

Physical activity impact on cognitive functions for patients with depressive disorder

Submission date 13/02/2018	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 15/02/2018	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 15/02/2018	Condition category Mental and Behavioural Disorders	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Depressive symptom are associated with poor cognitive function (mental capacity) and subsequent cognitive decline. Physical activity may be one of multiple therapies for improvement, maintenance and development of cognitive functions. The aim of this study is to evaluate the effect of group exercising on mood and cognitive functions in persons with depression.

Who can participate?

Adults aged 25-80 years who are diagnosed with depression disorder.

What does the study involve?

Participants are randomly allocated to one of four groups. Those in the first group receive physical activity sessions three times a week. Those in the second group receive physical activity sessions three times a week. Participants in the third group participate in the active video games physical activity session three times a week. Participants in the first three groups have their cognitive function measured before and after the programme. Those in the last group only have their cognitive function measured at the same times of the other groups.

What are the possible benefits and risks of participating?

There are direct benefit of participating in the research because participants will have acute improvement of the mood after each session and better thinking and attention possibilities (cognitive functions) after 4weeks. There are no direct risks with participating.

Where is the study run from?

Kėdainiai Hospital (Lithuania)

When is the study starting and how long is it expected to run for?

June 2017 to February 2019

Who is funding the study?

Lithuanian Sports University (Lithuania)

Who is the main contact?
Mrs Aiste Leleikiene (Scientific)

Contact information

Type(s)
Scientific

Contact name
Mrs Aiste Leleikiene

Contact details
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Additional identifiers

Protocol serial number
1(V-5)

Study information

Scientific Title
Physical activity impact on mental capacity for patients with depressive disorder

Study objectives
The physical activity sessions (group exercises, strength exercises and active video games) can improve the cognitive functions of patients with depression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kaunas regional biomedical research ethics committee, 22/12/2017, ref: Nr. BE-2-18

Primary study design
Interventional

Study design
Interventional randomised controlled study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Depressive disorder

Interventions

Participants are randomly allocated to one of four groups during hospitalisation:

First group: Participants are asked to participate in the group physical activity sessions (durations 45 minutes, 3 times a week). Cognitive functions are evaluated before and after 12 sessions of physical activity.

Second group: Participants are asked to participate in the strength physical activity sessions (durations 45 minutes, 3 times a week). Cognitive functions are evaluated before and after 12 sessions of physical activity.

Third group: Participants are asked to participate in the active video games physical activity sessions (durations 45 minutes, 3 times a week). Cognitive functions are evaluated before and after 12 sessions of physical activity.

Control group: Participants are asked to participate in the trial, and their cognitive functions are evaluated two times (first day and after 4 weeks).

Participants are followed up to measure their cognitive function before the intervention and after four weeks.

Intervention Type

Behavioural

Primary outcome(s)

Cognitive function is measured using the computerized automated neuropsychological assessment metrics version (ANAM4™ TBI Battery) at baseline and 4 weeks.

Key secondary outcome(s)

1. Mood is measured using Yvesage geriatric scale at baseline and 4 weeks
2. Level of physical activity measured using Modified Baecke Questionnaire at baseline
3. Mood measured using visual analogue scale at before and after each physical activity session

Completion date

23/02/2019

Eligibility

Key inclusion criteria

1. Diagnosed depression disorder
2. Don't have usual physical activity
3. Don't have acute psychosis
4. Don't have mental retardation
5. Don't have severe somatic disorder
6. Aged between 25-80 years old

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

1. Usual physical activity
2. Acute psychosis
3. Mental retardation
4. Have severe somatic disorder

Date of first enrolment

23/12/2017

Date of final enrolment

30/03/2018

Locations

Countries of recruitment

Lithuania

Study participating centre

Kėdainiai Hospital

Kėdainiai

Lithuania

LT-57164

Sponsor information

Organisation

Lithuanian Sports University

ROR

<https://ror.org/00hvk7s55>

Funder(s)

Funder type

University/education

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Aistė Leleikienė - digimaite@yahoo.com

IPD sharing plan summary

Available on request