Effectiveness and cost-effectiveness of the Transmural Trauma Care Model (TTCM), a non randomized controlled multicenter trial

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Primary objective: The primary objective of this study is to assess the effectiveness and cost-effectiveness of the Transmural Trauma Care Model (TTCM) as compared to usual care.The research question addressed is:Is the Transmural Trauma Care Model…

Ethical review	Approved WMO
Status	Completed
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON52603

Source
ToetsingOnline

Brief title
Transmural Trauma Care Model

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym
broken bone, fracture

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: cost-effectiveness, fracture, rehabilitation, trauma

Outcome measures

Primary outcome

Co-primary outcomes

The co-primary outcomes are generic quality of life (EQ 5D-5L) and

disease-specific quality of life (standardized Patient Reported Outcomes

[PROMS]). Choice of measurement of dis-ease-specific quality of life depends on

trauma location:

- upper extremity: QuickDASH DLV

- lower extremity: Lower Extremity Functional Scale (LEFS)

- multiple fractures and/or more locations: Groningen activiteiten restrictie

schaal (GARS)

- back: The Roland Morris Disability Questionnaire (RMDQ)

Co-primary outcomes are measured at baseline, 6 weeks, 3 months, 6 months and 9

months.

Secondary outcome

At baseline, relevant patient characteristics and important prognostic

variables are measured (patient characteristics/ trauma characteristics).

Secondary outcomes include functional status (Patient-Specific Functional Scale

PSFS), pain (11-point NRS), patient satisfaction (11-point NRS), perceived recovery (7- point Global Per-ceived Effect Scale) and patient-reported health based on physical functioning (PROMIS-PF(-UE)). For the economic evaluation, societal and healthcare costs are measured. Sec-ondary outcomes are measured at baseline, 3 months, 6 months and 9 months.

For the economic evaluation, societal as well as healthcare costs are assessed. Societal costs include all costs related to the TTCM, irrespective of who pays or benefits. Healthcare costs only include costs accruing to the formal Dutch healthcare sector. Intervention costs are micro-costed. Cost questionnaires based on the iMCQ (iMTA Medical Consumption Questionnaire), iPCQ (iMTA Productivity Cost Questionnaire), and WHO-HPQ (World Health Organization Health and Work Performance Questionnaire) are administered at baseline, 3, 6 and 9 months follow-up to collect data on healthcare utilization, the use of informal care, absenteeism, presenteeism and unpaid productivity losses [57]. Health care utilization includes the use of primary care (e.g. consultations at the general practitioner or physical therapist) and secondary care (e.g. consultations at the outpatient clinic for trauma patients, hospitalization) as well as the use of medication. Dutch standard costs are used to value healthcare costs [57]. Medication use is valued using the G-standard of the Dutch Society of Pharmacy [58]. Absenteeism is assessed by asking patients to report their total number of sick leave days [59]. Absenteeism is valued using gender-specific price weights [57]. Presenteeism is defined as reduced productivity while at work and is assessed using the WHO-HPQ [60]. Presenteeism

is valued using gender-specific price weights [57]. Unpaid productivity losses are assessed by asking patients for how many hours per week they were unable to perform unpaid activities, such as domestic work, school and voluntary work. Informal care is assessed by asking patients for how many hours per week they received help from family and friends. A recommended Dutch shadow price is used to value unpaid productivity and informal care [57].
All costs are presented in Euro and are converted to the same reference year using consumer price indices. Discounting of costs is not necessary due to the 9-month follow-up period

A qualitative process evaluation is performed to evaluate the implementation of the TTCM, and to identify possible facilitators and barriers associated with its implementation.
Treatment adherence in the control group is registered using the following process variables: number of post- clinical consultations of the trauma surgeon, discharge location, referral to primary care well or not and if so number of sessions attend by a patient at the primary care physical therapist.
In the intervention group treatment adherence is registered using the fol-lowing process variables: is the outpatient consultation provided by a trauma surgeon and a physical therapist (yes/no), is the standardized referral form used (yes/no), are the functional goals described (yes/no), are e-mails exchanged between hospital physical therapist and net-work physical therapist (yes/no) and the number of sessions attend by a patient at the primary care

physical therapist.

Study description

Background summary

Trauma remains one of the most common causes of death and disability worldwide. The economic burden of trauma is high. In the Netherlands, 80,000 patients were treated in trauma centers in 2017. Each year, traumatic injuries cost an estimated 300 million years of healthy life, translating to 11% of disability adjusted life years (DALY*s) experienced worldwide. An estimated 37 million trauma-related emergency visits occur yearly, of which 2.6 million result in a hospital admis-sion. Traumatic disorders rank among the five most costly medical conditions. The lifetime costs of traumatic injuries have been estimated at $406 billion dollars, with $80 billion repre-senting healthcare costs. The majority of trauma-related costs is due to increased absentee-ism and lost productivity.
Due to trauma*s major clinical and economic impact there has been an increased interest in the organization of trauma care. Trauma care is characterized as a chain of services, consisting of pre-hospital care, resuscitation and in-hospital care. In the last two decades, an improved organization of pre- and in-hospital trauma care has led to a 9%-25% decrease in mortality of severe trauma patients.
Since mortality has decreased significantly, it has been suggested that the focus of trauma care should shift to improving HR-QOL. This is because further improvements in survival rates are likely to be small. To improve patients* generic and disease-specific quality of life, more attention for optimizing the rehabilitation phase is crucial. The organization of the post-clinical rehabilitation of trauma patients is challenging and there are no nationally or inter-nationally coordinated trauma rehabilitation guidelines for the treatment of outpatients with trauma. Serious gaps exist between patients* transition from acute care to rehabilitation and their return to society. Research shows an under- and overtreatment of trauma patients by non-experienced physical therapists in primary care and a lack of assessment of trauma patients* physical functioning at the outpatient clinic. A trauma surgeon is not familiar with it and there are no clear recommendations about the choice of assessments.
After discharge from a hospital, the majority of Dutch trauma patients rehabilitate in primary care (mostly treated by a physical therapist). In contrast to secondary/tertiary care, guidelines an interdisciplinary coordination is lacking in primary care and the contact between primary and secondary care is minimal. A recent feasibility study among osteoarthritis patients showed improvements in health-related quality of life, function and patient satisfaction when primary care was coordinated by a clinical case manager (mostly a hospital based physical therapist or nurse practitioner) who

was in close contact with the surgeon. Bouman recently published an article of the effects of a fast-track rehabilitation service to tertiary care for multi-trauma patients. While patients received fast-track rehabilitation and usual care both improved in terms of their functional status and HR-QOL, no differential effects between groups were found. Not a faster discharge but an optimization of the collaboration in the reha-bilitation team as well as a concentration of knowledge and experience seemed to have im-prove the rehabilitation process of multi-trauma patients in both groups.
A feasibility study indicated that the implementation of a so-called Transmural Trauma Care Model (TTCM) at a Dutch level-one trauma center was feasible, that outcomes for patients were improved and costs were reduced. The Transmural Trauma Care Model (TTCM) for trauma patients with at least one fracture, aims to improve patient outcomes by refining the organization and quality of the post-clinical rehabilitation process [1]. Next to the aforemen-tioned health and financial effects of the TTCM, patients receiving the TTCM were also found to be more satisfied with the communication between the primary care and secondary care healthcare provider and with the presence of the physical therapist during the consultation with the trauma surgeon. However, in the feasibility study we had only access to cross-sectional control data, which may have biased our results to some extent. Therefore, the aim of the current study is to assess the effectiveness and cost-effectiveness of the TTCM as compared to usual care in a longitudinal, prospective multicenter trial with a before-and-after design.

The responsible institution for conducting the research is: Amsterdam UMC, VUmc location. The research is set up by Amsterdam UMC (location VUmc) and will be conducted by researchers from the Amsterdam UMC (location VUmc) and VU University Amsterdam, in collaboration with trauma surgeons and physiotherapists from various other Dutch hospitals.

Study objective

Primary objective: The primary objective of this study is to assess the effectiveness and cost-effectiveness of the Transmural Trauma Care Model (TTCM) as compared to usual care.

The research question addressed is:
Is the Transmural Trauma Care Model (TTCM) effective and cost-effective compared to usual care in post-clinical rehabilitation of trauma patients?

Answers to these questions are based upon the following validated outcomes:
a) Co-primary outcomes: generic quality of life (EQ 5D-5L) and disease-specific quality of life (standardized Patient Reported Outcomes [PROMS]). Choice of measurement of disease-specific quality of life depends on trauma location:
- upper extremity: QuickDASH DLV
- lower extremity: Lower Extremity Functional Scale (LEFS)
- multiple fractures and/or more locations: Groningen activiteiten restrictie

schaal (GARS)
- back: The Roland Morris Disability Questionnaire (RMDQ)
b) Secondary outcomes: functional status (Patient-specific Functional Scale PSFS), pain (11-point NRS), patient satisfaction (11-point NRS), perceived recovery (7-point Global Perceived Effect Scale) and patient-reported health based on physical functioning (PROMIS-PF CAT, PROMIS-PF-UE CAT). Choice of measurement of patient-reported health based on physical functioning depends on trauma location:
- lower extremity/ back/ multiple fractures, more locations: PROMIS-PF
- upper extremity: PROMIS-PF-UE
c) For the economic evaluation, societal and healthcare costs are assessed. This is described in detail in section 6 Methods (6.1.3 Other outcomes) and section 8 Statistical analysis (8.3 Other outcomes).
d) A qualitative process evaluation is performed to evaluate the implementation of the TTCM, and to identify possible facilitators and barriers associated with its implementation.

Hypothesis:
The TTCM is effective and cost-effective for generic and disease-specific quality of life, func-tional status, pain, and perceived recovery compared to usual care. Also, patients receiving the TTCM are hypothesized to be more satisfied with the communication between the primary care and secondary care healthcare provider and with the presence of the physical thera-pist during the consultation with the trauma surgeon than those receiving usual care.

Study design

This study is a multicenter trial in ten hospitals in The Netherlands with a controlled before-after design and economic evaluation. The non-randomized nature of the trial is dealt with using propensity score weights.
In this project, the pre- and in-hospital trauma care remains unchanged and is described in the LNAZ (Landelijk Netwerk Acute Zorg) recommendations [26]. At the start of the study, all par-ticipating hospitals include 322 patients in a control group. Inclusion takes place during the patients* first outpatient consultation with a trauma surgeon at the outpatient clinic of the participating hospitals. The control group receives usual care, where the trauma surgeon per-forms post-clinical consultations individually (2 to 10 consultations, depending on the severity of the trauma). The trauma surgeon focuses on fracture- and wound healing and medication management. Based on the clinical judgment of the surgeon, a patient might be referred to primary care, but there is no standardized policy for these referrals. If referred to a physical therapist, patients typically select their own physical therapist in primary care. Control group measurements take place at baseline, 6 weeks (co-primary outcomes only), 3 months, 6 months and 9 months. After the control period of investigating usual care, the Transmural Trauma Care Model is implemented in each hospital during a 6-month implementation phase. Subsequently, participating hospitals again include 322 patients, but now in

the intervention group. Again, inclusion takes place at the patients* first outpatient consultation with a trauma surgeon and measurements take place at baseline, 6 weeks (co-primary outcomes only), 3 months, 6 months and 9 months (Figure 1).
Treatment adherence in the control group is registered using the following process variables: number of post- clinical consultations of the trauma surgeon, referral to primary care well or not and if so number of sessions attend by a patient at the primary care physical therapist. In the intervention group treatment adherence is registered using the following process variables: is the outpatient consultation provided by a trauma surgeon and a physical therapist (yes/no), is the standardized referral form used (yes/no), are the functional goals described (yes/no), are e-mails exchanged between hospital physical therapist and network physical therapist (yes/no) and the number of sessions attend by a patient at the primary care physical therapist.

Intervention

In this project, pre- and in-hospital trauma care remains unchanged and is described in the LNAZ (Landelijk Netwerk Acute Zorg) recommendations [26]. The main aim of the TTCM is to improve trauma rehabilitation (i.e. improved health outcomes and reduced costs) by an increased focus on physical functioning, quality of life and a regular feedback loop between the hospital-team and the primary care physical therapy- network.
In the TTCM, a multidisciplinary team consisting of a trauma surgeon and a specialized hospi-talized based physical therapist examines the patients during his or her outpatient consulta-tions and coordinates the complete process of rehabilitation from the beginning to the end. Individual goal setting, an improved alignment of primary and secondary care (e.g. through a structured communication process), and a well-educated network of primary care physical therapists are important pillars of the TTCM.
This is accomplished by de following four components of the TTCM:
1) Intake and follow-up consultations by a multidisciplinary team on the outpatient clinic:
This joint consultation is carried out by a trauma surgeon and a specialized hospital-based trauma physical therapist. The trauma surgeon is responsible for medical procedures (e.g. indicating surgery, fracture- and wound healing), whereas the physical therapist assesses physical function (e.g. mobility). Before the intake the patient agrees with presence of a phys-ical therapist during this consultation on the outpatient consultation of the trauma surgeon.
2) Coordination and individual goal setting:
The hospital team coordinates the care, and the hospital-based physical therapist acts as a case manager throughout the rehabilitation process. Treatment goals are formulated at a functional level for each individual patient.
3) A transmural trauma rehabilitation primary care network of specifically trained trauma physical therapists:
The innovative 'trauma rehabilitation physical therapy- network' consists of

about 40 primary care physical therapists per hospital. All network physical therapists receive a at least two-day training by the hospital team, during which they are trained in treating patients with trauma.
4) E-health support for transmural communication (between hospital based physical therapist and network physical therapist) and treatment according to protocols:
A secured e-mail system is implemented in order to enable communication between the hos-pital physical therapist and the network physical therapist allowing them to exchange patient data. Moreover, electronic patient records are adapted and ten already developed rehabilita-tion protocols for the most common fractures (e.g. hip) are used by the primary care physical therapist. The protocols are linked to a secured email device through which case manager and primary care physical therapist communicate.

Study burden and risks

The risks associated with participation in this study are equal to the risks associated with daily practice. Currently, daily practice differs per hospital and treating doctor.
Based on the clinical judgment of the surgeon, a patient might be referred to primary care, but there is no standardized policy for these referrals. If referred to a physical therapist, patients select their own physical therapist in primary care. After implementing the TTCM daily practice is clearly structured, individual patient-oriented choices can be made and well-educated networks exist. Previous research in other patient groups indicates that post-clinical care organized in networks of experienced and specialized healthcare providers is likely to result in better clinical outcomes and lower costs compared to usual care models. Therefore, there is no additional risk for participants for taking part in this study.
Every treatment is associated with some risks. Patients receive the treatment that is usual in the participating hospital. As a result of this treatment, as with any medical and/or physical therapy treatment, patients can experience some short-term increase in discomfort and/or pain. The estimated extra risks associated with the study are minimal and no complications are expected. The TTCM has already been investigated in a feasibility study in Amsterdam UMC, location VUmc. Since then the TTCM is part of usual care in Amsterdam UMC, location VUmc. The feasibility study of Wiertsema [1] showed no additional risks to the patients due to TTCM. The limited additional burden that patients may experience is, completing questionnaires (both groups).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Age >= 16 years old
• 1 or more fracture(s) as a result of a trauma
• Able to fill in online questionnaires in Dutch
• Able to give informed consent
• At least one outpatient consultation of the trauma surgeon

Exclusion criteria

• Patients with traumatic brain injury
• Pathological fractures
• Severe psychopathology (e.g. schizophrenia, high risk suicidality)
• Cognitive limitations
• Living in an institution (e.g. nursing home)
• Does not speak/ understand Dutch

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	27-01-2020
Enrollment:	644
Type:	Actual

Ethics review

Approved WMO Date:	01-10-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-11-2019
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-02-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-08-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-08-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-11-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL70243.029.19