STUDY PROTOCOL:
Physical exercise as treatment for alcohol use disorder (FitForChange): randomized controlled trial.

Principal investigators:

Mats Hallgren PhD
Department of Public Health
Karolinska Institutet
171 77 Stockholm
Sweden
Tel: +46 12345780
Email:mats.hallgren@ki.se

Sven Andréasson MD PhD
Department of Public Health
Karolinska Institutet
171 77 Stockholm
Sweden
Tel: +46 12345780
Email: sven.andreasson@ki.se

BACKGROUND

Alcohol use disorder (AUD) is a debilitating condition associated with negative health and social outcomes. Rates of help seeking for AUD are low and conventional treatments are often perceived as stigmatising.Treatment outcomes are highly variable with many relapsing into the dependence syndrome following a period of abstinence.

A growing body of evidence suggests that individuals with substance use disorders are interested in exercising and may derive significant benefits from regular exercise, both in terms of general health/fitness and dependence recovery. Physical activity is associated with better mental health, and recent studies indicate that exercise can reduce tobacco cravings and cigarette use. However, the effects on alcohol consumption remain understudied.

AIMS

To compare the effects of aerobic exercise, yoga, and treatment as usual on alcohol consumption (primary outcome) among physically inactive, non-treatment seeking adults with AUD. Secondary aims are to examine the effects of these interventions on somatic and psychiatric health. We will also explore the effects of acute exercise on mood, anxiety and craving for alcohol alcohol (nested exercise study).

METHOD

Study design

Three group parallel, single-blind, randomized controlled trial (RCT). Two research assessment points; baseline (before randomization), and 12 weeks (post-intervention) – study end point.

Participants

Physically inactive adults aged 18-75 years who meet the DSM-5 criteria for AUD will be invited to participate. Exclusion criteria: a severe somatic illness, a primary psychiatric diagnosis that requires specialist treatment (e.g. psychosis, bipolar disorder), or health problems preventing exercise participation. Participants will be recruited through media advertising, posters in various clinical settings, including primary health care centres and outpatient addiction clinics (beoendecentrum Stockholm).

Randomization and blinding

The randomization procedure will be performed externally by a statistician at the Karolinska Institute using a random number generator. Follow-up assessments will be performed by research assistants blind to treatment allocation.

Interventions

Exercise sessions will be undertaken at 'SATS'; a modern fitness centre with multiple locations throughout Sweden. Free membership for 12 weeks will be provided to all exercise participants. All classes are supervised by trained instructors. The two exercise groups include: (1) beginner to intermediate level yoga-based classes with a focus on stretching, balance and controlled breathing (but without a strong 'mindfullness' component), and (2) aerobic exercise, consisting of stationary cycling or combined static/dynamic body movements performed to music. To optimize adherence, participants will be able to choose from three classes of yoga or aerobic training. Exercise sessions include between 5-40 people. Participants will be requested to exercise 3 times per week for 12 weeks. Adherence will be further supported by three one-to-one meetings with a personal trainer, and monitored electronically.

Outcomes

The primary study outcome is alcohol consumption measured by Timeline Follow-Back (TLFB). Using a calendar, respondents provide retrospective estimates of their daily drinking over the previous month. Changes in consumption and harms will also be assessed using the Alcohol Use Disorders Indentification Test (AUDIT). Secondary outcomes include depression, anxiety, perceived stress, sleep quality, fitness and physical activity levels.

Statistical analyses

Based on previous research, we estimate that 210 participants will need to be enrolled to detect an effect size of -0.3 with 90% power and .05 significance level. We will apply intention to treat (ITT) analysis using mixed linear regression models to examine effects of group allocation on the primary outcome. Moderating effects of gender will be explored. Multiple imputation will be used where appropriate to fill missing data and a sensitivity analysis performed.

ETHICAL CONSIDERATIONS

The study has received ethical approval from the regional ethics committee (EPN), Karolinska Institute (DRN: 2017-1380/31). All participants will sign an informed consent form. None of the treatments are expeced to have unwanted side effects, however, any detrimental effects of exercise will be recorded. Those with contraindications for exercise (e.g. history of heart disease or muscularskeletal injuries) will be excluded. Participants are free to withdraw at any time. For safety purposes, a brief (20 minute) mid-point assessment will be performed to monitor participant wellbeing. All participant data will be de-identified and kept in a secure place that can be accessed by the research team only.

FUNDING

Funding has been received from the Swedish Research Council for Health Working Life and Welfare (FORTE), and the Ekhaga Foundation, Sweden.

EXPECTED START DATE

January 2018

EXPECTED FINISHING DATE

December 2019

EXPECTED REPORTING DATE

December 2020