

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### The effect of a Communication Program on the Psychological Distress of Elderly Cancer Patients who referred to the Selected Centers Affiliated to the Isfahan University of Medical Sciences in 2015.

#### Protocol summary

##### Summary

Determining the effect of a communicational program on psychological distress of the elderly cancer patients who referred to selected medical centers of Isfahan University of Medical Sciences during 2015. This study was a two-group before-after clinical trial that was conducted during 2015 at Al-Zahra hospital and Seyyed-Al-Shohada hospital which are affiliated to Isfahan University of Medical Sciences. 64 elderly patients were randomly allocated into two groups of intervention and control groups. The intervention included three weeks of communicational program, educational booklet, giving homework and monitoring the distress before and after the communicational sessions. Communicational intervention was conducted in 6 20-minute sessions according to patient's needs and conditions. Sessions were conducted twice a week for three weeks individually and in person along with phone follow-ups and encouragement for doing the homework. The control group received the routine care and at the end of the intervention all of the issues were explained to them at one session. Demographic characteristics questionnaire and Kessler Psychological Distress Scale were used for measuring patient's distress. The inclusion criteria were being 60 years old or older and having cancer, having knowledge about their cancer diagnosis, being able to speak and make verbal communication, not participating in any other sessions for other treatment methods during the past 6 months and not being addicted to narcotics and psychotropic substances. Exclusion criteria were death of the patient and unwillingness to participate in the study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016010725897N1**

Registration date: **2016-05-28, 1395/03/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-05-28, 1395/03/08

##### Registrant information

###### Name

Fateme Hejazi

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Fateme Hejazi geriatric nursing graduate student & Isfahan University of Medical Sciences

##### Expected recruitment start date

2015-11-21, 1394/08/30

##### Expected recruitment end date

2016-02-19, 1394/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of a Communication Program on the Psychological Distress of Elderly Cancer Patients who referred to the Selected Centers Affiliated to the Isfahan University of Medical Sciences in 2015.

**Public title**

The effect of a Communication Program on the Psychological Distress of Elderly Cancer Patients

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: Seniors aged 60 years or older with cancer (Types of Cancer); The definitive diagnosis of cancer by medical oncologist & Life expectancy of at least six months (According to serfaty et al. 2012); Patients are aware of their cancer diagnosis; Patients have the ability to talk and communicate verbally; Willingness to participate in the study and randomly placed in groups; Previous participate in the meetings of up to six months before other treatments (Like therapy, spiritual therapy, relationship therapy, etc.) (According to serfaty et al. 2012); Lack of diseases other than cancer such as acute febrile or chronic physical disorders specialist physician and medical records. (Like the flu, debilitating diseases, cardiovascular, endocrine, respiratory, liver, skeletal muscle, kidney); Lack of mental disease or mental illness who have specialist physician and the patient is inserted; The absence of distress-causing accident, according to the patient in the last six months (Such as the recent death of a loved one such as a spouse or close friend, the loss of everything that is valuable for the individual, divorce, incurable diseases, loss of limb, loss of jobs, relocated to a new city, bankruptcy financial debt severe, imprisonment, disputes and persistent inconsistency with wife); Lack of addiction to narcotics and psychotropic substances, according to the patient and medical records Exclusion criteria: Not wanting to continue cooperation in research; The use of other types of communication programs while studying; Inability to attend meetings regularly so that communication meetings have missed two or more consecutive meetings; Elderly death during the study

**Age**

From **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****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**

University of Medical Sciences, Isfahan

**Street address**

School of Nursing and Midwifery, University of Medical Sciences, St. thousand acres, Isfahan, Iran

**City**

Isfahan

**Postal code****Approval date**

2015-11-21, 1394/08/30

**Ethics committee reference number**

ir.mui.rec.1394.3.585

**Health conditions studied****1****Description of health condition studied**

Psychological Distress

**ICD-10 code**

F99-F99

**ICD-10 code description**

Mental disorder, not otherwise specified

**Primary outcomes****1****Description**

Psychological Distress

**Timepoint**

Before intervention, after intervention

**Method of measurement**

Kessler Psychological Distress Scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

In the experimental group communications during the six sessions of approximately twenty minutes due to the conditions and needs of patients was performed. During the three-week sessions, twice a week were conducted individually and in person. Telephone follow-up to attend the next meeting to coordinate and encourage the patient to do homework. Time sessions with the

agreement of the patients was determined. All meetings were held in the hospital and at the time of admission. Training manual in the test group was placed in the first session, they were asked to provide manual control group did not. Join this session to order and mutual understanding, explain the objectives of the intervention, simple and concise explanation about cancer and its treatment process and effects of this disease on patients' quality of life. Patients the opportunity to talk about various topics, including the expression of uncertainties, questions and concerns and reveal the deepest feelings and emotions related to their experiences of illness and distress-inducing events were live. In the speech, physical, psychological, social and spiritual patient was evaluated as a basis for subsequent meetings. The next meeting, which is to help the client to cope and adapt to problems using strategies based assignments and training manual approved by the faculty of professors, to be discussed, explained. In the second session to encourage clients to speak on the issue of the impact of the disease on physical aspects (impact of the disease on physical conditions, beliefs and expectations of patients about their condition, plans and hopes for the progress of the disease), were encouraged. And obligations commensurate with their potential problems, it is presented. And the subjects were asked to do that task to the next meeting. In the second session, clients talking about psychological distress caused by the disease subject (patient relationship between different emotions, physical symptoms and disabilities caused by the disease and patients' concerns about the ability to adapt, loss of control, and readiness to accept help and discuss issues surrounding death), were encouraged. And adaptation strategies in accordance with the manual and training tailored to the patient's condition was presented to them. And the sample was asked to do the task to the next meeting. In the fourth session, clients to talk about the social effects of the disease (the disease affect behavior and mood, and ability to perform the role of the full impact of the disease on individuals favorite client) were encouraged. And how to manage it in accordance with the instruction manual and tailored to the patient, was presented to them. And the sample was asked to do the task to the next meeting. In the fifth session, clients are talking about spiritual matters illness and disease issues (issues surrounding the concept of disease, suicide and death, the ability to modify and spiritual changes, compromise and consistent with the spiritual, forgiveness of others and accept unfinished works), were encouraged. And the appropriate task presented to them. And the sample was asked to do the task to the next meeting. Sixth session, summing up previous sessions and announced the termination of negotiations. Also, researchers through questionnaires completed the questionnaire psychological distress, paid in the last session. In each session, then discuss things, applicable solutions discussed, and the optimum solution according to requirements and potential problems the patient is recommended. They also provide the basis for the assignment to be patient. And client feedback in each session examined the implementation of assignments in previous sessions. Telephone researcher

also laid the experimental and control groups, so if you create questions about the contents of the manual, they can contact the researcher.

### **Category**

Other

## **2**

### **Description**

The control group received routine care. Furthermore, after three weeks by nearly two-hour meeting, the contents of the manual are briefly described for each of the control group. And measures of psychological distress were completed the questionnaire again. In the end, brochure, available to patients and their families were in the control group. Telephone researcher also laid the experimental and control groups, so if you create questions about the contents of the manual, they can contact the researcher.

### **Category**

Other

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Al Zahra Hospital

##### **Full name of responsible person**

Fateme Hejazi

##### **Street address**

Al-Zahra hospital, Hakim Nezami street, Isfahan

##### **City**

Isfahan

### **2**

#### **Recruitment center**

##### **Name of recruitment center**

Sydalshhda Hospital

##### **Full name of responsible person**

Fateme hejazi

##### **Street address**

Sydalshhda Hospital, Shiry bridge., Isfahan

##### **City**

Isfahan

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Isfahan University of Medical Sciences

##### **Full name of responsible person**

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##### **Street address**

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##### **City**

Isfahan

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Isfahan University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
*empty*  
**Domestic or foreign origin**  
*empty*  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*