ISRCTN74750479 https://doi.org/10.1186/ISRCTN74750479

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

Registration date
17/06/2019

Overall study status
Completed

Last Edited
19/07/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
Øyvind Andreassen
oyvind.andreassen@frelsesarmeen.no

Contact information

Type(s)
Scientific

Contact name
Mr Oeyvind Andreassen

ORCID ID
http://orcid.org/0000-0003-1972-1652

Contact details
Frelsesarmeens behandlings senter Stavanger
Auglendsdalen 64
Stavanger
Norway
4017
+4740842545
oyvind.andreassen@frelsesarmeen.no

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 trail 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 trail, 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
Lagårdsveien 78 4010 Stavanger
Stavanger
Norway
4068
+47 481 36 702
liljan.kristensen@sus.no

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-publically 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