

Alcohol Cognitive Bias Modification training for problem drinkers via their  
smartphone: a pilot study

March 2017

Berdien Nicole Somsen

Supervision by: Marcel E. Pieterse, PhD<sup>1</sup> & Marloes G. Postel, PhD<sup>1,2</sup>

<sup>1</sup> *University of Twente, Faculty of Behavioural, Management and Social Sciences, Centre for eHealth and Well-being Research, Department of Psychology, Health & Technology, Enschede, the Netherlands*

<sup>2</sup> *Tactus Addiction Treatment, Department Web-based Treatment, Enschede, the Netherlands*

Please cite as: Somsen, B.N. (2017). Alcohol Cognitive Bias Modification training for problem drinkers via their smartphone: a pilot study. *Master dissertation, March 2017, University of Twente, Enschede*

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## **ABSTRACT**

**Background:** Previous research showed positive outcomes of a Cognitive Bias Modification (CBM) Alcohol Avoidance Training, using an adapted Approach-Avoidance Task (AAT) to change the automatic approach bias for alcohol of problem drinkers in a clinical and community sample. The CBM Alcohol Avoidance Training of alcohol was initially only offered by computer. Current pilot study examined a novel mobile version of the training in a self-selected non-clinical sample.

**Objective:** The main aim of the study was to test whether the mobile version provides a reduction of alcohol consumption in problem drinkers by providing the CBM Alcohol Avoidance Training.

**Methods:** Participants experiencing an alcohol problem, or being concerned about their drinking, were recruited through free publicity, which resulted in 1214 interested participants. The participants were instructed to complete two training sessions per week during the three weeks of the pilot study. Of these 1214 interested participants, 1082 participants could be included. The excluded participants did not have an alcohol-related reason to participate. After completing the three weeks training participants received the online posttest. A total of 410 were included for analysis. The primary outcome measure was a reduction in alcohol consumption and the secondary outcome measure was adherence.

**Results:** Findings show that a large part of the participants were problem drinkers (93.5%). The training completers reduced their drinking in mean weekly alcohol consumption with approximately eight standard units. The outcome indicated a positive correlation between adherence and reduction in weekly alcohol consumption. 78.8% of the participants completed the training sessions.

**Conclusions:** This pilot study reached the target group as intended, where mainly self-selected problem drinkers in a non-clinical setting participated. The results of this pilot study suggest that the mobile version of the CBM Alcohol Avoidance Training has the potential to reduce the alcohol consumption of problem drinkers in a non-clinical setting, corroborated by the indication for a dose-response relationship. Since a control group was not included in this study, the results cannot be ascertained with absolute certainty. Further research therefore is recommended.

## **Keywords**

Cognitive Bias Modification (CBM), Alcohol, Alcohol Avoidance Training, Approach-Avoidance Task (AAT), mobile version, app, adherence, alcohol consumption

## **PREFACE**

As I am writing this, my masters of Health Psychology and Applied Technology has really come to an end. Almost one year ago I had a choice to do an internship within an organization and I was determined to do this. It was my preference for a long time to gain experience in the addiction work field and I was lucky Tactus Addiction Treatment offered a combined internship and master thesis vacancy. I got the chance to take part in an innovative project, a new eHealth app 'Breindebaas' for problem drinkers, and to become acquainted with working as a health psychologist in an addiction treatment institute.

In my year within this organization, I learned many things. First of all, I had the opportunity to learn more about the use and application of eHealth. Secondly, preparing and conducting a pilot study offered me several challenging activities. Furthermore I learned how to do scientific research in practice and to write an academic thesis. I am very grateful that I took part in this subject; because of this eHealth has become one of my preferences in the work field, which I had never expected to happen. Besides the eHealth part, I have become very curious about the research field and I hope to gain more experience in this field in the future.

I would like to thank my two supervisors who made it possible for me to write my thesis for Tactus and who have contributed in this part. First, I would like to thank Marloes. We have worked together a lot and I could not have thought of a better person to do this with. I think you have everything for a good researcher, colleague and supervisor! You gave me a lot of patience, pleasant company and a lot of knowledge. I admire your workstyle and hopefully I can adopt a similar way of working in the future. Secondly, I would like to thank Marcel. Thank you for your critical eye and especially for sharing your statistical knowledge! Even though we worked at a distance, you were able to give me valuable feedback. Furthermore I would like to thank the Tactus staff I worked with, who assisted me on several activities.

Last but not least I also would like to thank my friends and family for their support. Writing this thesis went with its ups and downs and it gave me so much strength to share all these moments with good company. Thank you for that! It means a lot to me. Especially, I would like to thank Elske, who also worked for Tactus while writing her thesis. It was good to have someone nearby who is 'in the same boat'.

## **INTRODUCTION**

Recently an app has been developed which provides the Cognitive Bias Modification (CBM) Alcohol Avoidance Training for participants who experience an alcohol problem or are concerned about their drinking. This pilot study will give insight in the impact of the mobile version of the CBM Alcohol Avoidance Training on alcohol consumption among problem drinkers.

Nowadays alcohol use is still an ongoing health concern. First, excessive use of alcohol leads to economic and social losses and second, to a higher morbidity and mortality. 5.1 % of the global burden of disease and injury is caused by alcohol, as measured in disability-adjusted life years (DALYs). Alcohol use disorders (AUD) were the number four of mental and behavioural disorders that caused death in 2012 (WHO, 2014; WHO, 2015). According to van Laar and van Ooyen-Houben (2015) 12% of the population in 2014, aged 12 or older in the Netherlands, uses alcohol in an excessive way (i.e. more than 21 glasses of alcohol per week for men and more than 14 glasses of alcohol per week for woman). Excessive alcohol use may lead to the presence of an AUD, defined by the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM) as an integration of the two DSM-IV disorders, alcohol abuse and alcohol dependence (American Psychiatric Association, 2013). An attribute of alcohol abuse is a recurrent alcohol use, which can result in a failure to fulfil obligations at work, school, or at home, at social and interpersonal levels. Alcohol dependence is characterized by criteria such as tolerance, withdrawal and larger amounts of alcohol. In the Netherlands between 2007-2009 3.7% suffered from alcohol abuse and 0.7% suffered from alcohol dependence where the numbers of males were higher (de Graaf, ten Have, & van Dorsselaer, 2010).

Despite knowledge about the negative consequences of excessive alcohol use, addicted people continue their behaviour (Wiers & Stacy, 2006). Factors such as attitude, self-regulation, self-efficacy, skills and motivation contribute to this behaviour (Hofmann, Friese, & Wiers, 2008). Previous research explained appetitive motivation to consume alcohol with explicit, self-report measures. Examples are studies about alcohol expectancies (Brown, Goldman, Inn, & Anderson, 1980; Goldman, Del Boca, & Darkes, 1999) and drinking motives (Cooper, 1994; Cooper, Frone, Russell, & Mudar, 1995). Marteau, Hollands and Fletcher (2012) argued that these measures used in health behaviour change interventions are usually information-based and have the aim to encourage people to reflect on their

behaviours. However, interventions following this approach show only modest effects. The observation is that behaviour is not only driven by conscious reflection but also by other stimuli. Therefore the focus in studies of cognitive motivational processes nowadays is not only on explicit behaviours. Another factor that is relevant in explaining the continuation of addictive behaviour and has become more of interest are implicit or automatic processes. Addictive behaviour is partly affected by automatic processes that occur outside conscious control (Wiers & Stacy, 2006). This can be explained by dual process models of addictive behaviour (Dawe, Gullo, & Loxton, 2004; Jentsch & Taylor, 1999; Lubman, Yücel, & Pantelis, 2004). Addictive behaviour is predicted by two systems. In the impulsive system, behaviour is controlled by associativity and impulsivity. The impulsive system is also characterized by spontaneous and rapid processes, while the reflective system is characterized by slow and controlled processes. The development and maintenance of the addictive behaviour is often an interaction between both processes. Imbalance between those systems makes the individual sensitive to cues that trigger biases leading to the addictive behaviour. Consequently, even if problem drinkers are aware of the negative consequences of alcohol, their behaviour can be the result of different cognitive biases: an attentional bias for alcohol-related stimuli, a memory bias for the automatic activation of alcohol-related associations, and a bias toward automatically activated action tendencies to approach alcohol (Wiers et al., 2007; Wiers et al., 2009).

To influence and control the impulsive processes regarding addictive behaviour, CBM programs have been developed. The purpose of CBM is changing disorder-specific impulsive processes, also known as maladaptive cognitive motivational biases, through a computerised training program (Wiers, Gladwin, Hofmann, Salemink, & Ridderinkhof, 2013; van Deursen et al., 2013). In an assessment study an Approach Avoidance Task (AAT) was applied in CBM to examine the approach bias to alcohol and other alcohol-related stimuli in male heavy drinkers. Participants were shown different formats of pictures on a computer screen in which they had to pull or push a joystick. During the pull movement the picture size increased, while during the push movement the picture size decreased. The pull movement creates a sense of approach and the push movement a sense of avoidance. The results showed an approach bias to alcohol by heavy drinkers, in which they were faster to pull alcohol pictures than to push alcohol pictures away (Wiers et al., 2009).

After the assessment study the first training version was developed and tested in heavy drinking students and showed promising results whereby automatic processes were successfully changed (Wiers, Rinck, Kordts, Houben & Strack, 2010). Subsequently this type

of CBM Alcohol Avoidance Training was tested in a clinic in Germany among alcohol dependent patients (Wiers, Eberl, Rinck, Becker and Lindenmeyer (2011). There were two experimental conditions in which participants received the CBM Alcohol Avoidance Training and two control conditions explicitly or implicitly, in which participants received no training or a sham training. The results show that patients in the experimental conditions one year later had a relapse rate of 46% while patients in the control conditions had a relapse rate of 59%, which indicate a reduction higher than 10 percentage points for the experimental conditions. Also in a replication study the experimental condition resulted in better outcomes (Eberl et al., 2013). Besides alcohol studies other studies regarding addictive behaviour using AAT show promising results. For example, some studies focused at reducing cigarette smoking among participants, while performing an AAT. Wittekind, Feist, Schneider and Moritz (2015) revealed a significant reduction in cigarette smoking, cigarette dependence and compulsive drive. Moreover, a study with inpatient psychiatric smokers provides preliminary support that the training with AAT might reduce nicotine consumption (Machulska, Zlomuzica & Rinck, 2016).

Despite the positive results of the mentioned CBM studies, not all studies support a reduction in alcohol. Cristea, Kok, and Cuijpers (2016) studied the effectiveness of all types of CBM interventions, alone or combined with other treatments, for substance addictions, in a meta-analysis. At post-test no improvement in alcohol outcomes or other substances due to CBM were found. At follow-up the addiction outcomes showed a small positive effect, but the authors interpret this result cautiously as it was based on a small numbers of trials, which was insufficient according to their power analysis. Moreover, the follow-ups were naturalistic, making it was difficult to attribute the effect to the interventions. In contrast to the first meta-analysis, Kakoschke, Kemps and Tiggemann (2016) found positive effects of AAT including reduced consumption behaviour in the laboratory, lower relapse rates and improvements in self-reported consumption. They evaluated the effectiveness of modifying the approach bias to reduce unhealthy consumption behaviours, including excessive alcohol use, cigarette smoking and unhealthy eating. Five of the eight alcohol-related studies found a successful change in the approach bias within undergraduate and clinical samples. As a conclusion, there are opposite findings regarding CBM with inconclusive evidence and promising evidence. A difference in the meta-analyses is that Cristea et al. studied all types of CBM, while Kakoschke et al. focused only on CBM-AAT. Relevant in the current context is in particular the meta-analysis of Kakoschke et al., which focused on the approach bias. Still more evidence is needed to show the effectiveness of CBM.

In the interim, the CBM Alcohol Avoidance training was offered to the participant in several variations. A related question concerns the crucial ingredient of the CBM procedure in those variations. First there was a joystick version which provided the zooming feature and the arm movement. According to Neumann and Strack (2000) the zooming feature, whereby the pictures become bigger if the joystick was pulled and smaller when it was pushed, already has a sensation of approach or avoidance. Therefore, the AAT combines the arm movement and the zooming feature to create the approach and avoidance associations. Wiers et al. (2011) also mentioned the possibility that the arm movement was crucial to produce the effect found in their study. Palfai (2006) showed before that alcohol consumption was higher in males who lifted the glass (action prime) compared to males who leaned towards the glass (control) (Palfai, 2006). After the joystick version, it was suggested that the arm movement was not necessarily required to produce an effect; the keyboard version was introduced with only the zooming effect. Peeters et al. (2012) examined with an assessment study the role of alcohol-approach tendencies among at-risk adolescents. They used an AAT to assess the approach bias, while using arrows on the keyboard. The up arrow represented the pushing movement and the down arrow represented the pulling movement. Results showed that the keyboard version measured the approach bias in a decent way. It is important to keep adapting new interventions pursuant to new technological developments. Currently the CBM training is also provided on a touchscreen. In the app version, the arm movement is coming back, while it was missing in the keyboard version. The question remains whether the arm movement or the zooming effect is the crucial ingredient to produce a positive effect. However both factors seem to produce an effect.

While computer usage is reducing, the use of smartphones and tablets show an increase. A growing field in mHealth therefore exist where research to CBM in apps is needed. One study among CBM in apps was conducted and assessed whether providing an Attentional Bias Modification (ABM) task before the pre-sleep period could reduce insomnia and the cognitive symptoms of pre-sleep arousal (Clarke et al., 2015). Furthermore, up to now the CBM Alcohol Avoidance Training was only offered via a computer. Recently however, a mobile version has been developed. An app that runs the training on a smartphone, using swipe movements to simulate the approach versus avoid responses. Another reason for developing the mobile version was the expectation that it would reduce non-adherence. In the study of Wiers et al. (2015) the dropout within the computerized training intervention was high; half of the participants never started the training after they were included and of those remaining, half again dropped out during the training. According to Boendermaker et al.

(2015) the deployment of CBM interventions on a smartphone could maximize their effect and improve compliance. They examined the user experience, motivational aspects, and preliminary effectiveness in a pilot study of a mobile CBM intervention, compared to the standardized computer version, among a sample of young regular drinkers. Participants completed the training on a computer or on their smartphone. Results of the intervention showed that participants appeared to be more involved in the mobile group in comparison with the computer group. Thus, a mobile version could increase the adherence of a training. Another potential benefit of the mobile version may be the possibility to send reminders to participants. After receiving a reminder, participants could then perform the training sessions anywhere, which could also be a benefit of the mobile version; they can complete their sessions where their drinking begins.

The aim of the present study is to examine the impact of the CBM Alcohol Avoidance Training on alcohol consumption through a pre- and posttest comparison and to examine a dose-response effect of adherence in improvement of outcomes. The expectation is that the Breindebaas app will provide a reduction of the weekly alcohol consumption. Also a positive correlation between adherence and reduction in weekly alcohol consumption is expected.

## **METHOD**

### **Study design**

The present pilot study was a pretest-posttest single group design with three weeks in between. In those three weeks participants were invited to use the app twice a week.

### **Participants**

Problem drinking participants were recruited through free publicity in national and regional newspapers, radio stations and on television. A total of 1214 participants signed up for the study between November 10 and November 23, 2016. The criteria to participate for the pilot study were: 1) experiencing an alcohol problem or being concerned about their drinking; 2) aged 18 years or older; 3) access to and ability to use the internet via a smartphone or tablet; 4) ability to read and write Dutch; 5) a signed informed consent.

### **Intervention**

Subject of the current study was a smartphone version of the Cognitive Bias Modification (CBM) Alcohol Avoidance Training, called Breindebaas (see Figure 1). The app was available for smartphones and tablets with the operating systems Android and iOS.



Participants were instructed to complete training sessions twice a week, during a total of three weeks. Each session started with questions about well-being and the number of units of alcohol consumed since the last session. Within a training session, a total of 100 pictures were presented, 50 pictures of alcoholic beverages and 50 pictures of non-alcoholic beverages (Pronk, van Deursen, Beraha, Larsen, & Wiers, 2015). Participants were instructed to respond with a swipe movement. Swiping pictures of non-alcoholic beverages towards them represented the approach movement and swiping pictures of alcoholic beverages away represented the avoidance movement. Participants were also instructed to respond as quickly as possible and to minimize mistakes. They received a short error notification if they reacted too slowly, made a mistake or if the swipe movement was not completed correctly. After completion of 20, 50 and 80 pictures participants also received a notification, including some encouraging words, such as 'you're well on your way', to motivate them to complete the session. The time interval between the swipe movement and a new picture was one second and the time interval after the encouraging words was two seconds. The sessions ended with a score to motivate the participant to improve reaction time in the next session or to minimize mistakes. Latencies were recorded and a mean latency for each session was presented at the end. After each session participants also received their score regarding the percentage of good responses.

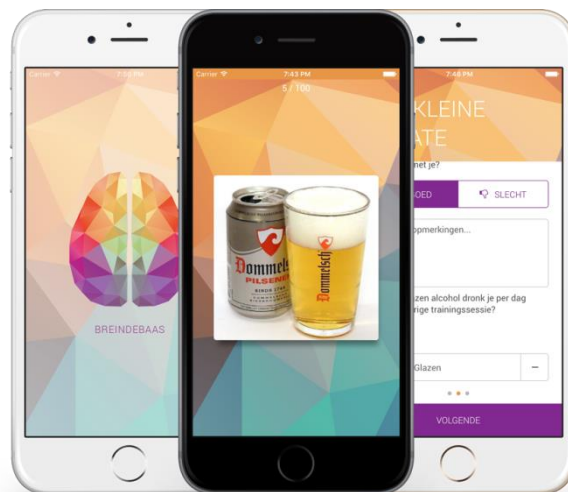


Figure 1. The Breindebaas app

## Procedure

Through publicity participants were directed to the website [www.breindebaasapp.nl](http://www.breindebaasapp.nl). The website provided information about the app and the pilot study. If participants were interested

in the study they were asked to sign a digital informed consent and to complete the online questionnaire afterwards. Once completed, participants received instructions about downloading the app via Play store or App store. They also received an access code needed to use the app, to exclude downloaders who did not participate in the study. After downloading and login on the Breindebaas app, the participants could start the training sessions. Before participants were starting their first session they could watch a short demo movie in which the training was explained. The participants received the instruction to complete two sessions weekly during the three weeks of the pilot study. There had to be at least 24 hours between two consecutive sessions. After three days participants received a push message that a new training session was available. After five days the app reminded them via a push message to start the session if they had not finished it yet. After three weeks participants received an e-mail to complete the online posttest. Participants could also choose to receive a SMS. Those who did not complete the online posttest received a reminder by e-mail after a week. A follow-up assessment was conducted three months after the posttest, and participants were also reminded by e-mail and (optionally by) SMS. A link to the online questionnaire was provided in the e-mail. Participants could win 1 of 5 available gift vouchers each worth 100 euros by completing all three questionnaires.

## **Measures**

### *Demographic characteristics*

At baseline participants reported their gender, date of birth, source of income, daily occupation and educational level.

### *Data smartphone or tablet*

At baseline participants were asked if they used a smartphone or tablet, the type of the device, the brand and the model.

### *Alcohol consumption*

The alcohol consumption was the primary outcome measure of this study. The Dutch adaptation (Wiers, Hoogveen, Sergeant & Gunning, 1997) of the self-report Timeline Followback (TLFB) procedure (Sobell & Sobell, 1992) was used to measure the alcohol consumption of participants. Participants indicated the number of standard units of alcohol consumed during each day in the past week. The total score of the scale was calculated by the total sum of each day.

### *Alcohol Use Disorders Identification Test (AUDIT)*

The Dutch version (Schippers & Broekman, 2010) of the AUDIT (Babor, Higgins-Biddle, Saunders & Monteiro, 2001) was used to identify likely hazardous alcohol use and alcohol-related problems. The questionnaire consisted of 10-items on drinking amount, frequency and negative consequences with a score ranging from 0 to 4. The total score of the scale was calculated by the total sum of each item. The cut-off point used for problematic alcohol use was 8.

### *Other substance-use*

Questions about the use of other substances at present and in the past year were asked to identify the target group.

### *Self-efficacy*

Self-efficacy was assessed with 8-items of the Drinking Refusal Self-efficacy Questionnaire (DRSEQ; Oei, Hasking, & Young, 2005). The original questionnaire consisted of 31-items divided in three subdimensions of self-efficacy: social pressure, emotional relief and opportunistic. Participants responded to a 5-point Likert-type scale. The analysis of self-efficacy in this study was measured as one dimension. The measured reliability for the scale was  $\alpha = 0.88$ .

### *Craving*

The 5-item Obsessive Compulsive Drinking Scale (OCDS; de Wildt et al., 2005) of the original 14-item OCDS scale was used to reflect obsessionality and compulsivity related to craving and drinking behavior (Anton et al., 1995). Participants responded to a 5-point scale (0-4) with a threshold of  $>12$ . No research has been done to the psychometric properties of the 5-item version, but the Dutch original version of the OCDS (14-item) was shown to be valid. The internal consistency was correct (0.85) and the intercorrelation within scale and subscales was 0.62 to 0.93 (Schippers et al., 1997). The total score of the scale was the total sum of the 5 items. The measured reliability in this study for the scale was  $\alpha = 0.74$ .

### *Readiness to Change Questionnaire (RCQ)*

The RCQ (Rollnick, Heather, Gold, & Hall, 1992) assigns respondents to the pre-contemplation, contemplation, or action stage. In this study the Dutch version of the RCQ

(Defuentes-Merillas, Dejong, & Schippers, 2002) was used to compare the stages of the target group with previous studies and to describe the current target group. The questionnaire consisted of 12 items and answers were given on a 5-point scale. The Dutch version was shown to be valid. The internal consistency of the scales was satisfactory: pre-contemplation,  $\alpha = 0.68$ ; contemplation,  $\alpha = 0.70$ ; action,  $\alpha = 0.81$ . The intercorrelations between the adjacent scales (between pre-contemplation and contemplation and between contemplation and action; 0.53) were higher compared to non-adjacent scales (between pre-contemplation and action; -0.49). To calculate the score for each scale, all item scores for the scale in question were added. The measured reliability in this study for the scales were: pre-contemplation,  $\alpha = 0.53$ ; contemplation,  $\alpha = 0.58$ ; action,  $\alpha = 0.79$ .

### *Satisfaction*

The client satisfaction regarding the CBM Alcohol Avoidance Training was assessed with the Dutch validation of the Client Satisfaction Questionnaire (CSQ; De Brey, 1983; De Wilde & Hendriks, 2005). The questionnaire consisted of 8-items and answers were given on a 4-point scale. The CSQ-8 was translated into Dutch by De Brey and has a high internal consistency ( $\alpha = 0.91$ ). De Wilde and Hendriks also found a high internal consistency ( $\alpha = 0.92$ ). The total score was calculated by adding up the individual item scores to produce a range of 8 to 32, with higher scores indicating greater satisfaction. The measured reliability in this study for the scale was  $\alpha = 0.91$ .

### **Analysis**

For the statistical analyses IBM SPSS Statistics, version 21, was used to determine any improvement after the training sessions. Descriptive statistics were used to describe the baseline characteristics of the participants and characteristics of the training completers at posttest. The independent-samples t-tests and chi-square tests were conducted to compare baseline characteristics between study completers and dropout. The independent sample t-test was also used to measure the influence of using a smartphone or a tablet in satisfaction and adherence of the participants. The paired sample t-test was performed to compare the alcohol consumption at baseline and posttest and the McNemar test was used to assess the significance of the difference between participants above the guidelines and within the guidelines of alcohol consumption at baseline and posttest. Furthermore repeated measures analyses (ANOVA) were done to investigate moderators of the change over time in alcohol consumption. In addition, correlation- and (multiple) regression analyses were conducted to

measure the predictors of adherence and change in alcohol consumption. For the primary outcome measure, Cohen's d effect size was calculated to analyze the strength of the observed effect.

## RESULTS

### Participant flow

Figure 2 presents the participants flowchart of the inclusion process and details for the exclusion of participants. 1082 participants were included for analysis at baseline and 410 participants for analysis at posttest.

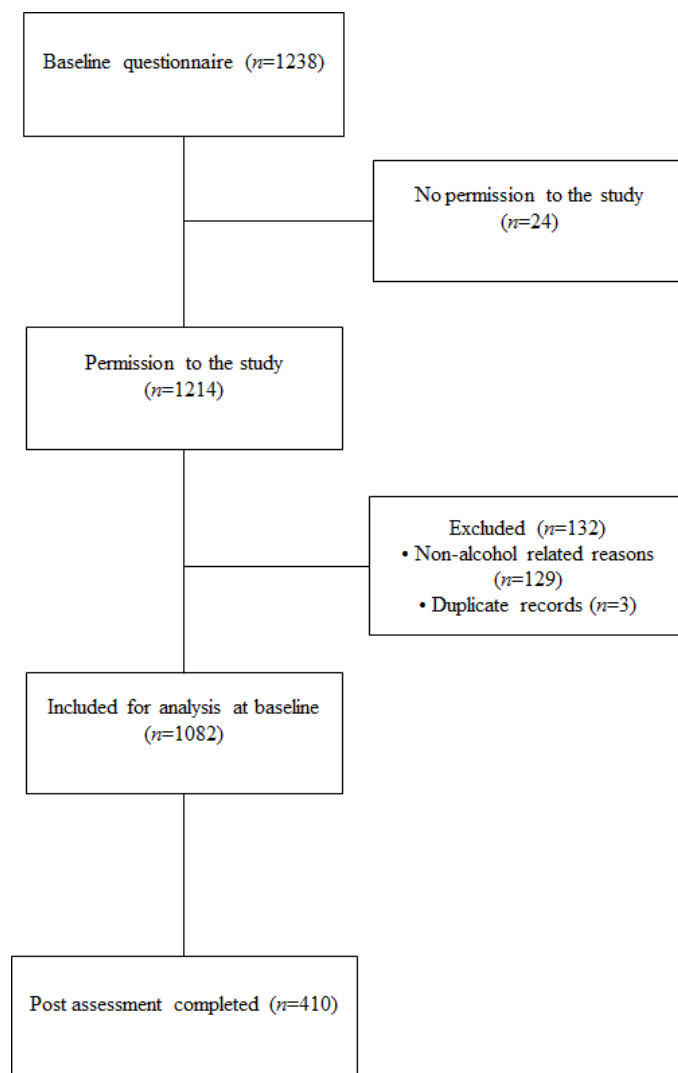


Figure 2. Participants flowchart.

### **Participants at baseline**

Table 1 shows the baseline characteristics of the 1082 participants with a drinking problem who enrolled in the pilot. Of these participants, 58.4% ( $n=632$ ) were male and 41.6% ( $n=450$ ) were female, with an average age of 49.1 year ( $SD=11.3$ ). Most participants were employed (70.9%) and higher educated (57.0%). The mean weekly alcohol consumption was 36.6 standard units a week ( $SD=24.5$ ): 42.4 for males ( $SD=26.5$ ) and 28.5 ( $SD=18.7$ ) for females. The mean AUDIT score was 17.2 ( $SD=6.7$ ) in which males scored 18.2 ( $SD=6.4$ ) and females 15.7 ( $SD=6.8$ ). 93.5% of the participants reported an AUDIT score of 8 or higher indicating problematic alcohol use in a large majority of the sample. Within the stages for readiness to change the contemplation stage scored highest with 66.2% ( $n=716$ ). The participants scored an average of 5.3 for craving ( $SD=3.2$ ) indicating relatively less craving and 25.4 ( $SD=7.4$ ) for drinking refusal self-efficacy with an average score of 3.2 at item level, indicating moderately low self-efficacy. 41.8% used other substances in the last year ( $n=452$ ). Most of them used tobacco ( $n=338$ ), benzodiazepines ( $n=142$ ) and cannabis ( $n=108$ ).

The most common motive to start with the app was to reduce alcohol consumption ( $n=819$ ) followed by participants who thought they were drinking too much ( $n=613$ ). 77.6% used a smartphone during the pilot, the others a tablet. Most of the participants were informed about the pilot via the newspaper (53.0%) followed by other media such as radio or social media (22.3%). 17.5% was informed via the website and 7.3% via an acquaintance or a friend.

Table 1  
 Participants characteristics at baseline (n=1082)

Variable	N	%
<b>Age (years), mean (SD)</b>	49.1 (11.3)	
<b>Gender</b>		
Male	632	58.4
Female	450	41.6
<b>Employed</b>	726	70.9
<b>Education</b>		
High <sup>1</sup>	583	57.0
Middle <sup>2</sup>	286	28.0
Low <sup>3</sup>	154	15.1
<b>Weekly alcohol consumption, mean (SD)</b>	36.6 (24.5)	
Male	42.4 (26.5)	
Female	28.5 (18.7)	
<b>AUDIT, mean (SD)</b>	17.2 (6.7)	
Male	18.2 (6.4)	
Female	15.7 (6.8)	
<b>RCQ</b>		
Precontemplation	58	5.4
Contemplation	716	66.2
Action	308	28.5
<b>OCDS, mean (SD)</b>	5.3 (3.2)	
<b>DRSE, mean (SD)</b>	25.4 (7.4)	
<b>Motive</b>		
Drink less	819	
Too much drinking	613	
Quit drinking	184	
Other people	147	
<b>Other substances</b>	452	41.8
Tobacco	338	
Benzodiazepines	142	
Cannabis	108	
Other	209	
<b>Device</b>		
Smartphone	840	77.6
Tablet	242	22.4
<b>Medium</b>		
Newspaper	573	53.0
Other	241	22.3
Website	189	17.5
Acquaintance or friend	79	7.3

<sup>1</sup> University of Research or University of Professional Education

<sup>2</sup> Higher General Secondary Education or Intermediate Vocational Education

<sup>3</sup> Primary school or Lower Vocational Education

### Study completers versus drop-out

As the post-assessment was completed by 410 of the initial 1082 participants at baseline (37.9%), we were interested whether baseline characteristics between study completers and dropouts differed. The results in Table 2 show that several demographic characteristics significantly differed between the two groups. Study completers were older compared to the dropouts ( $t=5.80$ ,  $p=.000$ ) and higher educated ( $X^2=26.60$ ,  $p=.000$ ). Also the weekly alcohol consumption significantly differed ( $t=-3.69$ ,  $p=.000$ ). This difference was fully explained by the weekly alcohol consumption of the female population ( $t=-2.91$ ,  $p=.004$ ). Furthermore the AUDIT score significantly differ ( $t=-5.13$ ,  $p=.000$ ) in which both male ( $t=-3.13$ ,  $p=.002$ ) and female ( $t=-3.71$ ,  $p=.000$ ) study completers had a lower score compared to the dropout. The study completers and dropout did not differentiate with regard to gender or employment. DRSE, OCDS and RCQ were also measured, but no differences were found.

Table 2

*Differences in baseline characteristics between study completers and dropout (n=1082)*

Variable	Completers (n=410)	Dropout (n=660)	Analysis	
			t value / X <sup>2</sup>	P
<b>Age (years), mean (SD)</b>	51.8 (10.2)	47.8 (11.7)	5.80	.000
<b>Gender, n (%)</b>			6.14	.013
Male	220 (53.7)	412 (61.3)		
Female	190 (46.3)	260 (38.7)		
<b>Employed, n (%)</b>	271 (70.6)	455 (71.1)	0.03	.859
<b>Education, n (%)</b>			26.60	.000
High <sup>1</sup>	257 (66.8)	326 (51.1)		
Middle <sup>2</sup>	91 (23.6)	195 (30.6)		
Low <sup>3</sup>	37 (9.6)	117 (18.3)		
<b>Weekly alcohol consumption, mean (SD)</b>	33.3 (21.8)	38.7 (25.8)	-3.69	.000
Male	40.0 (24.7)	43.7 (27.3)	-1.71	.087
Female	25.5 (14.4)	30.7 (21.0)	-2.91	.004
<b>AUDIT, mean (SD)</b>	15.8 (6.1)	18.0 (6.9)	-5.13	.000
Male	17.1 (6.0)	18.8 (6.5)	-3.13	.002
Female	14.4 (5.9)	16.7 (7.3)	-3.71	.000

<sup>1</sup> University of Research or University of Professional Education

<sup>2</sup> Higher General Secondary Education or Intermediate Vocational Education

<sup>3</sup> Primary school or Lower Vocational Education

\* $p<0.01$  (2-tailed).

### Characteristics of the training completers

In the first part of this thesis information was provided about the study completers. Below the results of the training completers will be shown.



The main reason for 56.6% of the training completers to use the app was to reduce alcohol consumption ( $n=232$ ) followed by 23.4% of the completers who thought they were drinking too much ( $n=96$ ). 77.3% of the participants never sought help for their alcohol problem, while 22.7% did. Of those who received help previously, most of them received face-to-face help or help via internet ( $n=40$ ) or used a self-help program ( $n=31$ ).

Most of the participants followed the training sessions at home ( $n=390$ ), 101 participants via tablet and 289 participants via smartphone. 30% ( $n=123$ ) followed the six recommended training sessions of the app, 41.7% ( $n=171$ ) less than six sessions and 28.4% ( $n=116$ ) more than six sessions. The most selected reasons for following less than six sessions were not enough time ( $n=32$ ) and the perception that the app did not have any effect ( $n=36$ ). In addition to this, several participants who dropped out mentioned not receiving reminders for a new training session ( $n=21$ ).

### **Pre-post comparisons of the alcohol consumption**

Table 3a shows the difference scores in weekly alcohol consumption between baseline and posttest for the training completers. The mean weekly alcohol consumption was 33.3 units at baseline ( $SD=21.8$ ) and 25.5 units at posttest ( $SD=20.4$ ). The decrease of 7.8 units was significant ( $t=9.63, p=.000$ ), with a small to moderate effect size ( $d=0.37$ ; Cohen, 1992).

Table 3b shows the difference scores in guidelines of alcohol consumption between baseline and posttest. At baseline 56.3% of the participants ( $n=231$ ) were drinking above the guidelines, and were still drinking above the guidelines at posttest, while 22.2% ( $n=91$ ) of the participants were drinking above the guidelines at baseline, and were drinking within the guidelines at posttest. 4.9% ( $n=20$ ) of the participants were drinking within the guidelines at baseline, and were drinking above the guidelines at posttest, while 16.% ( $n=68$ ) was drinking within the guidelines at baseline and was still drinking within the guidelines at posttest. The results significantly differ ( $X^2=44.14; p=.000$ ). Based on these results, the hypothesis that the Breindebaas app provides a reduction of the weekly alcohol consumption, is supported.

Table 3a  
 Difference scores in alcohol consumption at pre and posttest (n=410)

Variable	Baseline	Posttest	t value	P	d
<b>Weekly alcohol consumption, mean (SD)</b>	33.3 (21.8)	25.5 (20.4)	9.63	.000	0.37

\* $p < 0.01$  (2-tailed).

Table 3b  
 Difference scores in guidelines at pre and posttest (n=410)

Variable	Posttest		X <sup>2</sup>	P
<b>Baseline, n (%)</b>	Above guidelines	Within guidelines	44.14	.000
Above guidelines	231 (56.3)	91 (22.2)		
Within guidelines	20 (4.9)	68 (16.6)		

\* $p < 0.01$  (2-tailed).

### Moderators of change in alcohol consumption

Possible moderators of the change in alcohol consumption were examined. There was an interaction effect for gender ( $F=5.90$ ,  $p=.016$ ;  $\eta_p^2=.014$ ; see figure 3), in which men ( $n=220$ ) showed 40.0 units at baseline ( $SD=24.7$ ) and 30.4 units at posttest ( $SD=23.8$ ). Females ( $n=190$ ) showed 25.5 units at baseline ( $SD=14.4$ ) and 19.8 units at posttest ( $SD=13.7$ ). These results showed that male participants achieved a greater reduction in alcohol consumption compared to female participants.

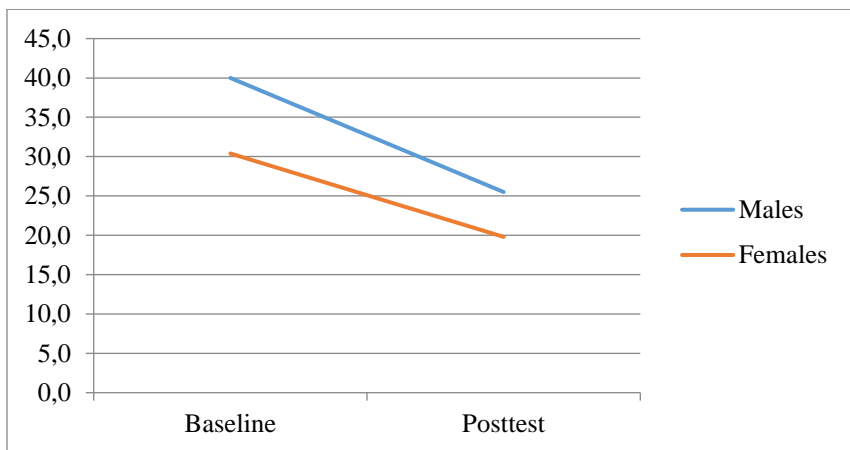


Figure 3. Interaction effect gender.

There was also an interaction effect for concentration ( $F=5.47$ ,  $p=.020$ ;  $\eta_p^2=.013$ ; see figure 4) in which the (highly) concentrated group ( $n=375$ ) showed a decrease from 33.8 units ( $SD=22.2$ ) at baseline to 25.5 units ( $SD=20.7$ ) at posttest. Participants in the minimally concentrated group ( $n=35$ ), showed a decrease from 27.1 units ( $SD=16.4$ ) at baseline to 25.4 units ( $SD=18.1$ ) at posttest. Thus, the findings showed a greater reduction of alcohol consumption for the (highly) concentrated group.

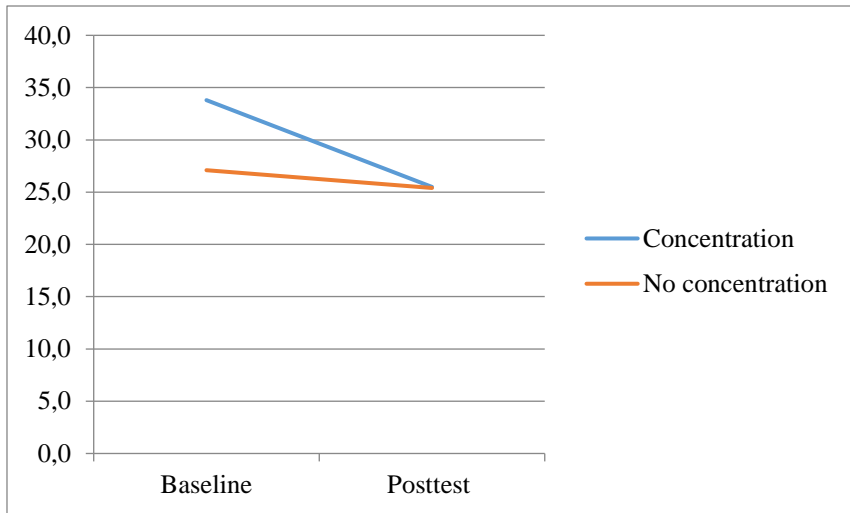


Figure 4. Interaction effect concentration.

An interaction effect was also found for adherence ( $F=8.41$ ,  $p=.004$ ;  $\eta_p^2=.020$ ; see figure 5) in which the cut off was 4 sessions. High adherence consisted of a completion of at least four sessions and low adherence of 1 to 3 sessions. Participants with low adherence ( $n=87$ ) showed 32.3 units at baseline ( $SD=21.4$ ) and 29.0 units at posttest ( $SD=26.4$ ) whereas participants with high adherence ( $n=323$ ) showed 33.5 units at baseline ( $SD=22.0$ ) and 24.5 units at posttest ( $SD=18.4$ ). Thus, participants with low adherence achieved a reduction of 3.2 units and participants with high adherence achieved a reduction of 9 units. An additional analysis indicated a reduction of 10.7 units for participants who completed 6 or more sessions. Results indicated that following more training sessions provided a greater reduction in alcohol consumption.

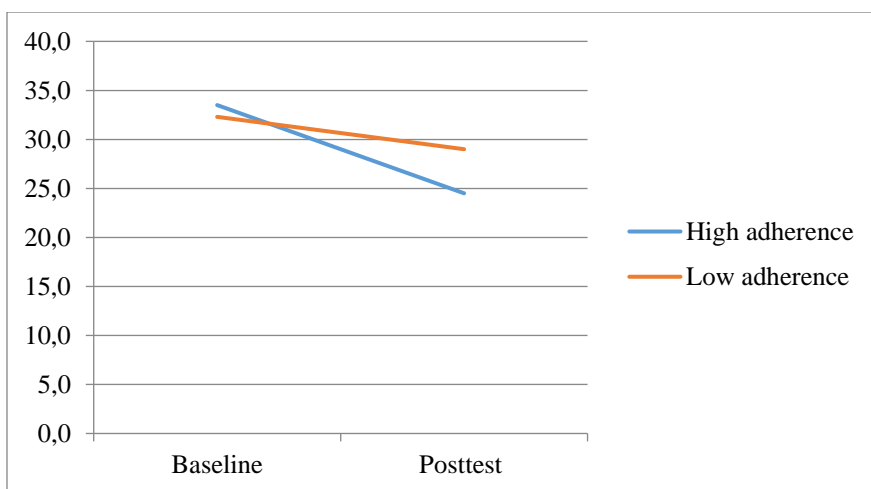


Figure 5. Interaction effect adherence.

To gain more insight whether adherence and a change in alcohol consumption are related with each other, a correlation analysis was conducted with adherence as a continuous measure. A correlation between adherence and alcohol consumption was found ( $r=0.13$ ;  $p=.010$ ).

Measures for device, age and motivation as moderators were also taken, but no effects were found. However, the no motivation group was small ( $n=28$ ). Furthermore the influence of device in outcomes at the CSQ and adherence was measured, but no significant effects were found.

### Predictors of change in alcohol consumption

Univariate analyses were used to determine if any baseline characteristic was correlated with the difference score of alcohol consumption. Afterwards linear regression analyses were conducted, of which the results are shown in Table 4. When all predictors were entered into the model, four predictors were found to be significant ( $F=7.77$ ;  $p=.000$ ) whereas the AUDIT was nonsignificant. They had a predictive value of  $R^2=0.09$ , indicating that approximately 10 percent of the change in alcohol consumption was accounted for by the four predictors in the model. Results indicate that males and participants with a lower education show a greater reduction of change in alcohol consumption. OCDS seems to be the strongest unique predictor.

Table 4  
 Linear multiple regressionanalyse with the change in alcohol consumption as dependent variable ( $n=410$ )

Variable	Alcohol consumption	
	$\beta$	$p$
Male	-0.12	.020
Lower education	0.10	.032
Source of income	0.11	.023
OCDS	0.17	.002
AUDIT	0.07	.242
$R^2$	0.09	
$F$	7.77	
Df	409	
$P$	.000	

\* $p < 0.05$  (2-tailed).

Furthermore an additional multiple regression analysis was conducted with adherence as dependent variable. This analysis, confirms the indication of a dose-response relationship even more. Therefore the five baseline characteristics used in Table 4, were added in the first step of the regression. Because an interaction effect was found for concentration, this variable was also added in this step. In the second step adherence was entered as a predictor. The results are shown in Table 5. The predictive value changed with 10% to 12% after adding adherence. Results indicate the expectation that participants with high adherence show a greater reduction in alcohol consumption. This indicates a small contribution of adherence as an independent predictor whereas a dosis-response relationship is more likely. Based on these results, the hypothesis that there will be a dose-response effect of adherence in improvement of outcomes, is supported.

Table 5  
 Linear multiple regression analyze with adherence as dependent variable  
 (n=410)

Variable	Alcohol consumption			
	Model 1		Model 2	
	$\beta$	<i>p</i>	$\beta$	<i>p</i>
Male	-0.11	.032	-0.12	.016
Lower	0.09	.055	0.09	.064
Source of income	0.11	.021	0.11	.020
OCDS	0.16	.002	0.16	.002
AUDIT	0.08	.141	0.08	.148
Concentration	-0.11	.020	-0.09	.063
Adherence			0.13	.006
<i>R</i> <sup>2</sup>	0.10		0.12	
<i>F</i>	7.46		7.71	
df	403		402	
<i>p</i>	.000		.006	

\**p* < 0.05 (2-tailed).

### Evaluation of the Breindebaas app

Of the training completers, 65.9% (n=270) indicated that their network was both positive and negative about using the app, 6.6% (n=68) was only positive and 14.4% (n=59) was only negative. Although a lot of participants mentioned positive effects, others reported no better outcomes after using the app (n=164), followed by more awareness of drinking alcohol (n=147) and skipping more drinks (n=91). Participants had an overall CSQ score of 20.90, with an average score of 2.6 at item level, indicating moderately high satisfaction. They also graded the Breindebaas app. The mean grade for participants with low adherence was 6.0 (SD=2.0) and the mean grade for participants with high adherence was 6.8 (SD=1.3). At

posttest open-ended responses were used where participants described several strong points of the Breindebaas app. First, most participants found the app easy ( $n=144$ ) and clear to use ( $n=71$ ); it was simple and user-friendly. Second, the app created awareness of alcohol consumption in a lot of participants ( $n=55$ ). Third, participants mentioned that the app worked fast ( $n=35$ ). Participants also described weak points. The app was seen by a large part of the participants as boring and monotonous ( $n=54$ ) and there were doubts whether the app had effect ( $n=53$ ). Another point was the presence of too many of the same pictures in the sessions ( $n=38$ ); for some participants it created habituation or prediction of pictures. Furthermore the slowness of the app ( $n=34$ ) and the bad alternatives for nonalcoholic drinks ( $n=30$ ) were mentioned; some participants thought that especially soft drinks were also unhealthy to approach because of the high levels of sugar. Several suggestions were given. Most of the participants suggested showing more different pictures of (non)alcoholic drinks to create more variety in the sessions ( $n=53$ ). Other suggestions were shortening the time interval between swipe movement and picture ( $n=20$ ), to create more levels or game options ( $n=18$ ), to improve the reminders (not every participant received the reminders) ( $n=16$ ) and to personalize the (non)alcoholic pictures whereby participants can choose which pictures are showing ( $n=13$ ).

## **DISCUSSION**

### **Main results**

The current pilot study consisted of a self-selected, non-clinical sample using a pretest-posttest single group design to assess the results of the Breindebaas app for participants who experienced an alcohol problem or who were concerned about their drinking. The study showed that most of the participants were problem drinkers. After using the app for three weeks, a reduction in weekly alcohol consumption of approximately eight units was found. Additional analyses confirmed that the effect is possibly attributed to the use of the CBM, indicating a dose-response relationship.

An interesting finding was that in particular problem drinkers participated and were using this relatively simple app in the pilot study. In comparison with other web-based self-help interventions this is a comparable group (Saitz et al., 2004; Koski-Jannes, Cunningham, Tolonen & Bothas, 2007; Riper, Kramer, Conijn, Smit, & Schippers, 2009). Of the completers, a large part never sought help for their alcohol problem before. The app could be

a first step for problem drinkers to do something about their alcohol problem in an easily accessible way. This is in line with studies on web-based self-help interventions for adult problem drinking who also mainly reached first-time help seekers, with rates from 80% to 90% (Hester, Lenberg, Campbell, Delaney, 2013; Cunningham, Wild, Cordingley, Van Mierlo, Humphreys, 2009).

The decrease in weekly alcohol consumption is in line with previous findings of brief online alcohol interventions. Riper et al. (2007) showed the effectiveness of a web-based self-help program, Drinking Less (DL), in a randomized controlled trial (RCT). In 2009 they examined whether those findings were also generalizable to a naturalistic setting. Participants who were already registered to the website DL were recruited in a pretest-posttest study. The data of participants in the published RCT of DL and data collected of participants in the naturalistic setting, were compared. The results for both groups were similar as both showed an reduction in alcohol consumption of 7.4 units. Furthermore, Koski-Jännes, Cunningham, Tolonen & Bothas (2007) evaluated an Internet-based self-assessment tool with a personalized feedback summary for Finnish drinkers and compared the alcohol consumption at baseline and three months later. Participants reduced their drinking at follow-up with approximately 5 units. Although there was a reduction in alcohol consumption the current study does have a limitation. As it did not have a control group, the reduction of alcohol consumption has to be interpreted carefully. Wiers et al. (2015) did have a control group, but indicated that in their study, where they examined the effects of web-based CBM in self-selected problem drinkers, participants in all four conditions reduced their drinking, including the control group. Relevant in the current context are the explicit condition ( $d=0.34$ ) and the control condition at posttest ( $d=0.19$ ) used in their study. A possible explanation mentioned for the result in the control condition was that, for motivated problem drinkers, the fact that they are doing something about their drinking problem could already reduce their drinking, also called a non-specific effect. Donovan, Kwekkeboom, Rosenzweig and Ward (2009) mentioned the 'non-specific effects' in psychoeducational intervention research as 'elements of the intervention not specified or directed by the theory'. Examples of these non-specific effects are outcome expectations of patients, the credibility of the treatment being delivered or the credibility of the person providing the intervention. Donovan et al. also mentioned 'Hawthorne effects' in which participants report an improvement in outcomes as a result of being studied. Such effects could also be an explanation for the reduction in alcohol consumption in the present study. To examine the working mechanism of the intervention, further research is needed.

If effects can be attributed to the app, an explanation may also be that a mobile CBM allows context-dependent training. Kuckertz et al. (2014) tested if fear activation prior to attention training sessions would increase the efficacy of attention modification programs (AMP) within participants with a social anxiety disorder. Participants who received instructions to activate social anxiety fears before their training sessions were compared to the active condition, in which participants only received AMP, and the attention control condition, both reported by Carlbring et al. (2012). The AMP condition with fear activation showed a greater reduction in social anxiety symptoms in comparison to the other conditions. An explanation mentioned for the stronger effect in AMP with fear activation compared to the AMP-only group could be the presence of social anxiety provoking situations, which may lead to stronger attentional processing. This suggests that in such a 'hot' state, effects are greater, which could also be the case in the current study. Participants could accomplish the training sessions anywhere, in a real-life context, where they would normally consume alcohol. Most of the participants followed the training sessions at home, which could be the environment where their drinking begins. In that case, this context may have led to the reduction in alcohol.

A positive correlation between adherence and reduction in weekly alcohol consumption was indicated. Participants with high adherence to the CBM training showed a greater reduction in weekly alcohol consumption in comparison with participants with low adherence. Before the training sessions, we recommended participants to complete two sessions weekly during the three weeks of the pilot study. During the analysis we conducted explorative research in which adherence was analyzed at four levels. It was clear that the group who performed less than four sessions differed in their slope from the other groups; indicating that performing four sessions was the minimum to show an effect. Wiers et al. (2011) already confirmed this in their clinical study, where participants completed four brief sessions and afterwards showed positive outcomes. We therefore chose a cut-off of four to which 78.8% of participants complied. But performing six sessions or more even showed more effect. Eberl et al. (2014) studied explicitly how many sessions are needed for alcohol-dependent patients in a clinical setting and reported six training sessions as the mean optimum. They also indicated that many patients improve further after those six sessions. Thus, reduction seems to be greater for participants who performed more training sessions. Question remains how many sessions are optimal in a non-clinical setting. Therefore more research is needed. Elfeddali, Bolman, Pronk and Wiers (2016) conducted a web-based Attentional Bias Modification (ABM) self-help intervention for smokers, in which participants were randomized over six



sessions of ABM- or a placebo-training in a period of two weeks. Of the training completers 91% participated in four to six sessions. In comparison with the current study, this study also has a high adherence rate. Other studies regarding the Alcohol Avoidance Training were often performed in a clinical setting. Therefore the adherence rate in our study cannot be compared with those studies. Several reasons could explain the high adherence in our study. First, the delivery of CBM Alcohol Avoidance Training as a mobile version better fits with the needs of the user. Most people have their smartphone with them at all times. As a result, participants could do the sessions everywhere. Second, we offered relatively brief sessions which are not very time consuming in comparison to other studies CBM studies (Eberl et al., 2013; Wiers et al., 2015, 2011). Third, we applied motivating elements, such as encouraging words and gamification elements, to the sessions to motivate the participant to complete all the sessions. Participants could also win a gift voucher of 100 euros. Wiers et al. (2015) already mentioned that introducing gaming elements could be a solution for the high dropout in their study. Also Boendermaker et al. (2015) indicated that the use of gaming elements can increase motivation to train using CBM. Kelders, Kok, Ossebaard and Van Gemert-Pijnen (2012) mentioned, in a systematic review of adherence to web-based interventions, the low adherence rate of approximately 50% in those interventions. This appears to reduce treatment effectiveness (Donkin et al., 2011). This may indicate that, when high adherence exist, the treatment outcome is better. But high adherence may also be an effect of successful behavior change. The completers could be satisfied about the reduction of their alcohol consumption and misattribute this change to the CBM protocol. As a conclusion it is clear that adherence and alcohol consumption are associated with each other, whereby a dose-response relationship is likely, but this cannot be concluded with certainty.

Significant differences were found on several baseline characteristics between study completers and dropout. Study completers were older and higher educated and female study completers had a lower weekly alcohol consumption at baseline. Both male and female study completers had a lower AUDIT score at baseline compared to the dropouts. As a result of the differences between the study completers and the dropouts, the outcomes of the study could not be generalized for the whole group. Apparently, current web-based interventions often reach a particular group of participants. Several studies have shown that these interventions most often reach higher-educated females participants (Postel et al., 2005; Kelders, Van Gemert-Pijnen, Werkman, Nijland, Seydel, 2011; Kelders, Bohlmijs, Van Gemert-Pijnen, 2013).

We further investigated if there were any moderators for a reduction in alcohol consumption. Besides adherence, interaction effects were also found for gender and concentration. Participants who were male or (highly) concentrated at the training sessions showed a greater reduction in alcohol consumption. An explanation for the difference in gender may be that male participants scored higher on their drinking in comparison with female participants at baseline, indicating that heavy drinkers could achieve a greater reduction in alcohol consumption. This could also apply to concentration; highly concentrated participants scored higher on their drinking at baseline than minimally concentrated participants. Results indicate that being concentrated at the sessions provides a greater reduction in alcohol consumption. This is confirmed in a study on attentional bias retraining in social anxiety where the importance of being concentrated at the effectiveness of the training is suggested (Carlbring et al., 2012).

Regarding the received user-data from the participants, several suggestions were provided for improving the app. The most mentioned suggestion was to show a greater variety of pictures of (non)alcoholic drinks in the sessions. To be the best of our knowledge, the literature does not explicitly describe whether a minimum or maximum of pictures is needed to produce a change. There is however one study that made a distinction in pictures during the assessment task and the task used in the pretest and posttest. In the assessment task participants were instructed to react to the format of the pictures, while during the training task participants responded to the content of the pictures (Wiers et al., 2011). Furthermore Pronk et al. (2015) conducted a validation study of the picture set used in this study, but no suggestions regarding the variety and the quantity of pictures were mentioned.

### **Strengths and limitations**

Several strengths of the present study can be mentioned. First, this study had a large sample of the general public from all parts of the Netherlands; the number that participated at both baseline and posttest was high. As a result, it was possible to do analyses with a large amount of self-selected problem drinkers. Second, the study consisted of high training adherence in comparison with other studies. Third, it was a naturalistic study in which participants performed the training sessions with minimal protocol. Because of this the ecological validity was high. Fourth, via the online posttest we gathered user data for the improvement of the Breindebaas app. The user data gave insight in the experiences of the participants who actually used the app and in what improvements are necessary in the future.

The present study also had a number of limitations. First, as mentioned before, the present study cannot attribute the observed improvements exclusively to the training sessions of the app due to the lack of a control group. Therefore, the results should be interpreted with caution; they could also be related to non-specific effects. Indications for a dose-response effect do however supports the notion that the effect could be attributed to the app. Second, there was no approach bias measurement in this study. Should this measurement have been included, it could have given insight into the causal mechanism of the intervention; the specific effect of the training. A last limitation is that the choice for the cut off at four sessions is based on empirical data of the current study. Besides the study of Wiers et al. (2011) there is a lack of evidence for this cut off. Nevertheless, is our study of value because the cut off as four could be the minimum of sessions that are actually needed to provide an effect.

### **Implications for practice and further research**

It is recommended that the suggestions that participants at posttest gave for the improvement of the app are adapted. The most important suggestion that was mentioned, is to show a greater variety of pictures of (non)alcohol drinks in the sessions. There is a lack of evidence regarding the minimum of pictures that is needed. Therefore it is important to do more research regarding the picture set. Furthermore several suggestions can be made for further research, in response to the limitations of the study. First, we cannot conclude with certainty that the intervention caused the reduction in alcohol consumption because of the lack of a control group. Therefore it is recommended to add a placebo-control CBM in further research. Additionally, more research is needed to investigate if four training sessions are the minimal number needed to show reduction. Moreover the short-term effect of the intervention was measured by current study with a pretest-posttest design with three weeks in between. The long-term effect of the intervention will be measured through the follow-up, three months after the posttest.

### **CONCLUSIONS**

The current study was the first (pilot) study that employed the CBM Alcohol Avoidance Training as a mobile version for problem drinkers. The preliminary findings provide a first indication that the training version of the CBM app fills a need for (mostly) problem drinkers, and a promising reduction in their alcohol consumption where indications for a dose-response relationship corroborate that the effect may be attributed to the CBM app. Results need to be replicated with a control condition before strong conclusions can be drawn.

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