

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The Effect of Continuous Care Model on General Health in Kidney Donors

Protocol summary

Study aim

The Effect of Continuous Care Model on General Health in Kidney Donors

Design

This study is a one-blinded clinical trial. The research population will include donors of all patients referred to hospitals in Isfahan. 72 eligible patients will be selected by available means and randomly assigned to intervention and control groups.

Settings and conduct

This study that will be conducted in Isfahan hospitals is a one-blinded one. In this way, the participants did not know about the follow-up care and how to take care of the other participants. At the beginning of the study, a general health questionnaire will be provided to the participants.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Donors must have the minimum literacy (fifth grade of elementary school, and higher); Being vigilant (conscious); Don't having eye and ear diseases preventing communication; Donors must be willing to participate in the study. Exclusion criteria: History of mental disorder

Intervention groups

The intervention group during the familiarization phase (30 to 45 minutes) and the sensitization phase will be followed up on a weekly basis for 3 weeks by telephone. They will then be monitored and evaluated weekly by telephone for 3 months. The control group will not receive any intervention.

Main outcome variables

General health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200818048449N1**
Registration date: **2020-10-10, 1399/07/19**

Registration timing: **retrospective**

Last update: **2020-10-10, 1399/07/19**

Update count: **0**

Registration date

2020-10-10, 1399/07/19

Registrant information

Name

Sadigheh Esmaeili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3470 4547

Email address

ali56ali86@chmail.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-16, 1399/07/25

Expected recruitment end date

2020-11-25, 1399/09/05

Actual recruitment start date

2019-06-27, 1398/04/06

Actual recruitment end date

2020-08-27, 1399/06/06

Trial completion date

2020-09-23, 1399/07/02

Scientific title

The Effect of Continuous Care Model on General Health in Kidney Donors

Public title

The Effect of Continuous Care Model on General Health in Kidney Donors

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Donors must have the minimum literacy (fifth grade of elementary school, and higher) Being vigilant (conscious) Do not have eye and ear diseases preventing communication Donors must be willing to participate in the study

Exclusion criteria:
History of mental disorder

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Actual sample size reached: **55**
Randomization (investigator's opinion)
Randomized

Randomization description
Using a block randomization method. In this study, the blocks are selected weekly, so that, the intervention group will be evaluated in the first week, and in the second week the control group will be evaluated randomly. This method will continue until the required number of samples will be obtained. To avoid bias, the start of sampling in each week will be subject to the clearance of all survey units in the last week.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants / that they did not know about follow-up care and how to care for the rest of the participants.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Islamic Azad University of Khorasgan Branch
Street address
University Blvd, Arghavaniyeh, East Jay St.
City
Esfahan
Province
Isfahan
Postal code

8198818139

Approval date
2020-06-14, 1399/03/25
Ethics committee reference number
IR.IAU.KHUISF.REC.1399.053

Health conditions studied

1

Description of health condition studied
General health
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
General health
Timepoint
Beginning of study, the third week, the third month
Method of measurement
Standard 28-Questions General Health Questionnaire (Goldberg 2009)

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group during the familiarization phase (30 to 45 minutes) and the sensitization phase will be followed up on a weekly basis for 3 weeks by telephone. They will then be monitored and evaluated weekly by telephone for 3 months
Category
Other

2

Description
The control group will not receive any intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Hospital
Full name of responsible person
Maryam Radmehr
Street address
Unit 3, No. 123, Chitsaz Alley, Sheikh Tusi Gharbi St.,

Parvin St.
City
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Isfahan
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8198818139
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+98 31 3470 4547
Email
ali56ali86@chmail.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Mohammad Roholah Yazdani
Street address
University Blvd, Arghavaniyeh, East Jay St.
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Isfahan
Postal code
8155139998
Phone
+98 31 3535 4001
Email
m.yazdani@hotmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Sedighes Esmaili
Position
Master of Nursing Student
Latest degree

Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Full name of responsible person
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Master of Nursing Student
Latest degree
Master
Other areas of specialty/work
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8155139998
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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

Just part of the data like the information related to original outcome

When the data will become available and for how long

Access period will be started six months after the results are published

To whom data/document is available

The data will be only accessed by the researchers working in academic and scientific institutions. Will be available

Under which criteria data/document could be used

The data will be only accessed by the researchers working in academic and scientific institutions. Will be available

From where data/document is obtainable

ali56ali86@chmail.ir

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

After obtaining permission from the supervisor, the data will be sent by email.

Comments