

# Behavioural problems and quality of life in children with burns

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Adjustment disorders (incl subtypes)
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON33627

### Source

ToetsingOnline

### Brief title

Children with burns

### Condition

- Adjustment disorders (incl subtypes)

### Synonym

behavioural problems, maladjustment

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vereniging Samenwerkende Brandwondencentra Nederland

**Source(s) of monetary or material Support:** Nederlandse Brandwonden Stichting

## Intervention

**Keyword:** behavioural, Burns, children, quality of life

## Outcome measures

### Primary outcome

- (1) To define the percentage of children with behavioural problems/  
posttraumatic stress problems;
- (2) To define quality of life in children with burns in comparison to the norm  
population;
- (3) To describe risk factors and protective factors for behavioural problems/  
posttraumatic stress problems;
- (4) To describe physical and psychological factors that are related to  
diminished quality of life.

### Secondary outcome

Is the BSPAS-C a useful instrument to measure anxiety related to pain in  
children aged 8 years and older?

## Study description

### Background summary

Half of the hospital admissions in burn centres consist of children. Research that focuses on their psychological health and quality of life, however, is scarce. Besides, many studies are hampered by small sample sizes (<100) and retrospective designs. In addition, the few reports available often report conflicting results. Prospective studies in European populations are not available. In conclusion, there is a need for empirical evidence on psychosocial functioning of children with burns and related risk factors of maladjustment.

### Study objective

The main objectives of this study are to describe behavioural problems in children aged 0 to 4 years and posttraumatic stress symptoms in children aged 8 to 17 years and to study the course and determinants of these problems. Further, this study focusses on generic and specific quality of life in children with burns.

## **Study design**

The current study is a prospective longitudinal cohort study with a follow-up of 18 months in children with burns. It is an international multi-centre study, comprising six burn centres in the Netherlands and Belgium. The total duration of the study is four years.

## **Study burden and risks**

Parents of children with burns and children older than 8 years are asked to complete self-report questionnaires during a period of 18 months following the burn injury. The estimated time required to fill in the questionnaires varies between 15 minutes and 60 minutes depending on the measurement. To the best of our knowledge, there are no reports available that document risks associated with participation in this type of research. The reason why also children are asked to complete questionnaires is related to the often documented deviating views of children and their parents on how children function. We believe it has a surplus value to include the children's self-reports.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

### Inclusion criteria

Consecutive admissions of children with burns aged 8 months to 4 years and 8 years to 17 years, sufficient Dutch proficiency.

### Exclusion criteria

Severe mental retardation, insufficient Dutch proficiency.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 15-10-2007

Enrollment: 150

Type: Actual

## Ethics review

Approved WMO

Date: 05-10-2007

Application type: First submission

Review commission: BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date: 18-11-2009

Application type: Amendment

Review commission: BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

## 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**

CCMO

**ID**

NL18008.056.07