Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Communication Therapy Based on the Peplau Model on Sense of Coherence and Psychological Well-Being in People Suffering from Chronic Renal Failure Undergoing Hemodialysis Referred to Hajar Hospital in Shahrekord

Protocol summary

Study aim

The Effect of Therapeutic Communication Based on Peplau's Model on the Sense of Coherence and Psychological Well-Being of Patients with Chronic Kidney Disease Undergoing Hemodialysis Referred to Hajar Hospital, Shahrekord

Design

Eligible hemodialysis patients are randomly assigned to intervention or control groups using a colored-card system: red cards for the intervention (even dialysis days) and yellow cards for the control (odd days). Each participant draws one card to determine the group.

Settings and conduct

This quasi-experimental study is conducted on hemodialysis patients at Hajar Hospital, Shahrekord. Participants are randomly assigned to the intervention group (7–8 Peplau-based therapeutic communication sessions) or control group (routine care). Data are collected using the Antonovsky Sense of Coherence Scale and the Ryff Psychological Well-being Scale and analyzed with SPSS 28.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adults (≥18 years) with ESRD on hemodialysis for ≥6 months, able to learn, and who gave informed consent. Exclusion criteria: Withdrawal, discontinuation of hemodialysis, or development of physical/psychological conditions preventing participation.

Intervention groups

nParticipants complete the demographic questionnaire, the Antonovsky Sense of Coherence Scale, and the Ryff Psychological Well-being Scale. The intervention group receives seven individual therapeutic communication sessions based on Peplau's model during their regular hemodialysis (three times per week), while the control group continues routine care.

Main outcome variables

ASense of coherence based on Antonovsky's Sense of Coherence Scale (SOC-13); Psychological well-being based on Ryff's Psychological Well-Being Scale (18-item short form)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251011067591N1**
Registration date: **2025-10-31, 1404/08/09**
Registration timing: **retrospective**

Last update: **2025-10-31, 1404/08/09**
Update count: **0**

Registration date

2025-10-31, 1404/08/09

Registrant information

Name

Fatemeh TAHMASEBIDEHKOEDI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3334 7986

Email address

tahmasebii77@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-10, 1403/04/20

Expected recruitment end date
2024-07-22, 1403/05/01
Actual recruitment start date
2024-07-10, 1403/04/20
Actual recruitment end date
2024-07-21, 1403/04/31
Trial completion date
2024-10-16, 1403/07/25

Scientific title
The Effect of Communication Therapy Based on the Peplau Model on Sense of Coherence and Psychological Well-Being in People Suffering from Chronic Renal Failure Undergoing Hemodialysis Referred to Hajar Hospital in Shahrekord

Public title
Communication therapy in chronic renal failure
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent of the patient indicating willingness to participate in the intended intervention Definitive diagnosis of ESRD confirmed by a nephrology specialist The patient's age is equal to or greater than 18 years history of hemodialysis for at least 6 months the patient's ability to learn
Exclusion criteria:
Patients with unstable physical conditions or those admitted to intensive care units Patients who are simultaneously enrolled in other clinical studies Patients with severe hearing or speech impairments that interfere with participation in therapeutic communication sessions.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Actual sample size reached: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants were then randomly assigned to either the intervention or control group using a card-based random allocation rule. For this purpose, 70 cards were prepared—35 red cards for the intervention group (assigned to even-numbered dialysis days) and 35 yellow cards for the control group (assigned to odd-numbered days). All cards were placed into a container. Each eligible participant randomly drew a card from the container and was assigned to the corresponding group based on the color of the card.
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
the ethics committee of Shahrekord University of Medical Sciences
Street address
No. 9, Shariati St
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815865489
Approval date
2024-06-30, 1403/04/10
Ethics committee reference number
IR.SKUMS.REC.1403.033

Health conditions studied

1

Description of health condition studied
Chronic Kidney Disease
ICD-10 code
N18.4
ICD-10 code description
Chronic kidney disease, stage 4 (severe)

Primary outcomes

1

Description
sense of coherence
Timepoint
At the beginning of the study (before the intervention), immediately after the intervention, and two months later.
Method of measurement
the 13-item short form of Antonovsky's Sense of Coherence questionnaire

2

Description
Psychological Well-Being
Timepoint
At the beginning of the study (before the intervention),

immediately after the intervention, and two months later.

Method of measurement

18-item short form of the Psychological Well-Being questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention is designed based on Peplau's Interpersonal Relations Model and is delivered in the inpatient dialysis unit. Sessions take place before or after dialysis treatments with a frequency of three times per week and 2–3 days between sessions, so that the complete intervention is delivered within three weeks for each participant. This schedule reduces patient fatigue, eliminates the need for additional clinic visits, and provides sufficient time for reflection and application of strategies between sessions.The intervention consists of seven individual sessions:Orientation Phase (1 session, 20–30 minutes)Introduction of the researcher and explanation of the intervention goalsInitial assessment including medical history, previous dialysis experiences, patient knowledge about the disease and treatment, support systems, and key concernsExplanation of required actions, physical setting, and available resourcesClarification of patient expectations from the healthcare team and establishment of trustIdentification Phase (1 session, 30–40 minutes, with a psychologist present)Encouragement of patients to express emotions and concernsCollection of psychological and physical data, including blood pressure, weight, dietary habits, and fluid intakeIdentification of care barriers and problems related to the disease and treatmentCompilation of a problem list and determination of an appropriate supportive care plan for each patientPromotion of belonging, self-efficacy, and reduction of helplessnessExploitation Phase (3 sessions, 40 minutes each)Implementation of a care plan tailored to each patient's psychological well-being and Sense of CoherenceUse of educational tools, including brochures, visual charts, and digital resourcesActive support to help patients achieve independence in disease managementTermination Phase (2 sessions, 20–30 minutes each)Evaluation of goal attainment, effectiveness of interventions, and observed emotional and behavioral changesReview of the therapeutic communication process and planning of ongoing supportAn optional eighth session is reserved for clinical need to ensure all patients reach their therapeutic goals and maintain fidelity to the intervention.

Category

Other

2

Description

Control group: Patients with chronic renal failure undergoing hemodialysis who received only their routine treatment

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Hajar Hospital

Full name of responsible person
Fatemeh Tahmasebidehkordi

Street address
No.9, Shariati St

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815865489

Phone
+98 38 3334 7986

Email
tahmasebii77@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Dr Akbar Soleimani

Street address
No.9, Shariati St

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815865489

Phone
+98 38 3334 1986

Email
tahmasebii77@gmail.com

Grant name

Grant code / Reference number
7188

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Fatemeh Tahmasebidehkordi
Position
Master's student of Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No.9,Shariati St
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815865489
Phone
+98 38 3334 7986
Email
tahmasebii77@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Fatemeh Tahmasebidehkordi
Position
Nursing student
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
No9, Shariati Street, Shahrekord
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815865489
Phone
+98 38 3334 7986
Fax
Email
tahmasebii77@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Fatemeh Tahmasebidehkordi
Position
Nursing student
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
No9, Shariati Street, Shahrekord
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815865489
Phone
+98 38 3334 7986
Fax
Email
tahmasebii77@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the confidentiality of patient information and the limitation of the data to the objectives of the present study, there is no plan to share the individual participant data (IPD).
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Due to the confidentiality of patient information and the limitation of the data to the objectives of the present study, there is no plan to share the individual participant data (IPD).
When the data will become available and for how long
As the individual participant data and related documents will not be shared due to confidentiality reasons, there is no timeframe for access to these data.
To whom data/document is available
As the individual participant data and related documents

will not be shared due to confidentiality reasons, no individual or group will have access to these data.

Under which criteria data/document could be used

As the individual participant data and related documents will not be shared due to confidentiality reasons, use of these data or documents is not permitted under any circumstances, and no analyses or other uses are allowed.

From where data/document is obtainable

As the individual participant data and related documents will not be shared due to confidentiality reasons, there is no person or institution to contact for access to these data.

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

s the individual participant data and related documents will not be shared due to confidentiality reasons, there is no process for requesting or accessing these data.

Comments