Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 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

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Eesa Mohammadi

Name of organization / entity
Faculty of Medical Sciences Tarbiat Modares University

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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
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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

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Sponsors / Funding sources

1

Sponsor

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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
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

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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
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