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Supported fast track multi-trauma rehabilitation service

Submission date	Recruitment status	[X] Prospectively registered
13/08/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/08/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/12/2019	Injury, Occupational Diseases, Poisoning	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ZonMw: 17088.2704; NTR1391

Study information

Scientific Title
Cost-effectiveness of an integrated fast track rehabilitation service for multi-trauma patients

Acronym
SFTRS

Study objectives
It is hypothesised that, from a societal point of view, the supported fast track multi-trauma rehabilitation service (SFTRS) is more (cost) effective relative to the conventional multi-trauma care service (CTCS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of the Rehabilitation Foundation Limburg, February 2008

Study design
Prospective multi-centre non-randomised clinical trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request patient information material

Health condition(s) or problem(s) studied
Multi-trauma rehabilitation

Interventions
Supported fast track multi-trauma rehabilitation service:
SFTRS involves the following:
1. The rehabilitation physician from the rehabilitation centre is routinely involved at a very early stage post-trauma. This allows an early start for multidisciplinary rehabilitation treatment.
2. Early transfer (within five days after having been added to the waiting list from the rehabilitation centre) to a centralised, specialised trauma rehabilitation unit equipped with facilities for early training programs
3. Early individual rehabilitation goal setting

4. Close co-operation and exchange of views and experiences between the trauma surgeon and the rehabilitation team by, for example, monthly clinical sessions and individual patient visits by the trauma surgeon in the first weeks after discharge
5. Well-documented treatment protocols for multi-trauma patients for both the hospital and rehabilitation centre phases

Three phases can be identified in the treatment of multi-trauma patients:
1. Early rehabilitation phase
2. Stage II rehabilitation phase
3. Discharge or post-discharge phase

Phase 1: Early rehabilitation phase
In the early rehabilitation phase, the patient is not allowed to mobilise weight bearing. Consequently, the physiotherapist is concerned with maintaining joint mobility, muscle strength, sitting balance, condition and training transfers as well as treatments with non-weight-bearing conditions such as hydrotherapy and non-weight-bearing gait training. There are 10 sessions per week of 30 minutes each. In addition, fitness, gymnastics, table tennis, swimming, bowling, hand bike, wheelchair training, and archery are given. There are 2 - 3 sessions per week for each treatment modality of 60 minutes each. The occupational therapist advises on bed posture, mattress types, aids for independent daily self-care, wheelchair-dependency training and meaningful activities that can be performed while bedridden. In addition, the wheelchair accessibility and wheelchair friendliness of the patient's home are studied. If necessary, written and oral advice on temporary and long-term adaptations to the home is given and support is given and the patient is helped to apply for financial support so that the patient can return home as soon as possible. At first, this would be for a day or two at the weekend, supervised by an occupational therapist, but would later become permanent. With regard to work, the patient's job is analysed and the patient's workplace is visited. There are 4 sessions per week of 30 minutes each. The social worker and the psychologist will see every multi-trauma patient within the first week after admission. The social worker helps the patient to return home by dealing with the family and offering advice and support to the patient on financial matters, transport facilities. The social worker also contacts the employer and company doctor to look into the possibility of reintegrating the patient into their present job. The psychologist will examine the patient with regard to such things as mood disorders, post-traumatic stress syndrome (PTSS), acceptance problems and cognitive problems. The latter requires extensive neuropsychological testing. In addition, individual and group psychological counseling and specialised treatment for PTSS are given. If necessary, the rehabilitation specialist can refer the patient to a consultant in psychiatry, a consultant in neurology, a consultant in internal medicine, a consultant in rheumatology and/or a consultant in urology, who come to the rehabilitation centre.

Phase 2: Stage II rehabilitation phase
In the Stage II rehabilitation phase, new treatment aims are added by the physiotherapist. These might include a gradual individual weight bearing scheme, co-ordination training and functional training. There are 7 therapy sessions per week of 30 minutes. In addition, fitness, gymnastics, table tennis, swimming, rowing, cycling and archery are given. This is offered in 2 - 4 sessions per week for each treatment modality of 60 minutes each.
The occupational therapist continues with the treatment goals as mentioned for phase I and trains the patient to perform household tasks, hobbies, etc. in a home-like environment. There are three sessions per week of 30 minutes each. In addition, group therapies such as occupational therapy and recreational therapy are given 2 - 4 times per week each. The social worker and the psychologist continue the work mentioned in phase I, depending on the individual needs of each patient.

Phase 3: (Post) discharge phase
In the discharge phase, the patient is prepared for living at home and is referred to local physiotherapists, specialised sport clubs and mental health care professionals.

Conventional multi-trauma care service:
CTCS is provided in several centres. Multi-trauma patients are admitted to hospital via the A&E department. After possible surgery, they are transferred to the IC-unit, followed by the hospital's nursing ward, where the patient may stay for several days or weeks. The trauma surgeon, as chief consultant, decides whether or not a rehabilitation physician will be consulted during hospitalisation. Next, ensuing treatment may take place in the hospital's outpatient clinic, in a rehabilitation centre, in a nursing home or with a local GP or physiotherapist. Typically, each of the CTCS "stages" may have its own more-or-less autonomous treatment perspective, depending on the professionals individual treatment views and experience.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Generic quality of life: 36-item Short Form Health Survey (SF-36)
2. Functional health status: Functional Independence Measure (FIM)

Outcome measures are collected at baseline (i.e. as soon as possible after trauma), 3, 6, 9 and 12 months post-trauma, i.e. T0, T1, T2, T3 and T4.

Secondary outcome measures
1. Extent to which individual ADL treatment goals are met: Canadian Occupational Performance Measure (COPM)
2. Anxiety and depression: Hospital Anxiety and Depression Scale (HADS)
3. Cognitive functioning: Mini-Mental State Examination (MMSE)

Next to that costs will be assessed using the PRODISQ, a cost questionnaire and data from the hospital databases. Outcome measures are collected at baseline (i.e. as soon as possible after trauma), 3, 6, 9 and 12 months post-trauma, i.e. T0, T1, T2, T3 and T4.

In studies comparing the effectiveness of different treatment regimes, differences in treatment credibility and expectancy may influence the outcome. In the proposed study the credibility /expectancy questionnaire (CEQ) will be administered directly following the explanation of the studys rationale to patients, i.e. after informed consent has been obtained.

Overall study start date
01/10/2008

Completion date
31/12/2012

Eligibility

Key inclusion criteria
Multi-trauma patients admitted to one of the Accident and Emergency Departments (A&E) of the participating hospitals are included. Multi-trauma is defined as having at least two or more injuries of which at least one is life-threatening, including:
1. Trauma with an Injury Severity Scale score (ISS) greater than or equal to 16
2. Complex multiple injuries on both lower extremities
3. A combination of one upper and one lower extremity injury, the latter of which can not be used in load-bearing, or
4. Complex pelvis/acetabulum fractures

Inclusion criteria are:
1. Aged 18 years or over, either sex
2. Multi-trauma (as defined above)
3. Hospitalisation after A&E admission
4. Rehabilitation indication, i.e. lasting impairments or handicaps are expected
5. Adequate Dutch language skills

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
164 patients admitted to one of the participating rehabilitation centres

Total final enrolment
132

Key exclusion criteria
1. Alcohol and/or drug abuse
2. Severe psychiatric problems

Date of first enrolment
01/10/2008

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
Adelante Rehabilitation Centre (formerly: Rehabilitation Foundation Limburg)
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Sponsor information

Organisation
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Sponsor type
Research organisation

Website
http://www.adelante-zorggroep.nl

ROR
https://ror.org/04f03nc30

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw (ref: 17088.2704)

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/01/2017		Yes	No
Results article	cost-effectiveness results	22/03/2019	18/12/2019	Yes	No