Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of self-care program training in two methods of SMS service and face-to-face training on coping styles of patients undergoing hemodialysis

Protocol summary

Study aim
Determining the effect of self-care program training in two methods of SMS service and face-to-face training on coping styles of patients undergoing hemodialysis

Design
Clinical trial with control group, with parallel, randomized groups, 80 patients

Settings and conduct
Approval of the research plan in the university ethics committee. At the beginning of the study, complete the demographic characteristics questionnaire and the Jalowiec Coping Scale. Intervention in the face-to-face training group, in 8 sessions, for one hour and one session per week (on days when patients are not on dialysis). In the training group by way of short message service: in 2 months, 60 short messages will be sent. The maximum text of each message will not be more than 160 characters. One month after completing the training, complete the Jalowiec Coping Scale. The training venue is the conference hall of Shahid Beheshti Hospital, which has audio-visual facilities.

Participants/Inclusion and exclusion criteria
Admission requirements: 1- Ability to communicate and answer questions by patients or with the patient 2- Not having anxiety disorders. Conditions of non-entry: 1- Taking anti-anxiety and anti-depressant drugs 2- Previous participation in studies similar to the current research

Intervention groups
Intervention group 1: SMS: which will send 60 SMS in 2 months. The maximum text of each message will not be more than 160 characters. Intervention group 2: Face to face: Training in this group will be in 8 sessions, the duration of each session will be one hour and one session per week (on days when patients are not on dialysis). Individuals will be categorized into groups of 5 to 10 people. Control group: Non-intervention: This training group will not be given.

Main outcome variables
Coping styles

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210420051024N1**
Registration date: **2021-07-07, 1400/04/16**
Registration timing: **prospective**

Last update: **2021-07-07, 1400/04/16**
Update count: **0**

Registration date
2021-07-07, 1400/04/16

Registrant information

Name
Ali Torabiasl

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2021-12-22, 1400/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of self-care program training in two methods of SMS service and face-to-face training on coping styles of patients undergoing hemodialysis

Public title
The effect of self-care program training in two methods of SMS service and face-to-face training on coping styles of patients undergoing hemodialysis
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Ability to communicate and answer questions by patients or with the patient Being over 18 years old Consent to participate in the study and sign the informed consent form No anxiety disorders At least 3 months after hemodialysis Having a mobile phone
Exclusion criteria:
Taking anti-anxiety and anti-depressant drugs Previous participation in studies similar to current research Diagnosed with self-reported mental illness and other chronic physical illnesses
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Random block allocation in such a way that first by multiplying the number of studied groups (two groups) by 2, the number of samples of each block is calculated equal to 4, then by factorial calculation, the number of samples of each block (4!= 4×3×2×1=24), the number of blocks resulting from all the modes of arrangement of individuals, 24 blocks are calculated, then, since the number of individuals in each block was 4, so using the Sample Randomizer software, how to arrange the research sample and assign each number One of the intervention groups 1 (SMS service) and intervention 2 (face to face) will be identified and a random block allocation list will be compiled. Then, qualified research samples will be selected and based on the time priority of the referral, a code will be assigned to each of them. By matching that number with the block random allocation list, the patients participating in the study will be assigned to One of the intervention groups 1 (SMS service) and intervention 2 (face to face) will be assigned.
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
Ethics committee of Yasuj University of Medical Sciences
Street address
Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran
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Postal code
7591741417
Approval date
2021-05-15, 1400/02/25
Ethics committee reference number
IR.YUMS.REC.1400.026

Health conditions studied

1

Description of health condition studied
Patients undergoing hemodialysis
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Coping styles
Timepoint
The extent of patients' coping styles at the beginning of the study (before the intervention) and one month after the start of the study
Method of measurement
Jalowiec Coping Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: SMS service: Training in this group will be such that messages related to self-care will be sent via mobile phone. Patients' mobile phones will be checked for the Persian menu and how to use the SMS service will be explained to them and the existing problems and questions will be answered. Also, one of the prepared messages will be sent to those present. To ensure that the messages are sent, the researcher will activate the option on his / her mobile phone and the phrase "delivered" by checking the message received by the patients, will ensure the timely and correct receipt of the message by the participants. One message will be sent to the research units every day, so that 60 short messages will be sent in 2 months. The maximum text of each message will not be more than 160 characters. Each message will be numbered and will be marked in front of the message for each message delivered to patients. If no more than two messages are sent, the patient's landline number will be contacted and the cause will be sought, and if necessary, another mobile number will be received from the patient or a family member living with him or her. A short message will be sent to the new number.

Category

Lifestyle

2

Description

Intervention group 2: Face to face: Training in this group will be in 8 sessions, the duration of each session will be one hour and one session per week (on days when patients are not on dialysis). Individuals will be categorized into groups of 5 to 10 people.

Category

Lifestyle

3

Description

Control group: Non-intervention: This training group will not be given.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Ali Torabiasl

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Shahid Beheshti Hospital, Shahid Montazeri Ave., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

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2

Recruitment center

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj 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
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Person responsible for updating data

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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