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Effects of exercise in non-treatment seeking adults with alcohol use disorder: A three-armed randomized controlled trial (FitForChange)

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ABSTRACT

Background: Most individuals with alcohol use disorder (AUD) do not seek treatment. Stigma and the desire to self-manage the problem are likely explanations. Exercise is an emerging treatment option but studies in non-treatment seeking individuals are lacking. We compared the effects of aerobic exercise, yoga, and treatment as usual (phone-based support) on alcohol consumption in non-treatment seeking adults with AUD. *Methods:* Three-group parallel, single blind, randomized controlled trial. 140 physically inactive adults aged

18–75 diagnosed with AUD were included in this community-based trial. Participants were randomized to either aerobic exercise (n = 49), yoga (n = 46) or treatment as usual (n = 45) for 12-weeks. The primary study outcome was weekly alcohol consumption at week 13 (Timeline Follow-back).

Results: A significant decrease in weekly alcohol consumption was seen in all three groups: aerobic exercise (mean $\Delta = -5.0$, 95% C = -10.3, -3.5), yoga group (mean $\Delta = -6.9$, 95% CI = -10.3, -3.5) and TAU (mean $\Delta = -6.6$, 95% CI = -8.8, -4.4). The between group changes were not statistically significant at follow-up. Per-protocol analyzes showed that the mean number of drinks per week reduced more in both TAU (mean $\Delta = -7.1$, 95% CI = -10.6, -3.7) and yoga (mean $\Delta = -8.7$, 95% CI = -13.2, -4.1) compared to aerobic exercise (mean $\Delta = -1.7$, 95% CI = -4.4, 1. 0), [F(2, 55) = 4.9, p = 0.011].

Conclusions: Participation in a 12-week stand-alone exercise program was associated with clinically meaningful reductions in alcohol consumption comparable to usual care (phone counseling) by an alcohol treatment specialist.

1. Introduction

Alcohol use disorders (AUD) are among the most common mental disorders, affecting an estimated 4.9% of the adult population worldwide (Gowing et al., 2015). Despite negative health and social outcomes treatment seeking remains low (~20%) (Rehm et al., 2015), especially in the group with mild to moderate dependence who comprise the majority (70–80%) of those with AUD (Andréasson et al., 2013). Current treatments for AUD include pharmacological-, behavioral- and psychosocial therapy. Non-treatment has been related to stigma associated with available treatment options and with the desire to autonomously manage the problem (Probst et al., 2015; Wallhed Finn et al., 2014). AUD commonly coexists with mood disorders such as anxiety and depression (Grant et al., 2004; Kushner et al., 2000). Furthermore, alcohol dependence often co-occurs with tobacco use and as a result accumulates the risk of harmful effects. In Sweden the prevalence of individuals with alcohol dependence using tobacco on daily basis is 29% (Ramstedt, 2019). Also of concern is that hazardous drinkers are shown to be less physically active than non-hazardous drinkers (Hallgren et al., 2021b) increasing the risk of cardiovascular disease, metabolic syndrome and diabetes in those with AUD (Vancampfort et al., 2016a, 2016b).

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Physical activity (PA) including exercise, a subset of PA that is planned, structured and repetitive (Caspersen et al., 1985), is known for its synergistic effects on physical fitness, somatic health and mood (Penedo and Dahn, 2005) and suggested to benefit those with AUD (Giesen et al., 2015; Hallgren et al., 2017). Underlying mechanisms of PA on drinking behavior may relate to better mood states (Abrantes and Blevins, 2019), lowered stress-reactivity (Manthou et al., 2016), and to changes in the dopaminergic system (Leasure and Nixon, 2010; Robison et al., 2018). Acute bouts of exercise are shown to improve mood states and reduce cravings for alcohol in those with AUD (Brown et al., 2016; Hallgren et al., 2021a). In terms of the long-term effects, Brown and colleagues randomized 49 AUD patients to a 12-week group aerobic exercise intervention or brief advice to exercise (Brown et al., 2014). Findings indicated that a moderate intensity exercise intervention was an efficacious adjunct to alcohol treatment, and that improving adherence to the intervention may enhance its beneficial effects on alcohol use. Recently, PA was evaluated in non-treatment seeking adults with AUD; 66 participants were randomized to either a 16-week gym membership or gym membership plus motivational interviewing and contingency management. Reductions in consumption were observed in both groups but no group differences were found (Weinstock et al., 2020).

A key question is whether type of exercise influence drinking outcomes. Although recommended for general health, aerobic exercise may not be appealing or feasible for everyone due to musculoskeletal injuries, which tend to increase with age. Yoga is a body-mind practice that incorporates physical postures and breathing exercises with documented mental (Brinsley et al., 2020; Pascoe and Bauer, 2015) and somatic health benefits (Cramer et al., 2014). Two reviews have evaluated the efficacy of yoga in substance use disorders (SUD), suggesting beneficial effects on AUD (Kuppili et al., 2018; Sarkar and Varshney, 2016). As most of those with AUD are physically inactive with below average physical fitness (Hallgren et al., 2021b) yoga-based exercise could be an appealing and effective way to increase PA levels, enhance mood states (Pascoe and Bauer, 2015) and potentially reduce alcohol consumption. While several trials have demonstrated the potential role of exercise in the treatment of AUD (Jensen et al., 2019; Roessler et al., 2017), most have been limited by small sample sizes, the absence of inactive control groups, and limited data on exercise adherence. To address the abovementioned evidence gaps, we conducted a randomized controlled trial to examine the effects of yoga-based exercise and aerobic exercise as stand-alone treatments for AUD. A comparison group received usual care (phone counseling) by an alcohol treatment specialist. We hypothesized that participation in aerobic exercise and yoga would be superior to TAU regarding (1) reduction in alcohol consumption; and (2) reduction in AUD severity, harmful use, and heavy drinking over time.

2. Methods

2.1. Study design

Randomized, single blind, three-group parallel trial with a 1:1:1 group allocation. Participants were randomly assigned to either aerobic exercise, yoga, or TAU. Due to the COVID19 pandemic, the trial closed in August 2020 with 140 participants.

2.2. Recruitment and participants

Participants were recruited from the county of Stockholm, Sweden, between January 2018, and August 2019, via advertisement in a local newspaper distributed on four occasions. Project coordination was performed at Riddargatan 1: an outpatient clinic within the Stockholm Center for Dependency Disorders. A telephone screening was initially performed by the study coordinator (specialist nurse) to determine eligibility using the following **inclusion criteria:** (1) clinician diagnosed AUD (DSM5 \geq 2 criteria); (2) hazardous drinking the past month

(i.e., more than 14 standard drinks per week for men and more than nine standard drinks per week for women or more than four and three drinks respectively per drinking occasion); (3) resident in Stockholm County; (4) aged between 18 and 75 years. Individuals were excluded on the basis of the following **exclusion criteria:** hypertension (i.e. systolic > 200 mm HG and/or diastole > 110 mm HG); having a somatic disease (e. g. history of heart disease, cancer, chronic obstructive pulmonary disease or unstable blood glucose); mental illness (e.g. psychosis, bipolar disorder, suicidal risk); current regular exercise, defined as two or more planned exercise sessions per week; currently in treatment for AUD; withdrawal symptoms during the past 12 months; pregnancy or current use of illicit drugs. Those eligible were invited to Riddargatan 1 to receive further information and assessment. Written informed consent was obtained from participants before the assessment. The intervention period started one week after inclusion. Assessments were performed at baseline (before randomization) and week 13 (i.e., 12-weeks after start of the intervention period). At week seven participants randomized to exercise were given heart rate monitors (Polar H7, Bluetooth) with user instructions to assess activity intensity. Participants who did not attend their 13-week follow-up were contacted by phone (up to three times) during a four-week period.

2.3. Randomization

An external statistician created a computer randomization tool performing a simple randomization. A research assistant not involved in the trial received a link to the randomization tool and prepared sequentially numbered opaque envelopes with the allocation sequence. Envelopes were opened by the participant directly after the baseline assessment. A different research assistant performed the 13-week assessment and was blinded to group allocation.

2.4. Measures

At baseline self-reported PA levels were assessed with the International Physical Activity Questionnaire (IPAQ) (Craig et al., 2003). The first question from the SF-12 Health Survey; "In general, would you say your health is" measured on a five-point Likert scale, assessed overall physical well-being (Bech et al., 2003). Blood pressure (BP) and resting heart rate were measured using the Omron (M6) BP monitor, and body mass index (BMI) by recording weight and height. Exercise adherence was objectively assessed by data from SATS electronic entry system and with a training calendar where participants documented all training \geq 20 min performed outside SATS, including brisk walking. Except for the socio-demographic variables, the same questionnaires were used at 13-weeks.

2.4.1. Primary outcome

Changes in **alcohol consumption** (standard drinks/week) were assessed using the 30-day Timeline Follow-Back method (TLFB) (Sobell et al., 1979). In Sweden, one standard drink contains ~12 g of pure ethanol. The TLFB was also used to assess (1) heavy drinking days (HDD) i.e., the number of days men consumed \geq five standard drinks/day, or \geq four drinks/day for women during the 30-day period; (2) number of sober days; (3) hazardous drinking defined as consumption exceeding 14 or nine standard drinks per week for men and women respectively and/or meeting threshold for HDD.

2.4.2. Secondary outcomes

AUD severity was assessed with The Diagnostic and Statistical manual of Mental disorders (DSM-5) (mild = 2–3, moderate = 4–5, severe \geq 6 criteria) (DSM-5, 2013). Harmful use was measured with the 10-item screening instrument Alcohol Use Disorders Identification Test (AUDIT) (WHO, 2001) and heavy drinking over time was assessed with two biomarkers; gamma-glutamyl transferase (GGT) and phosphatidy-lethanol (PEth) by blood samples. At 13-weeks, DSM-5 and the AUDIT

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questionnaire were adjusted to assess the past three months.

2.5. Interventions

Exercise interventions took place at SATS (Sport Aerobic Training Center), a large fitness chain within Stockholm municipality. A free membership for 12-weeks was offered to participants, and they were asked to attend classes at least three times a week over the 12-week intervention period. Qualified fitness instructors delivered the classes and groups were open for individuals not taking part in the trial. To monitor progress and help maintain motivation, participants were also offered three 30 min support sessions (week 1, 3 and 9) with a SATS personal trainer (PT).

2.5.1. Aerobic exercise

Aerobic exercise consisted of 60 min of group training. To optimize adherence, participants could choose one or more of the following classes: cycling/spinning, aerobic training (whole body movements, including running and jumps), boxercise (aerobic training with martial arts movements) and dance-based aerobic exercise. Participants could also perform individual aerobic exercise on a cross-trainer, treadmill, or on stationary cycles at SATS.

2.5.2. Yoga-based exercise

Yoga consisted of 60 min of group training involving physical postures and breathing exercises for beginners to intermediate level. Classes offered to participants were: ashtanga and hatha yoga, 'Les mills body balance' (combination of yoga, Pilates and Thai-chi), yin yoga and yin release (emphasizing calm postures with a focus on breathing).

2.5.3. Treatment as usual

TAU consisted of up to three 45-minute telephone counseling sessions with "Alcohol help", a nationwide alcohol service providing information and support to people concerned about their drinking habits. A qualified alcohol treatment specialist (i.e., psychologist or behavioral scientist) gave advice on treatment options based on AUDIT scores and participants wishes. By using Motivational interviewing (MI) techniques, motives for change were explored, and advice on treatment options were given, such as seeking treatment in primary or specialist care, Alcoholics Anonymous, internet-based Cognitive Behavioral Therapy (iCBT), telephone counseling or self-help material (sent by post). To monitor progress, using the same MI agenda, the treatment specialist contacted the participant up to three times (once a month) during the study period. In practice, these follow-ups frequently involved discussions about alcohol consumption, barriers to treatment, treatment preferences, and motives for change.

2.6. Sample size

Our initial power calculation showed that we required 210 participants to detect group differences at follow-up (Hallgren et al., 2018). Due to disruption to the trial caused by COVID19, sample size was recalculated by an external statistician in August 2020 based on results from the recent study by Weinstock and colleagues (Weinstock et al., 2020). Assuming an effect size of 0.3 favoring the exercise conditions (equally) compared to usual care, the revised calculation showed that we needed to enroll 123 participants in the study (41 in each group) to achieve 80% power at a significance level of 0.05. The power calculation was performed using G*Power version 3.1 (Faul et al., 2009).

2.7. Statistical analysis

The analysis plan was preregistered at Karolinska Institutet (https://medarbetare.ki.se/people/mats-hallgren). Fisher's exact test determined if there were significant differences in loss to follow up between groups or in baseline characteristics of completers and non-completers.

Little's missing completely at random (MCAR) test was performed to test the null hypothesis that missing data were Missing Completely At Random (MCAR) on primary and secondary outcomes. To assess baseline group differences between the three groups, analysis of variance (ANOVA) was used for continuous variables and chi square tests for categorical variables. Within-group mean difference (baseline to 13weeks) with 95% confidence intervals were analyzed using paired sample t-tests with an adjusted (p < 0.017) Bonferroni correction. The primary outcome, change in alcohol consumption, was analyzed using intention-to-treat (ITT). Effects of the interventions on alcohol consumption were assessed using Analysis of Covariance (ANCOVA). ANCOVA is a statistical method applied when comparing group differences in pretest-posttest designs, while controlling for pretest score differences in the dependent variable. Secondary outcomes and the perprotocol analysis (PP) used the same statistical model as the primary outcome analysis. Effect sizes are reported using the partial Eta-squared statistic (η 2) where: 0.01 = small, 0.06 = medium, > 0.14 = large. The PP-analysis included those randomized to aerobic or yoga who exercised > 12 times during the intervention period and those in TAU having a minimum of one contact with 'Alcohol help' and reporting no increase in exercise. Analyzes were stratified by age and gender. Linear mixed models with and without (multiple) imputed data were also used to assess between group changes in the primary outcome. Results were materially the same as the ANCOVA models (data not shown). All analyzes were performed using SPSS version 25.

3. Results

3.1. Participant retention and missing data

Fig. 1 shows the flow of participants through the trial. In total, 472 individuals were initially screened; of those, 140 met the inclusion criteria and were randomized to one of the three study arms. Forty-five individuals were allocated to TAU, 49 to aerobic exercise and 46 to yoga. Main reasons for not being included were: declined to participate (27%, n = 88), 42 of these wanted to commence exercise and were unwilling to be randomized. The other reason was current regular exercise 20% (n = 66). Thirteen participants (9%) were lost to follow-up. One person in the yoga group was excluded from the ITT analysis due to unstable blood glucose, and one person in TAU did not complete the TLFB questionnaire at the baseline assessment and was also excluded. The ITT analysis for the primary and secondary outcomes included 89% (n = 125) of the participants.

A two-sided Fisher's exact test showed no differences in complete loss to follow-up rate between the groups [p = 0.294, FET], nor for the primary outcome [p = 0.466, FET]. There was no association with loss to follow-up on any of the baseline variables. Complete loss to follow-up on the two biomarkers (PEth and GGT) was ~29% (n = 40 and 41, respectively). Little's MCAR test indicated that missing data on the primary outcome and secondary outcomes were missing completely at random; [$\chi 2 = 592.994$, DF = 650, p = 0.946]. Given these results, complete case analysis was performed on all outcomes (Jakobsen et al., 2017).

3.2. Participant characteristics

More women 70% (n = 98) participated in the study than men 30% (n = 42). Mean age was 53.7 years (SD = 11.8, range = 21–75), 78% were employed, 57% were living with a partner, and 69% had completed university studies. Participants drank on average 19.7 (SD = 11.4) standard drinks/week and engaged in 91.2 min of PA (SD = 70.5) per week, which is below WHO recommended levels (WHO, 2010); 10% were smokers and 22% used snuff (smokeless tobacco) daily. Complete baseline demographics and clinical values of each group are presented in Table 1.

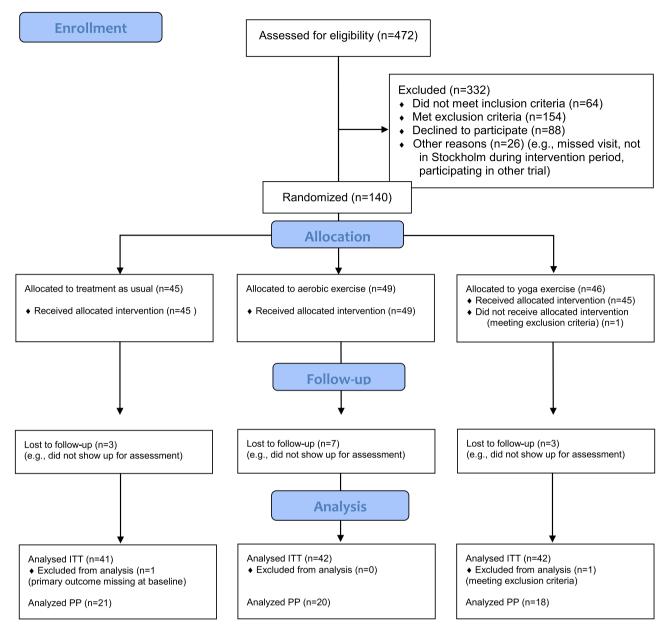


Fig. 1. Participant flow chart. ITT = intention-to-treat; PP = per protocol.

3.3. Adherence

Participants from both exercise groups attended SATS approximately once a week during the 12-week intervention period; aerobic exercise (mean = 12.0, SD = 9.8, range = 0-35) and voga (mean = 12.6, SD = 12.6,SD = 11.0, range = 0–38). There was a significant difference in mean heart rate (HR) per exercise session, between aerobic exercise (mean-= 133.5 BPM, SD = 15.6, range = 104–158.5) and yoga (mean = 94.8 BPM, SD = 12.7, range = 73.3–117.3), [t (42) = 9.0, p < 0.001]. Adding structured exercise performed outside SATS, the mean exercise frequency increased to almost twice a week in both groups; aerobic exercise (mean = 20.7, SD = 13.7, range = 0-59) and yoga (mean-= 23.4, SD = 14.5, range = 0-60). All TAU participants completed at least one phone consultation with 'Alcohol help'; 11 (27%) of the 41 TAU participants who completed their follow-up had three phone sessions with 'Alcohol help' and 22% (n = 9) reported seeking further help for their alcohol problems. TAU participants reported exercising on average once a week (mean = 11.0, SD = 17.2, range = 0–73) during the intervention period (primarily of brisk walking). None of the

participants in aerobic exercise or yoga reported receiving any other AUD-treatment during the intervention period.

3.4. Intention-to-treat analyzes

Table 2 shows the change in mean drinks per week (baseline to 13-weeks), and the group difference adjusted for baseline consumption: aerobic exercise (mean $\Delta = -5.0$, 95% CI = -10.3, -3.5), yoga (mean $\Delta = -6.9$, 95% CI = -10.3, -3.5) and TAU (mean $\Delta = -6.6$, 95% CI = -8.8, -4.4). These changes are also illustrated in Fig. 2A. Reductions in alcohol consumption did not differ significantly between the three groups at follow-up; [F(2, 121) = 0.9, p = 0.427]. Consistent with the main analyzes, there were no group differences when data was stratified by gender and age. Secondary outcome analyzes (HDD, sober days, DSM-5 scores, AUDIT scores, Peth and GT) were comparable to the main analyzes.

Table 1

Participant characteristics.

	TAU = 45	Aerobic = 49	Yoga = 46	Р
Demographics				
Age [mean (SD)	53 (12)	54 (11) 27–74	54 (13) 21–75	.853
range]	27–74			
Female [n (%)]	34 (76)	36 (74)	28 (61)	.251
Education [n (%)]				.419
University/College	31 (69)	38 (78)	28 (61)	
High school	13 (29)	10 (20)	17 (37)	
Elementary school	1 (2)	1 (2)	1 (2)	
Source of income [n (%)]				
Employed	36 (80)	36 (74)	37 (80)	.656
Pension	8 (18)	9 (18)	7 (15)	.912
Other	4 (9)	7 (14)	3 (7)	.435
Civil status [n (%)]				
Married/co-	23 (51)	29 (59)	29 (63)	.501
habiting				
Living alone	17 (38)	11 (22)	14 (30)	.268
Living with children	14 (31)	18 (37)	7 (15)	.055
Smoker [n (%)]	3 (7)	6 (12)	5 (11)	.686
Snuff (tobacco) [n	11 (24)	14 (29)	6 (13)	.172
(%)]				
Alcohol [mean (SD) ran	nge]			
Drinks per week	19.0 (10.1)	19.8 (11.2)	20.4 (13.0)	.856
	0–49	5.7–55	3.7-74.7	
Heavy drinking days/	8.7 (6.8)	9.3 (7.6) 0–29	8.4 (7.5) 0–30	.802
month	0–29			
DSM-5 AUD	4.9 (2.1) 2–10	4.9 (2.3) 2–10	4.9 (1.8) 2–11	.978
AUDIT	16.7 (6.3)	17.4 (5.4)	18.4 (6.0)	.411
	5–29	7–30	8–33	
PEth	0.4 (0.4) 0-2	0.4 (0.4) 0–1.6	0.3 (0.4) 0–2.1	.643
GGT	0.5(0.5)	0.5 (0.4)	0.7 (0.6)	.094
	0.2–2.8	0.2-2.2	0.2–2.4	
Physical activity				
Sitting time Median	420	360 [240-540]	420	.904
[IQR]	[300-600]		[300-600]	
MVPA min/week	96 (89)	82 (58)	96 (63)	.745
[mean (SD) range]	12-360	10–180	10–240	
Physical health Perceived health [n				.796
(%)]				
Excellent/Very good	7 (15.6)	6 (12.2)	5 (10.9)	
Good/Fair	34 (75.6)	39 (79.6)	34 (73.9)	
Poor	4 (8.9)	4 (8.2)	7 (15.2)	
BMI [mean (SD)	28 (5.5)	28 (4.6) 21–46	28 (5.1)	.891
range]	18-48		19–41	
BMI category [n (%)]				.578
Normal \leq 24.99	16 (35.6)	15 (30.6)	13 (28.3)	
Overweight	18 (40.0)	16 (32.7)	21 (45.7)	
25–29.99				
Obese ≥ 30	11 (24.4)	18 (36.7)	12 (26.1)	

Other source of income = sickness benefit, disability support, income support, other (e.g., student, unemployed, savings); DSM = Diagnostic and Statistical Manual; AUDIT = Alcohol Use Disorders Identification Test; Peth = Phosphatidylethanol; GGT = gamma-glutamyl transferase; MVPA = Moderate to Vigorous Physical Activity; BMI = Body mass index.

3.5. Per-protocol analyzes

Table 3 shows the PP analyzes. At study endpoint the mean within change in drinks per week were: aerobic exercise (mean $\Delta = -1.7, 95\%$ CI = -4.5, 1.0), yoga (mean $\Delta = -8.7, 95\%$ CI = -13.2, -4.1) and TAU (mean $\Delta = -7.1, 95\%$ CI = -10.6, -3.7). These changes are also shown in Fig. 2B. Between group analyzes at follow-up were statistically significant [F(2, 55) = 4.9, p = 0.011, $\eta 2 = 0.152$], favoring TAU (mean $\Delta = -5.40, 95\%$ CI = -10.28, -0.05) and yoga (mean $\Delta = -5.54, 95\%$ CI = -10.66, -0.42) compared to aerobic exercise. Estimates also showed that women in TAU drank fewer drinks/week (mean = 9.2, SD = 7.6) than women in aerobic group (mean = 16.8,

Table 2

Within and between group effects of the interventions on alcohol consumption and within and between group effects of the interventions on other drinking outcomes.

A) Within and	between gro	oup effects	of the interventions o	n alcoho	l consumpti	ion
	standard drii	nks/week)			-	
	Baseline	13 weeks	Within group difference		Main effe treatment group	
	Mean	Mean	MD (SD), 95%	Р	ANCOVA F (d.f)	Р
Total	(SD)	(SD)	CI		0.9 (2,	.427
sample					121)	
TAU	18.7	12.2	-6.6 (6.9) – 8.8,	.000		
(n = 41) Aerobic	(9.2) 20.1	(7.9) 15.1	– 4.4 -5.0 (7.9) – 10.3,	.000		
(n = 42)	(11.5)	(12.3)	- 3.5	.000		
Yoga	19.5	12.6	-6.9 (10.9)	.000		
(n = 42)	(10.5)	(11.8)	– 10.3,			
Men			- 3.53333.53.5		0.2 (2,	.840
TAU	25.4	16.9	-8.5 (5.5) – 12.7,	.002	32)	
(n = 9)	(8.0)	(9.1)	-6.5 (5.5) - 12.7, - 4.3	.002		
Aerobic	20.2	15.9	-4.3 (6.2) - 8.5,	.046		
(n = 11)	(11.4)	(14.0)	- 0.1			
Yoga	21.0	14.3	-6.8 (16.4)	.119		
(n = 16)	(10.1)	(10.1)	– 15.5, – 2.0,		1.0.(2)	202
Women					1.0 (2, 85)	.382
TAU	16.9	10.8	-6.1 (7.3) - 8.7,	.000	00)	
(n = 32)	(8.8)	(7.2)	- 3.4			
Aerobic	20.1	14.8	-5.3 (8.5) - 8.4,	.002		
(n = 31)	(11.7)	(12.0)	- 2.2			
Yoga	18.6	11.6	-7.0 (6.0) – 9.4, – 4.6,	.000		
(n = 26) Age 18–54	(10.8)	(8.8)	- 4.0,		1.0 (2, 58)	.385
TAU	17.1	10.6	-6.5 (6.1) - 9.3,	.000	00)	
(n = 21)	(8.0)	(6.7)	- 3.7			
Aerobic	20.1	13.6	-6.6 (9.3) – 10.3,	.001		
(n = 26)	(10.0)	(9.5)	- 2.8	~~-		
Yoga (n = 15)	18.4 (9.0)	9.7 (6.7)	-8.7 (10.1)	.005		
Age 55–75	(9.0)	(0.7)	- 14.3, - 3.1		1.1 (2, 59)	.348
TAU	20.4	13.8	-6.7 (7.8) – 10.3,	.001	0,5)	
(n = 20)	(10.3)	(8.9)	- 3.0			
Aerobic	20.1	17.6	-2.5 (4.1) - 4.7,	.026		
(n = 16)	(13.8)	(16.0)	- 0.3			
Yoga (n = 27)	20.2	14.3	-5.9 (11.4) - 10.4, - 1.4	.012		
	(11.3)	(13.7)				
B) Within and	Mean	Mean		other di P	rinking outo F (d.f)	omes P
HDD	(SD)	(SD)	CI		1.5	.222
ndb					(2121)	.222
TAU	8.7 (6.8)	5.1	-3.7 (6.5) - 5.7,	.001		
(n = 41)		(6.0)	- 1.6			
Aerobic	9.9 (7.7)	7.1	-2.8 (5.6) - 4.5,	.003		
(n = 42)	9 E (7 A)	(7.3) 4 E	-1.0	000		
Yoga (n = 42)	8.5 (7.4)	4.5 (6.1)	-4.0 (6.1) – 5.9, – 2.1	.000		
Sober		(0.12)			0.8 (2,	.453
days					121)	
TAU	11.1	15.1	4.1 (5,5) 2.3, 5.8	.000		
(n = 41)	(7.1)	(8.4)		000		
Aerobic $(n = 42)$	10.6 (7.7)	14.4 (8.1)	3.8 (5.4) 2.1, 5.5	.000		
Yoga	10.4	15.8	5.4 (6.8) 3.2, 7.5	.000		
(n = 42)	(7.4)	(9.0)				
DSM-5					0.1 (2,	.941
AUD					120)	
TAU	4.8 (2.0)	3.1	-1.7 (2,4) – 2.5,	.000		
(n = 43)	4.8 (2,3)	(2,2)	-1.0	.000		
	1.0 (2,0)				und on north	nage
				(contin	ued on next	pugej

Table 2 (continued)

Aerobic		3.1	-1.7 (1.9) – 2.3,			
(n = 39)		(2.1)	- 1.1			
Yoga	4.9 (1.8)	3.0	-1.9 (2.2) – 2.6,	.000		
(n = 42)		(2.0)	- 1.2,			
AUDIT					0.9 (2,	.393
					123)	
TAU	16.3	12.4	-3.9 (5.5) – 5.6,	.000		
(n = 43)	(6.1)	(6.1)	-2.2			
Aerobic	17.5	12.4	-5.2 (4.4) – 6.5,	.000		
(n = 42)	(4.9)	(5.6)	- 3.8			
Yoga	18.0	11.9	-6.0 (5.8) - 7.8,	.000		
(n = 42)	(5.8)	(4.9)	- 4.2			
PEth					0.5 (2,	.621
					96)	
TAU	0.4 (0.4)	0.4	0.01 (0.2),	.740		
(n = 34)		(0.5)	-0.06, 0.08			
Aerobic	0.4 (0.4)	0.5	0.04 (0.2)	.125		
(n = 35)		(0.5)	-0.01, 0, 11			
Yoga	0.3 (0.4)	0.3	0.003 (0.2)	.925		
(n = 31)		(0.4)	-0.06, 0.17			
GGT					1.0 (2,	.366
					95)	
TAU	0.4 (0.2)	0.4	-0.001 (0.1)	.935		
(n = 33)		(0.2)	- 0.05, 0.04			
Aerobic	0.5 (0.4)	0.5	0.02 (0.2)	.561		
(n = 35)		(0.5)	- 0.05, 0.09			
Yoga	0.7 (0.6)	0.6	-0.08 (0.3)	.140		
(n = 31)		(0.6)	- 0.19, 0.03			

Paired t-statistics with Bonferroni correction P < 0.017. ANCOVA analysis adjusted for baseline consumption. Effect size is not shown due to non-significant p-value.

HDD = Heavy drinking days, AUDIT = Alcohol Use Disorders Identification Test, PEth = Phosphatidylethanol, GGT = Gamma-glutamyltransferase

SD = 10.4), [F(2, 43) = 5.7, p = 0.007, $\eta 2 = 0.208$]. TAU (mean=16.1, SD = 8.4) and yoga participants (mean = 13.9, SD = 8.9) had more days in sobriety than those in the aerobic exercise group (mean=11.7, SD = 9.0), [F(2, 55) = 4.6, p = 0.014, $\eta 2 = 0.144$]. All significant results had large effect sizes; $\eta 2 > 0.14$. All other outcomes in the PP analysis were non-significant.

3.6. Clinical outcomes

Table 4 shows the change in clinical variables pre- to post intervention. The percentage of individuals reporting having a severe or moderate AUD decreased by more than 50% at 13-weeks in all groups except for moderate AUD in the aerobic group, where the reduction was slightly less (26%). None of these changes differed between groups [$\chi 2 = 5.201$, p = 0.518]. The decrease in those reporting hazardous/ severe consumption (8–40 p) according to AUDIT was low in all groups (range = 14–26%) and did not differ between groups [$\chi 2 = 0.821$,

A) Intention-to-treat analysis (n=125)

p = 0.663]. The decrease in hazardous drinking according to Swedish guidelines was greater in the yoga group at follow-up and approached statistical significance [$\chi 2 = 5.397$, p = 0067].

3.7. Adverse events

None reported.

4. Discussion

This is the first trial to evaluate the effects of two different types of exercise as stand-alone treatment for physically inactive, non-treatment seeking adults with AUD. Alcohol consumption reduced in all three groups. However, contrary to what we hypothesized (aerobic exercise and yoga being superior to TAU) no significant differences were found at follow-up on the primary or secondary drinking outcomes. Per-protocol analyzes favored yoga and usual care compared to aerobic exercise. Overall, these findings suggest that exercise, in particular yoga-based exercise, has beneficial effects on consumption comparable to the treatments offered by 'alcohol help' (usual care).

Recruitment into the trial was successful, with about 100 individuals showing interest after each advertisement. This was probably attributable to the non-stigmatizing approach, where individuals were asked if they were "Drinking too much and exercising too little?, and supports previous research showing that those with AUD are interested in exercise-based interventions (Abrantes et al., 2011; Giesen et al., 2015). Only nine out of the 41 participants in TAU sought specialized treatment. This could be the result of selection bias, as participants in TAU might have been more interested in exercise. Alternatively, it could indicate that those with AUD are reluctant to undergo specialized alcohol treatment (Wallhed Finn et al., 2014). The trial attracted more women than men. Given that women experience more barriers to alcohol treatment (McCrady et al., 2020), this is noteworthy from a gender perspective. Despite measures to increase compliance (e.g., free PT sessions), adherence was sub-optimal in both exercise groups with a mean frequency of approximately one exercise session per week (SATS only) out of the three requested; thus, low adherence may have impacted the results by underestimating the true effect of exercise.

The current findings are consistent with previous studies evaluating PA as an adjunct treatment for individuals with AUD (Hallgren et al., 2014; Jensen et al., 2019; Roessler et al., 2017). However, a notable difference is that in the current trial exercise was offered as stand-alone treatment, indicating that even with low adherence, exercise alone had beneficial effects on consumption comparable to a specialized (non-exercise) intervention. The per-protocol results add the observation that yoga-based exercise may be especially beneficial for this population. Participants in the yoga group drank approximately 5.5 drinks less per week than those in the aerobic exercise group. Yoga was also superior to

B) Per-protocol analysis (n=59)

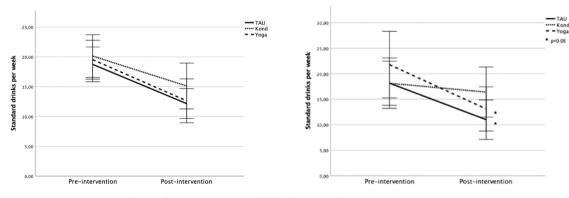


Fig. 2. Changes in mean standard drinks per week pre- to post intervention.

Table 3

Per protocol analyzes: within and between group effects of the interventions on alcohol consumption and within and between group effects of the interventions on other drinking outcomes.

A) Per protocol analyzes	. Within and betwee	en group effects of th	e interventions on alcohol consum	ption			
	Baseline	13 weeks	Within group difference		Main effect of	treatment group ANCOVA	
	Mean (SD)	Mean (SD)	MD (SD), 95% CI	Р	F (d.f)	Р	η2
Total sample					4.9 (2, 55)*	.011	0.15
TAU (n = 21)	18.2 (10.8)	11.0 (8.5)	-7.1 (7.5) - 10.6, - 3.7	.000			
Aerobic $(n = 20)$	18.1 (9.3)	16.4 (10.5)	-1.7 (5.9) - 4.5, 1.0	.203			
Yoga (n = 18)	21.8 (13.1)	13.1 (8.7)	-8.7 (9.1) - 13.2, - 4.1	.001			
Women					5.7 (2, 43)*	.007	0.21
TAU (no $= 18$)	16.7 (10.6)	9.2 (7.6)	-7.5 (7.9) - 11.4, - 3.6	.001			
Aerobic (no $= 16$)	18.2 (9.3)	16.8 (10.4)	1.4 (6.1) - 4.6, 1.9	.383			
Yoga (no = 13)	19.9 (13.7)	13.9 (10.1)	-6.0 (5.7) - 9.5, - 2.6	.002			
Age 18–54					2.6 (2, 23)	.097	-
TAU (no $= 8$)	17.3 (10.2)	9.6 (7.9)	-7.7 (6.7) - 13.3, - 2.1	.014			
Aerobic (no $= 13$)	17.7 (10.7)	16.5 (12.4)	-1.2 (6.8) - 5.3, 2.9,	.532			
Yoga (no $=$ 6)	17.3 (9.3)	10.5 (5.6)	-6.8 (10.3) - 17.6, 3.9,	.164			
Age 55–75					1.5 (2, 28)	.232	-
TAU (no = 13)	18.7 (11.6)	11.9 (9.0)	-6.8 (8.2) - 11.8, - 1.8	.012			
Aerobic (no $=$ 7)	18.9 (6.6)	16.2 (6.3)	-2.7 (4.0) - 6.4, 1.0	.123			
Yoga (no = 12)	24.0 (14.5)	14.4 (9.9)	-9.6 (8.8) - 15.2, - 4.0	.003			
P) Des suste col es elvaco	Within and batura	a analysis offerster of th	a intermentions on other duiphing of	t			
B) Per protocol analyzes			e interventions on other drinking ou	P	F (d.f)	Р	
HDD	Mean (SD)	Mean (SD)	MD (SD), 95% CI	r	2.6 (2, 55)	.083	η2
TAU (no $= 21$)	8.0 (1.9)	4.7 (1.4)	-3.3 (7.3) - 6.7, 0.006	.050	2.0 (2, 33)	.085	-
Aerobic (no $= 20$)	10.2 (1.7)	8.7 (1.8)	-3.5(7.3) = 0.7, 0.000 -1.6(5.3) = 4.0, 0.9	.208			
Yoga (no $= 18$)	10.2 (1.7)	5.1 (6.9)	-5.3(5.5) - 8.0, -2.5	.203			
Sober Days	10.3 (9.3)	5.1 (0.9)	-3.3 (3.3) - 8.0, - 2.3	.001	4.6 (2, 55)*	.014	0.14
TAU (no $= 21$)	11.0 (7.5)	16.1 (8.4)	5.1 (5.9) 2.5, 7.8	.001	4.0 (2, 55)	.014	0.14
Aerobic (no $= 20$)	11.0 (7.5)	11.7 (9.0)	0.7(2.8) - 0.6, 1.9	.305			
Yoga (no $= 18$)	8.8 (7.3)	13.9 (8.9)	5.1 (6.4) 1.9, 8.3	.004			
DSM-5 AUD	0.0 (7.3)	13.9 (0.9)	5.1 (0.4) 1.9, 8.5	.004	0.2 (2,56)	.793	
TAU (no $= 22$)	4.3 (1.6)	2.5 (1.5)	-1.8 (1.8) - 2.6, -1.0	.000	0.2 (2,30)	.793	-
Aerobic (no $= 22$)	3.9 (2.0)	2.6 (2.0)	-1.3(1.7) - 2.1, -0.5	.003			
Yoga (no $= 18$)	4.4 (1.7)	2.7 (1.8)	-1.8(1.8) - 2.7, -0.9	.003			
AUDIT	4.4 (1.7)	2.7 (1.6)	-1.8 (1.8) - 2.7, - 0.9	.001	1.0 (2, 56)	.361	
TAU (no $= 22$)	15.5 (6.1)	11.2 (4.6)	-4.3(4.8) - 6.4, -2.2	.000	1.0 (2, 50)	.301	-
Aerobic (no $= 22$)	17.4 (5.6)	13.2 (6.4)	-4.2(4.0) - 6.1, -2.3	.000			
Yoga (no $= 18$)	16.6 (5.4)	10.8 (4.4)	-5.7 (4.6) - 8.0, -3.4	.000			
PEth	10.0 (0.4)	10.0 (4.4)	-3.7 (4.0) - 0.0, - 3.4	.000	0.4 (2, 50)	. 665	
TAU (no $= 17$)	0.4 (0.5)	0.4(0.6)	0.06(0.2) - 0.05, 0.17	.298	0.4 (2, 30)	. 003	_
Aerobic (no = 17)	0.5 (0.4)	0.6 (0.5)	0.00(0.2) = 0.03, 0.17 0.07(0.2) = 0.03, 0.17	.154			
Yoga (no $= 18$)	0.3 (0.4)	0.3 (0.2)	0.07(0.2) = 0.03, 0.17 0.002(0.1) = 0.06, 0.07	.941			
GGT	0.3 (0.2)	0.3 (0.2)	0.002(0.1) - 0.00, 0.07	.941	0.3 (2, 47)	.732	
TAU (no $= 16$)	0.4 (0.1)	0.3 (0.1)	-0.01 (0.09) - 0.06, 0.04	.674	0.3 (2, 77)	./ 54	-
Aerobic (no = 10)	0.4 (0.1)	0.5 (0.4)	-0.01(0.09) = 0.00, 0.04 -0.03(0.2) = 0.08, 0.15	.562			
Yoga (no $= 16$)	0.7 (0.7)	0.6 (0.6)	-0.05(0.2) = 0.08, 0.13 -0.05(0.3) = 0.22, 0.12	.526			
10ga (10 = 10)	0.7 (0.7)	0.0 (0.0)	-0.03 (0.3) - 0.22, 0.12	.520			

Paired t-statistics with Bonferroni correction P < 0.017. ANCOVA analysis adjusted for baseline consumption.

aerobic exercise in terms of increasing the days of sobriety per month. As compliance was equal in both groups, this was probably not causing these differences. Another noteworthy finding is the decrease in hazardous alcohol consumption at 13-weeks, which was larger in the yoga group compared to aerobic exercise and TAU, suggesting a clinically meaningful effect of yoga on AUD.

Studies evaluating yoga as treatment for AUD have found positive effects on mood and wellbeing (Hallgren et al., 2014), antidepressant effects (Vedamurthachar et al., 2006) and reduced AUDIT scores (Reddy et al., 2014). As predicted, yoga was a lower intensity exercise compared aerobic exercise. Results also showed that aerobic exercise had smaller magnitude effect on most drinking measures. Vigorous aerobic exercise can be perceived as unpleasant, especially for those with limited exercise experience (Ekkekakis et al., 2011). We speculate that the larger magnitude effects seen in the yoga group could be explained by individual differences on how exercise is perceived. Yoga may have been perceived as less challenging and more pleasurable, which in turn may have resulted in less alcohol consumption by mediating positive mood states. Emerging work on the mood-enhancing effects of exercise in AUD supports this possibility (Abrantes and Blevins, 2019).

Strengths of the study include the large participant sample, the threearmed design and collection of data on adherence and exercise intensity. The dropout rate was only 10% which is low considering attrition of around 40% in previous trials (Hallgren et al., 2017). Some potential limitations are acknowledged. Despite offering personal trainers to monitor and motivate participants, adherence was sub-optimal. Commencing a new exercise regime is known to be difficult. Incentives (e.g., prize vouchers) (Brown et al., 2014) and MI sessions are methods that have been used previously to motivate exercise participants (Weinstock et al., 2020). The change (pre- to post exercise) in the two alcohol biomarkers PEth and GGT did not correlate with the self-reported change in the TLFB. This inconsistency has been raised as a common problem and is likely due to participants underreporting their consumption (Grüner Nielsen et al., 2021). However, missing data (~ 30%) on both Peth and GGT in this trial resulted in a small sample; these results should be interpreted with caution. Another possible weakness is the lack of long-term follow-up, which excludes the possibility of making estimates of the long-term effects of these interventions. Fewer men than women were included making results more generalizable for women. Giving participants the option to select different types of exercise is a potential strength as it gave them choice, which in theory should improve adherence, but it also makes the trial more difficult to replicate and the effects of specific exercise interventions less clear. Finally, treatment preferences and reasons for noncompliance were not assessed.

Table 4

Clinical outcomes.

	Baseline n (%)	13 weeks n (%)	Absolute change	Change (%)			
Severe AUD (DSM5)							
TAU	14 (31.1)	7 (16.3)	7	61			
Aerobic exercise	18 (36.7)	7 (17.9)	11	53			
Yoga	14 (30.4)	5 (11.9)	9	56			
Moderate AUD							
TAU	19 (42.2)	6 (14.0)	13	68			
Aerobic	12 (24.5)	7 (17.9)	5	26			
Yoga	22 (47.8)	11 (26.2)	11	50			
Mild AUD							
TAU	12 (26.7)	22 (51.2)	10	83			
Aerobic	19 (38.8)	13 (33,3)	6	32			
Yoga	10 (21.7)	16 (38.1)	6	60			
Harmful consum	ption (AUDIT)						
TAU	42 (93.3)	36 (83.7)	6	14			
Aerobic exercise	48 (98.0)	37 (88.1)	11	23			
Yoga	46 (100.0)	34 (81.0)	12	26			
Hazardous consu	mption						
TAU	42 (95.5)	37 (88.1)	5	12			
Aerobic exercise	48 (98.0)	37 (88.1)	11	23			
Yoga	43 (93.5)	30 (71.4)	13	30			

Even though usage rates vary, prescribed physical activity (PAP) is a known method used to increase PA in routine clinical care as prevention, first line treatment or as complement to other medical/rehabilitation treatment (Arsenijevic and Groot, 2017). One advantage of PAP is that it can be prescribed by any licensed health care professional with adequate expertize. By increasing the knowledge amongst health care personnel of using exercise as treatment for AUD, it could easily be implemented in both primary- and specialist health targeting those with AUD. A "lifestyle" focused treatment could attract not only those with mild to moderate dependence but also those suffering from more severe problems in need of specialist treatment. Using exercise as a gateway could facilitate offering adjunct specialist treatment for those in need.

4.1. Interpretation

Many adults with AUD are interested in exercise to reduce their alcohol consumption. These results indicate that exercise (in particular yoga-based exercise) has beneficial effects on consumption that are comparable to treatment via 'alcohol help'. These effects were seen for most secondary drinking outcomes. Per-protocol analyzes suggest that yoga may confer stronger magnitude effects than aerobic exercise alone. Future trials should include long-term follow-ups to examine changes over time. Studies of underlying psychological and biological mechanisms are also needed. Also, qualitative findings through interviews could lead to a better understanding of what components of the exercise interventions are most beneficial for individuals with AUD.

5. Other information

The trial has been approved by the Regional Ethics Committee (Regionala Etikprovningsnamnden, EPN), Stockholm; DNR: 2017/1380-31, and registered with German Clinical Trials Register on 14 July 2017: DRKS00012311 (www.drks.de).

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CRediT authorship contribution statement

Victoria Gunillasdotter: Contributed to project design, Project administration, Data curation, Formal analysis, Writing – original draft (under supervision). Sven Andréasson: Funding acquisition, Writing – review & editing, Supervision. Maria Jirwe: Writing – review & editing, Supervision. Örjan Ekblom: Writing – review & editing. Mats Hallgren: Conceptualization, Funding acquisition, Project design and administration, Writing – review & editing, main supervisor. All authors have approved the final article.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper..

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.drugalcdep.2022.109266.

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