

# Randomised controlled trial on the effectiveness of an E-therapy program for problem drinkers

<b>Submission date</b> 03/03/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/04/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/01/2012	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

**Study website**  
<https://www.alcoholdebaas.nl/onderzoek>

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

## Study objectives

The research questions of this study are:

1. Is an internet based therapy with therapist involvement, based on cognitive behaviour therapy, effective in terms of reducing alcohol consumption and improvement of health status?
2. Do patient's characteristics such as demographics, drinking amount, severity of health problems, motivation for treatment, and readiness to change, have predictive value on the effectiveness of the e-therapy?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics board METiGG (Medisch-Ethische Toetsingscommissie instellingen Geestelijke Gezondheidszorg, kamer Zuid). Date of approval: 30/01/2008. (CCMO number: NL20742.097.07, protocol number 7.133)

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Not Specified

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Problem drinking

## Interventions

Method of randomisation: Automatically by computer (according to a computer generated random list), in blocks of eight.

**Experimental group:** The E-therapy program ([www.alcoholdebaas.nl](http://www.alcoholdebaas.nl)) consists of an informational website with an online cognitive behavioural counselling program for problem drinkers. The aim of the E-therapy program is to motivate the patient to change their drinking habits with the ultimate goal of reducing or stopping alcohol intake. Phase 1 of the program consists of four assignments focusing on the analysis of the participants drinking habits. A personal advice is given at the end. Phase 2 consists of five assignments; the patient sets a goal to quit drinking or reduce drinking, and in four steps learns to reach this goal. The experimental group receives treatment immediately after randomization. Treatment will last for 3 months.

**Control group:** The waiting list control group receives an email from a therapist every two weeks. The messages involve alcohol related information, psycho-education, motivational messages or references to the website or the forum. The control group will receive the E-therapy intervention immediately after completion of the experimental group (approximately 3 months after randomization).

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

1. Mean weekly alcohol consumption in standard units a week (weekly recall)
2. Proportion of patients achieving their drinking goal (abstinence or moderate drinking)
3. Proportion of subjects not at risk (drinking 21 units or less for men and 14 units or less for women)

Timepoints of assessment:

E = Experimental group

C = Control group

T0: Baseline (E and C)

T1: Post-treatment (E) and pre-intervention (C)

T2: 3 months after T1 (E) and post treatment (C)

T3: 6 months after T1 (E) and 3 months after T2 (C)

T4: 9 months after T1 (E) and 6 months after T2 (C)

## **Secondary outcome measures**

1. Alcohol related problems, assessed by the Maudsley Addiction Profile Health Symptom Scale (MAP-HSS)
2. Health status, assessed by the 28-item General Health Questionnaire (GHQ)
3. Quality of life, assessed by the 5-item EuroQol-5D
4. Satisfaction

Timepoints of assessment:

E = Experimental group

C = Control group

T0: Baseline (E and C)

T1: Post-treatment (E) and pre-intervention (C)

T2: 3 months after T1 (E) and post treatment (C)

T3: 6 months after T1 (E) and 3 months after T2 (C)

T4: 9 months after T1 (E) and 6 months after T2 (C)

**Overall study start date**

01/06/2008

**Completion date**

01/08/2009

## **Eligibility**

**Key inclusion criteria**

1. Minimum age of 18
2. Minimum drinking amount of 14 (females) or 21 (males) standard units a week
3. Able to read and write in Dutch
4. Given informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

150

**Key exclusion criteria**

1. Receiving professional help for their drinking problem
2. Severe physical or psychiatric illness
3. Treatment or medication for psychiatric illnesses during the past six months

**Date of first enrolment**

01/06/2008

**Date of final enrolment**

01/08/2009

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**  
Institutenweg 1  
Enschede  
Netherlands  
7521 PH

## Sponsor information

**Organisation**  
Tactus Addiction Care Centre (The Netherlands)

**Sponsor details**  
Institutenweg 1  
Enschede  
Netherlands  
7521 PH

**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.tactus.nl>

**ROR**  
<https://ror.org/00v0vvh64>

## Funder(s)

**Funder type**  
Hospital/treatment centre

**Funder Name**  
Tactus Addiction Care Centre (The Netherlands)

**Funder Name**  
Nijmegen Institute of Scientific Practitioners in Addiction (NISPA) (The Netherlands)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	27/12/2011		Yes	No