Testing the effectiveness of Cognitive Bias Modification and moderation of baseline cravings on alcohol consumption in outpatient alcohol addiction treatment

Master thesis

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Abstract

Theoretical models suggest that alcohol addiction can be explained by an imbalance between conscious processes and automatic processes. Cognitive Bias Modification (CBM) Alcohol Avoidance Training was developed to train these automatic processes by using Approach-Avoidance training. Several studies found positive effects of this training in an inpatient clinical setting with patients who are addicted to alcohol. This study examines whether online Cognitive Bias Modification (CBM) Alcohol Avoidance Training increases the effectiveness of treatment as usual in alcohol addiction in an outpatient setting and whether baseline cravings moderate the effects of CBM training on alcohol consumption after the intervention. The double-blind, randomized controlled trial had 8 online CBM Alcohol Avoidance Training sessions which were added to treatment as usual (TAU) at Tactus Addiction Treatment Institute in the Netherlands, which is based on CBT and motivational interviewing and can be administered as a Web-based or face-to-face treatment. The adult patients completed a pre- and post-assessment and follow-up assessments after 3 and 6 months. Results show that the CBM Alcohol Avoidance Training does not increase effectiveness of the TAU and that baseline cravings do not moderate the effects of CBM training on alcohol consumption after the intervention. More research needs to be done using CBM in an outpatient setting and with different types of delivery modes. This could increase effectiveness and the possibility to replicate results of previous research.

Introduction

Harmful use of alcohol is related to over more than 200 injury and disease conditions and to 5.1 % of the global burden of disease and injury, which leads to a significant social and economic burden on society (WHO, 2018). People who are misusing alcohol are aware of the problems and consequences of their behaviour, but do not seem to be able to stop. This can be explained by viewing addictive behaviour as a "dual process" where there is an imbalance between these conscious/cognitive processes and automatic processes (Deutsch & Strack, 2006). This dual-process model describes that using the conscious process a person recognizes their alcohol problem and has a desire to stop drinking alcohol, however, this is overpowered by the automatic processes, which is the need to drink (Larsen, Engels, Wiers, Granic, & Spijkerman, 2012; Herschl, McChargue, MacKillop, Stoltenberg, & Highland, 2012; Larsen et al., 2012; Wiers et al., 2013). Accordingly, instead of displaying inhibitory control when being confronted with alcohol, addicted individuals react impulsively as part of an automatic process (Bratti-van der Werf et al, 2018).

Therefore, it is important to not only consider cognitive processes when treating alcohol use disorders, but also the automatic and impulsive processes. In many cultures' alcohol plays an important part in socializing and is therefore always present in the life of an individual (WHO, n.d.), which could play a role in automatic processes. Cognitive Bias Modification (CBM) training has been developed to address this issue. Computerized CBM training programs have the goal to reduce psychopathology by reducing automatic biases in information processing (Wiers, Gladwin, Hofmann, Salemink, & Ridderinkhof, 2013; Macleod, 2012). In the context of alcohol addiction, the CBM Alcohol Avoidance Training (AAT) has been developed to retrain the automatic behavioural tendency to approach alcohol when triggered by a stimulus. This training showed good results by reversing patients' approach bias into avoidance bias for alcohol in a first clinical trial (Wiers, Eberl, Rinck, Becker, & Lindenmeyer, 2011). CBM can also help in reducing relapse rates for alcohol addiction, as in this study patients in the training group showed better treatment outcomes after a year when compared to the placebo group. Another study has also shown higher effect rates at a 1-year follow-up compared to other types of training (Rinck, Wiers, Becker, & Lindemeyer, 2018). A recent meta-analysis indicated the importance to add CBM to established treatments in a clinical setting with alcohol-dependent patients for effectiveness, as CBM as a stand-alone treatment did not show significant effects (Wiers, Boffo, & Field, 2017).

Most studies tested whether CBM is effective in a clinical inpatient setting, meaning it was tested on patients who stayed for a prolonged period of time overnight in a hospital while staying abstinent, but it is important to study the possible effects of CBM in an outpatient treatment, meaning patients who continue to live at home following their normal routines and only receive treatment for a few hours per week either online or by going to a facility. Offering Internet-based CBM in combination with Internet-based Cognitive Behavioural Therapy (CBT), which both can be done remotely from home instead of going to a face to face treatment at a facility, has shown good adherence rates in patients with depression and anxiety (Williams, Blackwell, Mackenzie, Holmes, & Andrews, 2013; Salemink, Kindt, Rienties, & van den Hout, 2014). There are also preliminary results that training in a relevant and real-life context could lead to better results of CBM (Bratti-van der Werf et al, 2018).

The previously mentioned study by Wiers, Eberl, Rinck, Becker, & Lindenmeyer (2011) also showed that subjective craving for alcohol went down in the group that received CBM. Therefore, another topic we would like to investigate in this study is the role of alcohol cravings in alcohol addiction and CBM. A key point in alcohol addiction is the urge and strong desire to drink, which is often referred to as `craving` (Sayette, Shiffman, Tiffany, Niaura, Martin, & Shadel, 2000). Cravings can also be described as recurrent and persistent thoughts about alcohol, the struggle to control these drives, withdrawal symptoms, anticipation of positive outcome, relief from negative affect, lack of control over use, cue-induced autonomic responses, and others (Verheul, Van den Brink, & Geerlings, 1999). This shows that craving can be considered as part of automatic processes, which is what CBM targets to change. Additionally, alcohol craving is linked to greater dependence severity and a less favourable treatment prognosis (Flannery, Roberts, Cooney, Swift, Anton, & Rohsenow, 2001; Rohsenow, & Monti, 1999). A study by Soyka, Helten, & Schmidt (2010) showed that cravings after treatment and at follow-ups were higher in patients who had a lower reduction in alcohol consumption. A study with alcohol-dependent patients that were treated in an inpatient clinic with follow-ups after 6, 12 and 24 months showed that the higher the craving at one follow-up evaluation, the less likely patients were to be abstinent at the subsequent one (Schmidt, Helten, & Soyka, 2011).

Based on these findings, we want to research whether the positive effects of CBM training of the above mentioned clinical inpatient studies can be reproduced when CBM is used online in an outpatient setting. In this study online CBM is added to treatment as usual (TAU) at Tactus Addiction Treatment Institute in the Netherlands, which is based on CBT

and motivational interviewing and can be administered as a Web-based or face-to-face treatment. Therefore, this study wants to investigate if online CBM Alcohol Avoidance Training in combination with TAU is effective, how long these effects last and what factors in individuals could play a role for effectiveness. Additionally, we want to investigate whether alcohol cravings before the treatment are in relation with the amount of alcohol consumed after treatment. The research questions are:

1. Does adding online Cognitive Bias Modification (CBM) Alcohol Avoidance Training increase the effectiveness of treatment as usual in alcohol addiction?
2. Do baseline cravings moderate the effects of Cognitive Bias Modification (CBM) training on alcohol consumption after the intervention?

It is hypothesized that:

1. Cognitive Bias Modification (CBM) Alcohol Avoidance Training increases the effectiveness of treatment as usual in alcohol addiction.
2. Baseline craving is an enhancing moderator on the effect of CBM training on drinking outcomes (see Figure 1).

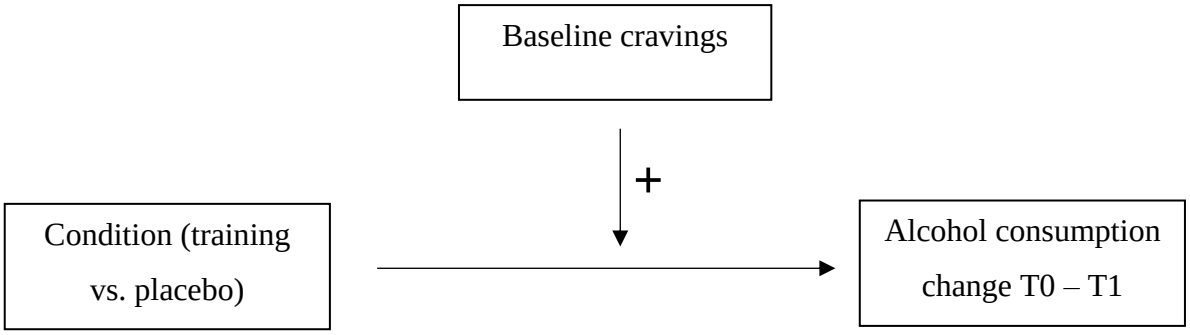

Figure 1. Conceptual model of the moderation effect.

Method

Design

A double-blind randomized placebo-controlled trial in a clinical context was employed. The study has been approved by the Ethics Committee of Amsterdam Academic Medical Centre in January 2015 (reference number 2014_154#C20141463) and has been registered at the Netherlands Trial Register (NTR5087). A protocol paper was published ((Bratti-van der Werf et al, 2018).

Participants

139 people participated in this study, consisting of patients aged 18 or older with a primary alcohol problem.

The study population was required to have access and the ability to use the internet for accessing CBM-training online. Persons with a serious psychiatric illness with a risk to decompensate while decreasing alcohol consumption or/and are at risk of severe physical illness as a consequence of decreased alcohol consumption were excluded of participation in this study.

The participants were recruited in TAU at Tactus Addiction Treatment Institute in the Netherlands, in this setting all patients with a primary alcohol problem following an outpatient treatment were invited by their therapist to participate in this study.

Procedure

After the regular intake procedure at the Tactus Addiction Treatment Institute, which includes baseline questionnaires (Demographics, MAP-HSS, DASS, OCDS, CIDI, Drinking refusal self-efficacy, Weekly alcohol consumption), the TAU started. Therapists gave their clients information about the CBM training and this study, and if participants decided to participate, they then signed an informed consent. Afterwards, participants received login credentials for the CBM training, registered and were randomly assigned to the Alcohol Avoidance Training or the placebo training. After logging in at the CBM training website patients received instructions about the training which included the recommendation to follow a 15-minute CBM session twice a week for a period of five weeks., which includes eight CBM training sessions and the pre- and post-assessment. At the start of each session, participants were asked to fill in two single-item questionnaires regarding their self-reported weekly alcohol consumption and desire for drinking. Before the first training session participants completed an online preassessment with two questionnaires (DMQ-R, Weekly alcohol consumption). The intervention included CBM 8 sessions which each took about 10-15 minutes, and the last session was followed by an online post-assessment questionnaire (Weekly alcohol consumption, CSQ). If patients completed all ten sessions, they would get a reward (20€ voucher). In addition to the online post-assessment, participants had a post-test at TAU, which included the MAP-HSS, DASS, OCDS and weekly alcohol consumption. Three and six months after the post-assessment, each patient was asked to answer an online follow-up questionnaire including the same measurements as the post-test at TAU.

Interventions

TAU was tailored to the individual needs of each participant, but is based on CBT and motivational interviewing. There were four different treatment subgroups: patients could receive Web-based or face-to-face treatment and a brief five week or intensive 3-month version. The basic ingredients for treatment were the same in all groups, and as in this study we were interested in the effectiveness of Alcohol Avoidance Training as an adjunct to TAU, we did not differentiate between these subgroups. Due to the randomization of this study it can be expected that all subgroups were equally divided into the experimental and control group.

In addition to TAU, participants got Alcohol Avoidance Training, which was based on the Approach-Avoidance Task (AAT). In this training, patients were shown pictures of alcoholic beverages or soft drinks, which were tilted 3 degrees to the left or right. Participants were instructed to strike the "u" key when the picture is tilted to one side which causes an avoidance movement by decreasing the size of the picture. This movement was paired with pictures of alcoholic beverages. When the picture was tilted to the other side, participants should press the "n" key to cause an approach movement by increasing the size of the picture. This movement was paired with pictures of soft drinks (see Figure 2). Patients were not instructed to react on the picture itself, just on the format of the picture, but alcoholic and soft drinks were each allocated to one format. This is termed as an irrelevant-feature version of the training, which makes it more indirect (de Houwer, 2003) and also conceals allocations to condition (training vs. placebo). A training session started with a practice block of 12 trials with grey squared pictures followed by 160 trials divided into 4 blocks to provide short breaks in between. Each block contained 20 images of alcoholic drinks and 20 images of soft drinks, then the block of 40 stimuli was repeated 4 times. Each stimulus was presented to the patient for 3000 ms. In the placebo condition, all 40 stimuli were presented 4 times. Two formats, which refers to a picture tilted to the left or right, were repeated two times. On both of these two formats alcoholic and soft drinks were presented equally often, which results in patients not being indirectly trained to approach or avoid a certain stimulus. This is in contrast to the training group where patients were indirectly trained to avoid alcohol and approach soft drinks.

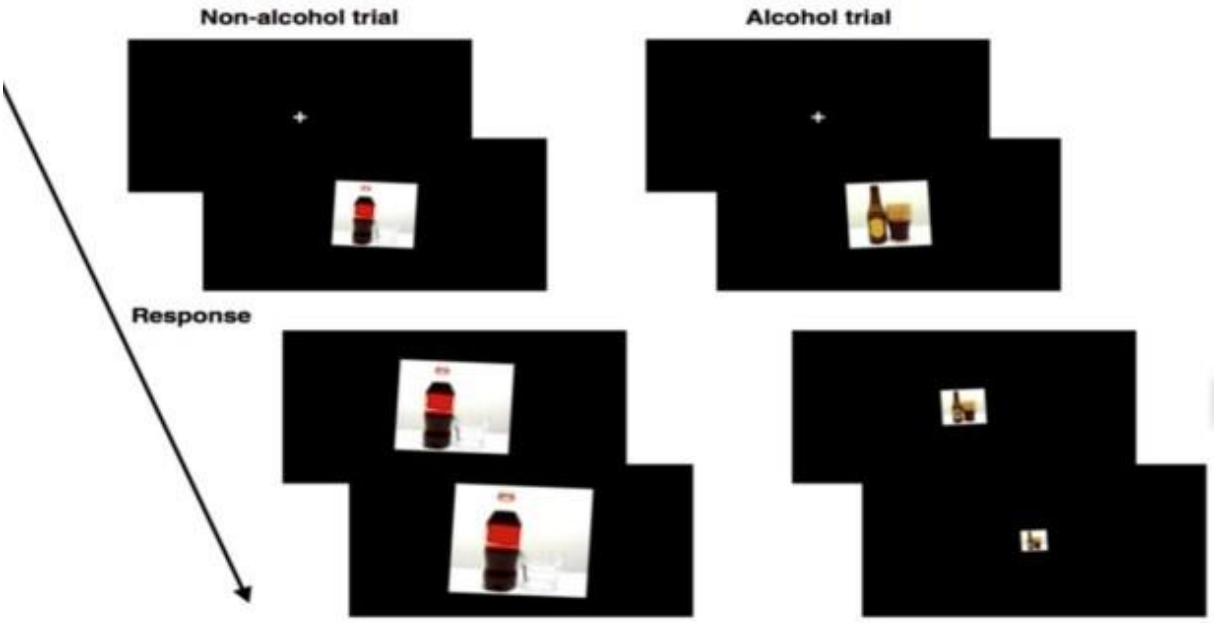

Figure 2. An example of Approach-Avoidance Training.

Measures

Demographic information was collected in the intake of the TAU. This study included multiple questionnaires, however, for this paper only three were used.

"Alcohol Timeline Follow Back" (TLFB) (Sobell, & Sobell, 1992) combined with the "Measurement in the addictions for triage and evaluation" (MATE) (Schippers, Broekman, Buchholz, Koeter, & van den Brink, 2010) was used to measure weekly alcohol consumption. In the TLFB questionnaire patients are asked at the end of every week to indicate estimates on the number of standard units alcohol the consumed each day. The MATE is an instrument based on the world health organization family of international classifications. From the MATE the amount of alcohol in standard drinks used on a typical day of use in the past 30 days was taken for this study.

To measure obsessionality and compulsivity related to craving and drinking behaviour the 5-item Obsessive Compulsive Drinking Scale (OCDS) (de Wildt, Lehert, Schippers, Nakovics, Mann, & van den Brink, 2005) was filled out by the patients at the beginning and end of the intervention. With this measure the baseline craving variable is operationalized.

Data analysis

The data was opened in and analysed by using the statistical computer program SPSS (Version 24; IBM Corp., 2016). In the following, weekly alcohol consumption before the intervention will be referred to as timepoint T0, the measuring point after the intervention is

T1, the measuring point three months after the post-assessment is T2, and the timepoint six months after the intervention is called T3. The variable alcohol consumption was calculated by combining TLFB and MATE scores because not all participants answered both questionnaires. Frequencies, means and standard deviations (SD) were calculated for data description. Univariate comparisons of the training and placebo group were performed by using the likelihood ratio statistic (for nominal data), and the Kolmogorov-Smirnov test (for metric data).

To answer the first research question, a two-way mixed ANOVA with weekly alcohol consumption (T0, T1, T2, T3) as dependent variable and condition (training vs. placebo) as independent variable was conducted. In order to deal with missing data, a second data set was created using multiple imputation with 10 imputation groups. As SPSS does not support pooled results for ANOVA's, a method by Dr. J.R. van Ginkel was followed (van Ginkel, & Kroonenberg, 2014), who has made a SPSS syntax available on his website to use for a multiple imputation ANOVA.

To answer the second research question a moderation analysis (model 1) was done with Hayes' program 'PROCESS' (Version 3.5; Hayes, 2017), with condition (training vs. placebo) as a predictor, baseline OCDS scores as a moderator and difference scores in alcohol consumption from T0 to T1 as the outcome variable.

Results

Descriptive statistics

This study had 139 participants, of which 72 were in the training and 67 in the placebo condition. Only 133 participants gave demographic information about themselves. Of those 58.6% were male, 91% were of Dutch nationality and their mean age was 47.8. At the beginning of the intervention cravings were measured with the OCDS questionnaire for 93 participants, the average score was 7.3. 139 participants indicated how many units of alcohol they drank weekly at the beginning of the intervention, the average there was 34.3. There were no significant differences between the training and placebo group for the demographic characteristics (see Table 1).

Table 1

Baseline characteristics of subjects - shown for the total sample and according to condition (training or placebo)

	Training (n = 70)	Placebo (n = 63)	Total (n = 133)	Difference training vs. placebo
Age (*M, SD)*	48.8 (10.7)	46.7 (12.3)	47.8 (11.5)	Z = .67; *p* = .77[a]
Gender (*n, %)*				LR(1, n = 133) = .00; *p* = .96[b]
Female	29 (41.4)	26 (41.3)	55 (41.4)	
Male	41 (58.6)	37 (58.7)	78 (58.6)	
Nationality (*n, %)*				LR(1, n = 133) = .17; *p* = .68[b]
Dutch	63 (90)	58 (92.1)	121 (91)	
Other	7 (10)	5 (7.9)	12 (9)	
Weekly alcohol use T0 (n = 136) (*M, SD)*	32.8 (26.6)	35.9 (38.3)	34.3 (32.8)	Z = .53; *p* = .94[a]
Craving[1] (n = 93) (*M, SD)*	7.9 (4.7)	6.8 (4.1)	7.3 (4.4)	Z = .72; *p* = .68[a]

[a] Kolmogorov-Smirnov test, [b] Likelihood ratio statistic

[1]OCDS scores range from 0 to 20

Participants had to be excluded from the analyses because of missing values (see Figure 3).

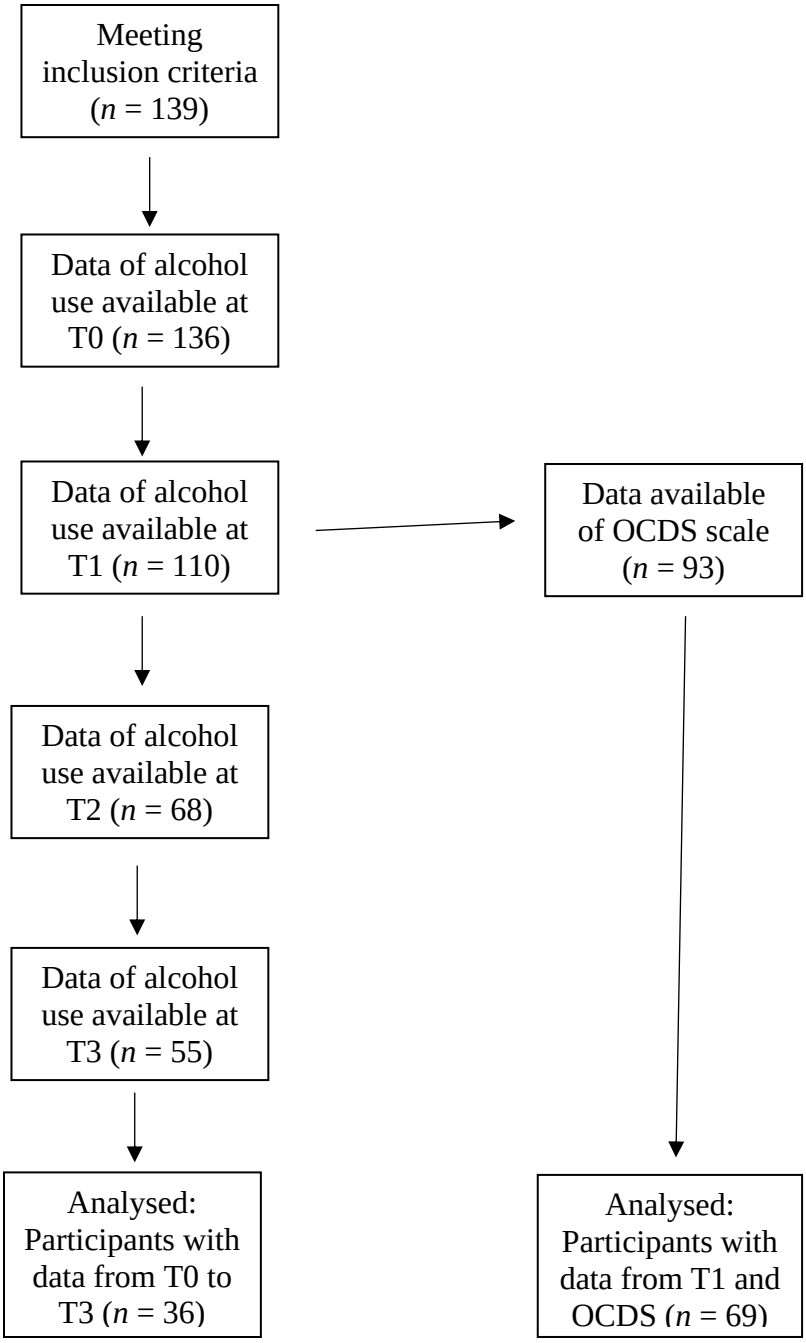

Figure 3. Flow chart showing which participants are included in the analyses.

Effectiveness of treatment

36 participants indicated their level of alcohol consumption at all timepoints, of those 15 were in the training condition and 21 in the placebo condition. Mauchly's test of significance showed non-significant results ($p = 0.058$), therefore none of the effects violate the assumption of sphericity.

Analysis of variance showed that the main effect of time was significant ($F(3,102) = 9.96$, $p < .001$, $\eta_p^2 = 0.23$). The Bonferroni-adjusted paired t-tests displays a significant

difference between T0 and T1 on alcohol consumption (p = .003), and there were no significant pairwise differences across other timepoints (see Figure 4). The interaction effect of condition (placebo vs. training) over time on alcohol was not significant (F(3,102) = .47, p = .703, η_p^2 = 0.02).

In the multiple imputation data set, analysis of variance showed that the pooled main effect of time was significant (F(3,137) = 12.36, p < .001). The pooled main effect of condition (placebo vs. training) was not significant over time (F(3,137) = .42, p = .74).

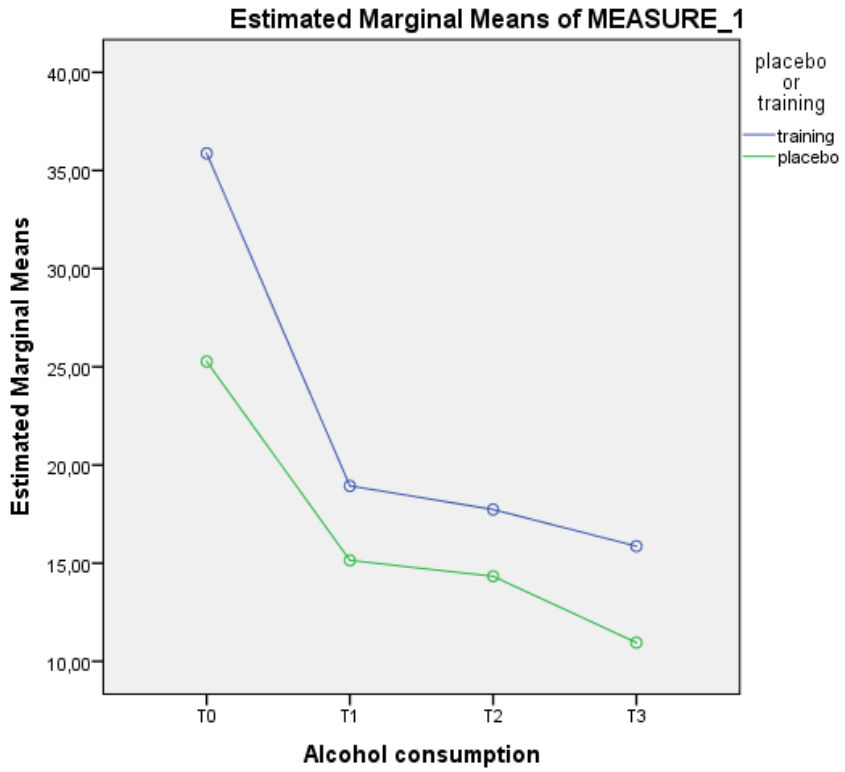

Figure 4. Means of Alcohol consumption at all timepoints in training and placebo condition.

Moderation of craving effects

The data of alcohol consumption at T0 and T1 and baseline cravings were available from 69 participants. The relationship between condition and reduction in alcohol consumption (T0-T1) is not moderated by baseline cravings (b = .74, 95% CI [-3.39, 4.87], t = .36, p = .72).

Discussion

This study aimed to investigate the effectiveness of adding online Cognitive Bias Modification (CBM) Alcohol Avoidance Training to treatment as usual in alcohol addiction

in an outpatient setting and whether baseline cravings moderate the effects of CBM training on alcohol consumption after the intervention. For this aim an RCT involving 139 patients with a primary alcohol problem following an online training in addition to regular outpatient treatment was performed.

The first research question was whether adding online Cognitive Bias Modification (CBM) Alcohol Avoidance Training increases the effectiveness of treatment as usual in alcohol addiction. The data shows that this is not the case. In general, the treatment does work, and participants drink significantly less after the intervention and in the months after. However, there was no difference in effectiveness between the placebo and training condition, which means that adding online CBM to treatment as usual does not increase the effectiveness. Therefore, the first hypothesis is rejected.

These results are not in line with previous research. Studies by Wiers et al. (2011), Rinck et al. (2018) and Wiers, Boffo, & Field (2017) showed that CBM can improve treatment outcomes, even at 1-year follow-ups. The preliminary results that training in a relevant and real-life context could lead to better results of CBM (Bratti-van der Werf et al, 2018) are not detected in this study. The CBM used in these studies is almost identical to the CBM in our study. However, these studies were conducted in a clinical inpatient setting, whereas our study was conducted in an outpatient setting. Additionally, most of these studies had fewer CBM training sessions in a shorter time period than our study, which might have made the interventions in these studies more intensive. Both of these factors, the difference in patient settings and amount of CBM sessions, could have led to the different results in previous studies and our study.

The second research question was whether baseline cravings moderate the effects of Cognitive Bias Modification (CBM) training on alcohol consumption after the intervention. The data shows that there is no moderation. Therefore, the second hypothesis is also rejected. The results of studies showing that alcohol cravings are linked to a less favourable treatment (Flannery et al., 2001; Rohsenow, & Monti, 1999) could not be replicated in this study. Soyka, Helten, & Schmidt (2010) showed that cravings measured with the OCDS after treatment and at follow-ups were higher in patients who had a less favourable treatment outcome. In our study it can be seen that this is not the case for cravings measured before the treatment. However, these studies used only CBT treatment without additional CBM training. Still, Wiers, Eberl, Rinck, Becker, & Lindenmeyer (2011) showed that craving for alcohol went down when getting CBM training. This led to the hypothesis that participants that score

high in craving may be more vulnerable to automatic processes and conversely, they should benefit more from CBM, which could not be proven in this study.

Strengths and limitations

Alcohol consumption in this study is measured in two different ways. Some participants answered the "Alcohol Timeline Follow Back" (TLFB) which measures weekly alcohol consumption while others indicated their alcohol consumption in the MATE intake, which measures monthly alcohol intake. To include as many participants as possible in the analyses, both questionnaires were calculated into one variable of alcohol consumption which could limit the validity of this study. This also indicates a general weakness of the study, as not every participant answered all measurements at all timepoints, and this can also result in an imbalance of the number of participants between the two conditions.

Another limitation of this study is that it has many missing values. Therefore, when using the completers-only data set by case deletion, the sample size is relatively small. To handle this issue, analyses were also computed with an imputed data set. Accordingly, we have two different results for the same analyses, and the question is which one is more reliable and should be used. A complete-case analysis can bias the results as the complete cases can be unrepresentative of the full population (Schafer, & Graham, 2002). Imputation can be dangerous when there is a systematic difference between responders and non-responders, as the results of analyses may be biased and precision is decreased (Huisman, 2000). However, in this study we used multiple imputation, which resulted in 10 data sets which analyses are combined into one conclusion, and, therefore, uncertainty about missing values is taken into account. Studies show that using multiple imputation produces statistical results with little bias (van Ginkel, van der Ark, & Sijtsma, 2007). Thus, in this study, the results from the imputed data set can be deemed more reliable and should be used.

A strength of this study is that the treatment is tested at the actual target group. Many CBM studies are experimental laboratory studies with healthy volunteers as participants, e.g., university students. First of all, Wiers, Boffo, & Field (2017) showed that CBMs for alcohol abuse in such a setting are not effective. Second of all, one can get a much better insight into the needs of the target group and the usefulness of the intervention when testing the intervention in a real-world setting with addicted patients in comparison to an experimental laboratory study.

In the future, more research must be done that investigates CBM in an outpatient setting to see if positive effects can only be found in an inpatient setting as the literature suggests, or also in an outpatient setting, which was not the case in this study. To increase effectiveness in using CBM in an outpatient setting, one could lower the amount of CBM sessions used as it was done in studies in an inpatient setting, which could also increase adherence. Furthermore, to increase effectiveness of CBM one could try out different types of delivery modes. For example, by using a joystick instead of the keyboard, the pushing and pulling motion can be better simulated and closely matched with a real-life situation. Another idea could be to use an app for smartphones for the CBM, as swiping or zooming with your fingers on a touchscreen could make the simulation more realistic, and using an app might motivate participants to do the CBM more often, as many people spend a lot of time on their smartphones anyways. Additionally, better incentives could be used to motivate patients to participate in and complete all measurements. Low adherence is a problem in addiction treatment in general, however, it is also relevant for CBM, as it can be better investigated if more participants adhere.

Conclusions

To conclude, in this study adding online Cognitive Bias Modification (CBM) Alcohol Avoidance Training does not increase the effectiveness of treatment as usual in patients who are treated for alcohol addiction in an outpatient setting. Additionally, in this study there were found no moderating effects of baseline cravings on the effects of Cognitive Bias Modification (CBM) training on alcohol consumption after the intervention. These results are in contrast with previous studies. More research needs to be done for testing CBM in an outpatient setting.

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