Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

The effect of supportive intervention based on social network on social isolation and loneliness in patients with heart failure

Protocol summary

Study aim

Determining the effect of social network-based support intervention on social isolation and loneliness of HF patients

Design

The CT with an intervention&control group will be conducted without blinding with randomization (through spss) phase 3 on 72 patients.

Settings and conduct

The research population is all HF patients in the cardiac department and CCU of Imam Reza and Qaim teaching hospitals.72 patients will be selected based on the entry criteria and available sampling method. The intervention will last 8-week, which will be in the form of communicating with each other and with relatives and friends. In this way, in the intervention group, 2 face-to-face meetings will be held at the beginning to teach how to perform the intervention and training items. Then, during 6 weeks, the groups will communicate with each other through messenger calls at least once a week.

Participants/Inclusion and exclusion criteria

Entry:consent/HF/SI/not having mental disorders &psychoactive drugs/access to smart phone&Qarar messenger/speaking Farsi/over18years old
Exclusion:instability of the patient's clinical condition/failure to participate in half of the meetings/unwillingness to continue the study/death

Intervention groups

In the intervention group, 2 face-to-face meetings in groups of 2-3 patients and caregivers will be held in the department,where the researcher will teach the intervention method to the families&patients.Then, during 6 weeks, the groups once a week with the presence of the researcher through messenger calls and with relatives&friends.In control group, only routine care and face-to-face education and pamphlet will be done.

Main outcome variables

The results of this study are the level of social isolation and loneliness of HF patients, which will be measured in two intervention and control groups using the social support questionnaire, Luben and UCLA before& after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221021056260N1**
Registration date: **2023-02-24, 1401/12/05**
Registration timing: **prospective**

Last update: **2023-02-24, 1401/12/05**
Update count: **0**

Registration date

2023-02-24, 1401/12/05

Registrant information

Name

Fatemeh Tajari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

tajarif992@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-05-22, 1402/03/01

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 social isolation and loneliness in patients with heart failure

Public title

the effect of social network support on on social isolation and loneliness in heart failures

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent Heart failure class 2 and above at least 6 months ago Social isolation based on Luben's social network tool (at a cut point of less than 12) Not having a history of known mental disorders and psychoactive drugs Access to a smart mobile phone and the ability to use the WhatsApp application (self or family caregiver). bility to speak Persian Age over 18 years

Exclusion criteria:

Instability of the patient's clinical condition Failure to participate in half of the WhatsApp meetings Unwillingness to continue studying 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

The method of randomly assigning people to two intervention and control groups will be by time block method. In this way, sampling in the intervention and control groups will be done on a weekly basis (even and odd weeks). The first group will be randomly selected using SPSS software. Then it will continue as even and odd weeks in two groups.

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

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

Street address

ibn sina st

City

mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2022-11-22, 1401/09/01

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.095

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

social isolation

Timepoint

The beginning of the study- The eighth week

Method of measurement

Luben Social Network Scale

2

Description

loneliness

Timepoint

The beginning of the study- The eighth week

Method of measurement

UCLA Loneliness Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, first, 2 face-to-face meetings in groups of 2-3 patients and family caregivers will be held in the department, in which training on how to perform the intervention in order to establish communication between patients and deal with loneliness and social isolation, encouraging the patient to communicate with Relatives and friends, as well as education related to heart failure will be provided by the researcher to families and patients. Then, during 6 weeks, the groups will communicate with each other through Qarar messenger calls once a week with the presence of the researcher, and they will communicate with relatives and friends once a week. The desired questionnaires (perceived social support, Luben social network scale and UCLA loneliness scale) will be completed by the researcher before the intervention (face-to-face) and after the end of the intervention via phone or messenger.

Category
Other

2

Description
Control group: In the control group, only routine care and face-to-face education and pamphlet presentation will be done. The desired questionnaires will be completed at the same time as the intervention group.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Qaem Aj educational research and treatment hospital

Full name of responsible person
Mohsen Muhebati

Street address
Dr. Shariati Square - the beginning of Ahmad Abad St. - Ghaem Aj

City
mashhad

Province
Razavi Khorasan

Postal code
9176699199

Phone
+98 51 3840 0001

Fax
+98 51 3845 3239

Email
b.ghaem@mums.ac.ir

2

Recruitment center

Name of recruitment center
Imam Reza Educational Research and Treatment Hospital (AS)

Full name of responsible person
Behzad Alizadeh

Street address
Ibn Sina St. - Imam Reza Hospital Square - Imam Reza Educational Research and Treatment Hospital (AS)

City
mashhad

Province
Razavi Khorasan

Postal code
9137913316

Phone
+98 51 3854 3031

Email
b.ImamReza@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Hasan Qavami

Street address
University Street, Central Organization of Qurashi Building University

City
mashhad

Province
Razavi Khorasan

Postal code
۱۳۹۴۴ ۹۱۳۸۸

Phone
+98 51 3841 2081

Email
presidentoffice@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

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

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
zahra Dalir
Position
professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
ibn sina St
City
mshhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
zdalir@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
zahra Dalir
Position
professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
ibn sina ST
City
mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 915 311 2764
Fax
Email
zdalir@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
zahra Dalir
Position
professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
ibn sina St
City
mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 911 311 2764
Fax
Email
zdalir@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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