

Fear of Flying; a randomised controlled trial. Using subjective and psychophysiological measures to evaluate a cognitive based behavioral psychotherapy.

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To evaluate the effectiveness of the cognitive based behavioral psychotherapy as given by the VALK Foundation by means of psychophysiological measures.

Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric disorders
Study type	Observational non invasive

Summary

ID

NL-OMON30487

Source

ToetsingOnline

Brief title

Fear of Flying: psychophysiological effects of cognitive behavioral therapy

Condition

- Psychiatric disorders

Synonym

Aviophobia, fear of flying

Research involving

Human

Sponsors and support

Primary sponsor: Stichting VALK

Source(s) of monetary or material Support: Het stichtingsbestuur maakt geld vrij voor het onderzoek.

Intervention

Keyword: Autonomic neural system, Cognitive behavioral psychotherapy, Fear of Flying

Outcome measures

Primary outcome

By means of the electrocardiogram (ECG) and the impedance cardiogram (ICG) it is possible to assess heart rate (HR), heart rate variability (HRV), respiratory sinus arrhythmia (RSA) and the pre-ejection period (PEP). From these variables, sympathetic and parasympathetic nervous system activity can be derived. These measures are well suited to show the physiological responses to fear and anxiety.

Secondary outcome

A secondary point in question in this study is if the relation between subjective experience and psychophysiological measures, especially during in vivo exposure, is modulated by personality, cognitive coping style and worry behavior. For this purpose two additional questionnaires will be added. The PSWQ measures the tendency for excessive and uncontrollable worry. The BIS/BAS questionnaire measures two personality traits.

Study description

Background summary

The VALK Foundation is a collaborative venture by the University of Leiden, KLM Royal Dutch Airlines and Amsterdam Airport Schiphol. The foundation was set up in 1989, and is devoted to treating fear of flying on the basis of many years of scientific research.

Study objective

To evaluate the effectiveness of the cognitive based behavioral psychotherapy as given by the VALK Foundation by means of psychophysiological measures.

Study design

This study is a randomized controlled trial in combination with a correlational design.

70 persons with fear of flying will after a diagnostic assesment randomly be assigned to either the normal waiting period between intake and therapy or to a 'fast track' in which the normal waiting period between intake and first therapy session is reduced from 5 to 6 weeks to 1 to 2 weeks. Both groups receive exactly the same therapy normally used at VALK, i.e intake, a couple of individual therapy sessions followed by a two-day grouptherapy.

Subjective and physiological responses to several flying related videos will be measured just before and after the therapy. The people in the normal waiting period group will receive an extra pretreatment measurement just before the first individual therapy session. Therefore the normal waiting period group members have measurement before and after the waiting period in which no therapy is given. Any changes in this waiting period can be compared to changes (due to therapy) found in the 'fast track' therapy group.

Study burden and risks

There is no risk associated with participating in this study. The burden is mainly the extra time involved. Generally the apparatus used does not hinder the client.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Fear of Flying

Exclusion criteria

Beta blockers

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-05-2007
Enrollment: 70
Type: Anticipated

Ethics review

Approved WMO
Application type: First submission
Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL13905.058.07