Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

The effect of professional support intervention through social network on fatigue, shock anxiety and acceptance of implantable cardiac defibrillator

Protocol summary

Study aim
The effect of professional support intervention through social network on fatigue, shock anxiety and acceptance of implantable cardiac defibrillator

Design
A clinical trial with control group, parallel group randomized trial, a single blinded

Settings and conduct
Setting: Faghihi, and Kowsar hospitals, Data collector and statistician are blind.

Participants/Inclusion and exclusion criteria
The inclusion criteria would be having implantable cardiac defibrillator, being 18 years old or above, being able to speak Persian, being oriented to time, person and place and have access to the Internet and social networks. The patients who are a known case of mental health disorders, and had major crises during the past 3 months would be excluded.

Intervention groups
Intervention group: Professional support intervention through WhatsApp social network would focus on provide content about the functioning of the cardiovascular system, how the cardiac defibrillator works and its impact on life and self-care, the emotional effects of having a defibrillator (worry about body image, and negative emotions), impact of this device on communications and roles, how emotional reactions affect on coping, spiritual and social strategies for coping to the device, and living with cardiac defibrillator. Moreover, Contents are also prepared on social support, support exchanges and people on the individual's social network, and the types of social support appropriate to their illness. The intervention is done daily for 4 weeks. Control group: In this group, any of the interventions of the intervention group is presented.

Main outcome variables
Fatigue, Shock anxiety, and acceptance implantable cardiac defibrillator

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130616013690N11**
Registration date: **2022-02-24, 1400/12/05**
Registration timing: **prospective**

Last update: **2022-02-24, 1400/12/05**
Update count: **0**

Registration date
2022-02-24, 1400/12/05

Registrant information

Name
Masoume Rambod

Name of organization / entity
Shiraz University of Medical Science

Country
Iran (Islamic Republic of)

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+98 71 1647 4258

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rambodm@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-06, 1400/12/15

Expected recruitment end date
2022-06-05, 1401/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of professional support intervention through social network on fatigue, shock anxiety and acceptance of implantable cardiac defibrillator

Public title
The effect of professional support intervention through social network on patients with implantable cardiac defibrillator

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Being 18 years old or above Having implantable cardiac defibrillator Ability to speak Persian Access to the Internet and social networks

Exclusion criteria:
Patients who are a known case of mental health disorders such as depression, anxiety, and psychosis. Patients had an emotional crisis such as the death of loved ones and getting a divorce past 6 months.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
First, 72 patients who have record in the pacemaker and ICD clinics of Shahid Faghihi and Kosar hospitals in Shiraz will be selected using a random number table. Then, random allocation software will be used to create 18 blocks of size 4. Then based on the list generated by this software (BABA, ABBA, BAAB, BABA, AABB, ...), individuals are assigned into the intervention (B) and control (A) groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
In order to provide blinding, assistant researcher who collects data before and after the intervention, as well as statistician who analyzes the data, are blinded to the groups and the assignment of individuals in the groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Nursing and Midwifery, Management and Medical Information Sc

Street address
Vice chancellor for research affairs, seven floor, Shiraz University of Medical Science, beside Helal Ahmar, Zand Ave, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
71348-14336

Approval date
2022-01-22, 1400/11/02

Ethics committee reference number
IR.SUMS.NUMIMG.REC.1400.068

Health conditions studied

1

Description of health condition studied
Implantable cardiac defibrillator

ICD-10 code
Z95.810

ICD-10 code description
Presence of automatic (implantable) cardiac defibrillator

Primary outcomes

1

Description
fatigue

Timepoint
Before and 4 weeks after the intervention

Method of measurement
Multidimensional Fatigue Inventory

2

Description
Shock anxiety

Timepoint
Before and 4 weeks after the intervention

Method of measurement
Florida Shock Anxiety Scale

3

Description
Acceptance of implantable cardiac defibrillator

Timepoint
Before and 4 weeks after the intervention
Method of measurement
Florida Patient Acceptance Survey

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Professional support intervention is done daily for patients through social network WhatsApp for 4 weeks. Contents are prepared in the form of text, audio and videos (MP4) prepared with Camtasia software. The patients communicate in the WhatsApp group for two hours daily and at a specific time. At the same time, they communicate with the researcher in her privet page via WhatsApp in the form of text and audio. The intervention focus on provide content about the functioning of the cardiovascular system, how the cardiac defibrillator works and its impact on life and self-care, the emotional effects of having a defibrillator (worry about body image, and negative emotions), impact of this device on communications and roles, how emotional reactions affect on coping, spiritual and social strategies for coping to the device, and living with cardiac defibrillator. Moreover, Contents are also prepared on social support, support exchanges and people on the individual's social network, and the types of social support appropriate to their illness.
Category
Rehabilitation

2

Description
Control group: This group typically receives medical care and will not receive any of the interventions that individuals in the intervention group receive.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi hospital
Full name of responsible person
Masoume Rambod
Street address
Nursing and Midwifery University, Namazee Sq, Zand Ave, Shiraz
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2

Recruitment center
Name of recruitment center
Kosar Hospital
Full name of responsible person
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Street address
Nursing and Midwifery University, Namazee Sq, Zand Ave, Shiraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahtab Meamarpour
Street address
Vice chancellor for research affairs of Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran
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71348-14336
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+98 71 3235 7282
Email
vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
24461
Is the source of funding the same sponsor organization/entity?
No
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
Masoume Rambod

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Others

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Person responsible for scientific inquiries

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Position
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Latest degree
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Other areas of specialty/work
Others

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Person responsible for updating data

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
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
Primary outcomes would be shared.

When the data will become available and for how long
Starting 6 months after publication article

To whom data/document is available
People and researchers working in academic institutions

Under which criteria data/document could be used
Data are provided for information only.

From where data/document is obtainable
Data is available via email rambodma@yahoo.com.

What processes are involved for a request to access data/document
Data is available via email rambodma@yahoo.com

Comments