Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Effectiveness of prospective memory training program on prospective memory performance in hospitalized elderly patients suffering from severe psychiatric disorders

Protocol summary

Study aim
Evaluating the effectiveness of a multi-component intervention to strengthen prospective memory performance in elderly patients with severe psychiatric disorders

Design
The present study is a single-blind clinical trial. The examiner/facilitator will be unaware of all the steps of randomization and allocation of intervention and control group members. In randomization, all potential participants are first screened, placed in random blocks. Then, using a table of random numbers or random blocks, the participants are assigned to the intervention and control groups step by step based on demographic information and input criteria. There are two follow-ups of 3 and 6 months in the plan.

Settings and conduct
The examiner/facilitator will be unaware of all the steps of randomization and allocation of intervention and control group members. Venue: Razi Psychiatric Hospital

Participants/Inclusion and exclusion criteria
The study inclusion criteria: a) The age of 55 years and older, b) Being of Iranian origin, c) suffer from severe psychiatric disorders, d) at least 5 years of history of the disorder, e) the desire to participate in the study and give informed consent f) Do not suffer from cognitive impairments. The study exclusion criteria: a) There are coexisting psychiatric disorders, including anxiety and mood disorders, b) a history of ECT treatment in the last 12 months, c) a history of alcohol and drug use in the last 12 months. d) Suffering from physical diseases that require treatment at the moment (including diabetes, heart disease, hypertension)

Intervention groups
The intervention group includes the prospective memory training program and the control group is actually the waiting list.

Main outcome variables
Prospective memory performance

General information

Reason for update

Acronym
Razi PM Study

IRCT registration information
IRCT registration number: **IRCT20230202057308N1**
Registration date: **2023-02-11, 1401/11/22**
Registration timing: **prospective**

Last update: **2023-02-11, 1401/11/22**
Update count: **0**

Registration date
2023-02-11, 1401/11/22

Registrant information

Name
Omid Rezaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 3340 1604

Email address
dr_omid_rezaee@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-03, 1402/01/14

Expected recruitment end date
2023-05-22, 1402/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of prospective memory training program on prospective memory performance in hospitalized elderly patients suffering from severe psychiatric disorders

Public title
Prospective Memory Training for Inpatient Older adults with Severe Mental Illness
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A) the age of the participants is 55 years and older, B) Being of Iranian origin (mother tongue is Farsi), C) suffering from severe psychiatric disorders (according to the definition, and using DSM 5 criteria) (schizophrenia spectrum and bipolar disorder, D) have at least 5 years of history of the disorder, E) have the desire to participate in the study and give informed consent ,and F) do not have cognitive impairment (have obtained a score of at least 23 on the MMSE scale).
Exclusion criteria:
A) There are coexisting psychiatric disorders, including anxiety and mood disorders, B) There is a history of ECT treatment in the last 12 months. C) There is a history of alcohol and drug use in the last 12 months, D) Suffering from physical diseases that require treatment at the moment (including diabetes, heart disease, blood pressure) (these diseases)Due to their effect on cognitive functions, especially prospective memory function, they should be controlled and removed in the study.
Age
From **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The present study is a single-blind clinical trial. In this sense, the CONSORT criteria will be fully observed. In order to comply with the mentioned criteria, some basic steps should be implemented in the study. The first step is blinding the study as follows: the experimenter/facilitator will be unaware of all the steps of randomization and allocation of intervention and control group members, and these tasks will be performed by other collaborators of the project (this study , one study is a blind examiner/facilitator). Another important step is randomization, which will be implemented as follows: First, all potential participants are screened (the participants, before entering the study, in terms of demographic information, level of symptoms, intelligence, entry and exit criteria and factors Affecting the homogeneity of the study groups, they are placed in random blocks (one person). Then, using a table of random numbers or random blocks (via the random block website, or online randomization), participants are randomized based on demographic information and entry criteria (for example, based on age equalization, gender, level of intelligence, etc.) are assigned to two intervention and control groups. The main examiner/facilitator will be unaware of the allocation of people in the study groups and this step will be done by other collaborators of the project who are not related to the examiner/facilitator.
Blinding (investigator's opinion)
Single blinded
Blinding description
Single blinding of the study is as follows: the experimenter/facilitator will be unaware of all the steps of randomization and allocation of members to the intervention and control groups, and these tasks will be performed by other collaborators of the project (this study is a study , the examiner/facilitator is blind).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the University of Rehabilitation Sciences and Social Health
Street address
Kodakyar Ave., Daneshjo Blvd., Evin
City
Tehran
Province
Tehran
Postal code
1985713871
Approval date
2023-01-29, 1401/11/09
Ethics committee reference number
IR.USWR.REC.1401.200

Health conditions studied

1

Description of health condition studied
Severe psychiatric disorders including the spectrum of

schizophrenia and bipolar disorder

ICD-10 code

F20

ICD-10 code description

Schizophrenia

2

Description of health condition studied

Bipolar Disorder

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes

1

Description

Prospective memory performance: Prospective memory is the memory related to doing tasks in the future (for example, remembering to take medicine at the appointed time), which tasks are divided into two types of temporal and event tasks.

Timepoint

One week before the intervention, 6, 18 and 30 weeks after the intervention

Method of measurement

Virtual Week Game: a computer-based tool designed to assess and enhance factors underlying prospective memory. The virtual week game simulates a number of PM tasks similar to real, everyday tasks associated with prospective memory tasks (for example, remembering to take an antibiotic pill at certain times of the day or returning a book to the library). The game paradigm has a general storyline for seven virtual days and several types of time- and event-dependent PM tasks for each day of the virtual week. Each virtual day includes a dedicated story with a number of PM assignments. The paradigm also allows the experimenter to record the participants' performance.

Secondary outcomes

1

Description

Level of independence: A person's ability to perform several skills such as shopping, cooking, and managing finances, which are critical skills for older adults to be able to live independently, is influenced by prospective memory performance.

Timepoint

1 week before the intervention (pre-test), immediately after the end of the intervention (at the end of week 6), 18 and 30 weeks after the end of the intervention (study follow-ups)

Method of measurement

Instrumental Daily Living Activities (IADL): A questionnaire to assess the level of individual independence that can be used as a self-report as well as an interview (in hospitalized conditions). The tool measures a person's ability in several skills, such as shopping, cooking and managing finances (which are critical skills for older adults to be able to live independently). This scale takes 10 to 15 minutes to complete and includes eight areas of daily functioning with scores of 0 to 8. This scale can be used as a written questionnaire or as an interview scale.

2

Description

Depression level: prospective memory performance in the elderly has a significant effect on factors related to mental health (anxiety and depression levels) of these people. Therefore, measuring the level of depression and anxiety in this study are considered as secondary variables.

Timepoint

1 week before the intervention (pre-test), immediately after the end of the intervention (at the end of week 6), 18 and 30 weeks after the end of the intervention (study follow-ups)

Method of measurement

The Geriatric Depression Scale (GDS): A questionnaire to assess the symptoms of depression in the elderly, which can be used in both normal and clinical populations. The GDS consists of 30 questions in which participants have to answer yes or no questions based on their mood about the situations mentioned in the past week. The cutoff score for this scale is 11 and above. Therefore, higher scores on the GDS indicate worse performance. It can be executed within 5 to 7 minutes. This scale can be used for healthy and sick elderly people (even with mild to moderate cognitive impairment). In GDS scoring, each question is given a score of 0 or 1 based on the nature of the question, so for some questions, if the answer is positive, the score will be 1, and for some, if the answer is positive, the score will be 0.

3

Description

Anxiety level: prospective memory performance in the elderly has a significant effect on factors related to mental health (anxiety and depression levels) of these people. Therefore, measuring the level of depression and anxiety in this study are considered as secondary variables.

Timepoint

1 week before the intervention (pre-test), immediately after the end of the intervention (at the end of week 6), 18 and 30 weeks after the end of the intervention (study follow-ups)

Method of measurement

The Geriatric Anxiety Inventory (GAI): (a questionnaire to assess anxiety symptoms in the elderly that can be used in both normal and clinical populations). This instrument has 30 items (the only scorable items are items 1 to 25. Items 26 to 30 can be used for clinical purposes to test individual domains of interest. They are used for a total score or none of the subscale scores are not calculated). This scale is used to assess anxiety symptoms among

the elderly. People respond to the items on a four-point Likert scale from "not at all" (0) to "always" (3). This scale does not have a clear cut score reported. Higher scores on this scale indicate higher levels of anxiety. It takes about 10 minutes to complete this test.

Intervention groups

1

Description

Intervention group: To present the present multi-centered intervention, it is necessary to teach its components to the participants before starting the intervention. First, an introduction in very simple language about prospective memory, its function and its tasks is presented. Then, "carrying out the intentions" is taught in simple language and with a concrete example (for example, first a small ball is shown to the participants and it is said that "every position you hold this ball in your hand , this simple command in the "Execution of Intentions" formula is as follows: "If I catch the ball, then I must raise my hand." Similar oral assignments are considered and made for each week. will be implemented. This introduction and, in fact, the warm-up exercise for the patients, prepares them to enter the next part, i.e. doing the tasks related to the PM-Tasks program (the details related to this program are given in the tools section). After practicing with the PM-Tasks program, the participants are ready to play the virtual week game and can play a certain number of game days in each session (details about this program are in the tools section). Since the training and strengthening of prospective memory performance requires continuous but short-term sessions, a program to strengthen this memory has been designed in the form of 6 two-hour sessions (including rest time between sessions). After the intervention, the first and second follow-ups (3 and 6 months) will be done respectively. This point should also be taken into account that according to the ethical duty of the researchers of this study, after the full implementation of the intervention and the completion of the two follow-ups of this study, the intervention will be implemented for the control group so that this group will also benefit from the intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Educational and Therapeutic Psychiatric Center

Full name of responsible person
Omid Rezaei

Street address
Shahid Rastegar Blvd., TaghiAabad triode, Shahr-e-Rey

City
Tehran

Province
Tehran

Postal code
1867612016

Phone
+98 21 3340 1600

Email
razi.pr@uswr.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Hamidreza Khankeh

Street address
Kodakyar Ave., Daneshjo Blvd., Evin

City
Tehran

Province
Tehran

Postal code
1985713871

Phone
+98 21 2218 0066

Email
audio.dep@uswr.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences

Full name of responsible person
Omid Rezaei

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work

Psychiatrics

Street address
Kodakyar Ave., Daneshjo Blvd., Evin

City
Tehran

Province
Tehran

Postal code
1985713871

Phone
+98 21 2218 0066

Email
azinfarzings@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Omid Rezaei

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Psychiatrics

Street address
Kodakyar Ave., Daneshjo Blvd., Evin

City
Tehran

Province
Tehran

Postal code
1985713871

Phone
+98 21 2218 0066

Email
azinfarzings@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Omid Rezaei

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Psychiatrics

Street address
Kodakyar Ave., Daneshjo Blvd., Evin

City
Tehran

Province
Tehran

Postal code
1985713871

Phone
+98 21 2218 0066

Email
azinfarzings@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
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

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Maintaining confidentiality and scientific use of data

From where data/document is obtainable
To the person in charge of this study

What processes are involved for a request to access data/document
After confirming the identity and purpose of the requester, the data will be sent to him within 3 months while maintaining confidentiality. It should be noted that a written commitment to not misuse the data will also be obtained.

Comments