

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of “care transition intervention” plan and routine care plan on health-related outcomes in the older adults with multiple chronic condition

Protocol summary

Study aim

Comparison of the effectiveness of “care transition intervention” plan and routine care plan on health-related outcomes in the older adults with multiple chronic condition

Design

Clinical trial with control group, with parallel groups, randomized on 90 patients. For randomization, the permutation block randomization technique will be used.

Settings and conduct

The study is an interventional study with a controlled and randomized clinical trial design with two intervention and control groups that will be performed in Imam Khomeini Hospital in Sari affiliated to Mazandaran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Age 60 years and older, Alertness and ability to communicate, Normal cognition, Having at least two Chronic condition, Having a telephone, Being transported home after discharge from hospital, Family caregivers must be at least 18 years old. Non-Inclusion include: Evidence of mental illness and dementia

Intervention groups

In the experimental group, the intervention is based on the care transition intervention model, which is the duration of the intervention from the time of patient admission to the hospital to 30 days after discharge. In general, the transition coach will perform the care transition intervention in three stages: 1- hospital visit, 2- home visit and 3- at least three telephone calls, with the participation of the patient and the caregiver. In the control group, the researcher does not intervene during the research period. The control group receives the routine hospital care.

Main outcome variables

Rehospitalization- Quality of Life - Activity of Daily Living

- Instrumental Activity of Daily Living - Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180930041185N3**

Registration date: **2022-09-23, 1401/07/01**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-23, 1401/07/01**

Update count: **0**

Registration date

2022-09-23, 1401/07/01

Registrant information

Name

Eesa Mohammadi

Name of organization / entity

Faculty of Medical Sciences Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 3585

Email address

mohamade@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-31, 1401/06/09

Expected recruitment end date

2024-03-17, 1402/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of “care transition intervention” plan and routine care plan on health-related outcomes in the older adults with multiple chronic condition

Public title

Effectiveness of “care transition intervention” plan in the older

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 60 years and older Alertness and ability to communicate Having a normal cognitive status based on the Abbreviated Mental Test (score 7 and above) Having at least two chronic condition (Congestive Heart Failure, Coronary Artery Disease, Hypertension, Cardiac Arrhythmia, Chronic Obstructive Pulmonary Disease, Diabetes, Peripheral Vascular Disease) Having a telephone Being transported home after hospital discharge Family caregivers must be at least Be 18 years old Willingness to continue participating in the study

Exclusion criteria:

Evidence of mental illness and dementia

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Sample allocation is done randomly (lottery) in two study groups, so that an allocation protocol is created using the permuted block randomization technique (Pocock, 2013). Since the sample framework or patient list is not clear and available before admission, 90 cards are first numbered for the 90 participants and placed in a basket. The cards are then randomly removed from the basket and placed in two intervention and control envelopes. Then, the eligible patients are assigned a number based on the order of admission to the hospital, and then, based on their placement in the replaced blocks, they are selected sequentially and placed in an intervention group or a control group. This ensures the random allocation of participants.

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**

Research Ethics Committees of Tarbiat Modares University

Street address

Bridge Nasr, Jalal Al-e Ahmad, Tehran

City

Tehran

Province

Tehran

Postal code

1411713116

Approval date

2022-08-27, 1401/06/05

Ethics committee reference number

IR.MODARES.REC.1401.108

Health conditions studied**1****Description of health condition studied**

Congestive Heart Failure

ICD-10 code

I50.42

ICD-10 code description

Chronic combined systolic (congestive) and diastolic (congestive) heart failure

2**Description of health condition studied**

Coronary Artery Disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

3**Description of health condition studied**

Hypertension

ICD-10 code

I87.3

ICD-10 code description

Chronic venous hypertension (idiopathic)

4**Description of health condition studied**

Cardiac Arrhythmia

ICD-10 code

I49.9

ICD-10 code description

Cardiac arrhythmia, unspecified

5**Description of health condition studied**

Chronic Obstructive Pulmonary Disease

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

6**Description of health condition studied**

Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

7**Description of health condition studied**

Peripheral Vascular Disease

ICD-10 code

I73.9

ICD-10 code description

Peripheral vascular disease, unspecified

Primary outcomes**1****Description**

Rehospitalization

Timepoint

The beginning of the study (Before intervention), 30, 90 and 180 days after discharge

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

Quality of Life

Timepoint

The beginning of the study (Before intervention), 30, 90 and 180 days after discharge

Method of measurement

World Health Organization Quality of Life Questionnaire, older adults Edition

2**Description**

Activity of Daily Living

Timepoint

The beginning of the study (Before intervention), 30, 90 and 180 days after discharge

Method of measurement

Activities of Daily Living Questionnaire

3**Description**

Instrumental Activity of Daily Living

Timepoint

The beginning of the study (Before intervention), 30, 90 and 180 days after discharge

Method of measurement

Instrumental Activity of Daily Living Questionnaire

4**Description**

Depression

Timepoint

The beginning of the study (Before intervention), 30, 90 and 180 days after discharge

Method of measurement

Geriatric Depression Scale

Intervention groups**1****Description**

Experimental group: The intervention in the experimental group is based on the care transition intervention model, which is the duration of the intervention from the time of admission to the hospital to 30 days after discharge. The care transition intervention is based on four pillars or conceptual areas, which include 1- medication self-management, 2- a patient-centered record kept by the patient to facilitate information transfer, 3- Follow-up (completing the patient's follow-up visits with the primary care provider Or other health professionals, suggest follow-up visits to the patient and support the patient to coordinate the time of the next visit with health professionals if necessary by the nurse), and 4- List of warning signs (red flags) indicating worsening of the condition and instructions about how to react to them. The above four conceptual areas are operational through two strategic mechanisms including personal health record building and visits and telephone calls by the researcher (coach transition), to encourage the elderly and their caregivers to play a more active role during the care transition and strengthen coordination and continuity of care throughout care facilities. In the present study, the role of transition instructor is assumed by the researcher who has a master's degree in geriatric nursing. In general, in three stages: 1- hospital visit, 2- home visit and 3- at least three telephone calls, the coach transition will perform the care transition intervention with the participation of the patient and the caregiver.

Category

Rehabilitation

2

Description

Control group: In the control group, the researcher does not intervene during the research period. The control group receives the same routine hospital care. Routine care is such that the nurse provides the patient with a discharge instruction sheet at the time of discharge. The contents of the discharge education leaflet include information about the patient's medication (when and how to take the medication), care at home, nutrition, the time of the next visit to the clinic, and the time of receiving the test / pathology results. The discharge form is a single format and stereotype and does not include specific considerations and content about the elderly and other chronic illnesses that were not the direct cause of hospitalization. The explanations and trainings mentioned in the discharge form are also provided orally to the patient on the day of discharge from the hospital. Due to the completion and presentation of the discharge training sheet, comprehensive and complete information regarding the items mentioned in the discharge training sheet and other items such as side effects of medications and warning signs appropriate to the patient's condition and disease are not provided to the patient and caregivers and the information provided is brief. After the patient is discharged from the hospital, no special care and follow-up action is taken by the hospital for patients and caregivers.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital of Sari

Full name of responsible person

Dr. Seyed Khosro Ghasempouri

Street address

Imam Khomeini Educational and Medical Center, Razi St., Sari

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3335 0672

Email

ravabetomoomi@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of Medical Sciences, Tarbiat Modares

University

Full name of responsible person

Dr. Seyed Gholamreza Mousavi

Street address

Bridge Nasr (Gisha), Tarbiat Modares University,
Faculty of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 3590

Email

med@modares.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Faculty of Medical Sciences, Tarbiat Modares 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

Faculty of Medical Sciences, Tarbiat Modares
University

Full name of responsible person

Dr. Eesa Mohammadi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Bridge Nasr (Gisha), Tarbiat Modares University,
Faculty of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 3550

Email

mohamade@modares.ac.ir

Web page address

<https://www.modares.ac.ir/~mohamade>

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

Faculty of Medical Sciences, Tarbiat Modares University

Full name of responsible person

Dr. Eesa Mohammadi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Paul Nasr (Gisha), Tarbiat Modares University, Faculty of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 3550

Email

mohamade@modares.ac.ir

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

Faculty of Medical Sciences, Tarbiat Modares University

Full name of responsible person

Dr. Eesa Mohammadi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Paul Nasr (Gisha), Tarbiat Modares University, Faculty of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 3550

Email

mohamade@modares.ac.ir

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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available