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### Well connected

#### Web-based treatment for problem drinkers

Een wetenschappelijke proeve op het gebied van de Sociale Wetenschappen

#### **PROFFSCHRIFT**

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#### CONTENTS

Chapter 1	
General Introduction	7
Chapter 2	
E-Therapy for Mental Health Problems: A Systematic Review	23
Chapter 3a	
Does E-Therapy for Problem Drinking Reach Hidden Populations?	43
Chapter 3b	
Characteristics of Problem Drinkers in E-Therapy versus Face-to-Face Treatment	47
Chapter 4	
Evaluation of an E-Therapy Program for Problem Drinkers: A Pilot Study	61
Chapter 5	
Effectiveness of a Web-based Intervention for Problem Drinkers and Reasons for Dropout: Randomized Controlled Trial	81
Chapter 6	
Therapeutic Alliance in E-Therapy versus Face-to-Face Addiction Treatment	103
Chapter 7	
Attrition in Web-based Treatment for Problem Drinkers	117
Chapter 8	
Summary and General Discussion	141
Appendices	
Samenvatting (Summary in Dutch)	162
Dankwoord (Acknowledgements)	170
Curriculum Vitae	173
List of publications	174

# CHAPTER 1 General Introduction

'It's not too late, it's never too late.

It is only too late if there is no way back...
and even then there is repentance and you can think
how it ever would have been...'

(Original Dutch text:

'Het is niet te laat, het is nimmer te laat.

Het is pas te laat als er geen weg terug is...
en zelfs dan is er berouw en kun je denken
hoe het ooit zou zijn geweest...')

(Anna-Eva on the forum of Alcoholdebaas.nl)

This introductory chapter starts with a description of problem drinking in the Netherlands along with the help-seeking behaviour of problem drinkers. The concept and the current state-of-the-art of e-health are explained, this is followed by a description of the e-therapy program Alcoholdebaas.nl. The chapter ends with an overview of the aims and structure of this thesis.

#### PROBLEM DRINKING

In the Netherlands, 10.3% of people between 16 and 69 years are defined as problem drinkers. These people do not just drink above the threshold of drinking 4 or 5 units (1 unit = 10 millilitres of ethanol) a day for at least 21 days per month or drinking 6 or more units at least once a week, but also report various negative consequences of their alcohol consumption such as health problems, family problems or poor work performance. Dutch men are more likely to be problem drinkers (16.8%) than women (4.2%). The percentage of problem drinkers in the general Dutch population (aged 16-69) seems to be fairly stable, as no changes have been observed from 1980 to 2003 (Van Dijck & Knibbe, 2005). Problem drinking is a highly prevalent public health issue, with serious consequences in terms of morbidity and mortality (Ezzati, Lopez, Rodgers, Vander Hoorn, & Murray, 2002), economic costs (Smit et al., 2006) and social problems (Bessell et al., 2002). Alcohol dependence, the most severe form of problem drinking, has been identified as one of the leading causes of morbidity and mortality (Room, Babor, & Rehm, 2005). The DSM-IV-TR distinguishes between alcohol abuse and alcohol dependence. Alcohol abuse is defined as the recurring or continued alcohol use despite negative consequences such as physically hazardous

situations, legal problems, failure to fulfil major role obligations at work, school, or home, or social or interpersonal problems (American Psychiatric Association, 2000). Alcohol dependence involves a maladaptive pattern of alcohol use, leading to clinically significant impairment or distress, occurring in a 12-month period. Alcohol dependence is characterised by three or more of the following seven criteria (American Psychiatric Association, 2000): (1) tolerance; (2) withdrawal; (3) use in larger amounts or over longer periods than intended; (4) persistent desire or unsuccessful efforts to cut down on alcohol use; (5) a great deal of time spent in obtaining alcohol or recovering from effects; (6) social, occupational and recreational pursuits being given up or reduced because of alcohol use; (7) use being continued despite knowledge of alcohol-related harm (physical or psychological). According to data from the NEMESIS-2 study (Netherlands Mental Health Survey and Incidence Study-2) from 2007-2009, it was estimated that 0.3 to 1.2% of the population aged 18 to 64 years met the diagnosis of alcohol dependence, which corresponds to the number 82.400 people with alcohol dependence. An estimated 2.9 to 4.5% of respondents met a diagnosis of alcohol abuse, corresponding to 395.600 people (De Graaf, Ten Have, & Van Dorsselaer, 2010). The DSM-V will probably merge alcohol abuse and alcohol dependence into a one-dimensional continuum, named alcohol-use disorder (American Psychiatric Association, 2010; Martin, Chung, & Langenbucher, 2008). Alcohol dependence is increasingly being viewed as a biopsychosocial disease with various biological, psychological and social causes and consequences (AFM, 2000; Wallace, 1985). The complex and ongoing interactions between these factors contribute to the development of alcohol addiction problems and vary between individuals. It is generally assumed that the more risk factors there are, the greater the vulnerability to alcohol dependence. Alcohol problems lie on a continuum of severity, varying from least risk to most risk (AFM, 2000; Wallace, 1985).

#### **HELP-SEEKING BEHAVIOUR**

Despite the high prevalence rate, most problem drinkers never seek treatment (Cunningham & Breslin, 2004). Only 34.646 problem drinkers, representing 3% of the Dutch population of problem drinkers, received professional help from an addiction treatment service in 2009 (Ouwehand, Kuijpers, Wisselink, & van Delden, 2010; van Laar, Cruts, van Ooyen-Houben, Meijer, & Brunt, 2010). This percentage has been stable for years. Alcohol use often only becomes defined as problematic after there have been serious consequences in health, work or in social life over a longer period. Subsequently, a lot of problem drinkers struggle for a very long time without seeking help; usually for 10 or more years of alcohol abuse or dependence (Bruffaerts, Bonnewyn, & Demyttenaere, 2007). Waiting too long before seeking help therefore seems to be a characteristic of people with an alcohol problem. The

The other side of this problem is that not enough effort is made by care providers to provide accessible interventions for problem drinkers. The current health care system is not always able to meet the needs of problem drinkers as the threshold for accessing professional help is too high. For years the Dutch government has focussed on the early identification of alcohol problems and improving of the accessibility of alcohol treatment services. Thus in 1986, Dutch government noted that treatment services for people with early alcohol problems should be more accessible. However, 15 years later (in 2001), the government stated that in their alcohol policy that this accessibility had not been achieved. In 2007, the then Minister of Health, Welfare and Sport, Mr. Hoogervorst again stated that the government wanted to prioritise the early identification of alcohol problems (Lemmers & Riper, 2007). Unfortunately, we have to conclude that over the past 25 years many alcohol related initiatives have been unsuccessful and have not lead to substantial improvement. Because of this delay it is likely that alcohol related problems have increased. The internet with its widespread access offers a novel opportunity to administer easily accessible interventions for problem drinkers and web-based interventions offer a solution for some of the aforementioned problems (Swan & Tyssen, 2009; Young, 2005).

#### E-HEALTH

#### Definition

E-health, or electronic health, refers to healthcare practices supported by all kinds of information and communication technology. It is a dynamic concept that is constantly moving and developing. Eysenbach defines the e-health concept in the following way: 'E-health is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology' (Eysenbach, 2001). E-health provides solutions in overcoming some of the barriers of regular face-to-face help, because it offers participants

information and treatment interventions in their own personal environment at a time of their own choosing. Participants no longer need to visit the therapist's office for scheduled weekly visits, which makes e-health programs more easily accessible and convenient. E-health broadens the scope of healthcare beyond its conventional boundaries. A precondition for the success of e-health interventions is good internet coverage. Internet usage has increased rapidly, from 52.5% of the Dutch population having Internet access in 2003, to 65.9% in 2006, and 88.6% in 2010 (www.internetworldstats.com). Although internet access is no longer a primary barrier in the Netherlands, it still remains a constraint for socially disadvantaged user groups like elderly people or people with a lower socioeconomic status.

#### **Availability**

The availability of online interventions for mental health problems in general and alcohol problems in particular has grown considerably in recent years (Bennett & Glasgow, 2009; Cuijpers, van Straten, & Andersson, 2008; Marks, Cavanagh, & Gega, 2007). At the start of this research thesis in 2005, the Pubmed search with the keywords 'web-based treatment' and 'alcohol' resulted in 17 hits, 'online treatment' and 'mental health' in 84 hits and 'ehealth' in 345 hits. On the 1<sup>st</sup> of March 2011, the same searches lead to respectively 106, 269 and 833 hits in Pubmed. Additionally, there were only two online alcohol interventions available in the Netherlands in 2005: a computer tailored advice (www.drinktest.nl) and an online self-help program Drinking Less (www.minderdrinken.nl) (Riper et al., 2008; Riper et al., 2007). In 2011, at least twenty different interventions are available for people with drinking problems, ranging in content, structure, duration, intensity and involvement of a professional.

As a result of the fast e-health developments over the past 5 years, there has been a great variety of terminology used. Initially, we chose to use the term e-therapy; however, during the research period we changed it into web-based treatment as this latter term better fitted the international terminology. Both terms are defined as online treatment with active involvement of a therapist, which takes place via asynchronous written internet communication only. In the first 4 articles of this thesis we therefore used the term e-therapy and from then we used the term web-based treatment.

#### Types of interventions

A wide variety of online interventions are currently available; they mainly differ in terms of the intensity of the therapist involvement: from (1) fully self-administered therapy or pure

self-help, (2) predominately self-help (i.e. therapist assesses and provides initial rationale, and teaches how to use the self-help tool), (3) minimal-contact therapy (i.e. active involvement of a therapist, but to a lesser degree than traditional therapy, for example using e-mail), to (4) predominantly therapist-administered therapy (i.e. regular contact with therapist for a number of sessions, but in conjunction with self-help material) (Andersson, Bergstrom, Carlbring, & Lindefors, 2005). In the context of this definition, the e-therapy program Alcoholdebaas.nl belongs to predominantly therapist-administered therapy with weekly contact with a personal therapist for a period of 3 months, in conjunction with psycho education, daily registration and homework assignments. The active involvement of a therapist leads to the question whether it is possible to establish a therapeutic relationship via the internet.

#### Therapeutic relationship

Although the therapeutic relationship between patient and therapist has been accepted as an important element of the therapeutic process in regular face-to-face treatment services (Martin, Garske, & Davis, 2000), the therapeutic alliance in online therapy raises questions. The physical absence of the therapist and the lack of social and nonverbal cues such as eye contact, body language, and vocal intonation, raise concerns about the therapeutic relationship becoming impersonal and unstable (Cook & Doyle, 2002; Lingley-Pottie & McGrath, 2007; Newman, 2004). However, a small amount of research has been conducted examining the nature and the relevance of the therapeutic alliance in online cognitive behavioural therapy for traumatized patients and for patients with chronic stress. These studies show that positive and trustworthy contact can be established via the Internet, comparable to or even better than the therapeutic alliance found in face-to-face treatment (Cook & Doyle, 2002; Knaevelsrud & Maercker, 2007; Lange, van de Ven, Schrieken, & Smit, 2003). There are no studies available that investigated the patients' perceived therapeutic alliance in web-based treatment for problem drinkers; to date alcohol intervention studies mainly focussed on the effectiveness of the intervention.

#### Effectiveness

The effectiveness of web-based alcohol interventions with active therapeutic involvement has not yet been examined. We therefore decided to broaden our scope to e-mental health interventions with active therapeutic involvement in other domains. Although we found many studies in the broad field of e-mental health interventions with active therapeutic involvement that showed promising results (Carlbring, Ekselius, & Andersson, 2003; Carlbring

et al., 2005; Devineni & Blanchard, 2005; Klein, Richards, & Austin, 2006; Lange, Rietdijk et al., 2003; Lange et al., 2005; Richards, Klein, & Austin, 2006; Ström, Pettersson, & Andersson, 2004; Tate, Jackvony, & Wing, 2003, 2006; Zabinski, Wilfley, Calfas, Winzelberg, & Taylor, 2004), their methodological quality had not been evaluated in a rigorous way. Reviews in the related field of online health information or computerized (fully automated or tailored) health interventions mentioned the tendency towards poor methodological quality of studies which show high drop-out rates, small sample sizes, lack of control groups, inadequate recruitment strategies, and very different inclusion criteria (Andersson et al., 2005; Bessell et al., 2002; Copeland & Martin, 2004; Kaltenthaler, Parry, & Beverley, 2004; Spek et al., 2007). We therefore assumed that it would be necessary to systematically assess the methodological quality of studies on mental health interventions with active therapeutic involvement.

The available randomized controlled trials of online alcohol interventions all involved pure self-help interventions without therapist involvement (Bewick et al., 2008; Chiauzzi, Green, Lord, Thum, & Goldstein, 2005; Cunningham, Wild, Cordingley, van Mierlo, & Humphreys, 2009; Doumas & Hannah, 2008; Doumas, McKinley, & Book, 2009; Kypri et al., 2004; Moore, Soderquist, & Werch, 2005; Riper et al., 2008; Saitz et al., 2007; Walters, Vader, & Harris, 2007). We decided to investigate the effectiveness of our e-therapy program with active therapeutic involvement as self-help is not comfortable for all problem drinkers and webbased interventions for people with anxiety and depression appeared to be more effective when a therapist was actively involved (Spek et al., 2007), Is the e-therapy program Alcoholdebaas.nl effective in terms of reducing alcohol consumption and improving health status? And does the program also lead to greater effect sizes compared to online self-help programs? We were also interested in more information about the target group of our intervention, attrition rates, and reasons for dropout.

#### Attrition

Despite the promising findings, the actual uptake of online alcohol interventions is low; they struggle with a huge proportion of participants discontinuing usage or failing to complete treatment sessions or assessments (Christensen, Griffiths, & Farrer, 2009; Eysenbach, 2005; Riper et al., 2008). Eysenbach refers to this substantial proportion of users that drop out in his "law of attrition", which illustrates that providing access to an intervention does not guarantee that participants use it (Eysenbach, 2005). Eysenbach distinguishes two processes of attrition: dropout attrition and non-usage attrition. Dropout attrition refers to participants being lost to follow-up; they do not return to fill in follow-up questionnaires but do complete

most of the intervention. Non-usage attrition refers to participants who stop using the intervention, but still fill in questionnaires. Unfortunately, high dropout rates seem to be a natural and typical feature of e-health interventions. As web-based intervention studies mainly focus on efficacy, less is known about attrition, the reasons for non-completion, and the specific components needed to improve adherence (Eysenbach, 2005). There is a need to gain more insight into the attrition process in order to improve the effectiveness of web-based alcohol interventions.

#### E-THERAPY PROGRAM ALCOHOLDEBAAS.NL

The Dutch e-therapy program Alcoholdebaas.nl (in English: Lookatyourdrinking.com) was developed in 2005 to provide an easily accessible treatment intervention for problem drinkers. Alcoholdebaas.nl is a complete treatment program accessed via the internet with active therapeutic involvement. The e-therapy program facilitates problem drinkers to seek professional help themselves directly. Participants access the e-therapy program in their personal environment via the homepage www.alcoholdebaas.nl. This website contains a lot of alcohol-related information and a forum for fellow-sufferers. The e-therapy program consists of a structured two-part online treatment program in which the participant and therapist communicate asynchronously, via the internet only. Participant and therapist are in separate or remote locations; the interaction occurs with a time delay between the responses. During the whole program the participant keeps the same therapist, who can be identified by a photograph in the participant's internet file. All communication between therapists and participants takes place through a secured web-based application. The aim of the e-therapy program is to motivate participants to change their drinking habits, with the ultimate goal of reducing or stopping alcohol intake. The method underlying the program is based on the principles of cognitive behaviour therapy (Hester, Miller, & Goldman, 1996; Irvin, 1999) and motivational interviewing (Britt, Hudson, & Blampied, 2004; Miller & Rollnick, 2002); empirically supported methods for substance use disorders in regular face-to-face addiction treatment.

Part 1 of the program consists of two assessments and four assignments, with the accompanying communication focusing on the analysis of the participants' drinking habits. Core concepts are: 1) Exploring advantages and disadvantages of alcohol use, 2+3) Understanding drinking patterns through completion of a daily drinking diary and descriptions of the craving moments, 4) Identifying risky drinking situations. The therapist helps the participant with every step in the program; he explains the assignments and provides feedback. The therapist always responds within three days. Messages are always

personalized, although therapists use pre-programmed text parts for the analogous parts, e.g. the explanation of an assignment. The therapist and participant cannot move on to the next assignment without completion of the previous one. At the end of part 1 personalized advice is given and the participant can choose whether to continue with treatment in part 2 or to stop. The multidisciplinary team, consisting of treatment staff, a physician specialised in addiction treatment, a psychiatrist, and two supervisors, evaluates every participant's record and gives advice to the therapist for the further treatment stages in part 2. The second part focuses on behavioural change and includes five central concepts: 1) Setting a drinking goal, which can be abstinence or moderate drinking, 2) Formulating helpful and non-helpful thoughts, 3) Considering helpful behaviours for moments of craving, 4) Identifying the moment of the decision to drink alcohol and 5) Formulating an action plan for maintaining the new drinking behaviour and for relapse prevention. The duration of the total e-therapy program is about 3 months, with one or two therapist contacts per week and daily self registration during the whole program. Besides registration, the participant usually responds every three or four days. If there is no response from the participant, the therapist contacts the participant three times during the following two weeks. If there is still no response, the participant receives a message that his record will be closed after two weeks. After finishing treatment, participants can still log on to their personal data file for six months. During this period, the therapist will respond twice for aftercare.

#### AIMS AND OUTLINE OF THE THESIS

The main purpose of this study is to investigate the effectiveness of the newly developed etherapy program for problem drinkers Alcoholdebaas.nl. The thesis examines the target population of the e-therapy program, its feasibility and clinical effectiveness. We also systematically investigate the reasons for dropout, and explore the association between participants' baseline characteristics and attrition.

The research questions of this study are:

- 1. What is the methodological quality of randomized controlled trials (RCTs) concerning e-therapy for mental-health problems?
- 2. Does e-therapy for problem drinking reach hidden populations?
- 3. Is the e-therapy program with therapist involvement, based on cognitive behaviour therapy, feasible for problem drinkers?
- 4. a) Is the e-therapy program with therapist involvement, based on cognitive behaviour therapy, effective in terms of reducing alcohol consumption and improving health status?

- b) What are the participants' reasons for dropout from the e-therapy program?
- 5. Is the therapeutic relationship in the e-therapy program comparable to the therapeutic relationship in face-to-face treatment?
- 6. What are the characteristics of attrition in the e-therapy program for problem drinkers and do patients' baseline characteristics have predictive value for treatment completion?

Chapter 2 contains a review of the literature on e-therapy for mental-health problems. We systematically assess the methodological quality of randomized controlled trials (RCTs) concerning e-therapy for mental-health problems. We therefore use the criteria list for the methodological quality assessment recommended by the Cochrane Back Review Group, adapted to e-therapy interventions (van Tulder, Furlan, Bombardier, Bouter, & Editorial Board Cochrane, 2003).

As the e-therapy program was developed to fill the gap in accessibility of alcohol treatment facilities, chapter 3 determines whether the e-therapy program indeed reaches a new population of problem drinkers, compared to current face-to-face treatment.

Chapter 4 presents the results of our pilot study. In a pre-post design, the feasibility and acceptability of the e-therapy program are assessed. Alcohol consumption and alcohol-related health problems are measured, as well as motivation for treatment and patient satisfaction.

In chapter 5, the results of our randomized controlled trial (RCT) are presented. In an open randomized controlled trial Dutch-speaking problem drinkers in the general population were randomly assigned to the 3-month e-therapy program (n=78) or the waiting list control group (n=78). The primary outcome measures are a) the difference in the score on weekly alcohol consumption, and b) the proportion of participants drinking under the problem drinking limit. Because of high dropout rates in e-health interventions, reasons for dropout were also systematically investigated.

Chapter 6 compares the therapeutic alliance of patients in an e-therapy program versus patients in traditional face-to-face addiction treatment. Alliance data from the RCT study (n=65) are compared with data from a RCT study concerning a 3-month inpatient face-to-face treatment setting for Dutch substance-dependent patients (n=77). The major outcome instrument is the Helping Alliance Questionnaire (HAQ).

Chapter 7 examines the prevalence rate of attrition, pre-treatment predictors of treatment completion, reasons for non-completion, and participants' suggestions to enhance treatment adherence. Data from the RCT sample (n=156) and from an open-access group of users (n=885) will be explored.

Finally, a general discussion completes the thesis and assesses the scientific and clinical relevance of this study. The main results are summarized, and strengths and limitations are pointed out.

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### CHAPTER 2

# E-Therapy for Mental Health Problems: A Systematic Review

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#### **ABSTRACT**

Background - The widespread availability of Internet offers opportunities for improving access to therapy for people with mental health problems. There is a seemingly infinite supply of Internet-based interventions available on the World Wide Web. The aim of the present study is to systematically assess the methodological quality of randomized controlled trials (RCTs) concerning e-therapy for mental health problems.

Methods - Two reviewers independently assessed the methodological quality of the RCTs, based on a list of criteria for the methodological quality assessment as recommended by the Cochrane Back Review Group.

Results - The search yielded 14 papers that reported RCTs concerning e-therapy for mental health problems. The methodological quality of studies included in this review was generally low.

Conclusions - It is concluded that e-therapy may turn out to be an appropriate therapeutic entity, but the evidence needs to be more convincing. Recommendations are made concerning the method of reporting RCTs and the need to add some content items to an e-therapy study.

#### INTRODUCTION

Nowadays, the Internet offers a wide variety of online treatment programs for mental health problems. However the question is: What is known about the effectiveness of these etherapy programs? To answer this question, this review will first provide background information and then systematically assess the quality of e-therapy studies.

Alcoholism, drug abuse, depression, anxiety disorders, and eating disorders are all common psychiatric disorders associated with considerable morbidity, mortality, social and psychosocial problems, violence, criminal behaviour, or accidents. In purely economic terms these problems cost American society more than \$150 billion per year, from both direct (treatment-related) and indirect (productivity loss at workplace, school, and home) expenses (Harwood, 1998; Insel, 2005).

People do not routinely report their mental health problems to medical and mental health practitioners (Substance Abuse and Mental Health Services Administration, 2005; Weisner & Matzger, 2003). Patients often withhold information because of shame or fear of stigmatization, with the result that many people with mental health problems will never seek or engage in treatment (Carlbring, Westling, Ljungstrand, Ekselius, & Andersson, 2001; Christensen, Griffiths, & Jorm, 2004; Kohn, Saxena, Levav, & Saraceno, 2004). The gap between need and actual treatment received for mental disorders is universally large. Kohn et al. (2004) examined this treatment gap in the regions studied by the World Health Organization. Gaps were estimated to be 32.2% for schizophrenia, 56.3% for depression, 56.0% for dysthymia, 50.2% for bipolar disorder, 55.9% for panic disorder, 57.5% for generalized anxiety disorder, 57.3% for obsessive-compulsive disorder and with 78.1% the widest for alcohol abuse and dependence. Reasons for not receiving treatment were access barriers, delay in treatment, stigma associated with treatment, patients not having time, and/or not knowing were to go for services.

The Internet offers opportunities for improving access to therapeutic interventions that are easy to engage in and are without thresholds requirements (Copeland & Martin, 2004; Humphreys & Tucker, 2002; Kaltenthaler, Parry, & Beverley, 2004). Moreover, the Internet serves a larger and more diverse segment of the population with mental health problems, compared to regular face-to-face treatment services (Ainsworth, 2000; Humphreys & Klaw, 2001; Manhal-Baugus, 2001; Postel, de Jong, & de Haan, 2005). As of 2007, 69.7% of people in the United States, and about the same percentage in West European countries have Internet access (www.internetworldstats.com). Involvement in therapy via the Internet arouses some

resistance, because of the idea that anonymity interferes with the development of a meaningful therapeutic relationship. However, it has been reported that, in general, patients as well as therapists experience a positive relationship during Internet therapy (Ainsworth, 2000; Knaevelsrud & Maercker, 2006; A. Lange, van de Ven, Schrieken, & Smit, 2003), suggesting that it is possible to form a meaningful relationship based on written e-mail messages.

In our opinion, the best definition of e-therapy is given by Andersson and colleagues (Andersson, Bergstrom, Carlbring, & Lindefors, 2005). In e-therapy there is active involvement of a therapist, and as a consequence the formation of an ongoing, helping relationship between therapists and patients can take place purely via Internet communication. This occurs although patient and therapist are in separate or remote locations. Communication is usually asynchronous (i.e., via e-mail the interaction occurs with a time gap between the patient's and the therapist's responses) (Ainsworth, 2000; Bloom; Manhal-Baugus, 2001).

Many studies have been conducted in the field of e-therapy, with promising results (Andersson et al., 2005; Carlbring, Ekselius, & Andersson, 2003; Carlbring et al., 2005; Devineni & Blanchard, 2005; Klein, Richards, & Austin, 2006; A. Lange et al., 2003; A. Lange et al., 2005; Richards, Klein, & Austin, 2006; Ström, Pettersson, & Andersson, 2004; Tate, Jackvony, & Wing, 2003, 2006; Zabinski, Wilfley, Calfas, Winzelberg, & Taylor, 2004). However, the quality of e-therapy studies has not been evaluated in a rigorous way. Reviews in the related field of computerized (fully automated or tailored) or Internet health interventions mention the tendency for poor methodological quality of studies. A review from Copeland & Martin (2004) on different types of programmed Internet interventions (with little or no direct therapist involvement) showed that many studies have high drop-out rates, involve small sample sizes, or lack control groups. Bessell and colleagues concluded their review on consumer use of online health information as follows (Bessell et al., 2002): "At present, there is almost no evidence regarding the effect of consumer Internet use on health outcomes. Well-designed controlled studies, instead of anecdotes and opinions, about the risks and benefits of using the Internet are urgently needed (p.34)." The systematic review from Kaltenthaler and others (2004) on the efficacy of computerized cognitive behaviour therapy (CCBT) for anxiety and depression showed that the quality of studies ranged from poor to moderate. Andersson and colleagues (2005) conducted a review on the use of the Internet for the treatment of anxiety disorders (different types of treatment) and concluded that trials have been small and that studies in psychiatric settings mostly recruited patients via advertisement. Spek and colleagues (Spek et al., 2007) conducted a meta-analysis of 12 randomized controlled trials of Internet-based CBT programs for symptoms of depression

and anxiety. Overall, the authors concluded that their analysis indicated that Internet-based interventions are effective, especially those with therapist involvement. However, Spek et al (2007) also emphasized the limitations: for example, the number of studies available, the small number of subjects in some studies, and the differing inclusion criteria. None of the reviews mentioned systematically assessed the methodological quality of studies based on a list of sound criteria. As a consequence, the major aims of the present study are to systematically assess the methodological quality of studies, to identify the weaknesses, and to address the difficulties. The quality of randomized controlled trials of stand-alone Internet interventions, with therapist involvement, for mental-health problems will be assessed. Not assessed are Internet interventions without therapist involvement (Andersson, Stromgren, Strom, & Lyttkens, 2002; Chiauzzi, Green, Lord, Thum, & Goldstein, 2005; Clarke et al., 2005; Clarke et al., 2002; Etter, 2005; Kenardy, McCafferty, & Rosa, 2003; Kypri et al., 2004; Low et al., 2006; Munoz et al., 2006; Oenema, Tan, & Brug, 2005; Strecher, Shiffman, & West, 2005; Swartz, Noell, Schroeder, & Ary, 2006; Taylor et al., 2006) or Internet interventions with faceto-face or telephone contact as part of the treatment (Celio et al., 2000; Litz, Engel, Bryant, & Papa, 2007; Schneider, Mataix-Cols, Marks, & Bachofen, 2005).

#### **METHODS**

Details of the protocol for the selection and evaluation of the published studies are given below.

#### Types of studies

This study compared randomized controlled trials (RCTs) of e-therapy versus control interventions.

#### Types of interventions

The Internet interventions comprised therapist involvement for problem drinking, drug abuse, and other mental health problems.

#### **Exclusion criteria**

 No therapist contact at all: studies with Web site access only or fully automated programs.

- Face-to-face therapy or telephone contact as an additional component of the treatment program.
- The Internet therapy program is not stand-alone.
- Age < 18</li>
- Exclusively group interventions

#### Inclusion criteria

- Primarily Internet-based interventions
- Therapist involvement
- Internet therapy is the exclusive treatment program (with the exception that an
  initial face-to-face meeting is permitted in order to explain the treatment in the
  beginning and/or for assessment purposes during treatment. Telephone contact is
  also permitted for assessment purposes).
- Age of target group at least 18.

#### Search strategy

Studies were identified using the computer-aided engines MEDLINE, EMBASE and PsychINFO. The Cochrane Library, 2006, issue 2 was screened. Reference lists of relevant studies were checked for potential sources. The search was conducted between October 2006 and February 2007. The search terms were the following: randomized controlled trial, Internet, e-health, online, Web-based, e-therapy, treatment, counseling, cognitive behavioural therapy, alcohol, problem drinking, substance abuse, dependence and addiction.

#### **Quality review**

The list of criteria for the methodological quality assessment recommended by the Cochrane Back Review Group (van Tulder, Furlan, Bombardier, Bouter, & Editorial Board Cochrane, 2003) was used (Table 1). An item was scored 'positive (+)' if the criterion was fulfilled, 'negative (-)' if not fulfilled, or registered as 'unclear (?)'. A total 'Quality Score' (QS) was computed by counting the number of positive scores. Two reviewers (first and second authors) independently assessed the methodological quality of the RCTs. If the two reviewers did not agree, the topic was discussed and a third reviewer (third author) was consulted. Due to the diversity of interventions, definitions of e-therapy, study populations, and outcome measures, no attempt was made to perform a meta-analysis of the results of QS.

Table 1. Methodological Quality of Randomized Controlled Trials

First author	Publication	Criterion validity/reliability											
i ii se dadiloi	year	1	2	3	4	5 <sup>a</sup>	6 b	7	8°	9	10 <sup>d</sup>	11	Total
Andersson	2005	+	?	?	-	-	+	+	?	-	+	+	5
Carlbring	2001	?	?	+	-	-	+	+	?	-	-	+	4
Carlbring	2003	+	+	+	-	-	+	+	?	-	+	+	7
Carlbring	2005	+	?	+	_ e	-	+	+	-	+	+	+	7
Devineni	2005	?	?	+	-	-	+	? <sup>f</sup>	-	-	?	-	2
Klein	2006	+	+	?	-	-	-	+	?	+	+	+	6
Lange	2003	?	?	+	-	-	+	+	-	-	+	-	4
Lange	2005	?	?	+	-	-	+	+	? <sup>g</sup>	+	+	-	5
Richards	2006	?	-	-	-	-	-	+	? <sup>g</sup>	+	+	+	4
Ström	2004	?	+	+	-	-	+	-	-	-	-	-	3
Tate	2003	+	?	+	-	-	?	? <sup>f</sup>	-	+	+	+	5
Tate	2006	+	?	+	-	-	?	?	?g	+	+	+	5
Wagner	2006	+	+	+	-	-	?	+	?	+	+	+	7
Zabinski	2004	?	?	+	-	-	?	+	? <sup>g</sup>	+	+	+	6

<sup>1 =</sup> Randomization, 2 = treatment allocation, 3 = similarity of baseline characteristics, 4 = blinding of patients, 5 = blinding of therapist, 6 = blinding of observer, 7 = co-intervention equal, 8 = compliance, 9 = dropout rate, 10 = timing of outcome assessment, 11 = intention-to-treat analysis

#### RESULTS

Fourteen papers were identified that reported RCTs concerning e-therapy for mental health problems (Table 2). These studies all met the inclusion criteria of therapist involvement and no face-to-face or telephone contact as part of the treatment program, except for the permitted telephone or face-to-face contact for assessment purposes or for explanation of treatment (participation) (Carlbring et al., 2003; Devineni & Blanchard, 2005; Klein et al.,

<sup>&</sup>lt;sup>a</sup> This item is scored negative if only self-report outcome measures were used; <sup>b</sup> This item is scored positive when online self-report questionnaires were used; <sup>c</sup> Compliance is mentioned sometimes, but no single study described a cut-off point about satisfied compliance; <sup>d</sup> This item is (also) scored positive if control group becomes treatment group immediately after post measure; <sup>e</sup> Treatment credibility was evaluated in this study; <sup>f</sup> Participants were not asked about use of other treatment programs; <sup>g</sup> Detailed description of the time spent on the assignments, log-in frequencies or number of sessions attended, but no cut off point mentioned.

2006; Richards et al., 2006; Tate et al., 2003, 2006; Zabinski et al., 2004). Most of the studies included describe e-mail or Internet-driven, asynchronous therapy (i.e., with a time lag in communication between therapist and patient).

#### Methodological quality

The results of the methodological quality assessment are presented in Table 2.

Half of the studies gave a detailed description of *randomization* procedure. The other half just mentioned that participants had been randomly assigned, without any explanation concerning the method of randomization.

Treatment allocation was scored positive (+) in four studies. In these studies the person who performed treatment allocation was unaware of the group to which the patient was allocated, or allocation was done by computer with notification of the randomization being done by an independent third party. The remaining studies mostly did not mention the methods of treatment allocation.

In eleven studies groups were similar at baseline with regard to the most important prognostic factors such as duration and severity of complaints, age, and demography.

Due to the nature of the interventions, *patients* mostly cannot be *blind* with regard to their treatment allocation. Just one study included an evaluation of treatment credibility (Carlbring et al., 2005).

Blinding of care providers to treatment is not possible in the interventions studied, because the type of communication between patient and care provider is part of the therapeutic program and what distinguishes the experimental condition from control condition.

Blinding of outcome assessor is possible and was done in nine of the studies that were scored positively, in the main, because of the use of online self-report questionnaires.

Tabel 2. Study Characteristics: Randomized Controlled Trials

Chudu	Country	Design	N	Subjects	Interve	Intervention		
Study	of origin	Design	IN	Subjects	Treatment	Control	Contact with therapist?	
Andersson et al. (2005)	Sweden	RCT	117	Individuals with depression	Internet-based CBT with minimal therapist con tact + participation in online discussion group (n=57)	Online discussion group only (n=60)	No Yes	
Carlbring et al. (2001)	Sweden	RT	26	Individuals suffering from panic disorder	Internet-delivered self-help program plus minimal therapist contact via e-mail (n=9)	Waiting-list control group (n=12)	No Yes	
Carlbring et al. (2003)	Sweden	RCT	22	Individuals suffering from panic disorder	Internet-delivered CBT self- help program plus minimal therapist contact via e-mail (n=11)	Applied Relaxation (a CD with instructions) plus minimal therapist feedback (n=11)	No (participants were just selected in an in-person interview) Yes	
Carlbring et al. (2005)	Sweden	RCT	49	Individuals with panic disorder	A 10-module self-help program, plus minimal therapist contact, on the Internet (n=25)	10 face-to-face weekly sessions of CBT (TAU) (n=24).	No (1 month and 1 year after treatment an in-person interview) Yes	
Devineni & Blanchard (2005)	USA	RCT	139	Individuals with chronic tension and/or migraine headache	Tension-type headache treatment 2. Migraine-only or mixed headache treatment; both are online self-help with minimal email assistance	Delayed treatment (online symptom monitoring)	No Yes	
Klein et al. (2006)	Australia	RCT	55	Individuals with	1. Internet-based CBT with e-mail contact (n=19)	Internet-based information-only with	No (clinical interview by telephone; by 2 students)	

					2. Therapist-assisted CBT manual with telephone contact (n=18)	telephone contact (n=18)	Yes
Lange et al. (2003)	The Netherlands	RCT	184	Individuals with mild to relative severe trauma symptoms	Internet-driven treatment of posttraumatic stress (n=122)	Waiting-list control group (n=62)	No Yes
Lange et al. (2005)	The Netherlands	RCT	57	Individuals with depression	Internet-driven treatment for depression (n=40)	Internet psycho- education control group (n=17)	No Yes
Richards et al. (2006)	Australia	RCT	32	Individuals with panic disorder	1. Internet-based CBT (n=12) 2. Internet-based CBT plus stress management (n=11)	Internet-based information-only (n=9)	No (initial brief assessment by phone, conducted by student and a 90- minute face-to-face assessment) Yes
Ström et al. (2004)	Sweden	RCT	109	People with insomnia	Cognitive behavioural self- help treatment (n=54)	Waiting list control group (n=55)	No Yes
Tate et al. (2003)	USA	RCT	92	Overweight or obese adults, and 1 or more other risk factors for type 2 diabetes	Internet weight loss program plus behavioural e-counselling (n=46)	Basic Internet weight loss program (n=46)	No (Participants attended a 1-hour introductory group weight loss session. Participants were seen at baseline and at 3, 6 and 12 months for measurements of weight, waist circumference, and fasting blood glucose)

group (n=61) 2. AF = computer

group (n=64)

automated feedback

1. HC = human e-counseling 3. NC = No counselling

(n=67)

No (screening by telephone. Written

person. All participants were seen in the clinic at baseline and at 3 and 6

months for objective measurement

informed consent and baseline

measurements were obtained in

Tate

et al. (2006)

USA

RCT

Overweight or

obese adults

- The second of the state of CDT

							of body weight and completion of questionnaires)
							Yes
Wagner	Germany,	RCT	55	Individuals	Internet-based treatment	Waiting group (n=26)	No
et al. (2006)	Switzerland			diagnosed with complicated grief	program (n=29)		Yes
Zabinski et al. (2004)	USA	RCT	60	College-age women at risk for developing an eating disorder	Chat-room group intervention (n=30)	Wait-list control group (n=30)	No (Screening over the telephone to determine eligibility) Yes

 $TAU, treatment\ as\ usual; CBT, cognitive\ behaviour\ the rapy;\ RCT, randomized\ controlled\ trial.$ 

In 10 studies *co-interventions* were mentioned as avoided in the design, or the numbers of co-interventions were equally divided among the study groups (+). In most of the studies participants were asked about any co-interventions and treatment received elsewhere was an exclusion criterion, however, regulation of medication use differed greatly between studies. Although in the majority of studies the dosage of any medications used had to be consistent for 3 months before starting the Internet treatment on occasions, a period of 4 weeks was approved. Furthermore, if participants were on a co-prescribed drug most studies asked them to agree on keeping the dosage constant throughout the study. Some studies, however, did not do this, or failed to give any information on co-prescriptions. Sometimes it was also not clear whether study participants were asked about their actual behaviour concerning co-interventions: At post treatment, for example, did participants really not change medication or visit any other therapist?

Compliance is scored positive if it was measured and was satisfactory in all study groups based on reported intensity, duration, and number and frequency of sessions. Besides Carlbring (2005), there is no study that describes a cut-off point for 'satisfactory' compliance. Although it was scored negative, Carlbring determined an intended time frame and described the percentage of participants who finished all modules within that time frame. Four other studies gave a detailed description of the time spent on the assignments, log-in frequencies, or the number of sessions attended, but gave no clear criterion to assess compliance (scored as ?).

Dropout rate is acceptable if the withdrawal/dropout rate is less than 20% for short-term follow-up and 30% for long-term follow-up (van Tulder et al., 2003). However, in six studies the drop-out rates were higher.

In 11 studies, timing of outcome assessment is identical for all intervention groups (+). This item is also scored positive if patients in the control group stepped over to the treatment group immediately after post measure.

Ten studies included an intention-to-treat analysis (+).

In conclusion, it transpires that the methodological quality of studies included in this review was generally low (Table 1). Only 5 of the 14 studies had six (>50%) or more positive quality scores on the validity criteria, which is the predetermined threshold for high quality (van Tulder et al., 2003).

#### 35

#### DISCUSSION

In this review, we identified 14 randomized controlled trials of e-therapy. Of these, only five studies showed high methodological quality; all other studies showed some degree of methodological limitations. Compared to other systematic reviews, the quality of studies about e-therapy is low. For example, in a systematic review about the community reinforcement approach, Roozen and colleagues (Roozen et al., 2004) found 10 of 11 studies of high quality using the same criteria list.

With respect to the promising results of individual studies of e-therapy, we need to take into account their methodological quality. Given the increasing number of e-therapy interventions for mental health problems, substance abuse, and problem drinking, it is unfortunate that high-quality research is scarce, although we realize that conducting high-quality research in the field of e-therapy can be difficult. Surfing the World Wide Web, one finds an overwhelming supply of Internet interventions for health problems. However, just a small number of research groups are studying e-therapy interventions, often using small sample sizes. Thus, the authors believe there is a need for more well-conducted studies in the field of e-therapy, using larger numbers of participants and conducted by a variety of study groups. Although e-therapy interventions face a promising future, we have to be careful with interpretation of the current results. E-therapy may turn out to be an appropriate kind of treatment that can broaden the possibilities of health care, but the evidence needs to be more convincing. As in regular face-to-face therapy, the quality of the e-therapy can only be as good as the therapist is doing it. An important factor in the efficacy of a given treatment is the skill and good sense of the therapist. Therefore, we emphasize the importance of working with professional therapists in online treatment programs.

Recommendations can be made about the method of reporting a study and some content items need attention. For example, research reports have to be complete in describing study details: It is striking that the description of randomization procedures and treatment allocation is frequently incomplete. The recommendation sounds simple: take care to report the complete study procedure and conduct. However, evidence indicates that in many research areas the quality of reporting randomized, controlled trials (RCTs) is less than optimal (Altman et al., 2001). In response to the need for improvement in the conduct and reporting of RCTs the CONSORT group developed a revised CONSORT statement with the intention of improving the procedures for the reporting of RCTs, enabling readers to understand a trial's design, conduct, analysis and interpretation, and to assess the validity of its results. It emphasizes that this can only be achieved through complete transparency from the authors. Besides the reporting requirements, actual performance of RCTs in general

practice also poses methodological and practical difficulties (Ward, King, Lloyd, Bower, & Friedli, 1999). Some clinicians might consider RCTs unethical; for instance, they may feel uncomfortable about offering an intervention to some patients while withholding it from others. Blinding of subjects and therapists to the allocated treatment can be complex, especially when the RCT protocol for evaluating of the experimental therapy does not always mirror the routine care.

We would like to focus on the three most important weaknesses observed in the quality of the e-therapy studies evaluated. First of all, we have seen that treatment compliance was never scored positively. With the online treatment interventions it was hard to decide whether compliance was satisfactory or not. We therefore recommend that before the study starts, the cut-off points for compliance should be defined in measurable terms in the protocol. Compliance can be expressed in quantity of time that patients have to spend on the e-therapy program or the minimum number of sessions that have to be finished. Such a cut-off point has to be formulated in advance, the main criteria being that it can be plausibly demonstrated that the patient could profit from the online treatment in the time frame specified. It would also be sensible to program the intervention in such a way that it is impossible to start a next treatment session if the preceding session is not fully completed.

A second aspect of studying e-therapy that needs attention is treatment credibility. Since it is nearly impossible to blind patients to treatment allocation, treatment credibility should always be evaluated as the next best option. This recommendation echoes that of the methodological quality assessment of the Cochrane Back Review Group, which also states that the credibility of treatment should be evaluated when it is difficult to blind the patients to therapy. Moreover, treatment conditions should also be judged credible and acceptable by patients; although this necessitates extra investment, this client feedback will provide extra information and as a consequence, increases the quality of the study.

Thirdly, it appears that information about co-interventions is not always complete. Consequently, this can lead to clinically significant differences between treatment and control groups, especially in studies with small sample sizes. It is important to get information about co-medication use and at the end of the study, to check whether the patient participated in other treatment programs. Even if patients have indicated, in advance, a willingness to keep medication levels stable and not contact any other therapist, their situation can change during the study period. Patients should always be asked, post-treatment, whether their medication was taken properly during study period and whether they have been in treatment elsewhere. In the case of current medications, we strongly

recommend keeping medication dosages constant for a period of at least 3 months because it is doubtful whether medication will be stabilized after 4 weeks.

The results of this review point to a serious need to improve the quality of future RCTs of etherapy. Improvement in the evidence that underpins e-therapy interventions requires sufficiently more large, high-quality RCTs that use the most appropriate methodology for the specific intervention and outcome measures. There is also a need for better and more accurate reporting of trials. The revised CONSORT statement aims to increase the quality of reporting RCTs, thus facilitating improvement in the interpretation and the use of the results of such trials.

Drawing an analogy with the introduction of new medications, where strict procedures have to be followed before a new medicine is allowed on the market, we recommend introducing a quality standard for Internet interventions. Above all, an intervention should only be given a 'seal of approval' if adequately documented evidence is supplied.

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# CHAPTER 3A

# Does E-Therapy for Problem Drinking Reach Hidden Populations?

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Currently, nearly one in every 13 adults abuses alcohol or is alcohol dependent. In addition, several million adults also engage in risky drinking behavior that could lead to alcohol-related problems. However, only a small proportion of the people with alcohol problems ever seek and engage in treatment (Kohn, Saxena, Levav, & Saraceno, 2004). A national survey in the United States (Harris & McKellar, 2003) found that only 16% of those with alcohol use disorder had received treatment in 2001. In the Netherlands (Van Laar, Cruts, Verdurmen, & Van Ooyen, 2004), only 10% of the problem drinkers ever got professional help. Women, higher-educated people, employees, and elderly people are harder to reach for face-to-face care. Several things have improved the accessibility of alcohol interventions (Copeland & Martin, 2004; Humphreys & Tucker, 2002).

To fill the gap in accessibility, an e-therapy program was developed in the Netherlands. The content and elements of the e-therapy program are comparable to the ones of face-to-face treatment as usual. This e-therapy program distinguishes from other Internet interventions by forming an ongoing personal relationship between the therapist and client that takes place solely via Internet communications. It involves more than self-help or answering a question online. It is a structured and complete treatment program in which clients remain anonymous. The aim of this study was to determine if e-therapy indeed reaches another population with alcohol problems.

We compared the baseline characteristics of 172 e-therapy clients with a consecutive series of 172 face-to-face clients admitted for treatment as usual. All e-therapy clients gave their informed consent to participate in the research project. For the face-to-face clients, we used anonymous data files. The results showed that the baseline characteristics of the two groups differed by gender, age, education, and work situation. Chi-square tests were used to compare proportions and t tests to compare means. The e-therapy group involved significantly more women than the face-to-face group ( $\chi^2$ =9.25, df=1, p=0.002). People in the e-therapy group were more highly educated ( $\chi^2$ =46.56, df=2, p<0.001) and more often employed ( $\chi^2$ =69.13, df=1, p<0.001) than the people in the face-to-face group. E-therapy clients were also significantly older than face-to-face clients (t=3.24, df=342, p=0.001).

Our conclusion is that e-therapy serves a new group of people with alcohol problems. We reach more women, higher-educated people, employed people, and elderly people - the groups that are difficult to reach in regular face-to-face therapy. The Internet offers an

opportunity for improving access to therapy for problem drinkers. Our next step is to compare the efficacy and effectiveness of e-therapy and face-to-face therapy.

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# CHAPTER 3B

# Characteristics of Problem Drinkers in E-Therapy versus Faceto-Face Treatment

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#### **ABSTRACT**

Background - The availability of online treatment programs offers the potential to reach more problem drinkers. This study compared the client populations of an e-therapy program (asynchronous client-therapist communication via the internet) and a face-to-face treatment program.

*Objective* - To determine whether e-therapy and face-to-face groups differed from each other and changed over time.

Methods - We compared the baseline characteristics of four naturalistic groups (N=4593): two e-therapy groups (2005-2006 and 2008-2009) and two consecutive series of ambulant face-to-face clients admitted for treatment as usual. The characteristics we were interested in were gender, age, education level, working situation, and earlier treatment for drinking problems.

Results - The results showed that the baseline characteristics of e-therapy and face-to-face clients differed by gender, education level, work situation, prior alcohol treatment and age. We also found that both e-therapy groups differed over time by gender, work situation and prior alcohol treatment.

Conclusions - The e-therapy program successfully attracted clients who were different from those who were represented in regular face-to-face alcohol treatment services. This indicates that e-therapy decreases the barriers to treatment facilities and enhances the accessibility. However, the e-therapy population changed over time. Although the e-therapy program still reached an important new group of clients in 2008-2009, this group showed more overlap with the traditional face-to-face group of clients probably as result of improved acceptance of e-therapy in the general population.

Scientific Significance - Although e-therapy seems to be better accepted in the general population, anonymous treatment seems necessary to reach a broader range of problem drinkers.

#### INTRODUCTION

The availability of online treatment programs offers the potential to enhance access to interventions for problem drinkers. Most problem drinkers never seek help from traditional treatment services (Cunningham & Breslin, 2004). In the United States, only 16% of people with an alcohol-abuse disorder had received treatment in 2001 (Weisner & Matzger, 2003), and in the Netherlands, only 10% of the problem drinkers received professional help in 2006 (van Laar, Cruts, Verdurmen, van Ooyen-Houben, & Meijer, 2007). Problem drinkers also seek help at a late stage; usually after 10 or more years of alcohol abuse or dependence (Bruffaerts, Bonnewyn, & Demyttenaere, 2007). Online treatment reduces obstacles related to shame, fear of stigmatization and limited availability because of office hours. Clients can interact with their therapist without having to worry about time, employment, child care responsibilities or distance (Swan & Tyssen, 2009; Young, 2005). Online interventions for problem drinking show promising results (Cunningham, Humphreys, Kypri, & van Mierlo, 2006; Kypri et al., 2004; Postel, de Haan, & de Jong, April 2010; Riper et al., 2008; Saitz et al., 2007) and reach a larger and more diverse segment of the population of problem drinkers (Humphreys & Klaw, 2001; Lieberman & Huang, 2008; M. G. Postel, de Jong, & de Haan, 2005; Swan & Tyssen, 2009). In an earlier study we investigated a Dutch e-therapy program: a webbased treatment program where the client and therapist communicated asynchronously via the Internet only. The results showed that the e-therapy program reached more women, higher-educated people, and employed people; groups that were underrepresented in regular face-to-face therapy. We also found that e-therapy clients were significantly older than face-to-face clients (Postel et al., 2005). As this study was conducted in 2005, a lot of things have changed in the recent years with regard to online treatment programs for problem drinkers.

In 2005, our e-therapy program was the first available Dutch online treatment program with active therapeutic involvement. We had the privilege to offer the e-therapy program completely anonymously to patients and also free of costs because it was a pilot study of a new intervention. In those days, the program received a lot of media attention on national television because of the novelty. However, the availability of online interventions for mental health problems in general and alcohol problems in particular has grown incredibly in recent years (Bennett & Glasgow, 2009; Cuijpers, van Straten, & Andersson, 2008; Marks, Cavanagh, & Gega, 2007). Nowadays, more e-therapy programs for problem drinking are available in the Netherlands, and we experience that the efficacy of online treatment programs is more generally accepted by clients as well as general practitioners and therapists. This acceptability is also reflected by the fact that the e-therapy program is now fully reimbursed

by the health insurance companies. As a consequence we use a new online platform and clients can no longer stay completely anonymous, because the Dutch health care system requires clients to provide their personal data. Because e-therapy no longer is a new kind of treatment, there is much less media attention for it. What consequences do these changes have on the client population that makes use of the e-therapy program and the group attending for face-to-face therapy?

This study reports on the client populations of a Dutch e-therapy and face-to-face treatment program at two different time periods. The aim of this study was to determine whether the populations differed from each other and whether they changed over time.

#### **METHOD**

# E-therapy Program

The e-therapy program available at www.alcoholdebaas.nl consisted of a structured two-part online treatment program in which the client and the therapist communicated asynchronously, via the Internet only. The content and elements of the e-therapy program were based on two evidence-based techniques: cognitive behavioural therapy (CBT) (Hester, Miller, & Goldman, 1996; Irvin, 1999) and motivational interviewing (Christensen, Griffiths, Korten, Brittliffe, & Groves, 2004; Miller & Rollnick, 2002). Clients accessed the e-therapy program in their personal environment. The client and the therapist were in separate or remote locations; the interaction occurred with a gap in time between the responses, with a maximum of 3 days. During the whole program the client kept the same therapist, who could be identified by a photograph in the clients' Internet record. The aim of the e-therapy program was to motivate clients to change their drinking habits, with the ultimate goal of reducing or stopping alcohol intake. The e-therapy intervention has been described in more detail elsewhere (Postel, de Haan, ter Huurne, Becker, & de Jong, 2010).

Part 1 of the program consisted of four assignments and accompanying communication, focusing on the analysis of the clients' drinking habits: (1) advantages and disadvantages; (2) drinking diary; (3) description of moments; (4) questionnaire about drinking situations. At the end of part 1, personal advice was given. Part 2 was the treatment phase, consisting of five assignments focusing on behavioural change. First, the client had to set a goal to quit drinking or to drink less, and than learned to reach this goal in four steps: (1) helpful thoughts; (2) helpful behaviours; (3) decision moments; (4) making an action plan to maintain the change and to prevent a relapse. Every step occurred in consultation with the

personal therapist. The average duration of the total e-therapy program was 3 months, with one or two contacts a week and daily registration during the whole program.

#### Face-to-Face Treatment

The face-to-face treatment group received treatment as usual in traditional outpatient settings from Tactus Addiction Treatment Institute in the Netherlands. The content and elements of the face-to-face treatment as usual were also based on CBT and motivational interviewing. In weekly structured face-to-face sessions client and therapist first analyzed the clients' drinking habits, and then set a goal of moderate drinking or abstinence. Homework assignments were used to reach this goal and to prevent a relapse. The average duration of the face-to-face treatment program was 3 months.

## **Participants**

All participants started the e-therapy or face-to-face treatment voluntary. Face-to-face clients were usually referred by their GP and e-therapy clients signed up on their own. Familiarity with both treatment modalities was generated by using the conventional strategies such as leaflet materials and informing GP's and other health professionals. Although we did not use any advertising, the e-therapy program received a lot of regional and national media attention, especially at the start.

We compared the baseline characteristics of four naturalistic groups: two e-therapy groups (1 and 2) and two consecutive series of ambulant face-to-face clients admitted for treatment as usual (3 and 4). Group 1 consisted of clients who registered for the e-therapy program during its first year, from 21 March 2005 till 20 March 2006 (n=896) and group 2 of clients who registered from 16 September 2008 till 15 September 2009, the first year of the renewed e-therapy platform with the non-anonymous treatment program (n=707). Clients who registered for face-to-face treatment during the same periods constituted group 3 (n=1506) and 4 (n=1484). All e-therapy clients gave their informed consent to participate in the research project. Concerning the face-to-face clients we used anonymous data files, in a way that is permitted and frequently used for epidemiological surveys in the Netherlands.

#### Measures

The key characteristics we were interested in were gender, age, education level, working situation, and earlier treatment for drinking problems. These characteristics were part of the standard intake questionnaires in both treatment programs.

#### **Analyses**

Pair-wise  $\chi^2$  tests were conducted to compare the groups on the nominal and ordinal characteristics. t-Tests were conducted to compare the mean ages in the four groups. SPSS version 17.0 (SPSS Inc, Chicago, IL, USA) was used to perform the statistical analyses.

#### **RESULTS**

#### Gender

Table 1 shows that e-therapy groups 1 and 2 involved significantly more women (44.0% and 50.9%) than face-to-face groups 3 and 4 (24.2% and 22.8%). Women were more represented in the online treatment program. Additionally, e-therapy group 2 involved more women than group 1. No significant difference was found between both face-to-face groups.

#### **Education Level**

Significantly more clients in the e-therapy groups were highly educated (49.8% and 52.0%) compared with the face-to-face groups (9.2% and 11.3%). There were no significant differences between the two e-therapy groups and the two face-to-face groups.

### **Work Situation**

The e-therapy groups involved significantly more clients with paid work (84.4% and 80.0%) than the face-to-face groups (46.1% and 48.4%). Besides that, e-therapy group 1 involved more employed clients than group 2. We found no significant difference between the two face-to-face groups.

Table 1. Client characteristics

	1. ET	2. ET	_	4. FTF 08-09	Group 1 vs			Group 2 vs			Group 1 vs			Group 3 vs		
	05-06															
	05-00				(	Group 3			Group 4	ŀ		Group 2			Group 4	ŀ
					X <sup>2</sup>	df	р	X <sup>2</sup>	df	р	X²	df	р	X <sup>2</sup>	df	р
Gender % female	44.0	50.9	24.2	22.8	101.39	1	<.001	173.74	1	<.001	7.63	1	<.01	0.73	1	ns
Education level % high	49.8	52.0	9.2	11.3	501.79	1	<.001	425.88	1	<.001	0.75	1	ns	3.55	1	ns
Work situation % employed	84.4	80.0	46.1	48.4	284.08	1	<.001	168.81	1	<.001	4.67	1	<.05	1.26	1	ns
Alcohol treatment % prior treatment	24.9	32.2	68.2	63.9	418.68	1	<.001	192.70	1	<.001	10.52	1	<.005	6.20	1	<.05
					t	df	р	t	df	р	t	df	р	t	df	р
Age Mean (SD)	45·9 (10.2)	45.4 (10.9)	42.4 (12.1)	43.5 (13.2)	7.58	2126.1	<.001	3.65	1650.7	<.001	0.98	1468.2	ns	-2.25	2960.3	<.05

ET = E-therapy; FTF = Face-to-face treatment; 05-06 = 2005-2006; 08-09 = 2008-2009

#### **Alcohol Treatment**

Table 1 shows that significantly less clients in the e-therapy groups received prior alcohol treatment (24.9% and 32.2%) compared to the face-to-face groups (68.2% and 63.9%). E-therapy clients more often were first-time treatment seekers. We also found that e-therapy group 2 more often received prior alcohol treatment than group 1. The difference between both face-to-face groups was also significant: group 4 less often had a history of alcohol treatment.

#### Age

t-Tests showed that e-therapy clients were significantly older than face-to-face clients, with a mean age of 42.4 and 43.5 years in the face-to-face groups compared with 45.9 and 45.4 years in the e-therapy groups. No difference was found between the two e-therapy groups, but face-to-face group 4 was significantly older than group 3.

## **DISCUSSION**

The first aim of this study was to determine whether the e-therapy and face-to-face client populations differed from each other. The results confirmed our previous findings: the e-therapy program reaches more women, higher-educated people, employed people, first-time treatment seekers and older people compared to regular face-to-face treatment programs. Our second aim was to find out whether the e-therapy and face-to-face populations changed over time. The results showed that the e-therapy population changed between 2005-2006 and 2008-2009 with respect to gender, work situation, and prior alcohol treatment. In 2008-2009, the program reached more women, less employed clients, and less first-time treatment seekers. The face-to-face populations showed changes on prior alcohol treatment and age: the 2008-2009 clients more often were first-time treatment seekers and they were older.

We found more women presented in the e-therapy program, compared to the proportion of women in face-to-face treatment as usual. This was expected because women are more likely than men to seek health-related information online (Fox, 2006), and women also experience more discomfort with participating in male-dominated face-to-face groups (Humphreys & Klaw, 2001). Another reason might be the fear of losing their children as a result of their substance abuse (Frank, Weihs, Minerva, & Lieberman, 1998); the perceived anonymity of

Internet can make it easier for women to seek help for their drinking problem. This applies to online interventions in general and not just for our e-therapy program. The fact that the 2008-2009 e-therapy program reached even more women than in 2005-2006 might be a consequence of the publicity. Because of our previous finding of reaching more women (Postel et al., 2005), in particular the women's press reported on the e-therapy program. Therefore, more women now know that there is an alcohol treatment program available that better fits their needs.

Clients in the e-therapy groups were higher educated than face-to-face clients. An explanation for this difference might be that individuals with a college degree are more frequent seekers of health-related information on the Internet (Fox, 2006). Besides that, it might also be a consequence of the negative image of addiction health care in general. This corresponds to our experiences in face-to-face addiction health care practice, where we see that higher educated people feel less comfortable being associated with addiction treatment.

The finding that more clients in the e-therapy groups are employed might be the result of the flexibility of the online treatment program. Clients can work on their alcohol problem on a moment they prefer, 24 hours a day. Therefore, they are no longer limited to the working hours of their therapist. This finding is in line with the results of Lieberman and Huang (2008), and we also agree with them that the higher levels of employment might also reflect the ability of online treatment programs to reach problem drinkers whose disease had not yet progressed to the point of job loss. Furthermore, the e-therapy program reached less employed people in 2008-2009 which could be the consequence of the non-anonymity of the renewed e-therapy program. Non-anonymity might cause an additional barrier, especially for employed people; they have every reason not being registered as an alcoholic. Another possible explanation might be that e-therapy was better known and more accepted in 2008-2009, and therefore increasingly used by different groups of problem drinkers in the general population.

The fact that more e-therapy clients were first-time treatment seekers compared to face-to-face clients reflects on the one hand the ability of the e-therapy program to reach problem drinkers in an early stage of their disease, and on the other hand that it is an easily accessible treatment intervention. The reason for seeing less first-time treatment seekers in the 2008-2009 e-therapy group compared to the 2005-2006 group can only in part be explained by a small group of e-therapy clients (3.8%) who started the e-therapy program for the second time. But is seems reasonable that the non-anonymity of the 2008-2009 e-therapy program causes an additional barrier for first-time treatment seekers, because people still are afraid of

providing their personal data and being registered as an alcoholic. During the first year of the e-therapy program clients' often explained that the main reason to finally seek help, after years of problem drinking, was the anonymity of the program. The better acceptance of e-therapy might also be a reason, resulting in an increased number of clients who already had a regular face-to-face treatment now opting for an e-therapy program. Surprisingly, there were more first-time treatment seekers in the 2008-2009 face-to-face group compared to the 2005-2006 group. This is in contrast with national data that show a decrease between 2003 and 2008 in the number of alcohol clients that were seeking treatment for the first time: 26% newcomers in 2003 compared to 22% in 2008 (<a href="https://www.ladisonline.nl">www.ladisonline.nl</a>). A possible explanation might be the investment of Tactus Addiction Treatment Institute to generate media attention and publicity for their face-to-face addiction health care, and also the improvement of the registration procedure to make it easier for clients to start a face-to-face addiction treatment program.

Our finding of the older age group in the e-therapy population is not in line with previous research, as other studies report younger clients in the online groups (Lieberman & Huang, 2008; Swan & Tyssen, 2009). The type of online intervention might be responsible for this difference: our e-therapy program belongs to the most intensive type of online programs according to the therapist-patient contact. Interventions that reach younger clients often involve less-intensive and shorter programs (Lieberman & Huang, 2008; Swan & Tyssen, 2009). Older clients seem to be attracted to an intensive treatment program with more active therapeutic involvement.

Although it is nice that e-therapy reaches a new population of problem drinkers, we recognize that a significant group of people with alcohol problems is still not reached with e-therapy interventions. This is in line with other studies that found web-based interventions to be particularly useful for specific groups of people such as women or higher educated people (White et al.). A significant challenge for the e-health field is to further expand the reach of new target groups. Future research should gain more insight into the reasons for not reaching those groups of problem drinkers and into their specific needs, and accordingly improve the online interventions and the marketing strategies to reach those groups as well.

There are some limitations to this study that should be noted. We did not have data available to compare e-therapy and face-to-face groups on addiction severity. It is a shortcoming that we do not know how both groups score on weekly alcohol consumption and alcohol dependence. Because of the inaccurate registration in face-to-face treatment it was impossible to compare both groups on those outcome measures. It is also uncertain if the validity of the data collection is comparable for both groups, because e-therapy data were

collected via online self-report questionnaires and face-to-face data were collected in an interview by the therapist. These limitations have to be kept in mind when interpreting the results of our study. Despite these shortcomings, our study provides insight into the differences in characteristics between face-to-face and online groups of problem drinkers.

#### CONCLUSIONS

We can conclude that the e-therapy program successfully attracted clients who were different from those who were represented in regular face-to-face alcohol treatment services. This indicates that e-therapy decreases the barriers to treatment facilities and enhances the accessibility. The e-therapy program reaches client groups that are still difficult to reach in regular face-to-face therapy. However, we saw that the e-therapy population changed over time. In 2005-2006, the e-therapy program really reached a new population of problem drinkers. Although the e-therapy program still did reach an important new group of clients in 2008-2009, this group showed more overlap with the traditional face-to-face group of clients: less employed clients and less first-time treatment seekers. On the one hand, we assume that the non-anonymity is responsible for these changes: staying anonymous still is very important for many problem drinkers. So if addiction health care really wants to reach a hidden population of problem drinkers, it seems necessary to offer the e-therapy program completely anonymous. On the other hand, these findings also might indicate the success of e-therapy and the better acceptance of it in the general population. Additional research is needed to justify this assumption.

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# CHAPTER 4

# Evaluation of an E-Therapy Program for Problem Drinkers: A Pilot Study

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#### **ABSTRACT**

An e-therapy program with therapist involvement for problem drinkers was evaluated in a population of 527 Dutch-speaking patients. In a pre-post design weekly alcohol consumption, alcohol-consumption-related health problems, and motivation were assessed. Although the drop-out rate was high, patients showed a significant decrease of alcohol consumption and alcohol-consumption-related health complaints. Patients' satisfaction with the e-therapy program was high. The e-therapy program proved to be feasible and attracted patients who were otherwise unlikely to seek help. A randomized controlled trial has to provide more information about reasons for dropout, effectiveness, and the population that benefits most from the e-therapy program. The study's limitations are noted.

#### INTRODUCTION

Most problem drinkers will never seek treatment (Cunningham and Breslin, 2004). In the United States, only 16% of people with an alcohol-use disorder had received treatment in 2001 (Harris and McKellar, 2003; Weisner and Matzger, 2003), and in the Netherlands, only 10% of the problem drinkers received professional help in 2006 (Van Laar et al., 2007). Consequently, the need to improve access to therapy for problem drinkers has been emphasized (Humphreys and Tucker, 2002; Copeland and Martin, 2004; Linke et al., 2004; Postel et al., 2005). Improved access results in early identification of a drinking problem and causes a healthier and more rewarding life (Humphreys and Tucker, 2002). The Internet with its widespread access offers a novel opportunity to administer interventions for problem drinkers. In 2007, nearly 70% of people in the United States and west European countries had Internet access (www.internetworldstats.com).

It is known that Internet interventions can reach a larger and more diverse segment of the population of problem drinkers (Humphreys and Klaw, 2001; Postel et al., 2005); furthermore, the efficacy of Internet interventions for the treatment of problem drinking seems promising. Although review studies in the field of computerized or Internet health interventions mention the tendency for poor methodological quality of studies owing to high dropout rates, small sample sizes, the manner of patient recruitment, and the incompleteness in reporting trials (Bessel et al., 2002; Copeland and Martin, 2004; Kaltenthaler et al., 2004; Postel et al, in press; Spek et al., 2007), a number of interesting studies have reported on feasibility and efficacy of Internet interventions for problem drinking (Kypri et al., 2004; Linke et al., 2004; Chiauzzi et al., 2005; Cunningham et al., 2006; Saitz et al., 2007), and have shown (some) reduction in unhealthy alcohol use and alcoholconsumption-related harm. However, all of these online alcohol interventions are self-help interventions without therapist involvement. There are no studies available for alcohol interventions that employ therapists. Our e-therapy intervention is new because it does involve therapist contact. Spek et al. (2007) found in their meta-analysis of online therapy for depression and anxiety a large mean effect size for online treatment with therapist involvement and on the other hand just a small mean effect size for online self-help. We defined e-therapy as online treatment with active involvement of a therapist, which takes place via written Internet communication only. Both patient and therapist are in separate locations, and communication is asynchronous (Andersson et al., 2005).

The demand for Internet interventions seems to be growing, and users themselves report satisfaction with this mode of treatment. One of the perceived advantages of e-therapy over

a face-to-face treatment is its anonymity. Patients no longer need to stay away from treatment because of shame, fear of stigmatization, or any other barrier to professional help. Furthermore, e-therapy can help patients in their own environment at a time of their own choosing; patients no longer need to visit the therapists' office; this makes e-therapy more easily accessible.

The Dutch e-therapy program (available at www.alcoholdebaas.nl) serves a new population of problem drinkers. A recent study by Postel et al. (2005) documented that e-therapy reaches more women, higher-educated people, and employed people, groups that are not represented in regular face-to-face therapy. This paper presents the outcome of a pilot study of the e-therapy program. Our hypothesis proposes that e-therapy patients will show a decrease in their alcohol consumption and alcohol-consumption-related harm.

#### **METHOD**

## **Participants**

Since March 21, 2005, the Dutch Web site www.alcoholdebaas.nl has been available. All visitors have access to the informational pages of the Web site and are free to decide whether they wanted to log on for the e-therapy treatment program, as long as they are at least 18 years old and have a thorough command of the Dutch language. The e-therapy program is accessible for all people who are concerned about their own drinking patterns.

# The e-therapy intervention

The e-therapy program consists of a structured two-part online treatment program in which the patient and his therapist communicate personally and asynchronously, via the Internet only. The patient and the therapist are in separate or remote locations; the interaction occurs with a gap in time between the responses. This interaction with a personal therapist is an essential element of our e-therapy program and distinguishes it from online self-help programs. During the whole program the patient keeps the same therapist, who can be identified by a photograph in the patients' Internet files. The aim of the e-therapy program is to motivate patients to change their drinking habits, with the ultimate goal of reducing or stopping alcohol intake. The method underlying the program is based on principles of the cognitive behaviour therapy (Hester et al., 1996; Irvin, 1999), motivational interviewing (Miller and Rollnick, 2002; Britt et al., 2004), and Prochaska and DiClemente's (1983) Stages

of Change Model, all empirically supported methods for substance-use disorders in regular face-to-face addiction treatment.

All communication between therapists and patients takes place through a Webbased application. The patients remain anonymous; they just need to make up a personal user name and password. The application is designed to run on personal computers with Microsoft Internet Explorer version 5.5 or Mozilla Firefox version 1.5 or higher, with Adobe Flash version 7 or higher installed. Individual patients and therapists have a login secured by Secure Sockets Layer to the application. All data transferred between the patient's personal computer and the application are encrypted and sent via the Hypertext Transfer Protocol Secure protocol. The application is entirely server based. All information gathered is stored on the server. Daily backups of the server are made to ensure further data security.

Part 1 of the program consists of four assignments and accompanying communication, focusing on the analysis of the patients' drinking habits: (1) advantages and disadvantages, (2) drinking diary, (3) description of moments, and (4) questionnaire about drinking situations. The therapist sends, explains, and gives feedback on each assignment. To move on to the next assignment patients need approval from their therapist. At the end of Part 1, personal advice is given, and the participant can choose to continue with treatment in Part 2 or to stop.

A multidisciplinary team, consisting of treatment staff, a physician specialized in addiction treatment, a psychiatrist, and two supervisors, is authorized to refuse a patient access to Part 2. In the current research, the team refused access just six times (1%), because of one of the exclusion 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 decreasing alcohol consumption; (3) insufficient assignments during Part 1; (4) the inability to set a well-considered target to change drinking behaviour. Once identified and excluded because of health reasons, the therapist supports the patient with contacting and visiting a general practitioner or an addiction treatment institute. The therapist always provides information to the patient about what to do in a crisis situation. If a patient needs help immediately, he can contact his e-therapist by phone or contact a nationwide help service that is available 24 hours a day.

Part 2 is the treatment phase, consisting of five assignments focusing on behavioural change. First, the patient sets a goal to quit drinking or to drink less and learns to reach this goal in four steps: (1) helpful thoughts, (2) helpful behaviour, (3) decision moments, and (4) making an action plan. Every step a patient takes occurs in consultation with the personal therapist.

The action plan is the final treatment step and helps patients in maintaining their change in drinking behaviour and preventing them from relapsing. After this last assignment, the treatment will be finished. The average duration of the total e-therapy program is 3 months, with one or two contacts a week and daily registration during the whole program. Besides registration, the patient usually responds every 3 or 4 days. If there is no response from the patient, the therapist will contact the patients three times during the following two weeks. If there is still no response, the therapist will send a message that he would have to close the patients' file if he does not receive a message within the next 2 weeks. After finishing treatment, patients can still log on to their personal data file for 6 months. During this period, the therapist will respond twice for aftercare: 6 weeks and 6 months after treatment completion.

## **Therapists**

The 15 online therapists were all qualified social workers with higher vocational education, who had received a special training. The training focused on technical aspects as well as the content of the e-therapy program, with special attention for motivational writing skills. During the training period all messages from the therapist were judged by a supervisor. The multidisciplinary team was responsible for medical and psychosocial consultations. The team met on regular basis, once a week, to judge all patients who finished Part 1, on the basis of their online files and a short description from their therapist. The multidisciplinary team could also be reached by phone in situations in which the therapist needed an answer immediately.

#### Measures

Patients completed self-report assessments at baseline, posttreatment, and after 6-week and 6-month follow-ups.

The primary endpoint was the proportion of patients who achieved their drinking goal (abstinence or moderate drinking), which was set in consultation with their therapist at the beginning of Part 2. The improvement in alcohol consumption was measured using a 7-day retrospective drinking diary, in which alcohol consumption was expressed in terms of total number of standard units a week. Information on how to calculate the units was supplied. In addition, a question about a typical drinking week was included to accurately capture a person's total alcohol consumption.

The Cutting Down, Annoyance by Criticism, Guilty Feeling, and Eye-Openers (CAGE) questionnaire, consisting of four clinical interview questions, was used for identifying problems with alcohol (Ewing, 1984). According to the questionnaire, alcohol dependence is considered likely if the patient gives two or more positive answers. Bernadt *et al.* (1982) have claimed that the CAGE test (scores ≥ 2) has a sensitivity of 91% and a specificity of 77% for the identification of alcoholism.

The 12 alcohol-consumption-related health complaints were adapted from the somatisation subscale of the 90-item Symptom Checklist (Derogatis, 1977) and in consultation with experienced therapists, specifically adapted for alcohol-dependent patients. Each item is scored on a 5-point Likert-type scale, ranging from 1 representing "complaint never present" to 5 representing "complaint very often present". Patients had to assess their current situation with regard to the following alcohol-related health complaints: fatigue, depressive symptoms, hyperventilation, sweating, flatulence, diarrhea, heart palpitations, headache, memory problems, sexual problems, shaking, gastric problems, and epilepsy.

The Readiness to Change Questionnaire - Dutch (RCQ-D) was used to measure patients' readiness to change their drinking behaviour. This Dutch version of the RCQ is a 12-item questionnaire consisting of three 4-item scales representing three stages of change described by Prochaska and DiClemente (1983): pre-contemplation, contemplation and action (Heather, Gold and Rollnick, 1991). The questionnaire is used to assess the stage of change for a patient. The factor structure of the RCQ-D was found to be consistent with the three-factor structure established for the original RCQ. The reliability of the items for each scale was found to be satisfactory (Defuentes-Merillas et al., 2002).

The Motivation for Treatment (MfT) scale of Texas Christian University is a valid instrument to measure the initial treatment motivation in people with alcohol dependence (Simpson and Joe, 1993). The scale contains four subscales: recognition of general problems, recognition of specific problems, desire for help, and treatment readiness. The Dutch version replicated the results of the original scale of Simpson and Joe (De Weert-van Oene *et al.*, 2002).

After the treatment, we asked patients to complete an evaluation form to gather information concerning the patients' opinion about the e-therapy program and their therapists.

It was impossible to provide activities to increase compliance or adherence, as we did not have any information like e-mail addresses or telephone numbers of patients. Accordingly, we had to contact patients by the internal communication system of the e-therapy program.

Completion and adherence depended totally on the patients' own initiative to log on again, although we motivated patients constantly. After finishing the e-therapy program, patients completed the posttest online. Six weeks and six months later patients received two follow-up questionnaires. Because of the design of the e-therapy program, there are no intermittent missing data; patients could not continue with the next assignment without completing the questionnaires.

#### **Analyses**

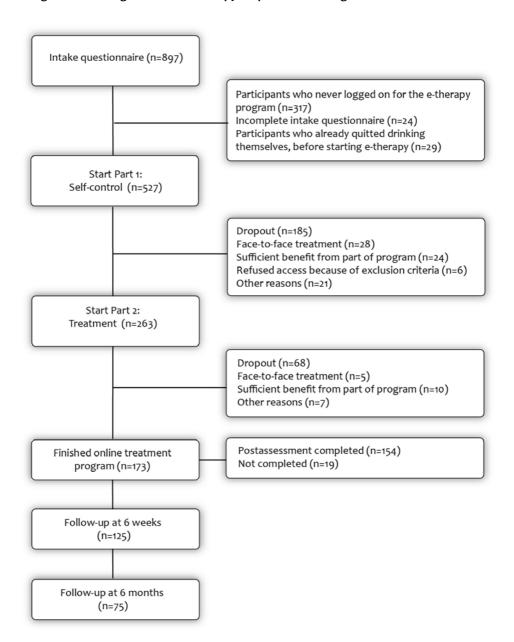
We used a pre-post design to compare outcome measures at the end of the e-therapy program with baseline data. We checked for differences between completers and dropouts using chi-square tests for ordinal and nominal variables, and analyses of variance (ANOVAs ) for scale variables. We analyzed the data using repeated-measures ANOVAs to test the improvement from pretreatment to posttreatment (only for those who completed) for each of the dependent variables. The primary dependent variable is patients' self-reported weekly alcohol consumption. Secondary dependent variables are the 12 alcohol-related health problems based on the 90-item Symptom Checklist. Effect sizes were calculated to compare the strength of the effects observed (Cohen, 1992).

# RESULTS

#### **Recruitment and Participant Flow**

Between March 21, 2005, and March 20, 2006, a total of 897 Web site visitors completed baseline intake assessment, although 317 did not start with the e-therapy program, 24 did not fully complete the intake questionnaire, and 29 already stopped their drinking before the start of the e-therapy program. Therefore, baseline data of 527 patients, who started Part 1, were included in the analysis. A total of 263 patients also started the second part (treatment phase) of the e-therapy program. The other 264 patients stopped during or at the end of Part 1 for one of the following reasons: moved on to face-to-face treatment (n=28), received sufficient help (n=24), access refused on the basis of one of the exclusion criteria (n=6), dropped out (n=185), or other reasons such as computer problems or a temporary delay due to family or work reasons (n=21). The dropout group contained 35% of patients whose reasons for dropout are mostly unknown. Figure 1 shows an overview of the flow of participants through each stage of the study.

Figure 1. Flow diagram of trial e-therapy for problem drinking



70

A total number of 173 out of 263 patients completed the entire treatment program. Reasons for noncompletion are shown in Figure 1. The dropout rate in Part 2 was 26%. Of the 173 patients who finished the e-therapy program, 154 fully completed the posttest questionnaires, 125 the 6-week follow-up measures and 75 the 6-month follow-up questionnaires.

#### **Baseline Data**

Among the 527 patients enrolled in the study, most were identified as problem drinkers (CAGE  $\ge$  2) (98%), were employed (86%), had a university education level (54%), and had never received treatment for their alcohol problems before (76%). The mean age was 45.5 years (SD=9.7). Men (51%) and women (49%) were equally represented. A gender effect for weekly alcohol consumption was found (F(1,520) = 73.57, p<.001), as baseline data showed that men (M=54.8) had a higher weekly consumption compared with women (M=36.0). Of the 527 patients, 50% reported medication use in the year preceding the study, with antidepressant drugs (n=113) and benzodiazepines (n=53) being most often mentioned. Other kinds of medication were mentioned no more than 10 times in total. Approximately half of the patients recorded that they had been in treatment for mental health problems before, most often for depressive symptoms (n=161). Other problems included burnout (n=23), anxiety disorder (n=19), relational problems (n=161), eating disorders (n=11), and stress (n=10).

We compared baseline characteristics between patients who ended the program prematurely during Part 1 self-control (Sep, n=264) and patients who continued with Part 2 treatment (T, n=263) and found that they differed on weekly drinking, drug use, working situation, and age (Table 1). Weekly alcohol consumption (in standard units a week) was higher for people who ended Part 1 self-control prematurely (M=49.2) compared with Part 2 treatment starters (M=42.1) (F(1,525) = 9.60, p<.01). The treatment group less often used drugs (5%) than the self-control group (10%) ( $X^2=6.30$ , df=1, p<.05) and was more often employed (89%) compared with the self-control group (82%) ( $X^2=4.91$ , df=1, p<.05). The mean age of the treatment group was 46.4 compared to 44.7 in the self-control group (F(1,525) = 4.33, p<.05).

We also compared baseline characteristics between patients who completed Part 2 of the treatment (Tc, n=173) and patients who ended the treatment prematurely (Tep, n=90) and found that they differed on three characteristics (Table 1). First, weekly alcohol consumption (in standard units a week) was higher for people who ended treatment prematurely (M=47.4) compared with those who completed (M=39.3; F(1,261)=7.78, p<.01). Second, the

mean total score of the action stage on the RCQ is higher for those who completed (M=13.1 vs. M=12.1; F(1,260) = 4.96, p<.05). Third, the mean score on the Treatment Readiness subscale of the MfT is higher for those who completed (M=4.1) compared with patients who ended treatment prematurely (M=3.9; F(1,261) = 14.83, p<.001). There were no significant differences on demographic variables between both groups.

Table 1. Comparison of baseline characteristics of participants

	Sep (n=264)	T (n=263)	F/X²	р	Tep (n=90)	Tc (n=173)	F/X²	р
Weekly drinking, mean (SD)	49.2 (29.9)	42.1 (22.5)	9.60	<.01	47.4 (23.6)	39.3 (21.5)	7.78	<.01
Age, mean (SD)	44.7 (10.0)	46.4 (9.3)	4.33	<.05	45.8 (10.2)	46.7 (8.8)	0.53	ns
Working situation			4.91	<.05			0.43	ns
Employed	82%	89%			87%	90%		
Not employed	18%	11%			13%	10%		
Drug use			6.30	<.05			3.21	ns
Yes	10	5				8	3	
No	90	95				92	97	
Readiness to change, mean (SD)								
Precontemplation	12.1 (1.8)	12.1 (1.5)	0.26	ns	12.3 (1.7)	12.0 (1.4)	2.27	ns
Contemplation	15.9 (3.7)	15.8 (3.5)	0.15	ns	15.9 (3.3)	15.7 (3.5)	0.32	ns
Action	12.7 (3.6)	12.7 (3.3)	0.02	ns	12.1 (3.4)	13.1 (3.2)	4.96	<.05
Motivation for treatment								
Problem recognition 1					3.4 (0.7)	3.5 (0.7)	2.85	ns
Problem recognition 2					2.2 (0.6)	2.2 (0.7)	0.54	ns
Desire for Help					3.8 (0.5)	3.8 (0.6)	0.55	ns
Treatment Readiness					3.9 (0.4)	4.1 (0.3)	14.83	<.001

**Note:** Sep = self-control (Part 1) ended prematurely, T = treatment (Part 2), Tep = treatment ended prematurely, Tc = completed the treatment. Motivation for Treatment is measured in Part 2; data are just available for treatment group.

At postassessment  $(n=143)^1$ , 58.1% of treatment completers achieved their drinking goal; of these patients 16.1% achieved abstinence and 42.0% achieved moderate drinking. The rest 41.9% of patients did not achieve their drinking goal, although one third of these patients exceeded their drinking goal limit by a minimum of 1-3 units. At 6-week follow-up (n=116), 45.7% of patients sustained their drinking goal and 54.3% did not sustain their goal. And at 6 months (n=74), 52.7% of patients sustained their drinking goal and 47.3% did not sustain their goal.

Overall, those who completed the treatment showed a significant decrease in weekly alcohol consumption (Table 2). In the "postassessment" group (n=154), the mean weekly alcohol consumption decreased from 38.8 units a week at baseline to 14.2 at posttest (F(1,153)=177.38, p<.001). In the "follow-up 6 weeks" group (n=125), weekly alcohol consumption decreased from 38.5 units a week at baseline to 17.7 units 6 weeks after treatment completion (F(2,123)=71.66, p<.001). And the "follow-up 6 months" group (n=75) decreased its weekly alcohol consumption from 38.6 units at baseline to 15.5 units at 6 months follow-up (F(3,70)=27.04, p<.001). For all three groups the effect sizes for change in alcohol consumption were large: d=1.11, d=0.95, and d=0.94 respectively (Cohen, 1992).

Table 2. Weekly alcohol consumption for treatment completers

	Postassessment (n=154)				Follow-up at 6 weeks (n=125)						Follow-up at 6 months (n=75)					
	1	PA	F	р	1	PA	F6w	F	р	I	PA	F6w	F6m	F	р	
Weekly alcohol consumption			177.38	<.001				71.66	<.001					27.04	<.001	
Mean	38.8	14.2			38.5	14.8	17.7			38.6	14.0	16.0	15.5			
SD	22.1	14.5			20.7	15.1	16.9			23.6	15.2	17.5	17.8			

Note: I = intake assessment, PA = postassessment, F6w = follow-up at 6 weeks, F6m = follow-up at 6 months

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<sup>&</sup>lt;sup>1</sup> Some patients' drinking goal data are not available, due to a temporary technical problem.

### Alcohol-Consumption-Related Health Problems

We found significant treatment effects for 8 of the 12 dependent alcohol-consumptionrelated health variables for those who completed the treatment. Table 3 shows that the effect sizes ranged from moderate to small (Cohen, 1992).

Table 3. Effect sizes for alcohol-related health problems for those who completed treatment

	Postassessment (n=154)	Follow-up at 6 weeks (n=125)	Follow-up at 6 months (n=75)
Depressive symptoms	0.50	0.51	0.41
Memory problems	0.48	0.41	0.27
Perspiration	0.42	0.47	0.60
Heart palpitations	0.42	0.27	0.37
Shaking	0.37	0.33	0.47
Diarrhea	0.33	0.39	0.38
Sexual problems	0.31	0.38	0.29
Gastric problems	0.20	0.20	0.22

### Patients' Satisfaction

Patients who completed the therapy indicated that they were very satisfied with the etherapy program and the therapist contact. Table 4 shows that on a 5-point scale, ranging from 1 representing "most negative" to 5 representing "most positive", patients evaluated the online treatment program and therapist contact as very personal (M=4.21), pleasant (M=4.64), and safe (M=4.77). Patients expressed increased insight into their own risk feelings, thoughts, and situations, as well as into advantages and disadvantages of their own alcohol consumption. Furthermore, half of the patients appreciated the personal contact with their therapist as the most valuable part of the e-therapy program. On a scale from 0 (low) to 10 (high), patients evaluated the assignment "questionnaire about drinking situations" with the lowest ranking of 7.1 and the assignment "decision making" with the highest ranking of 8.2.

Table 4. Evaluation of e-therapy program at posttest (n=154)

Question	Answer	Percentage	
How did you like having contact with your therapist solely via the	Pleasant	94	
Internet?	Unpleasant	3	
	Personal	89	
	Impersonal	6	
	Safe	99	
	Unsafe	1	
Did you miss other kinds of contact with your therapist, like through	Yes	12	
phone or face-to-face contact?	No	70	
	Do not know	18	
Do you consider the e-therapy program to be an effective method	Yes	92	
for changing your drinking habit?	No	7	
	Do not know	1	
Would you recommend the e-therapy program to others?	Yes	95	
	No	3	
	Do not know	2	
Did you experience an increased insight into the following?			
Your risk situations	Yes	96	
	No	4	
Your risk feelings	Yes	100	
	No	0	
Your risk thoughts	Yes	99	
	No	1	
The advantages of your alcohol consumption	Yes	77	
	No	23	
The disadvantages of your alcohol consumption	Yes	95	
	No	5	
Did your willingness to seek professional help for your drinking	Yes	59	
problem in regular treatment services increase during the e-therapy program?	No	41	

 $\textbf{Note:} \ \textbf{Only for those who completed the treatment. Percentages for 'no opinion' are not given in the table.}$ 

### DISCUSSION

In this study the e-therapy program has proven to be feasible. Patients evaluated the content of the program as very useful, with the personal contact with their therapist as most valuable. The easily accessible online therapy meets the patients' needs. A new group of patients sought help for their alcohol-consumption-related problems: 76% had never received treatment for their alcohol-consumption-related problems before. This is remarkable compared with face-to-face treatment programs, in which just 20% of patients with alcohol-consumption-related problems were "new" and had never received treatment before.

Patients demonstrated a significant reduction in alcohol consumption and alcohol-consumption-related harm after completing the e-therapy program. The decrease in alcohol consumption and alcohol-consumption-related harm was maintained at 6-week and 6-month follow-ups. Although not all patients could sustain their individual drinking goal at 6-month follow-up, still 58.1% of those who completed the treatment remained successful. These results indicate that e-therapy might be effective in helping problem drinkers to change their unhealthy drinking behaviour into healthier alcohol consumption.

The e-therapy program had a substantial dropout rate, especially after baseline intake assessment and during Part 1 of the program. It is likely that because of the novelty of the program and the national media attention, many of the dropouts were just curious about the new program but never had the intention to change their drinking habits. Besides that, the advantage of low accessibility of Internet is at the same a disadvantage because of the low threshold for patients to quit with the e-therapy. A closer look at the differences between those who completed the program and the dropouts showed that a higher weekly amount of alcohol consumption interfered with finishing the e-therapy program, which suggests that e-therapy might not be sufficiently effective or powerful for the severer problem drinkers. However, the e-therapy program proved to be very useful for identifying this group of severe problems drinkers. Elder people and working people more often were moving on to Part 2 of the e-therapy program, which might be a result of the greater importance for these groups to change their behavior for health reasons or to avoid problems at work. Patients with drugs problems more often dropped out during Part 1 of the program, which suggests that etherapy might not be sufficient and suitable for people who use drugs in addition to their alcohol problem. Differences were also found in the action score of the RCQ and the Treatment Readiness subscale of the MfT, which were both higher for those who completed the treatment. This suggests that patients who were already more conscious of their problem and felt ready for change before starting treatment benefited most.

We recognize several limitations to this study. First, we acknowledge that the results are limited to a nonrandomized evaluation. With this pilot study we did not attempt to evaluate the e-therapy program experimentally. In future research, comparisons of costs and effectiveness between e-therapy and face-to-face alcohol treatment programs should be made using rigorous research designs. Second, those who completed the e-therapy program represent only a small proportion of patients who completed the intake questionnaire, as we experienced high loss to follow-up. And because of the anonymity we could not send postassessment questionnaires to dropouts; so we do not know if they derived any benefit from parts of the e-therapy program or not. Because of the pilot nature of our study no intention-to-treat analysis was carried out; it would have indicated very little about the efficacy of the treatment program. There are no studies available that researched the treatment outcomes of patients who dropped out of Internet treatment programs. For future studies it would be very interesting and important to focus on reasons for drop out and failure to comply. Attrition rates are high for Internet interventions, as easy accessibility may also mean easy dropout (Eysenbach, 2005). Although their experiences are not representative for all users, those who completed provide us indications about the usefulness of the e-therapy program. In our randomized controlled trial that has been started recently, we planned to analyze data more rigorously. Because of the questions raised about dropout during our pilot study, we decided to acquire e-mail addresses and phone numbers of patients to contact treatment dropouts for more information. With more information about reasons for drop-out, we would like to improve the e-therapy program to decrease future dropouts. The randomized controlled trial will also give us more information about the effectiveness of the e-therapy program and the group of patients who benefit most from the online treatment program. A third limitation of this study is that the baseline assessment did not allow for making a diagnosis based on the Diagnostic and Statistical Manual, Fourth Edition, Text Revision (DSM IV-TR). Therefore, we do not know how far the present findings generalize to the population of patients with DSM IV-TR diagnoses of alcohol abuse or dependence. In our randomized controlled trial the DSM IV-TR assessment is one of the questionnaires we added to the baseline measurements.

Despite these limitations, the e-therapy program is an important additional tool to the public health interventions available for problem drinkers. E-therapy makes patients less dependent of health care institutions. It attracts patients who are otherwise unlikely to use the regular face-to-face treatment facilities or self-help programs. Many patients mentioned the important added value of personal contact with a professional therapist. Although (tailored) screening or self-help interventions have proven to be successful (Kypri et al., 2004; Linke et

al., 2004; Chiauzzi et al., 2005; Cunningham et al., 2006; Saitz et al., 2007), some patients prefer having contact with a therapist and getting individual feedback. On the basis of the findings of online treatment for depression and anxiety (Spek et al., 2007), online treatment with therapist involvement might also be more effective than online self-help for alcohol problems.

This easily accessible e-therapy intervention should be seen as a first step in a stepped-care approach; it is a brief, easily accessible treatment for reducing the alcohol use of heavy drinkers (Sobell and Sobell, 2000). If e-therapy has proven insufficient, patients will be recommended to seek face-to-face treatment for more extended care. The e-therapy program turned out to be functioning as a first step to regular face-to-face treatment. Patients who reported, at the beginning, that they would not seek regular face-to-face help, gradually turned out to be ready for a face-to-face treatment program. Via the e-therapy program more problem drinkers can find help at an earlier stage, resulting in a decrease of personal suffering and a reduction of costs to society (Fleming et al., 2002).

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# CHAPTER 5

# Effectiveness of a Web-based Intervention for Problem Drinkers and Reasons for Dropout: Randomized Controlled Trial

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### **ABSTRACT**

Background - Online self-help interventions for problem drinkers show promising results, but the effectiveness of online therapy with active involvement of a therapist via the Internet only has not been examined.

Objective - The objective of our study was to evaluate an e-therapy program with active therapeutic involvement for problem drinkers, with the hypotheses that e-therapy would (1) reduce weekly alcohol consumption, and (2) improve health status. Reasons for dropout were also systematically investigated.

Method - In an open randomized controlled trial, Dutch-speaking problem drinkers in the general population were randomly assigned (in blocks of 8, according to a computer-generated random list) to the 3-month e-therapy program (n=78) or the waiting list control group (n=78). The e-therapy program consisted of a structured 2-part online treatment program in which the participant and the therapist communicated asynchronously, via the Internet only. Participants in the waiting list control group received "no-reply" email messages once every 2 weeks. The primary outcome measures were (1) the difference in the score on weekly alcohol consumption, and (2) the proportion of participants drinking under the problem drinking limit. Intention-to-treat analyses were performed using multiple imputations to deal with loss to follow-up. A dropout questionnaire was sent to anyone who did not complete the 3-month assessment. Reasons for dropout were independently assessed by the first and third author.

Results - Of the 156 individuals who were randomly assigned, 102 (65%) completed assessments at 3 months. In the intention-to-treat analyses, the e-therapy group (n = 78) showed a significantly greater decrease in alcohol consumption than those in the control group (n = 78) at 3 months. The e-therapy group decreased their mean weekly alcohol consumption by 28.8 units compared with 3.1 units in the control group, a difference in means of 25.6 units on a weekly basis (95% confidence interval 15.69-35.80, P < .001). The between-group effect size (pooled SD) was large (d = 1.21). The results also showed that 68% (53/78) of the e-therapy group was drinking less than 15 (females) or 22 (males) units a week, compared with 15% (12/78) in the control group (OR 12.0, number needed to treat 1.9, P < .001). Dropout analysis showed that the main reasons for dropouts (n = 54) were personal reasons unrelated to the e-therapy program, discomfort with the treatment protocol, and satisfaction with the positive results achieved.

Conclusions - E-therapy for problem drinking is an effective intervention that can be delivered to a large population who otherwise do not seek help for their drinking problem. Insight into reasons for dropout can help improve e-therapy programs to decrease the number of dropouts. Additional research is needed to directly compare the effectiveness of the e-therapy program with a face-to-face treatment program.

### INTRODUCTION

Problem drinking is a highly prevalent public health issue, with serious consequences in terms of morbidity and mortality (Ezzati, Lopez, Rodgers, Vander Hoorn, & Murray, 2002), and associated economic costs (Smit et al., 2006) and social problems (Bessell et al., 2002). However, most problem drinkers will never seek treatment (Cunningham & Breslin, 2004). In the United States, only 16% of people with an alcohol-abuse disorder had received treatment in 2001 (Weisner & Matzger, 2003), and in the Netherlands, only 10% of the problem drinkers received professional help in 2006 (van Laar et al., 2007). Furthermore, people often seek help only at a late stage; usually after 10 or more years of alcohol abuse or dependence (Bruffaerts, Bonnewyn, & Demyttenaere, 2007). Therefore, improved access to therapy for problem drinkers is needed (Copeland & Martin, 2004; Humphreys & Tucker, 2002; Linke, Brown, & Wallace, 2004). The Internet offers a novel opportunity to reach a larger and more diverse segment of the population of problem drinkers (Humphreys & Klaw, 2001; Postel, de Jong, & de Haan, 2005) and improves the availability of alcohol treatment services. Online treatment programs are distinguishable by the intensity of the therapist involvement. Andersson and colleagues (Andersson, Bergstrom, Carlbring, & Lindefors, 2005) distinguished the different forms of Internet interventions in a clear manner: (1) fully selfadministered therapy or pure self-help, (2) predominately self-help (ie, therapist assesses and provides initial rationale, and teaches how to use the self-help tool), (3) minimal-contact therapy (ie, active involvement of a therapist, but to a lesser degree than in traditional therapy, eg, using email), and (4) predominantly therapist-administered therapy (ie, regular contact with therapist for a number of sessions, but in conjunction with self-help material). A meta-analysis of 12 randomized controlled trials (RCTs) of Internet-based cognitive behavioural therapy programs for depression and anxiety showed that Internet-based interventions are effective; especially those with therapist involvement (Spek et al., 2007).

RCTs of Internet interventions for problem drinking are available, and they show promising results (Bewick et al., 2008; Chiauzzi, Green, Lord, Thum, & Goldstein, 2005; Cunningham, Wild, Cordingley, van Mierlo, & Humphreys, 2009; Doumas & Hannah, 2008; Doumas, McKinley, & Book, 2009; Kypri et al., 2004; Moore, Soderquist, & Werch, 2005; Saitz et al., 2007; Walters, Vader, & Harris, 2007). However, all of these online alcohol interventions are fully self-help interventions without therapist involvement. The effectiveness of predominantly therapist-administered online therapy for problem drinkers solely via the Internet has not yet been examined in a RCT. It is expected that active therapeutic involvement will lead to greater treatment effects compared with self-help. In addition, we

expect to reach another group of people, who prefer intensive personal therapist contact instead of dealing with their problem themselves.

This report describes the main findings from a RCT in which participants were randomly assigned to the 3-month therapist-involved e-therapy program or to the waiting list control group. Because of poor adherence and high dropout rates in e-health interventions (Christensen, Griffiths, & Farrer, 2009; Eysenbach, 2005; Riper, Kramer, Smit et al., 2008), and a low completion rate (173/527, 33%) in our pilot study (Postel, de Haan, & de Jong, 2010), we decided to systematically investigate the reasons for dropout as part of our RCT study as well. Insight into those reasons may identify factors that are responsible for dropout, and online treatment programs can consequently be improved to reduce the number of participants ending treatment prematurely. Based on the prior results of our uncontrolled observations, where we found a significant decrease in alcohol consumption and alcohol-related health complaints (Postel et al., 2010), we tested the hypothesis that e-therapy would (1) reduce weekly alcohol consumption, and (2) improve health status. To our knowledge this is the first RCT that evaluates the effectiveness and reasons for dropout of an e-therapy program for problem drinking with active therapeutic involvement.

### **METHODS**

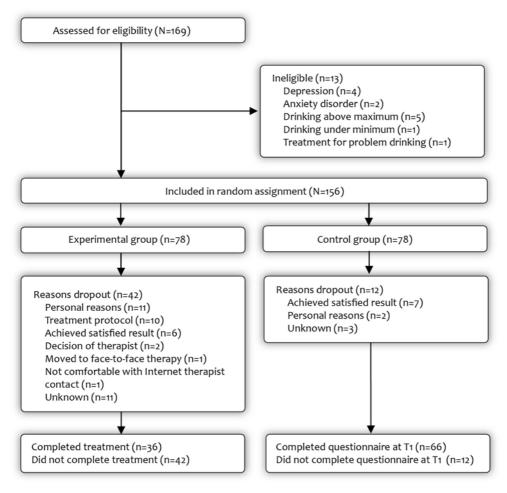
### Study design and participants

We undertook an open RCT, with recruitment taking place between October and December 2008. To be included in the trial, participants had to be Dutch-speaking problem drinkers in the general population aged 18 years or more. Problem drinking was defined as drinking currently at least 15 units (of 10 g of ethanol) a week for females and 22 units for males, with a maximum of 67 units a week for females and 99 units for males. This was based on the mean weekly alcohol consumption in the pilot study, added with 1.5 SD. We excluded participants treated for problem drinking in the preceding year and participants with psychiatric treatment in the past 6 months or those currently having a psychiatric disorder.

Participants were recruited through an advertisement on the website's homepage (http://www.alcoholdebaas.nl), through media attention on national television, and by responding to 500 expressions of interest that had been emailed to the website. Participants were referred to a research website for additional information about the study and encouraged to screen themselves on the inclusion criteria. A total of 169 participants deemed themselves eligible, provided online informed consent, and completed the baseline

questionnaire. Participants received the e-therapy intervention free of charge. We did not provide any kind of incentive for study participation. The study protocol was approved by the independent medical ethics board METiGG (ref. no. NL20742.097.07) and registered at http://www.controlled-trials.com (ISRCTN39104853).

Figure 1. CONSORT diagram: flow of participants through the study protocol



T1 = 3-months' follow-up for control group

### Procedure

As shown in the flow chart (Figure 1), 156 of the 169 participants screened were subsequently determined to be eligible for the study and were randomly assigned to either the e-therapy treatment group or to the waiting list control group. Participants were randomly assigned in blocks of 8, according to a computer-generated random list (based on a random generator and algorithm, Microsoft .NET Framework version 3, Microsoft, Bellevue, WA, USA), implemented by a technician who was not involved in the recruitment process. Block randomization ensures group numbers are evenly balanced at the end of each block. Because of the limited availability of the therapists, we needed to keep the numbers in both groups very close at all times. Participants were automatically allocated by computer.

Every e-therapy participant was assigned to a personal therapist for the duration of the study. The 12 experienced therapists were all qualified social workers with higher vocational education, who had received special training in the technical aspects and content of the e-therapy program, with special focus on motivational writing skills. Therapists could obtain expert advice from the multidisciplinary team, consisting of treatment staff, an addiction medicine specialist, a psychologist, and 2 supervisors. Both supervisors regularly checked the therapists' files for fidelity to treatment protocols. Participants were allocated on a sequential basis to the next available therapist. The mean total time spent on each participant was approximately 1.5 hours per week.

Figure 2. Homepage of http://www.alcoholdebaas.nl



### Interventions

The e-therapy program could be accessed via the homepage (Figure 2) and consisted of a structured 2-part online treatment program in which the participant and the therapist communicated asynchronously, via the Internet only. Participants accessed the e-therapy program in their personal environment. Participant and therapist were in separate or remote locations; the interaction occurred with a time delay between the responses. The aim of the e-therapy program was to reduce or stop the participant's alcohol intake. The method underlying the program was based on the principles of cognitive behaviour therapy (Hester, Miller, & Goldman, 2003) and motivational interviewing (Miller & Rollnick, 2002). All communication between therapists and participants took place through a Web-based application (Figure 3), as described previously (Postel et al., 2010).

Figure 3. Participant's personal record



Part 1 of the program consisted of 2 assessments and 4 assignments, with the accompanying communication focusing on the analysis of the participants' drinking habits. Part 1 covered the following core concepts: (1) exploring advantages and disadvantages of alcohol use, (2+3) understanding drinking patterns through completion of a daily drinking diary and descriptions of the craving moments, and (4) identifying risky drinking situations. The therapist helped the participant at every step in the program; he or she explained the assignments and provided feedback. The therapist always responded within 3 days.

Messages were always personalized, although therapists used preprogrammed text parts for the analogous parts, such as the explanation of an assignment. The therapist and participant could not move on to the next assignment until they completed the previous one. We chose a linear model, also called tunnel IA design, as the therapy program is most effective with a specific ordering of treatment steps, and this model is also useful in working with homework assignments and tailored feedback (Danaher, McKay, & Seeley, 2005). The therapist provided contact details of the institution that participants could reach 24 hours a day in case of crisis situations. At the end of part 1, personalized advice was given and the participant could choose whether to continue with treatment in part 2 or to stop. The multidisciplinary team evaluated every participant's record and gave advice to the therapist for the further treatment stages in part 2.

Part 2 focused on behavioural change and included 5 central concepts: (1) setting a drinking goal, which could be abstinence or moderate drinking, (2) formulating helpful and nonhelpful thoughts, (3) considering helpful behaviours for moments of craving, (4) identifying the moment of the decision to drink alcohol, and (5) formulating an action plan for maintaining the new drinking behaviour and for preventing relapse. The mean duration of the total etherapy program was 3 months, with 1 or 2 therapist contacts per week and daily self-registration during the whole program. Besides registration, the participant usually responded every 3 or 4 days. If there was no response from the participant, the therapist contacted the participant 3 times during the following 2 weeks. If there was still no response, the participant received a message that his or her record would be closed after 2 weeks. The posttreatment questionnaire was sent to the participant's personal data record.

Participants in the waiting list control group received "no-reply" email messages once every 2 weeks during the waiting period of 3 months to keep them involved in the study. The messages contained alcohol-related information, psychoeducational material, motivational messages, and references to the information website and the forum for online contact with fellow sufferers. Participants knew that they were assigned to the control group and that they could start the e-therapy intervention after they completed the assessment at 3 months.

### **Outcome measures**

All data were collected online. Participants completed online self-report questionnaires at baseline and at 3-months' follow-up (control group) or at posttreatment, which was at approximately 3 months (e-therapy group). Weekly alcohol consumption was assessed by a

7-day retrospective drinking diary (Sobell & Sobell, 2000). Type and severity of substance dependence was assessed by the Substance Abuse Module of the Composite International Diagnostic Interview (Compton, Cottler, Dorsey, Spitznagel, & Mager, 1996). The General Health Questionnaire (GHQ-28) and the Maudsley Addiction Profile, Health Symptom Scale (MAP-HSS) were used to assess health status (Marsden et al., 1998; Vallejo, Jordán, Díaz, Comeche, & Ortega, 2007). The 21-item Depression Anxiety Stress Scale (DASS-21) was used to measure the 3 related negative emotional states of depression, anxiety, and stress (Antony, Bieling, Cox, Enns, & Swinson, 1998). Quality of life was measured with the EuroQol-5D (EQ-5D) (Lamers, Stalmeier, McDonnell, Krabbe, & Busschbach, 2005) and initial treatment motivation with the TCU Motivation for Treatment (MfT) scale (De Weert-Van Oene, Schippers, De Jong, & Schrijvers, 2002). To determine the reasons for dropout, we sent an email to all dropouts with a link to an additional online questionnaire consisting mainly of open questions. If participants did not complete this questionnaire, they were contacted by telephone to remind them to complete the questionnaire online or to administer it by phone immediately. Dropout was defined as anyone who did not complete the 3-month assessment. Dropouts in the e-therapy group did not complete all 12 treatment sessions: 9 assignments and 3 assessments. Because of the design of the e-therapy program it was impossible for participants to skip parts of the intervention; therefore, adherence corresponds to the moment of dropout.

The primary outcome measures were (1) the difference in the score on weekly alcohol consumption, and (2) the proportion of participants drinking under the problem drinking limit. Secondary outcomes were difference scores on health status (GHQ-28 and MAP-HSS), DASS-21 scores, and quality-of-life ratings (EQ-5D).

### Sample size and statistical analysis

Based on the results of our explorative study, we anticipated a 50% reduction of mean weekly alcohol consumption in the experimental group and 25% in the control group. To detect a difference of 25% with an alpha of .05 and a power of 80%, 45 participants were required in each group. To allow for dropouts, our target sample size was 75 participants in each group.

We used chi-square and t tests for demographic data and pretreatment characteristics to assess whether randomization resulted in 2 comparable groups at baseline and whether any differential loss to follow-up had occurred. We performed intention-to-treat analysis using multiple imputations (SPSS version 17.0, SPSS Inc, Chicago, IL, USA) to deal with loss to

follow-up. We used 5 imputed data sets, and group was used as predictor in the imputation equation. We used t tests to assess the differences between pre- and posttreatment measures. Between-group effect sizes were calculated based on the pooled standard deviation, Cohen d. Effect sizes of .80 were considered to be large (Cohen, 1992).

Reasons for dropout were independently assessed by the first and third author. If the 2 authors did not agree, the topic was discussed to reach agreement. If necessary, the second author was consulted to arbitrate.

### RESULTS

### Participant characteristics

Table 1 presents baseline characteristics of the 156 participants who were included in the trial. Of these, 54% were women, 58% had a higher education level, and 82% were employed; age ranged from 22 to 66 years, with an mean of 45.3 years. A total of 127 participants reported alcohol dependence (81%). The majority (134/156, 86%) had never received professional help for their drinking problem. The mean weekly alcohol consumption was 41.9 standard units a week: 49.8 for men and 35.2 for women. Participants used a considerable amount of medication for somatic complaints, but no medication that interfered with the treatment program, with the exception of one person using anticraving medication.

Chi-square analysis indicated that there was a significant difference between the groups on prior alcohol treatment; the experimental group had received more alcohol addiction treatment than the control group (24% vs 4%,  $X_{1}^{2}$  = 13.5, P < .001). There were no other significant differences in treatment condition in any of the variables presented in Table 1.

### Loss to follow-up

Of the 156 individuals who were randomly assigned, 102 (65%) completed assessments at 3 months (Figure 1). Loss to follow-up at 3 months was higher in the e-therapy group (42/78, 54%) than in the control group (12/78, 15%,  $X_1^2 = 25.5$ , P < .001). Completers and noncompleters in the e-therapy condition differed in 1 variable at baseline: the mean score on the Treatment Readiness subscale of the MfT was higher for completers (mean = 4.23) than for noncompleters (mean = 3.98,  $F_{1,76} = 5.89$ , P = .02). In the control condition the groups differed in 2 variables: more noncompleters were male (92% vs 38%,  $X_1^2 = 11.82$ , P < .001) and fewer of them had a diagnosis of alcohol dependence (58% vs 83%,  $X_1^2 = 3.89$ , P = .04).

Table 1. Baseline characteristics of test populations

Variable	E-therapy Group (n = 78)		Control Group (n = 78)		Total (N = 156)		Analysis		
	n	%	n	%	n	%	X²	df	Р
Female	42	54	42	54	84	53.8	0.0	1	1.00
Higher education	42	54	48	62	90	57.7	0.9	1	·33
Employed	65	83	63	81	128	82.1	0.2	1	.68
DSM-IV <sup>a</sup> diagnoses							1.1	2	.56
Alcohol dependence	65	83	62	79	127	81.4			
Alcohol abuse	6	8	10	13	16	10.3			
No dependence or abuse	7	9	6	8	13	8.3			
Prior alcohol treatment	19	24	3	4	22	14.1	13.5	1	<.001
Problem drinking <sup>b</sup>	78	100	78	100	156	100	0.00	1	1.00
	Mean	SD	Mean	SD	Mean	SD	t	df	Р
Age (years)	46.7	9.7	43.9	9.7	45.3	9.8	1.8	1,154	.08
Weekly alcohol consumption									
Males	47.6	21.3	51.9	16.7	49.8	19.1	-1.0	1,70	·34
Females	36.3	13.0	34.1	14.5	35.2	13.7	0.7	1,82	.46
GHQ-28 score <sup>c</sup>	53.6	12.1	55.6	11.7	54.6	11.9	-1.1	1,154	.28
MAP-HSS score (0-40) <sup>d</sup>	20.3	6.6	20.0	5.3	20.2	6.0	0.3	1,148	.76
DASS-21 total score <sup>e</sup>	27.5	20.0	28.4	14.7	27.9	17.5	-0.3	1,154	<b>.</b> 75
MfT subscales <sup>f</sup>									
Recognition of General Problems	3.6	0.8	3.5	0.6	3.5	0.7	0.6	1,145	.58
Recognition of Specific Problems	2.2	0.7	2.2	0.5	2.2	0.6	-0.2	1,143	.86
Desire for Help	3.9	0.7	3.9	0.6	3.9	0.7	0.5	1,154	.63
Treatment Readiness	4.1	0.5	4.0	0.4	4.1	0.5	0.8	1,154	.45
EQ VAS <sup>g</sup>	60.2	22.3	59.7	21.8	59.9	22.0	0.1	1,154	.90

<sup>&</sup>lt;sup>a</sup> Diagnostic and Statistical Manual of Mental Disorders, 4th revision; <sup>b</sup> Drinking >21 (male) or >14 (female) units mean per week; <sup>c</sup> General Health Questionnaire; <sup>d</sup> Maudsley Addiction Profile, Health Symptom Scale; <sup>e</sup> Depression Anxiety Stress Scale; <sup>f</sup> TCU Motivation for Treatment scale; <sup>g</sup> EuroQol-5D visual analog scale.

### Outcome

Participants allocated to the e-therapy group showed a greater decrease in alcohol consumption than those in the control group at 3 months (Table 2). The e-therapy group significantly decreased their mean weekly alcohol consumption by 28.8 units compared with 3.1 units in the control group, a difference in means of 25.6 units on a weekly basis (95% confidence interval [CI] 15.69-35.80; P < .001). The between-group effect size (pooled SD) was large (d = 1.21). Additional analyses showed no effect modification and confounding for gender and prior alcohol treatment (data not shown).

Table 2. Difference scores by treatment condition at 3 months

	F-ther:	apy (n=78)	Control (n= 78)		Analysis				
	L-trierapy (II=70)		Control (II= 70)			Allalys			
	Mean	SD	Mear	n SD	95%	CI	Р	Effect size	
Weekly alcohol consumption	28.8	21.3	3.1	21.2	25.65 (15.6	9-35.80)	<.001	1.21	
MAP-HSS score (0-40) <sup>a</sup>	5.2	5.2	0.9	3.7	4.27 (2.37-6.17)		<.001	0.96	
GHQ-28 score b	12.8	12.0	4.3	10.4	8.46 (3.8	2-13.09)	<.005	0.76	
DASS-21 total score <sup>c</sup>	16.3	19.4	2.2	15.6	14.13 (7.96	5-20.29)	<.001	0.81	
EQ VAS <sup>d</sup>	-10.6	29.4	-2.7	25.6	-7.95 (-16.6	9 to 0.79)	0.08	-0.29	
	n	% success	n	% success	OR	NNT <sup>e</sup>	Р		
Drinking within guidelines	78	68%	78	15%	12.04	1.9	<.001		

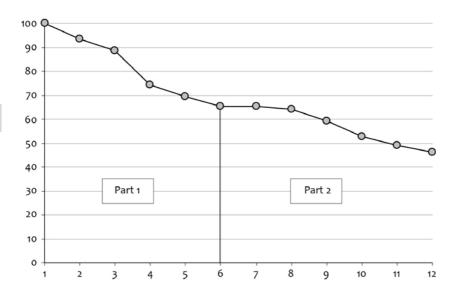
<sup>&</sup>lt;sup>a</sup> Maudsley Addiction Profile, Health Symptom Scale; <sup>b</sup> General Health Questionnaire; <sup>c</sup> Depression Anxiety Stress Scale; <sup>d</sup> EuroQol-5D visual analog scale; <sup>e</sup> Number needed to treat

The clinical significance of the e-therapy program was assessed using the number of participants with alcohol consumption under the problem drinking limit at 3 months. The results showed that 68% of the e-therapy group was drinking less than 15 (females) or 22 (males) units a week, compared with 15% in the control group (OR 12.0, number needed to treat 1.9, P < .001).

The secondary outcome data showed that participants in the e-therapy group scored significantly better on the MAP-HSS (95% CI 2.37-6.17, P < .001), GHQ-28 (95% CI 3.82-13.09, P < .005), and DASS-21 (95% CI 7.96-20.29, P < .001), but not on the EQ-5D (Table 2).

In the e-therapy group, the mean number of sessions completed was 8.3 (SD 4.2) out of 12. Participants completed the modules in the order that they were presented. Treatment completers (36/78, 46%) completed all 12 assignments and dropouts (n = 42) completed a mean of 5.1 (SD 3.2) assignments. The dropout rate was higher in part 1 (36%) than in part 2 (19%). Figure 4 shows the attrition curve for the e-therapy group. The mean duration of treatment completion was 16.6 weeks and the mean waiting time of the control group was 14.2 weeks.

Figure 4. Attrition curve e-therapy group: proportion participants by number of assignments



### Reasons for dropout

A substantial number of participants in the e-therapy group (n = 42) and in the control group (n = 12) did not complete postassessment. We were not able to contact 14 participants, because of nonresponse or an invalid phone number. However, we could establish that in the e-therapy group 11 participants dropped out because of personal reasons unrelated to the e-therapy program or the study (eg, ill family member), 10 because they were not

comfortable with the treatment protocol (eg, too intensive), and 6 because they were satisfied with the positive results being achieved (eg, "I have been sufficiently helped"). Additionally, 1 person was not comfortable with the Internet therapist contact, 1 participant moved on to face-to-face treatment, and the therapist decided to terminate the e-therapy on 2 occasions, 1 because of insufficient information and the other due to an inability to set a realistic drinking goal. In the control group, 7 participants quit because they were satisfied with the results achieved and 2 for personal reasons.

### DISCUSSION

### Main results

Participants who received the therapist-supported e-therapy program reported substantially greater gains than those who received no-reply email messages. At the end of treatment, 7 out of 10 participants in the e-therapy group achieved drinking behaviour within the guidelines for low-risk drinking. The e-therapy group also showed greater improvement than the control group on general health and depression symptoms. Besides the outcome measures, this study also gained insight into the reasons for dropout; the main reasons for dropping out of the e-therapy program were personal reasons unrelated to the program, the protocol or content of the e-therapy program, and satisfaction with the positive results that had been achieved.

### E-therapy with active therapeutic involvement

This is, to our knowledge, the first RCT evaluating an online treatment program with active therapeutic involvement for problem drinking solely via the Internet. The results of the present study replicate the results of our uncontrolled observations (Postel et al., 2010). The effect sizes in this study are quite large compared with effects found for other Web-based interventions designed to decrease alcohol consumption (Bewick et al., 2008; Riper, Kramer, Smit et al., 2008). A possible explanation might be the active therapeutic involvement in the present intervention, which replicates earlier findings from Spek et al (2007) that active therapeutic involvement seems to be especially effective. It also seems reasonable that the large effects are a result of the key ingredients of the e-therapy program: the therapy itself was intensive; the therapists were experienced, were well educated, and had special training and good supervision throughout the trial; and the recruitment process involves a certain amount of motivation and readiness to change. Further research is needed to identify the

effective elements of the e-therapy program and the optimal amount of therapeutic contact needed.

Although around 80% of participants were deemed to be dependent drinkers by Diagnostic and Statistical Manual of Mental Disorders, 4th revision (DSM-IV), it may be that the severity of dependence was actually quite low, as a high proportion of the participants were employed and well educated.

E-therapy attracts participants who are otherwise unlikely to use regular face-to-face treatment facilities or self-help programs. A study by Postel et al (2005) showed that etherapy reaches more women, higher-educated people, and employed people, groups that are underrepresented in regular face-to-face therapy. One of the perceived advantages of etherapy over a face-to-face treatment is its anonymity. Participants no longer need to stay away from treatment because of shame, fear of stigmatization, or another high barrier to professional help. Furthermore, e-therapy helps participants in their own environment at a time of their own choosing; they no longer need to visit the therapists' office for scheduled weekly visits, which makes e-therapy more easily accessible and convenient. This is also the reason for choosing asynchronous communication instead of chat; using chat these advantages would no longer exist. An advantage of active therapeutic involvement over selfhelp is the added value of personal contact with the professional therapist. Although (tailored) screening or self-help interventions have proven to be successful (Chiauzzi et al., 2005; Cunningham, Humphreys, Kypri, & van Mierlo, 2006; Kypri et al., 2004; Linke et al., 2004; Saitz et al., 2007), some participants prefer having contact with a professional therapist. Based on the findings of online treatment for depression and anxiety (Spek et al., 2007), online treatment with therapist involvement might also be more effective than online self-help for alcohol problems.

### Dropout

The dropout rate in this study was substantial (54/156, 35%). E-therapy dropouts showed less readiness for treatment. It is important to note that there were more dropouts in the e-therapy group (42/78, 54%) than in the control group (12/78, 15%), which suggests that actively working on behavioural change causes more resistance and fear than waiting for change. This corresponds to our experiences in regular addiction health care practice, where we see that as patients embark on changing their addictive behaviour, it is the fear that dominates. On the other hand, the intention to change your alcohol consumption in the near future is ego syntonic. This might explain the differences in dropout rate between the 2 groups, and

this may also be the reason for the overall high dropout rate in addiction treatment interventions.

Although e-therapy is suitable for a broad range of participants, it probably will not be the best alternative for each problem drinker. Some problem drinkers prefer real-life contact with their therapist, and for some participants another form of treatment is recommended because of their specific situation.

The main reasons for dropout in our study are in line with earlier findings on potential factors for attrition as described in the law of attrition by Eysenbach (Eysenbach, 2005). Personal reasons unrelated to the e-therapy program fall under "external events," and not being comfortable with the treatment protocol falls under "workload and time required." However, satisfaction with the positive results being achieved seems to be a new factor, not yet covered in the law of attrition. Eysenbach describes "tangible and intangible observable advantages in completing the trial or continuing to use it" as a potential factor, which refers to advantages when completing the trial or intervention. In our study, participants mentioned a different thing: since they already achieved their treatment goal during the intervention, they decided that completing the trial or continuing to use the intervention would not lead to additional advantages. It seems that some of the e-therapy participants who did not complete the entire program received what they considered to be enough therapy. It would be interesting to confirm this hypothesis, although we realize that it is difficult to obtain data from dropouts. Instead of sending a separate dropout questionnaire, the participants' situation could be monitored more closely by using interim questionnaires to measure more frequently during the study. Another possibility is to develop the daily registration tool (eg, drinking diary) in a way that data can easily be transported for research purposes.

### Methodological considerations

Despite randomization, a substantially higher proportion of participants in the e-therapy group than in the control group received prior alcohol treatment. Therefore, part of the reduction in alcohol consumption might be explained by this baseline difference. Prior alcohol treatment has been shown to have predictive power with regard to treatment outcome; however, other studies have shown the reverse (Adamson, Sellman, & Frampton, 2009). Although the large differences between both groups already suggested that prior treatment would play no meaningful role in our study, we performed additional analyses and revealed that prior alcohol treatment had no significant effect on treatment outcome.

Although high dropout rates seem to be characteristic of online interventions (Christensen et al., 2009), this highlights a weakness in our study; especially as we were not able to acquire posttest data from the dropouts as a consequence of the technical procedures of the etherapy program. We therefore could contact dropouts only by a dropout questionnaire sent separately by email. In future studies, procedures will be changed to ensure that posttreatment assessment can be completed, independent of treatment completion.

We consider the formal investigation of the reasons for dropout to be a strength of our study, as only 1 previous study has formally examined the reasons for dropout (Christensen et al., 2009; Lange et al., 2003). This study from Lange and colleagues studied online therapy for posttraumatic stress disorder and showed that the 2 reasons for quitting were technical problems and the form and content of the therapy (Lange et al., 2003). As their study was conducted in 2003, and computer and Internet technology has significantly improved since then, it could be expected that technical aspects would no longer be one of the main problems. In line with Lange and colleagues, we also found that dissatisfaction with the form or content of the e-therapy program is a reason for dropout. In addition to their findings, we also found that personal reasons and satisfaction with the results achieved were reasons for dropout. Contrary to our expectations, our results show that quitting the e-therapy program prematurely does not automatically mean that the participant has relapsed. Satisfaction with the results being achieved for 7 participants in the control group suggests that receiving informational email messages can be very helpful for some participants. This is most likely true for the group with less serious alcohol problems, as fewer dropouts in the control group had a diagnosis of alcohol dependence. Based on the information on dropout, the e-therapy program can be improved to decrease the number of participants dropping out.

We expect to be able to generalize the 3-month findings of our study to the general population of e-therapy clients, as our sample was comprehensively representative. We kept the exclusion criteria to a minimum, and therefore reached a population of problem drinkers that shows many similarities with participants in the daily practice open-access intervention of the e-therapy program.

We can only report short-term effects of the e-therapy intervention. It was not possible to compare group outcomes at 6 months because of a prior decision to permit the waiting list controls to receive e-therapy after 3 months; this was done for ethical reasons. We know that this is a serious study limitation, as it is important to know the longer-term effects of alcohol treatment programs. A study from Riper and colleagues (Riper, Kramer, Keuken et al., 2008) showed that the beneficial effect of their online alcohol self-help intervention had disappeared at 12 months.

### **Future directions and implications**

Until recently, the e-therapy program had been available only in Dutch. However since February 2010, the e-therapy program is also available in English (http://www.lookatyourdrinking.com). This greatly expands the implementation of this e-therapy program, and offers the possibility to reach a larger population of problem drinkers and to conduct cross-cultural research. Although the Dutch version of the e-therapy program is fully reimbursed by the health insurance companies and therefore free of charge for participants, the English version unfortunately is not yet. English participants have to pay for the treatment program themselves.

Insight into the reasons for dropout offers possibilities for the improvement of online treatment programs. For example, more therapist attention for participants' satisfaction will possibly result in more treatment terminations in good consultation. Sending an email alert to participants when they receive a new message from their therapist can easily eliminate part of the dissatisfaction. At this moment, the challenge of e-therapy programs no longer seems to be its effectiveness but keeping participants involved till the end of the treatment program.

In summary, it appears that, because many problem drinkers do not receive any kind of treatment, these initial results point to a meaningful way to deliver easily accessible and effective alcohol treatment to a larger population, members of which do not otherwise seek or receive help for their drinking problem. Additional research is needed to gain more insight into reasons for dropout and to directly compare the effectiveness of the e-therapy program with a face-to-face treatment program. We plan to conduct secondary analysis after treatment completion in both groups. We will then merge the experimental and control groups to explore whether e-therapy might work more effectively for some people than for others.

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# CHAPTER 6

# Therapeutic Alliance in E-Therapy versus Face-to-Face Addiction Treatment

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Submitted for publication

### **ABSTRACT**

Background - The nature of therapeutic alliance in online cognitive behavioural therapy has been hardly examined.

Objective - To compare therapeutic alliance in e-therapy versus traditional face-to-face addiction treatment.

Methods - Data of two RCT studies were compared. The first study concerned an e-therapy program for problem drinkers, with active therapeutic involvement (n=65). The second study concerned an inpatient face-to-face treatment program for substance-dependent patients (n=77). The principle instrument for measuring outcome was the Helping Alliance Questionnaire (HAQ).

Results - There were no differences between face-to-face and online group on any of the three HAQ-scores either at the interim point or post-treatment. The therapeutic alliance improved during the treatment program in both groups, and there were no significant differences between both groups on any of the HAQ difference scores.

Conclusions - It is possible to establish a positive therapeutic relationship between patient and therapist in face-to-face and distance online treatment modalities in addiction health care.

### INTRODUCTION

The therapeutic relationship between patient and therapist has been accepted as an important element of the therapeutic process (Martin, Garske, & Davis, 2000). The collaborative aspects of the therapeutic relationship are generally described as therapeutic alliance (Hougaard, 1994). Although different definitions are used, most have three components in common, identified by Bordin: (1) agreement between patient and therapist on the treatment goals, (2) agreement on the concrete interventions or tasks, and (3) the affective bond between patient and therapist (Bordin, 1979). Studies have demonstrated that the quality of the therapeutic relationship is a significant predictor of treatment adherence and outcome in face-to-face addiction health care (Meier, Barrowclough, & Donmall, 2005). In their meta-analysis, Martin and colleagues (2000) found that the strength of the therapeutic alliance accounted for 22% of therapeutic success independent of the type of outcome measure and treatment provided.

The therapeutic alliance in online therapy raises further questions. The physical absence of the therapist and the lack of social and nonverbal cues such as eye contact, body language, and vocal intonation, provide concerns about the therapeutic relationship becoming impersonal and unstable (Cook & Doyle, 2002; Lingley-Pottie & McGrath, 2007; Newman, 2004). However, these concerns do not seem to be justified as evidence shows that positive and trustworthy contact can be established via the Internet, comparable to the therapeutic alliance found in face-to-face treatment (Cook & Doyle, 2002; Knaevelsrud & Maercker, 2007; Lange, van de Ven, Schrieken, & Smit, 2003). In some studies, patients even report higher levels of therapeutic alliance than in face-to-face studies (Cook & Doyle, 2002; Knaevelsrud & Maercker, 2006). Establishing a stable relationship via the Internet is partly due to the perceived anonymity of patients. Anonymity produces a higher degree of openness and intimacy (Walter, 1996). Patients on the Internet feel less vulnerable about self-disclosing and taking action and therefore easily share very personal or intimate details (Suler, 2004). The strength of the therapeutic alliance varies with the intensity of the therapeutic contact. Knaevelsrud (2005) distinguished three different forms of online interventions according to the type and intensity of the therapist-patient contact: (1) Stand-alone self-help programs with very limited or no patient-therapist contact, (2) computer technology as an additional component to regular face-to-face therapy, and (3) internet-based therapeutic treatment, where patient and therapist communicate solely through the Internet (Knaevelsrud, 2005).

In the present study, we will compare an online intervention of the last category with a face-to-face treatment program. Although the importance of the therapeutic alliance is now

generally accepted, a relatively small amount of research has been conducted examining the nature and the relevance of the therapeutic alliance in online cognitive behavioural therapy. To our knowledge, this is the first study that investigates the patients' perceived therapeutic alliance in an e-therapy program for problem drinkers. Furthermore, it compares the helping alliance data of the e-therapy group with the same data from a representative group of substance-dependent patients in a traditional face-to-face addiction treatment program.

We hypothesize that e-therapy patients as well as face-to-face patients will establish a positive therapeutic relationship with their therapist, and that the perceived helping alliance will be of the same quality for both groups. We also hypothesize that patients' perceived therapeutic alliance will improve during both treatment programs.

### **METHODS**

### Design and interventions

The present study is part of two larger studies; both randomised controlled trials (RCT). The first study concerned a RCT for Dutch problem drinkers, with random assignment to either an e-therapy treatment group or to a waiting list control group (Postel, de Haan, ter Huurne, Becker, & de Jong, 2010). The e-therapy group started treatment immediately, consisting of a structured two-part online treatment program in which patient and therapist communicated asynchronously, via the Internet only. Part 1 focused on the analysis of the participants' drinking habits and part 2 on behavioural change. Participants were assigned set tasks and asked to record their alcohol consumption in an online diary; they received feedback from their assigned therapist on both twice a week. The method underlying the program was based on the principles of cognitive behaviour therapy (Hester, Miller, & Goldman, 1996) and motivational interviewing (Miller & Rollnick, 2002). The average duration of the program is 3 months. Participants in the waiting list control group received 'no-reply' email messages once every two weeks during the waiting period of 3 months, and afterwards they started the e-therapy program. The study protocol was approved by the independent medical ethics METIGG no. NL20742.097.07), registered at Controlled-trials.com board (ref. (ISRCTN39104853) and participants signed an online consent form. Based on the research question chosen in the present study, we merged the data from both groups after the control group had also completed the e-therapy program. This can be legitimated as no differences were found between the two groups on patients' perceptions of the therapeutic alliance. The total group consisted of 144 patients who started the e-therapy program. Unfortunately, perceived helping alliance was not measured when patients left treatment

before interim measurement (n=48). Therefore, helping alliance interim data is available for 96 patients and post treatment data for 65 patients in the e-therapy group.

The second RCT study was conducted in a Dutch, inpatient, face-to-face treatment settings for substance-dependent patients (Joosten, de Jong, de Weert-van Oene, Sensky, & van der Staak, 2009; Joosten, de Weert, Sensky, van der Staak, & de Jong, 2008). Patients received a 3-month, inpatient, cognitive behavioural treatment program focusing on relapse prevention and containing individual and group components. Therapists were randomly assigned to two treatment modalities. These were either shared-decision making or standard procedure to reach treatment agreement. The shared decision-making intervention (SDMI) involved a structured, manualised, 5-session procedure to facilitate treatment agreement. The standard procedure consisted of reaching and evaluating treatment agreement in the usual nonstructured way. Receipt of the SDMI depended on therapist allocation, which was conducted on the basis of availability. Participants provided written informed consent and the study protocol was approved by the Dutch Ethical Assessment Committee for Experimental Investigations on People (No. 4.108). The study was not registered in a public trial registry as enrolment started before July 1, 2005. We also merged the data from these two groups; there were no differences between the groups regarding patients' perceptions of the therapeutic alliance. The total group consisted of 212 included patients who started clinical face-to-face treatment. The perceived helping alliance was not measured when patients left treatment before interim measurement (n=92). Therefore, helping alliance interim data is available for 120 patients, post treatment data for 103 patients and for both measures in 77 patients in the face-to-face group.

Although separate, the therapists in both studies were qualified social workers or nurses with Higher Vocational Education and experience in addiction treatment. In both studies they received specific training on the aspects of the experimental intervention and therapists could obtain further expert advice from a multidisciplinary team, consisting of treatment staff, an addiction medical specialist, a psychologist, and supervisors.

### Sample

In both studies, participants chose their preferred treatment setting (face-to-face or internet) themselves. We therefore assume that the setting they were treated in was the setting they perceived to best meet their individual needs.

Participants in the e-therapy group were experiencing alcohol problems and registered online for the e-therapy program; 82% fulfilled the DSM IV criteria for alcohol dependence. Participants were aged between 25 and 66 years, with an average of 45.9 years. Of these, 57% were women, 57% had a higher education, and 83% were employed. The majority (86%) had never received professional help for their problematic drinking.

Participants in the face-to-face group were experiencing a substance-related disorder and required inpatient treatment; 92% of them fulfilled the DSM IV criteria for substance dependence. Participants were aged between 20 and 69 years, with an average of 40.9 years. 19% were women, 10% had a higher education, and 38% were employed. Most of the participants had received previous professional help for their addiction problem (76%).

### **Outcome measures**

Patients' perceived therapeutic relationship was measured with the Helping Alliance Questionnaire (HAQ). The Helping Alliance Questionnaire is a self-report questionnaire that measures the strength of the patient-therapist alliance (Luborsky et al., 1996). The Dutch version of the HAQ has 11 items which have to be rated on a 5-point likert scale. The questionnaire contains 2 subscales: (1) Cooperation ( $\alpha$  = .88), reflecting the perception of the patient to work together with the care provider; and (2) Helpfulness ( $\alpha$  = .76), referring to the patient's confidence in his own capacity to improve the situation. The psychometric properties of the HAQ are satisfactory (Joosten et al., 2009). Patients completed the patient version of the questionnaire at an interim measurement (after 4-6 weeks) and post treatment.

In addition to the HAQ, patients' satisfaction with the online therapeutic contact was explored as an additional indicator of the online therapeutic alliance, measured with five evaluation questions on this topic.

### Statistical analysis

Chi-square tests assessed whether completers and non-completers differed on baseline characteristics. Sum scores were computed for the HAQ total score and for the subscales Cooperation and Helpfulness. T-tests were used to assess the differences between the three HAQ-scales at the interim and post treatment between the e-therapy group and the face-to-face group. Paired t-tests were used to assess the improvement on the HAQ-scales between the interim and post treatment assessment for the e-therapy group and the face-to-face

group. Difference scores were computed by subtracting interim scores from the post treatment scores, and t-tests assessed whether the improvement differed between the etherapy and face-to-face group. All analyses were conducted for HAQ total, cooperation, and helpfulness score.

#### RESULTS

#### **Completers versus non-completers**

Due to the high attrition rates in the face-to-face sample (64%) and in the e-therapy sample (55%), we compared relevant baseline characteristics between completers and non-completers. In the face-to-face group as well as in the e-therapy group chi-square analysis indicated that there were no significant differences between completers and non-completers on gender, education level, work situation, DSM score or prior professional help.

#### Helping alliance: face-to-face versus online

Table 1 shows patients' perceived helping alliance at interim and post treatment. T-tests showed no differences between the face-to-face and online group on any of the three HAQ-scores at interim or post-treatment measure. Patients' scores on the HAQ were comparable for the e-therapy and the face-to-face group.

Paired t-tests showed significant differences on the three HAQ-scores between interim and post treatment measurement for both groups. In the e-therapy group, the HAQ total score increased from 43.9 at the interim point to 47.1 post treatment (t = -6.70, df = 64, P<.001) and in the face-to-face group from 44.2 to 46.7 (t = -4.13, df = 76, P<.001). HAQ Cooperation increased from 20.1 at the interim point to 21.0 post treatment (t = -3.33, df = 64, P=.001) in the e-therapy group and from 19.8 to 20.6 in the face-to-face group (t = -2.42, df = 76, P=.02). HAQ Helpfulness increased from 19.6 to 21.7 (t = -8.11, df = 64, P<.001) in the e-therapy group and from 20.1 to 21.7 in the face-to-face group (t = -5.16, df = 77, P<.001). This data show that the perceived therapeutic alliance on the three HAQ-scores improved during the treatment program in both groups.

Table 1. Patients' perceived helping alliance scores

	E-therapy (n=65)		Face-to-face (n=77)		Analysis		
	Mean	SD	Mean	SD	t	df	Р
HAQ total							
Interim	43.9	4.5	44.2	5.6	42	140	.68
Post treatment	47.1	5.2	46.7	5.5	.43	140	.67
Difference score	3.2	3.9	2.5	5.2	.95	140	·34
Cohen's d	.71	0.9	.44	0.9	1.77	140	.08
HAQ Cooperation							
Interim	20.1	2.5	19.8	3.2	.58	140	-57
Post treatment	21.0	3.0	20.6	3.0	.64	140	·53
Difference score	0.9	2.2	0.9	3.1	.08	140	.94
Cohen's d	.36	0.9	.26	1.0	.64	140	·53
HAQ Helpfulness							
Interim	19.6	2.4	20.1	2.7	-1.26	140	.21
Post treatment	21.7	2.3	21.7	2.7	.02	140	.98
Difference score	2.1	2.1	1.5	2.6	1.48	141	.14
Cohen's d	.90	0.9	.58	1.0	2.00	140	.047

HAQ = Helping Alliance Questionnaire

Table 1 shows the difference scores (post minus interim) and effect sizes of the e-therapy group and the face-to-face group (Cohen, 1992). T-tests revealed that there were no significant differences on the three HAQ difference scores. There were also no differences between both groups on the effect sizes of the HAQ total score and HAQ Cooperation score, but the results showed a significant difference between the effect sizes of both groups on the HAQ Helpfulness score. The e-therapy group showed a higher effect size (M=.90) than the face-to-face group (M=.58), t=2.00, df=140, P=.047. This means that the e-therapy group showed a greater increase in the confidence they had in their own capacity to improve their current situation.

#### Online helping alliance

E-therapy patients also gave their opinion on the online therapeutic contact on five evaluation questions. As table 2 shows, 59 out of 65 (91%) patients described the contact

with their therapist exclusively through Internet as pleasant, 44 (68%) as personal and 63 (97%) as safe. The patients judged their online therapist with an average grade of 8.4. Forty-five patients (69%) did not miss other forms of contact with their therapist, although eleven (17%) considered that they did miss additional forms of contact, such as telephone or face-to-face contact.

Table 2. Reponses on evaluation questions of the e-therapy program (n=65)

Que	estion	Answers	Percentage	
1.		Pleasant	90.8%	
	How did you experience the fact that you had contact with your therapist exclusively through the Internet?	Neutral	7.7%	
	,	Unpleasant	1.5%	
2.		Personal	67.7%	
	How did you experience the fact that you had contact with your therapist exclusively through the Internet?	Neutral	24.6%	
		Impersonal	7.7%	
3.		Safe	97.0%	
	How did you experience the fact that you had contact with your therapist exclusively through the Internet?	Neutral	1.5%	
		Unsafe	1.5%	
4.	Did you miss other forms of contact with your therapist (e.g. by telephone or face-to-face contact)?	No	69.2%	
		Yes	16.9%	
	.,	Don't know	13.9%	
5.	What grade would you give your therapist (ranging from 1 to 10, with 10 as highest rating)?	Mean = 8.4		

Some quotes to illustrate patients' opinions of the therapeutic relationship:

'I am really impressed; I did not expect that online therapy would work this well and it really is very personal'.

'The attention of the therapist is essential in addition to the theory and the assignments. I have noticed that support is a necessary part of an e-therapy program'.

'I think it is very impersonal, but as a result also very accessible. A combination with some face-to-face sessions would be better for me'.

'In a face-to-face situation I find it very difficult to be personal and to admit my failures. Through the Internet it is much easier to be honest'.

'It is unbelievable that I changed my drinking habits in a few weeks, after years of excessive alcohol consumption. This is the result of the e-therapy program and especially the personal comments of my therapist. I felt that she knew me very well and that I could share everything with her'.

#### DISCUSSION

Both patients who participated in the face-to-face treatment program and those who participated in the e-therapy program reported good ratings of helping alliance. These findings confirm our hypothesis that it is possible to establish a positive therapeutic relationship between patient and therapist in both types of treatment. Despite the very different settings and participants, the perceived helping alliance was of a comparable level for both groups of patients. In their comments, most e-therapy patients were positive about the distance relationship formed with their therapist, and they experienced unique advantages of this online treatment program. Significant improvement in the therapeutic alliance could also be observed during both treatment programs. E-therapy patients reported the same level of improvement from the interim point to the end of treatment as face-to-face patients did. Therefore, our second hypothesis was also confirmed. Our findings are in line with previous findings that a good therapeutic relationship can be established regardless of the modality of communication (Cook & Doyle, 2002; Knaevelsrud & Maercker, 2006, 2007). The only significant difference we found between both groups concerned the effect size of the difference score on the HAQ Helpfulness subscale. The e-therapy group showed a greater improvement on Helpfulness compared to the face-to-face group, which means that the confidence patients have in their own capacities to improve the situation increased more in the e-therapy group. A possible explanation might be the difference in addiction severity between both patient groups, as the problems of the patients who seek online treatment might be less severe than participants who seek face-to-face treatment. The e-therapy program also requires a greater degree of independence and participants' initiative.

#### Limitations

There are several limitations to the present study that should be noted. We did not compare face-to-face and online treatment groups in a randomized controlled design and therefore the two groups comprised large differences in addiction problems (alcohol versus substance misuse) and other baseline characteristics. The e-therapy group included more women, participants with higher educational attainments and more employed people, and they less previous were exposed to addiction treatment. We do not know what impact these differences had on the results. It seems reasonable that a previous experience with professional treatment creates expectations of the new therapeutic relationship. However, whether these expectations affect the current experience in a positive or negative way depends on the interpretation of the previous experiences. The results should be seen in the light of these difference between face-to-face and e-therapy participants and therefore interpreted with some caution. However, we assumed that it is not possible in daily practice to compare both groups directly, because of the differences in groups of participants that register for e-therapy versus face-to-face treatment (Postel, de Jong, & de Haan, 2005). This raises the question of how relevant and ethical a comparison in a randomized design would be. We therefore decided that the best alternative was to compare the HAQ scores that were already available from two separate studies. Although our samples concerned different groups of patients, both study samples were representative of the patient populations that are encountered in daily practice of face-to-face and of online addiction health care. Additional research is needed to investigate if our findings can be generalized to other faceto-face and online treatment programs. Of most interest would be a study with two more similar participant's samples.

Another serious limitation is that participants who left treatment prematurely did not complete the HAQ questionnaire. As attrition rates were high with 64% and 55% respectively, we unfortunately had a lot of missing data. However, we found no baseline differences between completers and non-completers in both samples. Future research should assess patient's perceptions of alliance before they drop-out of treatment.

Unfortunately, we were limited in our data as we only decided to compare both study samples in retrospect. If we had made this decision in advance we could have collected additional data, including information on patient and therapist satisfaction, total contact time, and treatment costs. Although we did not conduct an economic evaluation, we do not expect the e-therapy program to be much cheaper, because the e-therapy program involved a comparable amount of therapist – patient time. Obviously there will be some profit because participants have no travel costs and time, no surgery is needed for the therapist

contact, and therapists do not suffer from no show in the e-therapy program as it is asynchronous. Further research is needed to conduct a formal economic evaluation.

Despite the limitations, this study compared patients' perceived therapeutic alliance in an etherapy program with the same data from a group of substance-dependent patients in a traditional face-to-face addiction treatment program. This, at least, gives an indication of the similarities between both treatment modalities.

#### **Conclusions and implications**

The findings of this study stress the importance of treatment professionals giving attention to the therapeutic relationship whether it is face-to-face or online addiction treatment. It also strengthens the evidence that distance treatment modalities can offer treatment programs with a good therapeutic relationship. It seems obvious that online therapy is especially helpful for a group of patients who prefer online treatment instead of face-to-face treatment. This might be because of the flexibility of this type of treatment; patients do not have to worry about time, employment, child care responsibilities or distance. Online treatment reduces obstacles related to shame, fear of stigmatization and limited availability because of office hours, which might be especially important aspects for the less severe group of patients with addiction problems. In conclusion we can say that for some patient's e-therapy seems to be a valuable alternative to regular face-to-face treatment in addiction health care.

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### CHAPTER 7

## **Attrition in Web-Based Treatment for Problem Drinkers**

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#### **ABSTRACT**

Background - Web-based interventions for problem drinking are effective but characterised by high rates of attrition. There is a need to better understand attrition rates in order to improve the completion rates and the success of web-based treatment programs.

Objective - The aims of this paper are to (1) examine attrition prevalence and pre-treatment predictors of attrition in a sample of open-access users of a web-based program for problem drinkers and (2) to further explore attrition data from our randomized controlled trial (RCT) of the web-based program.

Methods - Attrition data from two groups of Dutch-speaking problem drinkers were collected: 1. open-access participants enrolled in the program in 2009 (n=885), and 2. RCT participants (n=156). Participants were classified as non-completers if they did not complete all 12 treatment sessions (9 assignments and 3 assessments). In both samples prevalence of attrition and pre-treatment predictors of treatment completion were assessed. Logistic regression analysis was used to explore predictors of treatment completion. In the RCT sample, additionally reasons for non-completion and participants' suggestions to enhance adherence were measured. The qualitative data were analysed using thematic analysis.

Results - The open-access and RCT group differed significantly in the percentage of treatment completers (35% vs 45%,  $X^2$ (1)=5.39, P = .02). Logistic regression analysis revealed a significant contribution of treatment readiness, gender, education level, age, baseline alcohol consumption, and readiness to change to predict treatment completion. The key reasons for non-completion were personal reasons, dissatisfaction with the intervention, and satisfaction with improvement. The main suggestions for boosting strategies involved email notification and more flexibility in the intervention.

Conclusions - The challenge of web-based alcohol treatment programs no longer seems to be their effectiveness but keeping participants involved until the end of the treatment program. Further research should investigate whether the suggested strategies to improve adherence decrease attrition rates in web-based interventions. If we can succeed in improving attrition rates, the success of web-based alcohol interventions will also improve and as a consequence its public health impact.

#### INTRODUCTION

Web-based interventions for problem drinkers improve the availability of alcohol treatment services and reach a more diverse segment of the population of problem drinkers (Humphreys & Klaw, 2001; Postel, de Jong, & de Haan, 2005). Evidence supports the clinical efficacy of a diversity of web-based interventions varying from pure self-help to predominantly therapist-administered therapy (Bewick, Trusler, Barkham et al., 2008; Bewick et al., 2010; Chiauzzi, Green, Lord, Thum, & Goldstein, 2005; Cunningham, Wild, Cordingley, van Mierlo, & Humphreys, 2009; Doumas & Hannah, 2008; Doumas, McKinley, & Book, 2009; Kypri et al., 2004; Moore, Soderquist, & Werch, 2005; Riper, Kramer, Smit et al., 2008; Saitz et al., 2007; Walters, Vader, & Harris, 2007), and it seems that the best results are achieved with interventions that use personalized feedback (Bewick, Trusler, Barkham et al., 2008). Despite these promising results, participants of web-based interventions show great variation in how they use the interventions in terms of frequency and duration of visits and they often fail to complete treatment sessions or assessments (Christensen, Griffiths, & Farrer, 2009; Eysenbach, 2005; Riper, Kramer, Smit et al., 2008). However, web-based intervention studies mainly focus on efficacy, and less is known about the reasons for non-completion and the specific components that improve adherence (Eysenbach, 2005). Although web-based interventions have the potential of easy data collection, the study of attrition is still rare. More insight into the attrition process can further improve the success of web-based alcohol interventions because more people will benefit from effectiveness if they complete the full treatment. We do not have quantitative data from our RCT study available to prove that noncompletion leads to lower efficacy rates. However, our qualitative data showed that completers achieved better effects than non-completers (Postel, de Haan, ter Huurne, Becker, & de Jong, 2010).

In his law of attrition, Eysenbach distinguished two processes of attrition: dropout attrition and non-usage attrition (Eysenbach, 2005). Dropout attrition refers to participants being lost to follow-up; they do not return to fill in follow-up questionnaires. Non-usage attrition refers to participants stop using the intervention, but still filling in questionnaires. Authors do not always describe dropout attrition and non-usage separately (Doumas & Hannah, 2008; Doumas et al., 2009; Finfgeld-Connett & Madsen, 2008; Saitz et al., 2007; Walters et al., 2007). And if they do, then there still is much variation possible within Eysenbach's conceptualisation, because of differences in treatment intervention and study design. Some studies for example only require filling out a single questionnaire on a shorter timeframe (Doumas et al., 2009; Saitz et al., 2007), while other studies require a wide range of questionnaires at a number of follow-up points (Cunningham et al., 2009; Riper, Kramer, Smit

et al., 2008). Therefore, comparing attrition rates alone does not make sense. A clear description of the study characteristics together with non-usage and follow-up attrition is necessary to interpret attrition data properly. Usage and follow-up completion rates of webbased alcohol interventions studies published to date range from 16.5% (Linke, Murray, Butler, & Wallace, 2007) to 92% (Cunningham et al., 2009). In face-to-face addiction treatment, overall around 50% of patients terminate treatment before the intended period is over (De Weert-Van Oene, Burger, Schrijvers, Grobbee, 2007). The great differences in attrition rates between web-based interventions can only partly be explained by the differences in definition, other factors play an important role as well. Such as payment of incentives, follow-up periods, intensity and duration of the web-based intervention, recruitment procedure, study population, and research environment (trial or open-access). It seems to be this combination of factors that is responsible for the attrition rate rather than a single factor (Bewick, Trusler, Mulhern, Barkham, & Hill, 2008; Bewick et al., 2010; Chiauzzi et al., 2005; Cunningham et al., 2009; Doumas & Hannah, 2008; Doumas et al., 2009; Kramer et al., 2009; Kypri et al., 2004; Linke et al., 2007; Postel et al., 2010; Riper et al., 2009; Riper, Kramer, Keuken et al., 2008; Riper, Kramer, Smit et al., 2008; Saitz et al., 2007; Walters et al., 2007). For example, Cunningham et al. (2009) found that 92% of participants completed baseline, 3 months, and 6 months follow-ups. This excellent follow-up completion rate might partly be explained by the incentive of a 20 dollar cheque for each follow-up survey, but also by the way participants were recruited. Respondents from an ongoing telephone survey, who confirmed that they had home internet access and were interested in a computerized program to check their drinking, were invited for the study and therefore only interested respondents were recruited. Doumas and colleagues (2009) also found a very good followup completion rate (88%) even without paying an incentive. However, their follow-up period was short with 30-days, and the motivation for completing the study might have been greater for their population of mandated college students. Attrition data have been mainly coming from trials. Compared to the drop-out and non-usage attrition rates in efficacy trials of web-based interventions, attrition rates in open access interventions are higher (Christensen et al., 2009). This might be due to the use of participant retention strategies in trials, and to the characteristics of trial participants (e.g. motivated participants). The study of Linke et al. (2007) with a follow-up and intervention completion rate of 16.5% involved a cohort study with 10.000 users of a free, web-based 6-week intervention. They used a very strict definition of attrition, as only registrants who completed the whole 6 weeks program and the final assessment were considered to be completers. In comparison, Cunningham et al. (2009) noted that despite their excellent 92% follow-up completion rate at 6 months, 35 of the 92 participants in the intervention condition (38%) never accessed the intervention. Riper and colleagues investigated their self-help intervention (Drinking Less) in a RCT and an openaccess sample. They reported a 54% follow-up completion rate for the 6-month follow-up in the RCT intervention group and 45% of the baseline participants actually made use of the intervention (Riper, Kramer, Smit et al., 2008). In their open-access sample, they found a follow-up completion rate of 40.5% but 12% of participants never using the program, 60% using it once or a few times, and 28% using the intervention more than a few times (Riper et al., 2009). The study examples above illustrate that providing access to an intervention does not guarantee that participants use it.

The high percentages of non-usage attrition lead to the question whether web-based alcohol treatment might work more effectively for some people than for others. Exploring the variables that make individuals more vulnerable for not completing treatment may help us to identify target groups and develop strategies to address the attrition problem. We examined three types of variables that were associated with non-usage or drop-out attrition: sociodemographic variables, drinking behaviour, and psychological variables. Those factors have been investigated in several online alcohol intervention studies, but most studies found no differences in baseline variables between completers and non-completers (Cunningham et al., 2009; Doumas & Hannah, 2008; Doumas et al., 2009; Finfgeld-Connett & Madsen, 2008; Kramer et al., 2009; Kypri et al., 2004; Riper, Kramer, Smit et al., 2008; Walters et al., 2007). However, other studies found support for baseline differences. Socio-demographic variables found to be positively associated with intervention or follow-up completion were being female (Bewick et al., 2010; Linke et al., 2007), married or living with a partner (Linke et al., 2007; Riper et al., 2009), and without children (Linke et al., 2007). Riper (2009) also found that non-completers were more likely to be above the median age of 47 (Riper et al., 2009). Chiauzzi et al. (2005) found that study site (2 out of 5 universities) was a predictor of noncompletion. Regarding baseline drinking-behaviour variables, completers showed less risk of alcohol dependency and harm from alcohol (Linke et al., 2007), and consumed less units a week and per occasion (Bewick, Trusler, Mulhern et al., 2008). Additionally, psychological predictor variables were found in two studies. Chiauzzi et al. (2005) found baseline stage of readiness for change (contemplation) to be a predictor of non-completion, and Postel et al. (2010) found that completers had a higher baseline score on treatment readiness. It could be suggested that the results concerning the differences between completers and noncompleters are frequently ambiguous and are often only found in a single study. This might be the result of the differences in target groups and intervention characteristics. In line with this, Murray and colleagues emphasized that it is important to adjust boosting strategies to the particular target population of the web-based intervention. Whereas studies of online weight loss programs for example have successfully boosted follow-up rates by using postal and telephone reminders for participants who did not respond to email reminders, Murray et al. (Murray et al., 2009) only received 3% additional responses from their population of

hazardous drinkers after an extensive additional follow-up using postal reminders and phone calls.

None of the web-based alcohol intervention studies formally examined the reasons for noncompletion, except our recently conducted RCT (Postel et al., 2010). This RCT of a Dutch webbased treatment program (http://www.alcoholdebaas.nl) has been shown to be effective for problem drinkers in reducing their alcohol consumption and improving health status, yielding a large effect size at post treatment (Postel et al., 2010). The attrition rate in our web-based treatment group (n=42) was high at 54%. As we used a linear model for the treatment program with technically integrated assessment points, dropout attrition and non-usage attrition were the same. Therefore, attrition was defined as not completing all 12 sessions of the web-based intervention: 9 assignments and 3 assessments. We investigated reasons for non-completion by sending an online questionnaire to all non-completers. As described previously (Postel et al., 2010), the results showed that the main reasons for non-completion in the web-based treatment group were personal reasons unrelated to the web-based treatment program, discomfort with the treatment protocol, and satisfaction with the positive results achieved to date. However, at that time only a limited part of our data was available. We now also have data from the delayed intervention group, and thus a larger dataset that allows performing prediction analyses and qualitative data analysis.

The first aim of this study is to examine attrition prevalence and pre-treatment predictors of attrition in a cohort of open-access users of the web-based treatment program. The second aim is to further explore attrition data from our RCT. We will investigate the prevalence of attrition, the reasons for non-completion, pre-treatment predictors of attrition, and participants' suggestions how to enhance treatment completion. Accordingly, the present study allows us to compare the attrition data of both samples: a trial and an open-access group of users.

#### **METHODS**

#### Study design and participants

The 'real-world' sample consisted of all open-access users of the web-based alcohol treatment program in 2009 (n= 885). The only inclusion criterion for open-access users was a minimum age of 18. All data entered by participants were stored in the web-based application. We could identify who accessed the web-based treatment program and who did not, the duration of treatment completers, and the number of completed sessions in case of

non-completion. Participants who dropped out were not assessed about their situation at that time; because of the feasibility nature of the open-access study it was not possible to send questionnaires to non-responders through the application.

We conducted secondary analyses of our randomized controlled trial; an open trial with participants randomly assigned to either the web-based treatment group or to the waiting list control group (Postel et al., 2010). The study protocol was approved by the independent medical ethics board METIGG (ref. no. NL20742.097.07) and registered at www.controlled-trials.com (ISRCTN39104853). In brief, we recruited Dutch-speaking problem drinkers in the general population aged 18+. Problem drinking was defined as drinking currently at least 15 units (of 10 grams of ethanol) a week for females and 22 units a week for males. We excluded participants treated for problem drinking in the preceding year and participants with psychiatric treatment in the past six months or those currently with a psychiatric disorder. 156 problem drinkers were screened and found to be eligible for the study and they were randomly assigned to either the web-based treatment group or to the waiting list control group. As the control group received the intervention immediately after treatment completion of the experimental group, we decided to merge the data from both groups for the present study. Participants received the e-therapy intervention free of charge. We did not provide any kind of incentive for study participation.

#### Intervention

The web-based alcohol treatment consisted of a structured two-part online treatment program in which the participant and the therapist communicated asynchronously, via the Internet only. The method underlying the program was based on the principles of cognitive behaviour therapy (Hester, Miller, & Goldman, 1996) and motivational interviewing (Miller & Rollnick, 2002). Part 1 of the program consisted of two assessments and four assignments and focused on the analysis of the participants' drinking habits. Part 2 focused on behavioural change and included five assignments and one final assessment. The average duration of the total treatment program was 3 months, with one or two therapist contacts per week and daily self reporting of alcohol intake during the whole program. The 12 treatment sessions were identical for RCT and open-access users, except for the 3 assessments being more extensive for RCT participants.

Participants' pre-treatment characteristics were derived from the baseline self-report questionnaire, for RCT as well as for open-access participants. Weekly alcohol consumption was assessed by a 7-day retrospective drinking diary, including a question about atypical drinking (Sobell & Sobell, 2000). Type and severity of substance dependence were assessed by the Substance Abuse Module of the Composite International Diagnostic Interview (CIDI-SAM) (Compton, Cottler, Dorsey, Spitznagel, & Mager, 1996). The General Health Questionnaire (GHQ-28) and the Maudsley Addiction Profile Health Symptom Scale (MAP-HSS) were used to assess health status (Marsden et al., 1998; Vallejo, Jordán, Díaz, Comeche, & Ortega, 2007). The 21-item Depression Anxiety Stress Scale (DASS-21) was used to measure the three related negative emotional states of depression, anxiety and stress (Antony, Bieling, Cox, Enns, & Swinson, 1998). To measure the quality of life, the EuroQol-5D was used (Lamers, Stalmeier, McDonnell, Krabbe, & Busschbach, 2005). Initial treatment motivation was measured with the TCU Motivation for Treatment scale (De Weert-Van Oene, Schippers, De Jong, & Schrijvers, 2002), and participants' readiness to change their drinking behaviour with the Dutch version of the Readiness to Change Questionnaire (RCQ-D) (Defuentes-Merillas, Dejong, & Schippers, 2002). For open-access participants the questionnaires were less extensive, as the GHQ-28 and MAP-HSS were left out.

The outcome measure of the logistic regression analysis was completion of the web-based alcohol treatment; this was defined as completion of all 12 treatment sessions: 9 assignments and 3 assessments. Because of the design of the treatment program it was impossible for participants to skip parts of the intervention; therefore the point at which they stop using the program indicates exactly how much treatment participants received.

In order to gain insight into the motives of participants to stop using the web-based treatment program, non-completers in the RCT group received an email with a link to an additional online questionnaire consisting mainly of open questions concerning their perception of the program, reasons for discontinuation and suggestions to improve the intervention and enhance treatment completion. If participants did not complete this questionnaire, they were contacted by telephone to remind them to complete the questionnaire either online or alternatively by phone.

#### Statistical analysis

Chi-square and t-tests were used to assess whether there were baseline differences between completers and non-completers. Multivariate logistic regression analysis was performed with

treatment completion as the dependent variable. Predictor variables with a p-value less than o.10 in the univariate analyses were entered in a full multivariate model. Subsequently, nonsignificant variables were removed, one by one, until -2 log likelihood deteriorated significantly. Goodness of fit of the model was determined by the Hosmer and Lemeshow test and the Nagelkerke R<sup>2</sup> was used for the pseudo proportion of variance. Three regression analyses were performed: (1) RCT sample, (2) open-access sample including treatment readiness variable, (3) open-access sample without treatment readiness variable. Because treatment readiness was measured after part 1 in the open-access sample, we have a lot of missing data for this variable (n=355). We therefore performed two regression analyses for the open-access sample, one including treatment readiness (and as a consequence only the non-completers from part 2) and one without this variable (all non-completers). The predictor variables for the RCT sample were age, gender, work, education level, baseline alcohol consumption, prior alcohol treatment, prior mental health treatment, readiness to change contemplation and action score, DASS-21 total score, and the Motivation for Treatment (MfT) questionnaire scores desire for help and treatment readiness. For the openaccess sample, the DASS-21 scores were not available and therefore left out of the regression analysis. All statistical tests were 2-sided, with a p value ≤ 0.05 considered to be significant, and performed using SPSS for Windows (release 17.0).

Reasons for attrition were independently assessed by the first and third author. The agreement level between both authors was 87%, which was considered acceptable. If the two authors did not agree, the topic was discussed in order to reach agreement. Participants' responses to open questions were analyzed using thematic analysis. The first author carefully searched through the data to identify and code all features concerning participants' reasons for non-completion. After collating relevant data to each code, related patterns were combined into themes. After refining and defining the themes, a brief description of each theme was formulated related to the research questions of the study.

#### RESULTS

#### Participant characteristics

Of the 885 registrants for the open-access version in 2009, 105 never started using the web-based alcohol treatment program of making the first assignment, sending a message to their therapist or logging into the daily alcohol diary. Of the 780 participants who started the open-access version, 54% were women, 50% had a higher education level, 69% were employed and age ranged from 20 to 78, with an average of 45.7 years (Table 1). Six hundred and eighty

four participants reported alcohol dependence (88%), but many (n=554, 71%) had never received professional help for their drinking problem. The mean weekly alcohol consumption was 42.7 standard units a week: 49.1 for men and 37.3 for women.

Table 1. Baseline characteristics

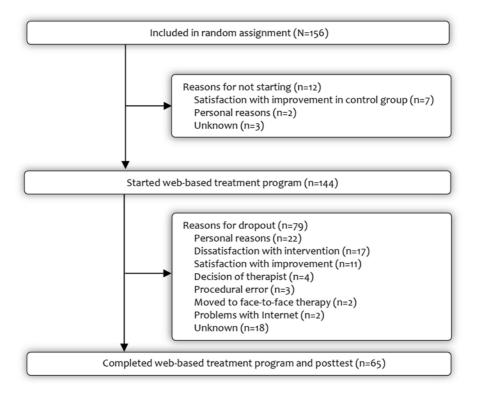
Variable		RCT particip	oants (N=144)	Open-access participants (N=780)		
		N	%	N	%	
Female		83	57.6	421	54.0	
Higher education		84	58.3	387	49.6	
Employed		117	81.3	538	69.0	
DSM-IV a dia	DSM-IV <sup>a</sup> diagnoses					
Alcohol dependence		120	83.3	684	87.7	
Alcohol abuse		14	9.7	42	5.4	
No dependence or abuse		10	6.9	54	6.9	
Prior alcohol treatment		22	15.3	226	29.0	
Prior treatment mental health problems		72	50.0	455	58.3	
Problem dri	Problem drinking <sup>b</sup>		100	689	88.3	
		Mean	SD	Mean	SD	
Age		45.8	9.7	45.7	10.8	
Weekly alco	Weekly alcohol consumption					
Males	Males		26.9	49.1	30.1	
Females		32.6	14.6	37.3	22.9	
GHQ-28 sco	GHQ-28 score <sup>c</sup>		11.9	-	-	
MAP-HSS so	core <sup>d</sup>	19.8	6.2	-	-	
DASS-21 e	Depression score	8.7	8.4	-	-	
	Anxiety score	5.9	5.9	-	-	
	Stress score	12.5	8.2	-	-	
RCQ <sup>f</sup>	Precontemplation	12.1	1.3	12.3	1.6	
	Contemplation	17.1	2.1	17.1	2.3	
	Action	12.4	3.5	13.3	3.3	
MFT <sup>g</sup>	Treatment Readiness	4.0	0.5	4.1	0.4	
	Desire for Help	3.9	0.7	3.9	0.6	

<sup>&</sup>lt;sup>a</sup> Diagnostic and Statistical Manual of Mental Disorders, 4th revision; <sup>b</sup> Drinking >21 (male) or >14 (female) units mean per week; <sup>c</sup> General Health Questionnaire; <sup>d</sup> Maudsley Addiction Profile, Health Symptom Scale; <sup>e</sup> Depression Anxiety Stress Scale; <sup>f</sup> Readiness to Change Questionnaire; <sup>g</sup> TCU Motivation for Treatment scale

Figure 1 shows the participant flow of the total RCT sample (n=144) along with reasons for not starting (n=12). Pre-treatment characteristics of the 144 RCT participants who started the web-based treatment program are presented in Table 1. Of these participants, 58% were women, 58% had a higher education level, and 81% were employed. Ages ranged from 22 to 66, with an average of 45.8 years. One-hundred and twenty participants reported dependence (83%). The majority (n=122, 85%) had never received professional help for their drinking problem. The mean weekly alcohol consumption was 39.9 standard units a week: 49.8 for men and 32.6 for women.

Chi-square analysis indicated that there was a significant difference between the RCT and open-access group on the number of problem drinkers; the open-access group involved more problem drinkers than the RCT group (100% versus 88.3%,  $X^2 = 18.64$ , P < .001).

Figure 1. RCT participants flow

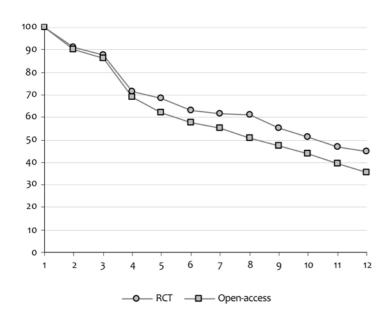


#### Attrition pattern

Of the 780 open-access participants, 65% were non-completers. Treatment completers (n=273, 35%) completed all 12 treatment sessions and non-completers (n=507, 65%) an average of 4.8 (SD=3.1) sessions. Of the 144 RCT participants, 55% were non-completers. Treatment completers (n=65, 45%) completed all 12 treatment sessions and non-completers (n=79, 55%) an average of 4.8 (SD=3.1) sessions. The open-access and RCT group differed significantly in the percentage of treatment completers ( $X^2 = 5.39$ ; Y = 0.02). Participants in the RCT sample were 1.29 (95% CI 1.05 – 1.58) times more likely to complete treatment.

Participants completed the sessions in the order that they were presented. The average duration of treatment completion was 16.1 weeks in the RCT sample and 17.1 weeks in the open-access sample. Figure 2 shows the attrition curves of both groups. Participants dropped out during all stages of treatment. However, the biggest loss was found after the third session possibly as a result of the daily drinking diary. In this session, participants were asked to register daily amounts of alcohol consumption for the whole treatment duration.

Figure 2. Attrition curve: Proportion participants by number of assignments



#### Predictors of treatment completion

We found only one significant difference between completers and non-completers in the RCT sample. The mean score on the TR (Treatment Readiness) subscale of the MfT was higher for completers (M=4.13) than for non-completers (M=3.97), t = -2.00, P = .047. There were no other significant differences between both groups on any of the variables presented in Table 1. Logistic regression analysis revealed a statistical significant contribution of treatment readiness score. The regression equation showed a negative predicted value of 70% and a positive predictive value of 53%, with a cut-off probability of the model of 0.4. The Nagelkerke  $R^2$  was .04, and the regression model showed sufficient goodness of fit ( $X^2 = 10.74$ ; P = .22). The area under the ROC curve revealed a model discrimination value of 0.60 (95% CI 0.51–0.70). The odds ratio indicated that if the treatment readiness score increases by one point (range 1-5), the odds of completion increases with 2.1. A score of 3 gives a chance of 27% on completion, a score of 4 a change of 44% and a score of 5 a 63% chance on treatment completion.

We found seven significant differences between completers and non-completers in the open-access sample: age, gender, education level, baseline alcohol consumption, prior mental health treatment, treatment readiness, and readiness to change action score. The differences are shown in Table 2. Multivariate logistic regression analysis with treatment readiness included (n=425), revealed a statistically significant independent contribution of age, baseline alcohol consumption, and treatment readiness. Predicted probabilities of the model of x, y, and z, respectively, led to a specificity of 89% with a sensitivity of 25%, a specificity of 84% with a sensitivity of 33%, and a specificity of 78% with a sensitivity of 40%, respectively. The Nagelkerke  $R^2$  was .09, and the regression model showed sufficient goodness of fit ( $X^2 = 11.70$ ; P = .17). The area under the ROC curve revealed a discrimination of the model of 0.64 (95% CI 0.59–0.70). When the treatment readiness score increases by one point (range 1-5), the odds of completion increases 2.1-fold. If age increases with five years, the odds of completion increases 1.12-fold, and if baseline alcohol consumption increases with ten standard units a week, the odds of completion decreased 0.87-fold.

Multivariate logistic regression analysis without treatment readiness (n=780) revealed a statistical significant contribution of age, gender, education level, baseline alcohol consumption, and readiness to change action score. Predicted probabilities of the model of x, y, and z, respectively, led to a specificity of 85% with a sensitivity of 25%, a specificity of 80% with a sensitivity of 35%, and a specificity of 75% with a sensitivity of 43%, respectively. The Nagelkerke  $R^2$  was .10, and the regression model showed sufficient goodness of fit ( $X^2 = 7.09$ ;

P = .53). The area under the ROC curve revealed a discrimination of the model of 0.63 (95% CI 0.59–0.67). The odds of treatment completion is 1.70-fold increased for females compared to males, and 1.79-fold increased for higher educated people compared to lower educated people. The odds ratios further indicated that if age increases with five years, the odds of completion increases 1.13-fold, and if baseline alcohol consumption increases with ten standard units, the odds of completion decreases 0.93-fold. If the readiness to change action score increases by one point (range 4-20), the odds of completion increases 2.1-fold.

Table 2. Differences open-access completers and non-completers

Variable	Comp (N=:		Non-completers (n=507)		Test result		
	N	%	N	%	X <sup>2</sup>	df	Р
Female	170	62.3	251	48.5	11.64	1	<.001
Higher education	163	59.7	224	44.2	17.11	1	<.001
Prior mental health treatment	175	64.1	280	55.2	5.75	1	.02
	Mean	SD	Mean	SD	t	df	Р
Age	47.8	10.4	44.5	10.9	-4.14	1,778	<.001
Baseline alcohol consumption <sup>a</sup>	37.4	24.0	45.6	28.2	4.05	1,778	<.001
MFT <sup>b</sup> Treatment Readiness	4.1	0.4	4.0	0.4	-3.30	1,423	.001
RCQ <sup>c</sup> Action Score	13.8	3.3	13.0	3.3	-3.43	1,778	<.001

<sup>&</sup>lt;sup>a</sup> Mean units per week; <sup>b</sup> TCU Motivation for Treatment scale; <sup>c</sup> Readiness to Change Questionnaire

#### Early versus late non-completers

We divided non-completers into early and late non-completers to determine whether the two groups differed. Non-completers who completed a maximum of 3 assignments belong to the early non-completers and those who completed at least 4 assignments to the late non-completers. We found no differences in the RCT sample (n = 144). However, in the open-access sample (n=780) we found that non-completers who completed at least four assignments more often had a high level of education than those who completed fewer assignments (58% vs. 47%,  $X^2 = 6.12$ ; P = .013), more often received prior mental health treatment (59% vs. 43%,  $X^2 = 12.02$ ; P < .001), and had a lower baseline alcohol consumption (43.2 vs. 48.3 standard units a week, t(1, 501) = 2.01, P = .045).

#### **Reasons for non-completion**

Figure 1 shows the reasons for non-completion (n=79). Self-reported reasons for non-completion were only collected in the RCT sample, and could be obtained from 61 of 79 participants (77%). We were not able to contact 18 participants because of non-response or an invalid phone number. The most common reason for non-completion consisted of personal reasons unrelated to the web-based intervention (n=22), followed by dissatisfaction with the intervention (n=17), and satisfaction with the improvement in their condition (n=11). On four occasions the therapist decided to terminate the treatment, because of insufficient response or information (n=3) or due to an inability to set a realistic drinking goal (n=1). Unfortunately, in three cases we got procedural problems during the trial, and those participants could not continue. Additionally, two participants moved on to face-to-face treatment and two participants experienced problems with the Internet during treatment participation.

Personal reasons: A diversity of personal reasons was given as reason for non-completion (n=22), including being too busy with work, a seriously ill family member or bereavement, other priorities, a hospitalization, no Internet access, or moving house.

Dissatisfaction with intervention: Participants who identified the web-based alcohol intervention itself as a reason for discontinuation (n=17), most commonly indicated that the program was too time-consuming or too demanding. Some participants reported that the program could not meet their personal needs.

Improvement in condition: Several participants reported that they no longer felt the need to continue the program, because of the progress they made (n=11). They gained from the intervention what they needed and felt in control of their drinking behaviour.

Other reasons: For two participants the web-based treatment program only was the first step in working on behavioural change, and they continued treatment in a face-to-face setting. Of the persons whose formal reason for dropout is unknown (n=18), the messages in their personal records provide some information. Participants mentioned several times that working on their alcohol problem was quite confronting, and overwhelmed them too much. More or less lack of motivation was also reported by a number of participants.

#### Suggestions to enhance treatment completion

Several RCT participants gave suggestions as how to improve the web-based treatment program. One of the suggestions was sending an email message to participants to notify them that they had received a new message or assignment from their therapist. This it was felt would act as a reminder and prevent unnecessary logging into the application. Another suggestion was to allow more flexibility in the treatment protocol, with the possibility of skipping sessions when required. For example, the possibility to start immediately with the goal setting assignment or no longer mandating daily registration. In its current form it was not possible to move on to the next assignment without completion of the previous one. Some participants also mentioned the need for additional contact: the choice to contact their therapist by phone or face-to-face and the chance to get in touch with fellow sufferers, with the suggestion to link each participant to his own buddy. A number of participants reported suggestions for improving the usability of the web-based treatment program, including the speed of the intervention, lay-out characteristics and button functions.

#### DISCUSSION

#### Main findings

The aim of this study was to explore the attrition data of an open-access and a RCT sample of a web-based treatment program for problem drinkers. The study demonstrated high prevalence of attrition in both samples, with 10% less treatment completers in the open-access sample. Participants' readiness for treatment, gender, education level, age, baseline alcohol consumption and readiness to change score were shown to predict treatment completion. The key reasons for non-completion were personal reasons, dissatisfaction with the intervention, and satisfaction with improvement. The main suggestions for boosting strategies involved email notification and more flexibility in the intervention.

#### Attrition

Attrition prevalence was high in both samples. Although our attrition rates of 65% in the open-access sample and 55% in the RCT sample are in line with those found in a number of web-based alcohol intervention studies (Bewick et al., 2010; Riper et al., 2009; Riper, Kramer, Smit et al., 2008), the majority of alcohol intervention studies found lower attrition rates (Chiauzzi et al., 2005; Cunningham et al., 2009; Doumas & Hannah, 2008; Doumas et al., 2009; Finfgeld-Connett & Madsen, 2008; Kramer et al., 2009; Kypri et al., 2004; Saitz et al., 2007;

Walters et al., 2007). However, comparing attrition rates alone does not make sense. A clear description of the study characteristics together with non-usage and follow-up attrition is necessary to interpret attrition data properly. Our attrition rates need to be seen in the light of a very strict definition of treatment completion including assessment completion, active usage of the intervention, a high intensity of the treatment program, and paying no incentive to participants. In comparison, Linke et al used a similar definition of attrition in their cohort sample and they found a completion rate of 16.5% (Linke et al., 2007). The variety of nonusage and drop-out attrition rates in web-based alcohol interventions is relatively similar to those found in web-based treatments for psychological disorders ranging from 2% to 83% (Melville, Casey, & Kavanagh, 2010). A higher number of non-completers in our open-access sample is consistent with earlier findings (Christensen et al., 2009). The fact that RCT participants were 1.5 times more likely to complete treatment might be the result of a selection bias, because of the pre-screening of trial participants and the exclusion criteria. It leads to the suggestion that it might be wise to always link some kind of research to a webbased intervention and to emphasize the importance of it at the start. Realizing that you cooperate in a research project, for example to improve the intervention, can perhaps be inspiring. We acknowledge that it is important to find a good balance between what is needed for attrition purposes and what is considered to be ethically appropriate. Finding the right 'tone' seems to be important. Further research needs to investigate whether this strategy will be effective in reducing the number of dropouts, and whether this works for participants and for therapists. What is the impact of this for participants? Do therapists' change the treatment or the communication with participants if they know that the data will be used for research purposes? Are therapists extra motivated or having an increased adherence to the treatment protocol?

In both study samples, the pattern of non-usage attrition was steady throughout the intervention period. This means that both groups showed the same trend of attrition; at each treatment session participants dropped out. The number of drop-outs gradually decreased, regardless of whether participants participated in the RCT or the open-access intervention. Although the gradually decrease is in contrast with the suggestion of Eysenbach (2005) that in the final stage of an intervention a hardcore group of users remain who will continue using the intervention, it is identical with the attrition pattern found by Neve and colleagues (Neve, Collins, & Morgan, 2010) in their 12-weeks web-based weight loss program.

The differences we found between early and late non-completers prove that non-completers who completed at least 4 assignments show more similarity with treatment completers than those who completed fewer assignments.

The only statistical significant predictor of treatment completion in the RCT sample was a higher treatment readiness score, measured with the Treatment Readiness subscale of the TCU MfT questionnaire. In the open-access sample higher treatment readiness also was a significant predictor, as well as higher age and lower baseline alcohol consumption when the treatment readiness variable was included (n=425). In the open-access sample without the treatment readiness variable (n=780) the statistical significant predictors were higher age, female gender, higher education level, lower baseline alcohol consumption, and higher readiness to change action score. Other factors were found to have no predictive value.

Based on our different findings in the three sub samples and in line with an analysis of literature from Melville and colleagues (Melville et al., 2010), we have to conclude that the current evidence found for predictors of attrition is ambiguous. Two other web-based alcohol intervention studies previously identified the fact that completers consumed less alcohol at baseline (Bewick, Trusler, Mulhern et al., 2008; Riper et al., 2009). Earlier findings of Bewick (2010) and Lange (Lange et al., 2003) also found that more males than females were non-completers, although Riper (Riper et al., 2009) did not find a significant association between gender and dropout. Male gender was also found to be associated with noncompliance in face-to-face addiction treatment (De Weert-Van Oene et al., 2007). A higher education level as predictor of treatment completion was not confirmed by three studies that explored the influence of education level on dropout from web-based interventions; they did not find a significant association (Lange et al., 2003; Riper et al., 2009; Ström, Pettersson, & Andersson, 2004). However, the association between compliance and higher education level was confirmed in face-to-face addiction treatment (De Weert-Van Oene et al., 2007). With regard to age, previous evidence was contrary to our findings. Riper et al (2009) found that non-completers were more likely to be above the median age of 47, whereas we found that non-completers were younger compared to completers. Previous web-based intervention studies could also not confirm the differences in treatment readiness between completers and non-completers and found no predictive value for readiness to change (Bewick et al., 2010). But, lower intention to comply with treatment and weaker initial treatment motivation were found to be associated with non-compliance in face-to-face addiction treatment (De Weert-Van Oene et al., 2007). Overall, the findings raise the question how useful this kind of prediction research is. Because of the considerable variation in findings, we would on the one hand suggest that further research is needed to confirm whether the same predictors exist in different web-based alcohol interventions but on the other hand we would also suggest not focussing too much on baseline predictors of online treatment completion. It might be more effective to focus on the therapist side and the effects of boosting strategies in online interventions. The clinical implications of this study

can therefore only be given with caution. It would be interesting to investigate whether increasing treatment readiness and readiness to change immediately from the start of treatment will decrease the number of non-completers. Additionally it might be interesting to find out if it matters how fast participants reduce their alcohol consumption or become abstinent after the start of the treatment program. Another question could be whether the pace at which participants experience a positive relationship with their therapist also has effect on treatment completion.

#### Reasons for non-completion

In addition to the quantitative data of the RCT and open-access sample, the qualitative data gained more insight into the reasons for non-completion and the possibilities to reduce potential loss. As discussed before (Postel et al., 2010), most reasons for non-completion are in line with the potential factors for attrition as described in the law of attrition by Eysenbach (2005), except for improvement in condition. Some participants significantly improved after just a small number of treatment sessions and they were convinced that no additional sessions were needed. This confirms Christensen's statement that low usage and dropout do not necessarily coincide with failure (Christensen & Mackinnon, 2006). Participants who fail to complete follow-up assessments may still derive much benefit from the web-based intervention. Continuous and frequent measurement, like diary surveys, can provide the necessary data (Couper, 2005). Although a disadvantage of diary surveys is that the respondents themselves are responsible for completion, a web-based intervention has the potential to easily prompt users by automatically sending reminders, motivational messages, or incentives. We also suggest investing in easy referral from web-based treatment to faceto-face treatment with the possibility of integrated treatment (web-based and face-to-face). Participants as well as their therapists expressed interest in this kind of integrated care. Professionals at the International Network of Brief Interventions for Alcohol Problems Conference also expressed interest in this (Cunningham, Khadjesari, Bewick, & Riper, 2010).

#### **Boosting strategies**

Boosting strategies are desirable to maximize the number of treatment completers in trial settings as well as in open-access interventions. Participants themselves suggested sending email reminders as an additional supportive resource. The use of push reminders, like phone calls, postcards and email messages, previously has shown improved completion rates (Brouwer et al., 2011; Clarke et al., 2005). Although participants already received therapists' messages in the web-based application, they preferred receiving reminders in their private

email account in order to be constantly kept reminded of their participation and to prevent unnecessary logging into the application. Participants also suggested more flexibility in the web-based treatment program. The most frequently mentioned fact was that daily alcohol registration was annoying to participants. This might be the explanation for the more pronounced loss of participants (16-17%) after the third session, as this assignment requested starting with daily alcohol registration. Another suggestion was to better adapt the pace of the treatment to the needs of the individual participant and not being too rigid in terms of the fixed treatment duration. Interestingly, none of the participants suggested incentives as a useful boosting strategy possibly because they thought this was embarrassing to suggest. Contingency management interventions have been shown to increase desired behaviour by offering valuable reinforces contingent on behavioural change (Petry, Martin, Cooney, & Kranzler, 2000). It would be an interesting direction for future research to apply the contingency management principles in internet interventions and investigate the effectiveness.

#### Methodological considerations

This study has several limitations that are important to acknowledge. Due to the technical structure of our intervention, non-completion included not just stopping using the intervention but also not receiving post-test and follow-up assessments anymore. As a consequence, we forced ourselves to use very strict criteria of attrition compared to other web-based intervention studies, and we unfortunately never obtained a lot of data from non-completers. This is definitely not desirable and needs to be changed in future studies. Additionally, we decided not to use push-factors in our randomized controlled trial to keep the trial setting as natural as possible. It is possible that if we had used push-factors we could have raised the response rate to generate a more complete dataset.

Another limitation is that only baseline characteristics were considered as potential predictors of treatment completion. It is possible that other factors like "forum use" or therapeutic relationship also influenced attrition rate. However, we aimed to determine at baseline which participants would complete the whole treatment program. We were also limited to the baseline characteristics we measured and therefore not able to include some of the variables previously found to have predictive value.

The difference in number of problem drinkers in the open-access and RCT group might have biased the prediction analysis. Because of our inclusion criteria in the RCT this group

comprised only problem drinkers, while the open-access group also involved a small group (12%) of non-problem drinkers.

Both study samples consisted largely of adults in the mid 40s. This can partly be explained because our samples consisted of problem drinkers from the general public. And although we previously found that the average age of face-to-face clients was slightly lower, face-to-face clients also have a mean age of around 43 years (Postel et al., 2005; Postel, de Haan, ter Huurne, Becker, & de Jong, *in press*). It often takes a long time before people experience excessive alcohol consumption as a problem. The physical and psychological damage will only be felt over time. People in the mid 40s often take responsibility for their own health and are looking for a healthier lifestyle, including drinking less. Web-based treatment is a pleasant option for them, because of the privacy and easily access to online help. Although they are an important target group for our intervention, it remains a challenge to reach younger and older problem drinkers via the Internet as well. Future research should focus on how these groups can be reached.

#### **Future directions and implications**

Nowadays, the challenge of web-based alcohol treatment programs no longer seems to be their effectiveness but keeping participants involved until the end of the treatment program. Our study provided some points that therapists might focus on, including helping participants to be ready for treatment and for change. We should also investigate the effect of starting immediately with reduction of alcohol consumption. Boosting strategies like email notification and more flexibility in the intervention might also help to improve adherence. Further research should investigate whether those changes lead to decreased attrition rates in web-based interventions. If we can succeed in improving attrition rates, the success of web-based alcohol interventions will further improve and as a consequence its public health impact.

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# CHAPTER 8 Summary and General Discussion

#### INTRODUCTION

The main aim of this thesis was to assess whether the web-based treatment program for problem drinking <a href="www.alcoholdebaas.nl">www.alcoholdebaas.nl</a> was effective in terms of reducing alcohol consumption and improving health status. We examined the target population of the web-based treatment program, its feasibility and clinical effectiveness. We also systematically investigated the reasons for dropout, and explored the association between participants' baseline characteristics and attrition.

This final chapter starts with a brief description of the web-based treatment intervention and a number of e-health related definitions, then the major findings are summarised, discussed and compared with the current state of the art in web-based therapy for problem drinking. Finally, study limitations, clinical implications and suggestions for future research are discussed.

#### Web-based treatment program Alcoholdebaas.nl

The Dutch web-based treatment program could be accessed via the homepage <a href="www.alcoholdebaas.nl">www.alcoholdebaas.nl</a> and consisted of a structured 2-part treatment program in which the participant and the therapist communicated asynchronously, via the internet only. The aim of the web-based treatment program was to reduce or stop the participants' alcohol intake, and the method underlying the program was based on principles of cognitive behaviour therapy and motivational interviewing (Hester, Miller, & Goldman, 2003; Miller & Rollnick, 2002). All communication between therapists and participants took place through a secure web-based application. Part 1 of the program focused on the analysis of the participants' drinking habits, and covered the advantages and disadvantages of alcohol use, daily drinking behaviour, description of craving moments, and identifying risky situations. Part 2 focused on behavioural change, including goal setting, helpful and non-helpful thoughts, helpful behaviours, decision moments, and making an action plan for relapse prevention. The duration of the total web-based treatment program was about 3 months with one or two therapist contacts per week and daily self registration during the whole program.

#### Definitions

E-health refers to broad scope of healthcare practices supported by all kinds of information and communication technology: 'E-health is an emerging field in the intersection of medical

informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology' (Eysenbach, 2001). A wide variety of web-based interventions is available which differ in terms of the intensity of the therapist involvement. Pure self-help consists of primarily written materials that are completed by the participant independently; there is no therapist involvement. In predominately self-help the therapist involvement is very minimal and mostly limited to providing the self-help materials or explaining the self-help tool. Minimal-contact therapy consists of active involvement of a therapist, but to a lesser degree than traditional therapy, for example using e-mail. Finally, predominantly therapist-administered therapy involves regular contact with a professional therapist for a number of sessions, but in conjunction with self-help materials (Andersson, Bergstrom, Carlbring, & Lindefors, 2005). In the context of Andersson's distinction, Alcoholdebaas.nl belongs to predominantly therapistadministered therapy with weekly contact with a personal therapist for a period of 3 months, in conjunction with psycho education, daily registration and homework assignments. However, we initially chose to use the term e-therapy for this concept, but during the research period we changed it into web-based treatment as this latter term best fitted the international terminology. The first 4 articles of this thesis therefore used the term e-therapy and from then the term web-based treatment was used.

#### **KEY FINDINGS**

#### Methodological quality of RCTs

Because of the seemingly infinite supply of internet-based interventions available on the World Wide Web, we decided to systematically assess the methodological quality of randomized controlled trials (RCTs) concerning web-based treatment for mental-health problems of which our literature search yielded 14 papers (Chapter 2) (Postel, de Haan, & de Jong, 2008). Two reviewers independently assessed these studies, based on a list of criteria for the methodological quality assessment as recommended by the Cochrane Back Review Group but adapted to web-based treatment interventions. Only five studies showed high methodological quality; the other nine studies showed some degree of methodological limitation. Compared to systematic reviews in other fields, the quality of web-based treatment studies was low. We therefore concluded that although web-based treatment interventions seemed to be promising, we should be careful with the interpretation of

results. The shortcomings were partly due to incomplete descriptions of the studies, but there were also some more substantive reasons. We therefore recommended using the revised CONSORT statement to increase the quality of RCT reports and to improve the interpretation of trials. In particular compliance needs to be defined in measurable terms at the start of a study and treatment credibility should be evaluated when participants are not blind to the treatment intervention. Furthermore, we suggested providing insight into the use of co-interventions and medication during the study.

The literature search for this review study was conducted in early 2007. In the past four years, many studies have been added in the area of e-mental health. Recently, a review of reviews on the impact and costs of the broad range of web-based health interventions was conducted (Ekeland, Bowes, & Flottorp, 2010). Although four years later, their overall conclusion was consistent with our conclusion at the time of our review study, namely that high quality studies are still lacking. Ekeland and colleagues concluded that there is a need for large studies with rigorous designs to get better evidence on the effectiveness of web-based health interventions, with especially attention to economic evaluations, participants' perspectives, formative assessments, the complex developmental process of telemedicine, as well as its effectiveness.

During the developmental and reporting stage of our RCT (Chapter 5), we were aware that it was hard to get positive scores on all the quality criteria. We tried, but unfortunately did not succeed in meeting every criterion: our drop-out rate was above 20%, and despite randomisation we found a significant difference on prior alcohol treatment; the experimental group had received more alcohol addiction treatment than the control group. We also did not evaluate treatment credibility, what we should have done because participants and care providers were not blind to the intervention.

#### Reaching new populations of problem drinkers

In order to determine whether the web-based treatment program reached a new population of problem drinkers, we compared the baseline characteristics of 172 web-based treatment participants with a consecutive series of 172 face-to-face participants admitted for treatment as usual (Chapter 3.1) (Postel, de Jong, & de Haan, 2005). The results showed that the baseline characteristics of the two groups differed by gender, age, education, and work situation. The web-based treatment group involved significantly more women than the face-to-face group, and people in the web-based treatment group were better educated and more frequently employed than the people in the face-to-face group. Web-based treatment

participants were also significantly older than face-to-face participants. This study confirmed that web-based treatment serves a new group of people with alcohol problems, especially the groups that are difficult to reach in regular face-to-face therapy. The internet therefore offers an opportunity to improve access to therapy for problem drinkers.

When we conducted the population study in 2005, our web-based treatment program was the first web-based treatment program for problem drinking with active therapeutic involvement available in the Netherlands. Four years later, more online treatment programs were available, but other things had changed as well, such as less media attention, difficulties with anonymous treatment participation, and greater acceptance of online treatment programs in the general population. We were interested in the consequences of these changes on clients, and therefore expanded our earlier population study to compare the baseline characteristics of four naturalistic groups (N=4593): two web-based treatment groups (2005-2006 and 2008-2009) and two consecutive series of ambulant face-to-face participants admitted for treatment as usual (Chapter 3.2) (Postel, de Haan, ter Huurne, Becker, & de Jong, submitted-b). The key characteristics we were interested in were gender, age, education level, working situation, and earlier treatment for drinking problems.

The results showed that the web-based treatment program successfully attracted different participants from those who are represented in regular face-to-face alcohol treatment services: more women, older and higher educated people, more people with jobs, and less people with prior alcohol treatment. This again suggested that web-based treatment decreases the barriers to treatment and enhances accessibility. However, we saw that the web-based treatment population changed over time. In 2005-2006, the web-based treatment program clearly reached a new population of problem drinkers. Although the web-based treatment program still reached an important new group of participants in 2008-2009, this group showed more overlap with the traditional face-to-face participants. Less employed participants and less first-time treatment seekers were evident. It is possible that nonanonymity is responsible for these changes as staying anonymous still remains very important for many problem drinkers. Therefore, if addiction health care services really want to reach a hidden population of problem drinkers, it would be necessary to offer the webbased treatment program completely anonymously. On the other hand, our findings might also indicate the success of web-based treatment and the better acceptance of it in the general population. Additional research is needed to confirm this latter assumption.

Before conducting our RCT, we investigated the feasibility and acceptability of the webbased treatment program in a pilot study with 527 Dutch-speaking problem drinkers (Chapter 4) (Postel, de Haan, & de Jong, 2010). In a pre-post design, weekly alcohol consumption, health problems, and satisfaction were assessed. Although the drop-out rate was high (67%), treatment completers showed a significant decrease in alcohol consumption and in health related complaints at post-treatment, and maintained these results at 6-weeks and 6-months follow-up. We also found significant improvement in health problems including depressive symptoms, memory problems, heart palpitations, and sexual problems. Participants' overall satisfaction with the web-based treatment program was high and the program fulfilled their needs. The personal contact with their therapist was rated as the most valuable part of the program. The results also showed that a new group of problem drinkers was reached: 76% of participants had never received treatment for their alcohol consumption before. Despite some serious study limitations, these pilot findings proved the feasibility of our web-based treatment program and supported the setting up of a RCT in order to gain more information on the effectiveness of the web-based treatment program and participants' reasons for dropout, and to determine which group of problem drinkers would benefit most from the web-based treatment program.

# **Effectiveness**

We conducted a randomized controlled trial (RCT) to evaluate the web-based treatment program and to systematically investigate reasons for drop-out (Chapter 5) (Postel, de Haan, ter Huurne, Becker, & de Jong, 2010). In an open RCT, Dutch-speaking problem drinkers in the general population were randomly assigned to the 3-month web-based treatment program (n=78) or the waiting list control group who received 'no-reply' email messages once every two weeks (n=78).

At post treatment, our findings showed that the web-based treatment program was effective. Participants who received the therapist supported web-based treatment program reported substantially better results than those who received 'no-reply' email messages. The web-based treatment group decreased their mean weekly alcohol consumption by 28.8 units compared to 3.1 units in the control group corresponding with a large between-group effect size (d=1.21). At the end of treatment, 68% of the participants in the web-based treatment group achieved drinking behaviour within the guidelines for low-risk drinking compared to 15% in the control group. The web-based treatment group also showed greater improvement on general health and depressive symptoms. We found no differences on quality of life.

Besides the outcome measures, our study also gained insight into the reasons for dropout. The main reasons for dropping out of the web-based treatment program were personal reasons unrelated to the program, discomfort with the treatment protocol, and satisfaction with the positive results that had been achieved.

This was, to our knowledge, the first randomized controlled trial evaluating an online treatment program with active therapeutic involvement for problem drinking solely via the internet. The RCT results replicated the results of our uncontrolled observations (Postel et al., 2010). The effect sizes in our study were quite large compared with effects found for other web-based interventions designed to decrease alcohol consumption (Bewick, Trusler, Barkham et al., 2008; Riper et al., 2008). A possible explanation might be the active therapeutic involvement in our intervention; Spek and colleagues (Spek et al., 2007) found that online treatment with active therapeutic involvement for depression and anxiety was more effective than self-help. It also seems reasonable that the large effects were a result of the key ingredients of the web-based treatment program: the therapy itself was intensive; the therapists were experienced, well educated, had special training and good supervision throughout the trial; and the recruitment process involved a certain amount of motivation and readiness to change.

The results of this RCT proved that web-based treatment for problem drinking can be an effective intervention for a large population who otherwise does not seek help for their drinking problem. The findings on reasons for dropout will be used to improve our web-based treatment program and to decrease the number of future dropouts. Additional research is needed to investigate the longer term effects of the web-based treatment program and to determine whether the changes to our program will decrease the dropout rate.

# Therapeutic relationship

Although the therapeutic relationship between patient and therapist has been accepted as an important element of the therapeutic process, the therapeutic alliance in online therapy still raises questions. Is it possible to establish a positive therapeutic relationship online? Is the therapeutic relationship in a web-based treatment program comparable to the therapeutic relationship in face-to-face treatment? A relatively small amount of research has been conducted examining the nature and the relevance of the therapeutic alliance in online cognitive behavioural therapy. We therefore compared the alliance data from our RCT study (n=65) with data from a RCT study concerning a 3-month inpatient face-to-face treatment

setting for Dutch substance-dependent participants (n=77) (Chapter 6) (Joosten, de Jong, de Weert-van Oene, Sensky, & van der Staak, 2009; Joosten, de Weert, Sensky, van der Staak, & de Jong, 2008; Postel, Joosten et al., submitted). The principle instrument for measuring outcome was the Helping Alliance Questionnaire (HAQ).

The results showed that it is possible to establish a positive therapeutic relationship between participant and therapist in both types of treatment. Despite the very different settings and participants, the perceived helping alliance was of a comparable level for both groups. Significant improvement in the therapeutic alliance could be observed during both treatment programs. Web-based treatment participants reported the same level of improvement from the interim point to the end of treatment as face-to-face participants did. In their comments, most web-based treatment participants were positive about the relationship formed with their therapist, and they appreciated the unique advantages of online treatment. The only significant difference we found between the groups concerned the effect size of the difference score on the HAQ Helpfulness subscale. The web-based treatment group showed a greater improvement on Helpfulness compared to the face-to-face group, which meant that the confidence participants had in their own capacities to improve the situation increased more in the web-based treatment group. A possible explanation could be the difference in addiction severity between both participant groups, as the problems of the participants who sought online treatment might have been less severe than participants who sought face-to-face treatment. The web-based treatment program also required a greater degree of independence and initiative. Web-based treatment studies concerning traumatized patients and patients with different kinds of mental health problems also found that a good therapeutic relationship could be established regardless of the modality of communication (Cook & Doyle, 2002; Knaevelsrud & Maercker, 2006, 2007).

#### Attrition

Despite the promising results of web-based interventions, participants show great variation in how they use the interventions in terms of frequency and duration of visits and they often fail to complete treatment sessions or assessments (Christensen, Griffiths, & Farrer, 2009; Eysenbach, 2005; Riper et al., 2008). The high numbers of non-completers suggests that web-based alcohol treatment might work more effectively for some people than for others. However, web-based intervention studies mainly focus on efficacy, and less is known about the reasons for non-completion and the specific components to improve adherence (Eysenbach, 2005). In order to gain more insight in attrition prevalence and pre-treatment predictors of attrition we decided to explore the attrition data from a cohort of open-access

users of the web-based treatment program and from our RCT group (Chapter 7) (Postel, de Haan, ter Huurne, Becker, & de Jong, submitted-a). We used the data from participants who enrolled in the web-based treatment program in 2009 (n=885) and from RCT participants (n=156). Attrition was defined as not completing all sessions of the web-based intervention: 9 assignments and 3 assessments.

The study demonstrated a significant difference in the attrition rates in both of the samples, respectively 65% in the open-access group and 55% in the RCT sample of problem drinkers. Although other alcohol intervention studies found better attrition rates, our completion rates are quite high compared to the 16.5% completion rate in the cohort sample of Linke and colleagues (Linke, Murray, Butler, & Wallace, 2007) who used a similar definition of attrition. A higher readiness for treatment score, female gender, higher education level, older age, lower baseline alcohol consumption and a higher readiness to change score were shown to predict treatment completion. However, the current evidence found for predictors of attrition is ambiguous (Bewick, Trusler, Mulhern, Barkham, & Hill, 2008; Postel, de Haan et al., submitted-a; Riper et al., 2009).

The key reasons for non-completion were personal reasons, dissatisfaction with the intervention, and satisfaction with improvements made before treatment completion. Only one previous study has formally examined the reasons for dropout (Christensen et al., 2009; Lange et al., 2003). Like Lange and colleagues we also found that dissatisfaction with the form and content of the web-based treatment program was a frequently cited reason for dropout. Interestingly, technical problems were not given as a reason for dropout in our study. This probably can be explained by the time difference, as Lange's study was conducted in 2003. In addition to their findings, we also found that personal reasons and satisfaction with the results already achieved were also cited as reasons for dropout. This latter reason confirmed the earlier findings of Christensen (Christensen & Mackinnon, 2006) that dropout does not necessarily coincide with a relapse, and that participants who fail to complete follow-up assessments may still derive much benefit from the web-based intervention. The main participants' suggestions for boosting strategies in our study involved email notification and more flexibility in the intervention. Further research should investigate whether the suggested strategies to improve adherence decrease attrition rates in webbased interventions. If we can succeed in improving attrition rates, the effectiveness of webbased alcohol interventions will improve and as a consequence have a positive impact on public health.

# CONCLUSIONS

Based on the key findings, the research questions that we sought to answer can be summarised as follows:

- 1. The methodological quality of RCTs concerning web-based treatment for mental health problems still remained limited.
- 2. The web-based treatment program Alcoholdebaas.nl did reach hidden populations of problem drinkers.
- 3. The web-based treatment program Alcoholdebaas.nl proved to be feasible and acceptable for problem drinkers.
- 4. a) The web-based treatment program Alcoholdebaas.nl proved to be effective in reducing alcohol consumption and improving health status at post-treatment.
  - b) The top-3 reasons for dropout consisted of personal reasons, dissatisfaction with the treatment program and satisfaction with the results already achieved.
- 5. The perceived therapeutic relationship was of a comparable level in the web-based treatment program and a face-to-face cognitive behavioural treatment programs.
- 6. The attrition rate was 65% in the open-access group and 55% in the RCT group. The top-3 reasons for dropout were confirmed, and suggested boosting strategies involved email notification and more flexibility in the web-based treatment program. Participants' treatment readiness, gender, education level, age, baseline alcohol consumption, and readiness to change score had predictive value for treatment completion.

## **LIMITATIONS**

Our pilot study and RCT have several limitations. A first limitation involves the considerable dropout rate in both studies. Although high dropout rates are a common problem in online intervention trials (Christensen et al., 2009; Eysenbach, 2005), it highlights a weakness in our study; especially because we were not able to acquire post-test data from the dropouts as a consequence of the technical procedures of the web-based treatment program. The program did not allow sending a next assignment or questionnaire without completion of the previous one. We chose this linear model because of the advantage that the therapists in this way could not forget to send a homework assignment or questionnaire. However, the disadvantage of so much missing data is certainly not desirable. In future studies, procedures will be changed to ensure that post treatment assessment can be completed independent of

treatment completion. We dealt with missing values by imputing 5 datasets, using the multiple imputations procedure of SPSS version 17.0. Although we chose multiple imputations because this was the most sophisticated method available, the SPSS procedure has recently been criticized as missing data approach in e-health research (Blankers, Koeter, & Schippers, 2010). Overall, Blankers and colleagues concluded that multiple imputations was the best approach to analyse datasets with missing values; they also concluded that the SPSS procedure leads to reliable results. However, it deals with less valid parameter estimations and a lower coverage compared to procedures such as Amelia II and EM imputation. Therefore, our choice for SPSS may have biased our findings somewhat.

A second limitation concerns our use of only online self-report questionnaires; we did not use any objective instrument to measure alcohol consumption like blood or urine tests. Although a number of studies found that the use of online questionnaires works as well as paper and pencil questionnaires regarding to outcomes, test-retest reliability, and response rates (Callas, Solomon, Hughes, & Livingston, 2010; Carlbring et al., 2007; Graham & Papandonatos, 2008; Ritter, Lorig, Laurent, & Matthews, 2004), the questions regarding the validity of online self-report questionnaires seem to be not yet resolved (Andersson, Carlbring, & Cuijpers, 2009). Currently, there are no validation data available for the online use of the questionnaires we used in our studies. Further research is needed in order to measure the validity of those instruments.

Another issue relates to the external validity of our results. As the web-based treatment intervention was intended for problem drinkers in the general population, the group was we wanted to reach was the 10.3% of Dutch people between 16 and 69 years who drink above the threshold of drinking 4 or 5 units (1 unit = 10 millilitres of ethanol) a day for at least 21 days per month or drinking at least once a week 6 or more units, and who also experience various negative consequences of their alcohol consumption (Van Dijck & Knibbe, 2005). Because of the novelty of the intervention in 2005 we did not know in advance what group of problem drinkers would be attracted by the web-based treatment program. The results of our population study revealed insight into some participant characteristics: 55% was women, 80% had a job, 54% was highly educated and 78% had never received professional help for their drinking problem before. This same group of participants was represent in our pilot study; the pilot data further indicated that 98% was likely to be problem drinker. Compared to the four (16.8%) to one (4.2%) male to female ratio of problem drinkers in the general population (Van Dijck & Knibbe, 2005), our studies involved relatively high proportions of women. This was also found in other web-based intervention research (Finfgeld-Connett, 2006; Lieberman & Huang, 2008; VanDeMark et al., 2010). Participants in the population study and pilot study were open-access participants who registered on their own initiative,

and followed the web-based treatment program in a real-world setting without exclusion criteria. We kept the exclusion criteria of our RCT also to a minimum (18-, no problem drinker, recent or current alcohol treatment, psychiatric treatment or a psychiatric disorder), and we did reach a population that matched with the real-world participants. Because all participants in our studies were self-selected, it is likely that only problem drinkers with interest in web-based treatment for drinking problems were included in our studies. Our results can therefore only be generalised to this population, and not to those problem drinkers who are referred by their GP or who are unmotivated to change their drinking patterns. Additionally, only 45% of the participants included in our RCT completed all treatment sessions; those completers therefore are only representative for treatment completers in general. Moreover, our prediction study showed that treatment completers more often were female, higher educated, older, having lower baseline alcohol consumption, and a higher score on treatment readiness and on readiness to change. These limitations should be kept in mind when generalizing our findings.

Finally, we only studied short term effects of the web-based treatment intervention. It was not possible to compare group outcomes at 6 months follow-up because of a prior decision to permit the waiting list controls to receive web-based treatment after 3 months; this was done for ethical reasons. Unfortunately, we therefore can not say anything about the long term results of our web-based treatment program. A study from Riper and colleagues showed at 12 months follow-up, the differences between their web-based self-help intervention (Drinking Less) and the control group (online psycho educational brochure) was no longer significant. They attributed this mainly to improvement in the control group. Additional research is needed to investigate the longer term results of our web-based treatment program and the persistence of the reduction in alcohol consumption and health improvements. Despite the limitation to short term results, it is worth emphasizing that this was the first randomized controlled trial evaluating an online treatment program with active therapeutic involvement for problem drinking solely via the internet. The results should thus be viewed in this context, and replication of our findings is necessary in order to assess the robustness of the results.

# **CLINICAL IMPLICATIONS**

The availability of a web-based treatment program meets the needs of a large group of problem drinkers, and attracts participants who are otherwise unlikely to use regular face-to-face treatment facilities and who are now receiving help in an earlier stage of their addiction problem. With web-based treatment a way was found to make alcohol treatment services

more easily accessible for problem drinkers in the general population. That is very valuable bearing in mind that many initiatives to improve the accessibility of alcohol treatment services were unsuccessful over the past 25 years. We therefore recommend investing in further embedding of web-based treatment programs in the Netherlands. Not only further embedding web-based interventions for alcohol problems, but also offering those interventions for other addiction problems such as cannabis, benzodiazepine and gambling as web-based treatment might also be suitable for those kinds of problems.

The success of a reaching a new population also confronts us with the limitation that there still remain many problem drinkers who are not reached (Cunningham & Van Mierlo, 2009; White et al., 2010), for example people with a lower socioeconomic status, the elderly and immigrants. A significant challenge for the e-health field is to further expand the reach of the intervention for new target groups. We therefore emphasize the importance of developing new strategies to reach more new groups of problem drinkers. Based on our experiences during the first years of the web-based treatment program, when we were able to offer it anonymously, we are convinced that anonymous web-based treatment will further improve the accessibility of alcohol health care. Non-anonymity causes an additional barrier as people are afraid of providing their personal data and being registered as having an alcohol problem. This dilemma has two sides. First, the stigma and shame will persist when offering the possibility to receive treatment anonymously. By maintaining this secrecy, having an alcohol problem remains to have a negative image. We therefore would like to promote that having an alcohol problem is a disease where people do not have to feel ashamed about. However, the other side is that as long as this stigma exists there will be problem drinkers who only seek help if they remain anonymous and we therefore should meet their needs. Reasons to remain anonymous are, for example a mother who fears for losing her child as a result of her alcohol abuse or a medical doctor or professional athlete who does not want to lose his or her job. Society has a keen interest in ensuring that those people receive professional help for their drinking problem. We will therefore continue to stimulate the government and health insurers to support anonymous web-based treatment participation. We believe that anonymous treatment has further potential and would help solving the major social problem of excessive alcohol consumption in the Netherlands. Our aim in this context will always be: preferably non-anonymous if possible, but anonymous if necessary.

The Netherlands is one of the leading countries when it comes to web-based treatment programs. Countries abroad, for example the United Kingdom are currently having discussions that occured in the Netherlands over five years ago. Health organizations, government, and health insurers are not yet convinced of the importance of web-based treatment, and as a result the dissemination and implementation of web-based treatment

programs in many countries is still very minimal. Since February 2010, the English version of the web-based treatment program has been available in the UK via <a href="https://www.lookatyourdrinking.com">www.lookatyourdrinking.com</a>. However, the program is not yet reimbursed by health insurance companies and is therefore only available for self-paying English participants. The Dutch research results and clinical experiences should be used more to stimulate web-based treatment development and implementation abroad, in order to give as many problem drinkers as possible the opportunity to participate in web-based treatment programs.

Addiction health care should invest in integration of web-based treatment and face-to-face treatment programs. First of all, better awareness of the possibilities of web-based interventions by a broader group of face-to-face healthcare professionals should be stimulated in order to attend more patients on the possibilities of web-based treatment. Secondly, using the structured web-based treatment contacts force therapists to work strictly according to the treatment protocol what is in interest of the patients. This is confirmed by Andersson who recently concluded that web-based cognitive behaviour therapy (CBT) increases therapist's adherence to treatment protocols, and also increases the number of therapists who can use CBT (Andersson, 2010). Using web-based elements in faceto-face treatment programs also makes the treatment process more transparent and has the advantage of automatic digital recording of participant files which reduces the likelihood that participants' records will be incomplete, something which is a major problem in addiction health care. Further advantage of the online contacts is that messages and homework assignments can be accomplished 24 hours a day, 7 days a week, which provides both the participant and therapist more freedom. For the therapist web-based treatment also has the advantage that 'no-show' time can be usefully spent on another participant. We would argue that a mixed version is in the interest of the participants. Participants no longer have to visit the addiction treatment institute for each contact; the amount of face-to-face consultation can easily be tailored to the individual needs. Participants who do not dare to seek help in regular face-to-face treatment, can now be easily referred from web-based treatment to face-to-face treatment. This lowers the threshold for additional face-to-face contacts.

Nowadays, the challenges of web-based treatment programs no longer seems to be their effectiveness but rather keeping participants involved until the end of the treatment program. Although there is a general assumption that dropout simply belongs to addiction treatment, this is not necessarily the case. Therapists in clinical practice should be challenged to keep as many participants in treatment as long as possible, something that could be described as being a cultural shift in treatment priorities. Our prediction study provided some points that therapists might focus on, namely: helping participants to be ready for treatment

and for change and encouraging reducing their alcohol consumption immediately. However, because the findings from several prediction studies showed considerable variation we would suggest not focussing too much on baseline predictors of online treatment completion, but instead focus more on the therapist side and the possibilities of boosting strategies in online interventions. Such strategies should be used wherever possible to improve online treatment programs not just in trial settings but also in open-access interventions. We recently have initiated this 'cultural change' carefully in our organization as a result of the feedback from the research findings. The therapists have taken the initiative to apply boosting strategies and to incorporate participants' suggestions for improvement. Some examples were pretty easy to implement: sending an email alert when participants receive a new message, discussing the dropout issue with the participants at the start of treatment, mentioning the expected end date of treatment, and sending a short drop-out questionnaire to all participants as part of the regular treatment program. Although it is too early to assess the results of these changes, we expect to find positive effects and will investigate the impact in the near future.

# **DIRECTIONS FOR FUTURE RESEARCH**

Further research on web-based interventions with active therapeutic involvement is needed. In order to assess the robustness and sustainability of the results, replication of our findings is necessary as well as longer follow-up studies. For ethical reasons, a different design should be chosen to prevent that treatment is withheld from problem drinkers unnecessarily long. A design that compares web-based treatment with a minimal intervention, such as an online self-help intervention, would therefore be more appropriate. We would also recommend more and longer follow-up studies of non-completers. Continuous and frequent measurements, for instance, with diary surveys, can be used to gain these data. Research is also needed to directly compare the effectiveness of web-based alcohol treatment programs with face-to-face treatment programs. Moreover, the cost-effectiveness of both treatment modalities should also be examined thoroughly. Accordingly, it would be interesting to expand the comparison of both target groups to more baseline variables such as alcohol consumption, perceived burden, and motivation for treatment.

Another interesting direction for further exploration is the acceptability of web-based treatment programs by participants and health professionals. Little is known about the implementation and dissemination of web-based alcohol interventions (Andersson, 2010; Cunningham & Van Mierlo, 2009). It would be interesting to evaluate the disclosure and referral behaviour of health care professionals. Are they willing to provide information about

web-based interventions and to refer their patients? Participants' arguments for choosing for web-based treatments could also be explored further. In line with this is the goal of expanding the range of new groups of problem drinkers. Additional research is needed to investigate how we can reach hidden populations of problem drinkers. The question why so many problem drinkers are not seeking professional help is certainly determined by feelings of shame and the taboo on having an alcohol problem. Ideally, problem drinkers should think 'I have a disease and I do not have to be ashamed'. Future research should find out if and how this shame and taboo can be reduced. Accordingly, we would also like to verify the added value and impact of offering web-based treatment programs anonymously. Further research should also investigate the feasibility and effectiveness of mixed treatment programs, when face-to-face and web-based treatment modalities will be combined.

Attrition should also be a topic of future research, in trial settings as well as in real world settings. Much is known about the success of web-based interventions, but we do not know enough about their failures. Prediction analysis can be used for this, but we also recommend focussing on the effects of boosting strategies to increase treatment adherence and to investigate whether generic or individually tailored boosting strategies work better. We expect that this would reduce dropout more than focussing on participants' baseline predictors.

As web-based treatment programs can easily add new treatment elements, our program can be extended with potentially effective elements to investigate their added value. Some interesting additional elements are: supportive medication by the GPs, an implicit alcohol-related cognitions training, additional sessions for partners or other family members, or working with exposure sessions.

"If it was not via the internet, then I would not dare telling how I felt. I would never have gone to an addiction treatment institute to say that I have a drinking problem. And if I did I honestly would not dare to say how much I drink (certainly not when it goes wrong). Now I can admit this. The accessibility of this web-based treatment made it very easy for me to follow this treatment."

# Original Dutch text:

`Als het niet via internet geweest was, had ik niet durven vertellen hoe ik me voelde. Ik had nooit naar een instelling durven stappen om te zeggen dat ik vind dat ik een drankprobleem heb. En als ik het wel zou doen, zou ik niet eerlijk durven te zeggen hoeveel ik drink (zeker niet als het een keer fout gaat). Nu durf ik dat wel toe te geven. Juist de laagdrempeligheid van deze online behandeling maakte voor mij de stap om dit te doen heel makkelijk.`

Daisy, 39 years, in a message to her therapist

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# **APPENDICES**

Summary in Dutch
Acknowledgements
Curriculum vitae
List of publications

# **SAMENVATTING**

'Het is niet te laat, het is nimmer te laat.

Het is pas te laat als er geen weg terug is...
en zelfs dan is er berouw en kun je denken
hoe het ooit zou zijn geweest...'

Anna-Eva op het forum van Alcoholdebaas.nl

In Nederland wordt 10,3% van de mensen tussen de 16 en 69 jaar gedefinieerd als probleemdrinker. Zij drinken boven de richtlijn voor verantwoord alcoholgebruik en ervaren vaak negatieve consequenties op het gebied van hun gezondheid, relaties en werk. Ondanks de hoge prevalentie, ontvangt slechts één op de tien probleemdrinkers professionele hulp. De drempel om hulp te zoeken is blijkbaar hoog. In de afgelopen 25 jaar heeft de overheid geïnvesteerd in vroegsignalering van alcoholproblemen en verbeterde toegang naar hulp. Helaas met weinig succes; de vele initiatieven hebben niet geleid tot substantiële verbetering. Het beschikbare behandelaanbod sluit onvoldoende aan bij de behoeften van probleemdrinkers en wordt ervaren als weinig toegankelijk: verbetering is dus nodig. De toegankelijkheid en brede beschikbaarheid van internet biedt hiertoe mogelijkheden. Dat was voor Tactus Verslavingszorg de aanleiding om de internetbehandeling Alcoholdebaas.nl te ontwikkelen.

#### Internetbehandeling Alcoholdebaas.nl

Alcoholdebaas.nl omvat een compleet behandelaanbod, bestaande uit een informatieve website, online lotgenotencontact via het forum, internetbehandeling en nazorg. De internetbehandeling is een gestructureerd behandelprogramma, bestaande uit 2 delen, waarbij de deelnemer persoonlijke één op één begeleiding krijgt van een professionele hulpverlener via het internet. De behandelmethode is gebaseerd op uitgangspunten van de cognitieve gedragstherapie en motiverende gespreksvoering. De interactie verloopt asynchroon, waardoor zowel de deelnemer als de hulpverlener de mogelijkheid heeft goed na te denken over een reactie of antwoord. Het doel van de behandeling is het minderen of stoppen van overmatig alcoholgebruik. Deel 1 is gericht op diagnostiek, het onderzoeken van de functie van het alcoholgebruik en educatie. De nadruk ligt op inzicht in eigen gebruik en het motiveren van de deelnemer voor verandering van het drinkgedrag en voor behandeling. In deel 2 start de deelnemer met het stellen van zijn doel en werkt hij vervolgens aan

gedragsverandering. De duur van de behandeling bedraagt ongeveer 3 maanden. Alle communicatie vindt plaats via een SSL-beveiligde website. Deelnemers kunnen inloggen in hun eigen dossier, waarin alle communicatie plaatsvindt en huiswerkopdrachten kunnen worden verstuurd en gelezen. De hulpverleningsrelatie tussen professionele hulpverlener en deelnemer is typerend voor de internetbehandeling Alcoholdebaas.nl en onderscheidt deze behandeling van online zelfhulpprogramma's op het gebied van probleemdrinken (al dan niet ondersteund met chat- of e-mailcontacten).

#### Onderzoek online alcohol interventies

Onderzoek dat tot op heden is gedaan naar internet interventies voor alcoholproblemen betreft overwegend zelfhulpinterventies. De effectiviteit van online alcohol interventies met actieve therapeutische betrokkenheid is tot op heden niet onderzocht. Daarom werd in het kader van dit proefschrift de afgelopen jaren onderzoek gedaan naar de uitvoerbaarheid en effectiviteit van de internetbehandeling Alcoholdebaas.nl. Er werd gestart met een review van de literatuur en een doelgroeponderzoek. Vervolgens werd in een pilot studie de haalbaarheid onderzocht en in een gerandomiseerde trial (RCT) de klinische effectiviteit. In de RCT werd de internetbehandeling vergeleken met een wachtlijst controlegroep die gedurende 3 maanden 2-wekelijks een ondersteunend e-mailbericht ontving. Binnen de RCT is tevens systematisch onderzoek gedaan naar de redenen voor drop-out, de therapeutische relatie en de voorspellende waarde van baseline kenmerken op behandeluitval.

#### **Kwaliteit RCTs internet interventies**

Vanwege het steeds groter wordende aanbod van internet interventies op het World Wide Web en het toenemende aantal studies, hebben wij begin 2007 besloten om de methodologische kwaliteit van gerandomiseerde gecontroleerde studies (RCTs) systematisch te beoordelen. Het zoekterrein werd beperkt tot internetbehandeling op het gebied van de geestelijke gezondheidszorg. Geautomatiseerde computer programma's en zelfhulp interventies werden niet meegenomen. In hoofdstuk 2 wordt een uitgebreid overzicht gegeven van de kwaliteit van de 14 gevonden studies. De methodologische kwaliteit bleek over het algemeen laag te zijn. Hoewel individuele studies zeer waardevolle behandelresultaten lieten zien, luidt de conclusie dat het noodzakelijk is de onderzoeksopzet en verslaglegging van RCT's op het gebied van internet interventies te verbeteren. De kwaliteit van de beschrijving van de studies kan worden vergroot door beter gebruik te maken van de CONSORT richtlijnen. De onderzoeksopzet kan worden verbeterd door vooraf duidelijk te definiëren wanneer er sprake is van 'voldoende behandeling' en door deelnemers

te vragen naar geloofwaardigheid van de interventie en het gebruik van co-interventies en medicatie tijdens de studieduur.

In de afgelopen 5 jaar is het aantal studies op het terrein van de online geestelijke gezondheidszorg sterk toegenomen. Op het moment dat een overzichtsartikel wordt gepubliceerd is de informatie alweer verouderd, doordat het terrein van online hulpverlening continu en zeer snel aan het ontwikkelen is. Uit een recente overzichtstudie naar een brede range van online gezondheidsinterventies blijkt echter dat de kwaliteit van studies nog steeds beperkt is (Ekeland, Bowes, & Flottorp, 2010).

# Bereik nieuwe groep probleemdrinkers

Om na te gaan of de internetbehandeling een nieuwe populatie probleemdrinkers bereikt, hebben we na de start in 2005 de baseline kenmerken van de eerste 172 deelnemers vergeleken met die van 172 face-to-face deelnemers. In hoofdstuk 3a worden de resultaten beschreven. Vooral de tot nu toe zeer moeilijk bereikbare probleemdrinkers worden bereikt: mensen met werk, vrouwen, nieuwkomers en hoog opgeleiden. Het internet biedt dus mogelijkheden om de toegang tot professionele hulp voor probleemdrinkers te verbeteren.

Vier jaar later hebben we opnieuw een doelgroeponderzoek uitgevoerd, omdat er een aantal belangrijke wijzigingen hadden plaatsgevonden. In 2009 was Alcoholdebaas.nl niet langer de enige internetbehandeling voor probleemdrinkers. Ook werd anonieme deelname niet langer vergoed door de zorgverzekeraar. En hoewel de hoeveelheid media-aandacht voor online behandeling flink was afgenomen, leek de algemene bevolking beter bekend met online behandelprogramma's. We waren geïnteresseerd in de gevolgen van deze veranderingen en hebben daarom de baseline kenmerken van vier groepen vergeleken (N = 4593): twee groepen deelnemers aan de internetbehandeling en twee groepen reguliere face-to-face deelnemers (2005-2006 en 2008-2009). De resultaten worden beschreven in hoofdstuk 3b en bevestigen de eerdere bevinding dat internetbehandeling een nieuwe groep probleemdrinkers bereikt: meer mensen met werk, vrouwen, hoog opgeleiden, ouderen en nieuwkomers. We zien echter wel een verschuiving in de populatie tussen 2005-2006 en 2008-2009. De deelnemers aan de internetbehandeling vertonen meer overlap met de reguliere face-to-face deelnemers in 2008-2009: minder werkende deelnemers en minder nieuwkomers. Het niet langer anoniem aanbieden van de behandeling lijkt verantwoordelijk voor deze veranderingen, omdat anonimiteit nog steeds erg belangrijk is voor veel probleemdrinkers. Anderzijds kan de verschuiving ook het gevolg zijn van het succes van

internetbehandeling en bijbehorende acceptatie bij de algemene bevolking. Aanvullend onderzoek is nodig om deze aannames te bevestigen.

#### Pilot studie

In hoofdstuk 4 wordt de pilot studie beschreven die is uitgevoerd direct na de start van de internetbehandeling. Gedurende het eerste jaar van de internetbehandeling werden alle gegevens uit voor-, na- en follow-up metingen verzameld en geanalyseerd. In een pre-post design, werden het alcoholgebruik, de gezondheid en de tevredenheid van 527 probleemdrinkers onderzocht. Deelnemers die de behandeling hebben afgerond lieten een significante afname van het alcoholgebruik en een verbetering van hun gezondheid zien aan het eind van de behandeling. Deze resultaten bleven ook 6 weken en 6 maanden na afronding gehandhaafd. Deelnemers waren daarnaast erg tevreden over de internetbehandeling en het persoonlijke contact met de hulpverlener werd beoordeeld als het meest waardevolle aspect van het programma. Ondanks de beperkingen van het prepost design en het hoge percentage uitvallers (67%), vormden de pilot bevindingen voor ons aanleiding tot de opzet en uitvoering van een gerandomiseerde trial.

#### Gerandomiseerde trial

De pilotstudie heeft een vervolg gekregen in de vorm van een gerandomiseerd onderzoek (RCT) waarin de effectiviteit van de internetbehandeling werd onderzocht. De experimentele groep kon na randomisatie direct starten met de internetbehandeling (n=75) en werd vergeleken met een wachtlijst controle groep die gedurende een periode van 3 maanden 2wekelijks een ondersteunend email ontving (n=75). Hoofdstuk 5 beschrijft de bevindingen. Uit de resultaten direct na afronding van de behandeling blijkt dat de internetbehandeling effectief is in het reduceren van de wekelijkse alcoholconsumptie en het verbeteren van de gezondheid van deelnemers. In de experimentele groep daalde de gemiddelde wekelijkse alcohol consumptie met 28.8 standaardglazen in vergelijking met 3.1 standaardglazen in de controle groep. Bijbehorende effect size was groot (d=1.21). Van de experimentele groep dronk 68% na afronding binnen de grenzen van laagrisico drinken, in vergelijking met 15% in de controle groep. Deelnemers aan de internetbehandeling hadden daarnaast een betere gezondheid en minder depressieve klachten dan deelnemers in de controlegroep. We vonden geen verschillen op de kwaliteit van leven. Naast de uitkomstmaten, leverde de gerandomiseerde trial ook inzicht in de redenen voor uitval. De belangrijkste redenen waren: (1) persoonlijke redenen (2) ontevredenheid over de behandeling en (3) tevredenheid met het al bereikte resultaat.

Voor zover bekend was dit de eerste gerandomiseerde studie van een online alcohol behandeling met actieve therapeutische betrokkenheid. De effecten in onze studie waren groot in vergelijking met eerder gevonden effecten voor online zelfhulp interventies voor probleemdrinkers. Een mogelijke verklaring hiervoor is de actieve betrokkenheid van de hulpverlener. Bij online behandeling van depressie en angst bleek eerder al dat de effecten van behandeling met actieve therapeutische betrokkenheid groter zijn dan die van zelfhulp. Daarnaast zullen de ingrediënten van de behandeling hebben bijgedragen aan de effecten. Kenmerkend zijn de intensiteit van de behandeling, de ervaring van de hulpverleners, de intensieve opleiding en coaching van internetbehandelaars en de manier van werving, waardoor deelnemers al beschikten over een zekere mate van motivatie en bereidheid om te veranderen. De resultaten van deze RCT bewijzen dat online behandeling van problematisch alcoholgebruik een effectieve vorm van hulp is voor een grote populatie die anders niet op zoek gaat naar hulp voor hun drankprobleem. De bevindingen rondom redenen voor uitval zullen worden gebruikt om de internetbehandeling te verbeteren en om het aantal uitvallers in de toekomst te verlagen. Aanvullend onderzoek is nodig om de lange termijn effecten van de internetbehandeling te onderzoeken en om te bepalen of de voorgestelde wijzigingen zullen leiden tot minder uitval.

# Therapeutische relatie

De aard van de therapeutische relatie in online behandelingen is nauwelijks onderzocht. Daarom hebben we de therapeutische relatie binnen de internetbehandeling (n=65) vergeleken met de therapeutische relatie binnen een face-to-face cognitieve gedragsinterventie (n=77). De data zijn verkregen via twee afzonderlijk studies: in beide studies werd de therapeutische relatie gemeten met de Helping Alliance Questionnaire (HAQ). De therapeutische relatie in beide settings bleek goed en van een vergelijkbaar niveau. Er zijn geen verschillen gevonden tussen de online groep en de face-to-face groep op één van de drie HAQ-scores halverwege of na afloop van de behandeling. De therapeutische relatie verbeterde gedurende de behandeling in beide groepen evenveel. We kunnen daarom concluderen dat het mogelijk is om een goede therapeutische relatie te vormen tussen patiënt en therapeut in zowel face-to-face als online behandelingen in de verslavingszorg.

# Drop-out

Ondanks de veelbelovende resultaten van online interventies voor alcohol problemen, worden ze vaak gekenmerkt door een hoog uitvalpercentage. Er is echter weinig bekend over de redenen voor uitval in online behandeling. Tevens roept het de vraag op of online

hulp voor alcoholproblemen efficiënter werkt voor sommige mensen dan voor anderen. In ons onderzoek hebben we de prevalentie van drop-out en de voorspellers voor afronding van de behandeling nader onderzocht in twee groepen: een steekproef van open-access deelnemers (n = 885) en de RCT deelnemers (n = 156). Uitval werd gedefinieerd als het niet afronden van alle 12 onderdelen van de online behandeling: 9 huiswerkopdrachten en 3 assessments. De RCT deelnemers werd ook gevraagd naar hun redenen voor het niet afronden van de behandeling en hun suggesties voor het verbeteren van de therapietrouw.

De open-access en RCT groep verschilden significant in het percentage uitvallers (65% versus 55%). Hoewel andere online alcohol interventie studies meestal minder uitvallers rapporteren, gebruiken zij vaak ook mildere definities van drop-out. Onze uitvalpercentages zijn goed in vergelijking met de 16.5% voltooiing in de cohort studie van Linke en collega's, die wel eenzelfde definitie van drop-out gebruikten (Linke, Murray, Butler & Wallace, 2007). De logistische regressie analyse liet zien dat vrouwelijke deelnemers en deelnemers met een hogere bereidheid tot behandeling, hoger opleidingsniveau, hogere leeftijd, lagere baseline alcohol consumptie en een hogere veranderingsbereidheid vaker de online behandeling voltooien. Op basis van onze en eerdere bevindingen moeten we echter wel concluderen dat de resultaten elkaar soms tegenspreken en de huidige bewijsvoering voor het voorspellen van uitval daardoor nog zeer beperkt is. De belangrijkste redenen voor het niet voltooien van de internetbehandeling waren persoonlijke redenen, ontevredenheid met de interventie, en tevredenheid met de bereikte verbetering. De meest genoemde suggesties voor het verbeteren van de therapietrouw waren meer flexibiliteit in de interventie en het versturen van een e-mail alert.

De uitdaging van online alcohol interventies betreft niet langer de effectiviteit, maar het behouden van deelnemers tot het einde van het behandelprogramma. Nader onderzoek moet uitwijzen of de voorgestelde verbeteringen ook daadwerkelijk leiden tot minder uitval. Als we slagen in het vermindering van het aantal uitvallers, zal de effectiviteit van online interventies ook verbeteren en als gevolg daarvan de impact voor de volksgezondheid.

#### Discussie en conclusie

De internetbehandeling <u>www.alcoholdebaas.nl</u> voorziet in de behoefte van een grote groep probleemdrinkers en bereikt een nieuwe groep die nu wel de weg naar de hulpverlening weet te vinden. Met de internetbehandeling is een manier gevonden om hulpverlening eenvoudig toegankelijk te maken voor probleemdrinkers in de algemene bevolking. Desondanks is er nog steeds een grote groep probleemdrinkers die niet wordt bereikt:

uitbreiding van het bereik blijft dus de uitdaging. Mogelijkheden om dit te realiseren liggen in het combineren van face-to-face behandeling met online elementen, het anoniem aanbieden van de internetbehandeling en door gebruik te maken van andere wervingsstrategieën.

De resultaten van het huidige onderzoek laten zien dat online behandeling van problematisch alcoholgebruik effectief is in het reduceren van de wekelijkse alcoholconsumptie en het verbeteren van de gezondheid van deelnemers. Deelnemers zijn erg tevreden met de internetbehandeling en waarderen vooral het persoonlijke contact met de hulpverlener. Aanvullend onderzoek is nodig om de langere termijn effecten van de internetbehandeling te meten.

De mogelijkheden van online hulpverlening zijn veel groter dan momenteel wordt benut. Enerzijds wat betreft de inbedding van de huidige alcohol internetbehandeling en anderzijds internetbehandelingen voor andere verslavingsproblemen zoals cannabis, benzodiazepinen, gokken en roken. Online hulp is voor veel professionals nog geen gemeengoed en daardoor krijgt het niet altijd de aandacht die het zou moeten hebben.

Vanwege het hoge uitvalpercentage (55-65%) ligt de belangrijkste uitdaging voor de toekomst in het behouden van meer deelnemers tot aan het einde van de behandeling. Het huidige onderzoek geeft inzicht in redenen voor uitval, strategieën voor het verminderen van uitval en voorspellers voor afronding van de behandeling. Deze bevindingen kunnen worden gebruikt om de internetbehandeling te verbeteren en om het aantal drop-outs in de toekomst te verlagen. Concrete verbeteringen zijn o.a. het versturen van een e-mail alert naar het reguliere e-mailadres van een deelnemer en meer flexibiliteit in de te volgen stappen van de behandeling. De predictie resultaten suggereren dat de hulpverlener bij aanvang direct zou moeten inzetten op een afname van het alcoholgebruik en het helpen van de deelnemer zich klaar te voelen voor de behandeling. Aanvullend onderzoek is nodig om te bepalen of de wijzigingen zullen leiden tot minder uitval.

Meer onderzoek is nodig naar de effectiviteit van online alcohol interventies met actieve therapeutische betrokkenheid. Om de robuustheid en duurzaamheid van onze bevindingen goed te kunnen beoordelen, is replicatie van onze bevindingen nodig evenals langere follow-up studies. Andere interessante domeinen voor vervolgonderzoek zijn de implementatie van online behandelingen en de waardering en acceptatie door hulpverleners en deelnemers. Toekomstig onderzoek zal zich ook moeten blijven richten op uitval.

'Als het niet via internet geweest was, had ik niet durven vertellen hoe ik me voelde. Ik had nooit naar een instelling durven stappen om te zeggen dat ik vind dat ik een drankprobleem heb. En als ik het wel zou doen, zou ik niet eerlijk durven te zeggen hoeveel ik drink (zeker niet als het een keer fout gaat). Nu durf ik dat wel toe te geven. Juist de laagdrempeligheid van deze online behandeling maakte voor mij de stap om dit te doen heel makkelijk'.

Daisy, 39 jaar, in een bericht naar haar hulpverlener.

# DANKWOORD

Ik kan weer iets afvinken van mijn 'Things-you-should-have-done' lijstje, joehoe! Ik ben blij dat het af is, maar heb met erg veel plezier de afgelopen jaren gewerkt aan dit proefschrift. Zonder het enthousiasme en de hulp van enorm veel mensen was dat niet gelukt. Tijd dus voor een bedankje.

Allereerst de deelnemers aan de internetbehandeling en het onderzoek. Hartelijk dank voor jullie medewerking! Ik kan me zo voorstellen dat jullie de term onderzoek of vragenlijst soms niet meer konden horen. Hoewel we ons uiterste best hebben gedaan een goede middenweg te vinden tussen 'wat is persé nodig' en 'wat is nog cliëntvriendelijk', waren het af en toe toch wel erg veel vragen. Zowel jullie kritische feedback als positieve woorden waren zeer waardevol. Door de kritische commentaren hebben we de behandeling verder kunnen optimaliseren. En jullie positieve woorden vormden een stimulans om zo door te gaan. Hartelijk dank daarvoor!

Cor, 't is dat jij in 2005 vroeg naar m'n ambities en het idee voor een promotietraject opperde... anders was dit proefschrift er nooit gekomen. Ik wist dat ik graag onderzoek wilde doen, maar heb daarbij nooit een promotietraject voor ogen gehad. Ik ben blij dat jij dit onderwerp aansneed, want ik kijk terug op een leerzaam en interessant traject. Je begeleiding en onze afspraken in Nijmegen, waren daarbij erg waardevol. Je hebt me enerzijds geholpen met richting geven, afbakenen en wetenschappelijk onderbouwen, maar anderzijds ook erg vrij gelaten. Voor mij de perfecte manier van werken. Cor, hartelijk dank voor je begeleiding!

Eni, jij bent op een later moment, in 2009, aangesloten. Passend bij het onderwerp van mijn proefschrift, hebben wij voornamelijk digitaal gecommuniceerd. Slechts een enkele keer was er sprake van een 'real-life' ontmoeting. Jij zorgde ervoor dat ik de grote lijn en juiste opzet van de artikelen niet uit het oog verloor. Ik heb je inbreng als zeer waardevol ervaren. Hartelijk dank daarvoor!

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Elke, wat fijn dat jij mijn onderzoekscollega bent! Wat was ik blij dat jij in december 2006 mijn collega werd. Een sparringpartner op de directe werkvloer is onmisbaar. Ik dacht dat ik perfectionistisch was en alles tot in de puntjes geregeld wilde hebben, maar jij bleek nog een graadje erger. Ideale eigenschappen voor een onderzoeker! Naast serieuze zaken maken we zo nu en dan ook tijd voor de nodige ontspanning: wandelen, terrasje, etentje of shoppen in Amsterdam. Bedankt voor de fijne samenwerking en geweldig dat jij mijn paranimf bent!

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#### **CURRICULUM VITAE**

Marloes Gerda Postel was born on August 23, 1977 in Enschede, the Netherlands. After graduating from secondary school (Thijcollege, Oldenzaal) in 1994 she continued to study social work at Saxion Hogeschool Enschede. In 1998 she started a master study psychology with a concentration in Social Psychology at the Radboud University Nijmegen. During her study, she worked as social worker in the youth care. She did also spend half a year of her study at Raonoke College in Salem, VA, USA. Her master's thesis consisted of a study investigating the added value of implicit measurements for measuring brand associations and predicting behaviour. In 2002, Marloes graduated cum laude from the Radboud University. In August 2002 she started working as a teacher in Social Work at the Saxion Hogeschool Enschede and as a prevention worker at Tactus Addiction Treatment. From 2004, she was involved as a researcher in the development process of the web-based treatment program www.alcoholdebaas.nl, sponsored by Resultaten Scoren. A year later she started her PhD project in collaboration with the NISPA (Nijmegen Institute for Scientist-Practitioners in Addiction) from the Radboud University Nijmegen, investigating the effectiveness of the web-based treatment program. During these years she supervised several students with writing their master thesis and has given several presentations and workshops on national and international level. In 2007, she was involved in obtaining a grant from the action program M&ICT (Social Sectors & ICT) for scaling up the web-based treatment program. In November 2009, she won the prize for the best poster on the Annual Symposium of the Society for the Study of Addiction. Currently, Marloes is working as senior researcher at Tactus Addiction Treatment and participates in the NISPA. Recently, she has also become assistant professor at the department of Psychology, Health & Technology at the University of Twente. She lives happily in Oldenzaal with her partner and daughter.

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