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

Submission date
03/03/2008

Recruitment status
No longer recruiting

Registration date
04/04/2008

Overall study status
Completed

Last Edited
03/01/2012

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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) consists of an informational website with an online cognitieve 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?
Results article	results	27/12/2011		Yes	No