	42.47 (20.10) 40.95 (20.16)	0.65 (0.52)	2.78 (-5.73; 11.28)	0.14 (-0.29; 0.57)	Time: 10.26 (0.001)	0.125
	Follow-up 1	23.91 (11.31) 41.16 (11.33)	42.20 (<0.001)	-17.25 (-22.55; -11.96)	-1.52 (-2.04; -1.01)	Group: 11.95 (0.001)	0.142
	Follow-up 2	23.26 (10.23) 38.50 (10.12)	40.59 (<0.001)	-15.24 (-20.01; -10.47)	-1.50 (-2.01; -0.99)	Time*Group: 24.26 (<0.001)	0.252

Table of adverse events

We did not encounter any adverse events.

First publication date

2025-08-01, 1404/05/10

Abstract of published paper

Abstract Purpose Demoralization is a common psychological distress experienced by cancer patients undergoing chemotherapy. This study aimed to evaluate the effectiveness of nurse-led dignity therapy in reducing demoralization syndrome among this patient population. Methods A randomized controlled trial was conducted with 84 patients undergoing chemotherapy, who were allocated to either an intervention group (n = 42) receiving three sessions of dignity therapy by a trained oncology nurse, or a control group (n = 42) receiving standard care. Assessments were

performed at baseline, one month, and three months post-intervention using a demographic questionnaire and the Demoralization Scale (DS). Data were analyzed using repeated-measures multivariate analysis of variance (MANOVA-RM) to examine changes in demoralization over time and between groups. Results The intervention group showed a significant reduction in demoralization symptoms compared to controls ($P < 0.001$, standardized mean difference = –1.65). The group-by-time interaction was significant ($P = 0.006$), indicating that the effects were maintained at follow-up. Conclusions Nurse-led dignity therapy is an effective psychotherapeutic intervention to alleviate demoralization syndrome in patients undergoing chemotherapy. Its integration into oncology nursing practice may enhance psychological outcomes and overall patient care. Keywords: Cancer, Chemotherapy, Dignity Therapy, Demoralization, Nurse-led Intervention