

# Physical activity impact on cognitive functions for patients with depressive disorder

<b>Submission date</b> 13/02/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 15/02/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 15/02/2018	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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**  
Lithuanian Sports University  
Sporto g. 6  
Kaunas  
Lithuania  
44221

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Study design**  
Interventional randomised controlled study

**Primary study design**  
Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Prevention

**Participant information sheet**

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

**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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/06/2017

**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

## Age group

Adult

## Sex

Not Specified

## Target number of participants

90

## 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

## Sponsor details

Sporto g. 6  
Kaunas  
Lithuania  
LT-44221

## Sponsor type

University/education

## ROR

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

# Funder(s)

## Funder type

University/education

## Funder Name

Lithuanian Sports University

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal. The protocol and statistical analysis plan is in Lithuanian language and can be sent upon request.

## Intention to publish date

## 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](mailto:digimaite@yahoo.com)

## IPD sharing plan summary

Available on request