Interpretive bias modification in the treatment of dental phobia

Gepubliceerd: 15-03-2017 Laatst bijgewerkt: 15-05-2024

Patients who received CBM-I training will start their exposure therapy with lower anxiety levels, and their anxiety levels will reduce faster compared to patients that receive a placebo training.

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22003

Bron
Nationaal Trial Register

Aandoening

dental phobia

Ondersteuning

Primaire sponsor: UMCG, MartiniZiekenhuis
Overige ondersteuning: in search for new funding source

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- DAS score (trait anxiety of dental treatment: Dental Anxiety Scale)
- Interpretive bias score (measured by the recognition task, see also: study procedures).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Cognitive biases play an important role in the etiology and continuation of anxiety disorders. These biases can be altered by ¡®cognitive bias modification¡¯ (CBM) and thereby . reduce psychological complaints.
Moreover, the method is not strainful to the patients. Interpretive bias is one of the major cognitive biases, especially in anxiety disorders. Anxiety symptoms can be reduced by CBM training of interpretive bias (CBM-I). For instance, this effect has been shown in generalized anxiety disorder, anxiety sensitivity, and social anxiety. However, no studies are known that investigate the effect of CBM-I on dental phobia. In the present study, the effect of CBM-I on specific anxiety complaints will be investigated in patients with dental phobia.
These patients will receive the CBM-I training prior to the treatment-as-usual (exposure therapy). We hypothesize that patients who received CBM-I training will start their exposure therapy with lower anxiety levels, and that their anxiety levels will reduce faster compared to patients who receive a placebo training.

Objective: The main objective in this study is to investigate the effect of interpretive bias modification on anxiety levels and interpretive bias in dental phobia.

Study design: Double-blind randomized controlled trial.

Study population: 48 Adult patients (¡Ý18 yrs), who have applied to the Centre for Special Dental Care (Martini Ziekenhuis), in order to treat their dental phobia. These patients have no mental disabilities and participate in the research fully voluntarily, with no material or financial compensation.

Intervention: The CBM-I training consists of short scenarios of initially ambiguous dental situations. A word is left out of the final sentence of the scenario. In the positive CBM-I group the missing word will give a positive meaning to the ambiguous situation, and participants are trained to make positive emotional interpretations. For the placebo group, only neutral meanings are given to the scenarios that are similar to those in the experimental group. All participants receive the training four times: two times per week, 20 minutes per session, 20 trials (scenarios) per session, during two weeks prior to the exposure therapy (the treatment-as-usual).

Main study parameters/endpoints: The main study parameters are the change in interpretive bias score and four anxiety scores (DPFR score: anticipation anxiety of dental treatment, the DAS and K-ATB score: both trait anxiety of dental treatment, and the AS-score Visual analogue scale that indicates the overall anxiety level of dental treatment).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participants receive four training sessions (20 minutes each, two sessions per week) during the two weeks prior to the exposure therapy. This is an online training which the participant can perform at home.
There will be no treatment delay; instead, the waiting weeks between the intake session and the first exposure therapy session will be usefully filled in. The training modifies the interpretive bias in a positive direction. This is considered a positive effect (a negative interpretive bias is associated with anxiety symptoms, whereas healthy, non-anxious individuals interpret ambiguous information in a positive direction.
The CBM-I training corrects the negative interpretive bias towards a positive outcome or stimulates a positive bias).
The placebo group receives a neutral computer task, similar to the CBM-I training (without stimulation towards a positive or negative direction). Both tasks are not psychological or physical strainful. There are no risks for the patients. Patients participate in the research fully voluntarily, they may withdraw from the research at any moment and without any consequences, data will be handled anonymously.

Doel van het onderzoek

Patients who received CBM-I training will start their exposure therapy with lower anxiety levels, and their anxiety levels will reduce faster compared to patients that receive a placebo training.

Onderzoeksopzet

t0 before training

t1 after training but before treatment

t2 after4th treatment session

Onderzoeksproduct en/of interventie

The CBM-I computerized training (also known as ¡®recognition task¡¯) consists of short scenarios of initially ambiguous dental situations. A word is left out of the final sentence of the scenario. In the positive CBM-I group the missing word will give a positive meaning to the ambiguous situation, and participants are trained to make positive emotional interpretations.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ¡Ý18 yrs

- No mental disabilities

- Main diagnosis is dental phobia, if other diagnoses are also applicable, they may not interfere with the treatment

- Availability of a computer (PC, laptop, tablet or Smartphone) and access to the internet

- Basic internet skills

- Dutch reading abilities

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

- Age < 18 yrs

- Mental disabilities

- Other diagnoses than dental phobia for which the patients is treated by the special care dentist (for example extreme gagging reflex)

- Treatment under general anaesthesia instead of exposure therapy

- No availability of a computer and internet

- Lack of basic internet skills

- Lack of Dutch reading abilities or illiteracy

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	21-10-2014
Aantal proefpersonen:	48
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	15-03-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40483
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6321
NTR-old	NTR6496
CCMO	NL47573.099.14
OMON	NL-OMON40483

Resultaten