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

Published: 18-03-2015
Last updated: 21-04-2024

To contribute to completion of the psychometric development of the Cleft Q

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Skin and subcutaneous tissue disorders congenital |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON42276

**Source**
ToetsingOnline

**Brief title**
Field testing the CLEFT-Q

### Condition

- Skin and subcutaneous tissue disorders congenital

**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,McMaster University in Canada gives us some funds;see G3

## Intervention

**Keyword:** Cleft patients, Patient Reported Outcome Measure, Quality of Life

## Outcome measures

### Primary outcome

Outcome of the study: An internationally validated PROM for use by patients

with cleft lip and/or palate.

### 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 Candada, USA and UK has taken up the challenge and is developing this PRO instrument, called the CLEFT-Q. The UMCG, MCL , UMCU, ErasmusMC and VUMC will participate in testing the dutch version of the CLEFT-Q.

### Study objective

To contribute to completion of the psychometric development of the Cleft Q

### Study design

Psychometric study that involves qualitative and quantitative methods, following international guidelines and criteria for the development of a PROM

### Study burden and risks

To implement the study there is no other way than to test the CLEFT-Q on the target group. This group consists partly f minors (WMO, art4 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 imcompetent adults: "no-unless" and "Code of conduct concerning objection of minors who take part in medical scientific research". There is no benefit to the subject directly but the outcomes of the study will halp future patients who face the same problems as the subject and improve treatment an care, deleiberd through the specialized cleft teams in and outside the Netherland. Therefore we feel that the burden to the pattient 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 CL, CP, CLP between 6 and 29 years of age.
* Who gave written informed consent (and/or their parents in case of minors)
* who are under treatment in our centres or
* who had treatment in our centres in the past:

### Exclusion criteria

* Children with a cognitive disability and/or who cannot read.
* Children who do not understand/speak Dutch.

## Study design

### Design

**Study type:** Observational non invasive

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-06-2015 |
| Enrollment: | 200 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 18-03-2015 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

Approved WMO

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|---|---|
| Date: | 28-09-2015 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO Date: | 02-05-2016 |
| Application type: | Amendment |
| 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 | NL51703.042.14 |
| Other | number not yet received. |