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Evaluation of a preventative multi-disciplinary training program for prospective memory among older adults

Submission date
06/01/2017

Recruitment status
No longer recruiting

Registration date
11/01/2017

Overall study status
Completed

Last Edited
11/05/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Prospective memory (PM) is a form of memory which involved remembering to perform intended actions in the future, simply, remembering to remember. It is an important function and is necessary in order for people to be able to live independently and be self-sufficient. Examples of prospective memory include: remembering to take medicine at night before going to bed, or remembering to go to an appointment. PM can be divided into three types; time-based, event-based, and activity-based. Time-based PM involves remembering to perform an action at a specific time or after a period of time. Event-based PM involves remembering to perform an intention when a cue (reminder) appears. Activity-based PM involves remembering to perform an intention upon the completion of an activity. Maintaining PM is very important for the elderly to be able to live independently. Forgetting things that they need to remember can be upsetting for some older adults, leading to mental health problems such as anxiety and depression. The aim of this study is to find out whether a short program designed to help exercise PM functions can lead to improvements in PM and mood in older adults.

Who can participate?
Adults aged 60 and over who are educated to at least secondary education level

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in a program designed to improve their prospective memory. This involves taking part in one two-hour session each week for a total of six weeks, where participants play a computerised board game designed to exercise their prospective memory as well as taking part in a memory strategy training. Those in the second group receive no extra training and continue as normal for the duration of the study. At the start of the study and then again after six and ten weeks, participants in both groups undergo a number of assessments to assess their prospective memory and mental wellbeing.

What are the possible benefits and risks of participating?
Participants may benefit from improvements to their prospective memory and mental wellbeing. There are no notable risks involved with participating in this study.

Where is the study run from?
University of the Third Age (Malaysia)

When is the study starting and how long is it expected to run for?
February 2016 to July 2017

Who is funding the study?
Universiti Putra Malaysia (Malaysia)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IG(EXP16)P115

Study information

Scientific Title
Evaluation of a preventative multi-disciplinary training program for prospective memory among older adults: a randomized controlled trial

Study objectives
There is a significant improvement in prospective memory functions among older adults following a 12-hour multi-component cognitive-based intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of University Putra Malaysia, 07/12/2016, ref: IG[EXP16]P115

Study design
Single-centre single-blinded randomised cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Memory function

Interventions
Participants will be randomly assigned to the intervention or control groups (1:1) in site-specific blocks that vary randomly in size to ensure adequate randomization, developed by http://www.randomization.net. The randomization sequence will be concealed from research staff.

Intervention group: Participants take part in a 12 hour intervention regarding exercising their prospective memory. This involves one two-hour session per week for six weeks, and involves a process-based intervention component (a computerized board game to exercise prospective memory - VIRTUAL WEEK board game) and a strategy-based intervention component (memory strategy training such as; intention implementation intentions).

Control group: Participants receive no additional treatment and continue as normal for the duration of the study.

Follow up takes place after six week, one month later (10 weeks) and three months later (14 weeks) and involves prospective memory, depression, anxiety and instrumental daily living activities assessments.

Intervention Type
Other

Primary outcome measure
Prospective memory (PM) functions are assessed at baseline, 6, 10 and 14 weeks using:
1. PM functions (time-, event-, and activity-based PM) are assessed using a computer-based test
2. PRMQ (a paper-pencil questionnaire) to be used as a subjective measure for PM functions

Secondary outcome measures
1. Instrumental daily living activities are measured using the Instrumental Activities of Daily Living Scale at baseline, 6, 10 and 14 weeks
2. Depression is measured using the Geriatric Depression Scale (GDS) at baseline, 6, 10 and 14 weeks
3. Anxiety is measured using the Geriatric Depression Scale (GDS) at baseline, 6, 10 and 14 weeks

Overall study start date
01/02/2016

Completion date
30/09/2018

Eligibility

Key inclusion criteria
1. Aged 60 years and above
2. Educational level of at least secondary educational level

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
42 participants for each arm (84 participants in total)

Total final enrolment
25

Key exclusion criteria
1. Aged less than 60 years old
2. Are not educated enough or are illiterate

3. Those who do not show normal cognitive functions
4. Suffering from a psychological or learning disability
5. History of nuerological impairments (measured by MMSE)
6. Any major psychiatric disorders (taking any psychoactive medication (e.g., anti-depressive, anxiolytics)) and learning disabilities
7. History of general anaesthesia, head truamas (in the last 6 months prior to the study), cerbrovascular disease, or neurological impairments
8. Drug/alcohol abuse

Date of first enrolment
01/05/2016

Date of final enrolment
28/01/2017

Locations

Countries of recruitment
Malaysia

Study participating centre
U3A (University of the Third Age)
Universiti Putra Malaysia
Selangor Darul Ehsan
Serdang
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43400

Sponsor information

Organisation
Universiti Putra Malaysia

Sponsor details
Jalan Upm
Serdang
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Sponsor type
University/education

ROR
https://ror.org/02e91jd64

Funder(s)

Funder type
University/education

Funder Name
Universiti Putra Malaysia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/09/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Rahimah binti Ibrahim (imahibrahim@upm.edu.my)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2018		Yes	No
Results article		22/04/2021	11/05/2021	Yes	No