Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

The effect of supportive intervention based on social network on psychological well-being and caregiving Appraisal in family caregivers of patients with heart failure

Protocol summary

Study aim

Determining the effect of supportive intervention based on social network on psychological well-being and caregiving Appraisal in family caregivers of patients with heart failure

Design

The clinical trial with two intervention and control groups, with parallel groups, without blinded, randomized, phase 3 on 72 caregivers. PASS 11 software is used for randomization.

Settings and conduct

The research population is all family caregivers of heart failure (main caregiver) hospitalized in the cardiac department, CCU and POST CCU of Imam Reza (AS) and Qaim (AS) teaching hospitals. The intervention will last for a period of one month. Blinding was not done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Family caregivers of heart failure patients who are willing to participate in research and have the ability to use a smartphone; Exit criteria: Caregiver's unwillingness to continue cooperation in the study, death of the patient

Intervention groups

In the intervention group, first a face-to-face meeting of half an hour to one hour will be held in the presence of the main family caregivers of the patients in the department, in which, in addition to introducing and stating the goals, explanations will be given on how to implement the research and the messenger, and help the caregiver to install it and provide training How to communicate in online meetings is provided.Then, after the patient's discharge, in 8 sessions for one month (twice a week), the researcher will communicate with the caregivers in specific groups of 5-6 people through online messenger and voice or video calls. The control group will receive routine care only.

Main outcome variables

Psychological well-being; caregiving appraisal

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231206060282N1**
Registration date: **2024-01-08, 1402/10/18**
Registration timing: **prospective**

Last update: **2024-01-08, 1402/10/18**
Update count: **0**

Registration date

2024-01-08, 1402/10/18

Registrant information

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Marzieh Kohantorabi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-10, 1402/10/20

Expected recruitment end date

2024-03-10, 1402/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supportive intervention based on social network on psychological well-being and caregiving Appraisal in family caregivers of patients with heart failure

Public title

The effect of social network support on psychological well-being and caregiving Appraisal of family caregivers

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

A patient with heart failure class 2 or higher for at least 3 months ago Hospitalization of the patient in the ward due to heart failure Caregiver's willingness to participate in research Caregiver age over 18 years Being the main caregiver of the patient in family A history of at least 3 months of caring for a heart failure patient Caregiver access to a smart phone and the ability to use messengers Ability to speak and understand Persian language Ability to read and write Not having a history of known mental disorders and psychoactive drugs

Exclusion criteria:

Caregiver's unwillingness to continue cooperation in any of the stages of the research Non-participation of the caregiver in half of the messenger sessions Transferring the care of the patient to someone other than the main caregiver at home Experiencing a stressful event or severe emotional problem during the follow-up period for the caregiver Death of the patient

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be done in such a way that people will be divided into two groups through the PASS 11 software using blocks of four. In this way, after determining the sequence, we put them in the envelopes and number them in order. Caregivers take the envelope in the order of their entry into the study and are placed in the intervention or control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The content of online meetings in Messenger is held as follows: Session 1: introducing people to the group members, questions and answers about heart failure disease and the care needed for these patients and their role in care, asking the group members to be ready to present their experiences in care for the next session. Session 2: Inviting the group members to share their negative and positive experiences in providing patient care, their solutions in providing care and how to deal with the patient's condition. Session 3: emphasizing the importance of physical and mental health of caregivers, asking caregivers to express how they take care of themselves, then providing self-care strategies for caregivers by the researcher. Session 4: Expressing the impact of stress on the health of caregivers and family members, asking caregivers to express their strategies to deal with caregiving stress, then presenting strategies for managing stress, anger, and depression with deep breathing techniques, relaxation, and planning to do favorite activities by researcher. Session 5: Ways to interact and communicate with other family members and others, peers, maintaining humor in difficult situations. Session 6: Emphasis on positive thinking, skills of creating and maintaining positive thoughts in daily life events, asking caregivers to express their strategies for positive thinking in caregiving and daily life. Session 7: Questions and answers from the caregivers about their experiences of using the strategies presented in the previous sessions by the peers and the researcher. Session 8: Final summary of the intervention, if necessary, refer the caregivers to available support resources in the community, such as (psychiatrist, psychologist, social worker...)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Nursing and Midwifery Faculty - Mashhad University of Medical Sciences

Street address

Shahid Dr. Kharazmi Educational Complex, East Gate of Ferdowsi University of Mashhad, Medical Sciences Campus, Azadi Square,

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Razavi Khorasan

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9177949025

Approval date

2023-11-28, 1402/09/07

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.106

Health conditions studied

1

Description of health condition studied
Heart failure
ICD-10 code
I50
ICD-10 code description
Heart failure

Primary outcomes

1

Description
Psychological well-being
Timepoint
The level of psychological well-being in the research units participating in the study will be measured at the beginning of the study (before the start of the intervention) and one month after the start of the intervention.
Method of measurement
In this research, the level of psychological well-being will be measured using Ryff's Psychological Well-being questionnaire.

2

Description
Caregiving appraisal
Timepoint
The level of caregiving appraisal in the research units participating in the study will be measured at the beginning of the study (before the start of the intervention) and one month after the start of the intervention.
Method of measurement
In this research, caregiving appraisal will be measured using revised caregiving appraisal scale(2000).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, First, a half-hour to one-hour face-to-face training session with the presence of the main family caregivers of the patients will be held in one of the rooms of the aforementioned departments that in this meeting, in addition to introducing and stating the goals, explanations about how to carry out the research and messenger and help the caregiver to install it and training how to communicate in online meetings will be provided. Then, after the patient's discharge, in 8 sessions for one month (2 times a week), the researcher will communicate with the caregivers in specific groups of 5-6 people through online messenger and audio or video calls whose content includes: The care needed by the patient and the caregiver's role in care, sharing their negative and positive experiences in providing patient care, the importance of the caregiver's physical and mental health and self-care strategies, stress and anger management, methods of interacting with others, maintaining a sense of humor, strategies Positive thinking in care and daily life events and if necessary referring caregivers to support resources available in society (psychiatrist, psychologist, social worker). The researcher will be present and actively cooperate in all face-to-face and non-face-to-face meetings of messaging groups and will use the advice of a psychologist.
Category
Other

2

Description
Control group: The control group will receive only usual care.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital, Heart, CCU and post CCU departments
Full name of responsible person
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2

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1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Mashhad 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
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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

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

Title and more details about the data/document

All the data obtained from this research will be shared after completion.

When the data will become available and for how long

Access to the data will be possible 3 months after the results are published.

To whom data/document is available

These data will be used for researchers working in academic and scientific institutions, as well as for family caregivers of heart failure patients.

Under which criteria data/document could be used

The data obtained from this research can be used in other scientific studies.

From where data/document is obtainable

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What processes are involved for a request to access data/document

The applicant should send an email to the responsible author and register his request. After verifying the correctness of the information of the mentioned person, the required content will be provided to him by mentioning the source.

Comments