

# Supported Fast-track multi-Trauma Rehabilitation Service

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The main objective is to examine the effectiveness, the costs and the cost-effectiveness of an integrated \*fast track\* rehabilitation service for multi-trauma patients (SFTRS) involving dedicated early rehab intervention programs. The SFTRS is...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON37135

### Source

ToetsingOnline

### Brief title

SFTRS

### Condition

- Other condition
- Muscle disorders
- Spinal cord and nerve root disorders

### Synonym

Multiple trauma defined as having at least 2 or more traumatic injuries of which at least one is life threatening, several severe injuries

### Health condition

multi-trauma

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Stichting Revalidatie Limburg

**Source(s) of monetary or material Support:** ZONMW;programma Doelmatigheidsonderzoek

## Intervention

**Keyword:** clinical trial, cost-effectiveness, multiple trauma, rehabilitation

## Outcome measures

### Primary outcome

Primary outcome measures are \*quality of life\* and \*functional health status\* (SF-36, FIM).

### Secondary outcome

Secondary outcome measures are \*anxiety and depression\*, \*cognitive functioning\* and \*extent to which individual ADL treatment goals are met\* (HADS, MMSE, COPM). Also costs will be assessed (cost-questionnaire).

## Study description

### Background summary

Annually +/- 99.000 people are admitted to hospital after an accident. 880.000 people visit the accident & emergency department (A&E) after an accident. These accidents lead to considerable societal costs. Direct medical costs are estimated at 1 billion euro annually, i.e. 3-4% of the total Dutch health care budget. Production losses due to acute trauma are estimated at 4 billion euro.

In conventional multi-trauma care service (CTCS) each of the partners has its own more or less autonomous treatment perspective, depending on the professional's individual treatment views and experience. Clinical evidence, however, suggests that an integrated multi-trauma rehabilitation service approach or \*Supported Fast track multi-Trauma Rehabilitation Service\* (SFTRS), featuring:

- 1) shorter stay in hospital and earlier transfer of multi-trauma patients to a specialised trauma rehabilitation unit
  - 2) an earlier start of both specific \*non-weight bearing\* rehab training and multidisciplinary treatment
  - 3) early individual goal setting
  - 4) an integrated co-ordination of treatment between trauma surgeon and rehabilitation physician
  - 5) shorter stay in trauma rehab unit
- may be more (cost-)effective.

SFTRS is expected to lead to:

- \* optimisation of treatment
- \* reduction of secondary complications
- \* reduction of function loss associated with prolonged bed rest (e.g. muscle atrophy, endurance loss, contractures)
- \* achievement of an optimal level of functioning, participation and quality of life.

## **Study objective**

The main objective is to examine the effectiveness, the costs and the cost-effectiveness of an integrated \*fast track\* rehabilitation service for multi-trauma patients (SFTRS) involving dedicated early rehab intervention programs. The SFTRS is contrasted with conventional multi-trauma care\*.

## **Study design**

In a prospective, multi-centre, non-randomised clinical trial 164 (2x 82) multi-trauma patients will participate. The duration of follow-up is 12 months. One group of patients will follow the SFTRS treatment, whereas the second group will receive conventional multi-trauma care.

## **Study burden and risks**

There is no risk to the patient regarding his/her participation in this study. Data will be collected from medical files and questionnaires.

## **Contacts**

### **Public**

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## **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

- Age  $\geq 18$  years
- multi-trauma
- Injury Severity Scale (ISS)score  $\geq 16$
- Hospitalisation after A&E admission
- Rehabilitation indication, i.e. lasting impairments or handicaps are expected
- Adequate Dutch language skills

### **Exclusion criteria**

- Alcohol and/or drug abuse
- Severe psychiatric problems

## **Study design**

## Design

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	
Recruitment status:	Recruiting
Start date (anticipated):	01-03-2008
Enrollment:	640
Type:	Actual

## Ethics review

Approved WMO	
Date:	20-02-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

## 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	NL20890.022.07