

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

Submission date 12/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/06/2019	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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