Evaluation of a new Transmural Trauma Care Model (TTCM) for the rehabilitation of trauma patients: a study protocol.

Gepubliceerd: 12-10-2015 Laatst bijgewerkt: 13-12-2022

1) The TTCM is effective in terms of HR-QOL, pain, functional status, patient satisfaction and perceived recovery compared to regular care in trauma patients with at least one fracture. 2) The TTCM is cost-effective from a societal perspective (...

Ethische beoordeling Positief advies **Status** Werving gestart

Type aandoening

Onderzoekstype Interventie onderzoek

Samenvatting

ID

NL-OMON21841

Bron

Nationaal Trial Register

Verkorte titel

TRAUFY

Aandoening

trauma patients, fractures, transmural care, rehabilitation, cost-effectiveness

Dutch: traumapatiënten, fracturen, transmurale zorg, revalidatie, kosteneffectiviteit

Ondersteuning

Primaire sponsor: VU University Medical Center **Overige ondersteuning:** Zilveren Kruis-Achmea

VU University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Health Related-Quality of Life (HR-QOL), measured with the EQ5D

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

During the past two decades, an improved organization of trauma care in the acute phase has reduced mortality of trauma patients. However, there has been limited attention for the optimal organization of the post-clinical rehabilitation of trauma patients. To improve this post-clinical rehabilitation we developed a Transmural Trauma Care Model (TTCM). This TTCM consists of four equally important components: 1) Intake and follow up consultations by a multidisciplinary team consisting of a trauma surgeon and a highly specialized hospital based trauma physical therapist, 2) coordination and individual goal setting for each patient by this team, 3) primary care physical therapy by specifically trained trauma physical therapists organized in a network and 4) E-health support for transmural communication (between hospital based trauma physical therapist and primary care based physical therapist) and treatment according to protocols. The aim of the current study is to assess the cost-effectiveness of the TTCM in trauma patients that have at least one fracture and rehabilitate in primary care after clinical treatment.

Methods/Design

Patients will be recruited from the outpatient clinic for trauma patients of the VU University Medical Center (VUmc) if they have at least one fracture and were discharged home. A controlled-before-and-after study design will be used to compare the TTCM with regular care. Measurements will take place within one week after the first outpatient clinical visit and after 3, 6 and 9 months. Prior to the implementation of the TTCM, 200 patients (50 patients per time point) will be included in the control group. After implementation 100 patients will be included in the intervention group and prospectively followed. Between-group comparisons will be made separately for each time point. In addition, the recovery pattern of patients in of the intervention group will be studied using longitudinal data analysis methods. Effectiveness will be evaluated in terms of health-related quality of life (HR-QOL), pain, functional status, patient satisfaction, and perceived recovery. Cost-effectiveness will be assessed from a societal perspective, meaning that all costs related to the TTCM will be taken into account including intervention, health care, absenteeism, presenteeism and unpaid productivity. Additionally, a process evaluation will be performed to explore the extent to which the TTCM was implemented as intended, and to identify the possible facilitators and barriers associated with its implementation.

Discussion

This study will give us a first indication of the cost-effectiveness of the TTCM and help us to further develop and improve post-clinical trauma care.

Doel van het onderzoek

- 1) The TTCM is effective in terms of HR-QOL, pain, functional status, patient satisfaction and perceived recovery compared to regular care in trauma patients with at least one fracture.
- 2) The TTCM is cost-effective from a societal perspective (including intervention costs, health care costs, absenteeism, presenteeism and unpaid productivity) compared to regular care.

Onderzoeksopzet

Baseline, 3, 6 and 9 months

Onderzoeksproduct en/of interventie

Patients in the intervention group will receive care according to the TTCM at the outpatient clinic for trauma patients at the VUmc. Pre- and in-hospital trauma care remains unchanged and is equal to that provided to the control group. The essence of the TTCM is a regular feedback loop, in which the hospital team guides the primary care team by individual goal setting for each patient (see Figure 2 for a schematic representation of the TTCM). The TTCM consists of four main components and will be explained below:

- a) Intake and follow up consultations by a multidisciplinary team consisting of a trauma surgeon and a highly specialized hospital based trauma physical therapist. The trauma surgeon acts as the chief consultant and is responsible for assessing the bone- and wound healing process and additional medical procedures, such as the prescription of medication and indicating surgery. The hospital based physical therapist, on the other hand, assesses physical function (e.g. mobility, strength, walking pattern). The trauma surgeon and hospital based physical therapist indicate -as a team- if and when physical therapy in primary care is needed.
- b) Coordination and individual goal setting for each patient by the multidisciplinary hospital team. This hospital team coordinates the patients' rehabilitation process. The hospital based trauma physical therapist acts as case manager and repeatedly sets individual goals with the patient during the rehabilitation period.
- c) Primary care physical therapy by specifically trained trauma physical therapists organized in a network.

This innovative "VUmc trauma rehabilitation network" consists of 40 physical therapists covering the region of Amsterdam. Patients in the intervention group with an indication for physical therapy treatment in primary care will be referred to one of the specialized trauma physical therapists of the VUmc trauma rehabilitation network. Prior to the implementation of TTCM, all 40 network physical therapists will follow a two-day training course led by trauma

surgeons and hospital physical therapists. The course covers topics such as fracture healing, fracture treatment, complications and the most important principles of trauma rehabilitation. In addition, written working agreements will be discussed during the training course to assure optimal communication and use of IT services.

d) E-health support for transmural communication (between hospital based trauma physical therapist and primary care based physical therapist) and treatment according to protocols.

For the purpose of the TTCM, an existing electronic patient record is adapted and 10 rehabilitation protocols have been developed for the most common fractures (e.g. hip, tibia, ankle, proximal humerus, vertebra), which will function as guidelines for the primary care trauma physical therapists. The protocols are linked to a secured email device through which hospital physical therapist and the primary care physical therapist will communicate repeatedly throughout the whole rehabilitation process.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 1) Trauma patients of the VU Medical Center with least one traumatic fracture
- 2) Aged >18 years
- 3) Able to fill out online questionnaires

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 1) Patients with traumatic brain injury, pathological fractures, and/or cognitive limitations.
- 2) Patients who do not speak Dutch,
- 3) Patients of whom the rehabilitation process takes place in a tertiary care facility,
- 4) patients who live outside the catchment area of the VU Medical Center

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel: Parallel

Toewijzing: Niet-gerandomiseerd

Blindering: Open / niet geblindeerd

Controle: Actieve controle groep

Deelname

Nederland

Status: Werving gestart

(Verwachte) startdatum: 01-01-2014

Aantal proefpersonen: 500

Type: Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 12-10-2015

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register ID

NTR-new NL5373 NTR-old NTR5474

Ander register METc VUmc : 2013.454

Resultaten