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Physical exercise as a supplement to treatment of alcohol use disorders

Submission date
16/05/2013

Recruitment status
No longer recruiting

Registration date
11/07/2013

Overall study status
Completed

Last Edited
17/12/2020

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
Alcohol use disorder is a widespread problem in Denmark and has harsh impacts on health and quality of life of each person. The treatment of alcohol use disorder involves evidence-based knowledge on medical treatment, physical training, and psychological management. The aim of this study is to find out the effect of physical exercise on alcohol intake, ability of the body to supply oxygen to working muscles during the exercise and socio-psychological outcomes.

Who can participate?
300 consecutive patients entering the alcohol outpatient clinic in Odense and suffering from alcohol use disorder, abuse or dependence according are enrolled in the study.

What does the study involve?
Over a period of 12 months, 300 patients will be enrolled in the study. After the patients have provided a written and an oral consent the initial interview is carried out. Then the patients are randomly allocated to one of three groups: (A) treatment as usual, (B) treatment as usual and physical exercise in groups, or (C) treatment as usual and physical exercise alone. Patients in groups B and C will follow a 24-week programme, either alone or in a training group. The exercise involves brisk walking or running. All patients will be tested and they will fill in a questionnaire at the start of the study, after 6 months and after 12 months. At the end of the study, these information will be analyzed. We will compare the groups B and C with the control group A, to see if there is any effect of adding physical exercise to alcohol treatment.

What are the possible benefits and risks of participating?
We hope that the benefits of participating will be better physical condition, better mood and well-being, and more sensible drinking behavior. There are no risks of participating in the study.

Where is the study run from?
The study has been set up by the University of Southern Denmark and Unit for Clinical Alcohol Research in Odense, Denmark.

When is study starting and how long is it expected to run for?
The study is starting to enroll participants from May 2013 to May 2014. The last enrolled

participant is expected to join physical exercise until May 2015. After that we have a year to complete analysis, documentation of results and conclusion.

Who is funding the study?
Funding has been provided by the Lundbeck-foundation, the Tryg-foundation and University of Southern Denmark, Denmark.

Who is the main contact?
Professor Kirsten Kaya Roessler
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Study information

Scientific Title
Physical exercise as a supplement to treatment of alcohol use disorders: a randomized controlled trial

Study objectives
The specific objectives of this study are to examine whether physical activity done alone or in groups as an adjunct to outpatient alcohol treatment has an effect on:
1. Alcohol intake 6 months and 12 months after initiation treatment
2. Patients wellbeing, fitness, anxiety, depression and interpersonal problems
We hypothesize that physical exercise with moderate intensity yields significant clinical improvements.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Scientific Ethical Committee for Southern Denmark (J.nr. S-20130031) and the Danish Data Protection Agency. All procedures in the study are in accordance with the second Declaration of Helsinki.

Primary study design
Interventional

Study design
Single-centred, randomized-controlled study

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Alcohol abuse

Interventions
1. Physical exercise in groups
2. Physical exercise alone
3. Control group (no physical exercise)

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The primary endpoint analysis (6 months) will be a comparison of outcomes for patients assigned to treatment-as-usual (TAU) group (A) versus the combined physical exercise experimental groups- TAU and group exercise (B) and TAU and individual exercise (C). The outcome will be measured by the proportion of patients with sensible drinking according to the limits by the Danish National Board of Health (Sensible drinking is defined as drinking maximum 14/21 drinks/week among women/men, one drink contain 12 grams of pure alcohol). The primary outcome will be in the intention to treat group using last observation carried forward.

Key secondary outcome(s)
1. 12 months analysis: When participant have participated 12 months in interventions or control group. First participant starts baseline testing 1st May 2013. Hence first outcome will be measured 1st May 2014.
2. The health status: at baseline, after 6 months participation and after 12 months participation
3. The percentage of patients with reduced depression, anxiety and interpersonal problems: at baseline, after 6 months participation and after 12 months participation
4. Maximum oxygen uptake: at baseline, after 6 months participation and after 12 months participation

Completion date
30/04/2014

Eligibility

Key inclusion criteria

Age between 18 and 60 years, Native Danish speaking, have no severe psychosis or cognitive impairment, have no severe physical disabilities or medical problems and accept participating in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
117

Key exclusion criteria
Age under 18 and over 60 years. None native Danish speaking, have severe psychosis or cognitive impairment, have severe physical disabilities or medical problems and don't accept participating in the study

Date of first enrolment
01/05/2013

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
Denmark

Study participating centre
Institute of Psychology
Odense
Denmark
5230

Sponsor information

Organisation
University of Southern Denmark (Denmark)

ROR
https://ror.org/03yrrjy16

Funder(s)

Funder type
Industry

Funder Name
The Lundbeck Foundation (Lundbeck-fonden) (Denmark) and Tryg-fonden (Denmark)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/03/2017	17/12/2020	Yes	No
Results article	results	11/06/2019	17/12/2020	Yes	No