

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of a complex multicomponent intervention on self-care, health literacy and social capital among older adults

Protocol summary

Self-care; Health literacy; Social capital; Quality of life

Study aim

The purpose of this study is to evaluate the effect of a complex multicomponent intervention on self-care, health literacy, and social capital among older adults compared to the usual care of older adults in health care centers.

Design

A pragmatic community-based, randomized controlled trial with parallel groups

Settings and conduct

The effect of the intervention on self-care, health literacy, social capital, and quality of life will be assessed before and immediately after and three months after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 60 year or above. minimum literacy skills. Exclusion criteria: need help to go to the primary health care centres. cognitive impairment or dementia. medical conditions that contraindicates physical activity. any severe mental health problem that hinders participation in a group participation.

Intervention groups

Intervention group: Educational intervention program for two groups of 20 elderly people is conducted in two urban health sites in intervention groups. The intervention program consists of twelve weekly and two-hour training sessions and local trips. Nine group training sessions at the health center with topics such as health and self-care, physical activity, emotional health, healthy eating habits, loneliness and social interaction, community participation, personal autonomy, communication with health professionals, and group discussion. Three more meetings: local trip, a park (or physical activity area), a large store, and a regional volunteer community center. The intervention team consists of four health care providers and one physician who take a two day workshop. control group: The two control groups continue to receive routine elderly care.

Main outcome variables

General information

Reason for update

1-Realized sample size correction 2- Elimination of randomization from study design, and implementation of study with quasi-experimental method due to executive constraints and non-random allocation of two centers to intervention and control groups to prevent contamination of samples.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191011045056N1**
Registration date: **2020-01-18, 1398/10/28**
Registration timing: **retrospective**

Last update: **2021-06-15, 1400/03/25**

Update count: **1**

Registration date

2020-01-18, 1398/10/28

Registrant information

Name

Narges Motamedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 8145

Email address

n_motamedi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2019-11-06, 1398/08/15
Actual recruitment start date
 2019-10-23, 1398/08/01
Actual recruitment end date
 2019-11-06, 1398/08/15
Trial completion date
 2020-02-01, 1398/11/12

Scientific title
 The effect of a complex multicomponent intervention on self-care, health literacy and social capital among older adults

Public title
 Promoting self-care, health literacy and social capital in older adults

Purpose
 Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 They are community-dwelling aged 60 year or above.
 They have minimum literacy skills.
Exclusion criteria:
 They need help to go to the primary health care centres (PCC). They have cognitive impairment or dementia.
 They have a medical condition that contraindicates physical activity. They have any severe mental health problem that hinders participation in a group participation.

Age
 From **60 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **80**
 Actual sample size reached: **86**

Randomization (investigator's opinion)
 Not randomized

Randomization description

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 Isfahan University of Medical Sciences

Street address

Isfahan University Of Medical Sciences, Hezar Jerib street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-03-07, 1397/12/16

Ethics committee reference number

IR.MUI.MED.REC.1397.311

Health conditions studied

1

Description of health condition studied

Elderly Quality of life

ICD-10 code

Z76.9

ICD-10 code description

Person encountering health services in unspecified circumstances

Primary outcomes

1

Description

Self-care

Timepoint

Self-care measurement at baseline (before intervention), immediately after, and 3 months after intervention

Method of measurement

Self-Care Questionnaire for the Elderly

2

Description

Health literacy

Timepoint

At baseline (before intervention), immediately, and 3 months after intervention

Method of measurement

Health Literacy for Iranian Adults (HELIA)

3

Description

Social Capital

Timepoint

At baseline (before intervention), immediately, and 3 months after intervention

Method of measurement

Onyx and Bullen Social Capital Questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

At baseline (before intervention), immediately, and 3 months after intervention

Method of measurement

short form 12 quality-of-life questionnaire (SF-12)

Intervention groups

1

Description

Intervention group: This study is a community-based study with multiple and varied components implemented in a multifaceted intervention program. Intervention and content of the sessions are based on a similar study protocol that was previously published in BMC Public Health (2018). the intervention is described with the TIDieR Guidelines below. It is designed to enhance social support and participation (social capital), Self-care, and health literacy in the elderly as mediating factors between social determinants and health outcomes, and with the potential to improve the quality of life and well-being of the elderly. Intervention materials and methods have been slightly adjusted to fit our country's cultural and indigenous conditions. The intervention program consists of 12 weekly and two-hour sessions with the following topics: Sessions (contents, materials and procedures) 1. Health and Self Care: Introducing the Program, Participants introduce themselves , group discussion using photos of self-care daily activities, asking the group to bring a personal item from home the next meeting, creating a wall newspaper of member paintings, handicrafts, writing and ... 2. Physical Activity: Participants talk about the personal object they brought from home, discussing and setting a specific goal of daily living achievable during the week. Identifying appropriate locations for physical activity using local mapping, short instruction and discussing about the benefits and limitations of physical activity, agreeing on the destination for a group walk in the next session 3. Local First Walk: Group does a Walk with Origins Start and end at the health center and do physical activity in a place like a park or gym 4. Emotional health: Talk about achieving personal goals. Short tutorials on problem-solving techniques, group discussion on coping strategies, a relaxation exercise 5. Healthy eating habits: short tutorials on healthy and inexpensive eating tips, group discussion on eating habits, and nutrition tips Cheaper and and about the places where they shop. Agree on the market or store for local circulation next week 6. Second local circulation: Groups visit the local supermarket. During the meeting they discuss their eating habits and preferences for shopping. 7. Loneliness and Social relationships: A brief tutorial on concepts of loneliness and social relationships, group discussion focusing on thoughts and perceptions of loneliness and

social relationships. Divide the group into subgroups to create keywords stories about social communication. 8. Community Participation: Reading a story about a woman participating in local community activities by a member aloud, identifying important local community activities using the local map and discussing them, group discussion on the limitations and benefits of social participation, Agree on an important social place in the area for the next visit 9. Third Local Circle: The group visits an important local place, one of the site's operators explains to the group about the place and its activities. Groups are encouraged to participate in social activities.10. Personal autonomy: A brief tutorial on the concept of personal autonomy, group discussion on personal autonomy, discussion of the practical case put forward by the trainer. 11. Get in touch with health professionals: A video showing how to prepare for a medical encounter. Describe the thoughts and feelings of the group members when meeting a health care provider and their personal knowledge of health resources in the community 12. Group Discussion Final Session: Expressing People's Thoughts and Feelings about the Program, Creating, and Donating an Imaginary Gift to Another Participant , The group shares a farewell meal. The intervention team consists of four health care providers and one physician (with experience in health care) will be previously trained as group facilitators by the research team during a two-day workshop based on the instructional guide. Intervention is carried out at two urban health sites including 12 weekly and two hour sessions and is conducted for two groups of 20. Each participant receives a code and completes the questionnaires at the beginning of the study by interviewing them. Outcome interviewers are selected from health care providers who are not involved in the intervention. They receive the necessary training on interviewing and filling out questionnaires before they start. One or two health care providers as observers record quantitative and qualitative measures of implementation such as fidelity and adherence.

Category

Lifestyle

2

Description

Control group: the participants from control group will receive the usual universal healthcare services available in health centers. At the end of the program, they are suggested to enter the intervention group in the next period of program implementation.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rezaian urban Health Center

Full name of responsible person

Narges Motamedi

Street address

Shahid Rezaian urban Health Center, Alley 61. Sayyad Shirazi Highway

City

Isfahan

Province

Isfahan

Postal code

8156698993

Phone

+98 31 3522 1780

Email

dean@med.mui.ac.ir

2

Recruitment center

Name of recruitment center

Ebnesina urban Health Center

Full name of responsible person

Narges Motamedi

Street address

Ebnesina urban Health Center, EbneSina Street

City

Isfahan

Province

Isfahan

Postal code

8148665923

Phone

+98 31 3445 9039

Email

dean@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjooye Javanmard

Street address

Bldg No. 4, Isfahan University of Medical Scien, Hezar Jerib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 8139

Email

research@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Narges Motamedi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

Street address

School of Medicine, Isfahan University Of Medical Sciences, Hezar Jerib street

City

Esfahan

Province

Isfahan

Postal code

7346181764

Phone

+98 31 3792 8145

Fax

Email

N_motamedi@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Narges Motamedi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

Street address

School of Medicine, Isfahan University Of Medical Sciences, Hezar Jerib street

City

Esfahan

Province

Isfahan
Postal code
8174673461
Phone
+98 31 3792 8145
Fax
Email
N_motamedi@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ziba Taherian
Position
Community Medicine Assistant
Latest degree
Medical doctor
Other areas of specialty/work
Public Health/Community Medicine
Street address
School of Medicine, Isfahan University Of Medical Sciences, Hezar Jerib street
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3660 5014
Email
Drztaherian@yahoo.com

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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data in the study population can be shared with the exception of private features.

When the data will become available and for how long

The access period will start 6 months after the results are published.

To whom data/document is available

At the present stage it will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

To the extent of analyzing data for academic researchers

From where data/document is obtainable

Department of Social and Family Medicine
N_motamedi@med.mui.ac.ir

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

Submit a written request to the Director of Department of Social and Family Medicine

Comments