THE EFFECTIVENESS OF AN ALCOHOL AVOIDANCE TRAINING IN REDUCING ALCOHOL CONSUMPTION AND THE RELATION BETWEEN ADHERENCE AND TREATMENT OUTCOME

Master Thesis
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Abstract

Introduction. In recent years, an increase in research concerning cognitive behavioural modification (CBM) in relation to alcohol use disorders could be observed. This can be explained by the fact that CBM represents a potential cost-effective addition to regular therapy (CBT) by addressing the unconscious and automatic approach tendencies related to alcohol. Therefore, this study discusses the effect of cognitive bias modification (CBM) in form of an approach avoidance training (AAT), as adjustment to therapy as usual (TAU). Moreover, this study focusses on the level of adherence, as the intervention is conducted in an outpatient treatment setting. *Methods*. This study involved a double-blind randomized placebo-controlled trial in an outpatient context. Patients received therapy as usual (CBT), as well as CBM alcohol avoidance training or a placebo training. In total, the study involved 139 participants. A two-way mixed ANOVA with repeated measurements was conducted to compare pre- and post-assessments, whereas the level of alcohol consumption was taken as outcome measure. *Results*. The results of the current study did not show a significant effect of AAT. However, participants in both groups showed a decreased alcohol consumption. There was a significant difference between adherent and non-adherent participants, whereof the latter showed a higher reduction in alcohol consumption compared to adherent participants. However, as the sample size was quite unequal, results must be regarded with caution. *Discussion*. The current results show that CBM does not have additional value to regular therapy, since both groups consumed less alcohol after going through AAT. Controversially, non-adherent participants manifest better treatment outcomes than adherent participants. However, further research needs to be investigated in order to draw an evidence-based conclusion.

Key words: cognitive bias modification, CBM, Alcohol Avoidance Training, Approach-Avoidance task, AAT, treatment as usual, TAU cognitive behavioural treatment, CBT, adherence

Introduction

Alcoholism can be defined as "a compulsion to seek and take [a] drug [alcohol], loss of control in limiting intake, and the emergence of a negative emotional state when access to the drug is prevented" (Koob, 2011, p.1). According to the WHO (2018), alcohol consumption causes three million deaths each year, representing 5.3% of all deaths worldwide. Within the age range of 20-39, even 13.5% of all deaths can be attributed to alcohol misuse. Alcohol use disorder represents the "second largest risk factor for disease burden in Europe" and leads to an increase of morbidity and mortality, including for instance cancer, road traffic injuries and liver cirrhosis (Alcoholism statistics, n.d). Beyond the health issues, it is associated with social problems, such as child neglect, violence, and absenteeism at the workplace. Based on this, it can be concluded that alcoholism represents an important concern for public health care and leads to enormous societal costs (Rehm, Mathers, Popova, Thavorncharoensap, Teerawattananon, & Patra, 2009; Alcoholism statistics, n.d.).

Although people are often aware of these negative effects of alcohol, they usually show difficulties to stop their consumption. This process appears to be associated with cognitive biases, involving impairments in selective information processing, approach tendencies, as well as interpretational biases (Field, Mogg, & Bradley, 2005; Woud, Fitzgerald, Wiers, Rinck, & Becker, 2012). According to Strack, Werth, and Deutsch (2006), alcoholism can be explained by a dual-system model, which assumes all human behaviour to be an interaction of reflective and impulsive systems. Adapted from this assumption, they suggest a lack of balance regarding automatic processes and conscious behaviour, which includes the already mentioned awareness of ones´ drinking behaviour. Hence, patients might have the desire to stop consuming alcohol, yet they fail to control this desire. In addition, the dual-system model includes unconscious processes, relating – amongst others – to the process of automatically approaching alcohol-related stimuli. This automatic process can be described as "the automatic tendency to faster approach than avoid alcohol compared with neutral cues, which has been associated with craving and relapse" (Wiers et al., 2014, p.688).

Regular treatment of uncontrolled alcohol consumption usually consists of cognitive behavioural therapy, which is an "evidence-based treatment for a variety of disorders including alcohol use disorders" (Bratti-van der Werf et. al., p.2). Several studies have investigated the positive effects of cognitive behavioural therapy upon alcoholism. Therefore, research has shown that CBT leads to a significant decrease in drinking patterns compared to control groups (Hides, Carroll, Catania, Cotton, Baker, Scaffidi, & Lubman, 2010). Another result showed an

enhanced well-being in patients after CBT (Feeney et. al., 2004). However, CBT primarily affects voluntary and reflective responses related to alcohol, leaving out the automatic and unconscious processes (Bratti-van der Werf et. al, 2018).

To measure the unconscious and automatic responses towards alcohol, an implicit association test (IAT) can be used. The IAT uses two response combinations for alcohol. If the participant reacts quicker to positive cues than to negative cues related to alcohol, one can conclude that the patient shows a stronger implicit attentional bias towards alcohol related cues (Houben & Wiers, 2008). This type of cognitive bias is also called approach avoidance bias (Wiers, Eberl, Rinck, Becker, & Lindenmeyer, 2011).

In order to retrain these biases, cognitive bias modification programmes have been developed, which are likely to represent a cost-effective addition to regular treatment (Boffo, Willemen, Pronk, Wiers, & Dom; 2017). One of these programmes is the alcohol avoidance training (AAT). Within the AAT, participants are instructed to approach non-alcoholic drinks and to avoid alcoholic drinks by reacting to two different response keys (Wiers, Eberl, Rinck, Becker, & Lindenmeyer, 2011). Originally, they are supposed to react to the pictures by using a joystick, however, more recent versions rely on keyboard versions or apps on the smartphone (Wiers, Eberl, Rinck, Becker, & Lindenmeyer, 2011; Machulska et. al, 2019).

The AAT has shown to be effective in reducing drinking patterns and changing approach bias into avoidance bias (Wiers, Houben, Fadardi, Van Beek, Rhemtulla, & Cox, 2015; Wiers, Eberl, Rinck, Becker, & Lindenmeyer, 2011). In addition, Wiers, Rinck, Kordts, Houben and Strack (2010) conclude that retraining automatic processes may help to regain control over approach tendencies, which supports the monitoring of drinking behaviour. Going into detail, they assigned forty-two hazardous drinkers to either an approach or to an avoid condition of the AAT. By using the joystick, they had to react to a picture-format (landscape or portrait), depicting alcoholic and non-alcoholic drinks. As they were asked to favour the non-alcoholic drinks, the task indirectly included a training to avoid alcohol. The results showed that this had an impact on the action tendencies of the participant, showing a lower alcohol consumption for the participants in the avoidance condition.

Additionally, a study by Wiers, Eberl, Rinck, Becker, and Lindenmeyer (2011) exposed that 59% of the patients in the control condition and 46% patients in the experimental condition relapsed, indicating a decreased risk to relapse for patients in the experimental condition of the AAT (Wiers, Eberl, Rinck, Becker, & Lindenmeyer, 2011).

In line with this, Eberl, Wiers, Pawelczack, Rinck, Becker, and Lindenmeyer (2013) conducted a study in which 509 participants were instructed to complete 12 sessions of AAT in

addition to therapy as usual (CBT). Results revealed that patients in the experimental condition reported significantly lower alcohol consumption than patients in the control group, as well as a lower rate of relapse at one-year follow-up.

Based on these studies, it can be assumed that treatment outcome is likely to be improved by means of providing AAT as addition to TAU. Moreover, CBM may enable the client to decrease cognitive biases related to alcohol-triggers and to lower the chance of relapse. However, as most of the previous work, all studies were conducted in an inpatient setting.

Since TAU is often delivered in an outpatient treatment setting, it is crucial to look at the added value of CBM in that setting, and the level of adherence among participants. This can be explained by "data [indicating] that considerable noncompliance occurs wherever some form of self-administration or discretionary action is involved" (Becker, 1985, p.539). Hence, Reetz et al. (2019) assume that adherence rates are lower "when the intervention is delivered at home when compared to staff-facilitated lab settings" (p.2). This assumption is supported by Bratti-van der Werf et al. (2018), who suggest that delivering CBM sessions in an outpatient setting might lead to a low rate of adherence compared to inpatient setting, however, delivering them online at home might, in turn, raise the level of adherence. Adherence, also called compliance, describes a user´s engagement in a program and relates to the "degree or extend of conformity to the recommendations about day-to-day treatment by the provider with respect to timing, dosage, and frequency" (Cramer, Roy, Burrell, Fairchild, Fuldeore, Ollendorf & Wong; 2008).

Moreover, it is known that adherence leads to positive treatment effects and its outcomes and that delivering CBM sessions at home might even generate higher effects. This is based on the fact that an outpatient setting contains a real-life and relevant context, including for instance alcohol-related cues, which enables a more holistic examination. Therefore, it is crucial to enhance adherence (Kuckertz et. al., 2014; Bratti-van der Werf et al.; 2018).

In line with this, a meta-analysis by Brent, Moore, Roesch, Cardenas, and Patterson (2010) found out that greater homework compliance is associated with a better treatment outcome, which is robust amongst several disorders. Additionally, Granger, Fehnel, Hogue, Bennett, and Edin (2006) stated that "greater adherence has been shown to facilitate symptom relief, improvements in quality of life, and reductions in healthcare expenses" (p.219).

In general, most of the studies conducting an approach avoidance task, include a range of 1-12 sessions (Kakoschke, Kemps, & Tiggemann, 2017). According to literature, "a short intervention can change alcoholics' automatic approach bias for alcohol and may improve treatment outcome" (Wier et al., 2011, p.490). Considering the number of units that have to be completed in order to report an effect, Wiers et al. (2011) executed a study with 214 alcohol

dependent participants who were instructed to complete four CBM sessions on a total of four days after regular inpatient treatment. As a result of the AAT, patients showed a change from alcohol-approach-bias into alcohol-avoidance-bias. In addition, one can observe a significant reduction in alcohol consumption within the experimental condition, whereas this does not appear within the control group in a one-year follow-up measurement. Another study conducted by Sharbanee et al. (2014), included 74 social drinkers, who were instructed to complete only one CBM session. Results indicate that participants within the training group consumed less beer after taking part in the intervention. Based on these results, it can be seen that only a small number of sessions can lead to an effective outcome. As this study involves individuals with problematic drinking behaviour, it relies on an amount of 4 sessions. Therefore, at least 4 sessions of the AAT need to be completed in order to be considered as adherent and to show a reduction in the consumed level of alcohol afterwards.

Aims and hypothesis

The current study focusses on the effect of CBM as an adjustment to TAU in an outpatient treatment setting. Participants undergo an AAT training which focusses on retraining automatic action tendencies. As part of this study, the experimental group is instructed to complete sessions of AAT, whereas the control group receives a placebo intervention. After finishing the intervention as well as two follow-up measurements after three and six months the levels of alcohol consumption are measured. Depending on their completion of the questionnaire, participants are categorized into adherent and non-adherent participants, and differences between groups are observed. Based on that, this study investigates whether there are distinctions between adherent and non-adherent participants regarding the effectiveness of the AAT in terms of a reduced alcohol consumption after treatment.

In order to gather information about the treatment outcome, relating to CBM and adherence, two research questions are posed.

1. Does CBM Alcohol Avoidance training as an adjustment to therapy as usual decrease alcohol consumption more compared to the CBM control group?

2. Do adherent participants show better treatment outcomes compared to non-adherent participants?

Based on the reviewed literature, it is hypothesized that participants in the experimental group show a higher decrease in alcohol consumption after treatment compared to participants in the placebo group. Furthermore, it is expected that patients who possess a higher level of adherence, consume less alcohol after going through the AAT compared to participants who show a low level of adherence.

Methods

Trial design

This study involved a double-blind randomized placebo-controlled trial in an outpatient context. Patients received care as usual, which refers to face-to-face or asynchronous web-based cognitive behavioural therapy for their alcohol problem. The experimental group received CBM alcohol avoidance training in addition to TAU, whereas the control condition took part in a placebo training. Data was gathered over a period of 5 years, starting in May 2015, and ending in February 2019.

The study has been approved by the Ethics Committee of Amsterdam Academic Medical Centre in January 2015 (reference number 2014_154#C20141463). Moreover, it has been registered at the Netherlands Trial Register (NTR5087).

Participants and procedure

The original data compromised a total of 139 participants. As these included extreme outliers and participants who did not complete the first assessment, only 133 of them were eligible. Further, the sample was aged between 23 and 69, of which 74 participants were male, and 53 females. All attendees followed therapy as usual at the Tactus addiction treatment institute in the Netherlands and suffered from a primary alcohol problem. Furthermore, they had access to the internet since this study involved doing CBM online-sessions. Participants were excluded from this study, if they (1) had a serious psychological illness, including a risk to decompensate based on alcohol reduction and (2) if alcohol reduction could lead to severe physical illness.

Patients were informed by their therapist about the possibility to take part in this study. If the patient was willing to participate, he or she got an informed consent from the therapist and was randomly allocated to the CBM Alcohol avoidance group or the CBM placebo training. Randomization to one of the conditions was based on the method of minimization and was computer-generated to ensure equal distribution. After signing the informed consent, login credentials for the online platform were provided to start the training. If the participant had logged in, instruction about the training was provided. Attendees were invited to complete eight sessions, each lasting about 15 minutes. This CBM training started at the same time as the behavioural change part of their therapy. However, patients were free to choose at what time and place they completed the sessions. Before beginning them, the participant was asked about weekly alcohol consumption and craving for alcohol. Moreover, they were required to fill in an online pre-assessment before completing the first session and an online post-assessment after

the last session. Based on the latter, the patient´s awareness of the experimental condition was tested by using a manipulation check. In case of completing all ten sessions (8 training sessions, and pre- and post-questionnaire), a voucher of 20 euro for Bol.com was handed out. Also, this study compromises two follow-up measurements. The first one took place three months after the last post-assessment, whereas the second one was conducted after six months. In order to encourage adherence, the participants regularly received automatically generated messages from the training program whenever a new training session was available, but also as a reminder in case the participant did not start the training session yet. Moreover, they got additional reminders and oral motivation from the therapist, for example when they did not finish a session (Bratti-van der Werf et al.; 2018).

Interventions

Treatment as usual

Treatment as usual represented an outpatient therapy and is based on principles of CBT (Hester & Miller; 1989) and motivational interviewing (Hettema, Steele, & Miller; 2005). Hence, each participant got individualized care, which comprised web-based or face-to-face treatment, depending on the preference of the client. Therefore, therapy including identical components for each patient was provided. Moreover, face-to-face and web-based training were the same, except for the fact that the former represents synchronous contact between patient and therapist, whereas the latter represents an asynchronous communication (Postel, De Haan & De Jong; 2010). Since randomization enabled a balanced allocation between the experimental and the placebo group, this study does not differentiate between the two modes of delivery.

Therapists in this study either had a bachelor´s degree in social work or a master´s degree in psychology. Moreover, they completed a two-day training regarding the treatment protocol of the web-based therapy to ensure familiarity with the web-based system (Bratti-van der Werf et al.; 2018).

CBM training

The CBM Alcohol Avoidance training was based on the approach-avoidance task (AAT) (Sharbanee, Stritzke, Wiers, Rinck, MacLeod; 2014; Wiers, Rinck, Dictus, & Van den Wildenberg; 2009). This was provided as online training, in which pictures of alcohol or soft drinks were presented. The participant had to respond to the image by clicking "u" in order to avoid an image, or "n" to approach an image. By approaching a picture, its size increased,

whereas it decreased by avoiding it. This effect generated an indirect sensation of approaching or avoiding a drink (Bratti-van der Werf et al.; 2018). The CBM training represents an irrelevant-feature version, which means that the pictures were either tilted 3 degrees to the left or to the right. The participant was not instructed to react on the picture itself, but rather on its format (Wiers, Eberl, Rinck, Becker, & Lindenmeyer; 2011). As this represents a more indirect version of the training, it enabled a blind condition allocation to intervention or training (Bratti-van der Werf et al.; 2018; Wiers, Gladwin & Rinck; 2013).

Each of the eight sessions started with a block of twelve trials with grey squared pictures, followed by 160 trials divided into four blocks. These blocks enabled a short break to make the task less monotonous. The program consisted of two sets (A and B) of 40 stimuli, including 20 alcoholic drinks and 20 soft drinks. Program A and B were randomly allocated. Within the CBM Alcohol Avoidance training condition, the four blocks were repeated four times. Hence, alcoholic drinks were tilted to the left, which represented an avoid-format, whereas soft drinks were tilted to the right, which showed an approach-format. Therefore, patients in the experimental group were indirectly trained to avoid alcohol and to approach soft drinks. Patients in the placebo condition received 4 repetitions of all 40 stimuli. They were provided in two formats, referring to a tilt to the left or the right, which were repeated two times. Within both, alcoholic and soft drinks were presented equally often. Based on that, patients in the placebo condition were not indirectly trained to approach or avoid a certain stimulus. Therefore, the placebo and experimental group differed through showing a different amount of alcoholic and non-alcoholic pictures that have to be approached and avoided. The pictures on the screen could be seen for a maximum of 3000 ms. If the participant did not respond, the picture restarted after repeating the instructions. In order to acquire the patient´s attention focussed, each round started with a fixation cross (Bratti-van der Werf et al.; 2018).

Measures

Demographics, such as gender and age were collected during regular intake procedure and accompanying baseline assessment of therapy. In the following section, the measurement instruments are presented. Since not all included measurement instruments of the RCT are relevant for the current research, this paper only describes those that were used for this sub-study.

Alcohol consumption

In order to measure weekly alcohol consumption, the Alcohol Timeline Follow Back (TLFB) was used (Sobell, & Sobell, 1992). This questionnaire is designed to report the absorbed number of drinks for each day of the last week. However, as the time interval between the sessions was sometimes shorter, the TLFB was adjusted to the number of days between two sessions. For the outcome measure, including baseline measurements and follow ups, the full version was used. They were required to fill in this scale before each session, which refers to baseline TAU and post-test TAU, pre- and post-assessment, as well as training and follow-up measurements (Table 1).

Alcohol dependence

The Diagnostic and Statistical Manual of Mental Disorders IV criteria was used to assess the type and severity of alcohol dependence and refers to the Substance Abuse Module (SAM) of the Composite International Diagnostic Interview (CIDI) (Compton, Cottler, Dorsey, Spitznagel, & Magera, 1996). This scale was used within baseline TAU.

Table 1. Measurement instruments: purpose, measures, and time points

Purpose and measure	Baseline TAU	Pre-assessment	Training	Post-assessment	Post-test TAU	Follow-up
CBT; AAT		x	x	x		
TLFB	x	x	x	x	x	x
SAM; CIDI	x					

CBT: cognitive behaviour therapy; AAT: Approach-avoidance training; TLFB: Alcohol Timeline Follow Back; SAM: Substance Abuse Module; CIDI: Composite International Diagnostic Interview

Adherence

Adherence was determined by the number of training sessions that the participants completed. The total number comprised eight training sessions. In this case, participants were defined as adherent if they completed at least four of the eight training session (4-8). As one can conclude from that, they were classified as non-adherent if they completed less than four sessions (0-3).

Data analysis

To analyse the data, SPSS version 24 was used (IBM Corporation, 2016). As the sample showed a lot of missing values, the expectation maximation technique was used. Hence, a completers-only as well as an intention-to-treat analysis was conducted.

Moreover, demographics were assessed, including means and standard deviations for the variable age and percentages for gender, nationality, condition, alcohol dependence and weekly alcohol consumption. To represent a reliable picture of the sample, participants who did not meet major entry criteria – such as extreme outliers and participants that did not complete baseline measurement (T0) – were excluded beforehand. Based on that, six participants were excluded so that this study shows the demographics of 133 participants. However, only 36 attendees were included in the completers-only analysis, since they filled out each measurement. Lastly, an identifying variable for adherence was added and participants who completed four to eight sessions were classified as adherent, whereas participants who did zero - three sessions were classified as non-adherent.

To test the differences in baseline characteristics between adherent and non-adherent participants, independent sample t-tests and chi-square tests were conducted. Moreover, a two-way mixed ANOVA with repeated measurements on alcohol consumption was conducted, including all four measurement points (alc_use_T0, T1, T2, T3). Independent variables were condition (AAT vs. placebo) and adherence.

Results

Participants

The total data set compromised 139 participants. However, three participants did not complete the baseline measurement and another three participants were identified as extreme outliers. Thus, six participants were excluded, leaving 133 in the final data set. Since this study conducts a completer-only analysis, only 36 participants were eligible for the main analysis. As can be seen in Figure 1, the sample shows several missing values, translating into a decrease in responses. Thus, the baseline measurement included 68 participants in the training condition and 65 attendees in the placebo condition, whereas the last follow-up measurement compromised 27 in the training and 26 participants in the placebo condition. Moreover, it can be seen that only one participant in each condition completed less than four training sessions, meaning that they are considered as non-adherent. Further, 14 participants in the training condition and 20 in the placebo condition completed more than 4 training sessions, which is why they are classified as adherent. Overall, 15 participants from the training condition and 21 from the placebo condition were included in the final analysis, as they completed all four assessments. Figure 2 shows the frequencies of completed AAT sessions.
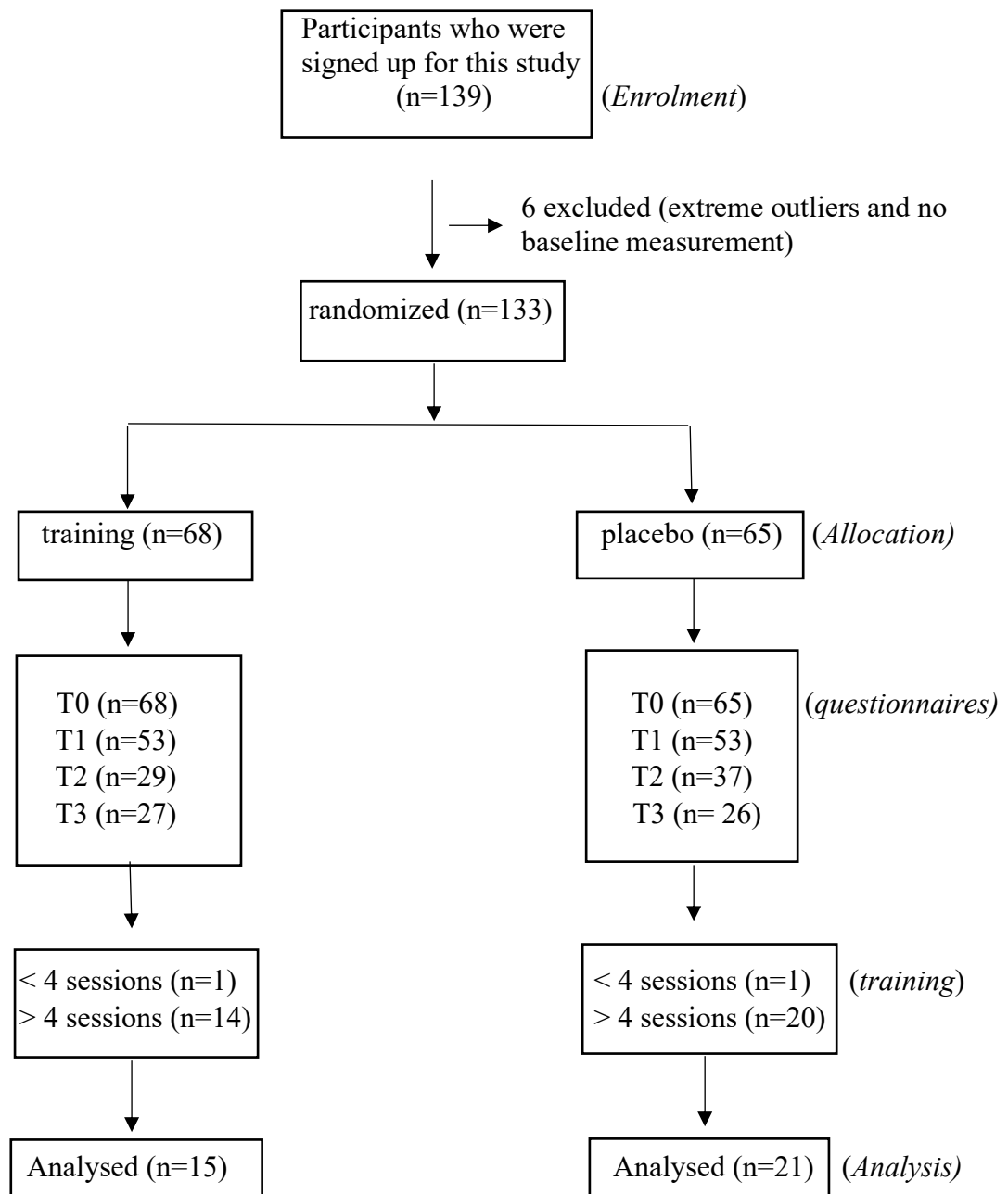
Figure 1. Flowchart showing number of participants for completers only-analysis and missing values at all assessment points (alc_use_T0, T1, T2, T3), as well as number of completed training sessions
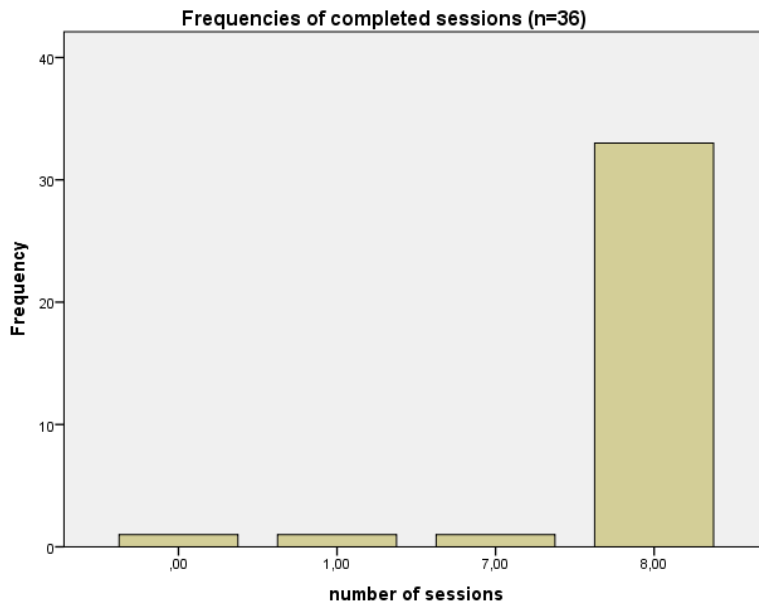
Figure 2. Histogram showing the frequencies of completed AAT sessions for the completers-only analysis

Baseline differences in demographics

Table 2 indicates that the majority of the sample were Dutch participants (80.6%). 15 attendees received the training condition, and 21 were assigned to the placebo training. The study incorporated slightly more males (n=18) than females (n=17) and the sample was aged between 23 and 68, whereas the mean age was 50. Further, 44.4% were alcohol dependent at baseline measurement, whereas only 13.9% were not considered dependent. 41.7% did not give information related to their level of dependence. Lastly, it can be seen that the average amount of weekly alcohol consumption included 29.7 drinking units at baseline measurement.

Demographics divided by adherence

Regarding the level of adherence, the sample shows an unequal distribution. Hence, 34 participants completed more than four sessions and were considered as adherent, whereas only two participants were considered as non-adherent. Thus, this study investigates the differences in characteristics between these groups. As illustrated in Table 2, adherent participants were slightly older (*M*=50.2), compared to non-adherent participants (*M*=38.5). However, this difference is not statistically significant (*p*=.207). The sample included only one non-adherent

15

man, and one woman, as well as 17 adherent men and 16 adherent women. Moreover, 27 of the Dutch participants were adherent, whereas 2 were non-adherent. Participants who are categorised as "other" regarding their nationality were entirely adherent and no one was non-adherent. Lastly, non-adherent participants showed an average of 44 drinking units at baseline, whereas the adherent participants drank only 29 units. However, this difference is not significant (p=.403)

Table 2. Differences in demographics of adherent versus non-adherent participants (n=36)

		Adherent (n=34)	Non-adherent (n=2)	Total (n=36)	Missing values	p-value
Age (mean, SD)		50.2 (12.0)	38.5 (21.9)	49.5 (12.5)	1	.207
Gender, n (%)	Female	16 (44.4%)	1 (2.8%)	17 (47.2%)	1 (2.8%)	.967
	Male	17 (47.2%)	1 (2.8%)	18 (50%)		
Nationality, n (%)	Dutch	27 (75%)	2 (5.6%)	29(80.6%)		.345
	Other	7 (19.4%)	0 (0%)	7 (19.4%)		
Condition, n (%)	Training	14 (38.9%)	1 (2.8%)	15 (41.7%)		.807
	Placebo	20 (55.6%)	1 (2.8%)	21 (58.3%)		
CIDI, n (%)	Dependent	15 (41.7%)	1 (2.8%)	16 (44.4%)	15(41.7%)	.455
	Non-dependent	5 (13.9%)	0 (0%)	5 (13.9%)		
Weekly alcohol consumption (TLFB & MATE)		28.8 (24.9)	44.4 (36.3)	29.7 (25.2)		.403

Note. Differences between groups were tested with an independent samples t-test and with a chi-square test. The mean difference is significant at the .05 level

Condition

A two-way mixed ANOVA with repeated measurements was conducted, whereof Mauchly´s test for sphericity showed that the assumption of sphericity has not been violated ($p > 0.05$).

The results determined that the mean level of alcohol differed in a statistically significant way between measurement points, ($F(3,102) = 9.959$; $p < .001$) with an effect size of .227. Table 3 conducts that the average units of alcohol consumption for the total sample decreased, showing a mean of 30 units at baseline measurement, and a mean of 13 units in the last measurement, which presents a reduction of 17 units. Hence, the consumed level of alcohol significantly changed for both groups after the intervention.

Results showed no significant differences in outcome regarding the condition, ($F(1,34) = 1,496$; $p = .230$), which indicates that the placebo group did not statistically significantly differ from the training group. However, the experimental condition indicated slightly better results compared to the placebo group. Going into detail, patients in the training condition drank on average 36 units at baseline and 16 at post-assessment, showing a decrease of 20 units. Patients in the placebo group showed a mean of 25 units at baseline and 11 at post-assessment, showing a difference of 14 units. In Figure 3, the means of alcohol consumption at all time points can be seen for both groups.

Moreover, a significant interaction effect between alcohol level and condition could not be found, ($F(3,102) = .471$, $p = .703$), indicating no added value of the CBM training.

Additionally, equality of error variance across groups cannot be assumed within the last post-assessment, which is based on the Leven´s test (T3; $p=.004$). However, as the sample is quite balanced (training=15; placebo=21), the ANOVA can still be considered as robust, but the results must be regarded with caution.
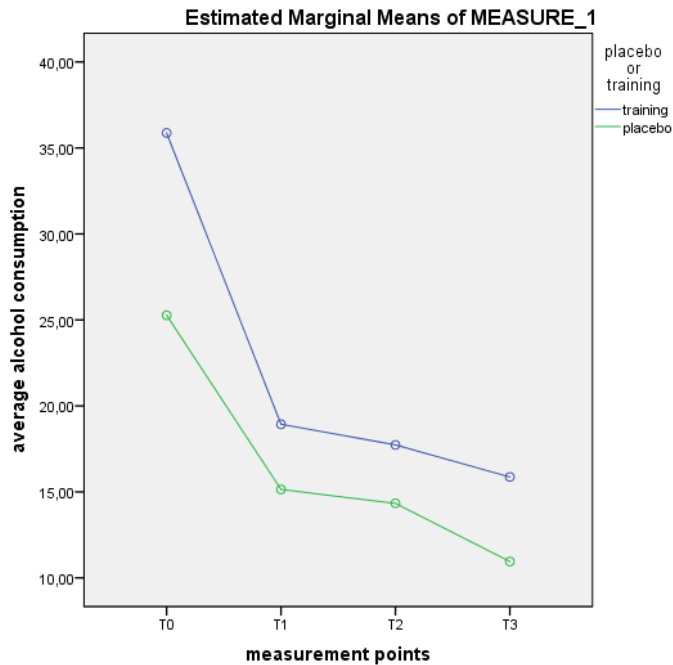
Figure 3. Means of Alcohol consumption at all timepoints (alc_T0, T1, T2, T3) in both conditions of training and placebo (N=36, completers only analysis).

Intention-to-treat analysis

Regarding the intention-to-treat analysis (n=133), Mauchly´s test for sphericity has been violated (p <.05), which explains the usage of the correction of Greenhouses Geiser. 68 participants were included in the training condition, and 65 in the placebo condition. The level of alcohol showed a significant difference between measurements points, ($F_{(1.761, 230.756)}$ = 40.653, p = .000). Hence, the total sample showed an average consumption of 31 units at baseline measurement and 15 in the last follow-up measurement, indicating a decrease of 16 units.

However, results show no significant differences in outcome related to the condition, ($F_{(1, 131)}$ = .358, p = .551) suggesting that the conditions did not statistically significantly differ.

Table 3. Mixed-design ANOVA with repeated measurements (n=36; iv=condition; dv=alcohol)

Predictor		Mean				$dfNum$	$dfDem$	Mean Square	F	p	η^2
		T0	T1	T2	T3						
Alcohol	Training (n=15)	35.87	18.93	17.73	15.87	3	102	2071.222	9.959	.000	.227
	Placebo (n=21)	25.27	15.14	14.33	10.95						
	Total (n=36)	29.69	16.72	15.75	13.00						
condition						1	34	281.960	1.496	.230	.042
Alcohol*condition						3	102	97.937	.471	.703	.014

Note. dfNum indicates the degrees of freedom numerator. dfDem indicates the degrees of freedom denominator. η^2 indicates generalized eta-squared effect size.

Adherence

In table 4, results for the second research question can be found. As the original data set compromised 15 participants in the training condition, whereof only one was classified as non-adherent and 14 as adherent, the results would not represent a reliable outcome, since the distribution is unequal. Hence, this section only contains the results of the ITT-analysis.

Intention-to-treat analysis

Mauchly´s Test of Sphericity indicated that the assumption of sphericity had been violated (p = .000). Therefore, the correction of Greenhous-Geiser will be used to estimate the outcome. The intention-to-treat analysis considered 35 participants as non-adherent and 98 as adherent. The level of alcohol showed a significant difference between measurement points, (F (1.797, 235.412) = 44,378, p = .000).

Further, results revealed a significant distinction in outcome regarding adherence, (F (1, 131) =5,224, p = .024), which indicates that the adherent group significantly differed from the non-adherent group. Looking at that in more detail, adherent participants had a mean weekly alcohol consumption of 27 units at baseline measurement, and 15 in the last assessment, which indicates a reduction of twelve units. Non-adherent participants showed a mean weekly consumption of 42 units at baseline measurement and 18 within the last assessment. Thus, they displayed a reduction of 24 drinking units. Based on that, non-adherent participants showed a higher reduction of alcohol consumption compared to adherent participants, also seen in Figure 4.

Leven´s test of equality of error variances indicates that variances across groups are not equal at T0 (p=.001), T2 (p=.019) and T3 (p=.019). Results must be regarded with caution.
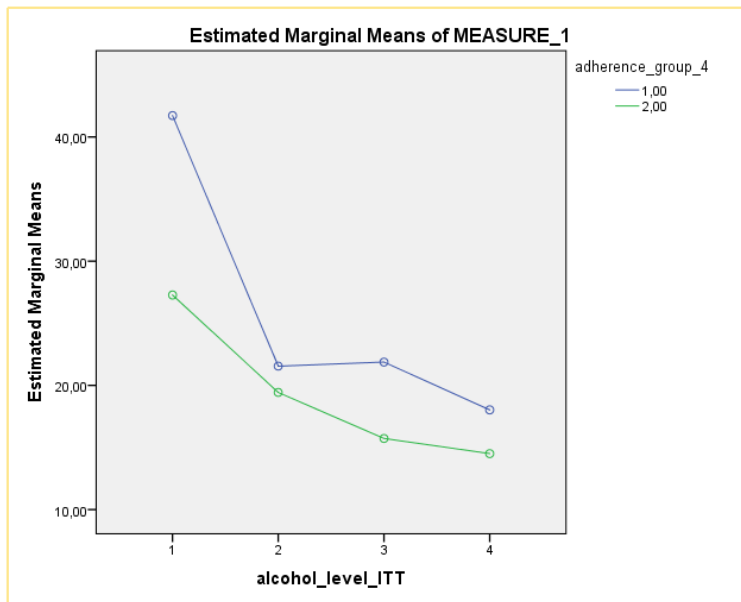
Figure 4. Means of Alcohol consumption at all timepoints (alc_T0, T1, T2, T3) divided by adherence (N=133; 1= non-adherent, 2= adherent).

Table 4. Mixed-design ANOVA with repeated measurements (n=133; iv=adherence, dv=alcohol)

Predictor			Mean				*dfNum*	*dfDem*	Mean Square	F	*p*	η^2
			T0	T1	T2	T3						
alcohol	Training	Non-adherent (n=35)	41.72	21.55	21.88	18.03	1.797	235.412	11511.522	44.378	.000	.253
		Adherent (n=98)	27.28	19.43	15.73	14.51						
		Total (n=133)	31.08	19.99	17.35	15.43						
adherence							1	131	1109.347	5.224	.024	.038
Alcohol*adherence							1.797	253.412	1310.724	5.503	.009	.037

Note. dfNum indicates the degrees of freedom numerator. dfDem indicates the degrees of freedom denominator. η^2 indicates generalized eta-squared effect size.

Discussion

The purpose of this study was to investigate the effectiveness of an AAT in addition to TAU. Moreover, it was tested whether adherence as an additional factor had an impact on the effectiveness. Expected was, that participants in the training condition of the AAT would show better results compared to participants in the placebo group. Moreover, it was suggested that adherent participants show better treatment outcomes than non-adherent participants.

Approach avoidance training
Overall, alcohol consumption decreased in both groups. That indicates that the CBM training did not have added value to regular CBT. Therefore, the first hypothesis should be rejected.

However, as this study included eight training sessions over a time period of five weeks, it might have been necessary to include more sessions in order to prove an effect. Although Wiers et al. (2011) found a reduction of alcohol consumption after four sessions in an inpatient setting, it is not recommended to reliably compare the results of the current findings, as this study was conducted in an outpatient setting. An inpatient setting would have offered a controlled environment, in which the participant is instructed to do the session in a given time and space. On the other hand, an outpatient setting represents a less structured and controlled environment which might interfere with the completion of the sessions. According to literature, there are several factors that influence homework compliance in an outpatient setting. These factors can be divided into internal and external factors. Internal factors describe for example the clients´ motivation, the wish to see immediate results and the tendency to disclaim the tasks´ importance for therapy outcome (Gaynor, Lawrence, & Nelson-Gray, 2006). External factors originate from a client´ external environment, such as not having enough time, the need to have pen-and-paper, lack of interest and understanding (Garland & Scott, 2002). Based on that, the patient might perform tasks in an outpatient setting not as precisely as he would do within an inpatient setting, leading to a possibly weaker effect of the CBM. Yet, more sessions could eventually compensate this weak effect, leading to an impact that can be seen after more than four to eight sessions.

However, as this research is one of the first studies investigating the effect of CBM in an outpatient setting, further research is needed.

Adherence

Looking at the second research question of this study, the stated hypothesis needs to be rejected as well. Within the completers-only analysis, a difference between adherent and non-adherent participants could not be found, yet the sample included just one participant in the non-adherent group. Surprisingly, the ITT analysis showed an effect, indicating that non-adherent participants consumed less alcohol than adherent participants after going through the AAT. Since this study expected a better outcome for the latter, the results show reserved findings. However, as the original data set compromised just one participant in the non-adherent group, this study cannot make a reliable conclusion regarding the effect of adherence. In fact, the participant within the non-adherent group showed a large decrease in alcohol consumption after the first assessment which is likely to influence the analysis. Going into detail, the participant reduced its drinking behaviour from 70 units in the first assessment to 0 units in the following time points (T1=.00; T2=.00; T3=.00). Since such behaviour is not likely to represent the average drinking pattern of an alcohol patient, the results are likely to be biased.

This bias might take different forms. One might be based on response bias. Hence, participants tend to response in a certain way, most likely in a way that seems to be right (Babor, Stephens, & Marlatt, 1987). Likewise, social desirability has an impact on response tendencies. According to Davis, Thake and Vilhena (2010), social desirability biases represent a main threat when it comes to self-reported alcohol consumption. They also state that self-reported drinking often compromises 20-50% less units than it was consumed. Thus, the patient might have reported less units than he really consumed.

To make final conclusions, further research is needed to investigate the effect of adherence in an outpatient setting.

Conclusively, it can be said that CBM as an addition to therapy as usual leads to better treatment outcomes when it comes to alcohol use disorders. Moreover, adherence did not have a positive impact on treatment outcome. However, as both groups showed a decline in drinking behaviour, one can assume that regular CBT had an impact on the client´ drinking behaviour. As literature states that CBT represents a common form of therapy for alcoholism and leads to a significant reduction in drinking patterns compared to patients with no treatment, the present study underlines the effectiveness of CBT (Hides, Carroll, Catania, Cotton, Baker, Scaffidi, & Lubman, 2010; Hodge, 2011). It furthermore helped to address conscious processes related to drinking behaviour, making patients more aware of their alcohol consumption.

Strengths & Limitations

The current study shows several strengths as well as limitations. One of the main advantages of this study is that it is one of the first to investigate the effect of a CBM-AAT as an addition to TAU in an outpatient treatment setting. Since most studies focused on clinical settings while investigating the effect of CBM, the current design enables a more naturalistic and holistic examination of CBM. Patients are instructed to complete the sessions at home while being in a familiar environment. As this setting might hold more alcohol-related cues compared to an inpatient setting, it enables training in a more relevant surrounding.

Moreover, CBM in an outpatient setting represents a cost-effective addition to regular therapy (Boffo, Willemen, Pronk, Wiers, & Dom; 2017). As patients with an alcohol use disorder are often characterized by cycles of multiple relapses, CBM might help to diminish the number of relapses and to extend the period of being abstinent. Based on that, the number of patients approaching the health sector in order to deal with that relapse, would decrease, leading to reduced health care costs (Boffo, Pronk, Wiers, & Mannarini, 2015).

Another strength of this study is the design. Since we are interested in investigating causations, a double-blind randomized placebo-controlled trial was used. As it enables eliminating of confounding variables and baseline differences, this design is common for investigating causations (Misra, 2012).

However, this survey encompasses some limitations as well. That means for instance that the process of data collection was not finished in time due to changes in technology. Moreover, the sample shows a huge proportion of dropouts, which is why this study must deal with a relatively small sample size (n=36). Based on that, only one participant was considered as non-adherent within the second analysis. Thus, it is not possible to reliably compare the subgroups. Moreover, Leven´s test of equality of error variances shows that variances across groups cannot be assumed to be equal in all groups, meaning that the sample size is not balanced. Based on that, results have to be interpreted carefully and further research should incorporate a higher number of participants.

Moreover, the current study only involves one control condition, in which participants follow a placebo CBM session. However, it would be interesting to have a control condition in which participants solely follow therapy as usual or CBM sessions to investigate their effectiveness. Regarding the results of the current research, we could be more confident about the effect of CBM in an outpatient setting and about potential benefits of adherence.

Conclusion

Based on the present study, it cannot be concluded that CBM as an addition to therapy as usual leads to better treatment outcomes when it comes to alcohol use disorders. Moreover, one cannot confirm adherence to have a positive impact on treatment outcome. However, as this is one of the first studies investigating the effect of CBM in an outpatient setting, further research should be investigated to collect more valuable data regarding the effectiveness of CBM as an addition to regular therapy.

Recommendations

Although the present study did not reveal significant findings regarding the added value of CBM as an addition to TAU and differences between adherent and non-adherent participants, it still offers a valuable indication regarding possible benefits. As this survey had a relatively small sample size, it would be valuable to investigate the effects of CBM further with a larger population. However, the mentioned limitations should be taken into consideration when conducting further research.

Moreover, as CBM sessions were given in an outpatient setting and adherence regarding the training as well as the assessments was low, further research should focus more on ways to enhance adherence. That refers for instance to a choice of different vouchers and additional reminders vocally in therapy sessions or as push notification on their phone in case adherence was a problem of memory.

In addition, future research could obtain qualitative aspects of research as well. Hence, patients are asked to report their drinking behaviour, including their current feeling regarding that drinking behaviour and reasons for a low/high consumption. Moreover, to increase adherence, data about the liking of the application can be gathered.

Lastly, as this CBM training was provided online, future research could incorporate an app for the training. Since an app enables reaching participants almost everywhere and at any time, it could enhance adherence as well (Klasnja & Pratt; 2012).

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