# The effect of severe injury on quality of life and the incidence of psychopathology. A pilot study.

Published: 05-01-2010
Last updated: 04-05-2024

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON33196

**Source**
ToetsingOnline

**Brief title**
injury and the effect on psychopathology and quality of life

### Condition

- Other condition
- Psychiatric and behavioural symptoms NEC

**Synonym**
psychological disorders, trauma

**Health condition**

angststoornissen

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Sint Elisabeth Ziekenhuis
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** injury, psychopahtology, quality of life

## Outcome measures

### Primary outcome

Quality of life of studied trauma patients

-Which limitations appeared as a consequence of the accident?

-Is there a relation between quality of life and demographic, medical and

injury characteristics of the patients?

Appearance of posttraumatic psychopathology in the studied cohort

-How often does psychopathology arise?

-Which psychopathology occurs within this group of patients?

-How many patients received psychological or psychiatric help?

-Is there a relation between psychopathology and demographic characteristics,

medical or injury characters of the patients or characteristics of the

accident?

### Secondary outcome

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# Study description

### Background summary

Trauma still remains the most important cause of death among people younger than 40 years old. Often it results in some disability if patients with serious injury survive. This has a lot of socialeconomic consequences.
In contrast to somatic sequelae, little is known about quality of life and appearance of psychopathology as a result of such accidents and corporal disability. The frequency and the intensity in which corporal damage can influence quality of life (negatively) are more or less unknown. A psychological reaction might have more effect on quality of life than somatic disability. Besides this shocking experiences (like an accident) are knonw to cause psychopathology (like posttraumatic stress syndrome - PTSS). It is not clear whether type of accident, seriousness of injury or corporal sequelae affect the appearance of PTSS.

The Dutch government assigned 11 trauma centres to improve the quality of trauma care. The responsibility given to these trauma centres is quality improvement for the entire chain of trauma care. One of these trauma centres is Trauma centre Brabant in St. Elisabeth Hospital.
To improve trauma care, Dutch trauma centres implemented a nationwide trauma registry, in which among other things, type of injury and accident, and information about mortality and treatment are registered. The collected data is used to investigate survival and mortality of trauma patients. Mortality is the commonly used outcome parameter in trauma care studies. However, quality of trauma care not only depends on lifetime and little is known about quality of life and received psychological assistance of (multi)trauma patients.

**Study objective**

The objective of this study is to provide understanding of the relation between effects of accidents (cause, type injury and sequelae) and appearance of psychopathology. It is not clear whether psychopathology that influences the quality of life in a negative way, caused by the accident exists.
Therefore, it is also important to find out how many and what type of patients it concerns and to distinguish the experienced quality of life of subgroups multitrauma patients based on demographic, psychological and psychosocial characteristics or characteristics of the accident.

After a general inventarisation, subgroup analysis will be performed to find out which relations exist between specific injury, quality of life and psychopathology and on the other hand to find out how many patients with a posttraumatic psychopathology have received an adequate treatment.

The results of this retrospective study will be a starting point for other studies and are essential for prospective observational or intervention

studies.

## Study design

It is a retrospective study in which data from trauma registry, (electronically) medical records and questionnaires will be used.

All suitable patients are asked to participate the study by a letter. If they agree and sign the informed consent, there medical records will be studied and they will be asked to answer some questionnaires. Trauma registration, medical records and the questionnaires mentioned below will be used to collect the study information.

Demographic data (age, gender, civil class, education, being in work), medical data (seriousness and type of injury, comorbidity), characteristics of the accident (traffic, at work, at home, sports, tentamen suicidi), destination after leaving the hospital (home, other hospital, rehabilitation centre, nursing home) and consultation will be extracted from the trauma registration, medical records or questionnaires.

Dutch translations of the following international accepted and validated questionnaires will be used to determine the quality of life and psychopathology and or malfunctioning of the patients:
World Health Organization Quality of Life assessment instrument-Bref (WHOQOL-Bref)
SchokVerwerkingslijst (SVL)
Hospital Anxiety and Depression Scale (HADS)
Cognitive Failures Questionnaire (CFQ)
Short Musculoskeletal Function Assessment (SMFA)

Frequencies will be used to describe the results of the study. To determine quality of life of multitrauma patients, an unpared student t-test will be used to compare the results with data from the reference group of WHOQOL-Bref (de Vries & Van Heck, 2003). To investigate the relation between quality of life and demographic, medical or injury and accident characteristics and psychopathology of the patients and the relation between unconsciousness, sedation or pain relieving-drug directly after the accident and quality of life or psychopathology, multilevel linear regression will be used. To investigate the relation between accident characteristics and psychopathology logistic regression will be used. The study results will also be compared with a - if possible matched - control group.

## Study burden and risks

about 30 minutes to answer the questionnaires.

# 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

Injury Severity Score > 15 as registrated in the local trauma registry of the St. Elisabeth Hospital

## Exclusion criteria

Patients who are unable to fill out questionaires or < 18 years old

# Study design

## Design

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|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Health services research |

## Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 13-04-2010 |
| Enrollment: | 300 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 05-01-2010 |
| Application type: | First submission |
| Review commission: | METC Brabant (Tilburg) |

# 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 | NL28343.008.09 |