

Can high-intensity interval/circuit training improve the cognitive function and quality of life of patients in recovery from substance use disorder?

Submission date 05/06/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 17/06/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/07/2023	Condition category 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

There is a lack of research on physical exercise as a treatment intervention for people with substance use disorder. This study protocol aims to increase the knowledge in physical exercise as an intervention and give a training protocol that is easy to implement in a clinical setting.

Who can participate?

Participants have a substance use disorder diagnosis and have been admitted as an inpatient to FAB. They must be 18 years of age or older, pass the physical evaluation for the institution to perform intensive training and have no medical history or illness that is contraindicated to participate in physical activity. Participants with light to moderate psychiatric diagnoses are included.

What does the study involve?

The study aims to compare two treatments against each other. Control intervention is walking. Intervention is high-intensity circuit training. The intervention for the participants goes over four weeks. Testing is done before and after.

What are the possible benefits and risks of participating?

Benefits of participating is a neurocognitive evaluation before and after the intervention. Which the patient can use in there own further treatment or just for self-interest. There is most likely an increase in physical health after participating in the study. Most likely a reduction in withdrawal symptoms. There is a chance of injury from being physically active. Screening of health and safety is done before starting training. There might be training associated injuries. Health staff is present to treat and stop training if an injury occurs or sings and symptoms of designs, chest pain or fainting.

Where is the study run from?

The Salvation Army treatment center Stavanger, Norway

When is the study starting and how long is it expected to run for?
The study started on 31/10/2017 and is expected to end on 20/09/2019.

Who is funding the study?
The project is funded by the Salvation Army Norway, KORFOR (Helse Vest) and Helsedirektoratet in Norway.
Contact:

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2011/1877

Study information

Scientific Title

A protocol to assess the effect of high-intensity interval/circuit training using functional and primitive reflex exercises on cognitive function and quality of life in the substance use disorder recovery

Acronym

N/A

Study objectives

1. This study protocol is designed to investigate HIIT and HICT combined with functional exercises and primitive reflex training, about the recovery of quality of life and cognitive functioning in patients with SUD. More specifically, the protocol aims to: Examine if structured physical activity reduces the recovery time of cognitive functioning when compared to a control group.
2. Examine if different intensities of physical activity, e.g. HIIT/HICT versus other types of physical activity, e.g. Hiking) is associated with different trajectories of cognitive recovery in the sub-acute phase of SUD treatment.
3. Examine if the presence of primitive reflexes is suited as a proxy-indicator of cognitive function.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 08/09/2017, the Regional Ethics Committee for Medical Research Ethics, Western Norway (+47 55975000; rek-vest@uib.no; <http://helseforskning.etikkom.no>), ref: 2011/1877.

Study design

A quasi-experimental single-centre longitudinal clinical trial with pretest and multiple post-tests, on two-time sequential groups that are naturally randomized before group entry. This trial is conducted in a running clinical setting as part of daily treatment interventions.

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

See additional files (Norwegian)

Health condition(s) or problem(s) studied

Substance use disorder

Interventions

Control group:

An active control group consisting of SUD inpatients recruited from the same treatment facility was included. The control group received treatment as usual (TAU) for substance use disorder patients. Focusing on activities of daily living (ADL) which consist of personal hygiene, e.g. washing oneself and brushing teeth. Sleep hygiene is focused on by regular rest times and wake up time to help normalizing sleep pattern. Learning or relearning preparing, making, and cooking food. Eating in a social setting at fixed times. House cleaning and work assignments relevant to make the ward work smoothly. Structured socializing, and group sessions, two times a day. Structured physical activity in the form of one daily hike with a duration of 30-120 min, and a long hike for a few hours once a week.

Intervention group:

Receive the exercise protocol four times per week, of 30-minute duration each session. This group have identical TAU as the other group

After completion of the trial, patients followed prospectively for one year.

Intervention Type

Procedure/Surgery

Primary outcome measure

Cognitive function over time is measured at baseline, quarterly and at 1 year using the following neurophysiological tests:

1. The Symptom Checklist90Revised (SCL90R).
2. The Montreal Cognitive Assessment (MoCA).
3. Behaviour Rate Inventory of Execution Function-Adult Version (The BRIEF-A).
4. The Stroop Color and Word Test (SCWT).
5. The Trail Making Test.

Secondary outcome measures

Physical fitness is with the Rockport 1-Mile Walk Test, 30 Second Chair Stand Test. 1-minute Burpee test and the presence of six different primitive reflexes including the Palmar Grasp Reflex, Glabellar Reflex, Moro Reflex at baseline and week 5.

Overall study start date

06/12/2016

Completion date

26/12/2020

Eligibility

Key inclusion criteria

1. SUD diagnosis.
2. Admitted as an inpatient to FAB.
3. 18 years of age or older.
4. Pass the physical evaluation for the institution to perform intensive training.
5. Light to moderate psychiatric diagnoses.

Participant type(s)

Patient

Age group

Mixed

Lower age limit

18 Years

Sex

Both

Target number of participants

60

Total final enrolment

60

Key exclusion criteria

1. Medical history that could interfere with or be worsened by physical activity e.g. paralysis, inability to sit, stand and/or walk, severe pain, obstructive disease, glaucoma.
2. Severe cognitive deficit e.g. dementia.
 - 2.1. A severe cognitive deficiency will be assessed based on two questions: 'Do you have troubles with your memory that affects your daily life?' and 'Do you have a diagnosis for dementia?'.

Date of first enrolment

31/10/2017

Date of final enrolment

26/10/2019

Locations**Countries of recruitment**

Norway

Study participating centre

Frelsesarmeens behandlings senter stavanger

Auglendsdalen 64,

Stavanger

Norway

4017

Sponsor information**Organisation**

Center for Alcohol and Drug Research Stavanger University Hospital, Stavanger, Norway

Sponsor details

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Sponsor type

Research organisation

Website

<https://helse-stavanger.no/en/avdelinger/klinikk-psykisk-helsevern-barn-unge-og-rusavhengige/avdeling-unge-voksne-og-flyktninger/korfor>

ROR

<https://ror.org/04zn72g03>

Funder(s)**Funder type**

Research organisation

Funder Name

Salvation Army Norway

Funder Name

Center for Alcohol and Drug Research Stavanger University Hospital, Stavanger, Norway
Regionalt Helseføretak

Funder Name

directorate of heaa

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

06/09/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. The contact details for this are Sverre Nesvåg, Registerleder KvaRus, Forskningsleder/Head of research, KORFOR/Centre for alcohol and drug research, Stavanger Universitetssjukehus/Stavanger University Hospital, ness@sus.no/+4790837431 Helse Stavanger HF, www.sus.no Via Helse Stavanger v/adm. dir som databehandlingsansvarlig og med Helse Vest IKT som databehandler (forskningsserver i Helse Vest IKT).

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1	14/06/2019	17/06/2019	No	Yes
Protocol file	version v1	14/06/2019	17/06/2019	No	No
Protocol article		15/11/2019	19/07/2023	Yes	No