

# The wound care of children with Epidermolysis Bullosa as a source of stress for their parents and themselves.

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The overall objective of this study is gaining insight into needs and options for psychological treatment of parents and their children with EB with regard to problems related to wound care. Specific objectives are: 1. To examine coping strategies of...

|                              |   |
|------------------------------|---|
| <b>Ethical review</b>        | Approved WMO                                      |
| <b>Status</b>                | Recruitment stopped                               |
| <b>Health condition type</b> | Skin and subcutaneous tissue disorders congenital |
| <b>Study type</b>            | Observational non invasive                        |

## Summary

### ID

NL-OMON45516

### Source

ToetsingOnline

### Brief title

Stress caused by EB

### Condition

- Skin and subcutaneous tissue disorders congenital

### Synonym

blistering diseases

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Dermatologie

**Source(s) of monetary or material Support:** Stichting Eleven Flowers Fund; Patiëntenvereniging Debra en Stichting Vlinderkind

## Intervention

**Keyword:** children, Epidermolysis Bullosa, Stress, Wound care

## Outcome measures

### Primary outcome

The most important parameters are HRQoL (child) and HRQoL (parent), and experienced stress regarding the wound care (pain and anxiety)

### Secondary outcome

Not applicable

## Study description

### Background summary

Epidermolysis Bullosa -abbreviated EB- is a rare inherited skin disorder which is congenital. There are different forms of EB, the nature and severity can vary widely. Currently, there is no treatment for this disease. One of the complex problems with EB is the repetitive, time-consuming and painful care of the skin. When parents undertake the care of the wounds of their child with EB, they often are the ones who cause the pain. It is clear from the clinical practice that some parents (partly) transfer the care to nurses because of the intensive appeal of the care. Observations from practice also show that patients often suffer from anticipatory anxiety, the fear of pain that is coming. It is likely that this wound care is stressful for both parents and child which thus influences parent-child relationship. Lack of knowledge on this issue makes it is difficult to develop proper interventions to give effective and targeted support to patients and their parents.

### Study objective

The overall objective of this study is gaining insight into needs and options for psychological treatment of parents and their children with EB with regard to problems related to wound care.

Specific objectives are:

1. To examine coping strategies of both children with EB and their parents in relation to their wellbeing.
2. To examine which coping strategies of children with EB and their parents

during wound care are associated with reduced stress for both members of the dyad.

3. To describe the aspects of the wound care that are stressful for children with EB and their parents.

4. To examine wellbeing of children with EB and their parents in relation to other norm groups.

## **Study design**

Observational, cohort study

Children with EB and their parents, registered at the Center for Blistering Diseases in Groningen, are asked by letter to take part in the current study.

The letter explains the purpose and design of the study. Also enclosed is an informed consent, which is to be completed, signed and returned by parents and children. Children with EB and their parents are asked to fill out an online questionnaire, over a secure portal. Completing the questionnaire takes approximately one hour

## **Study burden and risks**

The research is not risky. It might be confronting to think about the subject wound care and to answer questions about it.

## **Contacts**

### **Public**

Selecteer

Hanzeplein 1  
Groningen 9700 RB  
NL

### **Scientific**

Selecteer

Hanzeplein 1  
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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

1. Parent of a child with EB (EBS, JEB, DEB or Kindler syndrome)
2. Age of children / adolescents (boys and girls) between 0-25 years
3. The parent has the primary responsibility for the wound care
4. The child is registered as a patient at the Center for Blistering Diseases at the University Medical Center Groningen.

### Exclusion criteria

1. Age of patients > 25 years

## 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): | 22-01-2018 |
| Enrollment:               | 350        |
| Type:                     | Actual     |

## Ethics review

|                    |   |
|--------------------|---|
| Approved WMO       |   |
| Date:              | 27-07-2017  |
| 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     | NL61172.042.17 |