

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)

Phone

+98 71 1647 4258

Email address

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

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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

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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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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mahtab Meamarpour

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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
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Person responsible for updating data

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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