Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of written emotional disclosure on the care burden, anxiety and depression of the family caregivers of hemodialysis patients

Protocol summary

Study aim

Determination of the effect of written emotional disclosure on the care burden, anxiety and depression of the family caregivers of hemodialysis patients referring to selected hospitals of Tehran University of Medical Sciences in 2022.

Design

A quasi-experimental study with two intervention groups and a control group, each group is selected from a separate hospital, 99 caregivers, in each group 33 persons

Settings and conduct

This study will be conducted in Imam Khomeini, Sina and Shariati hospitals located in Iran, Tehran.

Participants/Inclusion and exclusion criteria

Incision criteria: age 18 to 75 years old; providing care directly to the patient under hemodialysis at least in the past 3 months; speaking in Persian; the ability to read and write in Persian; having physical and mental health necessary for caring role; consent to participate in the study; access to smartphone; ability to use smartphone. Exclusion criteria: parallel care of another patient with chronic illness.

Intervention groups

The guidelines of written emotional disclosure based on the evidence-based written program from Pennebaker and Beall will be presented verbally and written to participants. Instruction in the first intervention group is 'writing about the most traumatic experience of their entire life other than being a caregiver', in the second intervention group is 'writing about the stress of being a caregiver' and in the control group is neutral writing as 'time management'. Participants will write in 3 sessions of 20 minutes in 3 consecutive days at home or their choice, and after each session, will take a picture or if it's typed, copy their text and send for the researcher. After the last session, intervention groups 1 and 2 will be asked to write their opinions and satisfaction with these three sessions and writing experience in one paragraph.

Main outcome variables

Care burden; Anxiety; Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220315054296N1**
Registration date: **2022-04-07, 1401/01/18**
Registration timing: **prospective**

Last update: **2022-04-07, 1401/01/18**
Update count: **0**

Registration date

2022-04-07, 1401/01/18

Registrant information

Name

Zahra Lotfolahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-30, 1401/02/10

Expected recruitment end date

2022-05-14, 1401/02/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of written emotional disclosure on the care burden, anxiety and depression of the family caregivers of hemodialysis patients

Public title
The effect of written emotional disclosure on the care burden, anxiety and depression of the family caregivers of hemodialysis patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 75 years old Providing care directly to the patient under hemodialysis at least in the past 3 months Speaking in Persian The ability to read and write in Persian Having physical and mental health necessary for caring role Consent to participate in the study Access to smartphone Ability to use smartphone
Exclusion criteria:
Simultaneous care of another patient with chronic illness

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **99**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This research is a semi-experimental study with two intervention groups and a control group. Since the probability of information pollution is predicted, intervention groups 1 and 2 and control will be selected from three hospitals separately. Initially, 3 Imam Khomeini, Sina and Shariati hospitals will be randomly assigned to groups: first intervention, second intervention and control; Then sampling will be done using convenient method any of in these hospitals. In this way, all qualified caregivers will enter the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Institutional research ethics committee of Nursing, Midwifery & Rehabilitation school
Street address
School of Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat st. Tohid sq., Tehran I.IRAN
City
Tehran
Province
Tehran
Postal code
1419733171

Approval date
2022-03-13, 1400/12/22

Ethics committee reference number
IR.TUMS.FNM.REC.1400.224

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Care burden score in Caregiver Burden Inventory by Novak & Guest

Timepoint
Before and one month after the intervention

Method of measurement
24-item multi-dimensional questionnaire measuring caregiver burden with 5 subscales: Time Dependence; Developmental; Physical Burden; Social Burden; Emotional Burden. Scores for each item are evaluated using a 5-point Likert scale ranging from 0 (not at all disruptive) to 4 (very disruptive). The scores are variable from 0 to 96 and a higher score indicates a higher care burden.

2

Description
Anxiety score in Generalized Anxiety Disorder 7-item scale by Spitzer et al.

Timepoint
Before and one month after the intervention

Method of measurement
Generalized Anxiety Disorder 7-item scale designed by Spitzer et al. It has 7 items, and an additional question that measures the interference of anxiety in individual, social, family and occupational functions. The subjects with choosing one of the options for no time, more than

half of the days, and almost every day, answer questions, and options are graded with scores 1,0, 2 and 3, and thus the domain Scores are from 0 to 21. Score 0-4: Minimal Anxiety, Score 5-9: Mild Anxiety, Score 10-14: Moderate Anxiety, Score greater than 15: Severe Anxiety

3

Description

The symptoms of depression (not diagnosis of depression) with depression score in Beck Depression Inventory (II)

Timepoint

Before and one month after the intervention

Method of measurement

In this study, the symptoms of depression are identified (not diagnosis of depression), which is determined by the calculated score of the participants' response to the Beck Depression Inventory(II), which is a self-reporting tool for measuring the severity of depression. The overall score is in the range of 0 to 63, with a score of 0 to 13 no or low depression, 14 to 19 mild depression, 20 to 28 moderate depression and 29 to 63 severe depression.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first intervention group: After completing the initial questionnaires, the standard guidelines of written emotional disclosure based on the evidence-based written program from Pennebaker and Beall entitled: 'writing about the most traumatic experience of their entire life other than being a caregiver' will be presented verbally and written to the first intervention group. In order to maintain the adherence of participants to intervene, at the time agreed to start writing sessions, participants will be contacted and reminded to begin their writing session and again they will be contacted in the next two days or SMS Reminder will be sent. Also, caregivers will be requested to take pictures of their writings or if they have typed them, they will be requested to copy their texts and send them for researchers. The aim of this action is maintaining the adherence of the participants to the written intervention and increase their writing power (because they are sure that someone else reads their writings, although there is no direct interaction between participants and researchers about the writings). In addition to sending writings, the first intervention group will be asked to write their opinion and satisfaction of these three sessions and written experience in a paragraph and send it to the researcher. The text of the instruction is as follows: 'You are expected to write at home or place of your choice, within 3 sessions of 20 minutes in 3 consecutive days about the traumatic experience, evolution, stressful event, conflict or psychological problem you are currently facing or you have experienced in another period of your life. It is better that the topic is the one that you have not talked about it to anyone and it still annoys you or thinking about it makes you uncomfortable. You can write about anything you want, but whatever you choose should be something that has deeply affected you. When you write about the event, try to clarify your memories about the experience as possible as you can, including thoughts, feelings and any Physical sense you have experienced. It is important to free yourself and touch the deepest feelings and thoughts you have about this experience. You can also write about the effects of the experience. For example, how it has influenced your self-esteem, relationships and health. Please try to write about a particular event or experience during all three sessions, but this is not a requirement. If you feel that you have solved the stressful experience and it no longer hurts you, you can write about another experience. Time for writing in every session is 20 minutes, and do not worry about spelling, the structure of sentences and grammar, the only rule is that when you start writing, write freely and without trying to write a good story and continue this writing to finish the 20-minute time. In each session after your initial writing, please take time to read your writing again and think about it before starting the next session. After completing every 3 written sessions, take pictures of your writings or if you have typed them, copy the texts and send them to me. You do not need to write your name in the writing and your writings will be completely confidential, and your name and text will not be published somewhere. Also, after the last written session, please generally write your opinion and satisfaction of these three sessions and writing experience in a paragraph and send it to me a separate text '

Category

Rehabilitation

2

Description

Intervention group: The second intervention group: After completing the initial questionnaires, the standard guidelines of written emotional disclosure based on the evidence-based written program from Pennebaker and Beall entitled: 'writing about the stress of being a caregiver' will be presented verbally and written to the second intervention group. In order to maintain the adherence of participants to intervene, at the time agreed to start writing sessions, participants will be contacted and reminded to begin their writing session and again they will be contacted in the next two days or SMS Reminder will be sent. Also, caregivers will be requested to take pictures of their writings or if they have typed them, they will be requested to copy their texts and send them for researchers. The aim of this action is maintaining the adherence of the participants to the written intervention and increase their writing power (because they are sure that someone else reads their writings, although there is no direct interaction between participants and researchers about the writings). In addition to sending writings, the second intervention

group will be asked to write their opinion and satisfaction of these three sessions and written experience in a paragraph and send it to the researcher. The text of the instruction is as follows: 'You are expected to write at home or place of your choice, within 3 sessions of 20 minutes in 3 consecutive days about the the stress of being a caregiver. These stress could include traumatic experiences, conflicts or problems caused by caregiving role. It is better that the topic is the one that you have not talked about it to anyone and it still annoys you or thinking about it makes you uncomfortable. You can write about anything you want, but whatever you choose should be something that has deeply affected you and is related to your caregiving role. When you write about the event, try to clarify your memories about the experience as possible as you can, including thoughts, feelings and any Physical sense you have experienced. It is important to free yourself and touch the deepest feelings and thoughts you have about this experience. You can also write about the effects of the stress. For example, how it has influenced your self-esteem, relationships and health. Please try to write about a particular event or experience during all three sessions, but this is not a requirement. If you feel that you have solved the stressful experience and it no longer hurts you, you can write about another experience. Time for writing in every session is 20 minutes, and do not worry about spelling, the structure of sentences and grammar, the only rule is that when you start writing, write freely and without trying to write a good story and continue this writing to finish the 20-minute time. In each session after your initial writing, please take time to read your writing again and think about it before starting the next session. After completing every 3 written sessions, take pictures of your writings or if you have typed them, copy the texts and send them to me. You do not need to write your name in the writing and your writings will be completely confidential, and your name and text will not be published somewhere. Also, after the last written session, please generally write your opinion and satisfaction of these three sessions and writing experience in a paragraph and send it to me a separate text '

Category

Rehabilitation

3

Description

Control group: After completing the initial questionnaires, based on the standard guidelines of written emotional disclosure from Pennebaker and Beall, neutral writing instruction entitled: "Time management" will be presented verbally and written to the control group. In order to maintain the adherence of participants to intervene, at the time agreed to start writing sessions, participants will be contacted and reminded to begin their writing session and again they will be contacted in the next two days or SMS Reminder will be sent. Also, caregivers will be requested to take pictures of their writings or if they have typed them, they will be requested to copy their texts and send them for researchers. The text of the instruction is as follows: 'You are expected to write at home or place of your choice, within 3 sessions of 20 minutes in 3 consecutive days about how you manage your time. The subject will be different in every 3 days: Day 1: You should write in detail about how you spent your time and what you have done during the last week. Day 2: You should write about the works that you have done over the last 24 hours. Day3: You should write in detail about what you intend to do in next 24 hours. When writing, you should try to write the work you have done or your planned actions accurately and avoid writing your feelings or comments on the work done or planned. For example, what activities did you do day by day or hour to hours. The time of writing is 20 minutes and do not worry about spelling, the structure of sentences and grammar, the only rule is to write freely when you start writing, and continue it until 20 minutes. After completing every 3 written sessions, take pictures of your writings or if you have typed them, copy the texts and send them to me. You do not need to write your name in the writing and your writings will be completely confidential, and your name and text will not be published somewhere.'

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Dr. Seyed Ali Dehghan Manshadi

Street address

Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2755

Email

imamhospital@tums.ac.ir

Web page address

https://ikhc.tums.ac.ir/en/

2

Recruitment center

Name of recruitment center

Dr. Shariati Hospital

Full name of responsible person

Dr. Ahmadreza Jamshidi

Street address

Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy, Tehran, Iran

City

Tehran

Province
Tehran
Postal code
1411713135
Phone
+98 21 8822 1444
Email
Shariati-Hospital-IPD@tums.ac.ir
Web page address
http://shariati.tums.ac.ir/En

3

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Dr. Mohammad Talebpour
Street address
Sina Hospital, Hassan Abad Square, Imam Khomeini Avenue, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
Email
hosp_sina@sina.tums.ac.ir
Web page address
http://en.sinaih.com/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotouhi
Street address
Deputy of Research and Technology, Sixth Floor, Central Organization of Tehran University of Medical Sciences, Ghods St, Keshavarz Blvd
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Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 8163 3698
Email
vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Zahra Lotfolahi
Position
Student of mastership
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Postal code
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Phone
+98 21 6691 4368
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zahra.ltf1998@gmail.com

Person responsible for scientific inquiries

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Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Arpi Manookian
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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City
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Province
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ar-manookian@sina.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Zahra Lotfolahi
Position
Student of mastership
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
School of Nursing Midwifery, Tehran University of Medical Sciences, Nosrat st. Tohid sq. Tehran I.IRAN
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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