

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3322 4721

##### Email address

ali.torabi1155@gmail.com

##### 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 ( $4! = 4 \times 3 \times 2 \times 1 = 24$ ), 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

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyerahmad

**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

##### Street address

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

of Iran

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

7591794857

##### Phone

+98 74 3322 1813

##### Fax

+98 74 3322 1811

##### Email

beheshtihospital@yasooj.ir

### 2

#### Recruitment center

##### Name of recruitment center

Martyr Dr. Jalil Hospital

##### Full name of responsible person

Ali Torabiasl

##### Street address

Martyr Dr. Jalil Hospital, Qarani Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

7591387493

##### Phone

+98 74 3333 7001

##### Email

ali.torabi1155@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yasouj University of Medical Sciences

##### Full name of responsible person

Hossein Mari Oryad

##### Street address

Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

7591741417

##### Phone

+98 74 1333 7251

##### Fax

+98 74 3333 7230

##### Email

nursing@yums.ac.ir

#### 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****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Ali Torabiasl

**Position**

Master student of community health nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Unit 6, Baran Building, Iman St., next to Imam Khomeini Mosque, Yasuj

**City**

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**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

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**Position**

Master student of community health nursing

**Latest degree**

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**Person responsible for updating data****Contact****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Ali Torabiasl

**Position**

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**Latest degree**

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**Email**

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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