International Journal of Clinical Trials
Dowla RJ et al. Int J Clin Trials. 2022 Nov;9(4):279-285
http://www.ijclinicaltrials.com
pISSN 2349-3240 | eISSN 2349-3259
DOI: https://dx.doi.org/10.18203/2349-3259.ijct20222688

Protocol

Fitness in recovery: impact of exercise in people with substance use disorder in residential treatment

Rhiannon J. Dowla[1,2], Carolyn Stubley[3], Bridin Murnion[4], Elizabeth Cayanan[1,5], Yorgi Mavros[1], Scarlett Hardy[1], Kieron Rooney[1]*

[1]Department of Medicine and Health, Susan Wakil Health Building, University of Sydney, Sydney, Australia
[2]St. John of God Healthcare, Burwood Hospital, Australia
[3]We Help Ourselves, Lilyfield, Australia
[4]Western Sydney Local Health District, Australia
[5]The Woolcock Institute of Medical Research, Glebe, Australia

Received: 16 May 2022
Revised: 14 August 2022
Accepted: 20 August 2022

***Correspondence:**
Kieron Rooney,
E-mail: Kieron.Rooney@sydney.edu.au

ABSTRACT

Background: Opioid use disorder has the lowest quality of life (QOL) and highest disease burden of all substance use disorders (SUD). While opioid treatment does lead to initial improvements in QOL it remains below that of the general population. The integration of exercise programs as an adjunct therapy for SUD is gaining popularity. Previous reviews have indicated that exercise offers significant benefits for QOL, however the evidence in an opioid treatment population is lacking. This study will investigate the impact of a 12-week exercise intervention on QOL and mood in a residential opioid treatment rehabilitation program.
Methods: This is a 12-week single arm intervention with a natural history control. Participants will complete a baseline screening assessing QOL, mood and exercise habits and those who meet criteria for exercise participation will complete an exercise assessment. The exercise program will be delivered twice per week as part of the group therapy program. Exercise sessions will run for approximately 40 minutes and be at an intensity selected by each of the participants.
Conclusions: A recent review indicated that two sessions of exercise for a minimum of 12 weeks leads to an improvement in QOL in general SUD, however, to date minimal studies have been completed in people receiving opioid agonist treatment. Hence, this will be the first study to our knowledge, assessing the role of exercise as an adjunct treatment for QOL in this population.
Trial Registration: This trial has been registered with the Australian New Zealand clinical trials registry ACTRN12622000213741.

Keywords: Substance use disorder, Exercise, Physical activity, Cardiovascular health, Opioid

INTRODUCTION

Opioid agonist treatment programs (OAT) are a core component of drug and alcohol services in NSW. These programs involve administration of opioid agonists in addition to counselling and behaviour therapies and can assist in the management and relapse prevention of opioid use disorder.[1] It has been well documented however, that many of the vocational, social, physical and psychiatric health concerns common in an alcohol or other drug using population are not resolved when a person ceases drug use.[2] Quality of life (QOL) is a measure

encompassing all aspects of a person's health and engagement with society, including physical and psychiatric wellbeing, social and occupational engagement, and living conditions. Opioid use disorder has the lowest QOL, and highest disease burden of all substance use disorder (SUD) populations.[3] While OAT does lead to initial improvements in QOL, it remains below that of the general population.[4] There is a growing belief that QOL should be used as an outcome measure in OAT, or as an alternative measure of disease severity.[5] This considers the vast range of challenges experienced by people using OAT and offers a more patient centred measure of dependence severity and recovery. In addition to poorer QOL, SUD is correlated with elevated rates of physical illness, including diabetes and cardiovascular disease.[6] SUD patients have the largest gap in life expectancy of all mental health disorders when compared to the general population.[7] Furthermore, people with SUD have an increased prevalence of cardiovascular risk factors and a decreased exercise capacity.[8] People receiving OAT have been shown to have low rates of exercise and significantly elevated risk of comorbidities such as diabetes mellitus, cardiovascular disease, and depression compared to the general population.[9] The integration of exercise programs as an adjunct therapy for SUD is gaining popularity for their reported benefits to patient outcomes. Previous reviews have indicated that exercise is both feasible and safe in a SUD population, and that it offers significant benefits for QOL, depression and anxiety outcomes.[10] Furthermore, engagement with exercise-related activities has been reported to result in longer periods of abstinence during treatment for SUD.[11] Despite the growing body of evidence for exercise within SUD, evidence for exercise to improve QOL and related outcomes within OAT settings remains limited. The primary purpose of this study is to investigate the impact of a 12-week exercise intervention on mood and QOL of people in a residential OAT rehabilitation program. It will further characterise the physical health and fitness of patients with SUD, and their preferences regarding exercise interventions. Additionally, we will investigate the effect of performing an acute bout of exercise on psychological outcomes including mood and cravings as secondary outcomes in aid of identifying further motivators for participant engagement. We hypothesise that QOL, fitness and self-efficacy to exercise will increase following a 12-week exercise intervention. Furthermore, we hypothesise that the fitness levels of SUD patients will be below age and sex matched norms.

METHODS

Type of study

This is a 12-week single arm intervention with a natural history control. This trial has been registered with the Australian New Zealand clinical trials registry ACTRN12622000213741. The study was conducted in 3 phases, at the end of each phase participants will re-consent to voluntarily participate in subsequent phases:

Phase 1 will be a cross sectional study involving an interview assessing participant's demographics; anthropometry; Exercise preferences; QOL (EUROHIS-QOL8); mood (K10); SUD severity (SDS); sleep quality (PSQI); Epworth sleepiness scale (ESS); self-efficacy for exercise (SEE), Post traumatic stress disorder Checklist for DSM 5 (PCL-5) and the ACSM's exercise pre-screening tool.[12]

Phase 2 is an acute bout of fitness testing including the following assessments: 3-minute step test for cardiorespiratory fitness. Push up to fatigue for upper body muscular endurance. Hand grip dynamometer for general physical function and strength. Balance error scoring system (BESS) to assess balance. 3-minute curl up test for trunk muscular endurance. 30 second sit to stand for lower body muscular endurance. 6-minute Walk test to assess functional cardiorespiratory capacity. Positive and negative affect schedule (PANAS) (pre and post fitness testing)

Phase 3 is a 12-week exercise intervention. Exercise groups will be run twice per week and involving a combination of aerobic, strengthening and stretching activities. All sessions will be led by an Accredited Exercise Physiologist. Intensity of the exercise session will be determined by the participant and a rating of perceived exertion scale will be used to measure exercise intensity at the end of each session.[13] A brief Pain Inventory (BPI) will be completed weekly to assess subjective pain.
Following the final session of this 12-week program, Phase 1 and Phase 2 assessments will be repeated. A participant timeline is provided in (Figure 1).

Sample size

The primary outcome is QOL measured using the EUROHIS QOL 8. Based on the results of Muller et al., 2015 which had a calculated effect of 0.66. Utilising an a priori one tail difference between dependent means (matched pairs); Alpha set at 0.05 and power of 0.95, 27 participants are required to complete the study. Alternatively, if power is set at 0.8, a sample size of 16 participants is required to complete the study. We anticipate 10% of potential subjects will not meet the criteria to participate in exercise assessment and intervention. In addition, consistent with the average drop out of the treatment centre, we anticipate the attrition rate to be 50% from commencement of the intervention, therefore we intend to recruit a minimum of 36 and a maximum of 60 subjects to achieve a final sample of 16-27 participants.

Participating sites

This trial will be completed in a long term, voluntary residential rehabilitation program at We Help Ourselves (WHOS), Lilyfield, Sydney. There are two programs within WHOS for individuals on opioid agonist

treatment. One program is for the stabilisation of substance use for individuals already on opioid agonist treatment and the other is for the reduction and cessation of opioid agonist treatments whilst undertaking the residential program. Programs run for 12 to 16 weeks and are open to people aged 18 or over. The exercise program will be delivered as part of the group therapy program within each of these units.

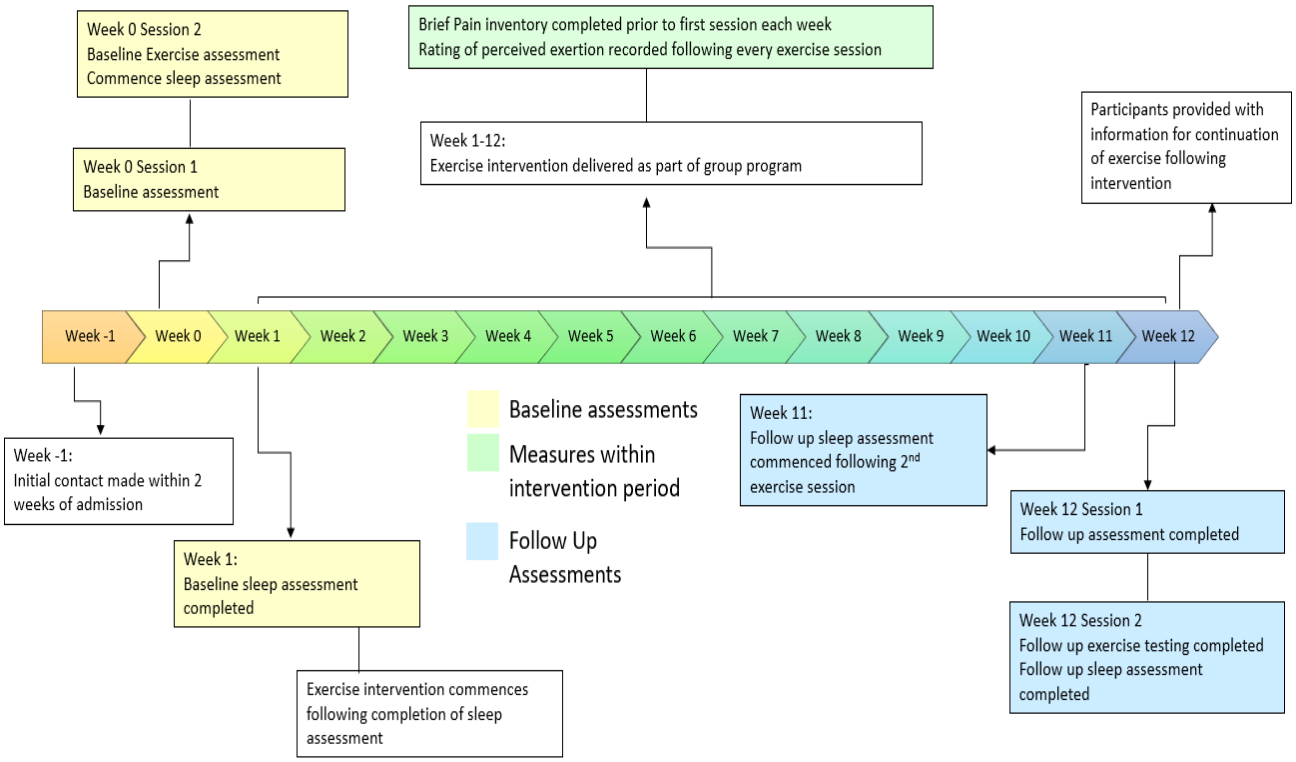

Figure 1: Participant timeline.

Table 1: Example session plan; participants will be able to choose the level of exercise, switching between levels as desired.

Exercises		Duration/reps and sets	Notes
Level 1	**Level 2**		
Sit to stand	Squat	15 reps 3 sets	Completed as circuit. 20 seconds rest between each exercise. 2 minutes rest between each circuit.
Leg abduction toe tap	Star jump	15 reps 3 sets	
Squat tap and reach	Ball slams	15 reps 3 sets	
Incline push ups	Modified or full push ups	15 reps 3 sets	
Calf raises	Lunges	15 reps 3 sets	
Bicep curl- resistance band light	Bicep curl- resistance band heavy	15 reps 3 sets	
Seated twist	Oblique crunch	15 reps 3 sets	
Static stretching	Static stretching	30 second hold	Stretching of quadriceps, gluteal, hamstrings, anterior shoulder, posterior shoulder and lower back

Recruitment

Participants will be offered the opportunity to participate in this study within their first two weeks of admission. Those interested will complete informed consent before completing several psychometric questionnaires as a baseline assessment. Those who are deemed suitable for participation in exercise based on the exercise pre-

screening will then complete an exercise assessment to complete their baseline assessment.[12]

Inclusion criteria

For inclusion in this study participants must be a resident at one of the opioid treatment program services at WHOS Lilyfield and have the capacity to provide informed consent. Participants will be excluded from participation in this study if they have a cognitive impairment leading to inability to cooperate or if they cannot communicate sufficiently in English. Additionally, participants will be excluded from exercise assessments and intervention if they do not meet the ACSM pre-screening criteria to participate in exercise without clearance from a medical officer, have an acute disorder that may be impacted by exercise (e.g., an infection) or have an orthopaedic condition that limits participation in exercise.

Control

A 3-month chart review of the facility will be completed separately from the period of the intervention. This will act as a natural history comparator for usual care treatment. This information will be used as control data in the absence of a formal control group. Data extracted during this review will include: Gender, SDS, K10, EUROHIS QOL8, PCL-5.

Intervention

Exercise program: the exercise intervention will involve two sessions per week, for 12 weeks duration. Existing studies have shown that a frequency of at least two sessions per week is required to illicit significant positive change in QOL, and that interventions longer than ten weeks see greater improvements in QOL.[10] Each session will run for approximately 40 minutes and will be scheduled within the group therapy program at WHOS. Sessions will be completed on hospital grounds outdoors where possible. However, an indoor recreation room is available for periods of poor weather. Sessions will involve a combination of cardiovascular, muscle strengthening and flexibility exercises. Session plans will be altered weekly to prevent boredom and to maximise exposure to a range of exercise techniques through the program. We are not able to provide exact session plans prospectively as they will be tailored to the exercise capacity, interest, and any orthopaedic limitations of participants each week by the study Exercise Physiologist, however an example session plan is presented in (Table 1).

Equipment used will be items which can be transported on and off wards, including resistance bands, boxing gloves and focus mitts, slam balls, balance pads and mats. There is also outdoor space for sports, walking and running activities. Session plans will be made available following the completion of the study as supplementary files in published works.

Exercise intensity: exercise intensity will be self-selected with participants being encouraged to work at an intensity that feels good for them that day. Exercises will be modified as required to allow participants to work at their preferred intensity. Following the completion of each session participants will be asked to rate their subjective level of exertion on a 0-10 scale as stated by Neeley et al 1992.

Baseline and follow up assessment

Baseline data will be collected by study personnel using interview, self-report questionnaires and exercise assessments. Information from participants files such as medication, physical and psychological diagnoses and substance abuse history including duration and substances of use will be extracted by clinic staff, deidentified and provided to investigators.

Sleep

In addition to the sleep measures taken in the baseline questionnaire, a subgroup of participants in the opioid reduction unit will also be asked to wear a wrist-worn actigraphy watch (GENEActiv) to monitor sleep and wake periods and activity in the first week of their intervention. Additionally, they will be required to complete a sleep diary during this period. This will be repeated during the 12th week of the exercise intervention.

Acute response to exercise

We plan to assess acute mood response to exercise. Mood will be measured using the positive and negative affect schedule (PANAS) immediately prior to completing the baseline exercise assessments, and again following the completion of the exercise assessments. This will be completed again at follow up assessments to evaluate if regular exercise has an impact on acute mood response to exercise.

Other interventions

Participants will continue with the residential program, which provides a therapeutic community model of care. This approach is peer based and aims to improve living and social skills of participants. The program includes a structured daily schedule of group programs, with three to four groups per day. Group content includes peer-based feedback groups, harm reduction principles, relapse prevention, PTSD groups, acceptance and commitment therapy and exercise. Participants will also have access to GP's psychologists, physiotherapy, and nursing staff throughout the program as required.

Primary outcomes

All outcomes were measured prior to commencing the exercise intervention and in week 12 of the intervention.

Quality of life: the primary outcome of interest in this study is change in quality of life (QOL) as measured by the EUROHIS quality of life 8 item scale.[14] This is an eight-item scale (overall QOL, general health, energy, daily life activities, esteem, relationships, finances, home) and a shortened version of the 25-item world health organisation quality of life brief scale (WHOQOL BREF) and uses the same 5-point response scale.

Secondary outcomes

Self-efficacy for exercise: the self-efficacy for exercise scale (SEE) nine item scale, is a validated scale requiring participants to rate their confidence to exercise three times per week for 20 minutes while experiencing nine situations.[15]

Psychological distress: the 10 item Kessler psychological distress scale (K10) will be used to assess the effects of the intervention on psychological distress.[16] This is a validated ten-item scale which can be self-reported by patients or administered by a clinician to assess level of psychological distress.

Exercise preferences: an exercise preferences questionnaire was developed based on the methods described in Abrantes.[17] This assesses preferences regarding type of activity, timing of exercise initiation in relation to SUD treatment, company, intensity, and structure of the intervention. Perceived benefits and barriers to physical activity and a scenario of possible interventions are also assessed in this questionnaire.

Positive and negative affect: the positive and negative affect schedule short form will be used to assess changes in affect from pre to post exercise session. This is a validated 20-item scale consisting of two mood scales measuring positive and negative mood states.[18]

Exercise capacity: A battery of exercise assessments will be completed at baseline and at 12 weeks to assess participants' exercise capacity. Exercise assessments will include a modified three-minute step test to evaluate cardiorespiratory fitness, the ACSM 3-minute curl up test and push up to fatigue to assess muscular endurance, a balance error scoring system test to assess balance, hand grip dynamometer to assess general body strength and a 6-minute walk test and sit to stand in 30 seconds to assess functional capacity.[19,20]

Additional outcomes

Sleep: sleep will be assessed using the Epworth sleepiness scale (ESS) and the Pittsburgh sleep quality index (PSQI).[21,22] The ESS is an eight-item self-report scale asking participants to rate the likelihood of them falling asleep during eight different activities. This is scored on a four-point scale (0-3). The PSQI is a self-report questionnaire assessing sleep quality over the last month, using 19 items. A subgroup of participants will also be invited to wear a wrist-worn actigraphy device (GENEActiv) to monitor sleep and wake periods and activity and asked to complete a Karolinksa sleep diary for 1-week during both the first and last week of the intervention.

Substance dependence: severity of dependence scale (SDS) is a five-item scale that provides a score indicating the severity of dependence on a range of substances. Each item is scored on a four-point scale (0-3).

Current exercise: the international physical activity questionnaire short form will be used to assess current exercise participation. This is a validated 7-item self-report measure assessing participation in vigorous and moderate intensity exercise, physical activity, and sedentary behaviours in the last seven days.[23]

Suitability for participation in exercise: the ACSM pre-screening for exercise participation tool will be used to assess suitability to participate in moderate intensity exercise.[12] This assesses risk based on current exercise, signs and symptoms of certain diseases and planned exercise intensity.

Pain: the brief pain inventory short form (BPI) assesses the severity of pain and its impact on functioning. It will be administered weekly, prior to participation in exercise session.[24]

Rating of perceived exertion: rating of perceived exertion will be assessed following each exercise session within the intervention using the 0-10 RPE scale.

Anthropometry: measures will include blood pressure, height, weight, body mass index, waist circumference (measured at the narrowest point from the back) and hip circumference (measured at the widest point of the gluteal region).

Continuation of therapy: following participation in the study, participants will be provided with information on available services and facilities to continue exercise. This may include non-government organisations, public health services, private services, and community-based facilities.

Statistical analysis

The primary analysis for phase 1 survey data and phase 2 fitness assessments will be descriptive statistics compared to age and sex matched normative data, except for the PANAS for which acute pre-post data will be assessed using separate within-subject ANOVAs including gender as a between-subjects factor. Following completion of phase 3, PANAS scores will be analysed using mixed-ANOVAs with factors of test (phase 2 vs. phase 3); Exercise (pre- vs. post.); and gender (male vs. female). Following completion of Phase 3, EUROHIS scores for each psychological and physiological domain will be

analysed using mixed-ANOVAs with factors of test (Phase 1 vs. Phase 3); and gender (male vs. female). Changes in fitness scores will be analysed using paired t test with Bonferroni correction as appropriate.

DISCUSSION

QOL is an important outcome in SUD, offering insight into the subjective impacts of the condition.[5] People receiving OAT experience the lowest QOL of all SUDs and the highest burden of disease including cardiovascular disease and depression. A recent systematic review assessing QOL in response to an exercise intervention identified that a minimum of 2 sessions per week for 12 weeks is required to improve quality of life in SUD, however none of the included studies were completed in people receiving OAT.[10] Hence, this will be the first study to our knowledge, assessing the role of exercise as an adjunct treatment for QOL in people receiving OAT.

This study also aims to characterise the exercise habits, preferences, and capacity of this population. The elevated rates of comorbid conditions such as diabetes mellitus and cardiovascular disease are well documented, with a likely conclusion being that this is in part, due to poor exercise participation. Increased knowledge of the preferences and capacity allows for the development of a tailored intervention, to achieve optimal long-term engagement.

We have designed this study for ease of replication in clinical practice, accounting for common barriers such as limited funding to ensure it is accessible for clinicians with simple and appropriate equipment. Using a group-based modality with low-cost equipment, this study aims to demonstrate that barriers such as a lack of space do not exclude a service from being able to provide an effective exercise intervention for their clients. Furthermore, we have chosen not to prospectively design exercise interventions in order to allow exercises to be matched to the physical capacity and orthopaedic needs of the participants in each session. All session plans will be recorded and made available following completion of the study, which will provide a clinical insight into the exercise capacity of this population. Along with the results of the questionnaire seeking participants preferences regarding exercise, this study will offer a patient centred summary of the exercise capacity and desires of an OAT population.

CONCLUSION

This study may have implications for the perceived importance of exercise within opioid treatment due to its positive impact on a range of outcomes such as QOL, pain and sleep. Furthermore, we hope that this study highlights the current physical health and the potential for clinical exercise to improve these outcomes.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Kresina TF, Lubran R. Improving public health through access to and utilization of medication assisted treatment. Int J Environ Res Public Health. 2011;8(10):4102-17.
2. Donovan D, Mattson ME, Cisler RA, Longabaugh R, Zweben A. Quality of life as an outcome measure in alcoholism treatment research. J Stud Alcohol Suppl. 2005;(15):119-39.
3. Aas CF, Vold JH, Skurtveit S, Lim AG, Ruths S, Islam K, Askildsen JE, Løberg EM, Fadnes LT, Johansson KA; INTRO-HCV Study Group. Health-related quality of life of long-term patients receiving opioid agonist therapy: a nested prospective cohort study in Norway. Subst Abuse Treat Prev Policy. 2020;15(1):68.
4. Nosyk B, Bray JW, Wittenberg E, Aden B, Eggman AA, Weiss RD, Potter J, Ang A, Hser YI, Ling W, Schackman BR. Short term health-related quality of life improvement during opioid agonist treatment. Drug Alcohol Depend. 2015;157:121-8.
5. Laudet AB. The case for considering quality of life in addiction research and clinical practice. Addict Sci Clin Pract. 2011;6(1):44-55.
6. Stenbacka M, Leifman A, Romelsjö A. Mortality and cause of death among 1705 illicit drug users: a 37 year follow up. Drug Alcohol Rev. 2010;29(1):21-7.
7. Nordentoft M, Wahlbeck K, Hällgren J, Westman J, Osby U, Alinaghizadeh H, Gissler M, Laursen TM. Excess mortality, causes of death and life expectancy in 270,770 patients with recent onset of mental disorders in Denmark, Finland and Sweden. PLoS One. 2013;8(1):e55176.
8. Dowla R, Murnion B, Hung C, Currell K, Kendig M, Freeston J, & Rooney K. (2021). Exercise capacity and acute effects of exercise on affect in a Substance Use Disorder Population. J Clin Exer Physiol. 2012; 10(4):23-8.
9. Caviness CM, Bird JL, Anderson BJ, Abrantes AM, Stein MD. Minimum recommended physical activity, and perceived barriers and benefits of exercise in methadone maintained persons. J Subst Abuse Treat. 2013;44(4):457-62.
10. Dowla R, Sinmaz H, Mavros Y, Murnion B, Cayanan E, Rooney K. The effectiveness of exercise as an adjunct intervention to improve quality of life and mood in substance use disorder: a systematic review. Subst Use Misuse. 2022;57(6):911-28.
11. Weinstock J, Barry D, Petry NM. Exercise-related activities are associated with positive outcome in contingency management treatment for substance use disorders. Addict Behav. 2008;33(8):1072-5.
12. Riebe D, Franklin BA, Thompson PD, Garber CE, Whitfield GP, Magal M, Pescatello LS. Updating

ACSM's recommendations for exercise preparticipation health screening. Med Sci Sports Exerc. 2015;47(11):2473-9.
13. Borg G. Psychophysical scaling with applications in physical work and the perception of exertion. Scand J Work Environ Health. 1990;16 Suppl 1:55-8.
14. Schmidt S, Mühlan H, Power M. The EUROHIS-QOL 8-item index: psychometric results of a cross-cultural field study. Eur J Public Health. 2006;16(4): 420-8.
15. Testing the reliability and validity of the self-efficacy for exercise scale. Available at: https://oce-ovid-com.ezproxy.library.sydney.edu.au/article/00006199-200005000-00007/PDF. Accessed on 20 August 2022.
16. Andrews G, Slade T. Interpreting scores on the Kessler Psychological Distress Scale (K10). Aust N Z J Public Health. 2001;25(6):494-7.
17. Abrantes AM, Battle CL, Strong DR, Ing E, Dubreuil ME, Gordon A, Brown RA. Exercise preferences of patients in substance abuse treatment. Ment Health Phys Act. 2011;4(2):79-87.
18. Thompson ER. Development and validation of an internationally reliable short-form of the positive and negative affect schedule (PANAS). J Cross-Cultural Psychol. 2007;38(2):227-42.
19. Dowla R, Murnion B, Roberts K, Freeston J, Rooney K. Physical activity assessment in clinical studies of substance use disorder. Methods Mol Biol. 2018; 1735:273-84.
20. ACSM's guidelines for exercise testing and prescription. Available at: ACSM_s_Guidelines_for_Exercise_Testing_a.html?id=qb6nuAAACAAJ&redir_esc=y. Accessed on 20 October 2021.
21. Buysse DJ, Reynolds CF 3rd, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry Res. 1989;28(2):193-213.
22. Johns MW. Reliability and factor analysis of the Epworth sleepiness scale. Sleep. 1992;15(4):376-81.
23. Craig CL, Marshall AL, Sjöström M, Bauman AE, Booth ML, Ainsworth BE, et al. International physical activity questionnaire: 12-country reliability and validity. Med Sci Sports Exerc. 2003;35(8): 1381-95.
24. Tan G, Jensen MP, Thornby JI, Shanti BF. Validation of the Brief Pain Inventory for chronic nonmalignant pain. J Pain. 2004;5(2):133-7.

Cite this article as: Dowla RJ, Stubley C, Murnion B, Cayanan E, Mavros Y, Hardy S, et al. Fitness in recovery: impact of exercise in people with substance use disorder in residential treatment. Int J Clin Trials 2022;9(4):279-85.