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The Teleac course for insomnia: a randomised controlled trial (RCT)

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/06/2019	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
NFGV 5978 (national fund public mental health); NTR62

Study information

Scientific Title
A randomised trial of a behavioural training programme through television for patients with insomnia

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Primary study design
Interventional

Study design
Randomised active controlled parallel group trial

Study type(s)
Treatment

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

Interventions
A behavioural training programme for insomnia will be broadcasted by Teleac this fall. This trial will take place before the start of the broadcasting with three groups:
1. Each week a DVD is sent to the patient's home for 6 weeks. Each DVD contains part of the behavioural training programme (25 minutes each) + book that belongs to the this television programme.
2. Same as the first condition without the book
3. Waiting list control group. These patients may watch the regular television programme later on when broadcasted by Teleac.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Sleep efficiency post-treatment (6 weeks) and 3 months later .

Key secondary outcome(s)
1. Quality of sleep
2. Cognitions about sleep
3. Use of sleep medication
4. Symptoms of depression and anxiety
5. Quality of life
6. Absence of work
7. Health care use

All measured post-treatment (6 weeks) and 3 months later.

Completion date
01/08/2006

Eligibility

Key inclusion criteria
A sleep problem defined as lying awake for at least 30 minutes for at least 3 nights a week for at least 1 month.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Total final enrolment
247

Key exclusion criteria
A high score on the screener for depression (Center for Epidemiologic Studies-Depression [CESD]) or anxiety (Hospital Anxiety and Depression Scale [HADS]).

Date of first enrolment
01/08/2005

Date of final enrolment
01/08/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Vrije Universiteit Amsterdam
Amsterdam
Netherlands
1081 BT

Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (The Netherlands)

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Government

Funder Name
The National Fund for Public Mental Health (Nationaal-Fonds-Geestelijke-Volksgezondheid [NFGV]) (The Netherlands)

Funder Name
Vrije University Medical Centre (VUMC) (The Netherlands) - Department of Clinical Psychology

Results and Publications

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	01/01/2009	28/06/2019	Yes	No