


Online Cognitive Bias Modification Alcohol Avoidance Training as Addition to  
treatment as usual: Preliminary results of a double-blind randomized controlled  
trial in an outpatient addiction treatment setting



Author	Elske Marijn Roeleveld
University	University of Twente
Masterthesis	Psychology: Health Psychology & Applied Technology
Faculty	Faculty of Behavioural, Management and Social Sciences
First Supervisor	Drs. M. E. Pieterse
Second Supervisor	Drs. M. G. Postel
External organization	Tactus Addiction Treatment
Date, place	March 2017, Enschede

## ABSTRACT

**Background:** Alcohol use disorders are common in the Netherlands. To treat these, Cognitive Behavioural Therapy (CBT) treatments are widely used. Although these treatments are evidence based, recent studies and models emphasize that the effectiveness can be endorsed by a Cognitive Bias Modification (CBM) training, in which impulsive processes can be retrained. The current study focused on these impulsive processes and in special on action tendencies that are activated relatively automatic. The aim was to examine the effectiveness of an computerized and online CBM Alcohol Avoidance Training by using an adapted Approach Avoidance Task (AAT) as addition to a CBT treatment in an outpatient treatment setting.

**Methods:** In a double-blind randomized controlled trial alcohol dependent patients ( $n = 104$ ) were randomly assigned to either the experimental or placebo version of eight sessions CBM Alcohol Avoidance Training. Patients were at least aged 18, followed treatment as usual at Tactus Addiction Treatment and were recruited by their therapist. Primary outcome measures were 1) the difference scores on self-reported weekly alcohol consumption and 2) the proportion of patients drinking under the responsible drinking limit. Secondary outcomes concerned mental health and craving. Furthermore, adherence to the treatment was examined. Intention-to-treat analysis were performed to deal with loss to follow-up.

**Results:** The results of the current study showed no additional effects of an online CBM-training with an AAT, in addition to CBT treatment. There were some indications for an adverse effect of the CBM-training, because the placebo condition showed a stronger decrease in alcohol consumption, in particular among male patients.

**Discussion:** The current study showed preliminary outcomes and the original RCT is still running. The sample size and power in the current study were low and therefore the results should be interpreted carefully. Randomization has not led to comparable groups and this made it difficult to draw well-substantiated statements on the results. The contradictory results and conclusions give reason to further investigate them in the future. The recruitment of patients for the original RCT is still running. Eventually the sample size will be bigger and analysis can be done with more power. Then, conclusions about the added value of the CBM training as addition to treatment as usual can be drawn with more statistical evidence.

**Keywords:** Alcohol, Addiction, Cognitive Bias Modification, CBM, Approach Avoidance Task, AAT, Alcohol Avoidance Training, web-based treatment, Cognitive Behavioural Therapy, CBT.

## INTRODUCTION

Excessive drinking is a highly prevalent health issue, with serious consequences for individuals in terms of unemployment, financial distress, addictions and social problems (WHO, 2016). Drinking unhealthy amounts of alcohol is related to cancer, heart disease and accidents, and may eventually lead to morbidity and mortality (Rehm, et al., 2009). Furthermore, the Dutch national institute for public health and environment estimates that the consequences of excessive drinking and alcohol addictions, costs its society about two and half a billion euro's a year (de Wit, 2016). Therefore, it is important to change unhealthy drinking behaviors and to improve health outcomes for individuals and society.

To treat disorders related to alcohol abuse, evidence-based treatments like Cognitive Behavioral Therapy (CBT) are widely used. These treatment programs focus on the reflective, conscious system and leave the automatic, impulsive system unaffected (Thush, et al., 2009). However, people are not always aware of their problematic drinking behavior. This is partly due to automatic processes that exert their influence outside of conscious control. Bentler and Speckart (1979) endorse this statement in their research, where they investigated students' consumption of alcohol (among other things). They suggested that the use of alcohol could become habitual over time and, maybe even more important, that the 'action' of drinking alcohol could also appear when a person did not have the intention to drink. This work of Bentler and Speckart has been replicated by many other researchers in a wide variety of domains, such as eating junk food, physical exercise, drug use and so on (Ouellette & Wood, 1998). These studies suggest that behaviour could be largely influenced by habit, which is an automatic process (Danner, Aarts & de Vries, 2008). Due to this previous work it is likely that automatic as well as reflective processes play a role in problematic drinking, suggesting that treatment programs could be improved by not only focusing on reflective processes, but also on processes that are primarily automatic (Wiers et al., 2007).

Strack and Deutsch (2004) emphasize the importance of considering the impulsive influences in performing behaviour and to study their interactions with reflective determinations. In their dual-process model, called the reflective-impulsive model, addictive behaviors are predicted by contradicting reflective and automatic processes, or so called 'systems'. They use the assumption of Smith and DeCoster (2000) that the automatic system is impulsive, fast of nature and evaluates stimuli automatically, based on emotional or motivational importance. The reflective system is slower, more controlled and consists of conscious deliberations. This model could give an explanation to the central paradox in

alcohol addictions: why problematic drinkers are mostly aware of the negative consequences, but keep continuing in self-destructive behaviour (Field, Schoenmakers, & Wiers, 2008). As we take the habitual perspective of Danner, Aarts and de Vries (2008) into account, the central paradox could be explained by the suggestion that frequently drinking alcohol makes it a habit. Therefore, it becomes an impulsive process, which exerts its influence outside reflective determinations. For example, not thinking of the negative consequences of drinking alcohol, while this person is drinking. Strack and Deutsch support this by stating that impulsive processes, like habit, overpowers the reflective processes and therefore, it has more influence in performing behaviour.

### **Cognitive biases**

A cognitive bias refers to automatic processing of relevant cues over other cues in the environment (MacLeod & Mathews, 2012). Cognitive biases could be reflected in a) an attentional bias for alcohol-related stimuli (Field & Cox, 2008), b) a memory bias for the automatic activations of alcohol-related associations (Wiers, van Woerden, Smulders & de Jong, 2002), and c) an approach bias which appears to automatically activate action tendencies to approach alcohol (Palfai & Ostafin, 2003). The current study is focusing on approach biases in addictive behaviour. Kakoschke, Kemps and Tiggemann (2016) suggest that having an approach bias toward appetitive cues is likely to be an important contributor to unhealthy consumptions, like in drinking unhealthy amounts of alcohol. Other researchers emphasize these findings by demonstrating that approach biases can cause increased consumption of alcohol (Wiers, et al., 2009; Wiers et al., 2010).

### **CBM-training & AAT**

In a Cognitive Bias Modification (CBM) training researchers try to modify cognitive biases and cognitive processes. In modifying approach biases most researchers use an Approach Avoidance Task (AAT), which is an Behavioral Assessment Task (BAT) and is originally designed for the anxiety domain (Rinck & Becker, 2007). An approach bias is the difference in response latency (i.e. reaction time) between pushing (avoiding) and pulling (approaching) in response to pictures. Extended reaction times appear when patients have to perform a incompatible reaction, like pushing alcohol away for an alcohol dependent patient. Shortened reaction times arise when patient perform a compatible reaction. Negative attitudes (incompatible) are related to avoidance tendencies, whereas positive attitudes (compatible) are related to approach tendencies. A positive score on the AAT indicates an approach bias towards alcohol. Problem drinkers appear to have a higher approach bias towards alcohol

related stimuli when compared to patients who do not experience problems with alcohol (Wiers, 2011). Furthermore, the seriousness of drinking correlates with the size of approach bias (Noel et al., 2006).

The current study uses an AAT within a CBM training to retrain automatically triggered action tendencies, and is also called the CBM Alcohol Avoidance training. In this training, patients receive pictures of alcoholic beverages and soft drinks on their computer screen and their task is to respond on an irrelevant feature with a ‘push’ (avoid) or ‘pull’ (approach) movement. This way, the patients are being trained to avoid alcohol instead of approaching it. Crucial in using an AAT is the zooming function (Klein, Becker, Rinck, 2011) in which the ‘pulling’ increases the size of the picture, and ‘pushing’ decreases the size. This creates the visual impression that pictures are coming closer to the individual when they are ‘pulling’, and vice versa for ‘pushing’. In the assessment study of Wiers, Rinck, Dictus and van den Wildenberg (2009) heavy drinkers appeared to be faster to pull than to push in response to alcohol related pictures. The results revealed an approach bias for these heavy drinkers.

A CBM based on an alcohol Approach Avoidance Task, was first tested among heavily drinking students and was successful in modifying the automatic action tendency to approach alcohol. More importantly, students who were successfully trained to avoid alcohol, drank less in a taste test which was taken directly after the training (Wiers, et al., 2010). This study has been replicated in an inpatient clinic in Germany and results showed that there was a mediation effect for approach bias. Here, extended reaction times became shortened due to the CBM-training, which caused a reduction in alcohol consumption (Eberl, et al., 2013).

### **Current Study**

Cognitive Bias Modification has been tested with dependent patients in clinical, inpatient, settings. However, many settings in the Netherlands are outpatient settings and a logical next step would be to test this kind of setting within the current study.

The current study uses an online CBM Alcohol Avoidance Training, which is offered in parallel with Treatment As Usual (TAU). The method underlying TAU is based on the principles of Cognitive Behavioral Therapy, which is effective in treating alcohol addictions (Hester & Miller, 2003). TAU consists of two delivery modes which could be Alcoholdebaas (web-based) or Verslavingdebaas (face-to-face), in either a brief or intensive version, tailored to the patients’ needs and preferences. Postel, de Haan, ter Huurne, Becker and de Jong (2010) examined the intensive version of Alcoholdebaas and it showed to be effective for

problem drinkers. After three month follow-up 68% of the participants within the intervention group showed a decrease in weekly alcohol consumption, compared to 15% in the control group. Furthermore, the intervention group showed better outcomes on depression, anxiety and perceived stress, and overall health status. Offering a CBM Alcohol Avoidance Training in parallel with TAU could accomplish even higher effectiveness levels.

## **Hypothesis**

The primary objective of this study is to investigate whether online CBM Alcohol Avoidance Training as addition to TAU decreases weekly alcohol consumption for problem drinkers, which leads to a higher proportion of patients reaching the low-risk drinking level (for men <22 standard units and for woman <15 standard units a week) in the post-assessment of the study. Expected is that patients within the experimental condition of the CBM will show a higher reduction in weekly alcohol consumption, and a higher percentage of these patients will reach the low-risk drinking level when compared to patients in the placebo condition. Outcome measure is self-reported weekly alcohol consumption at post-assessment.

### *Secondary outcomes*

For the secondary outcomes the effects of the CBM training on health status are examined, especially on depression, anxiety, stress and craving. Baborik, et al. (2016) suggest that a reduction in hazardous drinking is associated with faster improvement in depression and anxiety problems. Because of the hypothesis that patients within the experimental condition will show a higher reduction in alcohol consumption, it is also expected that these patients will show a greater reduction in depression and anxious feelings, compared to the placebo condition. Outcomes measure is the differences in total score of the DASS- 21 questionnaire at baseline TAU, and after completing TAU. For craving, we will assess the Obsessive Compulsive Drinking Scale (OCDS) at both moments.

Furthermore, the adherence of patients to the CBM-training is examined. The delivery mode of TAU is either web-based or face-to-face. Expected is that patients within the web-based treatment will have a higher adherence to the CBM-training compared to the face-to-face group, because of familiarity with an online intervention.

## **METHODS**

### **Study design**

The current study shows the preliminary results of a double-blind randomized placebo-controlled trial, in a real world setting. A double-blind design was used in this study,

because both therapist and patient remained ignorant about the condition the patients were assigned to. This could either be the experimental CBM Alcohol Avoidance training or the placebo condition. Allocation of patients was random, thus they had equal chances on being allocated to one of these conditions. Randomization was done computer-generated, without any involvement of the researchers. The method of minimisation (Scott et al., 2002) was used to balance for the type of CBT (web-based versus face-to-face TAU). In order to gain an equal number of patient with the same kind of treatment in both conditions, patients were randomly allocated to the conditions the fewest patients of that treatment have been assigned to so far.

Because of the two different types of delivery modes of TAU, there were different subgroups of patients. However, to examine the effectiveness the CBM training as an addition to TAU, there was no need to make a differentiation between these subgroups. Because of randomization it is expected that the experimental and placebo condition will be balanced concerning the kind and duration of treatment.

The Ethics Committee of Amsterdam Academic Medical Centre has approved the RCT on January 2015 (reference number 2014\_154#C20141463) and has been registered at the Netherlands Trial Register (NTR5087).

## **Participants**

All patients who completed the RCT before the 12<sup>th</sup> of October 2016 were included in the current study (n = 104). Computer-generated randomization assigned patients to either the CBM-training (experimental) condition or placebo (control) condition. Patients were at least aged 18, had a diagnosis of alcohol dependency and were following TAU at Tactus Addiction Treatment at the moment they participated in the CBM training. Furthermore, a good understanding of the Dutch language was needed, because the questionnaires, emails and explanatory texts were presented in Dutch. Also, Tactus applied two exclusion criteria for participating in the web-based TAU, and these were also used as exclusion criteria for the current study. These concerned the following criteria: (1) serious psychiatric illnesses with a chance to decompensate while decreasing alcohol consumption; (2) a chance of severe physical illnesses as a consequence of decreased alcohol consumption.

## **Procedure**

Patients received Treatment as Usual (TAU), existing of outpatient personalised care. They were recruited by their therapist, who invited them to participate in the CBM training. When informed consent was obtained, patients were randomly assigned to the experimental or

placebo condition of the CBM training. Figure 1 provides a flowchart of the way patients got included into the study and when baseline measurements and post-assessments were taken.

Before starting with their first session, patients received an email with instructions about the training and a link to login on the CBM-training website. Patients created an account with their user-ID to ensure anonymity and were recommended to follow two sessions a week, each with a duration of approximately ten minutes. The CBM training consisted of eight sessions, accompanied by a pre- and post-assessment session. At the start of each session, patients were asked to fill in additional questionnaires for the purpose of this study, concerning self-reported weekly alcohol consumption and the patients desire for drinking. Furthermore, the patients' awareness of the study condition was assessed during the post-assessment.

When patients followed the recommendations, the training should be completed after five weeks. As a reward for finishing the training, patients received a 20 euro voucher. Three, six and nine months after TAU started, participants were asked fill in follow-up assessments. In case of non-response regarding finishing training-sessions or filling in follow-up questionnaires, patients were contacted by either e-mail, telephone or both. Patients executed the training on their own computer. If necessary, they could contact the researcher by email to get help.



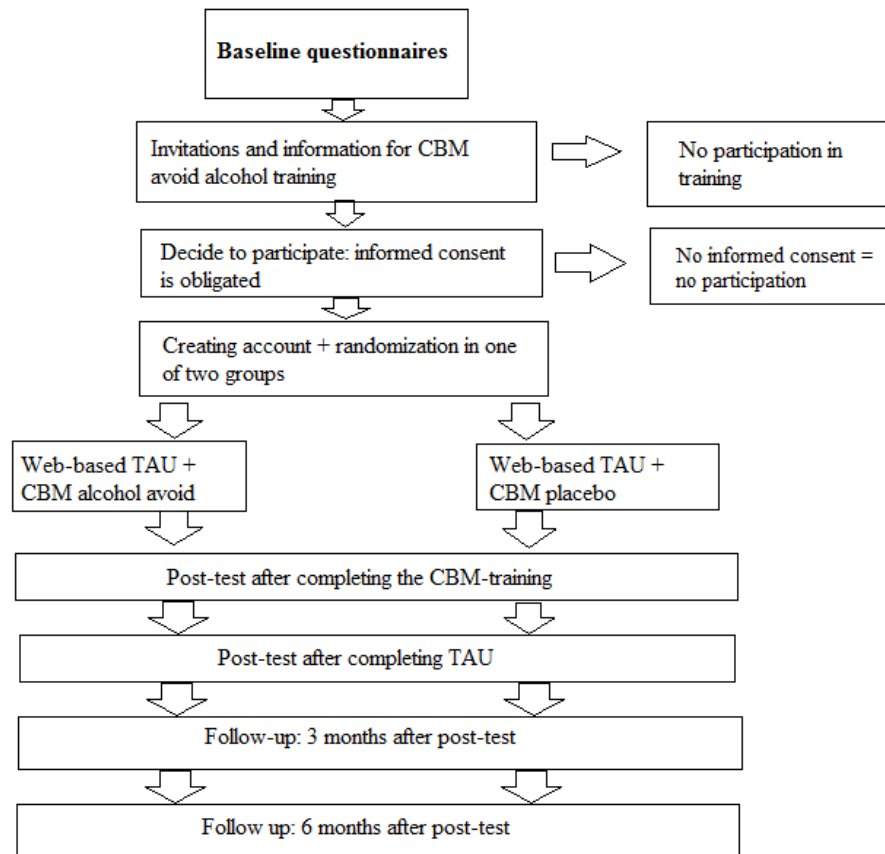


Figure 1. Flowchart participation into CBM-training and conducted measurements

Baseline questionnaires and post-assessments measurements were stored into several systems, depending on the patients TAU. For the web-based version, these data were retrieved from an online platform called ‘Alcoholdebaas-portal’, in which the researcher had a special account. Concerning the face-to-face treatment, Tactus stored all the data into their reporting system called USER. To gather the needed data for this study, intake and outcome questionnaires of TAU were requested at specialized staff of Tactus.

During the CBM-training, patients were asked to fill in certain questionnaires about drinking behaviour, refusal skills, motives for drinking and follow-ups. These questionnaires were designed and their data were stored in two online questionnaire platforms called ‘Qualtrics’ and ‘SurveyMonkey’. ‘Lotus’ was the driver behind the CBM Alcohol Avoidance training and executed the randomization of patients. Furthermore, Lotus saved (log)data about how the patients were performing in the training. Collected data from Lotus provided information about patients completing the training and which intervention group they were assigned to. All these systems and platforms were consulted. Figure 2 provides an overview of which systems this study consulted, with its specific data.

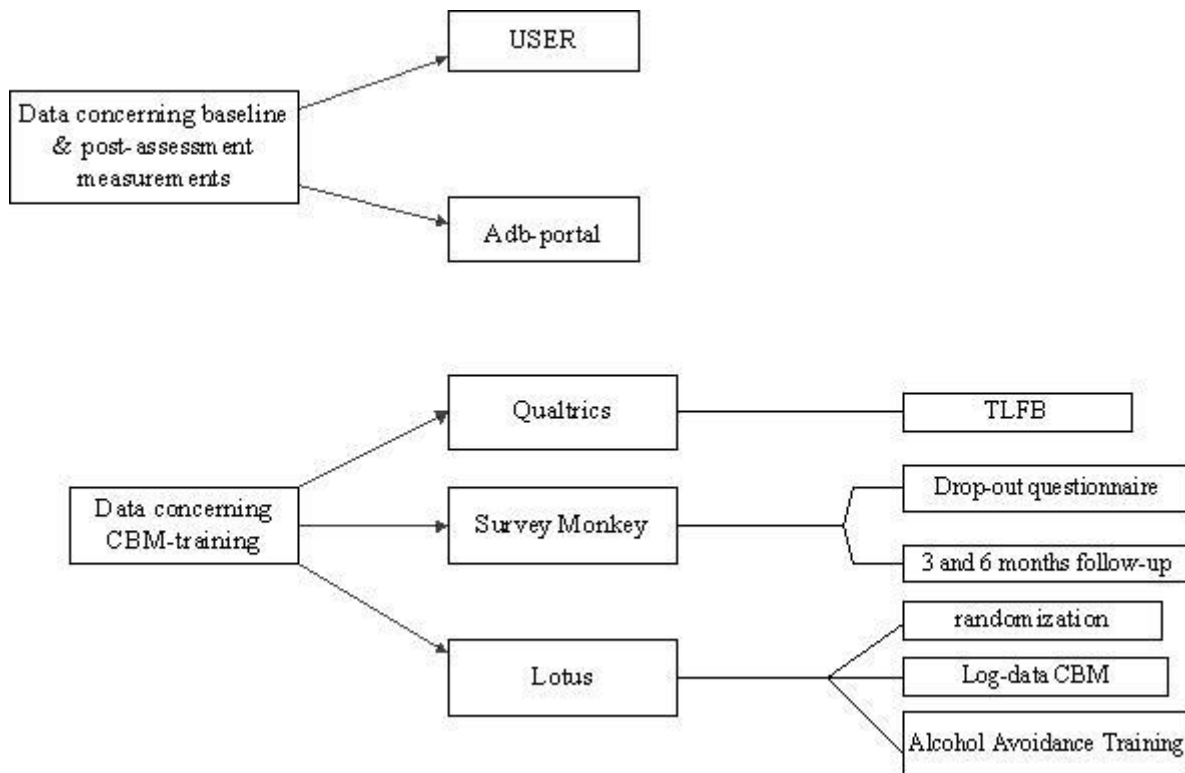


Figure 2. Consulted system and collected data

### Treatment as Usual (TAU)

Treatment as Usual (TAU) was based on principles of cognitive behavioral therapy (Hester & Miller, 2003) and motivational interviewing (Miller & Rollnick, 2002). These evidence-based techniques were applied during every treatment step of TAU. Cognitive behavioral therapy (CBT) is the most widely used evidence-based common practice in treating mental disorders. Briefly, the aim of CBT is changing unhelpful thoughts and attitudes, and trying to reverse these into helpful thoughts, in order to contribute to a behavioural change (Beck, 2011). According to Hester and Miller (2003) CBT is effective in treating alcohol addictions. Motivational interviewing is a counselling technique and focusses on exploring the health issue. The therapist asks questions about the pros and cons of the patients problem and behaviour (Rollnick, 2003). Therapists of Tactus used motivational interviewing during patient communication, motivation and adherence. CBT and motivational interviewing both consist of a general part in which the therapist tries to establish a behaviour change within the patient, by introducing or developing a concrete plan (Beck, 2011; Rollnick, 2003). Both techniques are broadly used by Tactus' therapists during TAU.

TAU had two different delivery modes. A face-to-face version which was called Verslavingdebaas, or a fully web-based version, called Alcoholdebaas. Depending on the patients individual preference and needs, patients followed either Verslavingdebaas or

Alcoholdebaas. Both treatments consist of the same basic ingredients; daily registration, function analysis of the patient’s drinking behaviour, behavioural change components and motivational interviewing. The only difference is the way of contact between therapist and patient, which happened synchronous in the real life face-to-face version and asynchronous via the online version (Postel, Haan & Jong, 2010).

The duration of TAU was either an intensive three month version or a shortened five week version, depending on the patients insight in their drinking behaviour. The intensive version consisted of two parts. Part one focused on the analysis of the patients drinking habits and consciousness of that behaviour. Part two was a goal setting assignment which guided patients towards reaching their goals, including a behaviour change. The shortened five week version solely focused on the behaviour change (part two). Figure 3 provides an overview of the main treatment steps, with a distinction between part one and part two.

Session	Part	Content	Intensive	Brief
1	1	Baseline assessment	x	x
2		Advantages and disadvantages	x	
3		Daily drinking diary	x	
4		Description of drinking moments	x	
5		Analysing drinking situations	x	
6	2	Goal setting	x	x
7		Helpful thoughts	x	x
8		Helpful behaviour	x	x
9		Decision moments	x	x
10		Action plan	x	x

Figure 3. Overview of treatment steps in TAU

During the whole treatment, therapists supported the patients with every step in their TAU by explaining assignments and providing feedback. Therapists either had a bachelor’s degree in social work or a master’s degree in psychology. They received a two-day training on the treatment protocol of TAU and could obtain advice form a multidisciplinary team. This multidisciplinary team consisted of treatment staff, an addiction medicine specialist, a psychologist and a supervisor. This team also assured quality through monitoring of client files and discussing fidelity during weekly client discussions (Bratti, et al. 2017).

For effectiveness of the treatment, skipping assignments or completing half of them, was not desired. To prevent this, tunnelling was implemented into TAU. This way, patients had to complete their current assignment, before they could move on to the next.

### **CBM-training**

The CBM training used in this study was based on the Approach Avoidance Task (AAT) (Wiers, et al. 2009). In this type of training, individuals received pictures of alcoholic beverages and soft drink on their computer screen, which were either tilted three degrees to the left or tilted to the right. Patients were instructed to respond to this irrelevant feature of the picture, instead of the content (i.e. alcohol or soft drink) to keep them ignorant about the intervention condition they were assigned to (Wiers, et al., 2011).

In the original version of an AAT, a joystick was used to perform 'push' or 'pull' movements (Wiers, Eberl, Rinck, Becker, & Lindenmeyer, 2011). However, assuming that most patients would not possess a joystick at home, a keyboard-operated version was developed to perform the AAT. In this version, keys on the computer-keyboard were assigned to create an approach/pull ('U'-key) or an avoidance/push ('N'-key) movement. Pressing the approach key, increased the size of the picture, whereas pressing the avoidance key decreased the size. This created the 'zooming'-effect, which was crucial in using an AAT, according to Klein, Becker, & Rinck, 2011.

Patients in the experimental condition of the CBM received 90% of the alcohol pictures presented in the push-format and 10% in the pull-format, and vice versa in formats for soft-drinks. In the placebo condition this ratio was 50-50. Pictures were presented in two formats (tilted left or right) x two repetitions. All pictures were repeated four times.

The complete CBM training consisted of eight sessions. Each session started with a practice block of twelve trails of grey squared pictures. After practice, the real training with 160 trails took place. These trails were divided over four blocks (40x4). Each block started with a fixation cross to keep patients attention focussed. Blocks were used to provide a short break and to make the task less boring. When patients did not respond, the trail was restarted after repeating the instructions.

## Measures

Table 1 shows which measurement instruments were used in the current study.

**Table 1.** *Measurement instruments: measures and assessment-time*

Measures	Baseline TAU	Pre-ass. CBM	Training	Post-ass. CBM	Post-test TAU
AAT		✓	✓	✓	
<b>Demographics</b>	✓				
DASS	✓				✓
OCDS	✓				✓
<b>Weekly alcohol consumption</b>	✓	✓	✓	✓	✓

*Note:* AAT: Approach-Avoidance Task, DASS: Depression Anxiety Stress Scale, OCDS: Obsessive Compulsive Drinking Scale Depression.

### *Primary outcome measures*

As for the primary objective, we assessed the proportion of patients reporting alcohol consumption below-risk drinking limits (< 22 for males and < 15 for females). Weekly alcohol consumption was measured by the Timeline Follow Back (TLFB) developed by Sobell and Sobell (1995), which concerned a self-report questionnaire. Within the TLFB patients were asked to estimate the amount of standard units alcohol they consumed during every day in the past week. Every session during the CBM training started with a TLFB, but only the ones from the pre-assessment CBM, post-assessment CBM and the ones from baseline TAU and post-assessment TAU were analysed to measure differences in alcohol use.

### *Secondary outcome measures*

Depression, anxiety and stress were measured with the brief 21-item version of the Depression Anxiety Stress Scale (Lovibond & Lovibond, 1995). According to Henry & Crawford (2005) and a study of Clara, Cox and Enns (2001), the DASS is a reliable ( $\alpha = .93$ ) and valid instrument to measure depression, anxiety and stress in non-clinical populations (Lovibond & Lovibond, 1995; Oei, Sawang, Goh, Mukhtar, 2013). Scores on DASS-21 were measured for all patients at pre-assessment TAU and post-assessment TAU. The severity labels of the DASS-21 items ranged from 'normal' to 'extremely severe'. Table 2 presents the cut-off scores for the conventional severity labels of depression, anxiety and stress based on the DASS-21.

**Table 2.** *Cut-off scores for severity labels of depression, anxiety and stress, derived from DASS-21 item questionnaire*

<b>Severity label</b>	<b>Depression</b>	<b>Anxiety</b>	<b>Stress</b>
Normal	0-9	0-7	0-14
Mild	10-13	8-9	15-18
Moderate	14-20	10-14	19-25
Severe	21-27	15-19	26-33
Extremely Severe	28+	20+	34+

The 5-item Obsessive Compulsive Drinking Scale (OCDS) was also implemented within pre-assessment TAU and used in analysis. This questionnaire measured the patients craving towards alcohol. With a total score above 12 patients had a high craving (De Wildt, et al., 2005). The OCDS was considered as a valid alcohol craving measurement (Anton, Moak & Latham, 1996; Young, Conner, Feeney, & Alyssa., 2010).

### **Statistical analysis**

*Statistical Package for the Social Science (SPSS) IBM Statistics version 21.0* was used for processing the collected data and for the analysis of results. Patient related data were made anonymous and hypotheses were examined with  $p < .05$  as statistically significant. Descriptive statistics were executed to represent numbers, means and standard deviations. The pre- and post-assessment measures were compared with repeated measures of ANOVA on the primary outcome of alcohol consumption and the secondary outcomes depression, anxiety, stress and craving. Differences in scores were analysed.

Effect sizes were measured by partial eta squared, which measured the proportion of total variance in a dependent variable that is associated with the membership of different groups, defined by an independent variable. A partial eta squared of 0.01 is considered a small effect, 0.06 a medium effect and a partial eta squared of 0.14 showed large effects (Levine, 2002).

### *Intention-to-treat analyses*

The measurements used for the analysis of alcohol consumption were derived from baseline TAU and post-assessment TAU. When data concerning post-assessment TAU were not available, post-assessment CBM was used by imputation through last observation carried forward, as data were longitudinal (Hamer & Simpson, 2009). However, this only counted for alcohol consumption, because neither DASS or craving were measured during post-

assessment CBM. For these variables, the last observation from baseline TAU were filled in as post-assessment. Missing data concerning baseline TAU were reported as missing and left out of the analyses.

## RESULTS

Figure 4 provides a flow-chart of the patients who participated into the current study. The study included 104 patients ( $n = 104$ ). Thirteen of these patient never started the CBM training and were therefore excluded from the study. This created a sample of 91 patients. However, data of three of these patients were removed because their baseline alcohol consumption was higher than three times the standard deviation above the average of the whole sample. Furthermore, two patients were excluded: one patient because of missing data concerning intake, and one patient because of a double registration. The non-active account of this last patient was removed, which created a final sample of 86 patients ( $n = 86$ ). All these patients completed at least one session of the CBM-training, yet not all filled in the last post-assessment questionnaire of the study ( $n = 9$ ) and therefore were considered non-completers. Concerning the CBM-completers group ( $n = 77$ ), 56 finished all 10 sessions of the CBM-training ( $n = 56$ ), the other patients ( $n = 21$ ) dropped-out from the training. The distribution of the CBM-completers into experimental ( $n = 27$ ) or placebo ( $n = 29$ ) condition was close to equal.

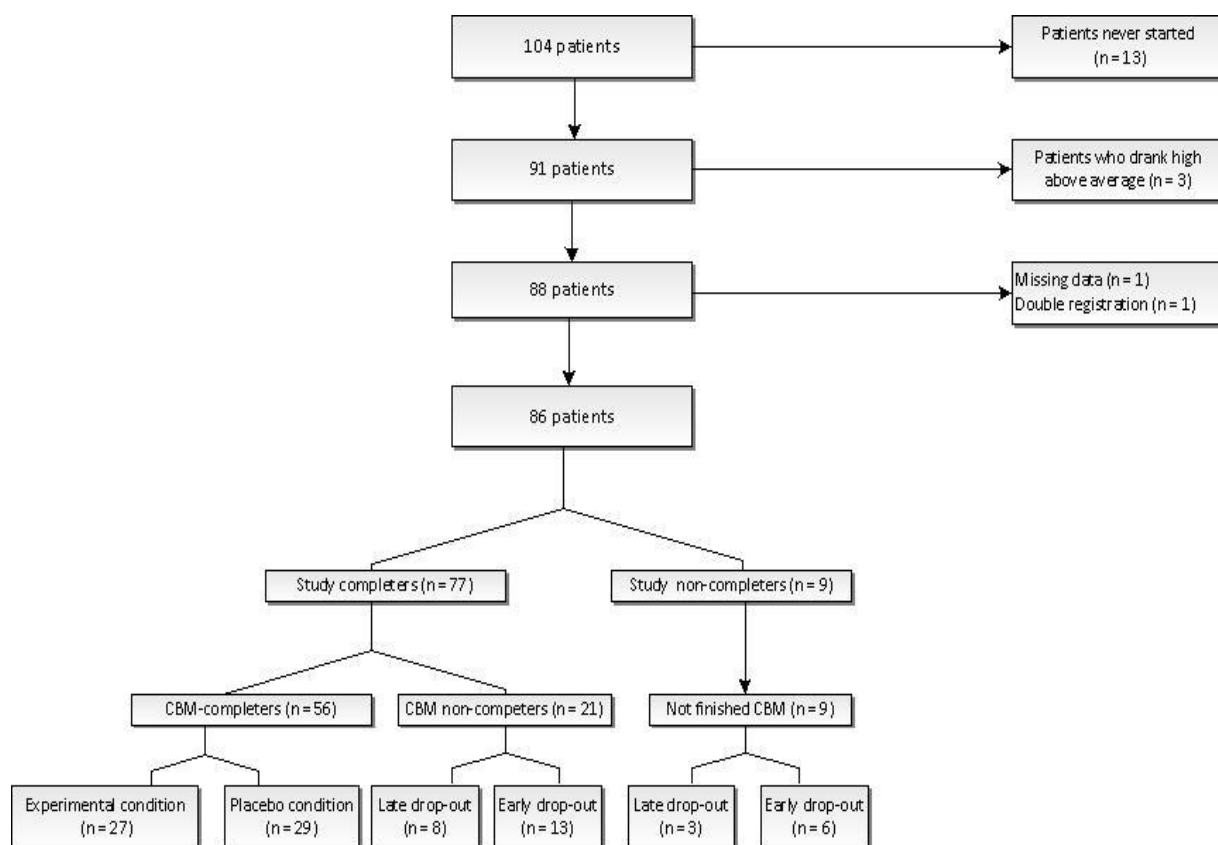


Figure 4. Flowchart

Note: Early drop-out = dropped-out in session 1 - 3

Late drop-out = dropped-out in session 4 - 10

## Baseline characteristics

The baseline characteristics of the patients are presented in table 3. Patients who started the study were 52 males (60.5%) and 34 females (39.5%) with an average age of 49.3 (M = 49.3, SD = 11.5, max. = 69, min. = 27) years. Most of the patients were higher educated (41.9%) and had an job (62%).

Regarding the whole intention-to-treat analysis, the distribution was 48 (55.8%) patients in the experimental and 38 (44.2%) patients in the placebo group. Furthermore, a higher number of patients followed the face-to-face version Vdb as TAU ( $n = 58$ ) when compared to the web-based version Adb ( $n = 28$ ). Concerning the CBM completers, the distribution was 27 patient in the experimental condition ( $n = 27$ ) and 29 patients in the placebo condition ( $n = 29$ ).

### Alcohol consumption

Overall, the average concerning alcohol consumption was 50.7 alcoholic beverages a week (M = 50.7, SD = 33.9) at baseline. Males drank an average of 51.4 (SD = 35.6) alcoholic beverages a week, whereas females drank 49.7 beverages a week (SD = 31.4). Average in the



experimental condition was lower ( $M = 44.7$ ), when compared to the placebo condition ( $M = 58.4$ ).

The differences in alcohol consumption showed no significance ( $p = .06$ ). Remarkable, differences between both intervention conditions were big. Males in the placebo condition drank more ( $M = 61.7$ ,  $SD = 38.1$ ) when compared to males in the experimental condition ( $M = 43.8$ ,  $SD = 32.3$ ). Females showed the same differences between groups. In the placebo condition females drank 53.8 alcoholic beverages a week and in the experimental condition they drank 46.1 alcoholic beverages a week. When comparing males and females in the experimental condition, males drank less ( $M = 43.8$ ,  $SD = 32.3$ ) when compared to females ( $M = 46.1$ ,  $SD = 26.9$ ). Additional analysis showed that there tended to be more males in the experimental condition who already drank within the responsible drinking limit at baseline. This could have caused the remarkable differences between males and females within the experimental condition

#### *DASS & Craving*

The experimental condition had an higher average concerning overall mental health ( $M = 30.7$ ,  $SD = 19.9$ ) than the placebo condition ( $M = 25.5$ ,  $SD = 18.5$ ). However, there were no significant differences found between the groups ( $t = 1.22$ ,  $p = .22$ ).

The average on craving for alcohol was 6.7 ( $SD = 4.0$ ) for all patients. With a threshold of 12, this was not considered a severe craving for alcohol. The experimental condition scored higher ( $M = 7.5$ ,  $SD = 4.1$ ) than the placebo condition ( $M = 6.2$ ,  $SD = 3.8$ ), but these differences were not significant ( $t = 1.55$ ,  $p = .12$ ). Considered these findings, the groups of patients appeared to experience relatively little complaints related to their alcohol consumption.

**Table 3.** Participant characteristics and differences between placebo and experimental group at baseline

Variable	Experimental (n = 48)	Placebo (n = 38)	X <sup>2</sup>	df	p
<b>Age, mean (SD)</b>	48.1 (11.3)	50.8 (11.7)	31.5	36	.681
<b>Gender, n (%)</b>			.188	1	.664
Male	30 (62.5)	22 (57.9)			
Female	18 (37.5)	16 (42.1)			
<b>Education, n (%<sup>a</sup>)</b>			.229	2	.892
Low <sup>b</sup>	20 (41.6)	16 (42.1)			
Intermediate <sup>c</sup>	13 (27.1)	8 (21.1)			
High <sup>d</sup>	13 (27.1)	9 (23.7)			
Missing, n	2 (4.2)	5 (13.1)			
<b>Treatment as Usual, n (%)</b>			.797	1	.671
Adb	15 (31.2)	13 (34.2)			
Vdb	33 (68.8)	25 (65.3)			
			<b>t</b>	<b>df</b>	<b>p</b>
<b>Alcoholconsumption<sup>e</sup>, mean (SD)</b>	44.7 (30.1)	58.4 (37.0)	-1.89	84	.062
Male, mean (SD)	43.8 (32.3)	61.7 (38.1)	-1.78	41	.083
Female, mean (SD)	46.1 (26.9)	53.8 (36.3)	-.696	27	.493
<b>Mental health<sup>f</sup>, mean (SD)</b>	30.7 (19.9)	25.5 (18.5)	1.22	84	.225
Depression (n = 83)	11.4 (9.2)	8.9 (8.2)	1.32	81	.190
Anxiety (n = 83)	7.1 (6.8)	5.9 (5.5)	.891	81	.376
Stress (n = 84)	12.5 (7.1)	11.2 (8.9)	.787	67	.434
<b>Craving<sup>g</sup> (n = 84), mean (SD)</b>	7.5 (4.1)	6.2 (3.8)	1.55	78	.124

Note. Adb = Web-based TAU Alcoholdebaas

Vdb = Face-to-face TAU Verslavingdebaas

<sup>a</sup> Percentage of all participants in experimental or control condition, excluded 7 missings

<sup>b</sup> A-level, HNC, level 3 NVQ / certificate, GCSE, O-level, levels 1 & 2 NVQ, or no qualifications

<sup>c</sup> BTEC, HND, diploma of higher education, foundation degree, level 4 & 5 NVQ

<sup>d</sup> Masters degree/post-graduate diploma & Bachelors degree, graduate diploma

<sup>e</sup> Weekly Alcohol consumption Time Line Follow Back, alcohol consumption measured in units

<sup>f</sup> Depression Anxiety Stress Scale

<sup>g</sup> Obsessive Compulsive Drinking Scale

## Treatment outcomes

### Alcohol consumption

For the intention-to-treat analyses table 4 is provided. The experimental condition started with an average of 44.7 (SD = 30.1) standard units alcohol per week at baseline, and 20.9 (SD = 26.9) after completing the treatment; a reduction of 23.8 units. Patients in the placebo condition drank an average of 58.4 (SD = 37.0) units at baseline and 17.4 (SD = 29.2) at post-assessment.

Results showed better outcomes for the placebo condition when compared to the experimental condition, see figure 5. The differences were significant ( $F = 6.22, p = .015$ ). This indicated an adverse treatment effect of the CBM training. Among males, this adverse effect of the treatment was confirmed ( $F = 7.95, p = .007$ ), with an effect size of .069. Remarkably, this effect was not found when analysing females ( $F = .250, p = .62$ ).

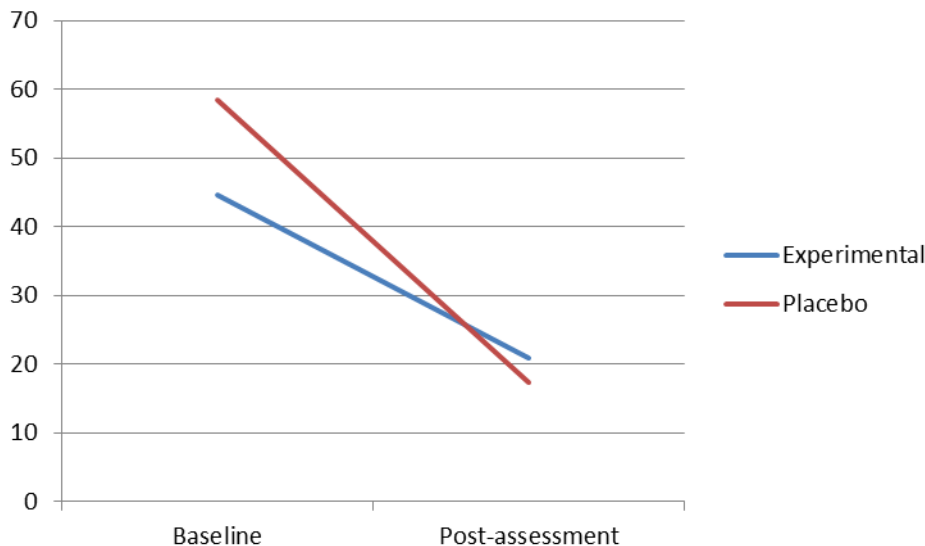


Figure 5. Interaction for time \* condition ( $n = 86$ ) on alcohol consumption

Regarding the responsible drinking limit, table 5 is presented. Both groups shifted obvious, from drinking above, towards drinking within the responsible limit. At pre-assessment, 77.1% of the patients in experimental condition and 89.5% of the patients in the placebo condition drank above the responsible limit. These percentages changed at post-assessment into 43.7% of the patients in the experimental condition and 28.9% in the placebo condition still drinking above the limit. When comparing the post-assessment of these conditions, the groups showed no significant difference for drinking above the limit ( $p = .570$ ), as well as for drinking the within limit ( $p = .947$ ).

Additional analysis were executed to examine whether excluding low drinking patients

(i.e. patients who already drank within the responsible drinking limit at baseline) would reduce the big difference between group averages. These results, presented in table 6, showed a higher reduction of alcohol consumption when comparing analysis with and without low-drinking patients. Both experimental ( $M = 53.5$ ) as well as the placebo condition ( $M = 65.2$ ) started with a higher average at baseline. When comparing these averages, significant differences were found among males ( $F = 5.41, p = .025$ ). However, this was not confirmed by females ( $F = .649, p = .427$ ).

**Table 4.** Treatment outcomes for the experimental and placebo condition separately, with an imputation for missing values at post-assessment ( $n = 86$ )

Variable	Experimental condition ( $n = 48$ )		Placebo condition ( $n = 38$ )		Difference scores		Test statistics <sup>a</sup>			
	Pre-assessment <sup>b</sup>	Post-assessment <sup>c</sup>	Pre-assessment	Post-assessment	Experimental	Placebo	F	df	p	$\eta^2$
<b>Alcohol consumption</b> , M (SD)	44.7 (30.1)	20.9 (26.9)	58.4 (37.0)	17.4 (29.2)	23.8	41.0	-	-	-	-
Interaction time*condition	-	-	-	-	-	-	6.22	86	.015	.069
- Males	43.8 (32.3)	26.0 (31.7)	61.7 (38.1)	19.6 (27.3)	17.8	42.1	7.95	52	.007	.137
- Females	46.1 (26.9)	12.4 (12.7)	53.8 (36.3)	14.5 (32.3)	33.7	39.3	.250	34	.621	
<b>Mental health</b> , M (SD)	30.7 (19.9)	18.0 (17.0)	25.5 (18.5)	17.2 (16.9)	12.7	8.3	-	-	-	-
Interaction time*condition	-	-	-	-	-	-	1.61	86	.207	
- Depression	11.4 (9.2)	7.4 (8.3)	8.9 (8.2)	5.1 (5.0)	4.0	3.8	.037	82	.847	
- Anxiety	7.9 (6.8)	3.1 (4.6)	5.9 (5.5)	4.2 (5.4)	4.8	1.7	4.63	82	.034	.054
- Stress	12.5 (6.6)	8.2 (6.3)	10.8 (8.8)	8.2 (9.0)	4.3	2.6	1.31	82	.255	
<b>Craving</b> , M (SD)	7.5 (4.1)	5.0 (2.6)	6.2 (3.9)	4.9 (3.4)	2.5	1.3	-	-	-	-
Interaction time*condition	-	-	-	-	-	-	1.39	84	.241	

Note:

<sup>a</sup>Treatment outcomes were measured with repeated measures (ANOVA), effect sizes with partial Eta squared

<sup>b</sup>Pre-assessment was measured before start of TAU

<sup>c</sup>Post-assessment was measured when TAU ended

**Table 5.** Responsible drinking limit patients at pre- and post-assessment

Variable	Experimental condition ( $n = 48$ )				Placebo condition ( $n = 38$ )				p	$X^2$
	Pre-assessment		Post-assessment		Pre-assessment		Post-assessment			
Responsible drinking	Male ( $n = 30$ )	Female ( $n = 18$ )	Males	Females	Males ( $n = 22$ )	Females ( $n = 16$ )	Males	Females		
Above limit, $n$ (%)	22 (73.3)	17 (94.4)	15 (50)	6 (33.7)	20 (90.9)	14 (87.5)	7 (31.8)	4 (25)	-	-
Within limit, $n$ (%)	8 (26.7)	1 (5.6)	15 (50)	12 (66.7)	2 (9.1)	2 (12.5)	15 (68.2)	12 (75)	-	-
Total above, $n$ (%)	37 (77.1)		21 (43.7)		34 (89.5)		11 (28.9)		.570	23.13
Total within, $n$ (%)	9 (22.9)		27 (56.3)		4 (10.5)		27 (71.1)		.947	6.67

Note: Responsible = drinking <22 (male) and <15 (female) weekly units of alcohol

**Table 6.** Analysis without low-drinking patients at baseline (n = 73)

Variable	Experimental (n = 39)			Placebo (n = 34)			Test statistics <sup>a</sup>			
	Pre-assessment	Post-assessment	Difference scores <sup>b</sup>	Pre-assessment	Post-assessment	Difference scores	F	df	p	np <sup>2</sup>
Alcohol consumption	53.5 ( <b>44.7</b> )	24.8 ( <b>20.9</b> )	28.7 ( <b>23.8</b> )	65.2 ( <b>58.4</b> )	19.5 ( <b>17.4</b> )	45.7 ( <b>41</b> )				
Interaction time * condition							5.19	73	.026	.068
- Males	57.6 ( <b>43.8</b> )	34.0 ( <b>26.0</b> )	23.6 ( <b>17.8</b> )	67.8 ( <b>61.7</b> )	21.5 ( <b>19.6</b> )	46.3 ( <b>42.1</b> )	5.41	42	.025	.119
- Females	48.7 ( <b>46.1</b> )	13.5 ( <b>12.4</b> )	35.2 ( <b>42.1</b> )	61.5 ( <b>53.8</b> )	16.5 ( <b>14.5</b> )	45.0 ( <b>39.3</b> )	.649	31	.427	

Note: In **bold** = mean alcohol consumption with low drinking patients (n = 86).

Low-drinking patients = Patients drinking within limit at baseline

<sup>a</sup>Test statistics were measured with repeated measures ANOVA

<sup>b</sup>Difference scores were based on differences between pre- and post-assessment

### *Mental health & Craving*

Table 4 also represents the results concerning the DASS total score, regarding the overall mental health as well as depression, anxiety and stress separately. Beneficial changes were found across all variables in both groups. Although the experimental condition started with an higher average at baseline ( $M = 30.7$ ,  $SD = 19.9$ ) than the placebo condition ( $M = 25.5$ ,  $SD = 18.5$ ). No significant differences were found ( $F = 1.61$ ,  $p > .05$ ).

Concerning the variables depression, anxiety and stress separately, there was found an intervention-effect for anxiety. The experimental group showed a stronger decrease in average compared to the placebo group. The differences between these groups were significant ( $F = 4.63$ ,  $p = .03$ ) with a medium effect size ( $\eta_p^2 = .054$ ). Figure 6 shows the interaction between groups for anxiety.

Concerning craving, the experimental as well as the placebo condition reduced in average. No significant differences were found between groups ( $F = 1.39$ ,  $p > .05$ ).

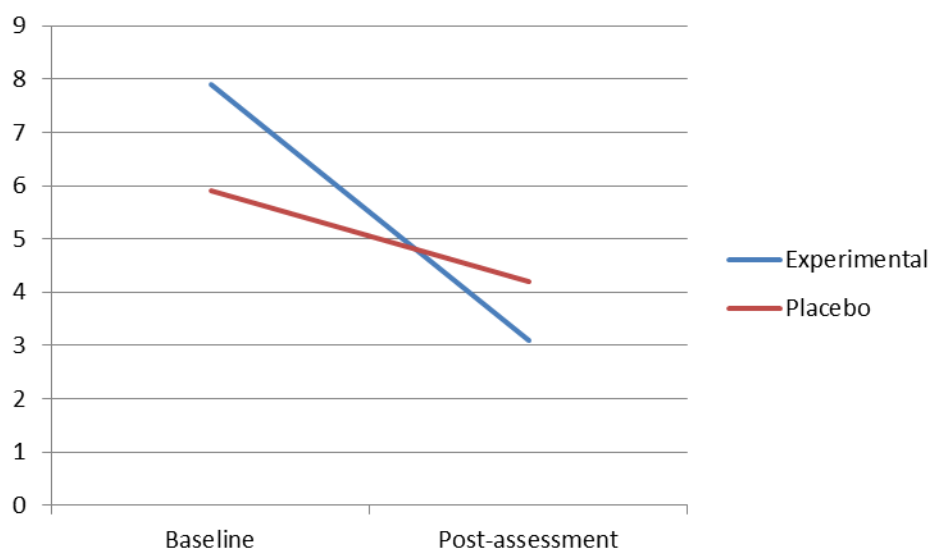


Figure 6. Interaction time \* condition for anxiety

### *CBM-completers*

Table 7 provides results concerning the patients who completed the CBM-training and thus finished all sessions ( $n = 56$ ). Although both groups showed reduction on all measured variables and this is beneficial for the CBM-completers, only alcohol consumption showed an significant effect of the intervention for the placebo condition ( $F = 7.27$ ,  $p = .009$ ). These results indicate an adverse effect of the treatment and are consistent with the previous findings of the current study on alcohol consumption. Differences between groups were significant for

males ( $F = 4.19$ ,  $p = .049$ ,  $\eta_p^2 = .113$ ), and thereby males confirmed the earlier findings within the intention to treat analyses. This adverse treatment effect could not be confirmed by females, because no significant differences were found ( $F = 3.32$ ,  $p > .05$ ), which is also consistent with the results for the intention to treat analyses.

#### *Adherence and completing CBM-training*

Table 8 concerned the intention-to-treat analyses ( $n = 86$ ) and the patients followed treatment. Almost all patients who followed an web-based Alcoholdebaas-treatment ( $n = 28$ ), completed the CBM-training (92.9%,  $n = 26$ ). In contrast, half of the patients who have followed face-to-face Verslavingdebaas ( $n = 55$ ) adhered and completed the training (52.7%,  $n = 30$ ). These differences were significant ( $p = .001$ ).



**Table 7.** Treatment outcomes for all CBM-completers and experimental and placebo group separately

Variable	Experimental condition (n = 27 )		Placebo condition (n = 29 )		Different scores		Test statistics			
	Pre-assessment <sup>a</sup>	Post-assessment <sup>b</sup>	Pre-assessment	Post-assessment	Experimental	Placebo	F	df	P	$\eta_p^2$
<b>Alcoholconsumption, M (SD)</b>	36.9 (24.5)	16.7 (13.5)	50.9 (34.1)	10.2 (16.9)	20.2	40.7	-	-	-	-
Interaction time*condition	-	-	-	-			7.27	56	.009	.119
- Males <sup>c</sup>	39.4 (27.8)	17.7 (13.9)	54.7 (36.8)	11.7 (18.8)	21.7	43.0	4.19	35	.049	.113
- Females <sup>d</sup>	32.0 (16.3)	14.8 (13.2)	45.6 (30.6)	8.2 (14.4)	15.4	37.4	3.32	21	.084	
<b>Mental health, M (SD)<sup>e</sup></b>	30.2 (20.9)	16.6 (15.9)	20.9 (16.1)	16.5 (16.3)	13.6	4.4	-	-	-	-
Interaction time*condition	-	-	-	-	-	-	2.32	56	.133.	
- Depression	11.9 (9.0)	7.1 (7.9)	8.3 (7.1)	4.8 (5.1)	4.8	3.5	.55	56	.463	
- Anxiety	7.2 (7.4)	3.2 (4.7)	5.9 (5.5)	3.9 (5.3)	4.0	2.0	2.83	56	.098	
- Stress	12.3 (7.1)	7.7 (6.3)	9.8 (6.5)	7.7 (7.8)	4.6	2.1	2.22	56	.142	
<b>Craving, M (SD)<sup>f</sup></b>	7.7 (3.7)	4.9 (3.6)	6.5 (3.6)	4.9 (3.6)	2.8	1.6	-	-	-	-
Interaction time*condition	-	-	-	-	-	-	1.23	56	.272	

Note: Treatment outcomes were measured with repeated measures (ANOVA), effect sizes with partial eta squared ( $\eta_p^2$ )

<sup>a</sup>Pre-assessment was measured before start of TAU

<sup>b</sup>Post-assessment was measured when TAU ended

<sup>c</sup>Males experimental group (n = 18), males in placebo group (n = 17)

<sup>d</sup>Females in experimental group (n = 9), females in placebo group (n = 12)

<sup>e</sup>Mental health = Depression Anxiety Stress Scale 21-item

<sup>f</sup>Craving = Total score of OCDS 5-items

**Table 8.** Test of CBM-training adherence, difference between followed TAU

Variable	Adb (n = 28)	Vdb (n = 58 )	p	$\chi^2$
Completers, n (%)	26 (92.9)	30 (51.7)	.001	14.56
Non-completers, n (%)	2 (7.1)	28 (48.3)		

Note: Adb = Alcoholdebaas

Vdb = Verslavingdebaas

## DISCUSSION

The aim of this study was to assesses the added value of an online CBM Alcohol Avoidance training as addition to treatment as usual in an outpatient alcohol treatment setting. The CBM-training aimed at re-training approach biases, such that patients would reduce their drinking behaviour. Expected was that a higher percentage of patients in the experimental condition would achieve a low-risk drinking limit (males < 22 units, females < 15 units) and would show better outcomes on depression, anxiety, stress and craving when compared to patients in the placebo condition.

### *Alcohol consumption*

A substantial reduction in average alcohol consumption was found in both groups. This corresponds with the expectations, because the effectiveness of TAU already has been proven (Postel, et al., 2010). However, we did not find an effect for the CBM-training as an addition to treatment as usual (TAU). Surprisingly, we did find indications for an adverse effect of the CBM-training on treatment outcomes. The placebo condition showed a stronger decrease in alcohol consumption, and this adverse effect was stronger for males and male CBM-completers. This is in contradiction with the expectations. An effect for the experimental condition was expected, because they started with an lower average at baseline. Wiers and colleagues (2011) suggest that the adverse effect could indicate that the approach bias within the experimental condition was possibly too low to measure an actual effect of the training. However, in the current study we did not involve measurements related to cognitive biases and so we cannot verify this statement. Other plausible explanations for the contradictory outcomes are that a) it could be an artefact due to 'regression to the mean', and b) the results of the placebo condition were different than what would be expected from a placebo condition. The patients within this condition got the 50/50 ratio of avoidance/approach pictures and this possibly re-trained their approach biases better than expected.

Several studies showed that combining a CBM-training with a CBT-treatment could be effective for a reduction in alcohol use (Wiers, Rink, Kordts, Houben, & Starck, 2010; Eberl, et al., 2013) and that treatment programs could be improved by focusing on automatic processes (Wiers, et al., 2007). Therefore, the CBM-training as addition to TAU used in the current study seemed valuable in treating problematic alcohol use. However, the current results cannot

support the findings and statements of Wiers, et al. (2007). Cristea, Kok and Cuijpers (2016) support the findings in the current study. They did a meta-analysis over 25 RCT's which all involved CBM interventions, 18 interventions on alcohol and 7 on smoking. They found no indication that CBM interventions, alone or in addition to another active intervention, would be effective on addiction outcomes and craving. However, a meta-analysis of Kakoschke, Kemps and Tiggemann (2017) showed that using an approach-avoidance task, like the CBM Alcohol Avoidance training in the current study, can successfully modify approach biases. This indicates that it could have beneficial outcomes in treating alcohol addictions. Because of these contradictory results of meta-analysis it is valuable to further investigate the effectiveness of the current CBM Alcohol Avoidance Training.

Another result worth arguing about are the differences in alcohol consumption between males and females within the sample. The percentage of males in the experimental condition that drank above the responsible drinking limit was lower when compared to females. This does not correspond with our expectations and national data concerning differences in alcohol consumption between males and females within the general population (van Laar & van Ooyen-Houben, 2016). Moreover, several studies have shown that males appear to drink more on average than females do (Popova, Rehm, Patra, Zatonski, 2007; Wilsnack, Wilsnack, Kristjanson, Vogeltanz-Holm & Gmel, 2009). For the current study the results could indicate that patients in the experimental condition are not representative for the target group. Low-drinking patients were included in the sample for practical reasons. Additional analysis without these low-drinkers showed that males drank more when compared to females, in both conditions. This indicates that excluding low drinkers from the sample would give a more representative experimental condition and groups would be better comparable due to less difference between averages at baseline.

### *Secondary outcomes*

Expected was that the CBM-training in addition to TAU would cause a reduction in depressive feelings. In general we found a reduction in depressive feelings, but not significant and no indication for an additional effect of the CBM-training. The same expectations counted for anxiety. For this variable we did find an effect of the CBM-training in the experimental condition. However, this was in contradiction with the outcomes of alcohol consumption, which appeared to be beneficial for patients in the placebo condition. It made it difficult to

draw conclusions because these results are contradictory. The tension-reduction theory (Greeley, & Oei, 1999) helps in giving plausible explanations for these results, by stating that people drink alcohol because it reduces tension and anxious feelings, which are very common in alcohol addictions. Thus, people who reduce their alcohol consumption seriously, could get more anxious, for example towards the consequences of not drinking alcohol. Probably, patients in the placebo condition experienced more anxiety, because they had a higher reduction in alcohol consumption than the experimental condition.

Although both groups appeared to have a lower craving at post-assessment, the results of the CBM-training did not show effects on craving towards alcohol. Thereby, the hypothesis that a reduction in alcohol would cause a reduction in craving, can be rejected. Our results corresponds with the findings of Cristea, Kok and Cuijpers (2016) where CBM-interventions showed no additional effects for craving. Probably, this is related to the fact that we did not find effects on reduction of alcohol use. Nevertheless, according to Manning (2016), relapse in craving commonly occurs within the first weeks after a treatment. The measurements used in the current analysis were not taken directly after the CBM-training, but three months after the start of TAU. Craving could be improved due to the CBM-training, but we did not measure it. Furthermore, the study of Manning uses a larger sample size. This indicates that when the current study would have a larger sample size, the possibility to find effects on craving would likely increase.

#### *Adherence & completing CBM-training*

Concerning the whole sample, the percentage of patients who followed web-based Alcoholdebaas as TAU and finished all the sessions of the CBM-training is much higher compared to patients who followed face-to-face Verslavingdebaas. There are many imaginable explanations for this result. Presumably, patients following Alcoholdebaas are more familiar with a web-based treatment and therefore have a higher adherence. Alcoholdebaas patients are possibly reminded more of the CBM-training, because their TAU is online and unconsciously their computer reminds them to adhere, while Verslavingdebaas patients should remind themselves. Although the adherence of the Verslavingdebaas patients was low, this could not be a possible explanation for the absence of a CBM-effect, because analysis with only fully adhered patients confirmed no effect of the CBM training.

## **Strengths & Limitations**

A strength of the current study was the examination of an online CBM Alcohol Avoidance training as addition to TAU in an outpatient setting. As most studies examine the effectiveness of CBM interventions in clinical or laboratory settings, the current study assesses the effectiveness in an ambulatory setting. Patients could practice and work on the training in their own personal environment, in which there would probably be more alcohol-related cues and challenges (like craving), when compared to a clinical setting. Therefore, the results of the current study are more applicable for 'real world' practice and non-clinical populations. Additionally, it gives a first impression of the possibilities and concerns of the broader dissemination of an online CBM-training.

A double-blind randomized controlled trial with an experimental and a placebo condition was used to assess the effectiveness of the online CBM Alcohol Avoidance training. Using this study design was a strength, as we were interested in the causation between the CBM training and alcohol consumption, overall mental health and craving. Regarding to Ernest, Jandrain and Scheen (2015), the use of an RCT is the most appropriate in establishing causation.

The current findings are in contradiction with the expectations and somewhat difficult to explain. Analysis has been done with preliminary data and therefore the sample size was not enough to make fundamental strong statements about the effectiveness of the CBM-training. A power calculation on the interaction of alcohol consumption showed a low power (.693) for the current study. That is why the conclusions about the effectiveness of the training should be carefully interpreted (Ellis, 2010). When the sample had more power, conclusion could have been drawn with more scientific evidence. Sample sizes in other and quite similar studies (Wiers, et al. 2010; Wiers, et al. 2011; Manning, et al., 2016) support this.

The method of last observation carried forward (LOCF) was used to impute missing data. Although this created a complete dataset on alcohol consumption and analysis could be executed, it may have caused a biased sample on all measured variables where LOCF was applied, as it ignores whether the patients situation was improving or deteriorating at the moment of drop-out. We used constructed data at post-assessment and it is arguable whether the last observation is appropriate for the patients circumstances at post-assessment (Hamer & Simpson, 2009). On the other hand, if we did not impute missing data, it could have generated false results in analysis.

The current study used an experimental and a placebo condition. However, we did not use a real control condition, in which patient solely followed TAU and no form of the CBM training. Neither we used a condition in which patient only followed the CBM training and no TAU at all. If we had added a control condition like this, we could investigate if the effects were solely due to TAU and state with more confidence that the CBM-training has no (additional) effects.

Although randomization was fully standardized by computers, it created large differences between group and this made drawing conclusions about the results of the CBM-training difficult. Given the results it seemed that low drinkers were assigned to the experimental condition more often and this made the procedure of randomizations doubtful. However, we did a check with a test-account and this secured that randomization happened randomly.

In cases of significant effects, we measured effect sizes with partial eta squared, which is common when using repeated measures. Deviating from the eta squared, the partial eta squared only measures effects and leaves other independent variables or interactions partially out (Richardson, 2011). Using partial eta squared was preferred, because it is not a percentage of the total sum of squares and not additive, which is the case when using eta squared. However, the use of partial eta squared could also have its limitations. It tends to be biased, especially when the sample size is small, which is the case in the current study. Probably, omega squared or epsilon squared would be better choices, because these effects sizes offer corrections (Levine, 2002).

All post-assessment measurements used in analysis were taken after patients completed their TAU. This could have caused some bias in reliability of the data, because we took the post-assessment of TAU as outcome measure and ignored the post-assessment of the CBM training. It is doubtful if only using post-assessment TAU is appropriate, because there was a period of three weeks between completing TAU and completing the CBM-training. Within this three weeks patients could have relapsed in or improved on their behaviour. For example, patients could have reduced their alcohol consumption during the CBM training. Yet, we did not use these measurements in analysis, although they could be valuable for treatment outcomes.

The study of Wiers, et al. (2007) showed that treatment programs could be improved when focussing more on automatic processes instead of reflective processes. Wiers, et al. (2011; 2013) used alcoholic inpatients in their study, but never offered CBM-AAT in parallel with another active treatment. Yet, they state that offering a CBM training could endorse the

effectiveness of the treatment. The current study examined if offering an CBM-AAT in parallel with TAU would improve treatment outcomes. However, our findings cannot support the statements of Wiers and colleagues. An explanation for this is that solely TAU caused desired results for patients and offering a CBM training had no added value. For this reason, it is recommended for further research to perform analysis with the TAU completers only. At first, to investigate if only following TAU was sufficient enough to accomplish desired results. And second to investigate if patients who not finished TAU, but were included, caused some bias in the reliability in the data.

### **Implications**

This study showed the preliminary outcomes of a randomized controlled trial, which is still in progress. Data will eventually be more extended, with a larger sample size and more power. Based on experience gathered during the current study, some implications can be done for the future.

There were several patients excluded from the current study because they were considered as outliers. Although this happened for the heavy drinking patients who drank high above average, very low drinking patients who drank below the responsible drinking limit were not removed. For example, patients who stopped their drinking at the start of TAU, because they followed the treatment for relapse prevention. Most of this group of low-drinking patients appeared to be within the experimental condition. Perhaps, the reason why we found no effects of the CBM training in the experimental condition was because of these low-drinking patients, as they had little or no room to show improvement. Their situation could only stay the same or deteriorate. However, additional analysis were done without low drinking patients and confirmed the results of the analysis with low-drinking patients; a significant effect among males in the placebo-condition, but not for the experimental condition. In contradiction, averages between groups got closer to each other and this made the groups better comparable. It is recommended for the current study to use analysis without the patients who drank extremely high and below the average of the whole sample.

It was surprising that only males within the placebo condition showed a significant difference on alcohol consumption. This adverse effect of the treatment was also found among males in the CBM-completers group. Despite the fact that the results of females were without any significant difference, the effect of the males should not be neglected. The effect of the

females in the CBM-completers group is almost significant. When this RCT continues with more power, it is possible that females will eventually also show significant differences. This gives an indication to examine this more comprehensively in the future. Then, statements about the adverse effect of the CBM-training can be stronger substantiated.

Several studies show that positive scores on approach biases could be a predictor for increased alcohol consumption (Wiers, et al., 2009; Wiers, et al. 2010). Other studies show that there could be an effect on approach bias, but not on behaviour change. When the RCT continues it is recommended to examine the (changes in) approach biases of patient, which are measured during the AAT-sessions within the CBM-training. In the current study we did not include analysis on reaction times, but it would be an added value to examine if changes in approach biases cause a behaviour change. Furthermore, it could be examined if patients in the placebo condition would have a stronger approach bias towards alcohol. Concerning Wiers, Eberl, Rinck, Becker and Lindenmeyer (2011) patients with a stronger approach bias, will show stronger effects of the CBM training. This could explain why there was found a CBM effect in only the placebo condition within the current study.

Significant differences were found between groups for anxiety. Also, when alcohol consumption, depressive and stressful feelings and craving towards alcohol were measured separately, the averages of these variables reduced. Thus, we found effects, but not all significant. This indicates that the follow-up study with extended data should perform a moderation-analysis for depression, anxiety, stress and craving to investigate if any of these variables would influence alcohol consumption.

Within the CBM-training it is the patients task to avoid alcohol and to approach soft-drinks. The pictures were derived from the Amsterdam Beverages Picture Set (ABPS), which was found to be valid (Pronk, Deursen, Beraha, Larsen & Wiers, 2015). However, the healthiness of the alternatives for alcohol are arguable. The Dutch council for health and welfare discourages the intake of soft drinks, because it would be bad for one's health at the long term. They advise to drink soft drinks only once a week, or not at all. Water, milk, coffee and tea are good alternatives for soft-drinks (Gezondheidsraad, 2015). The discussion about soft drinks not being healthy started after the validation of the ABPS. Therefore, the picture set should be adapted by transforming the 'unhealthy' alternatives for alcohol into healthy alternatives, and this should be applied into the CBM training. The current intervention is a



health promoting intervention and the aim is to teach the patients healthy behaviour, so offering healthy alternatives is desired.

When the alternatives are being adapted, another picture-related concern should be considered. Pictures within the CBM-training should be made more appealing and realistic, in order to prevent that patients react different than the instructions of the training and therefore cause bias in measurements. For example, a patient will push on a certain brand of beer because it is unfavourable, although the CBM format tells the patient to pull. Adding personalized and context related pictures could be a solution to this problem. For example, a beer standing on a bar or the patients preferable brand or type of alcohol. Regarding Nees, Diener, Smolka and Flor (2012) alcohol pictures displayed in a social setting causes a stronger emotional response. This way, patients could feel more attracted to the pictures and we avoid the problem that patients will lose their motivation to train because the pictures are not appealing enough. Furthermore, Boffo, Pronk, Wiers and Mannarini (2015) suggest that cognitive biases are most effectively triggered by simple stimuli, that solely feature a stand-alone alcoholic or non-alcoholic beverage. This suggests that context related pictures would be less effective. Thus, in order to be more appealing and effective, the pictures in the training should be adapted to personalized, stand-alone pictures.

### *Overall conclusion*

Based on the current findings, it cannot be concluded that a CBM-training has an added value to treatment as usual in treating alcohol addictions. However, the results show beneficial outcomes for patients on all measured variables and could reaffirm that CBT-treatments are effective in treating alcohol addictive patients. It is valuable to continue the RCT. Eventually, the study will have more power, aiming at a more plausible randomization of patients and smaller differences between averages within the groups. This way, more scientific evidence can be obtained to draw conclusions about the effectiveness of the CBM-training as addition to treatment as usual.

### *Recommendations for Tactus Addiction Treatment*

Although the current study had some limitations and the preliminary results are not promising, it is still valuable to continue the RCT to further investigate the added value of a CBM training as addition to TAU. The results and conclusion in the current study are based on

a relatively small sample and the study had little power. The contradictory results give even more reason to further investigate them in the future. Current results should be interpreted as a first indication, but had not enough scientific evidence and power to state with confidence that the CBM Alcohol Avoidance training would not have any added value to the treatment as usual. For further research, the limitations of the current study and the implications that have been done, should be taken into account.

### **ABBREVIATIONS**

CBT: Cognitive Behavioural Therapy; CBM: Cognitive Bias Modification; AAT: Approach-Avoidance Task; TAU: Treatment As Usual; RCT; Randomized Controlled Trial; TLFB: Time Line Follow Back; OCDS: Obsessive Compulsive Drinking Scale; DASS: Depression Anxiety Stress Scale.

### **ACKNOWLEDGEMENTS**

I would like to thank my supervisors Marcel Pieterse and Marloes Postel for their useful feedback and accompaniment during this thesis. Furthermore, I would like to thank Tactus Addiction Treatment and the University of Twente for offering me this research assignment. It was a great experience and one of the most challenging assignments during the whole master's program. A special thanks goes to Marleen Bratti, who started the RCT and always was accessible for questions, Marielle for teaching me everything about the various systems for assessing the data, and all the patients who participated into the study. I would like to thank several friends and family who always supported me during this period. Especially Bram for his comprehensive feedback during the writing process. Last, I would like to give my very best wishes to Melissa, in continuing this RCT and her PhD-project.

### **REFERENCES**

Anton, R.F, Moak, D.H., & Latham, P.K. (1996). The Obsessive Compulsive Drinking Scale: A new method of assessing outcome in alcoholism treatment studies. *General Psychiatry*, 53(3): 225-31.

Bahorik, A.L., Leibowitz, A., Sterling, S.A., Travis, A., Weisner, C., Satre, D.D. (2016). The role of hazardous drinking reduction in predicting depression and anxiety symptom improvement among psychiatric patients: A longitudinal Study. *Journal of Affective Disorders*, 206: 169-173.

- Baron, R.M., Kenny, D.A. (1986). The moderate-mediator variable distinction in social psychological research: conceptual, strategic and statistical considerations. *Journal of personality and social psychology*, 51(6): 1173-1182.
- Beck, J.S. (2011). *Cognitive Behavior Therapy: Basics and beyond* (2<sup>nd</sup> ed.). New York: The Guilford Press.
- Bentler, P.M., & Speckart, G. (1979). Models of attitude-behaviour relations. *Psychological Review*, 86, 452-464.
- Bewick, B.M., Trusler, K., Barkham, M., Hill, A.J., Cahill, J. & Mulhern, B. (2008). The effectiveness of web-based interventions designed to decrease alcohol consumption: A systematic review. *Preventive Medicine*, 47(1): 17-26.
- Boffo, M., Pronk, T., Wiers, R. & Mannarini, S. (2015). Combining Cognitive bias modification training with motivational support in alcohol dependent outpatients: study protocol for a randomized controlled trial. *Biomed Central: Trials*, 16(63).
- Bratti, M.K.J, Postel, M.G., Pieterse, M.E., Ben Allouch, S., Wiers, R.W., Bohlmeijer, E.T. & Salemink, E. (2017). Augmenting outpatient alcohol treatment as usual with online Alcohol Avoidance Training: Study protocol of a double-blind randomized controlled trial. *BMC Public Health*: In press.
- Clara, L.P., Cox, P.J. & Enns, M.W. (2001). Confirmatory Factor Analysis of the Depression Anxiety Stress Scales in depressed and anxious patients. *Journal of Psychopathology and Behavioral Assessments*, 23, 61-67.
- Cristea, I.A., Kok, R.N., & Cuijpers, P. (2016). The Effectiveness of Cognitive Bias Modification Interventions for Substance Addictions: A Meta-Analysis. *PLoS ONE*, 11(9): e0162226.
- Cunningham, J.A., Wild, T.C., Cordingley, J., van Miero, T. & Humphreys, K. (2009). A randomized controlled trial of an internet-based intervention for alcohol abusers. *Addiction* 104(12):2023-2032.
- Danner, U.N., Aarts, H. & de Vries, N.K. (2008). Habit vs. Intentions in the prediction of future behaviour: The role of frequency, context, stability and mental accessibility of past behaviour. *British Journal of Social Psychology*, 47, 245-265.

- Eberl, C., Wiers, R. W., Pawelczack, S, Rinck, M., Becker, E. S., & Lindenmeyer, J. (2013). Approach bias modification in alcohol dependence: Do clinical effects replicate and for whom does it work best? *Developmental Cognitive Neuroscience*, 4, 38-51.
- Ellis, P.D. (2010). *The Essential Guide to Effect Sizes: An introduction to Statistical Power, Meta-Analysis and the Interpretation of Research Results*. United Kingdom: Cambridge University Press
- Ernest, P., Jandrain, B. & Scheen, AJ. (2015). Strengths and weaknesses of randomised clinical trials: evolving changes according to personalized medicine. *Revue Medicale de Liege*, 70(5-6):232-6.
- Field, M. & Cox, W.M. (2008). Attentional bias in addictive behaviors: A review of its development, causes and consequences. *Drug and Alcohol Dependence*, 9:1-20.
- Field, M., Schoenmakers, T. & Wiers, R. W. (2008). Cognitive processes in alcohol binges: A review and research agenda. *Current Drug Abuse Reviews*, 1, 263-279
- Gezondheidsraad. (2015). *Alcohol - Achtergronddocument bij Richtlijnen goede voeding 2015*. Den Haag: Gezondheidsraad. Publicatienr. A15/05.
- Greeley, J. & Oei, T. (1999). *Psychological Theories of Drinking and Alcoholism* (2nd ed.). New York: The Guildford Press.
- Hamer, R. & Simpson, P. (2009). Last Observation Carried Forward versus Mixed Models in the Analysis of Psychiatric Clinical Trials. *American Journal of Psychiatry*, 166(6): 639-641
- Hester, R.K. & Miller, W.R. (2003). *Handbook of alcoholism treatment approaches: effective alternatives*. Bosten: Allyn and Bacon.
- Henry, J.D. & Crawford, J.R. (2005). The short-form version of the Depression Anxiety Stress Scales (DASS-21): construct validity and normative data in a large non-clinical sample. *British Journal of Clinical Psychology*, 44, 227-239.
- Heyes, A.F. (2009). Beyond Baron and Kenny: statistical mediation analysis in the New Millennium. *Communication Monographs* 76(4): 408-420.

- Houwer, J de. (2003). A structural analysis of indirect measures of attitudes. In: *The Psychology of Evaluation: affective processes in Cognition and Emotion*; p. 219-244.
- Kakoschke, N., Kemps, E., & Tiggemann, M. Approach bias modification training and consumption: A review of the literature. *Addictive behaviors*, 64(1):21-28
- Klein, A.M., Becker, E. S., & Rinck, M. (2011). Approach and Avoidance Tendencies in Spider-fearful Children: The Approach-Avoidance Task. *Journal of Child and Family Studies*, 20(2):224-231.
- Levine, T. (2002). Eta squared, Partial Eta Squared, and Misreporting of Effect Size in Communication Research. *Human Communication Research*, 28(4): 612-625.
- Locke, L.A., & Latham, G.P. (2002). Building a practically useful theory of goal setting and task motivation. *American Psychologist*, 57(9): 705-717.
- Lovibond, S.H., & Lovibond, P.F. (1995). *Manual for the Depression Anxiety Stress Scale* (2<sup>nd</sup> ed.). Sydney: Psychology Foundation.
- Nees, F., Diener, C., Smolka, M., & Flor, H. (2012). The role of context in the processing of alcohol-relevant cues. *Addiction Biology*, 17:441-51.
- Noel, X., Colmant, M., Linden, M. van der, Bechara, A., Bullens, Q., Hanak, C., & Verbanck, P. (2006). Time Course of Attention for Alcohol Cues in Abstinent Alcoholic Patients: The Role of Initial Orienting. *Alcoholism: Clinical and Experimental Research*, 30(11), 1871-1877.
- MacLeod, C. & Mathews, A.(2012). Cognitive bias modification approaches to anxiety. *Annual Review of Clinical Psychology*, 8,189-217
- Manning, V., Steiger, P.K., Hall, K., Garfield, J., Flaks, G., Leung, D., Hughes, L.K., Lum, J., Lubman, D., & Verdejo-Garcia, A. (2016). Cognitive Bias Modification Training During Inpatient Alcohol Detoxification Reduces Early Relapse: A Randomized Controlled Trial. *Alcoholism: Clinical and Experimental Research*, 40(9): 2011-2019
- Martenau, T.M., Hollands, G.J. & Fletcher, P.C. (2012). Changing Human behaviour to prevent disease: the importance of targeting automatic processes. *Science*, 337(6101): 1492-1495

- Miller, W.R. & Rollnick, S. (2003). Motivational Interviewing: preparing people for change, 2<sup>nd</sup> edition. *Journal for Healthcare Quality* 2003, 25(3): 46.
- Oei, T.P.S., Sawang, S., Goh, Y.W., & Mukhtar, F. (2013). Using the Depression Anxiety Stress Scale 21 (DASS-21) across cultures. *International Journal of Psycholog*, 48(6):1018-29
- Ouellette, J.A. & Wood, W. (1998). Habit and intention in everyday life: The multiple processes by which past behaviour predicts future behaviour. *Psychological Bulletin*, 124, 54-74.
- Palfai, T.P. & Ostafin, B.D. (2003). Alcohol-related motivational tendencies in hazardous drinkers: Assessing implicit response tendencies using the modified IAT. *Behaviour Research and Therapy*, 41:1149-1162.
- Popova, S., Rehm, J., Patra, J. & Zatonski, W. (2007). Comparing Alcohol consumption in central and eastern Europe to other European countries. *Alcohol Alcohol*, 42: 465-473.
- Postel, M.G., De Haan, H.A. & De Jong, C.A. (2010). Evaluation of a e-health program for problem drinkers: a pilot study. *Substance use & misuse*, 45(12): 2059-2075.
- Postel, M.G., de Haan, H.A., ter Huurne, E.D., Becker, E.S. & de Jong, C.A.J. (2010). Effectiveness of a Web-Based intervention for Problem Drinkers and Reasons for Dropout: Randomized Controlled Trial. *Journal of Medical Internet Research*, 12(4), e68.
- Preacher, K.J. & Heyes, A.F. (2004). SPSS and SAS procedures for estimating indirect effects in simple mediation models. *Behaviour research methods, instruments & computers* 2004, 36(4): 717- 731.
- Pronk, T., van Deursen, D.S., Beraha, E.M., Larsen, H., Wiers, R.W. (2015). Validation of the Amsterdam Picture Set: A controlled Pictures Set for Cognitive Bias Measurement and Modification Paradigms. *Alcoholism, clinical and experimental research*, 39(10): 2047-2055.
- Rehm, J., Mathers, C., Popova, S., Thavorncharoensap, M., Teerawattananon, Y., Patra, J. (2009). Global burden of disease and injury and economic cost attributable to alcohol use and alcohol-use disorder. *Lancet*, 373: 2223-2233.
- Rinck, M., & Becker, E. S. (2007). Approach and Avoidance in fear of spiders. *Journal of Behavior Therapy and Experimental Psychiatry*, 38, 105-120

- Salemink, E., van den Houdt, M., & Kindt, M. (2009). Effects of positive interpretive bias modification in highly anxious individuals. *Journal of Anxiety Disorders*, 23(5): 676-683.
- Scott N.W., McPherson, G.C., Ramsay, C.R., Campbell, M.K. (2002). The method of minimization for allocation to clinical trials: a review. *Control Clinical Trials*, 23(6):662-674.
- Smith, E.R. & DeCoster, J. (2000). Dual-Process Models in Social and Cognitive Psychology: Conceptual Integration and Links to Underlying Memory Systems. *Personality and Social Psychology Review* 2000, 4(2): 108-131.
- Sobell, L.C. & Sobell, M.B. (1995). *Alcohol Time Line Follow Back Users' Manual*. Toronto, Canada: Addiction Research Foundation.
- Strack, F. & Deutsch, F. (2004). Reflective and Impulsive Determinants of Social Behaviour. *Personality and Social Psychology Review*, 8(3), 220-247.
- Thush, C., Wiers, R. W., Moerbeek, M., Ames, S. L., Gernard, J. L., Sussman, S., Stacy, A. W. (2009). Influence of motivational interviewing on explicit and implicit alcohol-related cognition and alcohol use in at-risk adolescents. *Psychology of addictive behaviors: journal of the society of psychologist in addictive behaviors* 2009, 23(1): 146-151.
- Van Laar, M., & van Ooyen-Houben, M. (2016). *Nationale Drug Monitor*. Trimbos-instituut: Utrecht.
- Verhoeven, A.A.C., Adriaanse, M.A., Vet, de E., Fennis, B.M., & Ridder, de D.T.D. (2014). Identifying the 'if' for 'if-then' plans: Combining implementation intentions with cue-monitoring targeting unhealthy snacking behaviour. *Psychology & Health*, 29(12): 1476-1492
- Wiers, R.W., Rink, M., Dictus, M., & van den Wildenberg, E. (2009). Relatively strong automatic appetitive action-tendencies in male carriers of the OPRM1 G-allele. *Genes, Brain and Behavior*, 8, 101-106.
- Wiers, R.W., Eberl, C., Rinck, M., Becker, E., & Lindenmeyer, J. (2011). Retraining automatic action tendencies changes alcoholic patients' approach bias for alcohol and improves treatment outcome. *Psychological science*, 22(4):490-497.

Wiers, R.W. Rink, M. Kordts, R., Houben, K., & Starck, F. (2010). Retraining automatic action-tendencies to approach alcohol in hazardous drinkers. *Addiction*, *105*: 279-287

Wiers, R. W., Gladwin, T.E., Hofmann, W., Salemink, E. & Ridderinkhof, K.R. (2013). Cognitive bias modification and cognitive control training in addiction and related psychopathology mechanisms, clinical perspectives and ways forward. *Clinical Psychological Science*, *1*: 192-212.

Wiers, R. W., Bartholow, B.D., Van den Wildenberg, E., Thush, C., Engels, R.C. M. E. & Sher, K.J. (2007). Automatic and controlled processes and the development of addictive behaviours in adolescents: A review and a model. *Pharmacology, Biochemistry and Behavior*, *86*: 263-283

Wiers, R.W., Woerden, N. van, Smulders, F.T.Y., Jong, P.J. de. (2002). Implicit and explicit alcohol-related cognitions in heavy and light drinkers. *Journal of Abnormal Psychology*, *111*: 648-658.

Williams, A.D., Blackwell, S.E., Mackenzie, A., Holmes E.A. & Andrews, G. (2013). Combining Imagination and Reason in the treatment of Depression: A Randomized Controlled Trial of Internet-Based Cognitive-Bias Modification and Internet-CBT for Depression. *Journal of Consulting and Clinical Psychology*, *81*(5): 793-799.

Wilsnack, R.W., Wilsnack, S.C., Kirstjanson, A.F., Vogeltanz-Holm, N.D. & Gmel, G. (2009). Gender and alcohol consumption: Patterns from the multinational genacis project. *Addiction* *104*(9): 1487-1500.

Wildt, W.A.J.M. de, Lehert, P., Schippers, G.M., Nakovics, H., Mann, K. & van den Brink, W. (2005). Investigating the structure of craving using structural equation modeling in analysis of the Obsessive-Compulsive Drinking Scale: A multinational Study. *Alcoholism: Clinical and Experimental Research*, *29*(4): 509-516.

Wit, G.A. de (2016). *Social cost-benefit analysis of regulatory policies to reduce alcohol use in the Netherlands*. National Institute for Public Health and the Environment: Bilthoven.

World Health Organization (WHO). (2016). World Health Statistics 2016: Monitoring health for the SGDs. Retrieved from <http://www.who.int>



Young, R., Conner, J.P., Feeney, G.F.X., Alyssa, J. (2010). *The obsessive Compulsive Drinking Scale is a valid Measure of Alcohol Craving in Young Adults*. Queensland University of Technology: Brisbane Australia.