Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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); Dont 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)
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+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
Isfehan
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.
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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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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
Sedihgeh Esmaeili
Position
Master of Nursing Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for updating data

Contact
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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
Nursery
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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