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Exercise Clubs to Improve Quality of Life Among Substance Use Disorder Patients

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Objective. This pilot study sought to quantitatively evaluate quality of life changes among patients of substance use disorder (SUD) treatment institutions following participation in coach-led exercise groups. The pilot study also intended to use attendance data and qualitative feedback to assess the feasibility of such an exercise intervention and discuss the potentiality for scaling it up as a larger, adjunct therapeutic intervention.

Methods. 35 residents of four post-acute SUD treatment institutions enrolled in ten-week, low-intensity exercise groups that met for three days each week in half-hour sessions. Before and after the intervention, participants answered the World Health Organization's Quality of Life Brief (WHOQOL-BREF), the Hopkins Symptom Checklist (HSCL-25), and self-report inventories modified from the Norwegian Follow-up Study for Opioid Dependents that measured current substance use and somatic burden. Those who enrolled and exercised were analyzed as *exercisers*, and those who enrolled but did not exercise were analyzed as *non-exercisers.* Quantitative data on attendance was integrated with qualitative feedback from participants and coaches to evaluate program acceptability and feasibility.

Results. Physical health quality of life and psychological health quality of life increased with statistical and clinical significance among exercisers, but not among non-exercisers. Exercise had no impact on participants' social relationships quality of life or environment quality of life. Participants with clinical levels of emotional distress were more likely to exercise than those with sub-clinical levels, as were participants with a greater burden of somatic health problems. Coaches held important roles as motivators in order to engage participants and make the groups accessible.

Conclusion. This pilot study has provided novel, preliminary evidence of quantitative quality of life gains as a result of participation in a coach-led group exercise intervention. Several design elements have been identified for future interventions to replicate and improve upon, such as those that helped engage the most physically and mentally vulnerable participants.

Keywords: Substance use disorder, substance use treatment, exercise, physical activity, quality of life (QoL)

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1. Introduction

1.1 Study relevance

The prevalence and seriousness of substance use disorders (SUD) is a social problem that has repercussions far beyond the individuals affected. The manners in which countries choose to treat – in both the legal and social meanings of the word – persons with SUD can lend to their recovery or not. When a person does receive medical or behavioral treatment, recovery as defined by abstinence is a sparse outcome; relapse rates worldwide are between 60-90% in the first year after treatment [1].

Two important developments in the SUD treatment field have influenced this pilot study: first, the inclusion of outcomes within the concept of recovery besides abstinence, particular quality of life (QoL); and second, an interest in adjunct and/or alternative treatments that focus on improving some of the many physical, mental, and social comorbidities of SUD.

I used promising, pre-clinical research on animals and exercise, best practices from exercise interventions with SUD and other clinical populations, and my own experiences coaching to design an exercise-based intervention for SUD patients in Oslo. I hope that the knowledge arising from this pilot study will provide preliminary evidence as to the efficacy and replicability of an exercise intervention to increase QoL, and that I can provide both Norwegian and American practitioners with modest best practices.

1.2 Research aims

This thesis sought to design and implement, based on best practices from behavioral interventions with SUD patients and exercise interventions among other populations, an adjunct treatment of group exercise for SUD patients, then to measure whether participants experienced changes in their QoL. It is hypothesized that the physical health and social relationships domains of QoL will increase in a dose-response relationship to the amount of participation.

Specific aims include:

1. To describe quality of life and clinical variables of this sample of SUD patients, including differences between exercisers and non-exercisers.

2. To evaluate changes in domain-specific QoL following the pilot study among the exercise and non-exercise groups. To determine if exercise changed any domains of QoL, and if changes were clinically meaningful.
3. To discuss possible explanatory factors associated with QoL changes.
4. To evaluate the feasibility and replicability of this exercise intervention by analyzing who the group appealed to and which activities and factors increased attendance, and document best practices to help improve the design and reduce the attrition rates of a future, larger intervention.

1.3 Substance use disorders

1.3.1 Definition

The term “substance use disorders” (SUD) encompasses *substance dependence*, *harmful* or *problematic use*, and *abuse*. The World Health Organization’s International Classification of Diseases (ICD-10) includes as SUD both substance dependence and harmful use, while the American-produced Diagnostic and Statistical Manual of Mental Disorders (DSM-V) recently removed its separation of dependence and abuse from a SUD diagnosis [2-4]. In the WHO’s Global Burden of Disease report, discussed below, abuse of illicit drugs is called problematic use.

A diagnosis of a SUD according to either definition is made when a patient presents with at least two (DSM-V) or three (ICD-10) symptoms out of a possible seven (ICD-10) or nine (DSM-V). Both definitions include as symptoms risky use/behavior, impaired control, and pharmacological criteria such as tolerance and withdrawal. The ICD-10’s “abuse” symptom is evidenced by “physical or psychological harm, which may lead to disability/adverse consequences”. The DSM-V additionally includes “social impairment”, which the ICD-10 has omitted on the grounds that social consequences are culture-specific and a SUD diagnosis should be as globally relevant as possible [2].

The legality or illegality of the substance is not of importance to diagnostic criteria; rather, symptoms represent recognized impacts of substance use on mental health and psychosocial functioning [5].

1.3.2 Prevalence and population effect

The number of persons suffering worldwide from SUD is unknown, but the World Health Organization’s latest estimation of alcohol use disorder prevalence by region ranges from <1% in Africa to 16% in Eastern Europe [6]. Regional prevalence rates for drug use disorders are estimated to be far lower, from <1% in China, India, and Eastern Europe, to 3% in Eastern Mediterranean countries. The SUD population differs slightly in Norway and in the United States. At any given time, 9% of men in Norway have an alcohol use disorder, compared with 2.5% of women, while 0.4% of men and 0.1% of women have a drug use disorder and 0.14%. These numbers are 5.5% and 2% for alcohol use disorders and 1.8% and 0.6% for drug use disorders in the U.S. [7]. Prevalence is consistently higher for men than women, on a magnitude of seven to three globally for all SUD [6].

Another method exists to quantify the impact of SUD on human life: the Global Burden of Disease estimates the loss of healthy life years due to injury and illness by measuring both years loss to death and years spent disabled, resulting in a single, negative measure of disability-adjusted life years (DALY). Mental disorders and SUD account for 7.4% of the global burden of disease and are the fifth-largest category of DALYs. Among this group, SUD are the second most common cause of DALYs (20.5%), following only depressive disorders (40.5%) [8]. Nearly 13 DALYs per 1000 globally are due to SUD, of which 11 are due to alcohol and 2 to illicit drugs (although only opioid and cocaine are included, and Degenhardt interprets the same GBD data to suggest that drug use disorders account for at least as many DALYs as alcohol use disorders in high-income countries [9]). Europe has the highest regional amount of DALYs (23), followed by the Americas (18) [6].

1.3.3 Comorbidities

There are a number of mental and physical comorbidities associated with SUD. The label "co-occurring disorders" applies to the majority of persons with SUD who also have a mental health disorder (see Flynn and Brown for a review of American and international studies confirming these numbers [10]). SUD patients presenting for treatment display, at most estimates, an even higher prevalence of co-occurring disorders. The two most common are depressive and anxiety disorders followed by personality disorders and stress-related disorders [11-13]; the prevalence of these disorders has been verified among Norwegian patients by Ravndal and Lauritzen [14].

Physical comorbidities are also well-documented. Kearney et al's research in London found that 76% of SUD inpatients and outpatients received at least one physical health problem diagnosis at treatment entry, 51% received at least two, and 31% received three or more. Nearly half of the sample received diagnoses rated "moderate" or "severe", as assessed by the Health Morbidity Scale; the most common moderately/severe problems were cardiovascular, gastrointestinal, liver, and neurological [15]. De Alba's study of SUD patients in Boston found that half of all presenting patients had no primary care relationship, and that these patients had a higher burden of illness and worse physical health compared to the general population. Even excluding those with psychiatric comorbidities, these SUD patients had double the incidence rates of pneumonia, COPD, hypertension, stroke, and diabetes [16]. Sæland reports the magnification of certain physical comorbidities such as malnutrition and being underweight when persons with a SUD are not in treatment [17, 18].

Sæland also argues against the generally accepted opinion that the poor health of persons with a SUD (either in or out of treatment) is due mainly to their substance use [19], a type of blame-the-user approach that often underpins social unwillingness to provide a fuller breadth of treatments. She approaches health status from a nutritional and dietary point of view and asserts that a lack of access to food, particularly to nutritional food, homelessness, and sickness or pathological conditions that lead to nausea or other difficulties eating all lead to health conditions that should be considered as independent to SUD. Connections between nutrition, food content, and diet, "if neglected, can function as counter-productive forces in rehabilitation and treatment efforts."

Pursuant to SUD patients' worse overall physical health, multiple studies have found SUD patients to have lower level of aerobic fitness compared to the general population. Mamen and Martinsen [20] provide of a review of those studies indirectly measuring VO_{2max} (maximal oxygen uptake) and lactate threshold (the amount of physical activity one can undertake before the body produces lactic acid) [21]. Both tests measure endurance capacity, and VO_{2max} additionally measures aerobic capacity.

It is the interaction of SUD, mental health, and physical comorbidities that perhaps presents the greatest challenges in diagnoses, treatment, and outcome measurement. A national, longitudinal study in Finland found that 99% of SUD patients had either a physical comorbidity or a mental comorbidity [22]. Frasch reviews the physical comorbidities [23] associated with different substances among patients with both a SUD and psychiatric diagnosis: alcohol use is linked with injuries, diabetes, hypertension, coronary heart disease, and various cancers; cannabis and tobacco use with many chronic, high-mortality respiratory and cardiovascular diseases; injection drug use with tuberculosis, viral hepatitis, HIV, and skin and soft tissue infections; cocaine use with myocardial infarction and other heart complications; and amphetamine use with cardiac arrhythmia, stroke, renal failure, and hyperthermia. These comorbidities influence and interact with each other in ways that stifle efforts at siloed treatment. For example, Tripp found that physical health predicts treatment outcome for SUD patients with a depressive diagnosis [13]; physical health therefore must be treated on par with these patients' other diagnoses.

1.3.4 Etiology

Researchers', policy makers', and practitioners' understandings of the etiology of a SUD, described as "models of addiction", influence their development and defense of various treatment models and the outcomes measured after those treatments. *The Principles of Addiction* [24-27] provides a thorough overview of different addiction modes, of which I will highlight the most currently relevant and link to associated treatment models.

The moral model is perhaps the original understanding of addiction, and has no empirical support. Persons choose to use, abuse, and be addicted to a substance, and they can also choose to stop. Treatment, if one can call it that, is comprised simply of a person willing themselves into abstinence, and those who choose to continue substance use can be condemned as weak and immoral. The next historical development was the enlightenment/spiritual model, represented by Alcoholics Anonymous and its Twelve-Step program towards lasting sobriety. Substance users are responsible for the development of their addiction, but not for recovery; only submission and discipline to the authority of a higher, external power enables recovery.

The medical/disease model, in which we meet the term "substance use *disorder"*, responds to the moral and enlightenment models by removing both substance use development and recovery from the individual's responsibility, and by instead using scientific inquiry to define what was heretofore known only as problematic behavior. This is the model employed by the DSM-V, ICD-10, and the medical communities that created them, and while still evolving to include causes, particularly neurological, at its simplest defines a SUD as a chronic disease – a physiological pathology – underpinned by biological causes or predispositions that are deviations from the norm. Preclinical and clinical neurological research points towards the mesolimbic dopamine pathway as the reward- and emotion-mediating region of the brain, prospectively assessing both positive and negative experiences via the amygdala, hippocampus, prefrontal cortex, and orbitofrontal cortex [28, 29]. Early neurobiological exploration of SUD established that substance use increased dopamine transmission and thereby created a compulsive drive for further use [29], while more recent research suggests that the sections of the mesolimbic region responsible for restraining impulsivity are also compromised among SUD patients [28, 30, 31]. Substances appear to act, via direct and indirect changes in dopamine transmission, in ways that increase activity in the impulsive system and decrease activity in the executive/inhibitory system.

SUD-related behaviors are indicators and symptoms: tolerance and withdrawal are seen as physiological symptoms and used to measure the severity of a SUD, while cravings and loss of control perpetuate a SUD. The medical model does not presuppose that SUD manifests only along biological dimensions, but acknowledges the social/behavioral, psychological, and spiritual dimensions as well, hence the increasing interest in outcome measurements beyond reduced or eliminated substance use (discussed further in ***1.4 Quality of life***). Both the DSM-V and ICD-10 include reduced or impaired social, family, or work functioning's within diagnostic criteria for a SUD.

Given the understanding of extra-biological factors' involvement in the biochemical expression and development of SUD, Kincaid and Sullivan argue that the model espoused by the DSM-V and ICD-10 cannot be defended as a pure medical model [30]. A pure medical model would not include symptoms that rely on social conventions, such as "important alternative pleasures or interests given up or reduced" [2], which, they assert, borrow from the social model of SUD, and it would contain at least one diagnostically necessary physical condition. Indeed, much of how a SUD is understood to develop among the medical community bears similarities to the biopsychosocial model, which claims to not overstate the importance of biological factors when considering how "biological, genetic, personality, psychological, cognitive, social, cultural, and environmental factors interact to produce the SUD" [27]. The biopsychosocial model strives to include personality variables, learning conditions, cognitive processes regarding outcome expectancies and self-efficacy, peer and family pressure, and environmental factors as all equally important to the expression of a biologic predisposition to a SUD.

Much of the criticism of the medical model from the biopsychosocial model camp is that the former fails to address multiple extra-biological factors in prevention and treatment programs [27]. For the purposes of this review, adherence to one or the other models is unnecessary. No researcher espousing a medical model understanding of a SUD denies the influences of, for example, substance availability (i.e. environment), and neither would she support a treatment program that did not in turn support a person in recovery from finding a sober-living house and undergoing cognitive-behavioral therapy. At the same time, participants qualified for this pilot study in part by their treatment institution's diagnosis of a SUD according to the ICD-10 (see ***2.3 Sample***).

1.3.5 Recovery

Treatment, Laudet reminds us, has as its number one priority the advancement of a SUD patient's recovery [32]. But in light of the overlap of the medical model's neurological basis for SUD and the biopsychosocial model's interest in psychological and social factors, it has proved problematic for researchers to decide what exactly recovery from SUD includes: abstinence, full or partial? Abstinence or reduced use of only the substance with which a patient received a SUD diagnosis, thereby allowing for medication-assisted therapy such as opioid replacement therapy, or from all psychoactive substances? Improvement in concurrent emotional, mental, or physical health? Improvement in any of the wide range of functions that are also negatively affected? Can recovery be achieved in gradients, or is it a complete state? As recently as 2007, White claimed in *The Journal of Substance Abuse Treatment* that claimed the SUD treatment field had no clear definition of "recovery":

> It is not surprising in the face of such confusion that researchers tend to avoid the term, clinicians and mutual aid advocates use the term but with different meanings, and the public tends to understand recovery as an attempt to resolve, rather than the successful resolution of, [SUD]. [33]

The legacy of various etiological models of SUD are the treatment modals they employ, the post-treatment outcomes they measure, and particularly their definitions of recovery. The heavily-American moral model, advocated by the American medical establishment even after the failure of Prohibition, lead the World Health Organization to enshrine abstinence as necessary in recovery from alcoholism. Problematic substance use and recovery were dichotomous states.

The World Health Organization performed a "complete turnabout" in policy in 1980, prompted by pressure from European countries to address the HIV/AIDS epidemic among injecting drug users [34]. The harm reduction strategy was developed as an alternative to abstinence-only treatment and with attention to reducing adverse consequences of SUD, including patient mortalities and morbidities, and on measuring social, economic, and health outcomes instead of substance consumption. Van Wormer suggests that a harm reduction approach reflects an understanding of substance use as existing on a continuum, rather than a clear line dividing normality (health) from abnormality (SUD), and thereby relinquishing abstinence as a prerequisite of recovery. However, the UN Office on Drugs and Crimes is keen to support harm reduction as a strategy for all definitions of recovery, “whether your organization agrees or not that the ultimate goal for substance use treatment should be abstinence, drug use control, or both” [35]. In the UNODC’s white paper on harm reduction – published after White’s charge that the concept of “recovery” is both avoided and poorly defined – this word is not used once.

The US government’s evolving definition of recovery reflects the movement away from abstinence-as-prerequisite. Recovery according to the Substance Abuse and Mental Health Services Administration has been updated thrice since its 2005 definition of “abstinence and improved health, wellness, and quality of life” [36]. The first two revisions removed abstinence and defined recovery as a “process of change”, and the final revision reintroduced abstinence as an example of an improvement in health. Recovery is now “a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential.” This process is supported by the dimensions of health (e.g. abstinence; overcoming or managing disease/s or symptoms/), home, purpose (including individually selected social roles), and community [37].

The Norwegian Directorate of Health describes recovery in a similarly holistic manner, but does not mention abstinence:

> The goal is to find the patient's own resources when it comes to finding meaningful activities, getting a job, increase their social network, solving economic and housing needs, in order to increase quality of life and self-esteem. The person's own resources must be supported during the course of treatment in such a way to increase quality of life. (my translation) [38]

Recovery is defined by the Directorate as “the goal of overall improvement of quality of life”. Operationally, the *process* of recovery is also central, and the importance of social support in this process is perhaps given more weight than in the United States. Researchers from the Norwegian Center for Addiction Research set out to define a model of recovery and developed a “positive identity model of change” that focuses on social support given from a supporter to a recoverer [39]. In this model, a person with a SUD recovers when, over time, the supporter and the recoverer create a context in which the recoverer can build a positive self-identity that the supporter is able to affirm: “Recovery programs should entail opportunities for personally meaningful activities that can be socially shared.”

If SUD are understood as progressive and chronic (i.e. reoccurring) conditions [40, 41], recovery can understandably be a process with a similarly long duration and perhaps cyclical achievement.

1.3.6 Salient outcomes of treatment effectiveness

Many researchers have pointed towards the empirical difficulties of measuring recovery. For example, medication-assisted recovery such as opioid replacement therapy illegitimates abstinence-only recovery experiences. Only patients themselves can report improved quality of life or well-being, necessitating another layer of reporting. Thylstrup admits that "the recovery paradigm has thus been criticized for possibly contributing to the variability and confusion of outcome measures in substance abuse treatment" [42]. The addiction research field has not, as of yet, adopted any core set of outcomes [32, 43]. There is a further heterogeneity of measures and methodology even within shared outcomes. Tiffany et al reproach researchers for this failing, saying that it not only discourages further attempts at the adoption of a shared battery of outcomes/measures, but that it leads to an extreme amount of measures, and measurement decisions often occurring on a study-by-study, ad hoc basis [43].

The most consistently reported primary outcome is abstinence or its inverse, substance use. Tiffany et al argue that this outcome is an insufficient measure by itself, because SUD have negative consequences that are not "tightly coupled" to the amount of use. Interestingly, they suggest outcomes that Thylstrup labels "traditional" and belonging to a pre-recovery-orientation, such as employment and crime. These outcomes are understandable to communities and represent easily recognizable social consequences, and therefore may increase community support. Emergency room visits are an example of a health-related outcome that is considered socially salient. Other common health outcomes include reductions in depression or anxiety, other mood measurements, and a decrease in cravings.

Tiffany et al – presenting as a working group recommendations of clinically meaningful outcomes to the United States National Institute on Drug Abuse in 2011 – recommended five criteria for treatment outcomes:

1. the outcome is a consequence or a "strong, concurrent correlate" of a SUD;
2. the outcome is clinically and socially salient and relevant;
3. the outcome is widespread, and not limited to a single substance;
4. the outcome can be assessed via measures that have documented, strong psychometric properties; and
5. replicable evidence exists that SUD treatment can alter the outcome.

Using these criteria, the working group recommended as outcomes of all clinical SUD treatment trials: changes in quality of life, self-efficacy, craving, psychosocial functioning, and social network / social support.

A review of outcomes reported in SUD treatment follow-up studies in the US in the 1990s found that 72% of alcohol studies and 82% of drug studies measured at least one non-substance outcome [44]. At least 40% of alcohol studies measured either emotional, legal, vocational, physical health, or additional treatment outcomes. Drug studies were more likely to measure non-substance outcomes, but outcomes were more heterogeneous. 38% measured mortality, while only one-fifth measured either vocational, physical health, "additional treatment", or social/recreational outcomes. Psychological tests and residential outcomes were collected with the least frequency (among 4-7% of studies). This review concludes that both types of studies suffer from a lack of uniformity in measuring and reporting outcomes, and "a set of standard outcome measures would greatly increase the methodological rigor and comparability" of drug studies in particular.

1.4 Quality of life

1.4.1 Overview

The World Health Organization defines QoL as:

> "Individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns." It is a broad ranging concept incorporating in a complex way the persons' physical health, psychological state, level of independence, social relationships, personal beliefs and their relationships to salient features of the environment. [45]

QoL is a holistic ("multidimensional", in the WHO's words) measurement that seeks to account for the whole person, in accordance with the WHO's understanding of health as more than an absence of illness.

Importantly, this self-evaluation is embedded within an individual's cultural context, making it more complex than other measurements of "well being" or "life satisfaction". It is relevant to both sick and well people and has been a major outcome in health care since the 1970s [46]. Moons and others suggest that the health care focus on QoL among high-income countries arose as life expectancy increased, diagnoses of chronic but treatable conditions increased, and medical technologies improved, measures beyond mortality and morbidity were developed to evaluate treatment effectiveness [47]. QoL also moves beyond disability or functionality status, perceived health measures, and measures of disease/disabilities' impact on daily life [45].

Higginson and Carr [48] discuss QoL measurements as holding a vital communicative role in clinical practice. Patient problems and preferences beyond the disease being treated are identified and prioritized by the patient, facilitating communication between patient and provider, and providers are able to monitor changes and/or responses to treatment. QoL measures can also be used in clinical audits and clinical governance to improve treatment quality.

1.4.2 Salience to SUD

By the early 1990s, alcohol studies had regularly assessed QoL as an outcome, but drug studies were only beginning to collect QoL (although QoL was assessed by nearly all alcohol and drug studies involving dual-diagnosis patients) [40].

As reviewed earlier, the addiction field recognizes SUD as a preventable and treatable chronic condition [40, 41] that affects a wide range of patient functionings as well as physical and psychological health, relationships, and environment. This understanding is reflected in the numerous studies that report consistently lower QoL among the SUD population compared to the general population [11, 43, 49]; one twin study even held for physical and psychiatric comorbidities, combat status, income, marital status [50]. The relationship between SUD and QoL could exist in multiple directions: the detrimental effects of a SUD decrease QoL; a SUD develops after self-medicating substance use caused by attempts to increase QoL; or SUD patients' comorbidities or other characteristics that develop before, after, or concurrent to a SUD are the main affect on QoL [40]. (That there is a definitive association between comorbidities common to SUD patients and low QoL is undisputed, but the role of these comorbidities in the development of SUD is undetermined.) Laudet points out that the number of substances and severity of SUD are more strongly associated with low QoL than the length of SUD, age at onset, prior withdrawal distress, and amount of prior treatments, which are all commonly used measures of dependence [51]. The complexity of SUD regarding causes/determinants, individual symptoms and effects, and social repercussions speaks to the need to address SUD in an appropriately holistic way.

Poor QoL is both a determinant and outcome of SUD. It can therefore be used in both diagnostic and predictive capacities in the context of treatment. Diagnostic in that QoL assesses the "lived problems" of SUD better than measuring SUD severity [40], and by requiring/validating patient experiences, captures aspects of disorder and treatment that clinicians miss. Laudet also argues that low QoL indicates treatment readiness, as people with a SUD attempt to quit or reduce use "not as an end in itself, but as a means to escape these negative consequences and to gain a better life" [51]. These negative consequences deserve as much attention in and after treatment as substance consumption itself, and QoL measurements allow the patient to appraise her perceived functionings as well as her satisfaction with each level of functioning, thereby recognizing the negative, multidimensional effects of SUD in a patient's life [52, 53]. There is also some evidence that QoL at treatment completion can predict sustained remission [32, 53], on top of stronger evidence that QoL itself increases over the course of treatment [43, 54, 55].

1.4.3 Measures

The SUD field is slowly catching up to the rest of the medical field in treating QoL as a clinical outcome, but there exists heterogeneity in the different QoL constructs among this population. One construct is health-related QoL (HRQoL), an assessment perceived limitations to mental and physical well-being/functioning due to disease [56]. The Short Form 36 Health Survey and the 12-item abbreviated version common measurements of HRQoL, although some classify these tools as measures of general health status [57].[1]

Laudet advocates for a second construct, "generic" or "overall" QoL, as the most appropriate QoL outcome for the SUD population [51]. Overall QoL encompasses the physical and mental domains measured by HRQOL in addition to social relationships, religion/belief/spirituality, level of dependence, and living environment, such as housing and finances. More than HRQoL, overall QOL attempts to provide an insight into all areas of respondents' lives. Laudet argues that as SUD affects "nearly all areas of functioning," measuring OQOL and its improvements helps "capture the full impact of a medical condition and recommended treatment on an individual" [51]. The WHO's Quality of Life Assessment (100 or 26 items), Quality of Life Scale, and Life Situation Survey are common measurements of overall QoL.

Several substance-specific measures have also been developed, including the Injection Drug User QoL Scale [58] and the Health-Related Quality of Life for Drug Abusers Test [59]. These measures have only been validated among English, American,

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[1] *QoL* is often used interchangeably with *health*, and the WHO's broad definitions of both terms perhaps contribute to this conceptual ambiguity. The WHO defines health as "a state of complete physical, mental and social well-being and not merely absence of disease or infirmity" - the most noticeable difference between that and QoL is the latter's requirement of self-assessment. Both definitions appear to include each other as determinants or indicators, despite multiple meta-analyses' conclusions that QoL and health are separate concepts [see Hubley].

Canadian, and Spanish populations, and as their names suggest, do not measure global QoL for all persons with a SUD.

QoL may change with statistical significance as a result of an intervention, but it cannot be assumed that patients notice that change or that the change impacts them in any meaningful way. The former does not lead to the latter, Jones argues: even if the change is noticeable, measuring "just-noticeable change" does not confer meaningfulness [60]. The concept of a *minimal clinically important difference* (MCID) describes a minimum threshold of change above which a patient would consider a change in their QoL relevant [61, 62] and would consider repeating the intervention again [63]. MCID demonstrates the difference between statistical significance and clinical significance [64, 65]. Clinical trials and other pre/post studies provide changes in population means, or population-level differences in an outcome, and statistical analyses reveal whether the difference can be likely attributed to the intervention. "However, patients are not interested in knowing population-level differences. Rather, they wish to know the likelihood that they will experience a meaningful improvement for the risk they take with an intervention (ie, 'Is this change meaningful to me?')" [64]. Clinical significance can occur with or without statistical significance, and can be measured by the MCID.

1.5 Exercise and physical activity

1.5.1 As public health prescription

Exercise is largely considered an intentional subset of *physical activity*, the latter of which encompasses any bodily movement that expends energy [66]. While physical activity may be conducted without attention to physical improvement, or as a means to another end – such as walking to work or cleaning a floor – exercise is planned, structured, and conducted with a goal of maintaining or improving physical fitness. Nevertheless, as the two terms are often used as synonyms even within the research community, I review studies using both.

The WHO identifies physical inactivity as the fourth leading risk factor for global mortality [67]. Warburton et al's literature review of articles and meta-analyses involving the health benefits of physical activity concludes that there exists "irrefutable evidence" that physical activity plays an effective role in the primary and secondary prevention of premature death and several chronic diseases. The authors proffer a range of biological mechanisms that support this role, such as improved body composition, enhanced lipid lipoprotein profiles, reduced blood pressure, reduced systemic inflammation, improved glucose homeostasis and insulin sensitivity, improved autonomic tone, decreased blood coagulation, improved coronary blood flow, strengthened cardiac function, and enhanced endothelial function. These adaptations, which are not limited to regular physical activity, are of global benefit to multiple and individual disease states, specifically, cardiovascular disease, some cancers, diabetes mellitus, depression, osteoporosis, obesity, and hypertension [68]. Cardiovascular fitness measures improve in a dose-response relationship with physical activity [67].

Psychological gains deserve further explanation. Numerous cross-sectional and population studies have documented the association between exercise and better "mental health" [69, 70], a term that is often a proxy for the combination of depression and anxiety, indicative of any psychiatric diagnosis by the ICD or DSM, representative of mood or well-being, or reached by a particular score on a mental or emotional distress scale. Inversely, physical inactivity appears to be a factor in the development of depressive and anxious symptoms.

Depression is currently projected to be the second highest cause of the global illness burden by 2020, beyond coronary heart disease, due to the mortality, morbidity, and disability it causes; it currently causes the largest amount of non-fatal burden [71]. Exercise reduces depressive symptoms among individuals with major depression, as well as among well populations and the chronically ill [69, 72, 73]. Longitudinal studies have also confirmed that exercise protects depressive diagnoses after holding for variables such as age, sex, socioeconomic status, and health status [74]. One RCT found exercise to be as effective as pharmacological treatment in reducing depressive symptoms compared to a placebo [75]. Regular exercise also seems to protect against anxiety disorders in large, cross-sectional studies [70, 76]. Unlike depression, exercise does not appear to alleviate anxious symptoms to the same extent as pharmacological treatment. Exercise is still more effective than no treatment, and reduces anxious symptoms among well populations and those diagnosed with an anxiety disorder.

Cotman et al [77] suggest that exercise promotes mental health through directly and indirectly improving brain health in protective and therapeutic ways. Exercise directly improves cognition, plasticity, neurogenesis, and vascular function through the regulation of growth factors [78]. The molecules particularly explicated in neurogenesis that are affected by exercise are serotonin, β-endorphins, brain-derived neurotropic factor (BDNF), and vascular endothelial growth factor. (Exercise also reduces peripheral risk factors to the brain, most notably diabetes, hypertension, and cardiovascular disease, through reducing inflammation, which is the mechanism by which these disorders interfere with growth factor.) Many neuroadaptations are found in the same areas that undergo critical structural change during periods of depression and anxiety [73, 79]. For example, while exercise and antidepressants increase hippocampal volume, depression decreases it. Exercise increases levels of BDNF in the hippocampus, which decreases anxiety as well as protects against depression.

1.5.2 Relationship to QoL

In the past decade, exercise has also been explored among healthy and chronic disease populations as a way to increase QoL, thanks in part to exercise's conclusive positive health effects, and to the wealth of cross-sectional studies verifying the association between a physically active lifestyle and higher QoL [80-86]. Meta-analyses of longitudinal exercise interventions among healthy and clinical, non-SUD populations confirm that the physical and psychological domains of QoL improve after subjects undergo an exercise intervention [46, 87-90]. Sawatzky even suggests that it is exercise that mediates the negative affect of chronic conditions on older adults' QoL [86].

Explorations of a dose-response relationship between exercise and QoL are less common [83, 85, 89]. Reviews of cross-sectional and cohort studies, as well as the sparse longitudinal studies and RCTs suggest a tenuous dose-response relationship. One of the only randomized experiments to measure exercise dose and QoL is Martin et al's 2008 study [89]. The authors found a consistent dose-response relationship, but emphasized that even the lowest exercise dose (50% of the American government's physical activity recommendation, or 74 minutes a week), were associated, with statistical significance, with increases in seven out of eight measures of previously sedentary participants' mental and physical QoL. Martin et al note, "it is also of interest that physical activity–induced changes in QoL were independent of changes in fitness, suggesting that changes in fitness are not required for physical activity–induced improvements in QoL". Gillison et al's meta-analysis found that a dose-response relationship was potentially mediated by health status: well patients and patients exercising as a part of a disease management scheme experienced greater QoL gains the more they exercised (or the more intense their exercise program), whereas patients exercising for rehabilitative purposes benefited more from light over moderate or vigorous exercise [46].

The mechanisms by which exercise positively affects QoL are unknown. Elavsky's work among older adults has tested the mediating effects of self-esteem, self-efficacy, and positive affect on HRQoL. In one study, the direct effect between physical activity and HRQoL approached significance, but only positive affect was significantly increased by physical activity and then significantly increased HRQoL [88]. This finding contradicts Rejeski et al's findings that self-efficacy was the mediating agent between physical activity and HRQoL [52] and Phillips et al's findings through their longitudinal study that "the indirect effect of increases in physical activity on increases in QoL was significant only via changes in self-efficacy and physical self-worth" [91]. An earlier paper co-authored by Elavsky found physical activity and affect both mediated self-esteem [92]. Among cancer patients, a group of chronically ill for which exercise is often studied and HRQoL often measured, fatigue and stress/distress have been consistently found to be mediators [93]. It is important to note that most studies examining mediators of QoL have in fact focused only on HRQoL, with some suggesting that HRQoL is a subset and influencer of overall QoL [94]. Taken together, evidence points to a wealth of psychological outcomes that to various degrees mediate exercise's positive affect on QoL.

1.5.3 Salience to SUD

The American National Institute for Drug Abuse describes eighteen evidence-based components of comprehensive SUD treatment, and exercise is conspicuously absent [95]. This belies the frequency with which SUD treatment institutions appear to organize informal, unmeasured exercise schemes in both Norway and the U.S. Exercise is consistently found to have an inverse relationship with SUD, yet the causality in this relationship has been explored primarily on the preclinical level [96]. There are three possible causal relationships: first, an external factor could lead to lower exercise and higher substance rates, such as an element of the home environment, personality trait, or comorbidity. Second, substance use could causally decrease exercise, due to the time and resources substance use requires and/or to the adverse aerobic effect substance use has on users. Third, exercise could causally reduce substance use.

Preclinical evidence suggests that exercise bears striking similarities in neurological and behavioral consequences to substance use [96-101]. Both substances and exercise are positive reinforcers among humans and animals, activating the reward pathway through increases in dopamine concentrations and in dopamine receptor-binding. Additionally, exercise normalizes the signaling of other neurotransmitters pertinent to SUD (e.g.

norepinephrine and glutamate), and blocks and reverses some neuroadaptations in the mesolimbic region that develop in the maintenance of SUD, such as by dampening higher-receptivity among the opioid receptor system. Regarding SUD's inhibitory effect on the executive system (see ***1.3.4 Etiology***), exercise enhances the abilities of the hippocampus and prefrontal cortex to resist compulsive patterns of substance use via neurogenesis and gliogenesis. Among animal studies examining all phases of substance abuse – acquisition, maintenance, escalation, binge/compulsive use, and relapse/reinstatement – voluntary and involuntary exercise reduces the self-administration of cocaine, stimulants and opioids. (Fewer preclinical studies have reported on alcohol, and the evidence is mixed.) Human studies show the same results for nicotine and cannabis [102, 103].

Behaviorally, exercise reduces the relative reinforcing strength of substances and serves as an alternative, non-substance reinforcer to substance self-administration [96]. Exercise reduces negative affective states that have been identified as "initiating, maintaining, and accelerating" SUD [96]; for example, exercise decreases comorbid risk factors that lead to substance craving and relapse, such as depression, anxiety, and reactivity to stress [100]. Exercising subjects also consume fewer substances as a way of coping with stress. Exercise promotes positive effective states that are associated with low SUD and possibly protect against SUD, including QoL, as discussed above, self-efficacy, and self-esteem [104]. Exercise can also serve as a positive, non-substance activity, which patients recovering from SUD are in sore need of [105]

Finnish longitudinal twin data shows the protective effect of adolescent exercise against substance use in young adulthood, even when holding for familial factors [50]. Exercise has accordingly been used as a preventative measure, particularly among youth and other at-risk groups [106, 107]. Exercise has been introduced both adjunctly to and after treatment in order to decrease substance use, support abstinence, and improve substance use outcomes. Several studies suggest that physically active patients are significantly less likely to relapse than those who are sedentary [1, 105, 106, 108], while randomized control trials provide convincing evidence among the nicotine-abusing population [102, 104].

Exercise in the treatment setting often has additional goals. Most directly, exercise is used as a remedy for patients' typically dismal physical conditions, particularly cardiovascular health [105, 109], although numerous other chronic disease sufferers can enjoy definitive health improvements [46]. Symptom management or reduction is often a specific goal, and reductions or improvements in psychiatric comorbidities can be included here. Exercise-induced improvements in psychological outcomes within mood management, anxiety and depression, and improved resilience factors such as self-confidence have also been identified as factors leading to high SUD treatment adherence [109].

While attrition rates in exercise programs are no better than overall SUD treatment attrition rates, patients seem to be positive to the opportunity of group exercise. Recent Norwegian data confirms that SUD inpatients report a significant drop in activities, including physical activities, after the onset of a SUD, and that this drop is negatively associated with their reported well-being. Physical activity was the most commonly reported lost activity and the most commonly desired activity [110]. In the U.S., Read et al found that 75% of outpatients of an intensive alcohol treatment program expressed interest in an exercise scheme tailored to those with a SUD, with two-thirds selecting both walking and strength-training as activities they would enjoy [111]. Similarly, 95% of another substance abuse outpatient program reported interested in exercise targeted to them, and 75% identified walking as one preference and another 37% identified strength-training [112] . While those in treatment or recovering from a SUD are typically of markedly poorer physical condition than the general population, only three percent of participants Read et al’s study reported that their “poor physical condition” would be a barrier to exercise.

1.5.4 Best practices from exercise interventions

There is a wealth of literature published on determinants of adherence to exercise interventions, but far fewer analyses of adherence- and acceptability-maximizing factors of such interventions exist. Most literature reviewed applies to interventions engaging healthy or chronically ill populations, and the handful that involves SUD patients will be highlighted.

Group exercise appears to be more beneficial than individual exercise. Two meta-analyses have concluded that adherence to group- and facility-based interventions is higher than adherence to individual- and home-based programs [113, 114], possibly due to a consistent schedule and peer accountability [115]. If exercising in a group encourages adherence, then participants receive higher doses and longer durations of treatment, a hypothesis that seems to be confirmed by another meta-analysis of exercise interventions’ effect on QoL that finds improved QoL among healthy and clinical populations that exercised in groups but not among those with home-based or individual regimens [46]. Home-based training has the further drawback of being unsupervised, and adult participants have been found to consistently over-report the length and intensity of physical activity conducted individually [116].

The socialness of group exercise may add to positive neurochemical benefits. University of Oxford researchers recently found that pain tolerance, a noninvasive measure of endorphin production, was twice as high among subjects who performed an exercise session in a group compared to subjects who completed the same session alone [117]. While their sample was small, they suggest that physical group activities stimulate endorphin production, and that this endorphin release plays a role in social bonding as well as having a documented analgesic effect.

A meta-analysis of 11 RCTs using financial incentives as part of exercise interventions concluded that incentives improve exercise adherence in the short-term (less than 6 months) [118].

Perhaps the best design suggestions for this pilot study are surveys of exercise preferences among SUD patients. In these surveys, sedentary SUD patients identify nearly identical barriers to exercise as healthy populations: high perceived costs of equipment and facilities, low motivation, lack of transportation, lack of time, and low perceived social support [111, 112, 119]. The attributes of an exercise program may also prove problematic for some participants. For example, despite some evidence for a dose-response relationship between amount of exercise and QoL benefits, small studies such as this must also balance the potential decrease in adherence that accompanies increased intensity [120] and dose [113].

2. Methods

2.1 Theoretical assumption

I am approaching this project as a post-positivist. The vast majority of SUD and evidence-based research in general is constructed with an evidently positivist epistemological commitment: substance use, misuse, and abuse are evident and measureable by researchers through the diagnostic tools of the DSM or ICD, levels of exercise are similarly quantifiable, and so on. To a large extent, I am not questioning the truthfulness of such measurements.

My hypothesis, that exercising participants will have experienced changes to the physical health and social relationships domains of their QoL over the course of this intervention, includes multiple post-positivist assumptions that must be acknowledged. First, that the changes they experience are positive, that is, that participants themselves observe changes and will report them, given the correct reporting tools and asked the "correct" questions. At the same time, while I will defend my selected QoL tool as globally validated and cross-culturally sensitive in ***2.6 Measures***, it cannot possibly be purported to be an exhaustive measure. In Schwandt's words, "the language of science is irreducibly metaphorical and inexact," and thus cannot be expected to capture the inexactness of reality itself [121].

A second hallmark of post-positivism is the acknowledgement that "science consists of research projects or programs structured by presuppositions about the nature of reality" [121]. The researcher must be reflexive as to her impact on the design, implementation, and analysis of a project. I am keenly aware that my career in homelessness policy, wherein there exists some overlap with the field of addiction, my personal background as an athlete, and my experience with a running club for a similarly disadvantage group have, among others, shaped this study design and expectations. I chose primarily quantitative methods with validated measures in an attempt to exclude my presuppositions as much as possible. This is not to say, however, that quantitative methods bring me closer to an objective researcher ideal: "All our observing is done within a horizon of expectations and is therefore necessarily selective" [122].

The choice to make the bulk of analysis in this pilot study quantitative was also prompted by my intention to optimize cross-cultural transferability of knowledge, that is, to make even a modest claim of generalizability from Norway to for example the United States. I approached this study design with a goal of producing knowledge that would be useful also outside of the Norwegian context, and in order to limit the translation and re-translation of qualitative data and analysis, (ostensibly) supra-linguistic quantitative data seemed most desirable. That my interpretations and translations of qualitative information could be error-full is a particularly salient concern, given that I conducted this pilot study in a language and country that I had learned and lived in for less than one year. Relying on my ability to construct a narrative with participants by "disrupt[ing] the predictability that can occur in traditional interviews" would be to dangerously ignore the linguistic and cultural barriers between us, that is, the existence of discourse [123].

The subjectivity of the quantitative data I collected is also of methodological significance. The choice to collect QoL assessments privileges the knowledge of the participants themselves. I worked with a group of individuals that includes those engaging in extralegal activities (i.e. illicit substance use), deprived in most countries of the right to treatment and health care for such behavior, and mistrusted as an aggregate and as individuals. Their opinions are mistrusted for falseness, their motives are mistrusted for taints of addiction, their behaviors are mistrusted as symptoms, and their judgment is mistrusted as skewed. I trusted them with the ability to judge the quality of their own lives, and I did not verify these assessments against medical professionals' evaluations or adjunct measures of quality, such as decreased substance use. I have collected adjunct medical data, but this is to provide a fuller picture of the sample's characteristics and the changes they experienced throughout the study, and not to strengthen or prove findings about participants' own judgment of their quality of life.

In some ways, this choice could be viewed as an attempt to empower marginalized perspectives and their "distinctive, and discrepant, epistemological frameworks" [124], and indeed, I hope that participants will appreciate my technique of relying on their own knowledge. But any empowerment ends at this knowledge source – ultimately, I am treating participants as knowledge *sources*, not knowledge *makers*, thus excluding myself from a constructionist paradigm. Hammersley would see this methodology as an attempt to avoid creating etic-centric theory, a technique often employed by post-positivists as a response to intra-paradigmatic criticisms [124]. It is for this reason that I identify them as *participants* and not *subjects*. I am not asking participants for their own interpretations, or for knowledge in their own words. I am giving them questionnaires to indicate their agreement or disagreement with. (These questionnaires could perpetuate inequalities based on gender, race, socioeconomic status, SUD state, and others. A full analysis of such potential inequalities is not within the scope of this project, yet addressing their potentiality is required.) I will judge the quality of my project by "conventional benchmarks of 'rigor'", namely internal validity, external validity, and reliability [125].

The qualitative data collected is limited to that needed for a low-level process evaluation: what worked, what did not work, and whether the overall experience was positive or negative. A content analysis is performed on spontaneous and structured feedback participants during and after our sessions, in order to learn more about feasibility of the intervention.

2.2 Setting

The pilot study ran between August and November 2013. Study sites in Oslo were included after outreach from October 2012 to July 2013. Each site was an intensive residential program that treated patients with a SUD in the post-acute/post-detoxification phase. All four sites provided housing and supportive services such as on-site psychologists, psychiatrists, group therapy, group activities and outings, and some meals, as well as linkages to occupational training and continuing education. The table below shows the characteristics of the participating four institutions.

Table 2.1 Participating site characteristics

	Public/ private	No. of residents	Opioid replacement therapy	Residents' SUD profile	Expected length of stay
Site 1	Private	28	No	Mix	1-2 years
Site 2	Public	18	Yes	Mix	1-2 years
Site 3	Public	23	No	Mix	1-2 years
Site 4	Public	33	No	Alcohol	> 2 years

I and the second coach met with each group of participants at their institutions. The majority of sessions utilized on-site facilities, such as weight-lifting equipment, and freely accessible outdoor facilities within one kilometer, such as local parks, running paths, and sand volleyball courts.

2.3 Sample

Participants were recruited during 30-minute presentations in each institution. In institutions 1 and 2, I recruited only among a group that was already interested, while in institutions 3 and 4, I recruited among a majority of residents during mandatory resident meetings. 50 individuals were recruited, of which 35 enrolled and provided baseline data, and 31 provided data at the study's end.

Inclusion and exclusion criteria. Inclusion criteria, as measured on the screening tool, included: a) between the ages of 18-65; b) self-identification as sedentary, i.e. having not exercised for more than 20 minutes a day, three days a week, for the past six months; c) a recent history of a SUD, as demonstrated by participants' residence in the institutions; and d) ability to give informed consent. The only exclusion criterion was self-reported pregnancy or intent to become pregnant in the next ten weeks.

Comparison group. A comparison group was supposed to be established to attempt to exclude any effect arising from the non-intervention treatment itself during the 10 week exercise program. The comparison was intended to be comprised of patients and residents at each site who completed the screening tools and answered the QoL instrument both before and after the pilot study but chose not to participate in the exercise groups. Only three residents out of a goal of 30 were recruited into the comparison group. Instead of abandoning the data from these three residents, I have added them to the eight who enrolled in the exercise group but never attended a session, and I have analyzed this group of eleven as "non-exercisers". Non-exercisers received the same incentives at start-up, answered the same tools at baseline and follow-up, and took part in the follow-up data collection dinners. See ***2.7 Analysis*** for further discussion.

2.3.1 Ethics and consent

The study protocols and procedures were approved by the Norwegian Regional Committee for Medical and Health Research Ethics. Institutions were supplied upon request with the study design and questionnaires before recruiting residents.

Study participation did not interfere with or eclipse institution-provided services. The main points of the consent forms were repeated verbally to all residents during recruitment, namely: 1) withdrawal was possible at any point in the study; 2) injuries were possible, although unlikely; 3) muscular soreness was likely, although not dangerous; and 4) the data provided by participants would not be made available to their institutions, and would be anonymous during data analysis and in the final report.

2.4 Hypothesis

The only hypothesis tested in this pilot study is related to the second research aim, which is to determine if the exercise intervention had an effect on QoL:

H_0: QoL does not change after participation in an exercise intervention.

H_1: QoL changes after participation in an exercise intervention.

2.5 Intervention

2.5.1 Type

The pilot study engaged participants in each institution in aerobic exercise and strength-training sessions as a group, led by myself (institutions 1-3) and a trained, hired coach (institution 4) who I supervised for one-third of the program. Each institution began with a loose schedule that assigned, for example, ball sports on Mondays, running on Tuesdays, and circuit workouts on Thursdays. The social aspect of the intervention was highlighted through the tagline of the program, “a social, laid-back exercise club for those with a substance use history” [en sosial, lavintensiv treningsklubb for de med rusbakgrunn], and each session’s structure. Sessions began with the coaches thanking participants for coming and saying, “All of us are strong, and we can only get stronger” [Vi er allerede sterke, og kan bare bli enda sterkere].

2.5.2 Duration, dose and frequency

Each intervention site provided participants with ten weeks of low-intensity aerobic exercise, a duration attained by averaging the duration of 32 studies in Zschucke et al’s meta-analysis investigating the relapse effects of exercise interventions among subjects in treatment for nicotine, alcohol, or illicit substance abuse and dependence [126].

A variety of methods exist that could have been used to ensure participants exerted themselves to a specific degree, such as self-measured heart rates or Perceived Rates of Exertion [127]. However, these were abandoned in fear that prescribing a particular amount of exertion would deter participants who self-reported as sedentary and as having a large number of health problems. The focus was instead on completing the activity itself within 30 minutes – e.g. three sets of sand volleyball, one 3.2-kilometer lap around a lake, abdominal exercises to music – and participants were encouraged to push themselves, but also allowed to rest or stop at their discretion. 30 minutes was rounded down from 36 minutes, an average of Zschucke et al’s 32 studies. A three sessions/week prescription is again based on an average of studies’ frequencies (3.45) reviewed by Zschucke et al [126] .

2.5.3 Safety

I and the coach were certified in basic First Aid. I carried a small amount of bandages with me to each session, while institution 4 kept full First Aid kits on-site, where all of the sessions were held. With one exception – one institution’s weekly runs around a lake that required a subway trip – all sessions were held either on-site or in the very near vicinity of the institutions, and any safety concerns could be immediately relayed to institution staff.

2.5.4 Volunteers and other participants

The original goal of a one-to-one volunteer-to-participant ratio, for the sake of creating a club environment and maximizing social support of participants, was not achieved. Instead, institution 1 had two volunteers – one staff member and one former staff member – who attended one or two sessions per week, institution 3 had four volunteers, and institution 4 had one staff member who regularly attended one session per week. In addition, three non-enrolled residents from institutions 1 and 3 regularly attended sessions; they signed the consent form but did not provide any baseline or follow-data.

2.5.5 Adherence strategies

Table 2.2 Adherence strategies

- Group setting
- Supervised/coach-led sessions
- Positive adherence feedback from coach
- Coach independent from SUD treatment institution
- Incentives
- Training reminders via SMS
- No costs to participants
- Low dose and intensity of exercise
- Schedule set by participants
- No travel required; coaches met participants at institutions
- Variation in activities
- Activities selected with participant input

Neither coach was trained in motivational techniques, so the strategies used to increase motivation were rudimentary at best. A high amount of coach-to-participant communication was one important strategy. In addition to SMS reminders of sessions and upcoming incentives, coaches provided activity and adherence feedback in person and through SMSes. Groups received a common SMS every three weeks that summed up the minutes of activity, number of push-ups, kilometers walked, etc., that each group had collectively accomplished, and individuals were either told in person or received personalized SMSes describing particular exercise milestones.

Participants who expressed uncertainty about their participation in an upcoming session received a response from a coach that emphasized that participation was voluntary and the group was meant to be for the benefit and enjoyment of the participant, and added either a) the sessions were more fun when those participants were present, or b) the coaches would simply be happy to see them next time.

Incentives were used to stimulate enrollment and attendance. They took the form of small exercise-related prizes (e.g. water bottles, running gloves), supplemental activities near the end of the program (e.g. a kickboxing class, laser tag), personal training sessions, and one-month memberships to fitness centers. Incentives were procured through local training centers (Elixia Ullevaal, Mudo Kampsport), a sports organization (Kondis), running race (Sognsvann Rundt Medsols), and a physiotherapy center (NEMUS Bryn). To proactively motivate participants to participate and compensate for the potential lack of enjoyability accompanying a new exercise regime, incentives were given to all participants at weeks 1 and 3. To emphasize participants' successes, such as the highest participation rate or the most kilometers run/walked, and to assign value to those successes supplementary to the value that participants may have already assigned, further incentives were provided at weeks 7 and 9. All participants, including non-exercisers, received the last batch of incentives as completion prizes at follow-up.

2.6 Measures

2.6.1 World Health Organization's Quality of Life Brief (WHOQOL-BREF)

The WHOQOL-BREF is a self-administered, abbreviated version of the World Health Organization's 100-item Quality of Life assessment (WHOQOL-100). The instrument measures overall quality of life in the first item and overall health in the second item, and the remaining 24 items are divided into four domains: physical health (seven items), psychological health (six items), social relationships (three items), and environment (eight items). Response categories are rated on a 1-5 Likert scale, in which higher scores indicate higher QoL. Up to one missing item in the physical health and environment domains can be replaced with the domain mean. Domain means are then translated into domain scores comparable to the larger WHOQOL-100, via formula provided by the WHO [128].

The WHOQOL-BREF has been validated across 15 sites internationally, in 19 languages [128, 129], and among the SUD population [130, 131]. It has shown satisfactory psychometric values in Norwegian population studies [132, 133]. The original WHOQOL-BREF produced a Cronbach's alpha coefficient of 0.80 in the physical health domain, 0.76 in psychological health, 0.66 in social relationships, and 0.80 in environment [134], while the Norwegian version has produced a Cronbach's alpha of 0.84 in physical health, 0.82 in psychological health, 0.60 and social relationships, and 0.79 in environment [132]. Completion requires between ten and fifteen minutes.

2.6.2 Norwegian Follow-up Study of Opioid-dependents in Treatment

The screening tool included excerpts from the Norwegian Follow-up Study of Opioid-Dependents in Treatment (Norsk oppfølgingsstudie av opioid-avhengige i behandling, or "NorComt"), developed by the Norwegian Center for Addiction Research. It collected demographic, somatic and psychological health data through the inclusion of the 25-question Hopkins Symptoms Checklist (see below), SUD profile, and SUD treatment history. Substance use at baseline was measured by asking for all use over the past six months, while substance use at follow-up asked only for use since the intervention began, approximately two months. Participants selected from a comprehensive list of 19 substances, including an “other” option. Somatic health burden was measured by the amount of somatic conditions participants reported suffering from, out of a list of 25. This tool required approximately 40 minutes to complete.

2.6.3 Hopkins Symptoms Checklist

The 25-question Hopkins Symptoms Checklist (SCL-25 or HSCL-25) is a widely used screening tool for emotional distress, and includes two subscales for anxiety (10 items) and depression (15 items). The HSCL-25 has been translated into at least 15 languages and is used in both population studies and among clinical or traumatized respondents, such as refugees and asylum seekers, torture victims, and victims of assault [135-140]. Norwegian and Swedish researchers in particular have validated it through several longitudinal studies [136, 141].

An emotional distress score is achieved through a simple mean of all items, and likewise for the anxiety and depression scales. Missing item scores were replaced by the overall mean score, if two or less item scores were missing. A high score (≥1.75 when using a 1-4 Likert scale, and ≥1.0 when using a 0-4 Likert scale) has been shown to correlate with severe emotional distress [142, 143], and the depression subscale score correlates with the DSVM-IV’s measurement of major depression [137]. The HSCL-25’s utility in this intervention is suggested by its high internal reliability, cross-cultural validity, broad use among traumatized populations and populations being screened for psychiatric disorders, and the short amount of time required to complete it. The HSCL-25 and its variants, the HSCL-10 and HSCL-90, are used with regularity among the SUD population in Norway [12, 144, 145], which will enable comparison with this study’s results.

2.6.4 Intervention feasibility

Much of the data for this pilot study was collected to inform the design of a larger-scale study. The experiences of participants themselves were probed to ascertain intervention acceptability. Individual feedback was collected during and after each training session in an impromptu manner: I and the coach asked participants how easy/difficult it was for them to come to a session, if they liked that session and would like to repeat it, if they were seeing any results, and so on. Such feedback was used to make minor adjustments as needed, such as the time of day of sessions.

The intervention's study protocol originally called for a participant-by-participant exploration of reasons for non-attendance; the coaches intended on asking each participant who had missed a previous session for their reasons. This plan was soon abandoned after multiple participants reacted negatively to these questions, citing the voluntariness of the program and not wanting to feel guilty. After three participants mentioned that their "bad conscience" at missing a session led to further non-attendance, the coaches ceased asking for reasons for missed sessions. Coaches continued to send each participant, including non-exercisers enrolled in the exercise group, reminder SMSes, and after one missed session, added that the participant's presence was missed, with a positive emoticon. These SMSes often prompted a response, either through SMS or in person, during the next session, and some participants met with coaches before sessions to explain why they were not attending that day. This spontaneous feedback was recorded.

Each site provided follow-up data during the final celebration dinner. Participants were told that they could either give feedback orally or via the follow-up instrument, and were then asked for their recommendations for improvement (what did not work), the aspects of the intervention that they liked (what worked), and a description of their overall experience.

2.6.5 Assessment schedule

Participants completed the screening tool, WHOQOL-BREF, and consent forms before the intervention began. Coaches, participants, and comparison group members met again after ten weeks' of training to celebrate the program end with a group dinner. I distributed completion prizes, announced winners of a monthly membership to a training center, gave each participant a written record of the amount of training s/he had completed, and spoke briefly about how participants could maintain an exercise regimen in the future. Participants then completed the WHOQOL-BREF a second time as well as a follow-up instrument, which included recent substance use, somatic and psychological health data excerpts from the screening tool.

All instruments were completed with pen and paper by participants, with myself and in some cases a staff member present. In order to prevent the artificial under-reporting of distress and other sensitive problems that Sandager et al witnessed when their Norwegian subjects answered the HSCL-25 orally instead of privately [146], participants were assured that their individual answers would remain anonymous from the coaches and especially from institution staff.

2.7 Analysis

Participants who attended at least one session were analyzed as *exercisers*. Participants who enrolled in the exercise group but who did not attend any sessions were analyzed along with the comparison group members as *non-exercisers*. As one of the aims of this study is to explore whom the exercise group appealed to based on demographic, clinical, and QoL variables at baseline, the group of *non-exercisers* shares the important characteristic of never being interested enough in the exercise group to attend.

2.7.1 Quantitative analysis

The first aim in this pilot study was to describe this sample of SUD patients and discover whom the exercise groups appealed to based on the characteristics of those who exercised and those who did not. SPSS for Mac, version 21, was used for analysis. Because this pilot study involved a relatively small sample size (n=35), measurements could not be expected to follow a normal distribution. The study design includes an intervention group and a comparison group recruited from the same institutions. The participants in both groups self-selected, and no random assignment was performed. This may introduce the potential for selection/participant bias. The non-parametric equivalent of an independent t-test, Mann-Whitney *U* tests, were therefore used to compare exercisers' and non-exercisers' means in each QoL domain as well as major clinical variables of somatic health burden, mental health burden, and addiction severity at baseline. Only the significance values from these tests are included in the Results. Sections ***3.2 Research Aim 2: QoL changes*** and ***3.3.1 Changes in clinical variables*** present descriptive and statistical comparison of baseline means of QoL and clinical variables. Results are often presented with percentages in addition to amounts of participants (although a low n), as the unequal group sizes can make comparing *n*'s difficult.

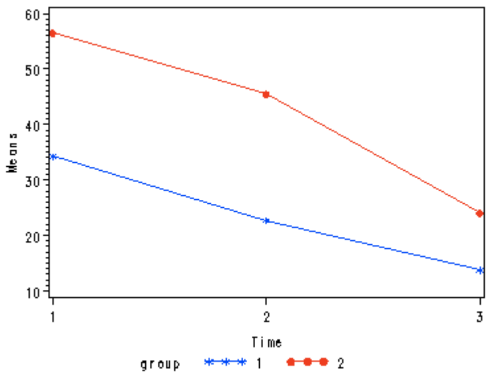
The second aim, and that for which a hypothesis is tested, involved measuring QoL changes in participants. All participants were currently undergoing residential SUD treatment, and QoL benefits can be expected as a result of treatment [147-150]. The question to answer, then, is if exercisers' QoL changed in a different manner than non-exercisers after ten weeks – if so, conscious of the methodological limits of this pilot study, additional changes can be suggested as arising from the exercise program. For descriptive statistics, exercisers were divided into three roughly even categories of attendance ("most active", between 20-29 sessions; "moderately active", between 11-20 session; and "least active", between 1-10 sessions) and their QoL changes compared to expose a potential dose-response relationship.

An appropriate and precise statistical technique to measure changes in QoL between the two groups is a general linear model (GLM) with repeated measures. This procedure uses analysis of variance to model a dependent variable. It is utilized specifically when the dependent variable is measured among the same subjects are at two or more points in time, and when subjects are exposed to a single independent variable, such as a treatment [151]. The robustness of repeated measure designs is that they measure between-group variance while allowing the subjects to serve as their own control (accounting for within-group variance), so significant, observed changes in the dependent variable between groups are not attributable to normal variation between participant's first and second measurements.

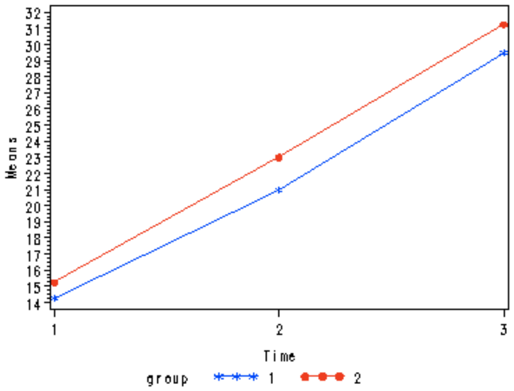
The GLM with repeated measures helps answer the second research aim in two steps. The first step is measuring within-group variance, or how exercisers' QoL changed over time and how non-exercisers' QoL change over time. `Time` is therefore the within-group factor in this study, as it signifies multiple measurements (baseline and follow-up) of each of the four dependent variables of QoL domain. A significant effect of the variable `time` indicates that all participants' follow-up scores in a domain were significantly different from their baseline scores; i.e. a particular domain of QoL changed positively or negatively over the course (that is, `time`) of the pilot study. Given existing research about the QoL-boosting effects of SUD treatment, it would be unsurprising if each domain had a significant effect of `time`.

The four plots below are sample output plots from a GLM with repeated measures [152]. Similar output plot will be presented and interpreted in the Results section. Here, the y-axis represents measurement of the dependent variable, and the x-axis shows that the dependent variable was measured at three points in time. Each line represents a different group. Slopes that are either both positive (sample plot 2) or both negative (sample plot 1), even if unequally so, reflect a significant effect of `time`, because all participants' dependent variables changed significantly over time. Slopes that are near zero, indicating no change in the dependent variable (sample plot 3) reflect an insignificant effect of `time.` Slopes that are both positive and negative, indicating changes in different directions (sample plot 4), also show insignificant effect of `time`, because if change for this entire cohort (i.e. both groups) were to be measured, there would be no net change and we would see a slope of near zero.

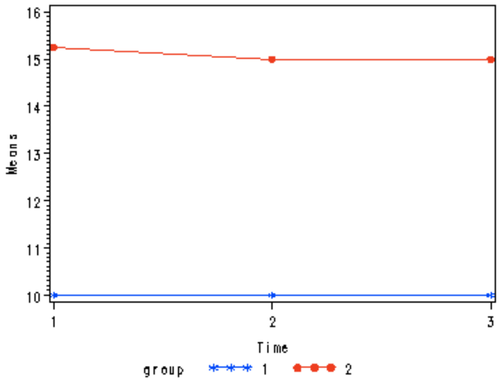
In effect, this part of the analysis will answer if QoL changed during the 10 weeks of observation (over time) while participants were in SUD treatment, comparing QoL scores from baseline with QoL scores at follow-up.



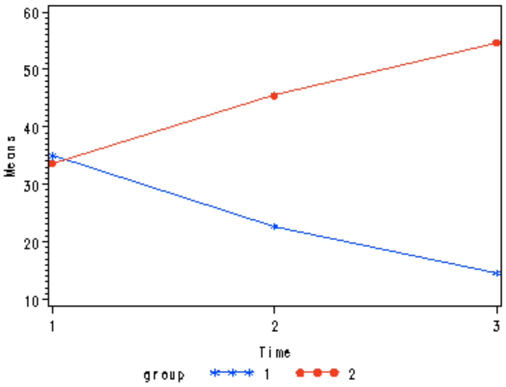
Sample plot 1



Sample plot 2



Sample plot 3



Sample plot 4

The second step is to measure QoL changes with attention to the between-group factor of `exercise`. This is the main independent variable, and delineates the treatment (exercisers) from the control/comparison (non-exercisers). A significant effect of an interaction between `time` and `exercise` indicates that a QoL domain change was different for the exercise and non-exercise groups. Such a domain change is reflected by the two lines in the above plots having different slopes, as seen in sample plots 1 and 4.

The model for each domain met the following assumptions: domain scores were normally distributed; independence of observations; homogeneity of variance; and homogeneity of intercorrelations. Mauchly's test of sphericity was violated in each, so the Greenhouse-Geisser F-tests were used. Plots of each model supplement the results and indicate the direction of QoL changes.

To assess whether any statistically significant changes attributable to exercise were meaningful, the minimum clinically important difference (MCID) was calculated. I applied the distribution-based method utilized by Den Oudsten et al in their estimation of the MCID of the WHOQOL-100 [61]. They calculated the MCID to be 0.5 of the standard deviation of each domain score; a mean change above the MCID can be considered clinically significant. There are several other possible distribution- and anchor-based methods [60, 62, 64], but Yost recommends this method as the most appropriate when an instrument-specific MCID is lacking [153, 154], and Norman et al's systematic review concludes that 0.5 of the standard deviation of change has a "remarkable universality" when used to discriminate HRQOL changes among chronic disease populations [155]. To my knowledge, this is the first study proposing MCID values for the WHOQOL-BREF.

The third aim of this study is to consider additional explanatory factors that may have influenced QoL changes. Adding baseline measurements of somatic health burden, mental health burden, and recent substance use as covariates to the GLM would have allowed for a test of the effect of exercise on QoL, controlling for the variation in covariate levels. Each of these variables have established relationships to QoL [11, 43, 49, 156, 157]. Covariates are particularly pertinent in non-experimental situations such as this pilot study, where subjects are not randomly assigned, and hence selection/participation bias may have influenced the results. However, with both positive and negative implications, each clinical variable violated a requisite assumption and therefore none could be added to the model. 1) Substance use was skewed towards abstinence and not normally distributed, although exercisers and non-exercisers' substance use were not statistically different. 2) Mental health burden at baseline was linearly related to only the first three QoL domains – the greater burden one had, the worse evaluation of physical health QoL, psychological health QoL, and social relationships QoL – and exercisers reported a higher mental health burden, with statistical significance, than non-exercisers. 3) Somatic health burden was also statistically higher for exercisers than non-exercisers. It was also linearly related to only the first QoL three domains; the more somatic problems a participant had, the lower they rated their physical health QoL, psychological health QoL, and social relationships QoL. In ay case, the low n in this pilot would have only allowed for the inclusion of one or two covariates, if requisite assumptions of the model were not violated, whereas a larger study could potentially have included several covariates.

That these clinical variables cannot be added to the statistical models requires consideration of their potential influence on QoL to instead utilize descriptive statistics and existing research. 3.3.1 Changes in clinical variables presents these descriptive statistics.

In a study with a larger n it would likely have been less problematic to include these covariates into the model, as larger samples often tend to show normal distribution properties, and hence do not violate model prerequisites, as was the case in this small pilot study. Including covariates would have been the next analytic step to dissect the potential effect of exercise on each QoL domain, and will be an appropriate measure in a future large-scale trial.

2.7.2 Qualitative feedback

To evaluate program feasibility for institutions and program acceptability by participants, a content analysis was conducted on spontaneous qualitative feedback collected during the program and with structured qualitative feedback collected at program end, and integrated with attendance data relating to particular activities. Content analysis identified the existence and frequency of themes relating to benefits, challenges, and recommendations.

2.7.3 Missing data

Three participants at baseline declined to answer most of the clinical questions, but answered the full QoL instrument. Four different participants could not be reached to answer the follow-up instruments. One of these was an exerciser, and the other three were non-exercisers.

3. Results

3.1 Research Aim 1: Sample description

3.1.1 Demographic and clinical variables[2] at baseline

Participants' ages ranged from 27 to 61 with a mean age of 41 and standard deviation of 8. Three-fourths of participants (74%) were male. Most participants were of Norwegian or Nordic descent (94%). The majority (62%) had never married. The largest group of participants (43%) responded that they were both outside of the labor market and not studying, although exercisers were four times more likely than non-exercisers to be in this position. Slightly fewer (34%) were students, and less than 12% were employed either full- or part-time. Nearly 80% of participants had completed secondary education/training or less.

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[2] For many demographic questions, at least one exerciser and one non-exerciser declined to answer; the percentages presented are of the participants who gave data.

17% had formal occupational training, above the secondary school level, and only one participant completed higher education.

Table 3.1 Sample description

	Total	Exercisers	Non-exercisers
Age	1972.5 (SD=8)	1973 (SD=8)	1972 (SD=10)
Gender	n=35	n=24	n=11
Female	9	8	1
Male	26	16	10
Education level	n=33	n=23	n=10
Primary school	11	7	4
Secondary school or occupational training	15	11	4
Trade school	6	4	2
University/university college	1	1	0
Above university	0	0	0
Did not complete primary school	0	0	0
Occupation	n=34	n=24	n=10
Neither employed nor a student	15	12	3
Student	12	7	5
Part-time work	2	2	0
Full-time work	2	1	1
Unknown	3	2	1
Civil status	n=32	n=22	n=10
Not provided	4	3	1
Never married	22	14	8
Widowed	0	0	0
Married	0	0	0
Separated from spouse/ cohabitant	3	2	1
Divorced	3	3	0
Most common somatic conditions	n=33	n=23	n=10
Impaired memory	22	17	5
Headaches	18	15	3
Tooth/gum problems	17	13	4
Dizziness	15	13	2
Constipation	15	15	0
Joint pain	14	14	1
Respiratory problems	10	10	0
Psychological conditions	n=33	n=23	n=10
Clinical emotional distress	18	17	1
Clinical depression	18	17	1
Clinical anxiety	16	13	3
Depression, lifetime	23	18	5
Anxiety, lifetime	21	15	6
Prescribed medicine for an emotional/ psychological problem, recent	11	10	1
Prescribed medicine for an emotional/ psychological problem, lifetime	17	13	4
Serious suicidal thoughts, recent	4	4	0
Serious suicidal thoughts, lifetime	16	12	4

The average participant suffered from 20 out of 25 somatic conditions, and there were no participants who did not suffer from at least one condition. Exercisers suffered significantly (p=0.004) more from somatic conditions than non-exercisers.

A majority of participants reported clinical emotional distress, as measured by the HSCL-25. 18 reported clinical depression, and 16 reported clinical anxiety. The four distress-related symptoms from the HSCL-25 that participants reported the highest levels of suffering from were nervousness and unsettlement, sleeping issues, loneliness, and a feeling of hopelessness regarding the future. A larger proportion of exercisers than non-exercisers reported emotional distress, depression, and anxiety; the difference in emotional distress was significant (p=0.002).

Historically, more than 94% of participants had received inpatient SUD treatment at some point in their lives (31), and for an average of 27 months. The majority entered their current institution from another SUD treatment institution or detoxification program. 90% (28) had also received outpatient treatment, for an average of 40 months.

75% reported using at least one substance/medicine over the six months prior to the intervention. Half used at least two substances over the past six months, 40% used at least three, and 25% used four or more (participants were asked only for their four most commonly used substances). There was no significant difference (p=0.725) between the addiction severity of exercisers and non-exercisers.

The most commonly used substances over the past six months were benzodiazepines (reported by 41% of participants), alcohol (38%), cannabis (28%), heroin/opiates (25%), amphetamines (25%), and opiate substitution drugs (19%). Three participants (9%) reported using performance-enhancing drugs. Similar proportions of active and non-exercisers used each substance.

Nicotine-dependence was not assessed, but 77% of participants smoked daily. More exercisers (91%) than non-exercisers (60%) smoked. Among smokers, exercisers reported an average of 15 cigarettes daily, while non-exercisers reported 10. Snus, a product similar to American dipping tobacco but rare in the United State and banned in the European Union, was used by 26% of exercisers but 60% of non-exercisers.

3.1.2 QoL at baseline

Participants scored their social relationships QoL to be the lowest of their four QoL domains, and their environment QoL to be the highest. This pattern is seen among both exercisers and non-exercisers. Exercisers rated their physical health, psychological health, and environment slightly lower than non-exercisers and lower than the total mean. Standard deviations among exercisers' means were also slightly larger than for non-exercisers for physical health, psychological health, and social relationships. Exercisers reported significantly (p=0.025) lower QoL in the physical health domain than non-exercisers; the remaining three domains were normally distributed.

3.2 Research Aim 2: QoL changes

3.2.1 Descriptive statistics

Measured on a 4-20 scale, average post-intervention domain means increased for exercisers in all domains, with the psychological health domain increasing the most (1.75 points), social relationships increasing by 1.37, physical health by 1.27, and environment by 1.18. Non-exercisers' physical health decreased by 0.71, but their social relationships increased by 1.5. Psychological health and environment increases were more modest for non-exercisers at 0.59 and 0.50, respectively. The following section statistically analyzes these changes.

Table 3.2 QoL Domain score means

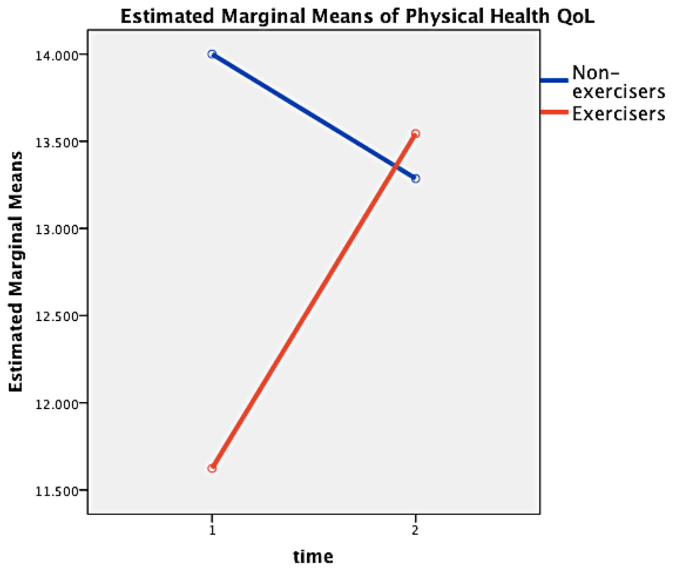
	Baseline			**Follow-up**		
	Total n=35	Exercisers n=24	Non-exercisers n=11	Total n=28[a]	Exercisers n=20	Non-exercisers n=8
Physical health	12.3 (SD=2.7)	11.6 (2.7)	13.9 (2.2)	13.8 (2.2)	13.5 (2.3)	13.3 (2.2)
Psychological health	11.9 (2.1)	11.6 (2.3)	12.5 (1.6)	13.5 (1.6)	13.8 (1.8)	12.8 (1.0)
Social relationships	11.4 (2.7)	11.5 (2.8)	11.2 (2.5)	13.4 (2.8)	13.8 (3.1)	12.7 (1.9)
Environment	13.5 (1.9)	13.4 (1.8)	13.7 (2.2)	14.7 (2.7)	14.8 (1.9)	14.4 (1.4)

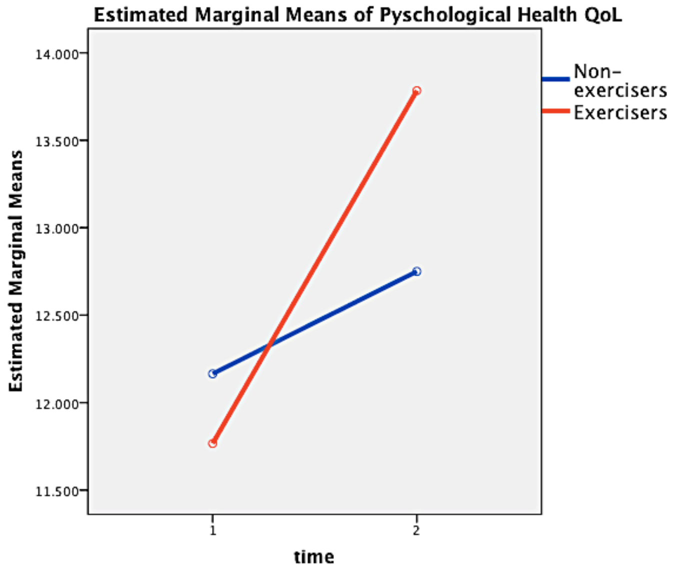
[a] Three injured participants are excluded at follow-up.

3.2.2 Statistical analysis

A significant effect of the interaction between `exercise` and `time` was seen for physical health QoL (p=.005) and psychological health QoL (p=0.023). No significant effects of an interaction were observed for social relationships or environment QoL. Significant main effects of `time` were observed for the psychological health (p<.0005), social relationships (p=.034) and environment (p=.045) domains of QoL.

Overall this can be interpreted as follows: patients in SUD treatment experienced changes to the QoL domains psychological health, social relationships, and environment during the 10 weeks of SUD treatment, regardless of whether they exercised. The exercise groups had an added and independent effect and resulted in a positive change of the QoL domain physical health in the exercise group only, and in an additional positive change in the psychological health domain in the exercise group only.



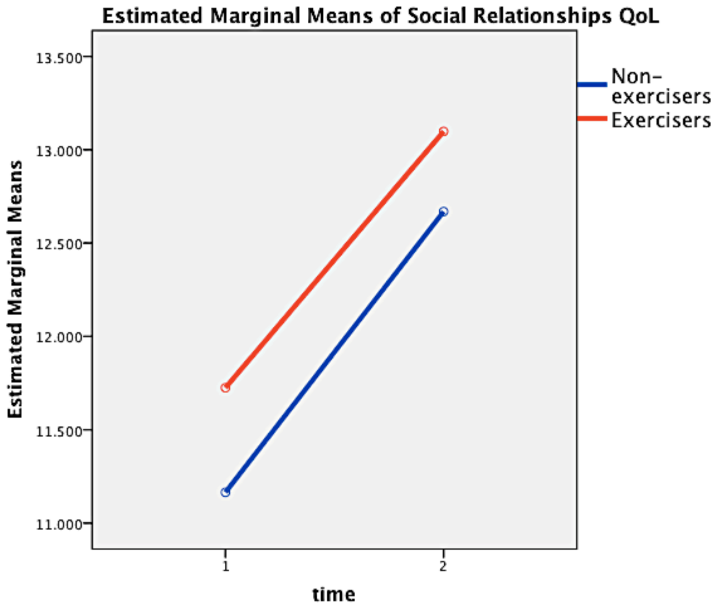


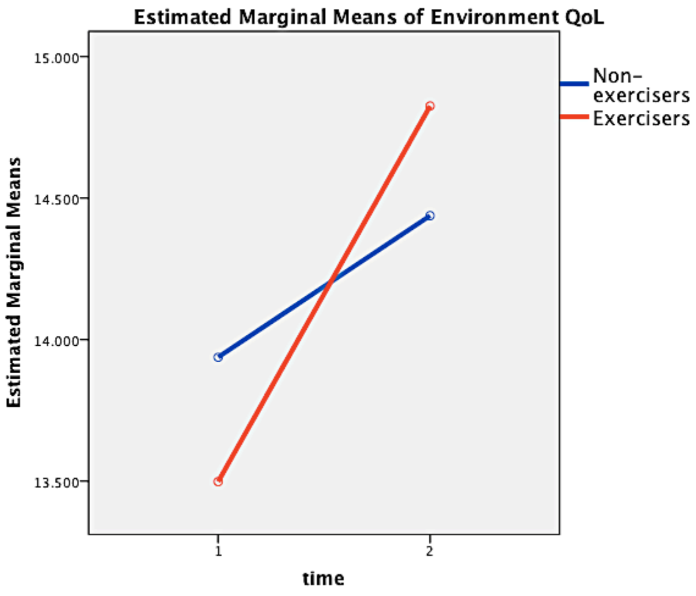
This plot shows that non-exercisers began with higher physical health QoL than exercisers (a difference that was statistically significant, as previously described). However, non-exercisers' QoL declined in this domain over the course of the pilot study, and exercisers' QoL increased enough to surpass non-exercisers. These groups' QoL changed in a manner significantly different from each other – specifically, the slopes of each line were different – thus the significant effect of an interaction between `time` and `exercise` (p=.005).

As both groups experienced different changes in QoL, there was no common trend of QoL change from baseline to follow-up. `Time` did not have a significant effect (p=.169) on participants as a cohort. According to this analysis, QoL increases in the physical health domain can be attributed to whether a participant was in the exercise or non-exercise group, but not to the simple passage of time in SUD treatment.

Unlike physical health QoL, both exercisers and non-exercisers experienced an increase in psychological health QoL. These increases were large enough for both groups that `time` was significant at p<.0005. Regardless of exercise, this plot suggests, participants experienced an upward trend in QoL over these ten weeks.

The small difference in QoL between the two groups widened over ten weeks, as exercisers again overtook non-exercisers' scores and ended the pilot study with higher QoL. Because the increase for exercisers was greater (i.e. the slopes of these lines were different, although both positive), this model reports that the interaction of `time` and `exercise` had a significant effect (p=.023). Participants improved their QoL even without exercise, but engagement in the exercise group resulted in additional, statistically significant benefits.





The social relationships domain presents a different story. There is no obvious difference in the slopes of the exercisers' and non-exercisers' QoL, indicating that QoL changed in a very similar manner for both groups. Group assignment was clearly irrelevant to QoL changes, hence the effect of the interaction of `time` and `exercise` was p=.919. Whether a participant exercised or not made next to no difference on the QoL changes, within this domain, that this cohort experienced over time.

These changes were definitively positive. The QoL increase among all participants from the beginning to the end of the program demonstrates the significant effect of `time` (p=.034). Participants' QoL in this domain simply increased over time in SUD treatment.

Exercisers began and ended the intervention with higher QoL than non-exercisers, but the difference in means was not significant.

All participants again experienced an increase in their environment domain of QoL, and the effect of `time` was significant at p=.045. As with the social relationship and psychological health domains, environment QoL increased over ten weeks, regardless of whether a participant exercised.

Unlike the psychological health domain, exercise did not lend additional QoL benefits, although exercisers began with lower QoL than non-exercisers and ended with higher QoL. This plot may be misleading, then, because the steepness of exercisers' QoL increase – visibly steeper than that of non-exercisers' – belies the non-significant result of the interaction between `time` and `exercise` (p=.348). A more helpful interpretation of this analysis might be to say that exercise appears to be associated with QoL gains, but that we cannot state this relationship with statistical certainty, with the included n in this study.

Thus the null hypotheses can be partially rejected and partially accepted, as we have examined the outcome in four domains. Exercisers' physical health and psychological health domains of QoL increased significantly more compared to non-exercisers. The null hypotheses for these two domains may be rejected. All participants' social relationships and environment domains of QoL increased, but there were no significant differences between active and non-exercisers' changes, and hence the null hypothesis is accepted for these two domains.

Exercisers' improvements in the physical health QoL, psychological health QoL, and environment health QoL domains were above the minimum clinically important difference (MCID) threshold and therefore considered meaningful to exercisers; that is, these improvements are assumed to have been noticed and appreciated. This is despite the fact that only their physical health QoL and psychological health QoL increases were statistically significant. The entire cohort's statistically significant improvements in psychological health QoL and environment QoL (attributable to normal SUD treatment) were above the MCID threshold. In contrast, the only statistically significant improvement among non-exercisers – the social relationships domain – exceeded the MCID threshold. Non-exercisers' decrease in physical health QoL was not above the MCID threshold, and therefore cannot be considered a meaningful decline.

Table 3.3 QoL Domain score mean changes and MCID

	Total n=28[a]		**Exercisers n=20**	**Non-exercisers n=8**
	Mean change (SDΔ)	MCID	Mean change (SDΔ)	Mean change (SDΔ)
Physical health	+1.3 (2.6)	1.3	+1.9* (2.0)	- 0.7 (2.1)
Psychological health	+1.8* (1.6)	0.8	+2.0* (1.4)	+0.6 (1.4)
Social relationships	+1.4 (2.8)	1.4	+1.4 (2.5)	+1.5* (3.8)
Environment	+1.2* (2.0)	1.0	+1.3* (2.0)	+0.5 (2.2)

[a] The domain scores of three injured participants are excluded.
* Clinically significant change
Abbreviations: *SDΔ* = standard deviation of change score; *MCID* = minimum clinically important difference, calculated as 0.5 SDΔ

The WHOQOL-100 MCID thresholds calculated by Den Oudsten et al among a cancer population were determined to be 1 for each domain, roughly corresponding to the range calculated here of 0.8 – 1.4.

3.3 Research Aim 3: Explanatory factors

QoL is a multidimensional measurement with numerous inputs, as described in the introduction. While exercising participants increased their physical health and psychological health domains of QoL with statistical significance compared to non-exercisers, changes in clinical variables that have demonstrated relationships to QoL were also measured. This section explores explanatory factors that may have been involved in QoL changes. None of the clinical variables could be added to the statistical analysis as covariates because one or more assumptions were violated, as described in ***2.7.1 Quantitative analysis***.

3.3.1 Changes in clinical variables

Psychological health

At the conclusion of the intervention, emotional distress, anxiety, and depression had reduced among exercisers, while non-exercisers experienced no changes. Exercisers' levels of total emotional distress and of depression reduced to nearly the cut-off point for normal findings.

Somatic health

At the end of the study, the only somatic condition to decrease in prevalence (from 21% to 13% among non-exercisers, and 71% to 42% among exercisers) was impaired memory. One condition, respiratory problems, affected three more participants during the intervention than before. Most conditions affected the same amount of participants and to the same extent as before the intervention. Difficulty breathing was a common complaint during sessions, and always attributed by participants to smoking.

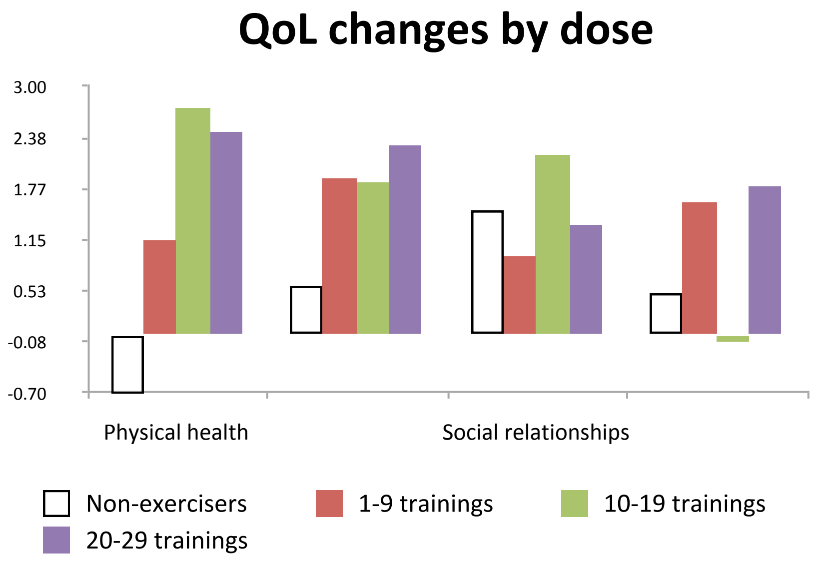
Substance use

Substance use and variety after the intervention decreased across the board, with the exception of program-prescribed substitution drugs (such as buprenorphine or methadone), which the same amount of participants used before and after. While 22% of participants reported abstinence at baseline, that number nearly tripled to 65% at the intervention's end, with eleven more exercisers reporting abstinence and only one more inactive participant. Non-exercisers were more likely to report substance use at follow-up: 62% used at least one substance compared to 26% of exercisers. Fewer exercisers smoked at follow-up (from 91% at baseline to 62%), but the proportion of non-exercisers remained the same (from 60% to 57%). Exercisers who smoked also reduced their daily average from 15 to 9 cigarettes, while non-exercisers cut down by one cigarette. Several participants reported substituting cigarettes with electronic cigarettes, but further data was not collected on e-cigarettes.

3.3.2 Dose received

The dose of group exercise received, represented by the amount of sessions attended, could also explain with finer detail QoL domain changes. The sample size was too small to explore a dose-response relationship statistically. Separating exercisers into three roughly equal groups according to attendance level reveals close to a descriptive dose-response relationship in the physical health and psychological health QoL domains. In all domains, the most active exercisers' averages increased more than the least active exercisers'. In the physical health, psychological health, and environment domains, exercisers' averages increased more than non-exercisers' averages.

Figure 3.1 QoL changes by dose



3.4 Research Aim 4: Assessing acceptability and replicability

Acceptability of the exercise groups to participants was assessed through integrating qualitative feedback on liked/disliked program aspects with attendance data. Feasibility/ replicability is assessed through reflections from myself and the other coach, as well as a break-down of costs and sponsorship. True to the qualitative research tradition, this section mixes qualitative results with discussion, although recommendations for best practices are reserved for *4. Discussion*.

3.4.1 Recruitment and assessment

Only three out of an intended 30 participants were recruited to the initial comparison group. This difficulty may partly be due to residents at two out of four institutional recruitment meetings being already interested in exercising, but the remaining two institutions' recruiting meetings involved all residents, and most of those who were not interested were not successfully motivated to fill out the screening questionnaire.

In one case, a participant who wanted to enroll into the exercise group did not complete the screening questionnaire and therefore was not enrolled because the mental health history questions disturbed him. His was the only situation in which the questionnaire directly hampered recruitment, but many other participants expressed displeasure at the intimacy of the questions. The questions about recent and historical suicide attempts and substance use were the most unpopular; one staff member explained that suicidal experiences were common recent occurrences, while the substance use question was disliked by currently abstinent participants who did not want to reflect upon any prior substance use and by using participants who were frustrated that they were forced to remember their usage.

3.4.2 Overall attendance

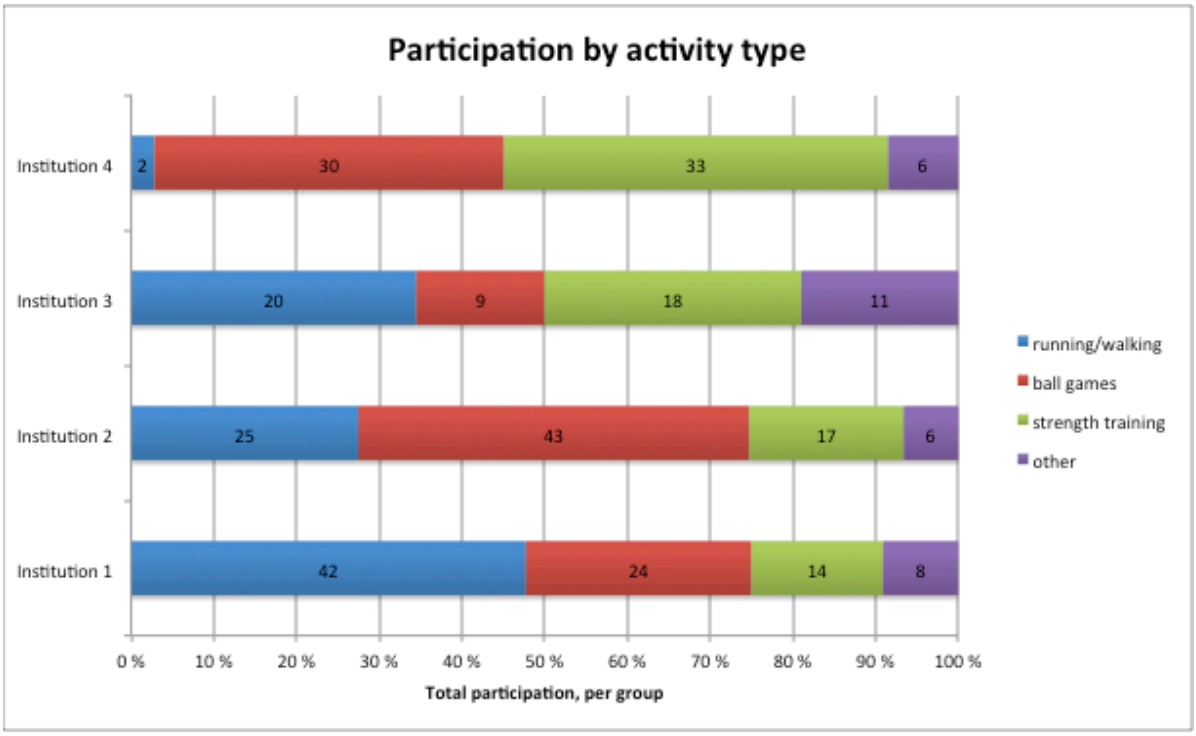
A histogram of attendance among exercisers reveals a fairly even spread: while the range is from one to 27 sessions, between one and three participants attended nearly every possible amount of sessions within this range. From this spread cannot be drawn a "magic number" of sessions which most participants liked/attended.

Among the entire exercise cohort, institution 1 had the highest mean number of sessions (15 out of a possible 30), followed by institution 2 (14), institution 3 (13), and institution 4 (11). Attendance peaked in weeks one through four and week nine, with these sessions serving between 14 and 17 participants across the four groups.

Among exercisers, the most common explanation for non-attendance was a lack of energy, expressed through the phrase "jeg orker ikke". This explanation was occasionally supplemented with a further cause – a busy day, a challenging therapy session, new medication – but most often stood alone. Scheduling conflicts were the second most common reason for non-attendance, and most of the time they were related to school or job training. In weeks five and six, four participants from institution 2 purchased memberships to a nearby gym and their attendance decreased. Among non-exercisers, the most common reason for non-attendance was an expectation that the exercise groups would not help, either because the exercises were of too low an intensity or because the participants already knew how to train themselves.

There was no common activity that produced higher attendance rates across institutions, but the activities themselves and the variety of activities was the most-liked aspect of the program. Given that each reminder SMS to participants contained the session's activity, and that each group collectively decided upon the pattern of activities, participants were free to decline the activities that they did not like and attendance rates per activity can therefore be interpreted as a reflection of their preferences. The figure below displays the relative popularity of four separate activity categories (walking/running; ball sports; indoor or outdoor strength-training; or other, including yoga, laser tag, and kickboxing) in each institution, via the activities' share of total participation. Walking/ running sessions were the most attended in institution 1, while institution 3 saw a nearly even split between walking/ running and strength-training. Institution 2 played ball sports most often, and institution 4 was split between ball sports and strength-training.

Figure 3.2 Relative activity popularity



The combination of staying on-site and with the normal coaches led to the highest attendance rates. Attendance did not drop when a session involved leaving the site with the coaches (e.g. weekly runs/walks around a lake in institution 1), but the fact that coaches came to the participants was specifically mentioned as a positive aspect. Attendance also did not drop when an external trainer came on-site (e.g. yoga), but the combination of both lead to sparsely attended sessions (e.g. laser tag and kickboxing). Some participants decided at the last minute to attend sessions after seeing their fellow participants assembled and greeting the coach. Staying on-site gave participants flexibility and reduced the pressure and time commitment of mentally and physically preparing themselves to exercise.

3.4.3 Additional popular program aspects

Several key programmatic elements were valued by participants, as expressed through spontaneous feedback and the follow-up questionnaire. Specific activities and the variety of activities was already discussed as the most popular aspect. The second most-mentioned aspect was that the sessions were of appropriate intensity and duration. Many participants – exercisers and non-exercisers – expressed embarrassment at their fitness levels and weights compared to before treatment. While several participants asked for more strenuous sessions mid-program, the low-intensity and 30-minute dose seemed to physically challenge, without overwhelming, the majority of participants. Thirty minutes was a sufficiently short amount of time to not be intimidating, and coaches used the phrase “only thirty minutes” liberally when encouraging an ambivalent participant to attend or join in.

Being trained by a coach, and coaches’ attributes, were two related and repeated themes. Coaches were described as motivating, engaging, skilled, and kind. The independence of the coaches from the institutions was also valued, as two participants appreciated the confidentiality of their conversations with coaches from their institutions, while several others said that they liked the fact that coaches cared enough to conduct this project – coaches were ostensibly not seen as constituents of their existing program staff.

Exercising not only with a coach but also with each other was another popular aspect. Participants mentioned that exercising in a group made the exercises easier, that it motivated them, and that they simply liked the socialness. One participant also reported that post-exercise attitudes were different among her fellow participants: “People are happier. Our relationships with each other are better; there’s more laughter.” Another participant said that this group was the first time he had looked forward to exercising with other people. Coaches observed how participants motivated each other in ways that the coaches could not have, such as by knowing that a particular participant would attend only if s/he was told by SMS how many others were already present, and importantly, by demonstrating through example that their fellow participants needed congratulation and recognition of the smallest accomplishments.

Seeing evidence of individual achievements or progress was not originally in the group design, but coaches quickly began tracking individual progress at several participants' requests, and this was a well-liked aspect at follow-up. Incentives, the original method for recognizing achievement, were also received positively and mentioned often during follow-up. However, it is unclear whether they achieved their second goal of increasing attendance, as attendance did not increase in the sessions leading up to incentive distribution.

Participant input being taken into account was also appreciated by many. This included, first, setting times and a preliminary activity schedule suggested by participants at recruitment, and as the program progressed, included changing times, switching activities, and adding new activities. Participants relayed their requests and preferences to coaches during sessions and by SMS, and nearly every active participant reported liking the SMS reminders and/or overall communication with the coach.

Only two negative elements were identified. The intensity was described as too low by four participants (three of whom specifically noted that the beginning few weeks' intensity was appropriate, but should have increased thereafter) and as too high by two participants). Three participants also pointed out the activities that they wished were excluded. Combined with attendance data, it can be added that traveling off-site and to meet with an external trainer were also unpopular aspects.

When asked to describe their experiences, participants responded positively. There were no negative experiences reported in the follow-up questionnaires, despite injuries and occasional frustration expressed at a participant's poor physical form. In response to this question, participants identified six categories of benefits, most of which were physical. Improved fitness and other physiological benefits were reported the most, with examples given of better respiratory health, improved stamina during sessions, and more toning. The adoption of health behaviors beyond the exercise groups, such as reduced smoking, replacing elevators with stairs, and purchasing a gym membership, were also reported. Several participants said they learned new training techniques that they would continue to use, and two said they had more energy to fulfill daily tasks. Among the psychological benefits were improved mood and motivation, both to continue training and to "get out the door when I don't want to". Staff echoed the motivational benefit, and reported surprise that the program engaged certain participants who they expected to lose interest, and engaged more participants who had been interested in exercising but who had no success beginning or maintaining exercise routines in the past. Mood-boosting effects were also noticed staff when they reported that participants liked and looked forward to sessions.

The only session-caused injury was a topical scrape after a participant fell into the sand during sand volleyball. The scrape required rinsing and a band-aid.

3.4.4 Labor and cost

Implementation of these exercise groups was more labor-intensive than cost-intensive. I led groups at three institutions, requiring around 15 hours of preparation, travel, exercise, data recording, and communication with participants each week, and hired another coach for the fourth institution. His group required more travel and therefore took six hours of his time each week. Communication between us required less than one hour each week. In sum, implementation of these four exercise groups took us an estimated minimum of 22 hours weekly.

This pilot study received 44 780 NOK (7 500 USD) of in-kind sponsorship from Norwegian companies, of which 28 290 NOK (4 735 USD) was utilized; and 8 771 NOK (1 468 USD) of subsidies from SERAF. One institution covered their own costs of 5 938 NOK (994 USD), and I paid for the balance, less than 1 000 NOK (167 USD). Sponsored costs accounted for 65% of total costs, and institutional reimbursements were 24%.

The largest single expense was payment of the additional coach. Incentives involving gym memberships, such as the ten one-month memberships and ten personal training hours donated by Elixia Ullevål, were worth nearly as much. By category, incentives represented 62% of the project's total costs, while session-related costs were 25%, data collection costs accounted for 7%, and equipment for only 6%. The low proportion of equipment-related costs is a result of conducting the majority of sessions either in public spaces outdoors or on institution property, thus avoiding the need to rent space.

Table 3.4 Costs by category[a]

	NOK	**USD**
Data collection (e.g. follow-up dinners)	3 156	528
Sessions (e.g. yoga teacher, race entry fees)	4 910	822
Equipment (e.g. football, volleyball)	2 531	424
Incentives (e.g. gym membership, water bottles)	27 202	4 553
Additional coach salary	6000	1 004
Total	43 799	7 330

[a] Includes the prices of utilized in-kind sponsorship as well as goods and services directly purchased. Unutilized in-kind sponsorship is excluded.

3.4.5 Institutional burden

The largest burden to institutional staff was when I recruited institutions and participants. Staff devoted the most time in the planning phase, when they met with me, reviewed the project plan and questionnaires, decided whether the project could be relevant to their residents, and facilitated the first recruitment meeting between myself and residents. Groups were conducted independently after those meetings and staff did not need to attend sessions, donate equipment, or be involved in scheduling. That being said, the institution with the highest attendance rate among exercisers was institution 1, with a dedicated staff member who attempted to attend at least one session per week, publicized sessions by posting the group schedule, prioritized the group by not scheduling overlapping institutional meetings or events, and informed me when conflicts were unavoidable.

4. Discussion

4.1 Summary

To my knowledge, this is the first study that has quantitatively measured QoL in a SUD population before and after a voluntary exercise intervention. Statistical analysis revealed that exercising participants experienced statistically and clinically significant increases in physical health and mental health domains of QoL compared to non-exercising participants, while exercise did not affect social relationships or environment domains. Given the methodological limitations of this study, exercise cannot be isolated as the sole contributor to QoL increases. The exercise groups succeeded in engaging participants with the worse physical and mental health, and design features that may have contributed to making the exercise groups so accessible and appealing have been recommended as easily and affordably replicable features for future interventions.

4.2 Methodological discussion

4.2.1 Theoretical assumption

Post-positivism as my theoretical assumption means that I anticipated that my own values, experiences, and expectations influenced all aspects of the design and implementation pilot study, including how I interpret those results. Rather than disregard findings as invalid, post-positivism requires the identification and enunciation of such influences.

4.2.2 Design

This pilot study utilized a non-experimental design with an ex post facto group assignment, wherein participants who did not exercise over the course of the intervention were analyzed along with the three participants enrolled into the comparison group as *non-exercisers*, and all participants who exercised were analyzed as *exercisers* (see ***2.7 Analysis*** for further explanation). The sample was drawn from four public and private institutions providing residential SUD programs dispersed around eastern, western, and downtown Oslo; these were real-world instead of controlled settings. The four institutions were not selected randomly, but chose to be included in the pilot study by virtue of staff interest (an opportunity for sample selection bias that impacts external validity). Two institutions provided all of their residents for recruitment, while the other two pre-screened residents and only those residents who were interested (or perhaps encouraged) attended the recruitment meetings (sample bias).

4.2.3 Internal validity

Validity concerns the goodness, or quality, of an inquiry. Post-positivism does not deviate from positivism's realist ontological benchmarks of internal validity and external validity to assess knowledge produced, but there must always be attention to the fallibility of such knowledge based on the theory that it and the study design was influenced by, the measurement that captured it, and the exceedingly irremovable interplay of researcher-and-participant [158].

Internal or causal validity is achieved when a researcher can assert that A (e.g. a treatment) caused B (e.g. an effect), "ceterus paribus". Such assertion is never absolute within post-positivism, as only one falsification is required in order to disprove causality [159] An ambitious aim of this pilot study was to determine, within the design limitations, whether participants (divided by the independent variable of group exercise) experienced a change in the dependent variable of QoL. Approaching a nonfalsified hypothesis of causality requires three conditions to be met, and this pilot study satisfied two of them [160].

First, measuring QoL after the exercise treatment had been received satisfied the requirement of time order, which requires the effect to be measured after the treatment.

Measuring QoL at baseline, before the exercise treatment, further allowed for more complex analysis of QoL at different time points. Second, there was an empirical association (correlation) between exercisers and changed QoL in all domains: if a participant exercised, QoL increased. As ***3.2.2 Statistical analysis*** discusses, the improvements were only unique to exercisers in the physical health and psychological domains, leading to the rejection of such association for the social relationships and environment domains.

The final requirement of causality, non-spuriousness, is violated due to a number of challenges to internal validity that are often present in non-experimental designs. Nonspuriousness is met when no variable can be found that changes the association between treatment and effect.

The sampling design itself leads to the first violation. Randomization was beyond the scope of this pilot study, although is the strongest method of ensuring internal validity because it enables the creation of two groups with the same random distribution of characteristics. Self-selection into the exercise or non-exercise groups instead of randomization is a major methodological weakness in this pilot study, because self-selection exposes findings to the obvious risk that any changes experienced over the course of the study are attributable to unexplored characteristics between the eleven participants who never attended a session and the twenty-four who did (e.g. motivation to exercise, self-control, self-efficacy, etc.) – in other words, the positive associations of exercise and increased QoL domains could be spurious, as the design was not randomized.

Knowing that the two groups may differ, three major characteristics that have a documented relationship with QoL and could therefore influence QoL over the course of the pilot study - physical health burden, mental health burden, and addiction severity - were measured at both baseline and follow-up. As ***2.7 Analysis*** explains, adding these variables as covariates to the GLM would have been one way to analyze changes in QoL while taking probable influences into account, in an attempt to make the two groups more comparable in regards to the outcome. Simple tests of means of each variable revealed that, as a result of self-selection, exercisers and non-exercisers were in fact different in some aspects and hence not truly comparable groups in statistical terms, another violation of nonspuriousness. This does not prevent the utilization of the existing literature reviewed in ***1.5 Exercise and physical activity*** about observed QoL levels and changes of non-SUD populations with and without exercise, and of SUD populations with and without SUD treatment. Each variable will be discussed in ***4.3.2.1 Engagement of the most suffering***, as part of the discussion of who the exercise groups managed to engage.

Exercisers and non-exercisers were housed together in institutions 2, 3, and 4, making group contamination a potential concern. Group contamination is seen if exercisers and non-exercisers, housed together in institutions 2, 3, and 4, influenced each other in ways that then led to QoL changes. A classic example would be if exercisers returned from sessions cheerful and with improved moods, thereby contributing to improved moods throughout their institutions, including among non-exercising participants. The better milieu could have increased the social relationships domain of QoL of non-exercisers, perhaps explaining the equal gain in this domain across both groups. It is important to note that group assignment was fluid, in that the three participants who enrolled in the comparison group were told they were free to begin exercising at any time, just as those enrolled in the treatment group were free to not exercise. The group assignment used in analysis was different than what participants had expected: it was only during data analysis that the comparison and treatment groups were changed to the non-exercising group (containing the comparison group plus the eight participants who enrolled into the exercise group but never exercised) and the exercising group (containing only the participants who exercised). That participants were free to exercise or not, regardless of initial enrollment, reduces the likelihood of *conscious* group contamination, such as non-exercising participants feeling excluded and their self-confidence and subsequent psychological health QoL decreasing.

Measurement errors are possible but unlikely due to use of previously validated instruments such as the WHOQOL-BREF to measure QoL and the HSCL-25 to measure mental health burden. One area of uncertainty is the social relationships domain of the WHOQOL-BREF, which may not have been appropriate to a residential population such as this sample. The three questions comprising this domain – how satisfied are you with your relationships to others, the support you receive from your friends, and your sex life? - are perhaps less relevant to respondents living in an institution, whose majority of relationships may be with other suffering patients, who may be isolated to some degree from their pre-institution friends, and for whom sexual activity could be of markedly lesser occurrence. If this domain's items were poorly equipped to measure social relationships QoL among a residential population, the impact of exercise could be masked by the model.

The NorComt instrument was used to measure physical health burden and was unvalidated, although used in previous large-scale studies of Norwegian SUD patients. It is also unlikely that it failed to capture physical problems which were alleviated over the course of the pilot study and resulted in increased physical health QoL. Qualitative feedback during the study and at follow up did identify three physical conditions that were underreported (thrombosis, causing leg pain and inflexibility) or excluded (intermittent claudication, causing muscle pain and cramping during exercise [138]; and epilepsy) from the questionnaires. However, seven exercisers and two non-exercisers reported a worsening of these conditions over the course of the study, not an improvement. These examples do not support the suggestion that a measurement error of the covariate physical health burden explains the increase of exercisers' physical health QoL.

Endogenous changes, developments independent to the exercise treatment, represent three additional threats to internal validity. The testing effect refers to how answering the same questionnaires at baseline and follow-up may have caused participants to alter their second answers. This effect is less applicable to the study's questionnaires and particularly to the QoL tool, both because aptitudes were not being tested and because the QoL tool has a high internal validity, suggesting that multiple testing does not increase scores. The maturation effect is also a less applicable threat, as ten weeks is not enough time for aging/maturation processes to change answers from baseline to follow-up.

Regression to the mean is the final endogenous change and applicable to repeated measures analyses such as this. It refers to the phenomenon of a sample having an extreme mean score on the first test scoring less extreme on the second test, due to movement towards the mean, as any score is a combination of a that being measured, systematic error, and random error. All participants scored lower than average in every domain of QoL at baseline (see ***4.2.4 Generalizability***), so increases in QoL at follow-up could, at first glance, be attributable to regression to the mean. However, this pilot study is not interested in QoL increases over time, but whether exercisers increase QoL over time in a manner significantly different than non-exercisers, and therefore both time and exercise assignment are included as variables in the GLM. The robustness of the GLM is that participants' baseline scores are taken into account (as within-subject factors) when the model analyzes changes at follow-up. This discussion is only relevant to the psychological health domain, in which both groups' QoL increased over time) (with statistical significance) and exercisers' QoL increased more than non-exercisers (also with statistical significance). The improvement of both groups' scores could be attributable to regression of the mean, if scores at baseline were very low only by chance, although this explanation is not of particular interest to this study. But as both groups began with statistically comparable QoL, it does not make sense that only exercisers would regress towards the mean *more*, and therefore the “extra” improvement can be attributed to exercise assignment. Regression to the mean is not applicable to the social relationships or environment domain, where exercising had no effect on QoL, or to the physical health domain, where non-exercisers’ QoL decreased over time.

Regression to the mean is of more concern in the covariate of mental health burden. Exercisers began the study with a significantly larger mental health burden than non-exercisers, and exercisers experienced a reduction in their mental health burden over the course of the study, while this burden did not change for non-exercisers. Exercisers’ mental health burden was still greater at follow-up than non-exercisers’. Regression to the mean could explain exercisers’ non-exercise-related reduction in mental distress than may have prompted an improvement in psychological health QoL.

Finally, two sources of treatment misidentification – when exercisers experienced additional “treatments” beyond group exercise, speaking to the value-ladenness of facts from both participants’ and researchers’ perspectives – are inapplicable to this pilot study. 1) There was no placebo given, and exercising was not an ambiguous activity. 2) The Hawthorne effect – when treatment group members feel special and therefore change in the dependent variable – is inapplicable because exercisers were not “chosen” to receive the treatment, as they voluntarily joined the exercise group just as non-exercisers voluntarily declined to exercise. Expectancies of experiment staff, the third source of treatment misidentification, is of ambiguous importance in terms of adding spuriousness. Experiment staff (the coaches) were intentionally positive and motivating as to the effects of exercise, and they emphasized tangible results such as less labored breathing, better sleeping, and less stress, not the outcome of QoL. But rather than considering such enthusiasm to create an unwanted self-fulfilling prophecy, such positivity and high expectations were an *intended* program feature. Even though this pilot study’s treatment is referred to as “group exercise”, the treatment specified positive coach leadership and involvement. ***4.3.2 Feasibility*** is vital in discussing the importance of the coaches’ relationships with participants and similar program features that cannot be captured by the term “group exercise”.

4.2.4 Generalizability

Chambliss and Schutt [160] divide generalizability into two aspects. Cross-population generalizability, which they equate with external validity, exists when one population's findings hold true for another population. If this pilot study was interested in exploring group exercise's effects on chronically ill populations, then the representativeness of this SUD sample to other chronically ill populations would be an application of external validity.

The aspect more germane to this study is sample generalizability, or how valid findings from this sample of SUD patients are to the SUD population in general. The study's small sample size prevents any statistical claim of sample generalizability. Two types of selection bias further dampen sample generalizability: first, only pre-selected residents were available for recruitment into the pilot study in two out of four institutions. Second, residents enrolled into the study based on their own interest (sample bias). Both aspects of this study's selection and sampling method expose the risks that the residents of the institutions which allowed me to recruit were different from the institutions that declined, and furthermore, the residents who deigned to participate were different than those who refused. Any of these differences could make the sample in this pilot study different than the larger SUD sample.

However, participants in this pilot study share characteristics with previous studies of Norwegian and American SUD patients in their mental health, physical health, and QoL, and in their lower scores in each of these categories than the healthy population. Demographically, men were slightly overrepresented (74%) compared to Norway and Nordic countries' average of 67% males in SUD treatment programs [143].

Participants reported worse mental and physical health at baseline than in non-SUD population [133, 161-163], validating previous surveys of SUD patients [14, 142]. Whereas only 11% of Norwegians have clinical levels of emotional distress [162], 55% of participants in this study were emotionally distressed, the same amount found by Ravndal and Laurizen's cross-sectional study of Norwegian SUD patients [14]. Physically, every participant reported at least one somatic disease or problem, compared to 37% of the general population [163].

Participants also reported worse QoL in all domains at baseline than healthy population norms from Denmark and Australia [161, 164], again validating prior studies [165]. The social relationships domain received the lowest score, followed by psychological health, physical health, and environment; this pattern mirrors the general Norwegian population's ranking of QoL domains [133].

Despite the sample sharing similar demographic and clinical characteristics with the overall SUD population, a larger sample would be needed to establish non-difference and therefore increase external validity. A larger sample may also increase the chances of normal distributions of clinical variables among exercisers and non-exercisers, instead of the skewness towards exercisers that was observed in this study.

The context of research is an important factor in a post-positivist assessment of both internal and external validity. The setting and time/history of this pilot study – three public and one private residential SUD treatment institutions, conducted in late summer and early autumn and without any new political or policy discourse or changes around SUD treatment or QoL research – do not pose challenges to sample generalizability. The geographic dispersion of the institutions within Oslo and real-world settings of the treatment may even contribute to such generalizability.

The greatest threat to sample generalizability of program findings is the novel nature of these exercise groups, both in terms of its flexibility and attention to participant accessibility and in the equally flexible and positive engagement of coaches. By nature of its novelty, this pilot study sought to develop a tailor-made intervention and produce suggestions for future interventions. In ***4.3.2 Feasibility***, I will argue for several design features that I think are partly responsible for its success, and I believe these features must be at least replicated and preferably strengthened in future interventions.

4.2.5 Summary

The non-experimental design of this pilot study and inability to use statistical control to account for possible confounding variables due to a low n limits claims of causal validity. Exercisers and non-exercisers were different at baseline in many variables that have established impact on QoL, therefore the impact of these variables – rather than exercise – could explain QoL improvements. The ability to answer the second research aim is reduced. It is tempting to interpret results as evidence that group exercise positively increased two domains of QoL, but this intervention must be replicated in a larger, experimental trial.

Concurrently, self-selection has its own benefits: it forms a clear picture of whom the exercise group appealed to versus whom it did not. This provides useful information that can help future programs target those who liked this program, and/or adjust the program to appeal to a wider variety of patients, helping to robustly answer the fourth research aim. The trade-off of self-selection seems to be that we learned the characteristics of the SUD patients interested in an exercise group, but lost the statistical ability to control for these characteristics when assessing treatment effect.

4.3 Results discussion

This section will discuss the significance and novelty of three categories of results: which effects on QoL were visible, who among this SUD sample the exercise groups engaged, and programmatic aspects that may be of interest to institutions designing or implementing similar interventions.

4.3.1 Effects on QoL

Overall, this pilot study provides further evidence that exercise can be used as an intervention among chronic disease populations to boost selected QoL domains, as meta-analysis of interventions among cancer, cardiovascular disease, neurological, obese, and pulmonary patient samples demonstrate [46, 87, 90]. Two domains of QoL increased over time for exercisers, while two did not change. This section explains the significance of these improvements and integrates alternative explanations. The study of other potential mediating effects, such as the psychological outcomes of positive affect or self-efficacy described in ***1.4 Quality of life*** was beyond the scope of this project.

Improved physical and mental health QoL among exercisers

To my knowledge, this is the first study that quantitatively measured overall QoL in a SUD population before and after an exercise intervention, and the first that estimates a minimum clinically important difference in the selected QoL tool. While one recent pilot study in Denmark qualitatively described increases in QoL after an exercise intervention [166] and an ongoing RCT in the United States called the STRIDE study will measure HRQOL of stimulant abusers after an exercise intervention [104], this pilot study provides quantitative evidence that exercise increased the physical health and mental health domains of QoL with both statistical and clinical significance among this small sample.

The GLM with repeated measures revealed that the interaction of time and participation had a significant effect on, first, the physical health QoL domain: exercisers' physical health domain of QoL positively increased over the course of the pilot study compared to non-exercisers, with statistical significance. After only ten weeks, and for an average of 13-14 training sessions, exercisers were happier with their physical health realm of quality of life. This finding supports Martin et al's finding that even a low dose of exercise can positively impact HRQoL among sedentary women [89], but is the first study that has measured this association among the SUD population., QoL increased among exercising participants even without concurrent health improvements and in the presence of injury. Physical health QoL also increased among exercisers with a heavy burden of mental suffering.

Physical health QoL improvements cannot be attributed to improvements among measured physical health conditions. All participants reported nearly the same amount of physical problems and the same degree of suffering at the start and end of the pilot study, yet exercisers were more satisfied with their physical health after the exercise program. The high prevalence of enduring physical conditions such as headache, tooth/gum problems, and dizziness is unsurprising; they may be connected to medications such as substitution treatment or may be side effects of substance use, such as tooth loss and gum disease resulting from cocaine, heroin, and methamphetamine use. Some of the somatic conditions reported by exercisers (e.g. reduced memory) [167] may be alleviated after a short-term exercise intervention, while others (e.g. respiratory problems [168], joint pain, headaches) have fewer or unclear expected mitigations after such a short program. Group exercise did not reduce the extent to which anyone suffered from each problem, but it lessoned the significance that exercisers assigned to these problems, as expressed through their QoL.

Physical health QoL also increased despite numerous reports of injuries. Participants were asked on the consent form if they had any known physical condition that could prevent them from participating (which none identified), but they were not asked at follow-up if they became injured over the course of the intervention. Aside from the three participants who were excluded from statistical analysis because they cited a severe injury as the reason for complete non-attendance, ten additional participants reported that an injury or health problem impacted their participation in some way. Injuries did not linearly lead to less or non-attendance. While some of these ten participants skipped a few sessions until they recovered, others conducted modified versions of what their group was doing, and others requested and received entirely different sessions. Possibly the worst injury of the analyzed participants was a broken wrist, and that participant only missed one session because of it. The participant requested modified sessions thereafter, and her/his group decided to replace the remaining sand volleyball sessions with running. It was impossible for me to ascertain whether participants' injuries were attributable to exercise (the broken wrist in question was decidedly not), both because of my lack of medical knowledge, and because of the existence of pre-existing conditions such as intermittent claudication; participants themselves may not have been sure about the cause of their injury.

One of the most commonly self-identified benefits of the exercise groups was improved fitness or other health measures. Changes in fitness were unmeasured, and could have increased by some other mechanism among exercisers and thereby attributed to the QoL increase in the physical health domain. Fitness was intentionally not measured so as to not dissuade potential participants who felt particularly unfit, and to keep the focus on the socialness of the groups. When observed progress on physical fitness was relayed to participants in order to increase motivation, a few participants who identified themselves as being previously very fit responded negatively, comparing their current fitness level to a prior level (prior either to SUD or to SUD treatment)[3]. A future intervention could measure fitness instead beginning at week two – after participants had familiarized themselves with the trainers – and/or only for interested participants, and again at follow-up.

As found by previous studies, SUD treatment itself appeared to have a positive impact on psychological health QoL, as this domain increased over time in all subjects with statistical and clinical significance [12, 169, 170]. Psychological health QoL among exercisers also increased *more* than non-exercisers. This finding is encouraging, as it mirrors the positive, exercise-induced QoL benefits related to mental health among healthy and other chronic disease populations reviewed in ***1.5.2 Relationship to QoL***. If SUD patients undergo the same sort of psychological QoL benefits after exercise as, for example, cancer patients – a population for which far more interventions attempting to increase QoL have been performed – the possibilities for knowledge transfer between interventions in each population can be exploited to a greater extent than they are now.

The mediation of mental health burden on psychological health QoL is likely [171, 172]. Exercisers' mental health burden reduced over the course of the study, consistent with several meta-analyses and reviews of mental health outcomes after exercise interventions [173-175], while non-exercisers' mental health burden remained exactly the same. Regression to the mean could explain this difference because non-exercisers' mental health was at a sub-clinical level and exercisers' was not, as could exercise itself, or an unmeasured factor.

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[3] Indeed, physical health QoL was the only domain in which time did not have a statistically significant effect; that is, physical health QoL did not increase over the course of the pilot study for the entire cohort, regardless of exercise. SUD treatment programs are renowned for a lack of attention paid to the physical self insofar as SUD effects are not directly identified, and numerous subjects mentioned that the their activity levels and fitness had decreased during treatment. As one participant remarked when discussing his/her change in fitness, "you can tell if someone went to rehab by how fat they got."

A final confounding factor of both QoL domains could be addiction severity, as measured by the amount of substance used at baseline and follow-up. Both groups began with equivalent levels of addiction severity and this severity reduced among all participants, but the reduction was the largest among exercisers. Exercisers' larger reduction could have been caused by an exercise-independent factor, and both groups' QoL may have increased as a result of less substance use.

No changes in the social relationships or environment domains of QoL

Part of my hypothesis that participation would increase the social relationship domain of QoL was based on a two-part assumption that participants possessed a paltry social network that could benefit from supplementation. The social relationship QoL domain increased almost exactly the same amount for exercisers as for non-exercisers, which could have been caused by several pathways: First, the social contact provided by the exercise group did not lend any benefits to exercisers' social relationship domain. Either they did not value the relationships they built in the groups, or additional relationships with exercising residents were not beneficial because fellow residents were struggling with similar problems. Second, a ceiling effect may have been observed, wherein participants already had a minimum amount of social contact at baseline and additional contact provided via the exercise groups had only marginal effects on social relationships QoL. This explanation is anecdotally supported by the larger amount, compared to my expectations developed in America, of structured and unstructured social activities in which participants partook. Several exercisers reported missing sessions to see friends or family, and sessions were occasionally rescheduled to accommodate formally organized activities such as group day trips. Third, exercisers could have benefited socially from the exercise group, but this gain was offset by decreased engagement with their existing social network, resulting in a null net change in social relationships QoL. Fourth, as described in ***4.2.3 Internal validity***, the QOL instrument may not be sufficient for measuring the social relationships domain of institutionalized patients. The popularity of the group/social aspect expressed through qualitative feedback suggests that the exercise groups were at least enjoyable on a social level, despite no change in this aspect of their QoL that can be attributed to exercise. As participants' social relationships QoL was still lower at baseline and follow-up than a healthy population, it would be unwise to deem supplementary social contact unnecessary.

Participation did not impact the exercising participants' environment domain of QoL in any significant way, which is unsurprising, given that no aspects of their environment were changed by the program. Only one out of eight items measuring environment appear related at first glance to the exercise group: "to what extent do you have the opportunity for leisure activities?"

4.3.2 Feasibility

4.3.2.1 Engagement of the most suffering

Given self-selection, it is expected that exercisers and non-exercisers would differ from each other. In the main outcome, QoL, the groups reported statistically non-different scores in three out of the four domains at baseline. The statistical analysis chosen was in any case robust enough to allow for the statistical difference in the physical health QoL domain.

Surprisingly, participants with the highest mental and physical health burdens selected *into* the exercise group, not out. Mental and physical health burdens were different with statistical significance between the two groups, preventing either measure from being added to the analysis as a covariate. This finding differs from numerous studies among non-SUD populations that show exercise is taken up by those with the fewest mental and physical health problems, and that exercise intervention drop-out is predicted by physical health problems [176, 177]. And while the general population is less mentally distressed and more physically active than the SUD population, those with the worst mental health among this sample of SUD patients actively engaged in the exercise program.

Rather than contradicting these studies, this pilot study's findings provide preliminary evidence that an exercise group, *designed to encourage and reduce barriers to attendance*, can be appealing and maintainable to the physically unhealthy and mentally suffering. I assume that institutions did not pre-select certain participants or discourage others (although this may have happened without my knowledge), because those who exercised were not always the ones providers expected to succeed in the program. At three institutions, providers expressed satisfied surprise over one or more exercisers who they "never thought would stick with it". The success of these exercise groups in engaging the worst off is an encouragement to institutions to extend an adjunct treatment such as exercise to a variety of patients, and not only to those judged to be physically or mentally capable or ready. It is important for treatment providers to not allow personal or clinical judgments of "readiness", even those based on mental and physical health metrics, to become self-fulfilling prophecies expressed in how they extend opportunities for innovative therapies.

A variety of explanations for the appeal of exercise groups to those with the worst mental and physical health problems exist. Perhaps the simplest is that those who felt the worst, emotionally, were also open to more potential opportunities to feel better. This explanation assumes participants had an expectation of the mood-increasing benefits of exercise. In the same way, those with the poorest physical health may have expected exercise to have positive, alleviatory effects on their physical conditions. Poorer physical/mental health may have also been a proxy for separation from the labor market – exercisers were four times more likely to be both unemployed and not studying than non-exercisers – and such separation gave exercisers more free time in which to participate. This latter explanation is unconvincing, given that all participants at the enrollment stage set their group's schedule, and the alteration of a session's time and even date in order to accommodate a change in a participant's work, school, or therapy schedule was a common occurrence. It is possible that I am overestimating the accessibility of these exercise groups and the willingness of participants to request changes, but an important design feature was flexibility in order to maximize attendance, leading me to believe that each exercise group could have met the needs of even the busiest participants, *if* they were interested.

4.3.2.2 Acceptability to participants

Acceptability to participants was demonstrated through exclusively positive feedback regarding their experiences. The lack of negative experiences, even when given through anonymous questionnaires, could reflect their sensitivity towards the coaches as much as a paucity of areas of improvement. Positive feedback also suggests that participants' expectations of the exercise group benefits were at least met and possibly exceeded. Gillison et al [46] found that subjects exercising for chronic disease management as opposed to rehabilitation or prevention improved their physical health QoL but declined in their psychological health QoL. They proffer that the chronic disease subjects' expectations of a novel and hopefully effective treatment may have been unrealistically high, "resulting in a negative impact on mood and emotions", even while recognizable physical benefits were conferred. If exercisers' psychological health QoL gains are interpreted according to Gillison et al's hypothesis, participants of this pilot study appear to have been satisfied by their experiences.

Participants were, without exception, kinder to coaches than the coaches expected, and relationships beyond participant-coach developed over the course of the study. The roles and impact of the coaches are therefore even more vital to discuss, via the qualitative research tool of reflexivity: working with vulnerable populations such as the chronically ill already elevates the likelihood that participants provide program evaluation and reflections that they expect their coaches to hear, and contact and relationships between participants and coaches (as researchers) adds to the likelihood that such evaluation is made with their audience in mind. I do not expect that participants were any less rational or honest than participants of a large, randomized study that minimized social contact researchers might be, because the presumption of rationality and unbiasedness does not underpin this study. Rather, coaches' relationships with participants developed into a program feature that must by identified and explored.

For example, beginning with some participants' interests in the design of the four exercise groups and in my motivation for conducting them, conversations about my background and reasons for moving to Norway developed. Over the course of ten weeks, many participants were aware of the importance I attached to the exercise groups and expressed this through complimenting the amount of time I spent traveling to each one, the amount of effort I used organizing, and so on. I can easily imagine that these same participants refrained from giving negative feedback that they may have contemplated. The lesson to draw from this is not to discount participant feedback in order to compensate for their sensitivity towards the coaches, but that investment by the coaches is an important design feature that impacts participants.

The manner by which these relationships developed was through a far larger degree of contact between coaches and participants than any study design could have prescribed. Some participants maintained a boundary between themselves and the coach, while others gladly talked for thirty minutes after sessions about topics unrelated to the exercise groups. SMS reminders provided a gateway for further communication and investment, as some participants gave more information about themselves and their lives over SMS than they did in person. Coaches used these offerings of information to follow-up with participants about, for example, how a recent family meeting went and if a new class schedule seemed manageable. Coaches' contact with participants was not limited to 30-minute sessions, and this had several results: as discussed above, it formed relationships between coaches and participants and transmitted coaches' investment to participants; and at the most topical, it reminded participants that they would always be welcome at a session, even if they had missed previous ones. This contact seemed to play an important role in participant motivation.

The elevation of the coaches as trained, physically fit specialists over their physically unfit participants, not to mention the setting of the groups which signaled participants to be patients undergoing treatment for a disorder, created an immediate power difference which needed to be recognized by coaches and the author of this study at the start, negated during the study, and taken into account as much possible during analysis. This power difference was acknowledged by participants-to-be when I pitched the idea of the exercise groups to one of the institutions. Two residents had been selected by institution staff to provide input on behalf of the their fellow residents, and after giving me feedback on the types of activities they would like and on the burden that answering the questionnaires might be to some residents with learning disabilities, their final suggestion was to have a coach "more like us, and less like you. Maybe a little fatter?" This jestful reference to the difference between our physical fitness was the first indication that I needed to talk less during recruiting meetings about my qualifications, and that I – despite being smaller, younger, and foreign, characteristics which I expected to damage my credibility unless buttressed by coaching qualifications – could be intimidating or alienating.

An unexpected amelioration of some of the coach-to-participant power difference occurred through language. Both I and, coincidentally, the hired coach were non-native Norwegian speakers, and after the first week or two of getting to know the participants, they became comfortable enough to tease us for our language mistakes. Participants often corrected my language when I described a day's session, and some appeared to enjoy teaching me; these participants made a point of asking me if I understood what they had said, and spelled out a particular word or took pains to explain a concept. When I thanked two participants who particularly liked "tutoring" me and added that I furthermore enjoyed the positive social contact of the groups, one responded, "I'm glad you're getting something out of it too, and it's not just us." The other added, "That's important." The coaches' imperfect language skills may not have negated the power differential of coaches holding instructive, inherently more knowledgeable positions, but it did open a channel of reciprocity, wherein participants became the correctors and teachers, the ones holding the power to either encourage or discourage. Indeed, Johansen et al's development of a social support model of SUD recovery (wherein a recoverer has a relationship with a sponsor) suggests that recoverers benefit from being able to help their sponsor in some way, and that attention to power differences can be paid through "giving the less secure individual position to contribute to the relationship" [39].

I cannot envision an alternative design that further reduces the power differential between coaches and participants, as the former must necessarily possess fitness training. Rather than recommending all future coaches have a handicap such as an imperfect grasp of their participants' language, coaches must simply be well-trained to respect their participants as complicated, sensitive individuals, *with* whom coaches are working, not *about* whom coaches are studying. Allowing opportunities for participants to set their own physical goals and for coaches to learn from participants – such as when participants taught me how to play sand volleyball and floorball/innebandy – appears to have helped create "mastery experiences" in which they "were of use" to me as a sponsor and I was then able to affirm those activities, to again borrow from Johansen et al's model [39].

Utilizing motivating and engaging coaches to supervise sessions are two design features that likely attributed to the groups' appeal to the physically and mentally worst off. Several additional features related to increasing to participants' motivation to attend and exercise: the group aspect, low-intensity (at least in the beginning), and feedback to participants of achievements and progress. Motivation to *attend* and to *exercise* are not entirely the same. Some exercisers attended even when they were not in the mood to exercise, because a) they felt an obligation to their coach, either in general or after having responded to a reminder SMS positively; b) they showed up only to explain their non-attendance and were convinced by their coach to participate; or c) they were forcing themselves to exercise despite not wanting to. It is clear that the exercise groups were more than exercise groups, as participants attended for reasons other than to exercise.

The importance of motivation during sessions cannot be understated. It was the program benefit most identified by participants as well as the characteristic most commonly ascribed to the coaches. Roessler et al wrote about a similar finding in their pilot study of SUD patients participating in a running program. Even though running itself was the explicit focus and the study took place in a laboratory setting, without emphasis on the socialness of the exercise or interactions between instructors and participants, instructors' "informal conversations with the patients showed to be very important to create a motivational environment...the feedback of the instructor and the other group members increased the dedication and commitment" [109]. Providing such constant motivation was a strain on the coaches and one for which we were not prepared or trained for, and each of us felt burned out after six or seven weeks of being relentlessly positive.

Nevertheless, one benefit of a lack of SUD-patient-training on the sides of the coaches was that I can confidently claim to have not created any self-fulfilling prophecies that underestimated participants' abilities. I was surprised by the poor physical form of participants in the first few sessions, and while I hope I did not embarrass them with my surprise, I do not anticipate that any participants exercised "down" to a level that I expected of them.

Volunteers, whether recruited volunteers from the community or institution staff, were also an enormous help, as they lessened the burden on coaches to single-handedly encourage and engage multiple participants. Recruiting volunteers was more difficult than I anticipated and the only institution that was interested in and received volunteers appeared ambivalent about them. Solutions to future interventions could be to hire one coach per group, or to maintain multiple groups per coach, but to train coaches in basic motivational techniques. Despite no program-attributable increases in participants' social relationship QoL domain, the group aspect of the exercise groups was a popular program facet. It was important for a participant to see that s/he was not the only one in poor shape, and I was surprised at the level of encouragement and motivation they gave to each other. To this end, exercising with fellow SUD patients appeared to be a better environment for many participants than exercising with external volunteers.

Behavioral adherence techniques have been widely explored in exercise interventions among the overweight and obese but seldom among the mentally ill or those with a SUD, perhaps reflecting researchers' greater uncertainty of exercise success among the latter than former clinical groups. Most successful design features in this pilot study that were related to motivation were borrowed from behavioral adherence techniques within exercise-for-weight-loss literature, providing further proof that exercise interventions for the SUD population should not hesitate in borrowing best practices from successful exercise interventions with other populations.

The second grouping of design features served to make the exercise groups as accessible as possible, namely, removing the need to travel, setting session times according to participant schedules, sending reminder SMSes before every session, and coordinating with institutions to avoid schedule conflicts. This last feature was implemented only in institutions 1 and 3, which had an increase in average attendance over time, while institutions’ 2 and 3 saw attendance decrease. Institution 1 had one staff member who attended half of all sessions, kept sessions on her calendar and reminded participants, avoided scheduling treatment-related events concurrently, and informed me in advance when conflicts were unavoidable. Institution 4 had one staff member who attended one-third of sessions, the same day each week, and alerted all participants as to this day. In contrast, it behooved participants in institutions 2 and 3 to alert me as to upcoming conflicts with institution meetings, which in turn required a higher degree of commitment to the program and organization from these participants than from the others. While a degree of independence between myself and their institutions seemed appreciated by at least two participants (those who liked that their conversations with me were confidential from their institutions), the exercise groups would have been more accessible to participants had the coaches and the institutions collaborated more. These four features are easily replicable design features. They are unusual in exercise intervention literature, because they require a commitment to participant accessibility and more flexibility from the researcher/coach’s side.

4.3.2.3 Implications and recommendations

Many of the methodological limitations discussed in ***4.2 Methodological discussion*** that challenge non-falsified causal validity can be alleviated through a proper experimental design. Random assignment into control and treatment groups would yield statistically non-different groups, allow for the subsequent inclusion of covariates into statistical analysis, and reduce the need to qualify results based on potential confounding variables. Control groups selected from different institutions than treatment groups would further reduce group contamination. Finally, a larger sample size could also pay more attention to possible subgroup differences by focusing on gender, race/ethnicity, or primary substance used.

A future randomized control trial should contain at least 200 participants; 100 receiving the exercise treatment and 100 in a control group. Sample size calculations shown on Appendix 7 [178] calculated with the MCID of each domain suggested 128 participants (64 in each group) is a sufficient amount to conduct an analysis, but taking attrition into account, a trial of at least 200 would be a safer way to ensure useable data from the necessary 128 is collected at both time points. An RCT of this size could produce further evidence of the statistical and clinical effect of group exercise on participants’ QoL.

This pilot study speaks to the importance of holistic SUD treatment. This offer – a social exercise group lead by coaches outside of participants' normal SUD treatment system – aimed to provide participants with a supportive environment, physical exercise and confidence, and novel activities in a way that then led them to more highly value their specific abilities and situations. Participants had additional access to guided meditation and mindfulness courses, yoga, activities in nature, equine-assisted therapy, art therapy, and courses in Christianity, as indicated by pamphlets and flyers in the various cooperating institutions. However, with the holistic outcome of QoL emerging as a clinically meaningful protective measure and goal of SUD treatment, further services could be added to the treatment field. Services such as nutrition and healthy-eating guidance, additional spiritual counseling, message therapy, and biofeedback could focus on further aspects of SUD patients' lives that have negatively affected by SUD, provide patients with supplementary skills and strengths on their recovery paths, and, ultimately, serve to improve QoL at whichever stage of treatment or recovery patients find themselves.

The success of the pilot study in improving exercisers' physical health QoL and mental health QoL can be attributed to four broad categories of design features, with some overlap, that I recommend future interventions replicate and strengthen:

1. Motivational techniques: For most participants, beginning a regular exercise program was physically difficult and a challenge to garner enough energy and motivation for. Motivating participants to attend involved counteracting any negative reactions or expectations to the groups, and making the groups engaging and interesting.
    a. Group exercise: exercising with peers made the sessions more enjoyable and approachable than one-on-one personal training sessions may have been. Larger groups also allowed for a variety of group sports.
    b. Begin with a low intensity: the vast majority of participants were physically unfit and smoked, which made breathing difficult even while walking.
    c. Incorporate a variety of activities
    d. Regular feedback about progress and accomplishments: notifying participants in person or via SMS of any positive aspects of their participation made it clear that even their participation was recognized and appreciated.
2. Maximizing accessibility: Qualitative research among chronically ill populations has identified even more barriers to them than to healthy populations when beginning

and maintaining an exercise program, such as a lack of program elements practically tailored to their particular situations or limitations, and the stigma or embarrassment felt by exercising among healthier individuals [179, 180]. Making the exercise groups accessible to participants therefore means attention to participants' treatment schedules, physical and mental conditions (particularly poor memory), uncertainties and discomforts, and more. Such attention must be balanced by not creating self-fulfilling prophecies. Removing barriers that other studies have identified is highly recommended.

   a. Use participant preferences to plan schedules and activities, and make ongoing adjustments as requested: this requires a large amount of flexibility and dedication to serving participants.
   b. Session reminders and open communication between coaches and participants: SMSes and informally meeting with participants both before and after sessions are easy, affordable communication mechanisms.
   c. Coordinate with institutions to avoid scheduling conflicts
   d. Remove the need for participants to travel or pay

3. Coach roles: Coaches should necessarily hold roles beyond those of skilled trainers. They could benefit from basic training in motivational techniques and/or in pre-exposure to this population's unique characteristics.
   a. Motivation
   b. Relationship-building with individual participants
   c. Attention to and engagement with participants as equal group members, not patients or subjects: attention to power differentials through constant reflexivity.
4. Institutional involvement:
   a. Add exercise group screening tools to institutional intake forms, to increase enrollment into at least the comparison group. Alternatively, staff encouragement to enroll.
   b. Review questionnaire content to identify potentially triggering questions and provide support to participants while answering the questionnaires.
   c. Publicize exercise group schedules: e.g. posting physical schedules in common areas, reminding residents during institution meetings.
   d. Communicate with coaches to handle schedule conflicts in advance.

5. Conclusion

5.1 Conclusions of the pilot study

The aims of this thesis were both scientific and procedural. Scientifically, the objectives were to evaluate changes in SUD patients' QoL who participated in a coach-led, group exercise intervention for ten weeks, and to explore the role of group exercise in addition to other factors in explaining these changes. The exercise groups appeared to increase, with statistical and clinical significance, exercisers' physical health QoL and psychological health QoL. Simply undergoing ten weeks of SUD treatment increased all participants' psychological health QoL, social relationships QoL, and environment QoL. The physical health QoL domain was unique in that non-exercisers' QoL declined over time, suggesting that the exercise groups provided positive effects here that usual SUD treatment could not. The uneven distribution of clinical variables between exercising and non-exercising participant made it impossible for the study to determine if QoL changes were due purely to the exercise group and not to other measured or unmeasured factors.

Procedurally, this thesis intended to design and implement these exercise groups and evaluate their feasibility and replicability. The voluntary group exercise regimen was well-received by this sample of sedentary SUD patients, and a set of affordable, easily replicable recommendations were made for the implementation of a future intervention: exercise should remain a social activity, involve motivating and engaged coaches, engage the treatment institutions, and incorporate with flexibility participants' preferences in order to maximize accessibility to them.

A unique accomplishment of this study as an exercise intervention was to attract participants with the highest burdens of physical and mental suffering into the exercise groups. These characteristics along with other baseline data collected can be used in the targeting of future interventions within SUD populations. The impact of QoL improvements after such a short intervention may be of interest to other SUD institutions, such as those providing outpatient services, and to institutions serving patients with dual diagnoses. Among institutions that offer such interventions, even without a pre-existing emphasis on QoL, this knowledge can be propagated to patients to allow them to make the most informed choices to participate.

Both the scientific and procedural findings of this pilot study encourage knowledge transfer. Exercise improved these patients' physical and psychological health QoL as other studies have shown it to do among different clinical subpopulations [46, 87, 90]. Similarly, the successful motivational techniques and behavioral adherence factors utilized were heavily borrowed from interventions among healthy, unhealthy, overweight, and elderly adults [111-113, 118, 119]. With these examples, the final recommendation from this pilot study is that the design of interventions to improve QoL should utilize knowledge transfer to a much greater extent between clinical and healthy populations and between different clinical subpopulations. There exist far more evidence-based recommendations about how to encourage non-SUD populations to begin and maintain beneficial exercise than about the SUD population, and the SUD research and treatment fields should not hesitate in examining the potential usefulness of these recommendations in an attempt to provide SUD patients with such a promising intervention.

Entering this project, research from the SUD field told us that patients have far lower QoL than a person without a SUD, and that higher QoL has an important predictive and possibly causal relationship with maintained treatment. From the exercise science research field, we knew that one of exercise's numerous benefits is increased QoL. And from patients and treatment providers themselves, we heard pleas for attention to QoL within treatment matrices and the recovery paradigm [32, 51, 53, 165, 181, 182]. This pilot study has provided preliminary evidence that even small amounts of exercise in a social context can have statistically and clinically significant positive impacts on SUD patients' physical health QoL and psychological health QoL. That which remains now is to use these design recommendations and findings to continue developing impactful, sustainable exercise interventions for this population.

5.2 Research limitations

The non-experimental design utilized in this pilot study limits my ability to assert the causal effects of the exercise groups. The lack of randomization and small sample size are particular violations of non-spuriousness that challenge internal validity, while the inability to statistically control for mental health burden, somatic health burden, and addiction severity require these variables to be taken into account when interpreting the study's positive results.

The sample was comprised of urban, predominantly middle-aged persons with an established history of SUD treatment and poly-substance use. The exercise groups may not have been accepted to the same extent or had similar effects if conducted within a different subpopulation of SUD patients, such as those with a lower addiction severity or participating in outpatient programs.

The dearth of in-depth qualitative data on participants' experiences with the exercise groups has lent less help than anticipated in crafting future intervention recommendations, the procedural objective of this thesis. Analysis of the qualitative data that was collected may have been affected by my translations from Norwegian to English.

5.3 Future research

The positive impacts of group exercise on two out of four domains of QoL are reason enough to pursue further research among a population with notoriously low QoL. In terms of substance, this pilot study's findings point to several areas that require further research:

First, while the longitudinal nature of this pilot study allowed for preliminary mentions of causality, further follow-up data collection regarding the maintenance of QoL changes and QoL's relationship to upkeep of exercise and SUD treatment retention should be added to future interventions. It is important to maintain usage of a standardized QoL tool to enable comparison with other chronic disease populations and other treatment interventions.

Second, given that the exercise groups appealed to those suffering the most physically and mentally, it would be interesting to explore modifications of this study's design recommendations that could solidify its appeal to this subset of patients. A multi-site experiment that varied design factors such as dose, intensity, or group size would provide information about the characteristics of SUD patients who respond to different factors. Qualitative research could provide deeper insight into participants' reasons and motivations for participating, of which various design features may play one of many roles. The theme of *motivation* could be an important focus in and of itself: how do participants motivate themselves to participate (e.g. incentives, a certain threshold of self-efficacy)?; does exercise motivate participants in other areas of their lives or treatment (e.g. increased health behaviors)?; and what are the gaps in motivation that could be addressed?.

Third, qualitative research could also help uncover patients' perspectives of the mechanisms by which group exercise affects each QoL domain, and further inform program design. If conducted as part of a longer study with further follow-up, such research could also explore the possible intersection of exercise, QoL, and recovery, and could probe for mediating factors such as self-confidence and self-efficacy that were outside the scope of this pilot study.

Fourth, the practicalities and possibilities of integrating a group exercise program into SUD treatment should be explored. This pilot study was low-cost but labor-intensive, and coaches were not employees of any participating institutions. Each subsequent, similar intervention implemented and evaluated will add experiential knowledge about how best to implement such a program. Organizations that struggle financially to provide adjunct therapies to SUD patients could benefit the most from further experimentation with this low-cost intervention.

The utility of an exercise intervention in improving QoL also speaks to the importance of treating SUD patients holistically. SUD treatment can and should include protective and alleviatory mechanisms to address the wide range of negative effects that SUD has on patients, those closest to them, and their societies. An exercise intervention is only one of many QoL-enhancing options that should be explored for its far-reaching benefits.

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Appendix 1

Seraf
Senter for rus- og avhengighetsforskning

Løpenr
☐☐☐

Fysisk aktivitet for å øke livskvalitet blant ruspasienter:

WHOQOL-BREF (III)

SERAF 2013

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World Health Organization Quality of Life Brief / WHOQOL-BREF (III)

Instruksjon

Dette spørreskjemaet spør etter hvordan du opplever din livskvalitet, helsen og andre sider ved livet ditt. **Vennligst besvar alle spørsmålene.** Hvis du er usikker på hvilket svaralternativ du skal velge, skal du velge det som synes å passe best. Dette kan ofte være din første reaksjon på spørsmålet.

Et eksempel

Tenk på dine håp og gleder, hva du er opptatt av og hvordan du ønsker livet skal være. Vi ber deg tenke på hvordan livet ditt har vært **de siste to ukene**. Med hensyn til de siste to ukene, kan **for eksempel** et spørsmål være:

Får du den type støtte som du trenger fra andre?	Ikke i det hele tatt	Litt	Ganske mye	Mye	Fullstendig
	1	2	3	4	5

Sett ring rundt det tallet som best svarer til hvor mye du har fått av den type støtte du trengte fra andre i de siste to ukene. Du vil da sette ring rundt tallet 4 dersom du fikk mye støtte fra andre.

Får du den type støtte som du trenger fra andre?	Ikke i det hele tatt	Litt	Ganske mye	Mye	Fullstendig
	1	2	3	4	5

Du vil sette ring rundt tallet 1 dersom du ikke i det hele tatt har fått den type støtte du trengte fra andre.

Vennligst les hvert spørsmål, tenk over hva du føler og sett ring rundt det tallet på svarskalaen som for deg gir det beste svaret på hvert spørsmål.

	Svært dårlig	**Dårlig**	**Verken god eller dårlig**	**God**	**Svært god**
Hvordan vil du vurdere kvaliteten på livet ditt?	1	2	3	4	5

	Svært utilfreds	**Utilfreds**	**Verken tilfreds eller utilfreds**	**Tilfreds**	**Svært tilfreds**
Hvor tilfreds er du med helsen din?	1	2	3	4	5

De følgende spørsmålene spør etter **hvor mye** du har opplevd av bestemte ting i de siste to ukene.

	Ikke i det hele tatt	**Litt**	**Til en viss grad**	**I høy grad**	**I svært høy grad**
I hvilken grad føler du at smerte hindrer deg i å gjøre det du må?	1	2	3	4	5
I hvilken grad trenger du medisinsk behandling for å kunne fungere til daglig?	1	2	3	4	5
Hvor mye gleder du deg over livet?	1	2	3	4	5
I hvilken grad føler du at livet ditt er meningsfullt?	1	2	3	4	5
Hvor godt kan du konsentrere deg?	1	2	3	4	5
Hvor trygg føler du deg til daglig?	1	2	3	4	5
Hvor sunne er dine fysiske omgivelser?	1	2	3	4	5

De følgende spørsmålene spør etter **hvor fullstendig** du opplevde eller kunne utføre bestemte ting i løpet av <u>de siste to ukene.</u>

	Ikke i det hele tatt	Litt	Til en viss grad	I høy grad	Fullstendig
Har du nok energi til dine daglige gjøremål?	1	2	3	4	5
Kan du akseptere utseende ditt?	1	2	3	4	5
Har du nok penger til å dekke dine behov?	1	2	3	4	5
Hvor tilgjengelig er den informasjonen som du trenger i dagliglivet?	1	2	3	4	5
I hvilken grad har du mulighet for å delta i fritidsaktiviteter?	1	2	3	4	5

	Svært dårlig	Dårlig	Verken godt eller dårlig	Godt	Svært godt
Hvor godt er du i stand til å komme deg dit du vil?	1	2	3	4	5

De følgende spørsmålene spør etter hvor **glad eller tilfreds** du har følt deg over bestemte sider ved livet i de siste to ukene.

	Svært utilfreds	**Utilfreds**	**Verken tilfreds eller utilfreds**	**Tilfreds**	**Svært tilfreds**
Hvor tilfreds er du med hvordan du sover?	1	2	3	4	5
Hvor tilfreds er du med din evne til å utføre dine daglige gjøremål?	1	2	3	4	5
Hvor tilfreds er du med din arbeidskapasitet?	1	2	3	4	5
Hvor tilfreds er du med deg selv?	1	2	3	4	5
Hvor tilfreds er du med ditt forhold til andre mennesker?	1	2	3	4	5
Hvor tilfreds er du med ditt seksualliv?	1	2	3	4	5
Hvor tilfreds er du med den støtten du får fra dine venner?	1	2	3	4	5
Hvor tilfreds er du med forholdene der du bor?	1	2	3	4	5
Hvor tilfreds er du med din tilgang til helsetjenester?	1	2	3	4	5
Hvor tilfreds er du med transportmulighetene dine?	1	2	3	4	5

Det følgende spørsmålet refererer seg til **hvor ofte** du har opplevd eller følt negative følelser i løpet av <u>de siste to ukene.</u>

	Aldri	**Sjelden**	**Ofte**	**Svært ofte**	**Alltid**
Hvor ofte opplever du negative følelser, som f.eks. at du er trist, fortvilet, engstelig eller deprimert?	1	2	3	4	5

Appendix 2

Senter for rus- og avhengighetsforskning

Løpenr

Fysisk aktivitet for å øke livskvalitet blant ruspasienter:

Inklusionsskjema (I)

SERAF 2013

Kontaktpersoner:
Ley Muller ley.muller@gmail.com
Thomas Clausen: thomas.clausen@medisin.uio.no

Kjønn

☐

1 = Mann
2 = Kvinne

Dato for start kartlegging

☐☐ ☐☐ ☐☐☐☐

dag måned år

Dato for første behandlingsdag

(for LAR-pasienter første dag med LAR medisin)

☐☐ ☐☐ ☐☐☐☐

dag måned år

Behov for tolk

☐

1 = Ja
2 = Nei

Fødeland og etnisk bakgrunn

1 = Norge
2 = Norden utenom Norge
3 = Vest-Euroopa utenom Norden
4 = Øst-Europa
5 = Asia (inkl. Tyrkia)
6 = Afrika
7= Sør- og Mellom-Amerika (ink.l Mexico)
8 = Nord-Amerika
9 = Oceania
99 = Ukjent

☐	☐	☐
Fødeland	Mors fødeland	Fars fødeland

Sivilstatus

☐

0 = Ikke oppgitt
1 = Aldri gift
2 = Gift
3 = Enke / enkemann
4 = Separert
5 = Skilt
6 = Registrert partner
7 = Separert partner
8 = Skilt partner
9 = Gjenlevende partner

Høyeste fullførte utdanning

☐

1 = Ikke avsluttet grunnskole
2 = Grunnskole
3 = Videregående skole/gymnas/yrkesskoleutdanninger
4 = Faglig yrkesutdanning
5 = Treårig høyskole/universitet
6 = Mer enn treårig høyskole/universitet
9 = Ukjent

Yrkesstatus

☐

1 = Utenfor arbeidsmarkedet og ikke under utdanning
2 = Heltidsjobb
3 = Deltidsjobb
4 = Under utdanning
5 = Deltidsjobb og under utdanning
9 = Ukjent

Viktigste inntekt siste 4 uker

☐

1 = Lønnet arbeid
2 = Forsørget
3 = Arbeidsledighetstrygd
4 = Syke-/rehabiliteringspenger
5 = Atføringspenger
6 = Uførepensjon
7 = Alderspensjon
8 = Sosial stønad
9 = Annet
10 = Ukjent
11 = Studielån/stipend
12 = Stønad til enslig forsørger

Bor sammen med (flere valg mulig)

☐ 1 = Bor alene
☐ 2 = Bor i parforhold
☐ 3 = Bor sammen med venner
☐ 4 = Bor sammen med foreldre
☐ 5 = Bor sammen med barn under 18 år
☐ 6 = Bor sammen med barn over 18 år
☐ 7 = Bor sammen med andre
☐ 9 = Ukjent

Boligforhold siste 4 uk

☐

1 = Ingen bolig
2 = Hospits/hybelhus/hotell
3 = Institusjon
4 = Egen privat bolig
5 = Privat bolig eid av annen
6 = Annet

Hatt en stabil bosituasjon siste 4 uker

☐

1 = Ja
2 = Nei
9 = Ukjent

Barn

Antall egne barn uansett alder og bosituasjon ☐

Alder og bosituasjon for barn under 18 år

	0-6 år	7-12 år	13-17 år
Hjemmeboende barn (egne), angi antall	☐	☐	☐
Hjemmeboende barn (andres), angi antall	☐	☐	☐

Tiltak for barn under 18 år (ikke NPR)

	1 = Ikke behov	2 = Bør iverksettes	3 = Er iverksatt	9 = Ukjent
Hjemmeboende barn (egne), angi antall	☐	☐	☐	☐
Hjemmeboende barn (andres), angi antall	☐	☐	☐	☐

Graviditet

☐
1 = Ja
2 = Nei
9 = Ukjent

☐☐ **Antall uker gravid**
(Eks.: 1 uke = 01; 2 uker = 02; 10 uker = 10)

Vedvarende somatiske sykdommer eller skader

☐
1 = Ja
2 = Nei
9 = Ukjent

Psykiske vansker/lidelser

Siste 4 uker	**Tidligere i livet**	(begge kolonnene må besvares for hvert spørsmål) 1 = Ja 2 = Nei 9 = Ukjent
☐	☐	Hatt alvorlige depresjoner
☐	☐	Hatt alvorlig angst
☐	☐	Hatt vrangforestillinger/hallusinasjoner
☐	☐	Blitt forskrevet medisiner for et eller annet psykisk/følelsesmessig problem
☐	☐	Hatt alvorlige tanker om å ta livet av seg

Type tidligere behandling rus

☐

1 = Kun avrusning (institusjon eller poliklinisk)
2 = Poliklinisk vedlikeholdsrehabilitering (LAR)
3 = Annen poliklinisk behandling, inkludert dagtilbud
4 = Døgnbehandling ut over avrusning
5 = Poliklinisk-(LAR eller annen) og døgnbehandling (inkludert avrusning)
6 = Behandling utenfor rusinstitusjon/rustiltak
8 = Ikke tidligere behandlet
9 = Ukjent

Tid siden siste behandling rus

☐☐☐ **Angi antall måneder siden siste behandling**
(Eks.: 1 mnd = 001; 12 mndr = 012; 12 år = 144)

000 = Vært i behandling, men ukjent når sist

Antall rusmidler brukt siste 6 måneder

☐☐ **Angi antall rusmidler**
(Eks.: 1 rusmiddel = 01; 2 rusmidler = 02; 10 rusmidler = 10)

00 = Ingen
99 = Ukjent

Rusmiddel-/medikamentprofil siste 2 måneder

	Type rusmiddel/medikament (Bruk koden nedenfor)	**Inntaksmåte** (Bruk koden nedenfor)	**Hvor ofte brukt siste 4 uker** (Bruk koden nedenfor)	**Alder brukt første gang**	**Hvor lenge problemfylt bruk** (Antall år)
Mest brukte rusmiddel/ medikament	☐	☐	☐	☐ ☐	☐ ☐
2. mest brukte	☐	☐	☐	☐ ☐	☐ ☐
3. mest brukte	☐	☐	☐	☐ ☐	☐ ☐
4. meste brukte	☐	☐	☐	☐ ☐	☐ ☐

0 = Ingen

1 = Alkohol

2 = Cannabis

3 = Heroin/Opium

4 = Metadon, buprenorfin, andre opiater/opioder forskrevet i LAR-program

5 = Metadon, buprenorfin, andre opiater/opioder forskrevet utenfor LAR-program

6 = Metadon, buprenorfin, andre opiater/opioder ervervet uten at forskrevet av lege

7 = Benzodiazepiner forskrevet av lege

8 = Benzodiazepiner ikke forskrevet av lege

9 = Andre vanedannende medikamenter

10 = Amfetamin

11 = Kokain

12 = Crack

13 = Andre sentralstimulerende midler

14 = LSD og likn.

15 = Ecstasy

16 = Løsemidler

17 = Rødsprit o.l

18 = Annet

99 = Ukjent

1 = Drikker/spiser

2 = Injiserer

3 = Røyker

4 = Sniffer

8 = Annet

9 = Ukjent

1 = Ikke brukt

2 = Sjeldnere enn 1 gang i uken

3 = Omtrent ukentlig

4 = 2-4 dager i uken

5 = 5-6 dager i uken

6 = Daglig

9 = Ukjent

99 = Ukjent

00 = Ikke
01 = Et år eller mindre
99 = Ukjent

Brukt sprøyter før?

☐

1 = Ja
2 = Nei
9 = Ukjent

Alder første sprøytebruk

☐ ☐

Angi alder i år

00 = Aldri brukt sprøyter
99 = Ukjent

Sprøytebruk siste 4 uker

☐

1 = Ikke brukt sprøyte
2 = Sjeldnere enn 1 gang i uken
3 = Omtrent ukentlig
4 = 2-4 dager i uken
5 = Daglig eller nesten daglig
9 = Ukjent

Antall ganger overdose hele livet

Antall for hvert av stoffområdene

☐ ☐ ☐ ☐

00 = Ingen ganger
99 = Ukjent

☐ ☐ ☐ ☐

Alkohol Narkotika

Opplysninger fra usikker kilde?

☐

1 = Ja
2 = Nei

Medikament Kombinasjon

Behandlingserfaring

Hvor mange måneder til sammen har du vært i døgnbehandling i ditt liv? ☐ ☐ ☐
(Eks.: 1 mnd = 001; 12 mndr = 012; 12 år = 144)

Hvor mange måneder til sammen har du vært i poliklinisk behandling i ditt liv? ☐ ☐ ☐
(Eks.: 1 mnd = 001; 12 mndr = 012; 12 år = 144)

Hva er ditt behandlingsmål med dette behandlingsopplegget? ☐

1 = Rehabilitering med rusfrihet
2 = Stabilisering med bedre rusmestring

Ønske for varighet av behandling? ☐ ☐ ☐
(Eks.: 1 mnd = 001; 12 mndr = 012; 12 år = 144, Livslang = 999)

Kontrollert miljø

I løpet av de siste 30 dagene før denne behandlingen,
har du vært innlagt i det vi kan kalle et «kontrollert miljø»? ☐

1 = Nei

2 = Fengsel

3 = Behandlingsinstitusjon for rusmiddelmisbrukere

4 = Somatisk sykehus

5 = Psykiatrisk sykehus/klinikk

6 = Bare avrusning/avgiftning

7 = Annet kontrollert miljø, spesifiser: ……………………………………

Var dette miljøet/behandling med LAR?

☐ Nei

☐ Ja

Tobakksvaner siste 6 måneder før behandling

Røyket du tobakk?

☐

1 = Ja
2 = Nei

Hvis ja, hvor mange sigaretter daglig? ☐

Brukte du snus?

☐

1 = Ja
2 = Nei

Hvis ja, antall bokser per dag? ☐

SCL – 25. Hvor mye har du vært plaget av: (den siste uka)

(samme spørsmål i SCL-90)

Sett en ring rundt det svaret som passer deg best.	0 Ikke i det hele tatt	1 Litt	2 Moderat	3 Ganske mye	4 Veldig mye
1. Hodepine	0	1	2	3	4
2. Skjelving	0	1	2	3	4
3. Matthet eller svimmelhet	0	1	2	3	4
4. Nervøsitet, indre uro	0	1	2	3	4
5. Plutselig frykt uten grunn	0	1	2	3	4
6. Stadig redd eller engstelig	0	1	2	3	4
7. Hjertebank, hjerteslag som løper avgårde	0	1	2	3	4
8. Følelse av å være anspent, oppjaget	0	1	2	3	4
9. Anfall av angst eller panikk	0	1	2	3	4
10. Så rastløs at det er vanskelig å sitte stille	0	1	2	3	4
11. Mangel på energi, alt går langsommere enn vanlig	0	1	2	3	4
12. Lett for å klandre seg selv	0	1	2	3	4
13. Lett for å gråte	0	1	2	3	4
14. Tanker om å ta ditt liv	0	1	2	3	4
15. Dårlig matlyst	0	1	2	3	4
16. Søvnproblemer	0	1	2	3	4
17. Følelse av håpløshet med tanke på fremtiden	0	1	2	3	4
18. Nedtrykt, tungsindig	0	1	2	3	4
19. Følelse av ensomhet	0	1	2	3	4
20. Tap av seksuell lyst og interesse	0	1	2	3	4
21. Følelse av å være lurt i en felle eller fanget	0	1	2	3	4
22. Mye bekymret eller urolig	0	1	2	3	4
23. Uten interesse for noe	0	1	2	3	4
24. Følelse av at alt er et slit	0	1	2	3	4

25. Følelse av å være unyttig	0	1	2	3	4

Somatisk helse. Hvor mye har du vært plaget av: (siste 2 måneder)

Sett en ring rundt det svaret som passer deg best.	0 Ikke i det hele tatt	1 Litt	2 Moderat	3 Ganske mye	4 Veldig mye	Kronisk lidelse? (minst 3 mnd i løpet av siste halvår før inntak) Ja	 Nei
Fordøyelsesplager	0	1	2	3	4	☐	☐
Diare	0	1	2	3	4	☐	☐
Forstoppelse	0	1	2	3	4	☐	☐
Luftveisplager	0	1	2	3	4	☐	☐
Eksem	0	1	2	3	4	☐	☐
Hudinfeksjoner	0	1	2	3	4	☐	☐
Leddsmerter	0	1	2	3	4	☐	☐
Hodepine	0	1	2	3	4	☐	☐
Brystsmerter	0	1	2	3	4	☐	☐
Svimmelhet	0	1	2	3	4	☐	☐
Nedsatt hukommelse	0	1	2	3	4	☐	☐
Synsforstyrrelser	0	1	2	3	4	☐	☐
Urinveisplager	0	1	2	3	4	☐	☐
Kjønnsykdommer	0	1	2	3	4	☐	☐
Blodpropp	0	1	2	3	4	☐	☐
Tann/tannkjøttsplager	0	1	2	3	4	☐	☐

Har du noen av de nevnte sykdommer per i dag?

	Ja	Nei	Ukjent/ vet ikke	Hvis Ja, har du i løpet av de siste 6 mnd fått behandling for din(e) sykdom(mer)? Ja	 Nei
Diabetes	☐	☐	☐	☐	☐
Høyt blodtrykk	☐	☐	☐	☐	☐
Hjertesykdom	☐	☐	☐	☐	☐
KOLS	☐	☐	☐	☐	☐
Astma	☐	☐	☐	☐	☐
Hepatitt B	☐	☐	☐	☐	☐

Hepatitt C	☐	☐	☐	☐	☐
Leverchirrose	☐	☐	☐	☐	☐
HIV	☐	☐	☐	☐	☐
Kreft	☐	☐	☐	☐	☐
Annet ………………………………..	☐	☐	☐	☐	☐

Dopingmidler siste 6 måneder før behandling

Brukte du dopingmidler? ☐ 1 = Ja 2 = Nei	Hvis ja, hvor mange ganger per uke? ☐

Hvis ja, hvilken type dopingmidler? ☐ Anabole steroider ☐ Andre: ……………………………

Fysisk trening siste 6 måneder før behandling

Drev du med fysisk trening, enten organisert eller i privat regi? ☐
1 = Ja
2 = Nei

Hvis ja, hva slags trening? …………………………………………………………

Hvis ja, hvor mange minutter per dag? ☐ Hvor mange dager per uke? ☐

Høyde og vekt

Selvrapportert vekt i kilo ☐☐☐

Selvrapportert høyde i cm ☐☐☐

Hvordan vurderer du din egen vekt i dag? ☐ For lav ☐ Passe ☐ For høy

Appendix 3

Senter for rus- og avhengighetsforskning

Løpenr

Fysisk aktivitet for å øke livskvalitet blant ruspasienter:

Oppfølgingsskjema (II)

SERAF 2013

Kontaktpersoner:

Ley Muller	ley.muller@gmail.com
Thomas Clausen:	thomas.clausen@medisin.uio.no

Rusmiddel-/medikamentprofil siste 2 måneder

	Type rusmiddel/medikament (Bruk koden nedenfor)	**Inntaksmåte** (Bruk koden nedenfor)	**Hvor ofte brukt siste 4 uker** (Bruk koden nedenfor)	**Alder brukt første gang**	**Hvor lenge problemfylt bruk** (Antall år)
Mest brukte rusmiddel/ medikament	☐	☐	☐	☐ ☐	☐ ☐
2. mest brukte	☐	☐	☐	☐ ☐	☐ ☐
3. mest brukte	☐	☐	☐	☐ ☐	☐ ☐
4. meste brukte	☐	☐	☐	☐ ☐	☐ ☐
0 = Ingen 1 = Alkohol 2 = Cannabis 3 = Heroin/Opium 4 = Metadon, buprenorfin, andre opiater/opioder forskrevet i LAR-program 5 = Metadon, buprenorfin, andre opiater/opioder forskrevet utenfor LAR-program 6 = Metadon, buprenorfin, andre opiater/opioder ervervet uten at forskrevet av lege 7 = Benzodiazepiner forskrevet av lege	8 = Benzodiazepiner ikke forskrevet av lege 9 = Andre vanedannende medikamenter 10 = Amfetamin 11 = Kokain 12 = Crack 13 = Andre sentralstimulerende midler 14 = LSD og likn. 15 = Ecstasy 16 = Løsemidler 17 = Rødsprit o.l 18 = Annet 99 = Ukjent	1 = Drikker/spiser 2 = Injiserer 3 = Røyker 4 = Sniffer 8 = Annet 9 = Ukjent	1 = Ikke brukt 2 = Sjeldnere enn 1 gang i uken 3 = Omtrent ukentlig 4 = 2-4 dager i uken 5 = 5-6 dager i uken 6 = Daglig 9 = Ukjent	99 = Ukjent	00 = Ikke 01 = Et år eller mindre 99 = Ukjent

Brukt sprøyter før?

☐

1 = Ja
2 = Nei
9 = Ukjent

Alder første sprøytebruk

☐ ☐

Angi alder i år

00 = Aldri brukt sprøyter
99 = Ukjent

Sprøytebruk siste 4 uker

☐

1 = Ikke brukt sprøyte
2 = Sjeldnere enn 1 gang i uken
3 = Omtrent ukentlig
4 = 2-4 dager i uken
5 = Daglig eller nesten daglig
9 = Ukjent

Tobakksvaner siste 2 måneder

Røyket du tobakk? ☐ 1 = Ja 2 = Nei Hvis ja, hvor mange sigaretter daglig? ☐	Brukte du snus? ☐ 1 = Ja 2 = Nei Hvis ja, antall bokser per dag? ☐

SCL – 25. Hvor mye har du vært plaget av: (den siste uka)

(samme spørsmål i SCL-90)

Sett en ring rundt det svaret som passer deg best.	0 Ikke i det hele tatt	1 Litt	2 Moderat	3 Ganske mye	4 Veldig mye
1. Hodepine	0	1	2	3	4
2. Skjelving	0	1	2	3	4
3. Matthet eller svimmelhet	0	1	2	3	4
4. Nervøsitet, indre uro	0	1	2	3	4
5. Plutselig frykt uten grunn	0	1	2	3	4
6. Stadig redd eller engstelig	0	1	2	3	4
7. Hjertebank, hjerteslag som løper avgårde	0	1	2	3	4
8. Følelse av å være anspent, oppjaget	0	1	2	3	4
9. Anfall av angst eller panikk	0	1	2	3	4
10. Så rastløs at det er vanskelig å sitte stille	0	1	2	3	4
11. Mangel på energi, alt går langsommere enn vanlig	0	1	2	3	4
12. Lett for å klandre seg selv	0	1	2	3	4
13. Lett for å gråte	0	1	2	3	4
14. Tanker om å ta ditt liv	0	1	2	3	4
15. Dårlig matlyst	0	1	2	3	4
16. Søvnproblemer	0	1	2	3	4
17. Følelse av håpløshet med tanke på fremtiden	0	1	2	3	4
18. Nedtrykt, tungsindig	0	1	2	3	4
19. Følelse av ensomhet	0	1	2	3	4
20. Tap av seksuell lyst og interesse	0	1	2	3	4
21. Følelse av å være lurt i en felle eller fanget	0	1	2	3	4
22. Mye bekymret eller urolig	0	1	2	3	4
23. Uten interesse for noe	0	1	2	3	4
24. Følelse av at alt er et slit	0	1	2	3	4
25. Følelse av å være unyttig	0	1	2	3	4

Somatisk helse. Hvor mye har du vært plaget av: (siste 6 måneder)

Sett en ring rundt det svaret som passer deg best.	0 Ikke i det hele tatt	1 Litt	2 Moderat	3 Ganske mye	4 Veldig mye	Kronisk lidelse? (minst 3 mnd i løpet av siste halvår før inntak) Ja	 Nei

Fordøyelsesplager	0	1	2	3	4	☐	☐
Diare	0	1	2	3	4	☐	☐
Forstoppelse	0	1	2	3	4	☐	☐
Luftveisplager	0	1	2	3	4	☐	☐
Eksem	0	1	2	3	4	☐	☐
Hudinfeksjoner	0	1	2	3	4	☐	☐
Leddsmerter	0	1	2	3	4	☐	☐
Hodepine	0	1	2	3	4	☐	☐
Brystsmerter	0	1	2	3	4	☐	☐
Svimmelhet	0	1	2	3	4	☐	☐
Nedsatt hukommelse	0	1	2	3	4	☐	☐
Synsforstyrrelser	0	1	2	3	4	☐	☐
Urinveisplager	0	1	2	3	4	☐	☐
Kjønnsykdommer	0	1	2	3	4	☐	☐
Blodpropp	0	1	2	3	4	☐	☐
Tann/tannkjøttsplager	0	1	2	3	4	☐	☐

Dopingmidler siste 2 måneder

Brukte du dopingmidler? ☐
1 = Ja
2 = Nei

Hvis ja, hvor mange ganger per uke? ☐

Hvis ja, hvilken type dopingmidler? ☐ Anabole steroider ☐ Andre: ………………………………

Fysisk trening siste 2 måneder

Skal du fortsette å drive med fysisk trening? ☐
1 = Ja
2 = Nei
3 = Vet ikke

Hvis ja, hva slags trening? ………………………………………………………………

Hvis ja, hvor mange minutter per dag? ☐

Hvor mange dager per uke? ☐

Hvordan kan du beskrive din erfaring med vår treningsgruppe? Tenk om din fysisk erfaring, kommunikasjon med din trainer og andre deltakere, hvor og når din gruppe møtet opp, o.s.v.

………

………

....

....

....

....

....

....

Hva kan gjøres forskellig eller bedre? Hva synes du ikke var bra?

....

....

....

Hva var bra gjennomført? Hva likter du spesiel godt?

....

....

....

Høyde og vekt

Selvrapportert vekt i kilo ☐☐☐

Selvrapportert høyde i cm ☐☐☐

Hvordan vurderer du din egen vekt i dag? ☐ For lav ☐ Passe ☐ For høy

Forespørsel om deltakelse i forskningsprosjektet
"Fysisk aktivitet for å øke livskvalitet blant ruspasienter"

Bakgrunn og hensikt
Dette er en forespørsel til deg om å delta i en forskningsstudie som inkluderer et treningsprogram eller som deltager i sammenligningsgruppen uten treningsprogram. Prosjektet skal undersøke om det er en sammenheng mellom fysisk trening og deltakernes livskvalitet. Du inviteres til å delta i denne studien fordi du nå er/har vært under behandling for rusmisbruk eller har et rusmisbruksproblem. Denne studien vil inngå i masteroppgaven til Ley Muller ved Høgskolen i Oslo, som er veiledet av professor Thomas Clausen ved Senter for rus- og avhengighetsforskning (SERAF).

Hva innebærer studien?
Deltagelse i sammenligningsgruppen innebærer at du må fylle ut noen spørreskjema angående ditt rusmiddelbruk, fysisk og psykisk helse og livskvalitet.
Deltakelse i treningsgruppen vil innebære et 10 ukers treningsprogram, med lett fysisk aktivitet i 30 minutter 3 ganger i uken. Treningene vil foregå i gruppe og vil bli ledet av en trener. I tillegg til deltagelse i treningsprogrammet, vil vi både før oppstart og etter endt 10-ukers program samle inn noen data ved hjelp av spørreskjema som vi ber deg fylle ut. Spørreskjemaet inkluderer spørsmål angående ditt rusmiddelbruk, fysisk og psykisk helse, og livskvalitet. Det vil også etter hver treningsøkt være mulig å mer uformelt fortelle treneren hvordan treningsøkten var, disse opplevelsene vil bli notert av treneren og informasjonen vil inngå i datamaterialet. Du kan også bli bedt om å delta i en fokusgruppe innen én måned etter at programmet er avsluttet. Tema for diskusjon i fokusgruppene vil være; hva som var bra og hva som kan forbedres ved treningsprogrammet og opplevelsen av trening som del av rusbehandlingen. Dataene fra denne studien vil brukes for å undersøke om en tidsbegrenset treningsintervensjon kan påvirke livskvaliteten til pasienter i rusbehandling.

Mulige fordeler og ulemper
Det forventes ingen konkrete ulemper med lavterskel trening, men noen vil kanskje oppleve muskelstølhet etter treningene. Støle muskler etter trening er ufarlig. Det er alltid en viss mulighet for uforutsette helsemessige komplikasjoner i tilknytning til utøvelse av fysisk aktivitet, men trening i moderat tempo i 30 minutter ansees å være en del av normalaktivitet som ikke innebærer nevneverdig øket risiko for sykdom eller skade. I forbindelse med inklusjon til studien vil vi stille noen spørsmål om helsen din for å forsøke å identifisere de som evt har en helsetilstand som tilsier at de ikke bør være med i studien.

Deltagelse i studien inkluderer fysisk aktivitet. Fysisk aktivitet kan bidra til forbedret kardiovaskulær helse, utholdenhet, styrke og fleksibilitet. Deltagelse i dette prosjektet, som inkluderer gruppebasert fysisk aktivitet, vil gi deg som deltager mulighet til å samhandle og dele opplevelser med andre deltakere og frivillige. Treningsprogrammet vil kunne oppleves som en pause fra den daglige rutinen. Til syvende og sist, forfatterens hypotese er at din generelle livskvalitet - målt som samlet kvalitet av dine sosiale relasjoner og miljø så vel som din fysiske og psykiske helse - vil kunne øke som et resultat av din deltagelse i treningsprogrammet.

Hva skjer med informasjonen om deg?
Prosjektet vil samle inn informasjon om deg og din helse, sammen med ditt navn og fødselsdato. Dette fordi vi skal kunne følge opp og koble sammen svarene du gir ved oppstart og avslutning av studien. Det er kun personell knyttet til prosjektet som har adgang til navnelisten.

Dataanalyser på sammenkoblede data etter endt inklusjonsperiode vil foregå i en datafil som bare inneholder et løpenummer og filen vil således være uten personidentifiserbare data. Løpenummeret vil

kun kunne kobles til persondata via en separat kodenøkkelfil. Kodenøkkelen vil slettes ved prosjektets slutt.
Ingen enkeltpersoner vil kunne identifiseres i materialet som inkluderes og publiseres fra prosjektet.

Frivillig deltakelse
Deltakelse i undersøkelsen er frivillig. Du kan trekke deg fra studien når som helst og uten å oppgi noen spesiell grunn. Dette vil ikke ha noen konsekvenser for din videre behandling. Hvis du ønsker å delta, må du undertegne samtykkeerklæringen på siste side. Hvis du senere ønsker å trekke tilbake ditt samtykke eller har spørsmål til studien, kan du kontakte Ley Muller på tlf: 4547 1880.

Ytterligere informasjon om studien finnes i kapittel ***A*** *– utdypende forklaring av hva studien innebærer.*

Ytterligere informasjon om personvern finnes i kapittel B – *Personvern.*

Samtykkeerklæring følger etter kapittel B.

Kapittel A- utdypende forklaring av hva studien innebærer

Kriterier for deltakelse:
Alle pasienter eller beboere på deltakende studiesteder vil bli invitert til å delta i studien. Alle som ønsker å delta vil bli bedt om å fylle ut inklusjonsskjema. For å være velgbar for deltagelse må følgende kriterier være oppfylt: a) alder mellom 18-65 år, b) selvrapportert stillesittende livsstil, f. eks. har trent mindre enn 20 minutter om dagen, i løpet av de siste seks måneder, c) har søkt seg til rusbehandling, d) evne til å gi informert samtykke. Deltagerne er de som allerede er i behandling, men som ikke har vært i organisert trening som del av behandlingen.

Bakgrunnsinformasjon om studien:
Denne pilotstudien ønsker å måle om ruspasienter opplever noen endringer i generell livskvalitet etter tilleggsbehandling av regelmessig fysisk aktivitet, og i så fall hvilke funksjonsområder (livskvalitet domener) som påvirkes mest. Intervensjonen vil engasjere inntil tretti deltakere i innendørs eller utendørs gåing eller jogging i tretti minutter, tre ganger i uken, i ti uker, under ledelse av en gruppe trener. Deltakerne vil trene sammen (med medpasienter og trener) der det er mulig. Innsamling «baseline» livskvalitetsdata vil være nyttig i seg selv, og vil bidra til økt kunnskap om rusmisbrukeres livskvalitet. Forventningen er at livskvalitet blant ruspasientene er lav ved inklusjonen også sammenlignet med andre pasientgrupper. Studien vil forsøke å rekruttere en kontrollgruppe blant pasienter i de samme institusjonene som intervensjonspasientene, som også er kjennetegnet ved lav fysisk aktivitet og som ikke ønsker å delta i det 10 ukers lange treningsprogrammet. Kvalitativ kunnskap fra fokusgruppene vil kunne belyse faktorer som kjennetegner de som fullførte versus de som ikke fullførte studien. Denne kunnskapen vil benyttes for å forbedre et eventuelt fremtidig design på en større intervensjonsstudie.

Pasienter / beboere vil ikke motta ytterligere eller alternative prosedyrer eller behandling dersom de velger å ikke delta i denne studien.

Tidsskjema:
Rekruttering av intervensjonssteder pågår våren 2013 og vil være avsluttet i juli, 2013. Planlagt oppstart av intervensjonen i deltagende institusjoner er juli/august 2013. Intervensjoner på hvert behandlingssted kan skje på rullerende basis (og nye deltakere kan legges til en gruppe som allerede er i gang), men alle må være fullført innen utgangen av desember 2013. Inklusjonsdata samles inn før første trening, og oppfølgingsdata etter siste treningsøkt etter 10 uker. Fokusgrupper vil være organisert innen en måned etter hvert intervensjonssteds siste trening.

Mulige fordeler:
Selvom dette treningsprogrammet er av lav intensitet, forventes en viss helsemessige gevinst som generell redusert risiko for hjerte-og karsykdommer, mens redusert hypertensjon ikke er forventet. Imidlertid er de kortsiktige fordelene knyttet til deltagelse i studien potensielt forbedret fysisk styrke, fleksibilitet og utholdenhet, redusert stressnivå, økt sosial støtte gjennom frivillig deltaker samhandlinger og økt søvnkvalitet og mengde. De generelle livskvalitetsdomener som omhandler fysisk helse, psykisk helse, sosiale relasjoner og miljø kan også bli forbedret.

Mulige ubehag/ulemper:
All trening innebærer en viss risiko for skade, og lav-intensitet trening er ikke noe unntak. I tillegg til å forverre en kjent eller ukjent tidligere tilstand, eksponerer dette programmet deltakerne for en viss risiko som alle turgåere eller løpere står overfor når du trener ute, som for eksempel vridning av en ankel eller snubling og fall.

Pasientens/studiedeltakerens ansvar:

Treningsprogram vil bli gjort så enkelt som mulig for deltakerne, som vil motta en SMS før hver økt, og vil møte på avtalte lett tilgjengelige steder. Deltakerne forventes å møte opp forberedt for hver økt i passende klær/sko. Utfylling av spørreskjemaer før og etter endt treningsprogram vil være nødvendig.

Studiedeltakeren bes opplyse til Ley Muller om mulige årsaker/situasjoner som gjør at deres deltagelse i studien evt ble avsluttet tidligere enn planlagt.

Kapittel B - Personvern, biobank, økonomi og forsikring

Personvern
Opplysninger som registreres om deg er a) data du gir via screening og oppfølgingsskjemaer om din fysiske og mentale helse, rusmiddelbruk, og nåværende historie, og b) en livskvalitets vurdering. SERAF ved forskningsdirektør; Professor Thomas Clausen er databehandlingsansvarlig.

Utlevering av materiale og opplysninger til andre
Data skal ikke utleveres til andre institusjoner enn SERAF, og de navngitte forskerne i prosjektet.

Rett til innsyn og sletting av opplysninger om deg
Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Informasjon om utfallet av studien
Deltakerne har rett til å få informasjon om utfallet/resultatet av studien, når studien er avsluttet og masteroppgaven har blitt skrevet og sendt til Høgskolen i Oslo. Interesserte deltakere bes kontakte Ley Muller på tlf: 4547 1880.

Samtykke til deltakelse i studie

Deltagelse i studiens aktivitetsprogram ☐
Deltagelse som sammenligningsgruppe, uten aktivitetsprogram ☐

Jeg forstår at min deltakelse i denne studiens fysiske aktivitetsprogram gjennomføres på eget ansvar.

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Appendix 5

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	**Saksbehandler:**	**Telefon:**	**Vår dato:**	**Vår referanse:**
REK sør-øst	Jakob Elster	22845530	30.07.2013	2013/1036/REK sør-øst B
			Deres dato:	**Deres referanse:**
			10.07.2013	

Vår referanse må oppgis ved alle henvendelser

Thomas Clausen
SERAF, Kirkeveien 166

2013/1036 Fysisk trening for å øke livskvalitet blant ruspasienter

Forskningsansvarlig: Senter for Rus og Avhengighetsforskning - SERAF
Prosjektleder: Thomas Clausen

Vi viser til tilbakemelding vedrørende ovennevnte forskningsprosjekt. Tilbakemeldingen er vurdert av komiteens leder på delegert fullmakt.

Prosjektomtale

Studien har til hensikt å måle om ruspasienter eller tidligere ruspasienter med "substance use disorders", eller "SUD" opplever noen endringer i sin generelle livskvalitet etter et 10-ukers program med fysisk aktivitet i grupper, og i så fall hvilke funksjonsområder som er mest påvirket. Det skal gjøres registreringer ved oppstart og ved oppfølging etter 10 uker med fysisk aktivitet. Intervensjonen innebærer fysisk aktivitet 30 min 3 ganger pr.uke. Datainnsamlingen omfatter variabler i to spørreskjemaer som er vedlagt. Det skal samles inn demografiske data, samt somatiske og psykiske helseopplysninger. I alt 60 pasienter eller beboere på deltakende studiesteder vil bli invitert til å delta i studien. Informantene fordeles etter gitte kriterier i 2 grupper à 30 personer.

Saksgang

Komiteen behandlet saken første gang i sitt møte den 12.06.2013. I sitt brev datert 28.06.2013, utsatte komiteen endelig vedtak i påvente av prosjektleders tilbakemelding på to punkter:

1. I informasjonsskrivet sto det at avidentifiserte livskvalitetsopplysninger ville utleveres til Diakanova Høgskolen i Oslo. Komiteen ba om en begrunnelse for dette, i og med at det ikke fremgikk av søknaden hvordan Diakanova Høgskolen var knyttet til prosjektet.

2. Komiteen skrev at informasjonsskrivet var utformet på en slik måte at det kan virke overtalende på de som forespørres om deltagelse. Komiteen ba om at informasjonsskrivet ble revidert slik at det fremstår som nøytralt ovenfor deltagerne.

Prosjektleder sendte inn sin tilbakemelding den 10.07.2013. Når det gjelder punkt 1), skriver prosjektleder at avidentifiserte livskvalitetsopplysninger ikke skal utleveres til Diakanova Høgskolen i Oslo. Når det gjelder punkt 2), har prosjektleder utarbeidet et revidert informasjonsskriv.

Komiteens vurdering

Komiteen tar til orientering at man ikke lenger planlegger å utlevere opplysninger til Diakanova Høgskolen i Oslo.

Komiteen anser at endringene i informasjonsskrivet er tilfredsstillende.

Komiteen har imidlertid notert seg at i sin nåværende form henvender informasjonsskrivet seg bare til de deltagerne som ønsker å ta del i treningsopplegget. Imidlertid skriver prosjektleder i søknaden at alle pasienter/beboere inviteres til å delta, også de som ikke ønsker å ta del i den fysiske aktiviteten. Disse vil da utgjøre en kontrollgruppe. Komiteen anbefaler at informasjonsskrivet revideres slik at det kommer bedre frem at at man kan delta i prosjektet uten å delta i den fysiske aktiviteten, og at det under overskriften ”Samtykke til deltakelse i studien” er to separate ”bokser”, slik at man kan presisere om man samtykker til deltagelse i behandlingsgruppen eller i sammenligningsgruppen. Komiteen beklager at den ikke gjorde oppmerksom på dette i sitt forrige brev. Komiteen ber om at et eventuelt revidert informasjonsskriv sendes komiteen til orientering.

Vedtak

Komiteen godkjenner prosjektet i henhold til helseforskningsloven § 9 og § 33.

Godkjenningen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknaden og i tilbakemelding fra prosjektleder.

Tillatelsen gjelder til 31.05.2014. Av dokumentasjonshensyn skal opplysningene likevel bevares inntil 31.05.2019. Opplysningene skal lagres avidentifisert, dvs. atskilt i en nøkkel- og en opplysningsfil. Opplysningene skal deretter slettes eller anonymiseres, senest innen et halvt år fra denne dato.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder ”Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren”

Sluttmelding og søknad om prosjektendring
Prosjektleder skal sende sluttmelding til REK sør-øst på eget skjema senest 30.11.2014, jf. hfl. § 12. Prosjektleder skal sende søknad om prosjektendring til REK sør-øst dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningslovens § 28 flg. Klagen sendes til REK sør-øst. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Grete Dyb
førsteamanuensis dr. med
Leder

Jakob Elster
Seniorrådgiver

Kopi til: seraf-admin@medisin.uio.no

Appendix 6

Photocredit http://www.freechick.com/sites/default/files/images/power_walk.jpg

"DRIVKRAFT IL":

EN SOSIAL, LAVINTENSIV TRENINGSKLUBB FOR DE MED RUSBAKGRUNN

Tren med oss, for å:
- ... få mer **energi**
- ... **redusere stress**
- ... forbedre **humøret**
- ... øke **selvtillit** (m.m)

September 2013.
30 min. hver gang.
3 dager hver uka.
10 uker.
Ikke bindende.

Turer, løping, fotball, sandvolleyball, utendørs styrketrening...

Vi søker deltakere!

Kontakt Ley Muller:
4547 1880
facebook.com / DrivkraftIL

Seraf
Senter for rus- og avhengighetsforskning
Kondis
ELIXIA
ULLEVAAL STADION

Appendix 7

Sample size calculations

$$n = \frac{2[(a+b)^2\sigma^2]}{(\mu_1 - \mu_2)^2}$$

n = sample size in each group
μ_1 = domain mean in treatment group
μ_2 = domain mean in control group
$\mu_1 - \mu_2$ = the difference the investigator wishes to detect; here the MCID of each domain
σ^2 = population variance (SD^2); here using SD of domain mean change
a = conventional multiplier for alpha of 0.05
b = conventional multiplier for power of 0.80

$$n = \frac{2[(1.96+0.842)^2 * 2.6^2]}{(1.3)^2}$$

Physical health QoL

$$n = 64$$

$$n = \frac{2[(1.96+0.842)^2 * 1.6^2]}{(0.8)^2}$$

Psychological health QoL

$$n = 64$$

$$n = \frac{2[(1.96+0.842)^2 * 2.8^2]}{(1.4)^2}$$

Social relationships QoL

$$n = 64$$

$$n = \frac{2[(1.96+0.842)^2 * 2.0^2]}{(1.0)^2}$$

Environment QoL

$$n = 64$$