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## Saying yes or no to physical activity – A comparative cohort analysis of patients seeking treatment for Alcohol Use Disorder



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## ABSTRACT

**Introduction:** Engaging individuals, suffering from alcohol use disorder (AUD), in a physical activity can be a challenge, and often it is a limitation of the quality of studies on the topic. The aim of the present study is to investigate differences between participants and non-participants in a randomized controlled trial on the effect of physical exercise as add-on to treatment as usual (TAU) to treatment for alcohol use disorder, thereby identifying potential factors that may predict lack of willingness or ability to consider increasing the level of physical activity.

**Method:** The Healthy Lifestyle Study was a randomized controlled trial with three arms, of which two included adding physical activities to treatment for AUD as usual. All patients from an outpatient alcohol treatment clinic were invited to participate in the study. 172 accepted participation, and 384 patients either did not show up for information about the study or declined to participate. All patients in the treatment clinic were assessed by means of European Addiction Severity Index (EuopASI).

**Results:** The only predictor of participation in the study was the drinking pattern. Patients, who had been drinking every day for the last 6 months were less likely to participate in the study (OR 0.7 CI 0.4–0.9). Neither somatic nor psychiatric health seemed to impact whether or not the patients participated in the study.

**Conclusion:** Non-participants did not differ from participants in this study except in their drinking pattern.

### 1. Introduction

Physical exercise is regarded as an important treatment strategy for many somatic and mental health conditions (Firth, Cotter, Elliott, French, & Yung, 2015; Hallgren, Vancampfort, Schuch, Lundin, & Stubbs, 2017), including Alcohol Use Disorder (AUD) (Vancampfort et al., 2015). Thus, it is not surprising that exercise and physical activity are central to public health recommendations to healthy and clinical groups, both acute and across the lifespan.

However, it is complicated to investigate the potential benefit of exercise treatment programs for AUD. On a patient level, the difficulties seem to consist of both structural, social and emotional barriers in addition to patient-related factors like somatic problems, psychiatric problems, use of alcohol, education level, and lack of social relations towards engaging in physical exercise (Sari, Muller, & Roessler, 2017). The limited number of controlled studies in the AUD field suffers from patient refusals to participate in the studies, and high drop-out rates

during the interventions. For instance, the study by Brown and colleagues assessed 1575 patients for eligibility in a controlled study of aerobic exercise for AUD patients. Of these, 810 patients did not suffer from dependence, and were excluded. Further 507 patients were excluded for reasons not accounted for 107 patients did not wish to participate, compared to only 93 who did. Of these, 44 patients did not show up or were ruled out, and only 49 ended up being randomized. During the study, 5 patients dropped out, and further 6 patients were lost to follow up (Brown et al., 2014). In another study by Bichler et al. (2017), 85 patients were recruited to participate in a randomized study of walking and yoga/gymnastics, but 54% of the patients approached were not interested to participate in the study, when they were expected to start (Bichler et al., 2017). Recurrently, a high level of non-participation is noted when performing studies using physical activity.

This high number of AUD patients, who are overlooked, not interested in participating, claim interest but do not show up or do not adhere to intervention in controlled trials including exercise is, in other

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words, not uncommon (Bichler et al., 2017; Brown et al., 2009; Brown et al., 2010; Roessler et al., 2017). Actually, it seems to be rather the rule than the exception, hence we may assume that it also have occurred in studies that do not describe refusal rates (Kendzor et al., 2008; Mamen, Pallesen, & Martinsen, 2011). A high number of patients seem disinterested or unable to participate in studies of physical exercise as an add-on to treatment for AUD. Therefore, we need to know if – and how – the participants differ from non-participants (e.g. those who are invited to participate, but for some reason refuse to participate or drop out before completion). The present brief report analyses potential differences between AUD patients, who were offered to participate in The Healthy Lifestyle Study (Sengul Sari et al., 2013), but did not, and the patients, who accepted inclusion in the study. The Healthy Lifestyle was a clinical randomized controlled study of the effect of adding physical exercise performed either individually or in groups to treatment as usual for AUD.

### 1.1. Aim of study

The aim of the study is to investigate differences between participants and non-participants in a randomized controlled trial concerning effect of adding physical exercise to treatment for AUD. The data for the analysis stem from the Healthy Lifestyle Study (Sari et al., 2013).

### 1.2. Hypothesis

We hypothesize that the following factors: somatic problems, psychiatric problems, regular high alcohol use, and lack of social relations will predict lack of willingness or ability to engage in a study of adding physical exercise to treatment for AUD.

## 2. Methods & material

### 2.1. Design of the healthy lifestyle study in brief

The Healthy Lifestyle Study (K. K. Roessler et al., 2017; Sengul Sari et al., 2013) was one of five RESCueH-studies (Nielsen et al., 2016) using different approaches of non-pharmacological interventions for AUD. The Healthy Lifestyle study was a randomized controlled trial, and participation was offered to all consecutive patients who sought treatment for AUD at the Alcohol Treatment Clinic in Odense, Denmark during the period of inclusion. The trial had three arms: (A) Standard treatment for AUD + physical exercise on an individual basis, (B) Standard treatment for AUD + physical exercise in groups, or (C) Standard treatment for AUD (Sengul Sari et al., 2013). The exercise programmes were conducted twice a week for a total of 24 weeks. The programme consisted of brisk walking or running, where the duration and intensity of the exercise increases each week as the patient's fitness level improved. Data was collected from the patient at baseline, and after six and 12 months (Sengul Sari et al., 2013), and comprised among others information about alcohol use, quality of life, and mental health. All patients received the standard outpatient treatment at the Alcohol Treatment Clinic in Odense, Denmark.

Enrolment of patients began in May 2013 and ended in April 2015.

### 2.2. Setting

The Healthy Lifestyle Study took place in the Alcohol Treatment Clinic in Odense, Denmark. The treatment is free of charge and open for self-referral. The main focus at the clinic is treatment of AUD. If the patients suffer from illegal substance use or from severe psychiatric disorders, the treatment takes place elsewhere.

The treatment offered is evidence-based and provided in accordance with the national clinical recommendations (Danish Health Authority, 2015, 2016). If suffering from withdrawal symptoms, patients are provided detoxification with benzodiazepines on an outpatient basis;

disulfiram, Acamprosate and/or naltrexone are also prescribed, when appropriate. When potential withdrawal symptoms are treated, patients are assessed by means of a baseline assessment interview before referral to psychosocial treatment (Nielsen & Nielsen, 2018b). The psychosocial treatment is carried out by teams of therapists in the clinic. Treatment begins with Motivational Interviewing, followed by cognitive behavioural therapy (CBT), family therapy, contract therapy or supportive consultations focusing on the AUD (Nielsen & Nielsen, 2015). All treatments are carried out during individual half- or one-hour sessions. A treatment course is scheduled to last three months and comprises eight psychosocial sessions, and afterwards an evaluation of the treatment course is conducted. The duration of treatment is decided together with the patient on an individual basis and can be extended as long as needed. Frequent supervision of the staff is undertaken.

During the period of inclusion in the study, all consecutive patients who sought treatment at the Clinic and who as a part of the usual clinical routine were assessed prior to treatment start, were invited to hear about and participate in the Healthy Lifestyle study (Sengul Sari et al., 2013). Thus, all patients, who were enrolled in the Healthy Lifestyle Study, had performed the standard baseline assessment interview prior to treatment start, as had the patients who declined enrolling in the Healthy Lifestyle Study. The patients who accepted enrollment were randomized to one of the three groups by a computer.

### 2.3. Participants

During the period of inclusion to the Healthy Lifestyle Study, the total number of patients being assessed before entering outpatient treatment for AUD, was 556. Of these a total of 345 accepted to meet the research assistant for information about the study. After having received detailed information, 175 (31.5%) patients accepted enrollment in the study. There were no significant differences regarding age and gender between participants and non-participants (See Table 1).

### 2.4. Data

Data in the present study stem from the baseline assessment interview at the treatment clinic and were collected prior to treatment start as part of the usual clinical routine. Data are stored in the Clinical Database in the treatment clinic where the Healthy Lifestyle study was conducted. The Clinical Database was developed with the purpose of monitoring the quality of treatment and conduct research to improve the treatment. Data derived for further analysis were anonymized and no personal identification information was extracted.

The baseline assessment at the Alcohol Treatment Clinic was performed by means of the European Addiction Severity Index (EuropASI) (Blacken et al., 2010; Kokkevi & Hartgers, 1995; McLellan et al., 1992). The EuropASI assesses sociodemographic, AUD-related variables (e.g. years with AUD, prior treatment) problems within nine areas of the patient's life. The areas include alcohol and drug use, medical and psychiatric status, family status and social status, economy and job satisfaction, and legal status. For each area, a composite score, ranging from 0 to 1, was calculated, with higher scores reflecting higher severity of problems. These composite scores are derived from items relating to the past 30 days (Blacken et al., 2010; McGahan, Griffith, Parente, & McLellan, 1986).

### 2.5. Data analysis

At first, a descriptive analysis of sample characteristics was made for the two groups (participants/non-participants) by means of Pearson's chi<sup>2</sup> test and Wilcoxon signed-rank test (Table 1). Subsequently, a multiple logistic regression was performed, with participation being the dependent variables, and independent variables being the variables hypothesized to predict participation, when the differences within the two groups was significant at a level of  $p < 0.05$ . The included

**Table 1**  
Baseline demographics and characteristics of the participants and non-participants ( $N = 556$ ).

	Participants ( $n = 172$ )	Non-participants ( $n = 384$ )	$p$ -Value
Gender, men	69.7%	65.6%	$p = 0.337$
Age (mean/SD)	49.5/11.4	51.3/11.7	$p = 0.636$
Civil status			
Living alone	63.4%	59.4%	$p = 0.373$
To have children (biological or adopted)	69.7%	76.0%	$p = 0.119$
Employment status for the last 3 years			
Not working (student, retired, ill and others not working)	48.5%	48.2%	$p = 0.950$
Physical problems			
Numbers of hospitalising (lifetime) (mean/SD) <sup>a</sup>	3.0/4.6	3.7/8.8	$p = 0.482$
Chronic physical problems (yes/no) <sup>b</sup>	56.7%	60.8%	$p = 0.368$
Treated by a doctor for the last 6 months (yes/no) <sup>b</sup>	43.0%	49.2%	$p = 0.181$
Use of prescription medicine (yes/no) <sup>c</sup>	34.9%	42.7%	$p = 0.082$
Psychological problems			
Numbers of hospitalising (lifetime) (mean/SD) <sup>d</sup>	1.1/7.9	0.7/2.2	$p = 0.602$
Numbers of outpatient treatment (mean/SD) <sup>e</sup>	1.2/1.5	1.2/2.0	$p = 0.479$
Experienced significant times with severe depression symptoms (yes/no) <sup>f</sup>	47.7%	44.9%	$p = 0.550$
Experienced significant times with severe anxiety symptoms (yes/no) <sup>f</sup>	40.6%	41.1%	$p = 0.905$
Alcohol			
Use of alcohol every day for the last 6 months	32.0%	75.3%	$p = 0.014^g$
Number of days for the last month with problems regarding alcohol intake (mean/SD) <sup>g</sup>	18.0/11.6	19.8/11.8	$p = 0.038^g$
Worried or troubled by alcohol problems for the last month (mean/SD) <sup>h,i</sup>	3.3/0.9	3.2/1.0	$p = 0.144$
Resources			
Number of close friends (mean/SD) <sup>j</sup>	3.4/3.3	3.5/3.9	$p = 0.047^e$
Living together with a person, with an AUD (yes/no) <sup>k</sup>	5.2%	6.5%	$p = 0.580$
Close relationship with your partner (yes/no) <sup>l</sup>	91.6%	91.0%	$p = 0.837$
Close relationship with your children (yes/no) <sup>m</sup>	92.5%	96.5%	$p = 0.087$
Composite score: (mean/SD)			
Alcohol	0.70/0.21	0.68/0.22	$p = 0.525$
Drugs	0.02/0.06	0.02/0.07	$p = 0.789$
Economy	0.63/0.47	0.61/0.46	$p = 0.749$
Job satisfaction	0.41/0.41	0.34/0.37	$p = 0.125$
Crime	0.02/0.07	0.02/0.07	$p = 0.876$
Social	0.03/0.14	0.02/0.11	$p = 0.362$
Psychological	0.23/0.23	0.20/0.22	$p = 0.506$
Family	0.10/0.23	0.09/0.21	$p = 0.488$
Somatic	0.30/0.37	0.37/0.37	$p = 0.298$
Beck's score			
Total score (mean/SD) <sup>n</sup>	3.9/4.0	3.9/4.1	$p = 0.751$

\* Significant level  $p < 0.05$ .

<sup>a</sup> Missing 15 participants – Two missing in participants and 13 in non-participants.

<sup>b</sup> Missing 15 participants – One missing in participants and 14 in non-participants.

<sup>c</sup> Missing 12 non-participants.

<sup>d</sup> Missing 37 participants – Nine missing in participants and 28 in non-participants.

<sup>e</sup> Missing 20 participants – Three in participants and 17 in non-participants.

<sup>f</sup> Missing 14 participants – Two in participants and 12 in non-participants.

<sup>g</sup> Missing twelve participants in non-participants.

<sup>h</sup> Scores from 0 to 4 and zero indicates no worry and troubles, and four many problems.

<sup>i</sup> Missing ten participants in non-participants.

<sup>j</sup> Missing 14 participants – No missing in participants and 13 missing in non-participants.

<sup>k</sup> Missing 12 in non-participants.

<sup>l</sup> Missing 69 participants – 18 missing in participants and 51 in non-participants.

<sup>m</sup> For 26% this question was irrelevant.

<sup>n</sup> Wilcoxon rank sum test.

variables were first analyzed unadjusted, and in a model, adjusting for all included variables.

In the final model, data from the baseline assessment, describing the patient's self-report on the last 6 months prior to treatment start, current somatic and psychiatric problems, number of close friends, and medication prescribed were included. Self-report of using prescribed medication for a somatic illness was considered proxy for somatic problems.

STATA data analysis and statistical software, version 15 for Windows was used. Results of the logistic regression are presented in odds ratios (ORs), 95% confidence intervals (CI) are reported and with level of significance  $p < 0.05$ .

### 3. Results

A description of participants ( $n = 172$ ) and non-participants ( $n = 384$ ) is provided in Table 1, including their level of problems in the nine areas of life (as described by means of the ASI composite score). No differences between participants and non-participants were seen, except in relation to somatic problems (both directly noted and indicated by prescription of medicine), alcohol use and social support (expressed by number of close friends). As can be seen from Tables 1, 75.3% of the non/participants had been drinking alcohol every day during the last 6 months compared to only 32.0% of the participants ( $p = 0.014$ ). Non-participants had more close friends than participants (mean 3.4 SD (3.3) for participants and mean 3.5 (SD 3.9) for non-participants ( $p = 0.047$ )).

**Table 2**  
Prediction of participation in healthy lifestyle study (N = 544).

	Unadjusted			Adjusted <sup>a</sup>				
	OR	95% CI for OR		p-Value	OR	95% CI for OR		p-Value
		Lower	Upper			Lower	Upper	
Use of prescription medicine	0.7	0.5	1.0	<i>p</i> = 0.083	0.7	0.4	1.1	<i>p</i> = 0.143
Use of alcohol every day for the last 6 months	0.6	0.4	0.9	<i>p</i> = 0.015 <sup>*</sup>	0.6	0.4	0.9	<i>p</i> = 0.023 <sup>*</sup>
Number of days for the last month with problems regarding alcohol intake	1.0	1.0	1.0	<i>p</i> = 0.417	1.0	1.0	1.0	<i>p</i> = 0.948
Number of close friends	1.0	1.0	1.1	<i>p</i> = 0.739	1.0	1.0	1.1	<i>p</i> = 0.702
Close relationship with your children	2.2	0.9	5.6	<i>p</i> = 0.095	2.1	0.9	5.6	<i>p</i> = 0.102

<sup>a</sup> Including current age and gender.

<sup>\*</sup> Significant level *p* < 0.05.

Table 2 shows unadjusted and adjusted ORs for participation, including variables from Table 1 with a *p* < 0.1 except close relationship with children, as 26% have answered irrelevantly. As can be seen, only daily alcohol consumption during the last six months significantly decreased OR for participation in the study both unadjusted OR 0.6 (CI 0.4–0.9), and adjusted for having medicine prescribed for somatic illness, problems with alcohol, number of close friends, gender, and age OR 0.7 (CI 0.4–0.9).

#### 4. Discussion

Randomized controlled trials of healthcare interventions depend on the participation of volunteer patients. Changing lifestyle, especially when vulnerable, needs high intrinsic motivation. Especially in Europe, where there is no tradition for giving participants in studies a financial reward (Weinstock, Capizzi, Weber, Pescatello, & Petry, 2014). Many trials recruit fewer patients than anticipated (Brown et al., 2009; Brown et al., 2014; Nielsen & Nielsen, 2018a; Tarp, Bojesen, Mejldal, & Nielsen, 2017). Thus, to be able to consider to which extent findings may be generalized, it is crucial to know how the participating patients in the study differ from non-participants. In the present study of participation and non-participation, it was expected that non-participants suffered more from somatic or mental illness, performed more excessive use of alcohol, and had fewer social relations. However, when comparing participating patients and non-participants in a controlled model, only daily use of alcohol during the six months prior to treatment start, predicted less likelihood to participate in the study. A tentative guess why we have these differences might be that patients who are able to postpone their alcohol intake for some days, are also able to perform physical activity. Studies on physical activities have shown that motivation is enhanced by structured activities (K.K. Roessler & Ibsen, 2009). If a patient can differ in the everyday life structure between days with alcohol intake and non-intake, this might strengthen the ability to delay satisfaction, a necessary ability when performing physical exercise.

In the present study, no differences in alcohol composite score between participants and non-participants were seen, indicating that alcohol problems were just as severe among participants as among non-participants. Only the drinking pattern of alcohol differed; drinking on a daily basis was more common among non-participants.

We were surprised that no differences were seen between the groups in relation to somatic health problems. Nor did we find differences in relation to social status. This indicates that non-participation in trials of using physical activity, is affected by something else rather than health problems or social problems.

In the present study, non-participation may be affected by several causes. It may be that the participants were so concerned by their alcohol problems at the time of treatment start that they were unable to participate in a research study. It may also be that they simply did not wish to participate in a study of physical exercise. Participating in a

long-term physical exercise program (6 months) may seem overwhelming to many patients.

Psychological research on alcohol abuse more generally suggest taking the individual's need for individuation and independence into account (Roessler, Mau, & Ekström, 2018). Instead of focusing on possible barriers, we should perhaps seek to understand people's individual needs, and open up the possibilities that physical activity can offer. Physical activity demands both high motivation and organizational skills (e.g. transportation to the training center), which may explain the higher participation rates seen in the other four RESCueH studies (Nielsen et al., 2016), which do not involve physical activity and have fewer or none logistic challenges and are, therefore, less demanding for the patients (Hell, Miller, Nielsen, & Nielsen, 2018).

The conclusion of the present study is that non-participants do not differ from participants except in relation to their drinking pattern prior recruitment. The results of the Healthy Lifestyle Study may tentatively be generalized to the whole population of treatment seeking patients, because we did not find any big differences between the two groups of participants and non-participants. However, patients may have a series of reasons for not participating in research studies using physical exercise that are not possible to investigate in the current design. Qualitative studies on non-participation suggest that one of the reasons for not participating is that if patients do not see or recognize any personally benefit of participating, they do not participate. This means that all the information given to upcoming participants should be very carefully presented, and future studies, perhaps, should be more careful and spend more time on this part of the studies, especially when they involve physical activities and have some logistics challenges for participants regarding to job, children care e.g. (Bleidorn, Bucak, Gagyor, Hummers-Pradier, & Dierks, 2015; McCann, Campbell, & Entwistle, 2010; Sari et al., 2017).

#### Conflict of interest

None of the authors have any conflicts of interest, and funding did not have any role in the study or this article.

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