Cognitive testing of a Patient-Reported Outcome Measure for Cleft Lip and Palate: The Cleft Q

Published: 19-03-2014
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To determine the appropriateness of scale content of the preliminary CLEFT-Q scales by age and culture and to identify unclear or ambiguous items, instructions and response options

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and hereditary disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON40315

Source
ToetsingOnline

Brief title
Testing the CLEFT-Q

Condition

- Congenital and hereditary disorders NEC

Synonym
cleft lip and palate

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cleft, PROM (Patient-reported outcome measure), Quality of life

Outcome measures

Primary outcome

There are no clear study parameters in this qualitative study. The interviewer will use the cognitive interview guide to probe the child (appendix 2) He/she will record participant*s answers on a computerized spreadsheet.
After each interview, the interviewer will complete a summary statement for each item and the child*s comments. After completing all initial cognitive interviews for an item, the interviewer will compile reports that include all comments for an item. The team will review all the comments to determine issues with formatting, item comprehension, instructions, tense and response options. Items deemed problematic by 2 or more children of any age will be revised for clarity. Other items similar to those revised after the initial interview process are also changed to maintain consistency across item stems or wording.

Secondary outcome

Not applicable

Study description

Background summary

So far outcomes in cleft treatment have mainly been measured in objective and biomedical outcomes. Patient perspectives are often overlooked, because an appropriate, well-defined, valid, reliable and responsive Patient Reported Outcome measurement tool is not available An international team of experts from Canada, USA and UK has taken up the challenge and is developing this PRO

instrument, called the CLEFT-Q

Study objective

To determine the appropriateness of scale content of the preliminary CLEFT-Q scales by age and culture and to identify unclear or ambiguous items, instructions and response options

Study design

This study is an observational study following recommended guidelines and criteria for the development of a PRO instrument . The CLEFT-Q scales are preliminary and need to be refined through cognitive interviewing with patients. This will involve interviews with patients, asking them to complete CLEFT-Q scales using the think-aloud-technique, in which patients verbalize their thoughts as they work through the questionnaire.

Study burden and risks

To implement the study there is no other way than to interview this target group consisting partly of minors (WMO, art 4, lid 1). The study is group related, the risks are minimal/negligible and there is no pain and minimal discomfort. Therefore the study is in line with the codes of conduct as found on the CCMO website: *Non therapeutic research with minors and legally incompetent adults: *no-unless* * (12) and *Code of conduct concerning objection of minors who take part in medical scientific research*.(13)
There is no benefit to the subject directly, but the outcomes of the study will help future patients who face the same problems as the subject and improve treatment and care, delivered through the specialized cleft teams in and outside the Netherlands. Therefore we feel that the burden to the patient will be in proportion to the potential value of the study

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

• Children/adolescents with CLP between 8 and 22 years of age.
• 6 participants in the age group 8-12 and 7 in the age group of 13-17 and 18-22 years
• who are under treatment in our cleft centre or
• who had treatment in our centre in the close past
* written informed consent of subject and/or parents/legal representative
*

Exclusion criteria

• Children with a cognitive disability and/or who cannot read.
• Children who do not understand/speak Dutch.
• Children who have any other congenital syndrome of craniofacial anomaly besides cleft lip and/or palate

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-05-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	19-03-2014
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	NL47560.042.13