

Reliability and validity of the Gagging Problems Questionnaire (GPQ) - development of a measurement instrument for gagging problems in dental situations.

Published: 22-12-2006

Last updated: 24-08-2024

The aim of this study is to develop a valid and reliable instrument to estimate the extent to which gagging problems will interfere with adequate dental treatment and to evaluate possible progress after psychological treatment of gagging problems.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30318

Source

ToetsingOnline

Brief title

Reliability and validity of the Gagging Problem Questionnaire (GPQ)

Condition

- Other condition

Synonym

gagging/retching during dental treatment

Health condition

psychogene en somatogene kokhalsproblematiek

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W, zorgverzekeraars

Intervention

Keyword: dental, gagging, measurement

Outcome measures

Primary outcome

- difference in scores on the GPQ and other questionnaires

Secondary outcome

- difference in scores between group 1 (1a and 1b) and group 2
- difference in scores within group 1, between the group with and without additional psychological treatment.
- difference in scores, by condition, between the different measuring moments.

Study description

Background summary

In order to establish a thorough assessment, people referred to the Center for Special Dental Care of the University Medical Center Groningen fill in at home a package of questionnaires prior to their first visit. The questionnaires refer to general health, psychosomatic complaints and dental anxiety. This information will facilitate the relevant questions during the first visit. The Center for Special Dental Care regularly offers help to people with gagging problems who can only be treated with a lot of effort, from the dentist as well as from the patient. For some of these patients it is impossible to get measured for or to wear a prosthesis: Being touched in or close to the mouth they immediately start to gag, sometimes resulting in vomiting as well. No national or international questionnaire for this problem area appears to exist however. Therefore, an instrument is needed with which it will be possible to

distinguish between people with and without serious gagging problems in dental situations. In addition, an instrument is needed to assess possible progress after psychological treatment of these problems. Such an instrument would mean a useful and necessary addition to the present package of questionnaires in aid of the first visit to the dental clinic.

Study objective

The aim of this study is to develop a valid and reliable instrument to estimate the extent to which gagging problems will interfere with adequate dental treatment and to evaluate possible progress after psychological treatment of gagging problems.

Study design

Fill in five paper and pencil questionnaire three times, short examination in and close to the mouth four times.

Intervention

Both experimental groups receive group wise standard information, 30 minutes.

One of these two groups also receives a psychological treatment, consisting of gradual exposure in vivo, 5 sessions of 45 minutes each.

Study burden and risks

To fill in the questionnaires takes about half an hour each time. The examination in and close to the mouth takes about five minutes. As soon as the participant will start to gag, the dentist will stop further exploration of the relevant item.

Taken together participation in this study requires a minimal time effort of each participant, without any risks reasonably. The treatment to reduce gagging problems does not know any medical risks, taken into account the exclusion criterion: ASA-score higher than 2.

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

control group: people that consider themselves as a person without gagging problems.

experimental group: people knowing or estimating their dental visit to be problematic due to gagging.

Exclusion criteria

people with mental disability,

people with insufficient knowledge of dutch language

people under 18 years of age

people that already filled in a GPQ once

people living more than 50 kilometers of the research institutes

people with ASA score higher than 2.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	15-12-2007
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO	
Date:	22-12-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL11306.042.06