UiT Norges arktiske universitet

Det helsevitenskapelige fakultet

Physical Activity and Quality of Life among Substance Use Disorder Patients – An Observational Pilot study

Eirik Inge Johnsen

Masteroppgave i Idrettsvitenskap IDR-3901 Mai 2023

Abstract

Introduction

Substance abuse is a global health concern that affects individuals, families, and communities worldwide. Regular and sufficient physical activity (PA) has proven to have a positive effect on key elements in substance use disorder (SUD) treatment. The aim of this study was to examine participation in PA and the association of PA with health-related physical fitness, and quality of life (QoL) among users undergoing SUD treatment.

Method

The subjects (n = 7) were men aged 26-40 years, all undergoing SUD treatment. The protocol included the use of the SIMPAQ questionnaire for observing time spent in PA and type of activity during a follow-up of six weeks. Health-related physical fitness was measured using the single-leg balance test, sit-to-stand, stair climb test, and 6MWT, before and after follow-up. The SF-36 and HSCL-25 questionnaires were used to assessing the development in quality of life during a period of six weeks. PA levels and patterns, and development in physical fitness and quality of life over a 6-week follow-up period were described. Preliminary correlation analyses were used to indicate the association of PA measures with health-related physical fitness and quality of life.

Result

Time spent on PA per week was significantly associated with the positive development in four out of ten subscales associated with QoL: Physical functioning ($p = 0.04$), limitations due to physical health ($p = 0.04$), emotional well-being ($p = 0.02$), and depression ($p = 0.03$).

Conclusion

During a 6-week follow-up period, all subjects spent a considerable amount of time on PA. At group level, this resulted in signs of improved levels of health-related fitness and improvement in four out of ten subscales associated with QoL. This study suggests walking and several other forms of PA could assist in the development of QoL among this user group.

Keywords

Physical activity, substance use disorder treatment, Quality of life, Health-related fitness

Sammendrag

Introduksjon

Rusmisbruk er et globalt helseproblem som påvirker enkeltpersoner, familier og samfunn over hele verden. Gitt de utbredte problemene med rusmisbruk, har deltagelse i regelmessig og tilstrekkelig fysisk aktivitet (FA) vist seg å ha en positiv effekt på sentrale elementer i rusbehandling. Målet med denne studien var å observere deltakelse i FA blant brukere som gjennomgår rusbehandling og sammenligne resultatet med utvalgte helsevariabler assosiert med livskvalitet (LK).

Metode

Forsøkspersonene (n = 7) var menn i alderen 26-40 år, alle under rusbehandling. Protokollen inkluderte bruk av spørreskjemaet SIMPAQ for observasjon av tid brukt på FA og type aktivitet, over en periode på seks uker. Helserelatert treningstilstand ble målt ved bruk av ett-bens balansetest, sit-to-stand, trappetest og 6MWT, før og etter oppfølgingsperioden. Spørreskjemaene SF-36 og HSCL-25 ble brukt til å vurdere endringer i livskvalitet under oppfølgingsperioden. Mønstre og nivåer av FA, samt endringer i treningstilstand og livskvalitet under oppfølgingsperioden ble beskrevet. Innledende korrelasjonsanalyser ble brukt for å indikere sammenhengen mellom FA-målinger, treningstilstand og livskvalitet.

Resultat

Tid brukt på FA ukentlig var signifikant assosiert med den positive utviklingen i fire av ti underkategorier assosiert med LK: fysisk funksjon ($p = 0,04$), begrensninger på grunn av fysisk helse ($p = 0,04$), emosjonelt velvære ($p = 0,02$), og depresjon ($p = 0,03$).

Konklusjon

I løpet av oppfølgingsperioden tilbragte alle brukerne betydelig tid på FA. På gruppenivå resulterte dette i tegn på forbedret nivå av helserelatert treningstilstand og forbedring i fire av ti underkategorier assosiert med LK. Funnene i denne studien fremhever variabler som bør vurderes i framtidig forskning og bidrar til forståelse av rusbehandling.

Nøkkelord

Fysisk aktivitet, rusmisbruk behandling, livskvalitet, helserelatert treningstilstand

Contents

Acknowledgements

This thesis marks the end of my master's degree and a journey I'm sure I wouldn't be able to complete without great support from my university, friends, and family.

First and foremost, I would like to extend my gratitude to Professor Solfrid Bratland-Sanda for allowing me to be a part of a new and exciting research project. Your publications were a source of inspiration for my Bachelor thesis, and I feel privileged to have been working with you on this project.

Professor Bente Morseth, thank you for taking time off to guide me on this thesis. You have inspired and pushed me as a student to keep up with a steep learning curve and in this process, I learned so much about myself. Although, it has often felt overwhelming, I always left our meetings motivated to push forward. Your guidance has truly been second to none.

Lastly, I would like to send a special thanks to my girlfriend, Therese Fredriksen. During my education your endless love has made it possible for me to balance work, school, and most important our life together. I'm eternal grateful for your love and support.

Preface

With this chapter I hope to inform the reader on how this thesis is structured and provide a basic understanding on how this study came to life.

In my bachelor thesis, I used literature study as method and upon completion, I have felt motivated to explore a new research experience. When consulting professors at my institution, I came to realize that none of the available projects sparked my curiosity. Instead, I agreed to categorize and analyze data for another university in exchange that I could use the data for my master thesis. I proceeded to contact the mentor I felt was best suited to guide me, luckily, she was available. During our first conversations I was encouraged by my mentor to write this thesis as a paper. Therefore, this thesis inhabits a structure close to a PhD-layout with the following main parts; abstract, Part 1: Theoretical background and methods, Part 2: Paper, and Part 3: Appendices.

My role in the research group has been a point of contact for the different institutions involved in this study. I have participated in discussions about the layout of the project and had a key role in formulating applications for REK (Regionale komiteer for medisinsk og helsefaglig forskningsetikk) and NSD (Norsk senter for forskningsdata). During the project, I have visited the clinic twice, once in the fall of 2022 to oversee the first users being tested and once at the beginning of 2023 to extract and categorize data. Lastly, I was given the responsibility of analyzing and present our findings to the research group.

Abbreviations and acronyms:

AA = aerobic activities

ANOVA = analysis of variance

BSL = baseline

d = Cohen's measure of effect size

HRmax = maximum heart rate

PA = physical activity

r = Pearson's correlation

RT = resistance training

SUD = substance use disorder

QoL = quality of life

Part 1

Theoretical Background and Methods

Eirik Inge Johnsen

UiT The Arctic University of Norway

May 2023

Table of Contents

Introduction

Substance abuse is a global public health problem that affects individuals, families, and communities worldwide. According to the World Drug Report approximately 250 million people between the age of 15-64 consumed at least one type of substance in 2014 (UN, 2016). Among them, almost one in ten was categorized as a "problematic consumer" and inhabited signs of suffering from a substance use disorder. Thus, its estimated that 29 million people worldwide are suffering from a condition derived from a substance use disorder. In addition to illegal drugs, alcohol abuse is also a significant public health concern. The World Health Organization (2018) reports that harmful use of alcohol contributes to 3 million deaths each year, equivalent to 5.3% of all deaths worldwide. It is important to highlight that not only does drug abuse have a drastic negative impact on the user's quality of life, such as having physical and/or psychological problems, the consequences of substance abuse also include family problems and social exclusions. Therefore, a single case of substance abuse can lead to several people experiencing reduced quality of life (Giménez-Meseguer et al., 2015; UN, 2016).

Considering the widespread issues of substance abuse, participation in regular and sufficient physical activity has proven to have a positive effect on key elements in treatment for substance use disorders (Read & Brown, 2003; Nugroho et al., 2020; Hidalgo, 2019; Zangeneh et al., 2007). According to Read & Brown (2003) this phenomenon is a result of possibly; (1) physical activities leads to stimulation of the neurotransmitters in the brain, which contributes to increased dopamine production; (2) physical activity can lead to reduced symptoms of mental health issues associated with long term substance abuse, such as anxiety and depression; (3) through participation in physical activity, users are likely to experience regained control over their bodies, where this newfound control can be used in situations outside the initial activity (Read & Brown, 2003). Moreover, people who tend to engage in physical activity on a regular basis also tend to have lower rate of substance abuse disorders, thus physical activities seem to provide a preventative factor (Giménez-Meseguer et al., 2020; Read & Brown, 2003).

Upon reviewing existing literature, several studies support the use of including aerobic exercise programs in treatment for substance abuse (Brown et al., 2016; Buchowski et al., 2011; Mamen & Martinsen, 2010; Garza et al., 2016), others have reached similar goals when utilizing exercise programs based on both aerobic and strength training (Giesen & Bloch,

2016; Muller & Clausen, 2015; Dolezal et al., 2014). Lastly, body-mind activities such as yoga and long walks, also seem to be a valid alternative as tools to improve the quality of life (Hallgren et al., 2014), suggesting that several forms of physical activities can be useful to include in treatment of substance use disorders. Giménez-Meseguer et al. (2020) suggests the exercise program used, and its structural design (type of activity, intensity, volume, or frequency) could play a key role in the effects of participating in physical activities in this patient group. Finally, tailoring exercise programs after users' needs have proven to increase compliance and possibly the effect of the program in this patient group (Colledege et al., 2017; Giménez-Meseguer et al., 2020).

However, some studies suggest that participation in physical activity does not consistently result in beneficial development for people undergoing treatment for substance abuse. When tested, a varied physical exercise program lasting for 12 weeks did not result in significant benefits in stress, anxiety, or quality of life, among heroin addicts (Colledge et al., 2017). Moreover, a study examining users undergoing treatment for alcohol use disorders, also did not find exercising to be significant in the development of quality of life (Sari et al., 2019). These studies represent conflicting findings compared to studies mentioned earlier in this paper, suggesting further research is necessary to understand the complex role of physical activities in treatment for substance use disorders.

The main objective of this master's thesis is to examine participation in physical activity among inpatients receiving treatment for a substance use disorder, as well as development in health-related fitness and quality of life during a 6-week period. Moreover, we examined whether physical activity was associated with selected health variables associated with quality of life. With this study, we aim to identify physical activity levels and the potential of physical activity among patients with substance use disorders to aid future research for this user group.

1 Research question and hypothesis

1.1 Research questions

We aimed to examine

1) Physical activity levels and types among inpatients receiving treatment for substance use disorders.

2) Improvements in health-related physical fitness during a 6-weeks follow-up among the inpatients.

3) Associations between physical activity and health-related physical fitness levels.

4) Associations between physical activity and quality of life.

1.2 Hypotheses

This study`s hypotheses are the following:

- Regular physical activity leads to improved health-related fitness levels among users receiving treatment for substance use disorders.
- Physical activity's leads to increased quality of life among users receiving treatment for substance use disorders.

2 Theoretical background

2.1 Substance use disorders

Substance use disorders are an umbrella term consisting of the *harmful use,* and *dependency*, of a substance. The *harmful use* of a substance refers to a person's abuse of a substance and involves the physical and/or psychological harm to the individual's health. Substance *dependency* (addiction) is identified as a user having a strong desire to consume a substance and finding it difficult to limit his or hers use. This involves abusing a substance regardless of having somewhat knowledge of the harmful consequences. Moreover, abusing a substance often leads to a need to take increasing doses (tolerance development) and often withdrawal symptoms (abstinence). In addition, the severity of a substance use disorder is typically determined by the frequency and amount of substance use, as well as the degree to which it interferes with the individual's daily life. This includes an individual prioritizing abusing substance before daily activities and commitments, such as social life, work and so forth (Bramness, 2019).

The following list includes some of the most known substances being abused in Norway:

- Alcohol
- Addictive prescription drugs
- Heroin and other opioids
- Cannabis (hashish and marijuana)

- Amphetamines

(Bramness, 2019).

2.1.1 Alcohol: Dependency and harmful use

Existing literature points to a wide variation between countries regarding prevalence of alcohol disorders. According to international studies, the number of people who suffer from an alcohol associated disorder ranges from one to over twelve per cent (Bramness, 2019). Annually, it's estimated that about eight per cent of men and three per cent of females in Norway, are in danger of developing an alcohol use disorder (Kringlen et al, 2001, 2006; Bramness, 2019). According to the Center for Behavioral Health Statistics and Quality (CBHSQ, 2018) are alcohol use disorders often observed among young adults between the ages of 18 and 35. Symptoms of the disorders can often be traced back to the early stages of teenage years, were prevalence steadily increases during adolescence and young adulthood (Bramness, 2019). Regardless of age groups, men are found to be at a greater risk than females of developing alcohol use disorders. The Oslo and Sogn og Fjordane surveys from the 1990s and the twin study from around 2000, indicates that men were two to three times more prominent to developing an alcohol use disorders (Kringlen et al, 2001, 2006; Ystrom, 2014). International studies have also shown an increase in prevalence of both alcohol use disorders and drug use disorders among men, compared to females in all age groups (CBHSQ, 2018; Hasin, 2015).

2.1.2 Illicit drugs: Addiction and harmful use

According to Bramness (2019), drug addiction is a significant global public health problem, affecting millions of individuals worldwide, although, the prevalence is substantially lower than for alcohol misuse in Norway. The prevalence of harmful drug use varies by region and by type of drug, but its estimated lifetime prevalence was 3.4 per cent in Oslo, and 0.4 per cent in the original Sogn og Fjordane study, with the twin sample study indicating 1.4 per cent (Bramness, 2019).

Cannabis was the most reported used illicit drug, with about 4 per cent of the population aged 16-64 reporting having used cannabis during the past 12 months. Roughly 20 per cent stated they had tried cannabis once or more during their lifetime (Bramness, 2019). Moreover, addiction to illicit drugs is perceived to be one of the main causes of years of living lost, and among the main causes of years living with disability, in Norway (Bramness, 2019). A higher

proportion of men are reported to be addicted to illicit drugs, but among addicts, women are revealed to have a higher mortality rate than men (Bramness, 2019).

2.2 Physical activity, exercise and substance use disorders

Physical activity can be defined as any bodily movement that requires energy expenditure and involves the contraction of skeletal muscles (Caspersen et al., 1985). For example, walking, running, cycling, sports or even cleaning your house can be considered engaging in physical activities. Exercise is a subset of physical activity that is structured, planned, repetitive, and with the purpose of improving or maintaining a physical fitness and/or health level (WHO, 2022). Regular physical activity and exercise have been associated with numerous health benefits, including reduced risk of chronic diseases such as cardiovascular disease, diabetes, and cancer, improved mental health, and better overall quality of life (WHO, 2022).

Existing literature suggest physical activities can play an important role in the treatment of substance use disorders (Read & Brown, 2003; Linke & Ussher, 2015; NIDA, 2022; Zangeneh et al., 2007; Vancampfort et al., 2019). Engaging in regular and sufficient physical activity can lead to reducing symptoms associated with stress, anxiety, and depression, which are common among this patient group (Read & Brown, 2003; Linke & Ussher, 2015; NIDA, 2022). Exercise has been shown to release endorphins and boost dopamine production, which are natural feel-good chemicals in the brain, and can lead to improving mood and increasing self-esteem (Read & Brown, 2003; Zangeneh et al., 2007). Engaging in regular exercise can also lead to a sense of purpose and provides structures, which can assist in establishing daily routines for this patient group (Read & Brown, 2003; Linke & Ussher, 2015; NIDA, 2022). Lastly, Read & Brown (2003) suggests participation in physical activities can provide a sense of social connection and support.

However, Sari et al. (2019) and Colledge et al. (2017) suggest that physical activity does not consistently produce beneficial development among users undergoing treatment for substance use, thus providing conflicting results on this subject. Also, Giménez-Meseguer et al. (2020) suggests different individuals tend to find different activities and their structural design (intensity, volume, or frequency) useful and meaningful. Unfortunately, this can lead to inconsistent results when researching the effect of different physical activities on this population, as the result can be depending on the preference of the specific users being observed Giménez-Meseguer et al. (2020). Therefore, more research is needed to understand

the complex processes surrounding physical activities use in treatment for substance use disorders.

2.3 Health-related physical fitness in substance use disorder

Health-related physical fitness is a term used to describe several components of physical qualities and abilities that are necessary for a person's good health and wellbeing. The term includes a wide range of components, such as, cardiovascular endurance, muscular strength, flexibility, body composition, and muscular endurance, to name a few. Overall, health-related physical fitness is important for maintaining a level of good health and preventing chronic diseases such as obesity, diabetes, and heart disease (Britton et al., 2020).

Research has shown that individuals suffering from a substance use disorder often have decreased health-related physical fitness levels compared to the general population (Linke & Ussher, 2015; NIDA, 2022; Vancampfort et al., 2019). For example, individuals suffering from alcohol use disorder and opioid use disorder often have lower aerobic capacity and muscle strength compared to the general population (Vancampfort et al., 2019; Linke & Usser, 2015). It is important to mention that fitness levels among substance abuse patients can vary widely depending on a variety of factors, such as the type of substance used, the length and severity of the addiction, co-occurring health conditions, and the individual's lifestyle and habits (NIDA, 2022; WHO, 2022).

2.4 Quality of life among substance use patients

Quality of life (QoL) refers to the overall well-being and satisfaction of an individual or group of individuals, with regards to their physical, mental, social, and emotional health. It is a subjective measure that considers factors such as personal fulfillment, happiness, and access to basic needs and resources (Teoli & Bhardwaj, 2022). The World Health Organization (WHO) defines quality of life as "*Individuals perception of their position in life in the context of the culture and value system in which they live, and in relation to their goals, expectations, standards and concerns*" (WHO, 2023). The concept of quality of life has been studied extensively in fields such as psychology, sociology, and medicine, and is often used as a measure of the effectiveness of healthcare interventions or public policies (WHO, 2023).

The quality of life among substance abuse patients is often negatively affected by their addiction, as drug and alcohol abuse can have serious physical, psychological and social consequence. Substance abuse often leads to physical health problems, mental health

disorders, social isolation and difficulties in relationships, employment, and other areas of life. Physical activity has been shown to play a positive role in improving the quality of life among substance abuse patients. Exercise can help reduce stress, anxiety, and depression, which are common among individuals with addiction. It can also help improve physical health, increase self-esteem, and provide a sense of accomplishment and purpose (Giménez-Meseguer et al., 2015; NIDA, 2022; UN, 2016; WHO, 2022).

Studies have found that participation in physical activity are associated with improvements in health-related physical fitness and different aspects of quality of life, such as physical function, mental health, vitality, social function, and general health perception (Giménez-Meseguer et al., 2015; Giménez-Meseguer et al., 2020; Köhlerová et al., 2023; Muller & Clausen, 2015). This suggests physical activity can be an effective supplement to substance abuse treatment and underlining the importance of exercise for the quality of life, and recovery process of drug-dependent patients (Giménez-Meseguer et al., 2015; Giménez-Meseguer et al., 2020; Köhlerová et al., 2023; Muller & Clausen, 2015).

3 Materials and Methods

3.1 Design and recruitment

This study design of this master thesis is a prospective observational study, designed to assess the association between physical activities and the patients' quality of life using observational data. Seven male users undergoing treatment for a substance use disorder were recruited during the fall of 2022. Ethical considerations are presented in section 5.

3.2 Subjects

Users were recruited from Vitalis Helse and were all patients undergoing treatment for a substance use disorder. Vitalis Helse offers treatment in two different locations: Kragerø and Holmen Gård (Gjerstad). Both Vitalis Kragerø and Holmen Gård offers specialist interdisciplinary treatment for substance abuse – including treatment for mental health issues. Vitalis Kragerø offers 46 bedposts and Holmen Gård offers 31. According to Vitalis the course of an average treatment plan last between 6-12 months, depending on the individual user's course of treatment (Vitalis, 2022).

The participants in this study included users from both Vitalis Kragerø and Holmen Gård. Recruited users were all patients undergoing treatment for a substance use disorder, although,

some of the patients also showed signs of struggling with mental disorders (anxiety and depression), which is not unusual for this patient group. At group level, subjects were categorized as male users undergoing treatment for substance use disorders.

3.2.1 Criteria for inclusion/exclusion of subjects

It is estimated that approximately 90 users were offered to participate in this project. Users were introduced to this project several weeks before the first users were tested (September 2022). Information was given to the users during morning meetings and as part of individual patient conversations. Originally, all users undergoing treatment at Vitalis Helse for a substance abuse disorder qualified for inclusion in this study. Upon reviewing the data, we decided to only use data from male users in this thesis, as there were few females. Moreover, to enable data comparisons and analysis, we also decided to only include data from users who completed both baseline and follow-up measurements.

The inclusion criteria were:

- Users undergoing treatment for substance use disorders.

The exclusion criteria were:

- Disease/injuries preventing users from carrying out baseline and follow-up tests.
- Not taking part and/or not being able to log participation in physical activities.

3.2.2 Dropouts and exclusion

A total of 14 users agreed to join this project. After initial testing, three subjects decided to drop out due to personal reasons. One user (female) was excluded as she did not qualify for a substance abuse disorder. After reviewing the data, three other subjects were excluded for providing missing items in questionnaires, in addition, these three participants had potential outliers on the balance test, suggesting mistakes were made during the measurements of the three users. Therefore, this study includes 7 subjects (50% of the subjects recruited) in the statistical analysis.

3.3 Testing procedure and measurements

This study used questionnaires to assess the development in QoL and participation in PA among the subjects. All subscales of the Short Form Health Survey-36 (SF-36) questionnaire and both subscales of the Hopkins Symptom Checklist-25 (HSCL-25) were used to assess development in QoL, and the Simple Physical Activity Questionnaire (SIMPAQ) was used to

collect data on PA. All questionnaires were used during baseline and follow-up measurements. Additionally, the SIMPAQ questionnaires was also filled out on a weekly basis and parts of the SIMPAQ were also used daily to log PA.

Questionnaires:

SIMPAQ (Simple Physical Activity Questionnaire)

SIMPAQ was designed to be an easily administrated and applicable tool for collecting and categorizing data associated with physical activity and sedentary behavior. The questionnaire is regarded a valid and reliable tool among populations at high risk of sedentary behavior, especially patient groups including people living with mental illness (Rosenbaum et al., 2020). SIMPAQ measures physical activity across all domains including leisure time, domestic work, and transport-related activities. SIMPAQ does not specify or assess activities based on intensity level, the questionnaire simply aims to provide a base to measure and compare time spent on physical activities and sedentary behavior.

SIMPAQ is constructed as an interview and contains of 5 parts. The first part concerns information about *sedentary behavior*, including time spent in bed, sleep, or napping time during the day. The next part asks for *time spent walking* as part of transport-related activities, before lastly, collecting time spent on *structured exercise*, such as sports, workouts, or other activities. In this study SIMPAQ is used as part of pre- and post-test measurements, as well as being used to log daily activities during the intervention period.

HSCL-25 (Hopkins Symptom Checklist-25)

The HSCL-25 (Hopkins Symptom Checklist-25) is a self-report questionnaire used to assess symptoms of anxiety and depression. The checklist consists of 25 items, with each item rated on a scale from 1 (not at all) to 4 (extremely). The questionnaire covers a range of symptoms, including nervousness, worry, sadness, loss of interest, fatigue, and sleep disturbance. The standard practice for the scoring on this questionnaire is to calculate the average of all 25 items, in addition, to scoring based on means of the subscale's anxiety (10 items) and depression (15 items). Across several populations, the total score of the HSCL-25 has consistently shown a high correlation with severe emotional distress for unspecified diagnosis. Moreover, the Diagnostic and Statistical Manual of the American Psychiatric Association (DSM-5) has shown a great correlation between the score of the 15 items for

depression in HSCL-25, and signs of a severe depression, underlining why the HSCL-25 has been widely used in both clinical and research settings and acknowledge as a reliable and valid tool for various populations (Bell, 1994; Strand et al., 2003; Vindbjerg et al., 2021).

SF-36v2 (Short Form Health Survey)

The SF-36 (Short Form Health Survey-36) is a widely used health-related quality of life instrument that measures an individual's perception of their overall health status. It consists of 36 items that assess eight different domains of health: *General health*, *Physical functioning, Limitations due to physical health*, *Emotional well-being*, *Limitations due to emotional problems*, *Social functioning*, *Bodily pain* and *Level of energy*. The questionnaire is self-administered and can be completed in 5-10 minutes, making it easily accessible and applicable. The SF-36 is often used to compare the health status of different populations, to evaluate the effectiveness of interventions, and to monitor changes in an individual's health over time. Overall, the questionnaire is a reliable and valid instrument for measuring health-related quality of life and is often used in clinical trials, epidemiological studies, and populations surveys. This study used the newest version of the SF-36 (Health Survey) named SF-36v2 (Jacobsen et al., 2018).

Health-Related Physical Fitness tests

During treatment at Vitalis Helse, users are encouraged to measure their health-related fitness level, through a series of tests. These tests seek to measure variables associated with health-related fitness, and includes measurements of balance, agility, and aerobic exercise capacity. The test battery was constructed by members of the Vitalis Helse staff, with backgrounds within physiotherapy and sports science. In line with course of treatment at Vitalis Helse, this study utilizes the same measurements of health-related fitness. Participants in this study preformed following measurements at baseline and after a follow-up period of six weeks:

- Single leg: Balance test
- 6-minute walk test
- Stair Climb Test
- 30-second sit-to-stand test

Single Leg Stance Test:

The Single Leg Stance Test (with eyes closed) is a physical assessment commonly used by healthcare professionals to evaluate a person`s balance and proprioception (the ability to sense the position and movement of the body). It is performed by asking the patient to stand on one foot with their eyes closed for a period of time. The test is considered to be a valid and reliable tool of measuring a person`s balance and proprioception (Springer et al., 2007).

Following are the general steps used to perform the Single Leg Stance Test with eyes closed at Vitalis Helse:

1. Ask the patient to stand on one foot with their arms crossed over their chest and their eyes closed.
2. Start a stopwatch and time how long the patient can maintain their balance.
3. If the patient is unable to maintain their balance for the full duration of the test (30 seconds), stop the test and record the time.
4. Repeat the test on the other foot.

(Springer et al., 2007).

The procedure was repeated three times per foot, a total of six measurements per user. The mean value of all trails was used per user in the data analysis. Springer et al. (2007) recommend at least five minutes break between each measurement to avoid fatigue. In this study a break of two minute between each trail was deemed sufficient.

6-minute Walk Test:

The 6-minute walk test (6MWT) is a simple and widely used test of exercise capacity and functional status. It involves measuring the distance that an individual can walk in six minutes along a flat and straight course. The 6MWT often includes observing several variables during the test, such as, assessing heart rate, oxygen saturation, and perceived exertion. To perform the 6MWT, the individual is instructed to walk as far as possible for six minutes, and the distance covered is recorded. During the test, the participants is allowed to take breaks or stop if they feel any discomfort or fatigue. The test can be conducted indoors or outdoors, and can be performed in various settings, including hospitals, clinics, and research settings (Tveter et al., 2014).

In the original protocol of the 6MWT described by Tveter et al. (2014) are subjects instructed to walk for as long as possible and never to run. Vitalis Helse uses a modified version of this

test where users are free to pace them self by walking, jogging, or running. The decision to include the test was based on inclusion as subjects felt demotivated by the original protocol to the extent of wanting to drop out. Running tests such as a 1-3k was discussed, but was deemed to be deterrent, given this patient group wide variety in fitness levels. The treadmill used was an Abilica TM 45 BT (item: 300304) and was preset with a two percent incline for the test. Subjects was given 5 minutes before test start to familiarize with the treadmill and warm up, during this time the users were free to walk or run. Borg scale was used to assess perceived exertion (RPE) before and after the 6MWT.

Stair Climb Test:

The Stair Climb Test (SCT) is a physical fitness test used to assess an individual's lower body strength and endurance. In this test, the individual is asked to climb a set of stairs for a specific amount of time or until they reach a predetermined number of steps. To perform the SCT, the individual should start at the bottom of the stairs and climb to the top, taking one step at a time. Once they reach the top, they should turn around and descend the stairs, again taking one step at a time. This cycle should be repeated for the set amount of time or until the predetermined number of steps is reached (Ronai & Gallo, 2020; Tveter et al., 2014).

The test can be modified to suit the individual's fitness level with variations including:

- Number of steps: The number of steps climbed can be adjusted based on the individual's fitness level and ability.
- Time limit: The individual can be asked to climb for a set amount of time, with the time adjusted based on their fitness level.
- Weighted vest: A weighted vest can be added to increase the intensity of the test.

(Ronai & Gallo, 2020; Tveter et al., 2014).

The staircase used in this study was U-shaped staircase, consisting of two flights of stairs going in opposite directions, with a landing at the switchback. Each flight consisted of 9 steps (total 18 steps) and each step was measured to be 18 centimeters high and 27 centimeters deep. Moreover, the space between the last step (bottom and top level) measured 195 centimeters to the door.

The procedure used in this study was as follows: Users were instructed to walk/run as fast as possible up and down the staircase in three consecutive repetitions. Time spent was measured and started as soon as the first step was made. During each interval, the subjects were

instructed to use every step of the stairs and touch the door at the end of the top and bottom level of the staircase. The users were instructed to only use the handle at the staircase when in danger of losing balance and never as support to gain speed, if used, the trail would reset after sufficient break (5 min). There was no need to reset any trials during testing. At the end, Borg scale was used to assess perceived exertion.

30-second sit-to-stand test:

The 30-second sit-to-stand test is a clinical assessment that measures lower extremity strength and endurance. The test requires the participant to stand up from a chair/bench and sit back down as many times as possible in 30 seconds. This test is commonly used in populations where other more physically demanding tests are deemed unfit, such as, geriatric populations (Jones et al., 1999; Tveter et al., 2014).

The test is performed using a standard chair/or bench. The subject sits with their feet flat on the ground, arms crossed over their chest, and back straight. The timer is started when the participant stands up and ends after 30 seconds or when the subject sits back down for the final time. The number of completed stand-to-sit repetition completed in 30 seconds is recorded as the test score. The test has been shown to be reliable and valid in measuring lower extremity strength and endurance in older adults and other populations with reduced strength in the lower extremities (Jones et al., 1999; Tveter et al., 2014). In this study an Abilica WeightBench 2.0 (model: TT1003) with the height of 46 centimeters was used.

3.4 Statistical analyses

To assist in the understanding of the relationships between physical activity and quality of life, statistical methods were used despite a small sample size, to aid in the interpretation of the data. However, the results from statistical analysis in small samples must be interpreted with caution. The following statistical methods were used in IBM® SPSS® Statistics for Macintosh (Version 28.0.0.0): Descriptive statistics, Pearson correlation coefficient, Paired sample t-test and standard/repeated measures ANOVA.

This study used descriptive statistics to gain information about time spent in PA and PA types, and to describe the development during follow-up in health-related physical fitness and quality of life. Paired sample t-test was used to examine the relationship between pre and follow-up measurements in the health-related physical fitness tests. Pearson's correlation coefficient was used to describe the strength and direction of the linear relationship between

physical activity variables and the development in physical fitness, and the development in subscales of the SF-36 and HSCL-25 questionnaire. The p-value was used to indicate the statistical significance of the correlation coefficient, with alpha set to 0.05. Repeated measures ANOVA was used to adjust for time from admission to start of follow-up, as this may influence PA levels and development in quality of life. Moreover, ANOVA was also used to adjust the development in quality of life according to different subgroups of different physical activities (types of activity and time spent).

Wilkinson (1999) recommends that researchers report effect sizes, as they can provide information about the magnitude of the difference or relationship between variables being observed. Reporting effect size helps to contextualize the statistical significance of findings and provides information about the practical significance and meaningfulness of the results. In this study, Pearson' *r* (correlation defined as: low = <0.30, moderate = 0.30 - <0.5, high = >0.5) and Cohen's *d* (correlation defined as: low = 0.20, moderate = 0.50, - <0.80, high = 0.80) was used to indicate effect sizes (Cohen's, 1999, 1992).

Microsoft® Excel for Macintosh (Version 16.72) was used to categorize and assist in some minor calculations of variables. Lastly, tables and charts were constructed using Microsoft® Word for Macintosh (Version 16.72). License to all programs were provided by UiT.

4 Method discussion

When conducting research that involves physical activity, several key factors must be considered. These include issues related to participant recruitment, sample size, ethical considerations, study design, instrumentation and measurement, data collection and analysis, and interpretation of results (Thomas et al., 2011). Researchers must ensure that their methods first and foremost are appropriate for their research question, further, ensuring the data collection and analysis methods are valid and reliable. Moreover, researchers must also consider ethical considerations, such as obtaining informed consent from participants and protecting their privacy and confidentiality. Additionally, researchers must consider potential biases in their data, such as participant self-reporting bias or selection bias, and take steps to minimize or account for these biases in their analysis. Overall**,** careful attention to these and other important considerations is critical for producing valid and reliable results within the field of sports science (Thomas et al., 2011).

4.1 Design

Observational study design is a type of research method in which the researcher observes and measures a group of individuals or phenomena, without manipulating any variables. This involves conducting the study in real-world settings. The method can be used to identify potential associations or correlations between variables, leading to new gained information for future research or describing a particular phenomenon. An observational study design is commonly used within fields such as epidemiology, sociology, and psychology (Salkind, 2010; Thiese, 2013). Given the premises and resources available during this master thesis, this type of method seems to be suitable option for investigating the aim of this paper.

Observational studies are limited in the way they cannot establish causality, as there may be other factors that are influencing the outcome being observed. This type of method is therefore not suited for drawing any conclusions about cause-and-effect, since the researcher may not have control over the variables being observed, which can lead to bias or confounding. Moreover, the study population may not be representative for the larger population, which can limit the generalizability of the results (Salkind, 2010; Thiese, 2013).

4.2 Study sample

This study recruited 7 male patients undergoing treatment for a substance abuse disorder at Vitalis Helse. Several studies suggest the prevalence of substance use disorders are higher among male users, than females, thus the population of this study is somewhat representative for similar specialist health institutions and this patient group (Cornish et al., 2021; Fonseca et al., 2021; Greenfield et al., 2010; Wilsnack et al., 2000). Even though the sample size is considered to be rather small, in an effort to identify variables for future research, findings in this study were analyzed using either Cohen's measure of effect size (d) or Pearson's correlation coefficient (r), regardless of statistical significance. The results must therefore be interpreted and used with caution.

4.3 Measurements

This study does not seek to compare workout interventions or programs, but rather observe the natural changes as they unfold. Historically, researchers have primarily viewed substance abuse as a male dominant problem. However, in recent years, there has been a growing recognition of the importance of studying substance abuse disorders in female populations. Unfortunately, only male subjects qualified for inclusion in this study, therefor, making this

study somewhat limited (Cornish et al., 2021; Fonseca et al., 2021; Greenfield et al., 2010; Wilsnack et al., 2000).

In this study, every effort was made to increase both the reliability and validity of all measurements by using well established questionnaires (HSCL-25, SF-36, and SIMPAQ) and adopting the already exiting measurements of health-related physical fitness at Vitalis Helse. Utilizing the same measurements for health-related physical fitness ensured the study was integrated with the daily life at Vitalis Helse in the best possible way, thus increasing the clinical use of the findings in this study. Moreover, only a few persons (all members of the Vitalis Helse staff) was directly involved in collecting data, ensuring measurements were conducted in similar way between subjects and the two locations of Vitalis Helse. Also, a procedure for the measurements was made in an attempt, to eliminate any possible elements that could influence the result. This procedure included clear instructions prior to tests, supervision of subjects, and well-established communication between subjects and test-personnel.

4.4 Strengths and limitations

The main strengths of the present study are the fact that it utilizes an observational study design, that allows the researchers to investigate a phenom in its natural real-world settings. Previous research conducted on the same subjects and similar research questions (Brown et al., 2016; Flemmen et al., 2014; Palmer et al., 1995; Zhu et al., 2022) often falls under the category of experimental study designs, where randomized control trails (RCT) commonly are referred to as the golden standard. Although, result derived from such designs are undoubtably useful, some studies suggest the result can be limited when researching social phenoms. According to Deaton & Cartwright (2018) the method often focusses more attention on obtaining result, rather than justify the use of it. Thus, seeking to asking the question *"what works"* instead of *"why"*. In this case, studies testing different exercise methods effect on the same subjects, often construct a scenario that is not necessarily representable to a real-world setting outside the study. In addition, this study is further strengthened by using several well-established and objective measuring methods. All questionnaires included in this study are well-established and validated research methods (Bell, 1994; Jacobsen et al., 2018; Rosenbaum et al., 2020; Strand et al., 2003), whereas the physical tests conducted are all deemed valid and reliable by existing literature (Jones et al., 1999; Ronai & Gallo, 2020; Springer et al., 2007; Tveter et al., 2014).

However, this study has several limitations. For instance, the observational design precludes the establishment of a causal relationship between the various variables measured. Also, the follow-up time in this study lasts for a relatively short duration of time (six weeks), and therefore may not be able to identify patterns of development that can be expected to last for a prolonged period of time. The lack of a control group in this study makes it difficult to compare the result to other populations of substance abuse patients. Moreover, this study only investigated seven subjects, leading to very low statistical power when trying to detect differences between groups within the population.

Lastly, the vast selection of measurements, and the time restriction that comes with writing a master thesis, precluded the use of semi structured interview, which could have added further understanding. Also, given the limited time to analyze, interpret, and write the thesis, this study does not track other markers such as sleep, illness, injuries, or disordered eating patterns, which further adds to the limitation of this thesis.

5 Ethical considerations, privacy, and data management

This project was performed among users receiving treatment for substance abuse disorders. The data used in this thesis is a result of a collaborative project between the institutions USN (University of South-Eastern Norway), UiT (The Arctic University of Norway) and Vitalis Helse. Both the Regional Committees for Medical and Health Research Ethics (REK) and the Norwegian Centre for Research Data (NSD) approved this study. Before participating in this study subjects were informed that participation would not interfere with the original treatment plan or effect resources available during treatment. Furthermore, all participants were informed they could at any time withdraw from the project without listing any reason, written consent form, from all subjects were signed before participation. Data and information about all participants were anonymized using a person-specific code, were the only person with the information to identify any subject is a member of the staff at Vitalis Helse. All data about the subjects (including test results) was first archived in folders, and kept in a locked room, before being transferred to an online database. The following programs was used to archive and store the data. Microsoft® Teams for Mac (Version 1.6.00.4464), Microsoft® Excel (Version 16.71), and IBM® SPSS® Statistics (Version 28.0.0.0). Representatives from USN and UiT have been given access to the online database, although during the process of archiving data to folders, all data was anonymized. As such, the single staff member at Vitalis Helse is the only one with information to identify any subject in this project.

References

Bell, C. C. (1994). DSM-IV: Diagnostic and Statistical Manual of Mental Disorders. *JAMA*, *272*(10), 828–829. https://doi.org/10.1001/jama.1994.03520100096046

Bramness, J. G. (2019). Substance use disorders in Norway. Norwegian Institute of Public Health: *Public Health Report.* https://www.fhi.no/en/op/hin/mental-health/intoxicants-and-substance-use/

Britton, Ú., Issartel, J., Fahey, G., Conyngham, G. & Belton, S. (2020). What is health-related fitness? Investigating the underlying factor structure of fitness in youth. *European Physical Education Review*, *26*(4), 782–796. https://doi.org/10.1177/1356336X19882060

Brown, R. A., Prince, M. A., Minami, H. & Abrantes, A. M. (2016). An exploratory analysis of changes in mood, anxiety and craving from pre- to post-single sessions of exercise, over 12 weeks, among patients with alcohol dependence. *Mental Health and Physical Activity, 11,* 1–6. https://doi.org/10.1016/j.mhpa.2016.04.002

Buchowski, M. S., Meade, N. N., Charboneau, E., Park, S., Dietrich, M. S., Cowan, R. L. & Martin, P. R. (2011). Aerobic exercise training reduces cannabis craving and use in non-treatment seeking cannabis-dependent adults. *PLoS ONE, 6*(3). https://doi.org/10.1371/journal.pone.0017465

Caspersen, C. J., Powell, K. E. & Christenson, G. M. (1985). Physical activity, exercise, and physical fitness: definitions and distinctions for health-related research. *Public health reports (Washington, D.C. : 1974)*, *100*(2), 126–131.

Center for Behavioral Health Statistics and Quality. (2018). 2017 National Survey on Drug Use and Health: Methodological summary and definitions. Rockville, MD: *Substance Abuse and Mental Health Services Administration.* https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHMethodSummDefs2017/NSDUHMethodSummDefs2017.pdf

Cohen, J. (1988). Statistical power analysis for the behavioral sci- ences (2nd ed.). *Hillside, NJ: Lawrence Erlbaum Associates.* Retrieved from: https://www.utstat.toronto.edu/~brunner/oldclass/378f16/readings/CohenPower.pdf

Cohen J. (1992). A power primer. *Psychological bulletin*, *112*(1), 155–159. https://doi.org/10.1037//0033-2909.112.1.155

Colledge, F., Vogel, M., Dürsteler-Macfarland, K., Strom, J., Schoen, S., Pühse, U. & Gerber, M. (2017). A pilot randomized trial of exercise as adjunct therapy in a heroin-assisted treatment setting. *Journal of Substance Abuse Treatment*, *76*, 49–57. https://doi.org/10.1016/j.jsat.2017.01.012

Cornish, J. L. & Prasad, A. A. (2021). Sex Differences in Substance Use Disorders: A Neurobiological Perspective. *Frontiers in global women's health*, *2*, 778514. https://doi.org/10.3389/fgwh.2021.778514

Deaton, A. & Cartwright, N. (2018). Understanding and misunderstanding randomized controlled trials. *Social science & medicine (1982)*, *210*, 2–21. https://doi.org/10.1016/j.socscimed.2017.12.005

Dolezal, B. A., Chudzynski, J., Dickerson, D., Mooney, L., Rawson, R. A., Garfinkel, A. & Cooper, C. B. (2014). Exercise training improves heart rate variability after methamphetamine dependency. *Medicine and science in sports and exercise*, *46*(6), 1057–1066. https://doi.org/10.1249/MSS.0000000000000201

Fonseca, F., Robles-Martínez, M., Tirado-Muñoz, J., Alías-Ferri, M., Mestre-Pintó, J. I., Coratu, A. M. & Torrens, M. (2021). A Gender Perspective of Addictive Disorders. *Current addiction reports*, *8*(1), 89–99. https://doi.org/10.1007/s40429-021-00357-9

De La Garza, R., 2nd, Yoon, J. H., Thompson-Lake, D. G., Haile, C. N., Eisenhofer, J. D., Newton, T. F. & Mahoney, J. J., 3rd (2016). Treadmill exercise improves fitness and reduces craving and use of cocaine in individuals with concurrent cocaine and tobacco-use disorder. *Psychiatry research*, *245*, 133–140. https://doi.org/10.1016/j.psychres.2016.08.003

Greenfield, S. F., Back, S. E., Lawson, K. & Brady, K. T. (2010). Substance abuse in women. *The Psychiatric clinics of North America*, *33*(2), 339–355. https://doi.org/10.1016/j.psc.2010.01.004

Giesen, E. S. & Bloch. (2016). The Role of Exercise Therapy as a Complementary Measure in the Addiction Treatment of a Multiply Impaired Alcohol Dependent Client: A Case Report. *Journal of Substance Abuse and Alcoholism* (4). https://doi.org/10.47739/2373-9363/1041

Giménez-Meseguer, J., Tortosa-Martínez, J. & Cortell-Tormo, J. M. (2020). The Benefits of Physical Exercise on Mental Disorders and Quality of Life in Substance Use Disorders Patients. *Systematic Review and Meta-Analysis. International journal of environmental research and public health, 17*(10), 3680. https://doi.org/10.3390/ijerph17103680

Giménez-Meseguer, J., Tortosa-Martínez, J. & de los Remedios Fernández-Valenciano, M. (2015). Benefits of Exercise for the Quality of Life of Drug-Dependent Patients. *Journal of psychoactive drugs, 47*(5), 409–416. https://doi.org/10.1080/02791072.2015.1102991

Hallgren, M., Romberg, K., Bakshi, A. S. & Andréasson, S. (2014). Yoga as an adjunct treatment for alcohol dependence: a pilot study. *Complementary therapies in medicine*, *22*(3), 441–445. https://doi.org/10.1016/j.ctim.2014.03.003

Hasin, D. S., Saha, T. D., Kerridge, B. T., Goldstein, R. B., Chou, S. P., Zhang, H., Jung, J., Pickering, R. P., Ruan, W. J., Smith, S. M., Huang, B. & Grant, B. F. (2015). Prevalence of Marijuana Use Disorders in the United States Between 2001-2002 and 2012-2013. *JAMA psychiatry*, *72*(12), 1235–1242. https://doi.org/10.1001/jamapsychiatry.2015.1858

Hidalgo, J. L.-T. & the DEP-EXERCISE group. (2019). Effectiveness of physical exercise in the treatment of depression in older adults as an alternative to antidepressant drugs in primary care. *Annals of Family Medicine, 19*(4), 302-309. https://doi.org/10.1370/afm.2670

Jacobsen, E. L., Bye, A., Aass, N., Fosså, S. D., Grotmol, K. S., Kaasa, S., Loge, J. H., Moum, T. & Hjermstad, M. J. (2018). Norwegian reference values for the Short-Form Health Survey 36: development over time. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation*, *27*(5), 1201–1212. https://doi.org/10.1007/s11136-017-1684-4

Jones, C. J., Rikli, R. E. & Beam, W. C. (1999). A 30-s chair-stand test as a measure of lower body strength in community-residing older adults. *Research quarterly for exercise and sport*, *70*(2), 113–119. https://doi.org/10.1080/02701367.1999.10608028

Kringlen, E., Torgersen, S. & Cramer, V. (2001). A Norwegian psychiatric epidemiological study. *The American journal of psychiatry*, *158*(7), 1091–1098. https://doi.org/10.1176/appi.ajp.158.7.1091

Kringlen, E., Torgersen, S. & Cramer, V. (2006). Mental illness in a rural area: a Norwegian psychiatric epidemiological study. *Social psychiatry and psychiatric epidemiology*, *41*(9), 713–719. https://doi.org/10.1007/s00127-006-0080-0

Köhlerová, M.Z., Fišerová, Z. & Páv, M. Physical activity habits and their effects on quality of life in patients with addiction: data from the Czech Republic. *Curr Psychol* (2023). https://doi.org/10.1007/s12144-023-04402-w

Linke, S. E. & Ussher, M. (2015). Exercise-based treatments for substance use disorders: evidence, theory, and practicality. *The American journal of drug and alcohol abuse*, *41*(1), 7–15. https://doi.org/10.3109/00952990.2014.976708

Mamen, A. & Martinsen, E. W. (2010). Development of aerobic fitness of individuals with substance abuse/dependence following long-term individual physical activity. *European Journal of Sport Science, 2010* (10) https://doi.org/10.1080/17461390903377126

Muller, A. E. & Clausen, T. (2015). Group exercise to improve quality of life among substance use disorder patients. *Scandinavian journal of public health*, *43*(2), 146–152. https://doi.org/10.1177/1403494814561819

National Institute on Drug Abuse (NIDA). (2022). Addiction and Health. *Drugs, Brains, and behavior: The Science of Addiction. NIDA. 2022, March 22. Addiction and Health*. Retrieved from https://nida.nih.gov/publications/drugs-brains-behavior-science-addiction/addiction-health on 2023, May 11

Nugroho, A. I., Riyanto, P. Lahinda, J. & Hidayat, S. H. (2020). Effectiveness of physical condition training on the fitness of drug abuse victims, BRSPP Yogyakarta. *Enfermería Clínica, 30*(6), 63-66. https://doi.org/10.1016/j.enfcli.2020.06.015

Read, J. P. & Brown, R. A. (2003). The role of physical exercise in alcoholism treatment and recovery. *Professional Psychology: Research and Practice, 34*(1), 49–56. https://doi.org/10.1037/0735-7028.34.1.49

Ronai, P. M. S. & Gallo, P. M. (2020). The Stair Climb Power Test. *ACSM's Health & Fitness Journal*, *24*(4), 38-42. https://doi.org/10.1249/FIT.0000000000000589

Rosenbaum, S., Morell, R., Abdel-Baki, A., Ahmadpanah, M., Anilkumar, T. V., Baie, L., Bauman, A., Bender, S., Boyan Han, J., Brand, S., Bratland-Sanda, S., Bueno-Antequera, J., Camaz Deslandes, A., Carneiro, L., Carraro, A., Castañeda, C. P., Castro Monteiro, F., Chapman, J., Chau, J. Y., Chen, L. J., … Ward, P. B. (2020). Assessing physical activity in people with mental illness: 23-country reliability and validity of the simple physical activity questionnaire (SIMPAQ). *BMC psychiatry*, *20*(1), 108. https://doi.org/10.1186/s12888-020-2473-0

Sari, S., Bilberg, R., Søgaard Nielsen, A. & Roessler, K. K. (2019). The effect of exercise as adjunctive treatment on quality of life for individuals with alcohol use disorders: a randomized controlled trial. *BMC public health*, *19*(1), 727. https://doi.org/10.1186/s12889019-7083-8

Salkind, N. J. (Ed.) (2010). *Encyclopedia of research design*. SAGE Publications. https://doi.org/10.4135/9781412961288

Springer, B. A., Marin, R., Cyhan, T., Roberts, H., & Gill, N. W. (2007). Normative values for the unipedal stance test with eyes open and closed. *Journal of geriatric physical therapy (2001)*, *30*(1), 8–15. https://doi.org/10.1519/00139143-200704000-00003

Strand, B. H., Dalgard, O. S., Tambs, K. & Rognerud, M. (2003). Measuring the mental health status of the Norwegian population: a comparison of the instruments SCL-25, SCL-10, SCL-5 and MHI-5 (SF-36). *Nordic journal of psychiatry*, *57*(2), 113–118. https://doi.org/10.1080/08039480310000932

Teoli, D. & Bhardwaj, A. (2022). Quality Of Life. In *StatPearls*. StatPearls Publishing. Bookshelf ID: NBK536962

Thiese, M. S. (2014). Observational and interventional study design types; an overview. Biochemia Medica, 24(2), 199–210. https://doi.org/10.11613/BM.2014.022

Thomas, J. R., Nelson, J. K. & Silverman, S. J. (2011). *Research methods in physical activity* (6th ed.). Human Kinetics.

Tveter, A. T., Dagfinrud, H., Moseng, T. & Holm, I. (2014). Health-related physical fitness measures: reference values and reference equations for use in clinical practice. *Archives of physical medicine and rehabilitation*, *95*(7), 1366–1373. https://doi.org/10.1016/j.apmr.2014.02.016

United Nations office on drugs and crime, Vienna. (2016). *World Drug Report* (ISBN: 978-92-1-148286-7). United Nations. https://www.unodc.org/doc/wdr2016/WORLD_DRUG_REPORT_2016_web.pdf

Vancampfort, D., Vandael, H., Hallgren, M., Probst, M., Hagemann, N., Bouckaert, F. & Van Damme, T. (2019). Physical fitness and physical activity levels in people with alcohol use disorder versus matched healthy controls: *A pilot study. Alcohol (Fayetteville, N.Y.), 76*, 73–79. https://doi.org/10.1016/j.alcohol.2018.07.014

Vindbjerg, E., Mortensen, E. L., Makransky, G., Nielsen, T. & Carlsson, J. (2021). A rasch-based validity study of the HSCL-25. *Journal of Affective Disorders Reports*, *4*. https://doi.org/10.1016/j.jadr.2021.100096

Vitalis Helse. (2022, 21. april). *Velkommen til Vitalis Helse avd. Kragerø og avd. Holmen Gård.* http://vitalis.no/

Wilkinson, L. & Task Force on Statistical Inference, American Psychological Association, Science Directorate. (1999). Statistical methods in psychology journals: Guidelines and explanations. *American Psychologist, 54*(8), 594–604. https://doi.org/10.1037/0003-066X.54.8.594

Wilsnack, R. W., Vogeltanz, N. D., Wilsnack, S. C., Harris, T. R., Ahlström, S., Bondy, S., Csémy, L., Ferrence, R., Ferris, J., Fleming, J., Graham, K., Greenfield, T., Guyon, L., Haavio-Mannila, E., Kellner, F., Knibbe, R., Kubicka, L., Loukomskaia, M., Mustonen, H., Nadeau, L., … Weiss, S. (2000). Gender differences in alcohol consumption and adverse drinking consequences: cross-cultural patterns. *Addiction (Abingdon, England)*, *95*(2), 251–265. https://doi.org/10.1046/j.1360-0443.2000.95225112.x

World Health Organization. (2018). *Global status report on alcohol and health 2018* (ISBN: 978-92-4-156563-9). World Health Organization. https://www.who.int/publications/i/item/9789241565639

World Health Organization. (2022). *Physical activity.* World Health Organization. https://www.who.int/news-room/fact-sheets/detail/physical-activity

World Health Organization. (2023). *WHOQOL: Measuring Quality of Life.* World Health Organization. Retrieved from https://www.who.int/tools/whoqol

Ystrom, E., Kendler, K. S. & Reichborn-Kjennerud, T. (2014). Early age of alcohol initiation is not the cause of alcohol use disorders in adulthood, but is a major indicator of genetic risk. A population-based twin study. *Addiction (Abingdon, England)*, *109*(11), 1824–1832. https://doi.org/10.1111/add.12620

Zangeneh, M., Barmaki, R., Ala-leppilampi, K. & Peric, T. (2007). The Potential Role of Physical Exercise in Addiction Treatment and Recovery: The Social Costs of Substance Misuse. *International Journal of Mental Health and Addiction, 5*(3), 210-218. https://doi.org/10.1007/s11469-007-9111-7

Part 2:
Paper

Physical Activity and the Development in Quality of Life among Substance Use Disorder Patients – An Observational Pilot study

Eirik Inge Johnsen
UiT The Arctic University of Norway

May 2023

Abstract

Introduction

Substance abuse is a global health concern that affects individuals, families, and communities worldwide. Regular and sufficient physical activity (PA) has proven to have a positive effect on key elements in substance use disorder (SUD) treatment. The aim of this study was to examine participation in PA and the association of PA with health-related physical fitness, and quality of life (QoL) among users undergoing SUD treatment.

Method

The subjects (n = 7) were men aged 26-40 years, all undergoing SUD treatment. The protocol included the use of the SIMPAQ questionnaire for observing time spent in PA and type of activity during a follow-up of six weeks. Health-related physical fitness was measured using the single-leg balance test, sit-to-stand, stair climb test, and 6MWT, before and after follow-up. The SF-36 and HSCL-25 questionnaires were used to assessing the development in quality of life during a period of six weeks. PA levels and patterns, and development in physical fitness and quality of life over a 6-week follow-up period were described. Preliminary correlation analyses were used to indicate the association of PA measures with health-related physical fitness and quality of life.

Result

Time spent on PA per week was significantly associated with the positive development in four out of ten subscales associated with QoL: Physical functioning ($p = 0.04$), limitations due to physical health ($p = 0.04$), emotional well-being ($p = 0.02$), and depression ($p = 0.03$).

Conclusion

During a 6-week follow-up period, all subjects spent a considerable amount of time on PA. At group level, this resulted in signs of improved levels of health-related fitness and improvement in four out of ten subscales associated with QoL. This study suggests walking and several other forms of PA could assist in the development of QoL among this user group.

Keywords

Physical activity, substance use disorder treatment, Quality of life, Health-related fitness

Introduction

Substance abuse is a global issue affecting millions of people worldwide. According to the World Drug Report approximately 250 million people between the age of 16-64 use illicit drugs, were one in ten was categorized as a "problematic consumer" (UN, 2016). It is therefore estimated that 29 million people worldwide are suffering from a condition derived from a substance use disorder (SUD). Substance abuse is not limited to illicit drugs but also includes the misuse of prescription drugs and alcohol. The World Health Organization (WHO, 2018) reports that harmful use of alcohol is responsible for 3 million deaths each year, equivalent to 5.3% of all deaths worldwide. It is worth mentioning that not only does SUD result in drastic negative impact on the user's quality of life (QoL), such as experiencing physical and/or psychological issues, the consequences of SUD also involve social exclusions and/or family problems. It is therefore likely that a single case of SUD can lead to several people experiencing reduced QoL (Giménez-Meseguer et al., 2015; UN, 2016).

Considering the widespread issue of substance abuse, engaging in regular and sufficient physical activity has proven to have a positive effect on key elements in treatment of SUD (Read & Brown, 2003; Nugroho et al., 2020; Hidalgo, 2019; Zangeneh et al., 2007). Read & Brown (2003) describes this phenomenon as a result of possibly; (1) PA leads to stimulation of the neurotransmitters in the brain, contributing to increased dopamine production; (2) Participation in PA can lead to reduced symptoms of anxiety and depression; (3) Physically active users are likely to experience regained control over their bodies, where this newfound control can transfer to situations beyond the initial activity. In addition, individuals who exercise on regular basis also tend to have reduced occurrences of SUD, thus PA seems to provide a preventative factor (Giménez-Meseguer et al., 2020).

Several studies support the use of aerobic activities in the treatment of SUD (Brown et al., 2016; Buchowski et al., 2011; Garza et al., 2016; Mamen & Martinsen, 2010), and other studies (Dolezal et al., 2014; Giesen & Bloch, 2016; Muller & Clausen, 2015) have obtained promising results utilizing exercise programs based on both aerobic and resistance training. Moreover, engaging in body-mind activities such as yoga and long walks seem to have a positive effect on QoL among this patient group (Hallgren et al., 2014). However, some studies suggest that participation in PA does not consistently result in beneficial development in QoL. A study investigating a varied exercise program lasting for 12 weeks did not find any significant benefits in levels of stress, anxiety or QoL, among heroin addicts (Colledge et al.,

2017). According to Giménez-Meseguer et al. (2020) the structural design (type of activity, intensity, volume, or frequency) is essential to this patient group effect. The exercise program must therefore be tailored to the specific patient group/user, as individuals are likely to find different activities, intensity, frequency, and volume to be meaningful. Finally, tailoring PA to individuals needs and liking, have proven to increase compliance and possibly overall effect of SUD treatment for this patient group (Colledege et al., 2017; Giménez-Meseguer et al., 2020).

The aim of this study was to examine participation in PA among inpatients receiving treatment for SUD as well as development in health-related physical fitness and QoL, during a 6-week period. Moreover, we examined whether PA was associated with selected health variables associated with QoL. With this study, we aim to identify PA levels and the potential of PA among patients with SUD to aid future research for this user group.

Materials and methods

Subjects

Participants were recruited through Vitalis Helse (a specialist health institution) at two separate locations Holmen Gård (Gjerstad) and Vitalis Helse Kragerø. Recruited subjects were all users undergoing treatment for a SUD, with some individuals showing symptoms of anxiety and/or depression. Approximately 90 subjects were invited to participate in this project, out of these, 14 individuals agreed to join. After initial testing three subjects decided to drop out due to personal reasons. One subject (female) was excluded as she did not qualify for a SUD, and after reviewing data, three other subjects were excluded for providing missing items in questionnaires. Therefore, this thesis includes 7 subjects in the final analysis (50% of total subjects recruited). Prior to the study, all participants were given information about the background and test-procedures of this study and signed an informed consent document. The Regional Committees for Medical and Health Research Ethics (REK) and the Norwegian Center for Research Data (NSD) approved this study.

Methods

The study design of this master thesis is a prospective, observational pilot study.

Testing procedure and measurements

This study used questionnaires to assess the development in QoL and participation in PA among subjects. All subscales of the Short Form Health Survey-36 (SF-36) and both subscales of the Hopkins Symptom Checklist-25 (HSCL-25) questionnaire were used to assess development in QoL. In addition, the Simple Physical Activity Questionnaire (SIMPAQ) was used to collect data on PA (Rosenbaum et al., 2020). All questionnaires were used during baseline and follow-up measurements. Additionally, SIMPAQ was also filled out on a weekly basis and parts of the questionnaire were also used daily to log PA.

Statistical analysis

The statistical procedures were conducted using IBM® SPSS® Statistics for Macintosh (V.28). Microsoft® Excel for Macintosh (V.16) was used to categorize and assist in some minor calculations of variables. Tables and graphs were constructed using Microsoft® Word for Macintosh (V.16).

Descriptive statistics (mean and standard deviation) were calculated and paired sample t-test was used to examine changes in physical function during follow-up. Correlations between the development of PA variables and subscales of SF-36 and HSCL-25 were calculated using Pearson's correlation. Effect sizes (Pearson's r <0.3 indicating low correlation, 0.3-<.05 a moderate correlation, and >0.5 high correlation). Cohen's d of 0.2 indicate a small effect, 0.5 a medium effect, and 0.8 a large effect (Cohen's, 1988, 1992; Wilkinson, 1999). Repeated measures ANOVA was used to adjust the analysis for time of admission and the development of QoL according to different subgroups of different PA (types of activity and time spent).

Results

The participants (n = 7) were men aged 26-40 years, all undergoing SUD treatment at Vitalis Helse. Table 1 shows subjects characteristics.

Table 1 Subjects attendance

Males (n = 7)	Age	Date of admission	Date start of follow-up	Date end of follow-up	Time between admission and start of follow-up

	Mean 32.71 years (range 26-40)	17.11.2021-12.09.2022	12.09.2022-19.10.2022	26.10.2022-30.11.2022	Mean 21.42 weeks (range 5-54)

Physical activity time and patterns

During the follow-up period, the subjects engaged in a wide variety of PA. The most popular activities (categorized after number of subjects using and time spent) were: resistance training, hiking, walk, yoga, and running/jogging on treadmill (Table 2).

Table 2 Time spent on physical activities (per week)

Activity	Time spent (min)	Sessions (n)	Users (n)
Resistance training	776.6	15.7	7
Hiking	390.0	4.7	5
Walk	180.0	3.5	5
Yoga	304.7	8.7	4
Running/jogging (treadmill)	87.5	4.8	4
Walk (store)	37.5	0.7	2
Horseback riding	20.0	0.3	2
Physical work	550.0	2.0	1
Boat trip	60.0	0.5	1
Jogging (outside)	7.5	0.2	1
Pool (game)	10.0	0.3	1

During a week, the subjects in this study spent on average between 125-680 minutes on PA. Per week, the time users spent walking ranged between 0-97.7 minutes (as an activity and walking to the store). Time spent on aerobic activities (including running/jogging on

treadmill, running/jogging outside, and mountain hiking) ranged between 0-191.7 minutes per week. Lastly, several subjects spent a considerable amount of time on resistance training during the follow-up period, with time spent ranging between 25-269.2 minutes per week.

Development health-related physical fitness and association with PA

6-minute walk test

Five subjects (71.43%) had results suggesting a significant improvement in the 6MWT, walking/running at least 200 meters longer after the intervention, with the two remaining individuals (28.57%) showing no significant changes. Correlation between changes in 6MWT and time spent on PA per week was low and non-significant (r = 0.39, p = 0.37). Moreover, no significant correlation was found between development in 6MWT, and time spent walking (r = 0.38, p = 0.39) or time spent on aerobic activities (r = 0.38, p = 0.38).

Stair climb test

At group level, the subjects improved on average 1.46 seconds on the stair climb test. Six subjects (85.71%) improved time spent completing the stair climb test, and one subject (14.29%) spent more time at follow-up. The stair climb test results were not significantly correlated with time spent on PA per week (r = 0.43, p = 0.33), nor did we find any significant correlation with time spent on aerobic activities per week (r = 0.14, p = 0.76), time spent on resistance training per week (p = 0.50, r = 0.30) or time spent walking per week (r = 0.09, p = 0.84).

Sit-to-stand test

All subjects improved in the sit-to-stand agility test, although, the result was not significantly correlated with time spent on PA per week (r = -0.45, p = 0.30). Furthermore, the result is not significantly correlated with time spent on aerobic activities per week (r = -0.02, p = 0.96) and time spent on resistance training (r = -0.43, p = 0.32). Lastly, analyses adjusted for spending more or less time (+/- 60min) on resistance training per week (r = 0.70, p = 0.07,) showed no significant correlation.

Single leg balance test

At group level, the subjects improved on average 1.36 seconds on the single leg balance test. All subjects improved their results, but the result was not significantly correlated with time spent on PA per week (r = -0.51, p = 0.24) or time spent on aerobic activities per week (r = -0.50, p = 0.25). However, time spent on resistance training (r = -0.79, p = 0.03,) proved to be significantly correlated with development in the single leg balance test.

Table 3: Development health-related physical fitness

	BSL	**Follow-up**	***P* Value**
6-Minute walk (m)	947.14 ± 261.45	1098.57 ± 261.05	.007*
6-Minute walk (Borg-RPE)	15.43 ± 2.14	17.14 ± 2.03	.277
Stair climb test (sec)	33.56 ± 14.81	32.10 ± 14.70	<.001*
Stair climb test (Borg-RPE)	13.14 ± 1.67	13.43 ± 2.50	.040*
Sit-to-stand (rep)	21.71 ± 4.30	25.86 ± 4.10	.162
Balance: single leg (sec)	27.45 ± 24.81	28.81 ± 19.19	.296

(*Data is presented as mean ± SD. *p*<0.05)*

Development in Quality of Life and association with PA

General health

Based on the subscales of SF36, a total of four subjects (57.14%) showed signs of improved *general health.* General health was not significantly correlated with time spent on PA per week (r = 0.67, p = 0.09), time spent on aerobic activities per week (r = 0.25, p = 0.57), time spent on resistance training per week (r = 0.26, p = 0.56) or time spent walking (r = 0.68, p = 0.08). Adjusting for subjects spending more or less time (two months) at the institution prior to the intervention resulting in a weak association between time spent on PA per week and changes in general health (d = 0.31, p = 0.059,) indicating that time spent in the clinic prior to the study may impacted the result.

Physical functioning and limitations due to physical health

Overall, the group did not show significant changes in *physical functioning* and *limitations due to physical health. Physical functioning* was correlated with time spent on PA per week (r = 0.76, $p = 0.04$) and time spent walking per week (r = 0.80, $p = 0.02$). Time spent on aerobic activities per week (($p = 0.97$, r = 0.16) and time spent on resistance training per week ($p = 0.26$, r = -0.48) did not provide any significant correlation with physical functioning.

Emotional well-being

At group-level, the participants showed a slight increase in *emotional well-being*, with relatively large SD (2.977) in the post-test measurement, suggesting the development of emotional well-being was highly individual. Emotional well-being correlated negatively with time spent on PA per week (r = -0.85, $p = 0.02$), but showed no correlations with time spent on aerobic activities per week (r = -0.25, $p = 0.58$), time spent on resistance training per week (r = -0.56, $p = 0.19$), or time spent walking per week (r = -0.72, $p = 0.06$). Adjusting for time of admission resulted in a strong correlation between PA per week and changes in emotional well-being (d = 0.88, $p = 0.008$).

Social functioning and limitations due to emotional problems

Three subjects (42.86%) showed signs of improved *social functioning* and remaining four subjects (57.14%) had scores suggesting negative development. The result did not significantly correlate with time spent on PA per week (r = -0.11, $p = 0.80$), time spent on resistance training per week (r = 0.25, $p = 0.58$) or time spent walking per week (r = -0.05, $p = 0.90$). However, time spent on aerobic activities proved to be significantly correlated with social functioning (r = 0.82), $p = 0.02$).

At group level, the changes in mean (0.28, sd 0.07) suggest the group did not experience significant changes in *limitations due to emotional problems*. However, two subjects showed signs of improvement and four individuals had symptoms of increased levels of emotional problems, indicating changes at an individual level. *Limitations due to emotional problems* did not correlate with time spent per week on PA (r = -0.43, $p = 0.32$), or time spent on aerobic activities per week ($p = 0.08$, r = -0.43), time spent on resistance training per week (r = -0.60, $p = 0.15$) or time spent walking per week (r = -0.15, $p = 0.74$). Although, the changes

in *limitations du to emotional problems* was in correlation with users spending < 2 months in the institution, prior to the follow-up ($p = 0.04$, d = 0.91).

Development in experienced bodily pain

A total of five subjects (71.43%) had slightly lower occurrences of bodily pain, with only one (14.29%) individual reporting increased occurrences. The result was not significantly correlated with time spent on PA per week ($p = 0.15$, r = 0.60), time spent on aerobic activities per week (r = -0.45, $p = 0.30$,), time spent on resistance training per week ($p = 0.39$, r = -0.39) or time spent on walking per week (r = 0.70, $p = 0.07$).

Development in low energy/fatigue

Two individuals reported slight gains in energy levels, while two subjects reporting decreased levels of energy. Moreover, one of the two with decreased levels, reported a value eight times (-8) than any other individual, suggesting the result at group level is highly impacted by one subject's result. The changes in energy level were not correlated with time spent on PA per week (r = 0.65, $p = 0.10$) or time spent on aerobic activities per week (r = 0.65, $p = 0.41$).

Development in symptoms of Anxiety and Depression

Six of the seven subjects (85.71%) reported reduced symptoms for anxiety. Although, no significant correlation was found between changes in anxiety and time spent on PA per week (r = -0.07, $p = 0.87$), time spent on aerobic activities per week (r = 0.44, $p = 0.31$), time spent on resistance training per week (r -0.22, $p = 0.63$) or time spent walking per week (r = -0.27, $p = 0.55$).

Five subjects (71.43%) reported reduced symptoms of depression, one user (14.29%) had increased symptoms of depression, and the last individual reported no changes. The changes in depression were significantly correlated with time spent on PA per week (r = -0.78, $p = 0.03$), and time spent walking per week (r = -0.85, 0.01), but not with time spent on aerobic activities per week (r = 0.32, $p = 0.48$). or time spent on resistance training per week (r = 0.12, $p = 0.79$).

Table 4 Development in Questionnaires related to users Quality of Life

Questionnaire: Subscale	**BSL**	**Follow-up**	**Range:** BSL | F-U	***P* Value**
SF-36:				
General Health	20.42 ± 1.27	21.00 ± 3.60	3 | 11	.938
Physical Functioning	29.28 ± 0.75	29.28 ± 1.25	2 | 3	.152
Limitations Physical Health	18.57 ± 2.99	18.85 ± 1.57	6 | 4	.452
Emotional Well-being	21.57 ± 2.07	20.71 ± 2.69	18 | 16	.127
Limitations Emotional Problems	13.00 ± 1.63	13.28 ± 1.70	4 | 11	.605
Social Functioning	8.14 ± 1.57	8.00 ± 1.52	4 | 5	1.00
Bodily Pain	10.57 ± 0.53	11.00 ± 1.52	1 | 4	.025*
Level of Fatigue	16.85 ± 2.47	15.28 ± 3.94	8 | 11	.088
HSCL-25:				
Level of Anxiety	1.80 ± 0.28	1.62 ± 0.37	0.8 | 1.2	.006*
Level of Depression	1.67 ± 0.31	1.61 ± 0.37	0.87 | 0.93	.088

*(Significant value = *p<0.05)*

Discussion

The main findings in this study were that users receiving treatment for SUD were relatively physically active during a 6-week follow-up period, averaging between 125-680 minutes (per week on PA), although only a modest improvement in physical fitness was observed. Further, the participants improved significantly in four out of ten (*general health, emotional well-being, level of fatigue,* and *anxiety*) subscales associated with QoL, although only the result

on *emotional well-being* was significantly correlated with time spent on PA per week (p = 0.02, r =-.85). In addition, PA was associated with three subscales of QoL (*physical functioning, limitations due to physical health,* and *depression*) although there were no improvements in these categories during follow-up, suggesting the association of PA and development in QoL was highly individual.

Participation in Physical Activity

Public health guidelines suggest 150-300 minutes per week of aerobic activity with moderate intensity (Piercy et al., 2018; WHO, 2022). It its estimated that within SUD treatment populations, only 40-50% of subjects fulfil these guidelines (Read et al., 2001; Weinstock et al, 2016). In this study, five out of seven (71.43%) subjects average more than 150 minute of PA per week. However, the method used to measure PA did not observe intensity, therefore this finding should be interpreted with caution.

Moreover, this study used a questionnaire (SIMPAQ) to assess the participation in PA. Shepard (2003) discusses some limitations associated with the use of questionnaires when measuring PA. Questionnaires rely on self-reporting, which can lead to inaccuracies due to bias or errors in recall. Participants my intentionally or unintentionally overestimate or underestimate their PA levels, leading to inaccurate data. Furthermore, questionnaires may also be limited in capturing all types of PA, particularly those that are not traditionally considered exercise, such as occupational or household activities. The result can therefore provide an incomplete picture of an Individual's PA levels (Shepard, 2003).

Quality of life

The result of this study suggest that several forms of PA can assist in the development of QoL among patients undergoing treatment for SUD. The findings are in line with existing literature, as several studies suggests, PA can have a positive impact on the development of QoL for this user group (Giménez-Meseguer et al., 2020; Köhlerová et al., 2023; Muller & Clausen, 2015). However, when compared to participation in PA, changes in QoL are often inconsistent for this user group (Giménez-Meseguer et al., 2020; Köhlerová et al., 2023; Muller & Clausen, 2015). Although, this is to be expected given QoL is a subjective measurement surrounding several different aspects, and the fact that users are likely to find different activities and their structural design (intensity, volume, or frequency) useful and meaningful (Giménez-Meseguer et al., 2020).

Compared to aerobic PA and resistance training, relatively few studies have examined walking and its impact on QoL in SUD treatment. Existing literature often focuses on high intensity aerobic activities (>75% HRmax) such as running or power walks (Brown et al., 2016; Buchowski et al., 2011; Dai et al., 2020; Garza et al., 2016; Mamen & Martinsen, 2010), while walking is often combined with other PA and/or not recognized as a therapeutic tool (Dai et al., 2020; Hallgren et al., 2017). Findings in this study suggests walking may be a suitable tool for improving QoL in SUD treatment, although, more extensive research is needed.

Time of admission

Although the males in this study (n = 7, age = 26-40) represents a rather homogenous group, time spent in the clinic before the intervention was highly individual. Analyses accounting for subjects spending more or less than two months prior to the follow-up suggested the results for *general health, emotional well-being* and *limitations du to emotion problems* were impacted by the subjects' different time of admission.

Strengths and limitations

Few studies have utilized an observational study design when examining the relationship between PA and QoL among SUD patients. Thus, this study represents a new view on this issue from a real-world setting. The study is further strengthened by using several well-established and objective measuring methods. All questionnaires included in this study are well-established and validated research methods (Bell, 1994; Jacobsen et al., 2018; Rosenbaum et al., 2020; Strand et al., 2003), whereas the physical tests conducted are all deemed valid and reliable by existing literature (Jones et al., 1999; Ronai & Gallo, 2020; Springer et al., 2007; Tveter et al., 2014).

However, the observational design precludes establishment of a causal relationship between any variables measured. Moreover, a follow-up time of six weeks may be too short – given the circumstances of SUD treatment – to identify patterns of development that can be expected to last for a prolonged period of time. Moreover, this study only included seven subjects, thus resulting in very low statistical power when examining relationships between variables. Furthermore, this study did not track other markers such as sleep, illness, injuries, or disordered eating patterns, which further adds to the limitation of this study.

Lastly, all subscales of the SF-36v2 (health survey) were used in this study to assess the development in QoL. Although efforts were made to obtain the correct scoring key for SF-36v2, given restrictions it was not attainable. Unfortunately, this renders the results of the SF-36v2 subscales in this study more difficult to compare with findings outside this study.

Perspectives

This study is one of few to assess the development in QoL and PA among SUD patients while utilizing an observational study design. The development in QoL and health-related fitness levels suggest this patient group did benefit from the use of PA in treatment, although the results in this study must be interpreted and used with caution as this study represent several limitations. The low number of participants results in low statistical power, and the method used excludes any causal relationship between any variables observed. That said, the result in this study is somewhat in line with several studies indicating walking/running as suitable tools in SUD treatment (Buchowski et al., 2011; Dai et al., 2020; Hallgren et al., 2017). Going forward, future research should include a larger sample size along with measures to counter the possible effect different dates of admission can produce. Moreover, the findings in this study, regardless of its limitations, adds to the understanding of the complexity of SUD treatment and highlights variables to consider in the future.

In conclusion, the subjects in this study all spent a considerable amount of time on PA during the follow-up period. At group level, this resulted in signs of improved levels of health-related fitness and improvement in four out of ten subscales associated with QoL. Moreover, this study suggests walking and several other forms of PA could assist in the development of QoL among this user group.

Reference:

Bell, C. C. (1994). DSM-IV: Diagnostic and Statistical Manual of Mental Disorders. *JAMA*, *272*(10), 828–829. https://doi.org/10.1001/jama.1994.03520100096046

Brown, R. A., Prince, M. A., Minami, H. & Abrantes, A. M. (2016). An exploratory analysis of changes in mood, anxiety and craving from pre- to post-single sessions of exercise, over 12 weeks, among patients with alcohol dependence. *Mental Health and Physical Activity*, *11*, 1–6. https://doi.org/10.1016/j.mhpa.2016.04.002

Buchowski, M. S., Meade, N. N., Charboneau, E., Park, S., Dietrich, M. S., Cowan, R. L. & Martin, P. R. (2011). Aerobic exercise training reduces cannabis craving and use in non-treatment seeking cannabis-dependent adults. *PLoS ONE, 6*(3). https://doi.org/10.1371/journal.pone.0017465

Cohen, J. (1988). Statistical power analysis for the behavioral sci- ences (2nd ed.). *Hillside, NJ: Lawrence Erlbaum Associates.* https://www.utstat.toronto.edu/~brunner/oldclass/378f16/readings/CohenPower.pdf

Cohen J. (1992). A power primer. *Psychological bulletin*, *112*(1), 155–159. https://doi.org/10.1037//0033-2909.112.1.155

Colledge, F., Vogel, M., Dürsteler-Macfarland, K., Strom, J., Schoen, S., Pühse, U. & Gerber, M. (2017). A pilot randomized trial of exercise as adjunct therapy in a heroin-assisted treatment setting. *Journal of Substance Abuse Treatment*, *76*, 49–57. https://doi.org/10.1016/j.jsat.2017.01.012

Dai, C. L., Chen, C. C., Richardson, G. B., & Gordon, H. R. D. (2020). Managing Substance Use Disorder through a Walking/Running Training Program. Substance abuse : research and treatment, *14*, 1178221820936681. https://doi.org/10.1177/1178221820936681

Dolezal, B. A., Chudzynski, J., Dickerson, D., Mooney, L., Rawson, R. A., Garfinkel, A. & Cooper, C. B. (2014). Exercise training improves heart rate variability after methamphetamine dependency. *Medicine and science in sports and exercise*, *46*(6), 1057–1066. https://doi.org/10.1249/MSS.0000000000000201

De La Garza, R., 2nd, Yoon, J. H., Thompson-Lake, D. G., Haile, C. N., Eisenhofer, J. D., Newton, T. F. & Mahoney, J. J., 3rd (2016). Treadmill exercise improves fitness and reduces craving and use of cocaine in individuals with concurrent cocaine and tobacco-use disorder. *Psychiatry research*, *245*, 133–140. https://doi.org/10.1016/j.psychres.2016.08.003

Giesen, E. S. & Bloch. (2016). The Role of Exercise Therapy as a Complementary Measure in the Addiction Treatment of a Multiply Impaired Alcohol Dependent Client: A Case Report. *Journal of Substance Abuse and Alcoholism* (4). https://doi.org/10.47739/2373-9363/1041

Giménez-Meseguer, J., Tortosa-Martínez, J., & Cortell-Tormo, J. M. (2020). The Benefits of Physical Exercise on Mental Disorders and Quality of Life in Substance Use Disorders Patients. *Systematic Review and Meta-Analysis. International journal of environmental research and public health, 17*(10), 3680. https://doi.org/10.3390/ijerph17103680

Giménez-Meseguer, J., Tortosa-Martínez, J. & de los Remedios Fernández-Valenciano, M. (2015). Benefits of Exercise for the Quality of Life of Drug-Dependent Patients. *Journal of psychoactive drugs, 47*(5), 409–416. https://doi.org/10.1080/02791072.2015.1102991

Hallgren, M., Romberg, K., Bakshi, A. S. & Andréasson, S. (2014). Yoga as an adjunct treatment for alcohol dependence: a pilot study. *Complementary therapies in medicine*, *22*(3), 441–445. https://doi.org/10.1016/j.ctim.2014.03.003

Hallgren, M., Vancampfort, D., Giesen, E. S., Lundin, A. & Stubbs, B. (2017). Exercise as treatment for alcohol use disorders: systematic review and meta-analysis. *British journal of sports medicine*, *51*(14), 1058–1064. https://doi.org/10.1136/bjsports-2016-096814

Hidalgo, J. L.-T. & the DEP-EXERCISE group. (2019). Effectiveness of physical exercise in the treatment of depression in older adults as an alternative to antidepressant drugs in primary care. *Annals of Family Medicine, 19*(4), 302-309. https://doi.org/10.1370/afm.2670

Jacobsen, E. L., Bye, A., Aass, N., Fosså, S. D., Grotmol, K. S., Kaasa, S., Loge, J. H., Moum, T. & Hjermstad, M. J. (2018). Norwegian reference values for the Short-Form Health Survey 36: development over time. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation*, *27*(5), 1201–1212. https://doi.org/10.1007/s11136-017-1684-4

Köhlerová, M.Z., Fišerová, Z. & Páv, M. Physical activity habits and their effects on quality of life in patients with addiction: data from the Czech Republic. *Curr Psychol* (2023). https://doi.org/10.1007/s12144-023-04402-w

Mamen, A. & Martinsen, E. W. (2010). Development of aerobic fitness of individuals with substance abuse/dependence following long-term individual physical activity. *European Journal of Sport Science, 2010*(10). https://doi.org/10.1080/17461390903377126

Muller, A. E. & Clausen, T. (2015). Group exercise to improve quality of life among substance use disorder patients. *Scandinavian journal of public health*, *43*(2), 146–152. https://doi.org/10.1177/1403494814561819

Nugroho, A. I., Riyanto, P. Lahinda, J. & Hidayat, S. H. (2020). Effectiveness of physical condition training on the fitness of drug abuse victims, BRSPP Yogyakarta. *Enfermería Clínica, 30*(6), 63-66. https://doi.org/10.1016/j.enfcli.2020.06.015

Piercy, K. L., Troiano, R. P., Ballard, R. M., Carlson, S. A., Fulton, J. E., Galuska, D. A., George, S. M. & Olson, R. D. (2018). The Physical Activity Guidelines for Americans. *JAMA*, *320*(19), 2020–2028. https://doi.org/10.1001/jama.2018.14854

Read, J. P., Brown, R. A., Marcus, B. H., Kahler, C. W., Ramsey, S. E., Dubreuil, M. E., Jakicic, J. M. & Francione, C. (2001). Exercise attitudes and behaviors among persons in treatment for alcohol use disorders. *Journal of substance abuse treatment*, *21*(4), 199–206. https://doi.org/10.1016/s0740-5472(01)00203-3

Read, J. P. & Brown, R. A. (2003). The role of physical exercise in alcoholism treatment and recovery. *Professional Psychology: Research and Practice, 34*(1), 49–56. https://doi.org/10.1037/0735-7028.34.1.49

Rosenbaum, S., Morell, R., Abdel-Baki, A., Ahmadpanah, M., Anilkumar, T. V., Baie, L., Bauman, A., Bender, S., Boyan Han, J., Brand, S., Bratland-Sanda, S., Bueno-Antequera, J., Camaz Deslandes, A., Carneiro, L., Carraro, A., Castañeda, C. P., Castro Monteiro, F., Chapman, J., Chau, J. Y., Chen, L. J., … Ward, P. B. (2020). Assessing physical activity in people with mental illness: 23-country reliability and validity of the simple physical activity questionnaire (SIMPAQ). *BMC psychiatry*, *20*(1), 108. https://doi.org/10.1186/s12888-020-2473-0

Ronai, P. M. S. & Gallo, P. M. (2020). The Stair Climb Power Test. *ACSM's Health & Fitness Journal*, *24*(4), 38-42. https://doi.org/10.1249/FIT.0000000000000589

Shephard R. J. (2003). Limits to the measurement of habitual physical activity by questionnaires. British journal of sports medicine, 37(3), 197–206. https://doi.org/10.1136/bjsm.37.3.197

Springer, B. A., Marin, R., Cyhan, T., Roberts, H. & Gill, N. W. (2007). Normative values for the unipedal stance test with eyes open and closed. *Journal of geriatric physical therapy (2001)*, *30*(1), 8–15. https://doi.org/10.1519/00139143-200704000-00003

Strand, B. H., Dalgard, O. S., Tambs, K. & Rognerud, M. (2003). Measuring the mental health status of the Norwegian population: a comparison of the instruments SCL-25, SCL-10, SCL-5 and MHI-5 (SF-36). *Nordic journal of psychiatry*, *57*(2), 113–118. https://doi.org/10.1080/08039480310000932

Tveter, A. T., Dagfinrud, H., Moseng, T. & Holm, I. (2014). Health-related physical fitness measures: reference values and reference equations for use in clinical practice. *Archives of physical medicine and rehabilitation*, *95*(7), 1366–1373. https://doi.org/10.1016/j.apmr.2014.02.016

United Nations office on drugs and crime, Vienna. (2016). *World Drug Report* (ISBN: 978-92-1-148286-7). United Nations. https://www.unodc.org/doc/wdr2016/WORLD_DRUG_REPORT_2016_web.pdf

Weinstock, J., Farney, M. R., Elrod, N. M., Henderson, C. E. & Weiss, E. P. (2017). Exercise as an Adjunctive Treatment for Substance Use Disorders: Rationale and Intervention

Description. *Journal of substance abuse treatment*, *72*, 40–47. https://doi.org/10.1016/j.jsat.2016.09.002

Wilkinson, L. & Task Force on Statistical Inference, American Psychological Association, Science Directorate. (1999). Statistical methods in psychology journals: Guidelines and explanations. *American Psychologist, 54*(8), 594–604. https://doi.org/10.1037/0003-066X.54.8.594

World Health Organization. (2018). *Global status report on alcohol and health 2018* (ISBN: 978-92-4-156563-9). World Health Organization. https://www.who.int/publications/i/item/9789241565639

World Health Organization. (2022). *Physical activity.* World Health Organization. https://www.who.int/news-room/fact-sheets/detail/physical-activity

Zangeneh, M., Barmaki, R., Ala-leppilampi, K. & Peric, T. (2007). The Potential Role of Physical Exercise in Addiction Treatment and Recovery: The Social Costs of Substance Misuse. *International Journal of Mental Health and Addiction, 5*(3), 210-218. https://doi.org/10.1007/s11469-007-9111-7

Part 3

Appendices

Appendix

Contents:

Appendix 1

Meldeskjema / Fysisk aktivitet, fysisk form og psykiatrisk behandling - en observasjon... / Vurdering

Vurdering

Referansenummer	Type	Dato
343821	Standard	13.09.2022

Prosjekttittel
Fysisk aktivitet, fysisk form og psykiatrisk behandling - en observasjonell studie

Behandlingsansvarlig institusjon
Universitetet i Sørøst-Norge / Fakultet for humaniora, idrett- og utdanningsvitenskap / Institutt for friluftsliv, idrett og kroppsøving

Prosjektansvarlig
Solfrid Bratland-Sanda

Prosjektperiode
12.09.2022 - 30.09.2024

Kategorier personopplysninger
Alminnelige
Særlige

Meldeskjema

Kommentar
OM VURDERINGEN
Personverntjenester har en avtale med institusjonen du forsker eller studerer ved. Denne avtalen innebærer at vi skal gi deg råd slik at behandlingen av personopplysninger i prosjektet ditt er lovlig etter personvernregelverket.

Personverntjenester har nå vurdert den planlagte behandlingen av personopplysninger. Vår vurdering er at behandlingen er lovlig, hvis den gjennomføres slik den er beskrevet i meldeskjemaet med dialog og vedlegg.

BAKGRUNN
Prosjektet er vurdert og godkjent med vilkår etter helseforskningsloven § 10 av Regionale komiteer for medisinsk og helsefaglig forskningsetikk (REK sør-øst) i vedtak av 5.9.2022 (deres referanse: 479258).

VURDERING AV BEHOV FOR DPIA
Prosjektet behandler særlige kategorier av personopplysninger (helseopplysninger) om en sårbar gruppe (pasienter), noe som kan utløse en plikt til å foreta personvernkonsenkvensvurdering (DPIA).

Personverntjenester har vurdert at det ikke var behov for å gjøre en DPIA jf. personvernforordningen art. 35 nr. 1 for dette prosjektet. Dette var basert på en helhetsvurdering der følgende momenter ble vektlagt:

- De registrerte samtykker til bruk av sine personopplysninger
- De registrerte får god informasjon om behandlingen av personopplysningene og sine rettigheter
- Få personer har tilgang til personopplysningene
- Opplysningene oppbevares trygt på maskinvare hos behandlingsansvarlig institusjon
- Regionale komiteer for medisinsk og helsefaglig forskningsetikk (REK) har gjort en forskningsetisk vurdering og godkjent prosjektet
- Behandlingen har kort varighet
- Det behandles få personopplysninger

TYPE OPPLYSNINGER OG VARIGHET
Prosjektet vil behandle alminnelige personopplysninger og særlige kategorier av personopplysninger om helseforhold frem til 30.9.2024. Etter prosjektslutt skal opplysningene oppbevares i fem år av dokumentasjonshensyn. Enhver tilgang til prosjektdataene skal da være knyttet til behovet for etterkontroll. Prosjektdata skal da ikke være tilgjengelig for prosjektet.

Prosjektleder og forskningsansvarlig institusjon er ansvarlig for at opplysningene oppbevares pseudonymisert (av-identifisert) i denne perioden, dvs. atskilt i en nøkkel- og en datafil. Etter disse fem årene skal data slettes eller anonymiseres.

LOVLIG GRUNNLAG
Prosjektet vil innhente samtykke fra de registrerte til behandlingen av personopplysninger. Vår vurdering er at prosjektet legger opp til et samtykke i samsvar med kravene i art. 4 nr. 11 og 7, ved at det er en frivillig, spesifikk, informert og utvetydig bekreftelse, som kan dokumenteres, og som den registrerte kan trekke tilbake.

For alminnelige personopplysninger vil lovlig grunnlag for behandlingen være den registrertes samtykke, jf. personvernforordningen art. 6 nr. 1 a.

For særlige kategorier av personopplysninger vil lovlig grunnlag for behandlingen være den registrertes uttrykkelige samtykke, jf. personvernforordningen art. 9 nr. 2 bokstav a, jf. personopplysningsloven § 10, jf. § 9 (2).

PERSONVERNPRINSIPPER
Personverntjenester vurderer at den planlagte behandlingen av personopplysninger vil følge prinsippene i personvernforordningen:

om lovlighet, rettferdighet og åpenhet (art. 5.1 a), ved at de registrerte får tilfredsstillende informasjon om og samtykker til behandlingen

formålsbegrensning (art. 5.1 b), ved at personopplysninger samles inn for spesifikke, uttrykkelig angitte og berettigede formål, og ikke viderebehandles til nye uforenlige formål

dataminimering (art. 5.1 c), ved at det kun behandles opplysninger som er adekvate, relevante og nødvendige for formålet med prosjektet

lagringsbegrensning (art. 5.1 e), ved at personopplysningene ikke lagres lengre enn nødvendig for å oppfylle formålet.

DE REGISTRERTES RETTIGHETER
Personverntjenester vurderer at informasjonen om behandlingen som de registrerte vil motta oppfyller lovens krav til form og innhold, jf. art. 12.1 og art. 13.

Så lenge de registrerte kan identifiseres i datamaterialet vil de ha følgende rettigheter: innsyn (art. 15), retting (art. 16), sletting (art. 17), begrensning (art. 18) og dataportabilitet (art. 20).

Vi minner om at hvis en registrert tar kontakt om sine rettigheter, har behandlingsansvarlig institusjon plikt til å svare innen en måned.

UNNTAK FRA RETTEN TIL SLETTING
I utgangspunktet har alle som registreres i forskningsprosjektet rett til å få slettet opplysninger som er registrert om dem. Etter helseforskningsloven § 16 tredje ledd vil imidlertid adgangen til å kreve sletting av sine helseopplysninger ikke gjelde dersom materialet eller opplysningene er anonymisert, dersom materialet etter bearbeidelse inngår i et annet biologisk produkt, eller dersom opplysningene allerede er inngått i utførte analyser. Regelen henviser til at sletting i slike situasjoner vil være svært vanskelig og/eller ødeleggende for forskningen, og dermed forhindre at formålet med forskningen oppnås.

Etter personvernforordningen art 17 nr. 3 d kan man unnta fra retten til sletting dersom behandlingen er nødvendig for formål knyttet til vitenskapelig eller historisk forskning eller for statistiske formål i samsvar med artikkel 89 nr. 1 i den grad sletting sannsynligvis vil gjøre det umulig eller i alvorlig grad vil hindre at målene med nevnte behandling nås.

Personverntjenester vurderer dermed at det er grunnlag for å gjøre unntak fra retten til sletting av helseopplysninger etter helseforskningslovens § 16 tredje ledd og personvernforordningen art 17 nr. 3 d, når materialet er bearbeidet slik at det inngår i et annet biologisk produkt, eller dersom opplysningene allerede er inngått i utførte analyser.

Vi presiserer at helseopplysninger inngår i utførte analyser dersom de er sammenstilt eller koblet med andre opplysninger eller prøvesvar. Vi gjør oppmerksom på at øvrige opplysninger må slettes og det kan ikke innhentes ytterligere opplysninger fra deltakeren.

FØLG DIN INSTITUSJONS RETNINGSLINJER
Personverntjenester legger til grunn at behandlingen oppfyller kravene i personvernforordningen om riktighet (art. 5.1 d), integritet og konfidensialitet (art. 5.1. f) og sikkerhet (art. 32).

Ved bruk av databehandler (spørreskjemaleverandør, skylagring, videosamtale o.l.) må behandlingen oppfylle kravene til bruk av databehandler, jf. art 28 og 29. Bruk leverandører som din institusjon har avtale med.

For å forsikre dere om at kravene oppfylles, må prosjektansvarlig følge interne retningslinjer/rådføre dere med behandlingsansvarlig institusjon.

MELD VESENTLIGE ENDRINGER
Dersom det skjer vesentlige endringer i behandlingen av personopplysninger, kan det være nødvendig å melde dette til Personverntjenester ved å oppdatere meldeskjemaet. Før du melder inn en endring, oppfordrer vi deg til å lese om hvilken type

endringer det er nødvendig å melde:

https://www.nsd.no/personverntjenester/fylle-ut-meldeskjema-for-personopplysninger/melde-endringer-i-meldeskjema

Du må vente på svar fra Personverntjenester før endringen gjennomføres.

OPPFØLGING AV PROSJEKTET
Personverntjenester vil følge opp underveis (hvert annet år) og ved planlagt avslutning for å avklare om behandlingen av personopplysningene er avsluttet/pågår i tråd med den behandlingen som er dokumentert.

Kontaktperson hos Personverntjenester: Lisa Lie Bjordal

Lykke til med prosjektet!

Appendix 2

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst A	Elin Evju Sagbakken	22845502	05.09.2022	479256

Solfrid Bratland-Sanda

Prosjektsøknad: Fysisk aktivitet, fysisk form og psykiatrisk behandling - en observasjonell studie
Søknadsnummer: 479256
Forskningsansvarlig institusjon: Universitetet i Sørøst-Norge
Samarbeidende forskningsansvarlige institusjoner: UiT Norges arktiske universitet

Prosjektsøknad godkjennes med vilkår

Søkers beskrivelse

Hensikten med denne studien er å undersøke forløp av fysisk form og deltakelse i fysisk aktivitet i løpet av den første fasen av behandlingsforløpet for voksne pasienter innlagt for behandling av rusavhengighet og psykiske lidelser, samt identifisere faktorer som kan predikere gunstig endring i fysisk form i denne fasen. Bakgrunnen for prosjektet er at fysisk aktivitet har en dokumentert positiv effekt som del av behandling for denne pasientpopulasjonen, samtidig som det er manglende kunnskap om hvordan faktisk deltakelse er i fysisk aktivitetsøkter under behandling. Vitalis Helse er en behandlingsinstitusjon som har stort fokus på bruk av fysisk aktivitet som del av behandlingstilbudet, og prosjektet tar defor utgangspunkt i observasjon av et eksisterende behandlingstilbud.

*I denne observasjonelle studien vil vi inkludere pasienter som mottar døgnbehandling hos Vitalis Helse Kragerø. Styrkeberegning gjort med G*power viser at vi trenger 32 deltakere for en power på 0.8, signifikansnivå 0.05 og en effektstørrelse på 0.5. Eksklusjonskriterier er skader og/eller fysisk sykdom som hindrer testing av fysisk form. De inkluderte pasientene vil fylle ut spørreskjema ved innleggelse og etter 6-8 uker av behandlingsforløpet. Dette spørreskjemaet inneholder følgende validerte instrumenter: Behavioural Regulation of Exercise Questionnaire - 2 (mål på motivasjon for fysisk aktivitet og trening), Compulsive Exercise Test (mål på tvangstrening), Symptom Check List - 25 (mål på angst- og depresjonssymptomer), og SF-36 (mål på helserelatert livskvalitet). I tillegg vil pasientene ha ukentlig utfylling av SIMPAQ, et validert spørreskjema som måler fysisk aktivitetsatferd, og ukentlig utfylling av en aktivitetslogg.*

Nytteverdien til prosjektet er å skaffe til veie kunnskap om deltakelse i fysisk aktivitet under første del av behandlingsforløpet for pasienter med rusavhengighet og psykiske lidelser. Studien vil danne grunnlag for fremtidige eksperimentelle studier på effekter av fysisk aktivitet, forekomst og håndtering av tvangstrening, samt fremme motivasjon for deltakelse i fysisk aktivitet under behandling. Praktiske implikasjoner av studien omhandler hvordan personalet kan fasilitere og tilrettelegge for deltakelse i fysisk aktivitet, samt hvordan de kan møte pasienter som har behov for å endre tvangspreget forhold til fysisk aktivitet og

REK sør-øst A
Besøksadresse: Gullhaugveien 1-3, 0484 Oslo
Telefon:22 84 55 11 | **E-post**:rek-sorost@medisin.uio.no
Web:https://rekportalen.no

trening.

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst A) i møtet 18.08.2022. Vurderingen er gjort med hjemmel i helseforskningslovens § 10.

REKs vurdering

Slik komiteen forstår søknad og protokoll er hensikten med prosjektet å undersøke forløp av fysisk form og deltakelse i fysisk aktivitet i løpet av den første fasen av behandlingsforløpet for voksne pasienter innlagt for behandling av rusavhengighet og psykiske lidelser, samt identifisere faktorer som kan predikere gunstig endring i fysisk form i denne fasen.

Prosjektleder omtaler at fysisk aktivitet har en dokumentert positiv effekt som del av behandling for denne pasientpopulasjonen, samtidig som det er manglende kunnskap om hvordan faktisk deltakelse er i fysisk aktivitetsøkter under behandling.

Vitalis Helse Kragerø er en behandlingsinstitusjon som har fokus på bruk av fysisk aktivitet som del av behandlingstilbudet, og prosjektet tar derfor utgangspunkt i observasjon av et eksisterende behandlingstilbud.

Det planlegges å inkludere 34 pasienter. Deltakelse i prosjektet innebærer å svare på et spørreskjema og gjennomføre tester av fysisk form ved innleggelse, og etter 6 og 8 uker med behandling, der hver test tar ca. 30 minutter. Det skal i tillegg skrives ukentlig aktivitetslogg og svares på et ukentlig spørreskjema. Det er angitt tidsbruk for alle aktiviteter og besvarelse av spørreskjema i informasjonsskrivet.

Det vil også innhentes opplysninger fra pasientjournal som alder, kjønn, tidligere erfaringer med fysisk aktivitet, trening og idrett, diagnoser og medikamentbruk.

Prosjektet er samtykkebasert og informasjonsskrivet gir god oversikt over deltakelse i prosjektet men mangler informasjon om rekrutteringsprosedyren og må derfor revideres.

Rekrutteringsprosedyren er også dårlig beskrevet i protokoll, men i søknadsskjema står det følgende:
«Potensielle deltakere vil bli identifisert etter innleggelse. De vil forespørres om deltakelse fra én av de ansatte på Vitalis helse, forespørselen blir forelagt gjennom informasjonsskriv med samtykkeerklæring. Potensielle deltakere får to dagers betenkningstid. De forespurte skal svare til én av de ansatte på Vitalis helse, som så vil meddele prosjektmedarbeider (masterstudent).»

Slik komiteen forstår det er det en av de ansatte ved Vitalis Helse som skal innhente samtykke fra deltakerne. Komiteen presiserer at den som innhenter samtykke ikke må være samme person som har ansvaret for behandling av pasienten, dette for å unngå opplevelse av press til deltakelse. Informasjon om prosjektet og forespørsel om samtykke bør derfor komme fra en person deltakerne ikke står i et slikt forhold til, jf. helseforskningsloven § 13, tredje ledd.

Komiteen vurderer prosjektet som forsvarlig å gjennomføre og godkjenner prosjektet med følgende vilkår.

- Informasjonsskrivet må revideres der det tas inn en informasjon om korrekt rekrutteringsprosedyren jf. komiteens ovennevnte kommentarer og kravet i helseforskningsloven § 13, tredje ledd.

Revidert informasjonsskriv med markerte endringer og en endelig versjoner innsendes REK ved å benytte skjema for «Endring og/eller henvendelse» som finnes etter innlogging på http://rekportalen.no.

Vedtak

REK har gjort en helhetlig forskningsetisk vurdering av alle prosjektets sider. Prosjektet godkjennes med hjemmel i helseforskningsloven § 10, under forutsetning av at ovennevnte vilkår er oppfylt.

I tillegg til vilkår som fremgår av dette vedtaket, er godkjenningen gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknad og protokoll, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Vi gjør samtidig oppmerksom på at etter ny personopplysningslov må det også foreligge et behandlingsgrunnlag etter personvernforordningen. Det må forankres i egen institusjon.

Komiteens avgjørelse var enstemmig.

Prosjektet er godkjent frem til **31.12.2024**. Etter prosjektslutt skal opplysningene oppbevares i fem år eller mer, dersom norske regler krever det, for dokumentasjonshensyn. Enhver tilgang til prosjektdataene skal da være knyttet til behovet for etterkontroll. Prosjektdata skal dermed ikke være tilgjengelig for prosjektet. Prosjektleder og forskningsansvarlig institusjon er ansvarlig for at opplysningene oppbevares indirekte personidentifiserbart i denne perioden, dvs. atskilt i en nøkkel- og en datafil. Deretter skal data slettes eller anonymiseres. Vi gjør oppmerksom på at anonymisering kan være mer omfattende enn å kun slette koblingsnøkkelen, jf. Datatilsynets veileder om anonymiserings-teknikker.

Vi gjør samtidig oppmerksom på at det også må foreligge et behandlingsgrunnlag etter personvernforordningen. Dette må forankres i egen institusjon.

Sluttmelding
Prosjektleder skal sende sluttmelding til REK på eget skjema via REK-portalen senest 6 måneder etter sluttdato 31.12.2024, jf. helseforskningsloven § 12. Dersom prosjektet ikke starter opp eller gjennomføres meldes dette også via skjemaet for sluttmelding.

Søknad om endring
Dersom man ønsker å foreta vesentlige endringer i formål, metode, tidsløp eller organisering må prosjektleder sende søknad om endring via portalen på eget skjema til REK, jf. helseforskningsloven § 11.

Klageadgang
Du kan klage på REKs vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes på eget skjema via REK portalen. Klagefristen er tre uker fra du mottar dette brevet. Dersom REK opprettholder vedtaket, sender REK klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag (NEM) for endelig vurdering, jf. forskningsetikkloven § 10 og helseforskningsloven § 10.

Med vennlig hilsen

Kristian Bjøro
Professor dr. med.

Leder REK sør-øst A

Elin Evju Sagbakken
Seniorrådgiver, REK sør-øst A

Kopi til:

Universitetet i Sørøst-Norge
UiT Norges arktiske universitet

Appendix 3

VIL DU DELTA I FORSKNINGSPROSJEKTET «FYSISK AKTIVITET OG FYSISK FORM I PSYKIATRI OG RUSBEHANDLING – EN OBSERVASJONELL STUDIE VED VITALIS HELSE»?

FORMÅLET MED PROSJEKTET OG HVORFOR DU BLIR SPURT

Dette er et spørsmål til deg om å delta i et forskningsprosjekt for å undersøke hvordan fysisk aktivitet og fysisk form endrer seg i løpet av den første perioden av behandlingsforløpet hos Vitalis Helse. Du blir spurt om å delta i studien fordi du er innlagt for behandling på Vitalis Helse.

HVA INNEBÆRER PROSJEKTET FOR DEG?

Deltakelse i forskningsprosjektet innebærer å svare på spørreskjema og gjennomføre tre tester av fysisk form ved innleggelse og etter 6-8 uker med behandling. Spørreskjemaene tar cirka 10 minutter å fylle ut, og de fysiske testene tar cirka 30 minutter å gjennomføre. Du vil også fylle ut en ukentlig fysisk aktivitetslogg og et ukentlig spørreskjema om fysisk aktivitet, dette tar cirka 5 minutter å fylle ut per gang.

I prosjektet vil vi innhente og registrere opplysninger om deg. Dette er alder, kjønn, tidligere erfaringer med fysisk aktivitet, trening og idrett, diagnoser og medikamentbruk. Dette er opplysninger vi vil hente fra pasientjournal på Vitalis.

MULIGE FORDELER OG ULEMPER

Fordelen ved deltakelse er at du får testet fysisk form, og du kan få tilbakemeldinger på aktivitetsnivå og motivasjon. De fysiske testene kan oppleves litt anstrengende og fysisk krevende, men det er forbigående. Testene gjennomføres også av personer som har god kompetanse på fysisk aktivitet, trening og testing. Siden prosjektet kun observerer det som skjer i behandling så vil alle som deltar i prosjektet få samme behandling som de som ikke deltar i prosjektet.

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Det vil ikke ha noen negative konsekvenser for deg eller din behandling hvis du ikke vil delta eller senere velger å trekke deg. Dersom du trekker tilbake samtykket, vil det ikke forskes videre på dine opplysninger og ditt biologiske materiale. Du kan kreve innsyn i opplysningene som er lagret om deg, og disse vil da utleveres innen 30 dager. Du kan også kreve at dine opplysninger i prosjektet slettes og at det biologiske materialet destrueres.
Adgangen til å kreve destruksjon, sletting eller utlevering gjelder ikke dersom materialet eller opplysningene er anonymisert eller publisert. Denne adgangen kan også begrenses dersom opplysningene er inngått i utførte analyser.

Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektleder (se kontaktinformasjon på siste side).

HVA SKJER MED OPPLYSNINGENE OM DEG?

Opplysningene som registreres om deg skal kun brukes slik som beskrevet under formålet med prosjektet, og planlegges brukt til 2024. Eventuelle utvidelser i bruk og oppbevaringstid kan kun skje etter godkjenning fra REK og andre relevante myndigheter. Du har rett til innsyn i hvilke opplysninger som er registrert om deg og

rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Du har også rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene. Du kan klage på behandlingen av dine opplysninger til Datatilsynet og institusjonen sitt personvernombud.

Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger (=kodede opplysninger). En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun prosjektleder professor Solfrid Bratland-Sanda som har tilgang til denne listen.

Publisering av resultater er en nødvendig del av forskningsprosessen. All publisering skal gjøres slik at enkeltdeltakere ikke skal kunne gjenkjennes, men vi plikter å informere deg om at vi ikke kan utelukke at det kan skje.

Etter at forskningsprosjektet er ferdig, vil opplysningene om deg bli oppbevart i fem år av kontrollhensyn.

FORSIKRING

Universitetet i Sørøst-Norge er selvassurandør.

GODKJENNINGER

Regional komité for medisinsk og helsefaglig forskningsetikk har gjort en forskningsetisk vurdering og godkjent prosjektet. Saksnr. hos REK er 479256.

Universitetet i Sørøst-Norge og prosjektleder professor Solfrid Bratland-Sanda er ansvarlig for personvernet i prosjektet.

Vi behandler opplysningene basert på godkjenning fra NSD, saksnr. 343821.

KONTAKTOPPLYSNINGER

Dersom du har spørsmål til prosjektet eller ønsker å trekke deg fra deltakelse, kan du kontakte prosjektleder Solfrid Bratland-Sanda, tlf 35952798, e-post solfrid.bratland-sanda@usn.no. Du kan også kontakte masterstudent i prosjektet, Eirik Inge Johnsen, e-post ejo097@uit.no, så vil han videreformidle til prosjektleder.

Dersom du har spørsmål om personvernet i prosjektet, kan du kontakte personvernombudet ved institusjonen: paal.a.solberg@usn.no.

Du kan få inntil to dagers betenkningstid på om du ønsker å delta i studien. I henhold til helseforskningsloven §13, tredje ledd, skal informasjonen om studien eller ditt samtykke ikke gis til din behandlingsansvarlige. Du kan derfor gi beskjed til en av idrettspedagogene på Vitalis helse om du ønsker å delta i studien. De vil så videreformidle dette til prosjektgruppen v/ masterstudent Eirik Inge Johnsen.

JEG SAMTYKKER TIL Å DELTA I PROSJEKTET OG TIL AT MINE PERSONOPPLYSNINGER BRUKES SLIK DET ER BESKREVET

Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver

Appendix 4

SIMPLE PHYSICAL ACTIVITY QUESTIONNAIRE (SIMPAQ)

Introduksjon: Jeg kommer nå til å spørre deg om hva du har gjort de siste syv dager, inkludert tiden du har brukt i senga, stillesittende eller liggende aktiviteter, gange, trening, idrett og andre aktiviteter.

1A. Hvilket klokkeslett har du vanligvis lagt deg de siste syv dagene?
Presiser: mellom kl_____ og _____?

Svar: Kl_____

1B. Hvilket klokkeslett har du vanligvis stått opp de siste syv dagene?
Svar: Kl_____

1. Gjennomsnittlig antall timer i senga per natt: _____

2A. Dette gir omtrent _____ timer per dag ute av senga. Av de _____ timene, hvor mange har du brukt sittende eller liggende som når du spiser, leser, ser på TV, eller bruker data?
Presiser: sittende på jobb, hjemme, transport, fritid.

Svar: _____ timer _____ minutter / dag

2B. Hvor mye av denne tiden bruker du på å ta deg en lur?

Svar: _____timer _____ minutter / dag

2. Gjennomsnittlig antall sedate timer per dag: _____

3.Dette gir omtrent _____ timer per dag til annen aktivitet. Hvilke dager de siste syv dagene har du gått som trening, rekreasjon eller for å komme deg til og fra steder? Hvor mange minutter gikk du vanligvis disse dagene?

Mandag	Tirsdag	Onsdag	Torsdag	Fredag	Lørdag	Søndag

3. Gjennomsnittlig antall timer gange per dag: _____

4A. Tenk på aktiviteter du bruker for å trene eller drive med idrett, som for eksempel jogging, løping, svømming, sykling, trene på treningssenter, yoga, _____ [eksempel 1] eller _____ [eksempel 2] (se manual). Hvilke dager siste uke har du drevet med disse eller lignende aktiviteter?

4B. Hvilke aktiviteter gjorde du og hvor mye tid brukte du på hver aktivitet hver enkelt dag?

	Aktivitet og intensitet (0-10)	Antall økter	Minutter	Total
Eksempel	Styrketrening (5/10); tennis (9/10)	1 ; 1	15; 50	65
Mandag				
Tirsdag				

Onsdag				
Torsdag				
Fredag				
Lørdag				
Søndag				
	Total			

4. Gjennomsnittlig antall timer idrett/trening per dag: _____

5 Tenk på andre fysiske aktiviteter som du gjorde som del av jobb, eller aktiviteter du gjorde hjemme som hagearbeid eller husarbeid. Hvor mange minutter brukte du på disse aktivitetene de fleste dagene?
Presiser: Dette inkluderer ikke gange, idrett eller trening

Svar: _____ minutter per dag

5. Gjennomsnittlig antall timer med andre aktiviteter per dag: _____

Appendix 5

Hvordan har du det?

Når smerter og andre plager har vart en tid, blir en gjerne sliten og oppgitt. Dette gir ofte slike plager som nevnt nedenfor. Samlet blir disse her brukt som mål på at en er legemlig og psykisk presset. Vurder hvor mye hvert symptom har vært til plage eller ulempe for deg de siste 14 dagene (til og med i dag). Sett ring rundt tallet som passer best. Husk å sette en ring rundt aktuelt tall for hver plage/hvert symptom.

(sett ring rundt tallet)	Ikke i det hele tatt	Litt	En god del	Svært mye
1. Plutselig skremt uten grunn.	1	2	3	4
2. Føler du deg engstelig.	1	2	3	4
3. Føler du deg svimmel eller kraftløs.	1	2	3	4
4. Nervøs eller urolig.	1	2	3	4
5. Hjertebank.	1	2	3	4
6. Skjelving.	1	2	3	4
7. Føler deg anspent eller opphisset.	1	2	3	4
8. Hodepine.	1	2	3	4
9. Anfall av redsel eller panikk	1	2	3	4
10. Rastløshet, kan ikke sitte rolig	1	2	3	4
11. Føler deg slapp og uten energi.	1	2	3	4
12. Anklager deg selv for ting.	1	2	3	4
13. Har lett for å gråte.	1	2	3	4
14. Tap av seksuell interesse/opplevelse.	1	2	3	4
15. Dårlig appetitt.	1	2	3	4
16. Vanskelig for å sove.	1	2	3	4
17. Følelse av håpløshet mht. framtiden.	1	2	3	4
18. Føler deg nedfor.	1	2	3	4
19. Føler deg ensom.	1	2	3	4
20. Har tanker om å ta ditt eget liv.	1	2	3	4
21. Følelse av å være fanget.	1	2	3	4
22. Bekymrer deg for mye.	1	2	3	4
23. Føler ikke interesse for noe.	1	2	3	4
24. Føler at alt krever stor anstrengelse.	1	2	3	4
25. Føler at du ikke er noe verd.	1	2	3	4

HSCL-25

Appendix 6

RAND-36 Din helse

Spørsmålene under handler om hvordan du oppfatter helsen din. Disse opplysningene vil hjelpe oss til å forstå hvordan du føler deg og hvor godt du er i stand til å utføre dine vanlige aktiviteter.

Hvert spørsmål skal besvares ved å sette et kryss (X) i den boksen som passer best for deg.

1. Stort sett, vil du si at helsen din er:

Utmerket	Veldig god	God	Nokså god	Dårlig
☐	☐	☐	☐	☐

2. Sammenlignet med for ett år siden, hvordan vil du si at helsen din stort sett er nå?

Mye bedre nå enn for ett år siden	Litt bedre nå enn for ett år siden	Omtrent som for ett år siden	Litt dårligere nå enn for ett år siden	Mye dårligere nå enn for ett år siden
☐	☐	☐	☐	☐

3. De neste spørsmålene handler om aktiviteter som du kanskje utfører i løpet av en vanlig dag. Er helsen din slik at den begrenser deg i utførelsen av disse aktivitetene nå? Hvis ja, hvor mye? [Kryss (X) en boks på hver linje.]

		Ja, begrenser meg mye	Ja, begrenser meg litt	Nei, begrenser meg ikke i det hele tatt
a	**Anstrengende aktiviteter** som å løpe, løfte tunge gjenstander, delta i anstrengende idrett	☐	☐	☐
b	**Moderate aktiviteter** som å flytte et bord, støvsuge, gå en spasertur eller drive med hagearbeid	☐	☐	☐
c	Løfte eller bære poser med dagligvarer	☐	☐	☐
d	Gå opp trappen **flere** etasjer	☐	☐	☐
e	Gå opp trappen **én** etasje	☐	☐	☐
f	Bøye deg eller gå ned på kne	☐	☐	☐
g	Gå **mer enn to kilometer**	☐	☐	☐
h	Gå **flere hundre meter**	☐	☐	☐
i	Gå **hundre meter**	☐	☐	☐
j	Dusje eller kle på deg	☐	☐	☐

4. I løpet av de siste fire ukene, har du hatt noen av de følgende problemene i arbeidet ditt eller i andre daglige aktiviteter på grunn av din fysiske helse?

		Ja	Nei
a	Kuttet ned på **hvor mye tid** du brukte på arbeid eller andre aktiviteter	☐	☐
b	**Fått gjort mindre** enn du ønsket	☐	☐
c	Vært begrenset i type **arbeidsoppgaver** eller andre aktiviteter	☐	☐
d	Hatt **problemer** med å utføre arbeidet eller andre aktiviteter (for eksempel at det krevde en ekstra innsats av deg)	☐	☐

5. I løpet av de siste fire ukene, har du hatt noen av de følgende problemene i arbeidet ditt eller i andre daglige aktiviteter på grunn av følelsesmessige problemer (som å føle seg engstelig eller deprimert)?

		Ja	Nei
a	Kuttet ned på **hvor mye tid** du brukte på arbeid eller andre aktiviteter	☐	☐
b	**Fått gjort mindre** enn du ønsket	☐	☐
c	Utført arbeid eller andre aktiviteter **mindre grundig** enn vanlig	☐	☐

6. I løpet av de siste fire ukene, i hvilken grad har den fysiske helsen din eller følelsesmessige problemer påvirket dine vanlige sosiale aktiviteter med familie, venner, naboer eller andre grupper mennesker?

Ikke i det hele tatt	Litt	Moderat	Ganske mye	Ekstremt mye
☐	☐	☐	☐	☐

7. Hvor mye kroppslige smerter har du hatt i løpet av de siste fire ukene?

Ingen	Veldig svake	Svake	Moderate	Sterke	Veldig sterke
☐	☐	☐	☐	☐	☐

8. I løpet av de siste fire ukene, hvor mye har smerter påvirket det vanlige arbeidet ditt (gjelder både arbeid utenfor hjemmet og husarbeid)?

Ikke i det hele tatt	Litt	Moderat	Ganske mye	Ekstremt mye
☐	☐	☐	☐	☐

9. De neste spørsmålene handler om hvordan du føler deg og hvordan du har hatt det i løpet av de siste fire ukene. For hvert spørsmål, ber vi deg velge det svaret som best beskriver hvordan du har følt deg.

Hvor ofte i løpet av de siste fire ukene:

		Hele tiden	Mesteparten av tiden	En god del av tiden	Noe av tiden	Litt av tiden	Aldri
a	Har du følt deg full av liv?	☐	☐	☐	☐	☐	☐
b	Har du vært veldig nervøs?	☐	☐	☐	☐	☐	☐
c	Har du følt deg så langt nede at ingenting kunne gjøre deg glad?	☐	☐	☐	☐	☐	☐
d	Har du følt deg rolig og avslappet?	☐	☐	☐	☐	☐	☐
e	Har du hatt mye overskudd?	☐	☐	☐	☐	☐	☐
f	Har du følt deg nedfor og deprimert?	☐	☐	☐	☐	☐	☐
g	Har du følt deg utslitt	☐	☐	☐	☐	☐	☐
h	Har du følt deg glad?	☐	☐	☐	☐	☐	☐
i	Har du følt deg sliten?	☐	☐	☐	☐	☐	☐

10. I løpet av de siste fire ukene, hvor mye av tiden har den fysiske helsen din eller følelsesmessige problemer påvirket dine sosiale aktiviteter (som å besøke venner, slektninger osv.)?

Hele tiden	Mesteparten av tiden	En del av tiden	Litt av tiden	Aldri
☐	☐	☐	☐	☐

11. Hvor RIKTIG eller GAL er hver av de følgende påstandene for deg?

		Helt riktig	Stort sett riktig	Vet ikke	Stort sett galt	Helt galt
a	Det virker som om jeg blir syk litt lettere enn andre	☐	☐	☐	☐	☐
b	Jeg er like frisk som de fleste jeg kjenner	☐	☐	☐	☐	☐
c	Jeg regner med at helsen min blir dårligere	☐	☐	☐	☐	☐
d	Helsen min er utmerket	☐	☐	☐	☐	☐