TOWARDS AN OPTIMAL OUTCOME FOR TRAUMA PATIENTS

THE TRANSMURAL TRAUMA CARE MODEL

SUZANNE H. WIERTSEMA

Towards an optimal outcome for trauma patients

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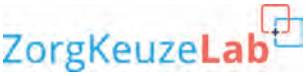
Suzanne Wiertsema

The research in this thesis was embedded within Amsterdam Movement Sciences Research Institute, the Department of Rehabilitation Medicine, the Department of Trauma Surgery and the Department of Epidemiology and Data Science, Amsterdam UMC, location VUmc, Amsterdam, The Netherlands & the Department of Health Sciences, Faculty of Science, VU University, Amsterdam, The Netherlands.

The studies described in this thesis where were funded by "Zilveren Kruis Health Insurer" (grant number Z516) and ZonMw (grant number 80-85200-98-91009).

Financial support for the printing of this thesis has been kindly provided by Netwerk Acute Zorg Noordwest, FysioRoadmap, Nederlandse Vereniging voor Traumachirurgie (NVT), Zorgkeuzelab, the Scientific College Physical Therapy (WCF) of the Royal Dutch Society for Physical Therapy (KNGF) and the Dutch Institute of Allied Health Care (NPi).



Towards an optimal outcome for trauma patients
The Transmural Trauma Care Model
Thesis, VU University, Amsterdam, The Netherlands

Cover	Wendy Schoneveld | wenz iD
Photography	Patients provided photos from their private collection and gave written consent for using them. The photos show patients that achieved their personal rehabilitation goal.
Layout	Renate Siebes | Proefschrift.nu
Printed by	ProefschriftMaken | De Bilt
ISBN	978-94-90791-85-8

VRIJE UNIVERSITEIT

Towards an optimal outcome for trauma patients

The Transmural Trauma Care Model

ACADEMISCH PROEFSCHRIFT

ter verkrijging van de graad Doctor
aan de Vrije Universiteit Amsterdam,
op gezag van de rector magnificus
prof.dr. V. Subramaniam,
in het openbaar te verdedigen
ten overstaan van de promotiecommissie
van de Faculteit der Geneeskunde
op vrijdag 2 juli 2021 om 11.45 uur
in de aula van de universiteit,
De Boelelaan 1105

door

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geboren te Nieuwegein

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“I was not talented enough to run and smile at the same time.”

Emil Zátopek, winner of three golden medals in the Helsinki Olympics 1952
(5K, 10K and marathon)

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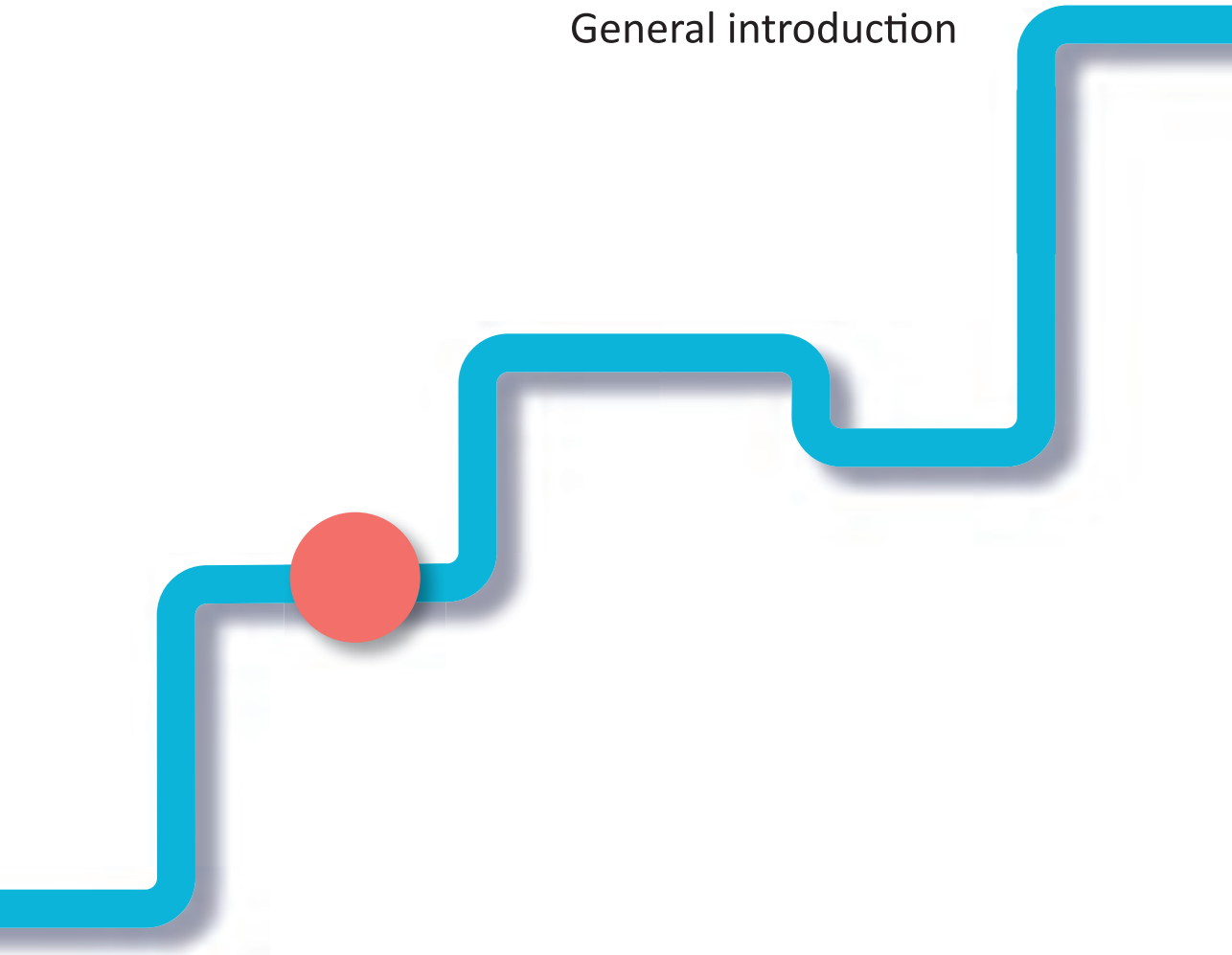
CO (79) | FELL DOWN THE STAIRS 1 YEAR AGO

Cervical, thoracic and lumbar fractures

1

General introduction



INTRODUCTION

Traumatic injury is a major global health problem, and one of the main causes of death and disability worldwide [1,2]. It accounts for 9.6% of global mortality and major trauma in particular was found to be the most important cause of long-term functional limitations in adults younger than 45 years [3,4]. Moreover, the disease burden of trauma is high and traumatic injuries rank among the five most costly medical conditions worldwide [5]. To illustrate, traumatic injuries cost the global population about 300 million years of healthy life per year, equaling 11% of the total number of disability adjusted life years (DALYs) experienced worldwide [6]. Furthermore, it is recognized that direct medical costs as well as lost productivity costs increase with injury severity [7]. During the last decades, trauma care improved substantially and mortality due to traumatic injury decreased accordingly [8,9]. Consequently, the focus of trauma care has moved from reducing mortality to improving quality of life and outcome, which in turn resulted in a growing interest in improving the quality of trauma rehabilitation [10].

FRACTURE HEALING AND TREATMENT

Most trauma patients have one or more fractures due to their trauma. A fracture is a complete or incomplete break in a bone, mostly as a result of an external force like a fall, an accident, or a sports-injury. Fractures are classified by describing the bone, the segment of the fractured bone, the fracture line (e.g. linear, oblique, transverse, longitudinal, spiral) and whether the fracture is dislocated or not [11]. Additionally, it is important to identify whether a fracture is open or closed and if accompanied neurological- and/or vascular damage occurred. Fractures have a major impact on a patient's functional status and health-related quality of life (HR-QOL) and the accompanying damage of soft tissue has a significant impact on treatment and outcome [12]. Treatment depends on the aforementioned fracture characteristics and patient characteristics, such as age, comorbidity, health status and activity level prior to the injury. Following the "damage control" phase in the emergency situation, including control of blood loss and monitoring vital signs, the primary goal of fracture treatment is reduction of the fracture, meaning realignment of the bone in its original position. Moreover, depending on fracture type, degree of (soft tissue) damage, and patient characteristics, the trauma surgeon decides upon the most optimal treatment strategy for a specific fracture. Treatment can be conservative (e.g. with a plaster, a sling or a limited weight-bearing policy) or surgical, which in most cases means intramedullary nailing or open reduction and internal fixation (ORIF) with plates and screws.

A fracture needs stability and an optimal biological situation to heal [13]. Roughly speaking, there are two pathways through which a fracture can heal. The first pathway, secondary (or indirect) bone healing, occurs in four fluent stages, all of which have considerable overlap, i.e. 1) hematoma formation, 2) fibrocartilaginous callus formation, 3) bony callus formation, and 4) bone remodeling (Figure 1.1). This recovery pathway typically occurs in conservatively treated fractures and after operative treatment with intramedullary nailing, during which some micro-motion occurs at the fracture site [14].

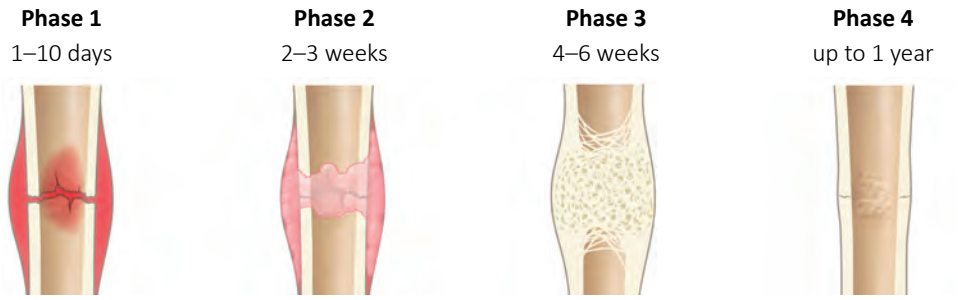


Figure 1.1 Secondary (or indirect) fracture healing.

The second pathway, primary (or direct) bone healing, needs a rigid fixation of fracture ends and can only occur by direct remodeling of lamellar bone, the Haversian canals and blood vessels (Figure 1.2). Primary fracture healing occurs without callus formation and typically occurs when fracture ends are rigidly fixated with a plate and screws and usually takes a few months up to one year (or more) [15]. During the trauma rehabilitation process, it is of utmost importance that the treating physical therapists have specific knowledge of fracture treatment and the stages of fracture healing, and are able to recognize possible complications during the fracture healing process.

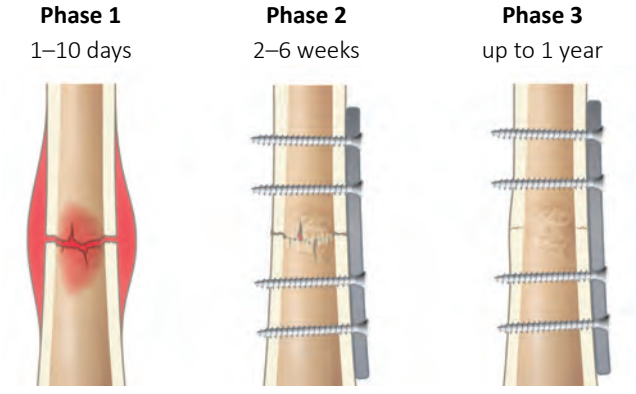


Figure 1.2 Primary (or direct) fracture healing.

TRAUMA AND FRACTURE REHABILITATION

Van Beeck et al. identified four stages of trauma recovery, i.e. 1) the acute treatment phase, 2) the rehabilitation phase, 3) the adaption phase, and 4) the stable end situation [16]. For physical therapists treating trauma patients it is important to deal with each phase of recovery in an appropriate way. As indicated above, in-depth knowledge of fracture classification, fracture treatment, and the process of normal fracture healing is needed. To illustrate, in the case of secondary fracture healing, micro-motion and weight-bearing enhance the healing process. However, too much motion and/or load is known to possibly result in delayed healing or even non-union [17]. On top of that, it is important that physical therapists are able to recognize signs of abnormal fracture healing and other possible complications in order to timely adapt their treatment plan and inform the responsible trauma surgeon. In doing so, they will be able to give – within a certain margin – an estimate of a trauma patient's length and outcome of the rehabilitation process. This is important, because it is recognized that managing trauma patients' expectations is a critical element of their rehabilitation process and necessary to achieve an optimal outcome [18]. Hence, rehabilitation of fractures is about guiding and coaching the trauma patient through the complex fracture healing process as well as finding the right balance between undertreatment and overtreatment. A helpful tool during this process is the International Classification of Functioning, Disability and Health (ICF) model, because its provides a framework to understand the extent of problems due to physical disorders (e.g. fractures) [19]. The ICF model includes environmental and personal factors in addition to function, activities and participation (Figure 1.3). During trauma- and fracture rehabilitation, physical therapists need to make sure that every domain of the ICF model is addressed and related to one another.

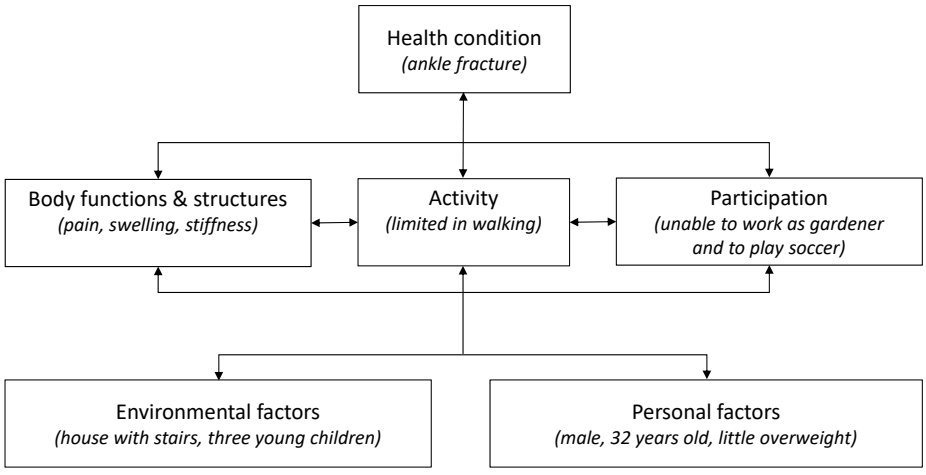


Figure 1.3 The ICF model applied to fractures.

ORGANIZATION OF TRAUMA CARE

Traditionally, the organization of trauma care focused on pre-hospital and in-hospital care more than on the rehabilitation phase, because trauma patients' survival was the first and most important goal [20]. Early rehabilitation was first mentioned as an important link in the trauma chain of survival in 2002 during the TraumaCare conference in Stavanger, Norway [21]. As illustrated in Figure 1.4, the trauma chain of survival consists of four links, with the last one being early rehabilitation that is aimed at restoring a trauma patient's HR-QOL.

Figure 1.4 The trauma chain of survival.

In recent decades, mortality of severe trauma patients decreased with the development of specialized trauma centers using Advanced Trauma Life Support (ATLS®) guidelines [8,9]. To illustrate, mortality due to traumatic injury decreased with 15–25% [8,9]. Consequently, the focus of trauma care shifted from reducing mortality to improving trauma patients' HR-QOL and outcome, which in turn resulted in a growing interest in improving the quality of trauma rehabilitation [10]. However, rehabilitation after trauma is challenging, for several reasons. First, the variety in cause, impact, and severity of traumatic injuries is large. Second, the trauma population differs widely in terms of patient characteristics, such as age, gender, socio-economic status and health status prior to the injury. Third, because of this wide variety in trauma patients' sociodemographic, injury-related, and physical determinants, recovery after injury is complex and is typically characterized by a large variety of recovery trajectories [22]. And fourth, whereas the acute care of trauma patients is systematically and concisely organized (e.g. through the Advanced Trauma Life Support® [ATLS®] program [23] and the existence of the AO/OTA classification system [11]), this is not the case for trauma rehabilitation, which seems to be a rather unexplored area. There is a lack of programs and guidelines for the rehabilitation of trauma patients following their medical treatment, and the ones we found merely focused on the most severely injured

trauma patients who typically needed an inpatient rehabilitation program [24]. Hence, it seems to be of great importance to develop patient-specific rehabilitation plans to improve outcomes, which might possibly be accomplished by formulating an individual rehabilitation plan for every single patient [22,25].

After being discharged from a hospital, the majority of Dutch trauma patients rehabilitated with the help of a primary care physical therapist, but their rehabilitation treatment was rarely based on trauma-specific guidelines and/or interdisciplinary coordination (e.g. between the physical therapist and the treating trauma surgeon). Although it is recognized that post-clinical care organized in primary care networks of experienced and specialized healthcare providers results in better clinical outcomes, this was typically lacking for trauma patients [26,27].

THE TRANSMURAL TRAUMA CARE MODEL

To contribute to the improvement of trauma rehabilitation, this thesis describes the development of the Transmural Trauma Care Model (TTCM), a joint initiative of hospital-based physical therapists and trauma surgeons, that aimed to improve trauma patients' outcomes after mild, moderate or severe injury, by refining the organization and quality of the rehabilitation process. The TTCM consists of four components, all of which are linked to one another (Figure 1.5).

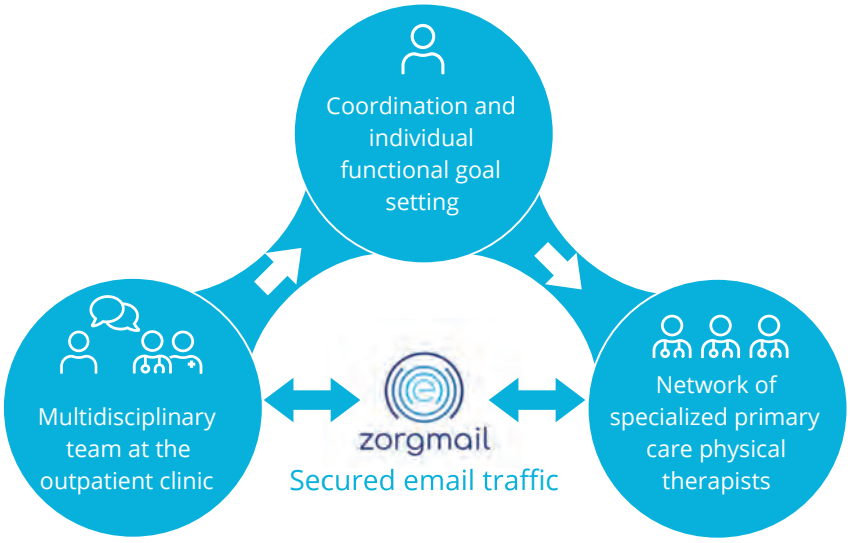


Figure 1.5 The Transmural Trauma Care Model.

1. **A multidisciplinary consultation hour at the outpatient clinic for trauma patients**. A trauma surgeon and a trauma-specialized hospital-based physical therapist examine the patient and focus on their own professional domain. Trauma surgeons evaluate the bone- and wound-healing process and act as chief consultant. The physical therapist assesses physical function and acts as case manager throughout the rehabilitation process.

2. **Coordination and individual functional goal setting for each patient by the multidisciplinary hospital-based team**. The hospital-based team coordinates the patients' rehabilitation process in primary care. In a shared-decision making process, functional rehabilitation goals are determined, which are repeatedly updated and adapted during the rehabilitation period. To support this process, 10 rehabilitation protocols for the most common fractures exist.

3. **A network of specialized primary care physical therapists**. This "Network Trauma Rehabilitation VUmc" consists of 40 specialized primary care physical therapists, each working in a primary care practice in the region of Amsterdam. They are specifically trained by the hospital-based team (www.traumarevalidatie.nl).

4. **Secured email traffic between the hospital-based physical therapist and the primary care network physical therapist**. A secured email system ("Zorgmail") for healthcare professionals is used for communication between the hospital-based physical therapist and the primary care network physical therapist throughout the rehabilitation process. For this purpose, the electronic patient records of both hospital and primary care practices were linked.

AIMS OF THE THESIS

In this thesis the development of the Transmural Trauma Care Model (TTCM) is described. The primary aim was to assess the effectiveness and cost-effectiveness of the TTCM within a controlled-before-and-after study. Secondary aims included the assessment of the TTCM's reach, dose delivered, dose received, and fidelity, supplemented by identifying possible barriers and facilitators associated with the implementation of the TTCM. Additionally, data collected in the context of this study were used to explore the association of specific trauma- and fracture-related factors with disease-specific HR-QOL, functional outcome, and costs and to further improve the TTCM. After receiving additional funding from ZonMw (grant number: 80-85200-98-91009) we are now in the process of assessing the generalizability and validity of our initial findings on the TTCM's effectiveness and cost-effectiveness in a multicenter trial.

OUTLINE OF THE THESIS

Chapter 2 describes the study protocol of the controlled-before-and-after study assessing the effectiveness and cost-effectiveness of the TTCM and describes the outline of the process evaluation.

Chapter 3 presents the results of the controlled-before-and-after study that assesses the effectiveness of the TTCM in trauma patients with at least one fracture, compared to regular care in terms of HR-QOL, pain, functional status, patient satisfaction, and perceived recovery.

Chapter 4 presents the results of the economic evaluation that was aimed at evaluating the cost-effectiveness of the TTCM from a societal perspective compared to regular care.

Chapter 5 describes the results of the mixed-methods process evaluation that provides insight in the possible barriers and facilitators associated with the implementation of the TTCM and in its reach, dose delivered, dose received, and fidelity.

Chapter 6 is aimed at assessing the association of specific trauma- and fracture-related factors with disease-specific HR-QOL, functional outcome, and costs in trauma patients with at least one fracture.

Chapter 7 describes the study protocol of a multicenter trial, which is based on the results of chapter 3, 4, 5 and 6 of this thesis. The multicenter trial aims to assess the effectiveness and cost-effectiveness of an improved version of the TTCM compared to regular care, on a wider scale and using an improved design.

Chapter 8 presents a general discussion and gives recommendations for clinical practice as well as recommendations for further research.

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STEVE (44) | MOTORCYCLE ACCIDENT 2 YEARS AGO

Crush injury lower leg

2

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

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BMC Health Serv Res. 2017;17(1):99

ABSTRACT

Background: 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 post-clinical rehabilitation of trauma patients. Therefore 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 trauma surgeon and hospital based trauma physical therapist, 2) coordination and individual goal setting for each patient by this team, 3) primary care physical therapy by specialized physical therapists organized in a network and 4) E-health support for transmural communication and treatment according to protocols. The aim of the current study is to assess the cost-effectiveness of the TTCM.

Methods: 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 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 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 possible facilitators and barriers associated with its implementation.

Discussion: This planned research will give insight into the feasibility of the TTCM model in clinical practice and will give a first indication of the cost-effectiveness of the TTCM and help us to further develop post-clinical trauma care.

BACKGROUND

Trauma accounts for 9.6% of global mortality and is the leading cause of death during the first four decades of life [1,2]. Since trauma patients are typically relatively young, the amount of Disability-Adjusted Life Years (DALYs) lost due to trauma, is larger than from any other disease and causes an important part of worldwide morbidity [3]. Furthermore, major trauma has shown to be the most important cause of long-term functional limitations in adults aged younger than 45 years [4].

The majority of trauma patients have one or more fractures due to their trauma, sometimes in combination with organ system injuries. Fractures of the lower extremities in particular have a major impact on functional status and health-related quality of life (HR-QOL) [5,6]. Moreover, the economic burden of trauma to society is extensive due to the associated high *direct* as well as *indirect* costs (e.g. absenteeism costs). To illustrate, the total costs per patient with an operatively treated vertebral fracture is estimated to be EUR66,000, of which the majority (i.e. EUR47,000) is due to increased absenteeism [7]. Due to the major impact of trauma on mortality, morbidity, and (societal) costs, there has been increased interest in the organization of trauma care over the last three decades. In the literature it is frequently mentioned that trauma care is a chain of services, consisting of pre-hospital care, resuscitation and in-hospital care. During the last two decades, an improved organization of *pre-hospital* and *in-hospital* care by developing specialized trauma centers using Advanced Trauma Life Support (ATLS®) guidelines, has led to a 15–25% decrease in mortality of severe trauma patients [8-11]. Since mortality has decreased significantly due to this re-organization of trauma care, it has been suggested that the focus of trauma care should shift to *improving quality of life and outcome*, rather than on survival of trauma patients, because further improvements in survival rates are likely to be small [8,11]. To improve quality of life and outcome among trauma patients, more attention for optimizing the rehabilitation phase is crucial. Even though numerous studies investigated the outcome of trauma patients, none of these studies focused on the *organization* and *content* of post-clinical trauma care. It is recognized that serious gaps exist between patients' transition from acute care to rehabilitation and their return to society [12-14]. Therefore the limited focus on post-clinical trauma care is remarkable. Recently the American Trauma Society developed a post-clinical psychological support program, including self-management and peer support to improve the trauma patients' psychosocial outcomes [15]. Nonetheless, there is limited attention for optimizing the organization of the post-clinical *physical* rehabilitation of trauma patients in primary care, which may have led to an inefficient and/or suboptimal rehabilitation process. After being discharged from a hospital, the majority of Dutch trauma patients rehabilitates in the primary care setting (i.e. treatment by a

primary care physical therapist). In contrast to secondary and tertiary care, however, guidelines and protocols, as well as an interdisciplinary coordination, are lacking in primary care.

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 regular care models [16]. Furthermore, 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 [17]. However, whether such an organization of the post-clinical rehabilitation process of trauma patients also leads to improved treatment outcomes is currently unknown.

The aforementioned considerations led us to develop a new Transmural Trauma Care Model (TTCM) for trauma patients with at least one fracture, aiming to improve patient outcomes by refining the organization and quality of the post-clinical rehabilitation process. The TTCM is a joint initiative of hospital based physical therapists and trauma surgeons working closely together in the development of TTCM. The 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. To gain insight to the new care models' cost-effectiveness a *controlled-before-and-after* study will be conducted [18]. This article describes the study protocol.

The proposed study aims to answer the following research questions:

1. Is the TTCM 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. Is the TTCM cost-effective from a societal perspective (including intervention costs, health care costs, absenteeism, presenteeism and unpaid productivity) compared to regular care?
3. What is the recovery pattern of patients receiving the TTCM in terms of HR-QOL, pain, functional status, patient satisfaction and perceived recovery during the nine-month follow-up period?
4. What are the barriers and facilitators associated with the implementation of the TTCM?
5. What is the reach, dose delivered, dose received, and fidelity of the TTCM?

METHODS

Design

To answer the research questions, a modified *controlled-before-and-after* study will be conducted at the outpatient clinic for trauma patients of the VU University Medical Center (VUmc), Amsterdam, The Netherlands. The modification of the original study design – in which both control group and intervention group are observed prospectively – is that in our design only the intervention group will be prospectively followed. This modification is required due to the limited resources available. Prior to the implementation of the TTCM, data of 200 control patients who received care as usual will be collected during an inclusion period of 4 months. The control group will consist of 4 clusters of patients who either had their first consultation at the outpatient clinic for trauma patients of the VUmc 0 (i.e. baseline), 3, 6 or 9 months ago. Per cluster, we aim to include approximately 50 patients, all of whom will be asked to fill out an online questionnaire once after providing informed consent. After implementing the TTCM, patients who enter the outpatient clinic for trauma patients of the VUmc and meet the inclusion criteria will be asked to participate in the intervention group of the study. Patients in the intervention group will be prospectively followed for 9 months (n=100) and will be asked to fill out online questionnaires at baseline, 3, 6 and 9 months after their first consultation at the outpatient clinic for trauma patients. See Figure 2.1 for a detailed illustration of the study design.

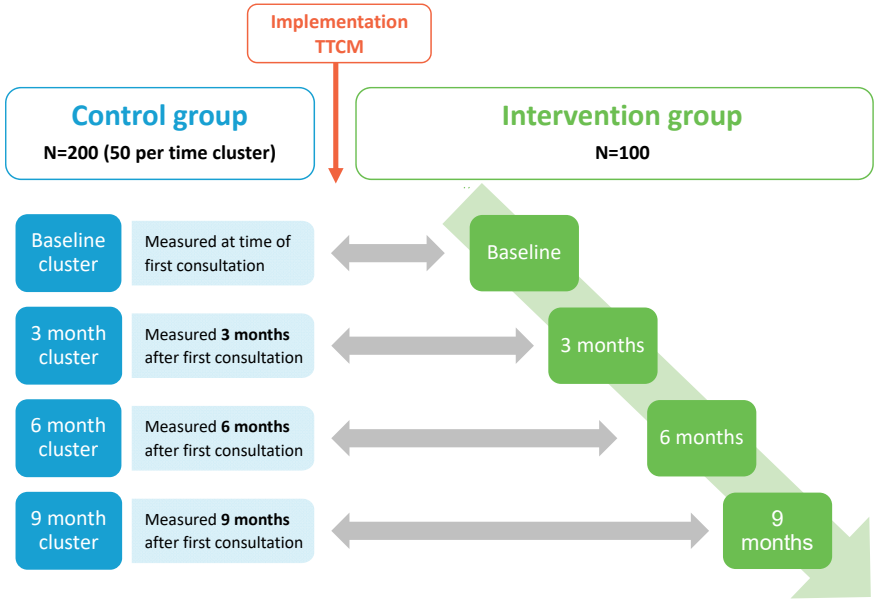

Figure 2.1 Study design.

Population

A total of 300 trauma patients will be included in the study. Both operatively and non-operatively treated patients will be included, irrespective of whether or not they were admitted to the hospital. In order to be eligible for inclusion, trauma patients have to meet the following inclusion criteria: having at least one traumatic fracture, being aged >18 years, and being able to fill out online questionnaires. In both the intervention- and control group, the duration between the patients' actual trauma and their first consultation at the outpatient clinic for trauma patients can vary, depending on the treatment that was selected at the emergency department (i.e. admitted to hospital or sent home). Patients will be excluded if they have red flags (i.e. traumatic brain injury, pathological fractures, and/or cognitive limitations), if they do not speak Dutch, if their rehabilitation process takes place in a tertiary care facility, and/or when patients live outside the catchment area of the VUmc.

Recruitment

Control group

Control group patients will be identified from hospital records. All eligible patients will be contacted by phone by one of the investigators. At this point, patients receive further information about the study, and in- and exclusion criteria will be verified by the coordinating investigator. Patients who are willing to participate and eligible will then receive an email containing a link to an online questionnaire. Clicking the link to the online questionnaire will serve as informed consent. Patients who do not respond within 1 week will receive a reminder email which will be resent after another week of not responding. If the patient does not reply to both emails one of the coordinating investigators will contact the patient by phone to inquire whether the patient is still interested and willing to participate as indicated earlier.

Intervention group

Intervention group patients will be identified during their first consultation at the outpatient clinic for trauma patients. During this consultation, patients will be informed about the study purpose and procedures by one of the investigators. Also, in- and exclusion criteria will be verified. Patients who are willing to participate and are eligible will receive an email containing a link to an online questionnaire. Clicking the link to the online questionnaire will serve as informed consent. Subsequently, patients will be prospectively followed and will receive additional online questionnaires at 3, 6 and 9 months follow-up. Patients who do not respond within 1 week to one of the aforementioned online questionnaires will receive a reminder email which will be resent after another week of non-responding. If the patient does not reply to both emails one of

the coordinating investigators will contact the patient by phone to inquire whether the patient is still interested and willing to participate.

Intervention conditions

Regular care

Patients in the control group received regular care (i.e. trauma care that was provided at the VUmc prior to implementation of the TTCM). During regular care, the trauma surgeon acts as the chief consultant and performs the post-clinical consultations, unaccompanied by professionals of other disciplines. Based on personal judgement, the trauma surgeon decides if and when physical therapy in primary care is needed. After referral to a physical therapist, patients select a primary care physical therapist themselves, usually in their residential area. Moreover, during a patients' treatment by a primary care physical therapist, there is typically no regular contact between the surgeon and the primary care physical therapist.

The Transmural Trauma Care Model (TTCM)

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 2.2 for a schematic representation of the TTCM.

The TTCM consists of four main components and will be explained below:

1. *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.

2. *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.

3. *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.

4. *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 the hospital physical therapist and the primary care physical therapist will communicate repeatedly throughout the whole rehabilitation process.

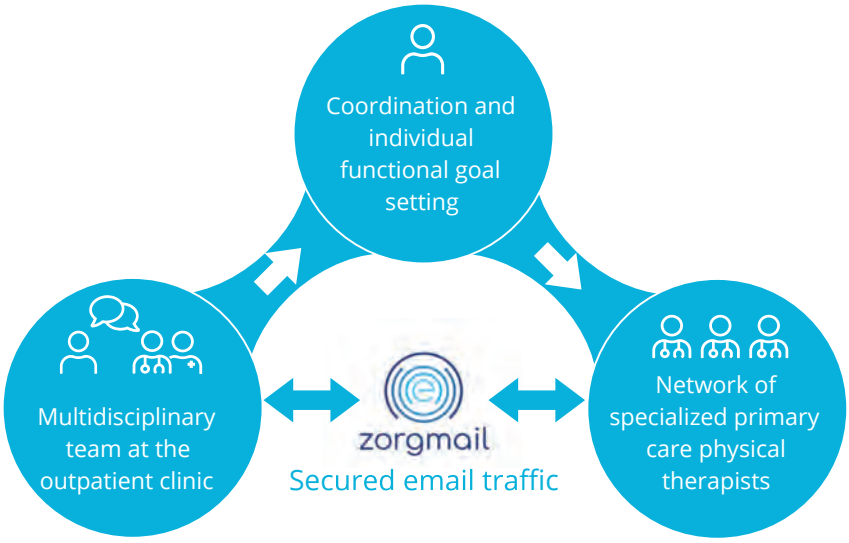

Figure 2.2 Schematic representation of the TTCM.

Outcome assessment

An overview of all outcome measurements is provided in Table 2.1.

Table 2.1 Overview of all outcome measurements

Outcome	Measurement Instrument	Short term	Items	Item score	Interpretation
General HR-QOL	EQ5D	EQ5D	5	1–3	Higher score: better health
Pain	Numeric Pain Rating Scale	NPRS	1	0–10	Higher score: more pain
Perceived recovery	Global Perceived Effect	GPE	2	1–7	Higher score: less recovery
Functional status	Patient Specific Function Scale	PSFS	3	100 mm VAS	Higher score: less function
Patient satisfaction	Numeric Rating Scale	NRS	5	0–10	Higher score: more satisfaction
Disease specific HR-QOL (upper extremity)	Quick Dash Score	Q-DASH	11	1–5	Sum score 0–100, higher score: less function
Disease specific HR-QOL (lower extremity)	Lower Extremity Functional Scale	LEFS	20	0–4	Sum score 0–80, higher score: better function
Disease specific HR-QOL (vertebral fractures)	Roland Morris Disability Score	RMDS	24	yes/no	Sum score 0–24, higher score: more disability
Disease specific HR-QOL (multi-trauma patients)	Groningen Activity Restriction Scale	GARS	18	1–4	Sum score 18–72, higher score: more restrictions
Healthcare utilization	Retrospective Cost Questionnaires				Costs in Euros
Absenteeism	PROductivity and DISease Questionnaire	PRODISQ	1		Total number of sick leave days
Presenteeism	WHO Health and Work Performance Questionnaire (NRS)	WHO-HPQ	1	0–10	Higher score: better performance at work
Unpaid productivity loss			1		Hours per week unable to perform unpaid activities

Baseline characteristics

At baseline, various demographic and trauma-related characteristics will be collected for all patients in the control- and intervention group, including age (years), gender (male/female), level of education (low/middle/high), medical history (none/chronic illness/musculoskeletal disease), type of trauma (traffic/fall/sport), injuries (upper extremity fracture/lower extremity fracture/vertebral fracture/multi-trauma), treatment (operatively/conservatively), length of stay (days), and the well validated Injury Severity Score (ISS), used to provide an overall injury severity score for trauma patients [19]. The ISS score takes values from 0 to 75, and patients with an ISS>16 are defined as multi-trauma patients. In the current study multi-trauma patients are defined as having an ISS>16 and/or having at least fractures in 2 or more extremities. Baseline characteristics will be collected using online questionnaires as well as data derived from electronic patient records.

Primary outcome measure

The primary outcome measure is general HR-QOL, measured using the Dutch version of the EQ-5D [20]. The EQ-5D consists of 5 questions representing 5 dimensions; mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each question is scored on a three-point scale (1–3) with higher scores indicating greater severity level, resulting in a 5 digit index representing one of the 243 health status of the EQ-5D. Using the Dutch tariff, the participants' EQ-5D health status will be converted into a utility score ranging from 0 (dead) to 1 (healthy). Additionally, quality adjusted life years (QALYs) will be calculated using linear interpolation between measurement points. The EQ-5D shows good psychometric properties in trauma patients with one or more fractures [21-23].

Secondary outcome measures

Secondary outcome measures include pain, perceived recovery, functional status, patient satisfaction, and disease-specific HR-QOL.

Pain

Pain will be measured using an 11-point numeric rating scale (NRS) ranging from 0 (no pain) to 10 (worst possible pain) [24]. Patients will be asked to rate their average pain over the last 7 days.

Perceived recovery

Perceived recovery will be measured using the Global Perceived Effect Scale. In clinical practice, measurement of patient-rated recovery often takes the form of the question: to what extent have you improved (or deteriorated) since last time? This type of rating of perceived recovery is a ''transition scale'' or Global Perceived Effect (GPE) scale, which has been advocated to

increase the relevance of information from clinical trials to clinical practice [25]. From the patients' perspective, the question is intuitively easy to understand and it allows them to rate those aspects of recovery that are most important to them. In the current study, patients will be asked the following question: "to what extend have you recovered since your trauma?" The GPE scale asks the patient to rate, on a 7 item scale, how much their condition has improved or deteriorated since their trauma. Possible answers include 1) completely recovered, 2) much improved, 3) slightly improved, 4) not changed, 5) slightly worsened 6) much worsened and 7) worse than ever [26].

Functional status

Functional status will be measured using the Patient Specific Function Scale (PSFS), a patient specific outcome measure that is intended to complement the findings of generic- or condition-specific measures [27]. Patients will be asked to identify 3 important activities that they are having difficulty with or are unable to perform. Subsequently, patients are asked to rate their current level of difficulty associated with each activity, on an 11-point numeric rating scale ranging from 0 ("unable to perform activity") to 10 ("able to perform activity at same level as before injury or problem"). The PSFS is translated and validated for the Dutch population [28].

Patient satisfaction

Patient satisfaction will be scored using an 11-point numeric rating scale ranging from 0 (very dissatisfied) to 10 (excellent). Five patient satisfaction components related to the TTCM will be evaluated: 1) total treatment, 2) treatment at the outpatient clinic, 3) treatment in primary care, 4) collaboration between practitioners from the hospital team and 5) collaboration between the hospital team and the primary care physical therapist.

Disease-specific HR-QOL

Disease-specific HR-QOL will be measured using one of the following disease-specific function scales, appropriate to the patients' specific injury type (i.e. upper extremity fractures, lower extremity- and hip fractures, vertebral fractures and multi-trauma patients):

Patients with fractures of the upper extremity will fill out the Quick Dash score, a short version of the Dash score (Disabilities of the Arm, Shoulder and Hand score) [29]. The Quick Dash score consists of 11 items, measuring physical function and symptoms on a five-point scale (1–5 with higher scores indicating greater difficulty) in people with any or multiple musculoskeletal disorders of the upper limb. A validated Dutch version is available and will be used in this study [30].

Physical function in patients with hip fractures or other lower extremity fractures will be measured using the Lower Extremity Functional Scale (LEFS) [31]. The LEFS is a 20-item disease-specific questionnaire developed for measuring physical function in patients with musculoskeletal problems of the lower extremities. Each item is rated on a five-point scale (0–4 with higher scores representing higher levels of functioning). The LEFS is frequently used as outcome measure in patients with fractures of the lower extremity [32]. A validated Dutch version of the LEFS will be used in this study [33].

Patients with vertebral fractures will fill out the Roland Morris Disability Score (RMDS) [34]. The RMDS is a disease-specific self-reported questionnaire consisting of 24 items all of which contain 2 answering categories (yes/no). The RMDS was originally developed for measuring function in patients with chronic low back pain, but is frequently used to evaluate outcome in patients with traumatic vertebral fractures (operated as well as conservatively treated). A validated Dutch version is available and will be used in this study [35].

Physical functioning in multi-trauma patients will be assessed using the Groningen Activity Restriction Scale (GARS) [36]. The GARS is an 18 item scale on daily activities, all of which contain 4 response categories ranging from 1 to 4 representing 1 (being fully independent of other people) to 4 (being fully dependent of other people). The sum score provides information on the level of difficulty a person experiences in care taking and household activities. Recent research indicates good psychometric properties in a Dutch population of multi-trauma patients [37].

Costs

Costs will be considered 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. Except for intervention costs, costs will be assessed using retrospective cost questionnaires at baseline, 3, 6 and 9 months follow-up. Recall periods of these questionnaires will vary between treatment groups and measurement points in order to cover the complete duration of follow-up. To illustrate, 3-month recall periods will be used for the intervention group at all measurement points, whereas recall periods of 3, 6 and 9 months will be used for baseline/3-month follow-up, 6-month follow-up, and 9-month follow-up for the control group, respectively. All costs will be converted to the same reference year using consumer price indices. Discounting of costs will not be necessary due to the 9-month follow-up period.

Intervention costs

Intervention costs will consist of all costs related to development and implementation of the TTCM (i.e. personnel costs, material costs, costs of the electronic patient record, educational costs). Intervention costs will be estimated using a bottom-up micro costing approach in which detailed data are collected regarding the TTCM's units of resource use as well as their respective unit prices [38,39].

Health care utilization

Health care utilization will include 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 will be used to value health care costs [39]. Use of medication will be valued using the G-standard of the Dutch Society of Pharmacy [40].

Absenteeism

Absenteeism will be retrospectively assessed using the "PROductivity and DISease Questionnaire" (PRODISQ) asking patients to report their total number of sick leave days [41]. Absenteeism will be valued using age- and gender-specific price weights [39].

Presenteeism

Presenteeism is defined as reduced productivity while at work and will be assessed using the World Health Organization Health and Work Performance Questionnaire [42]. Presenteeism will be valued using age- and gender-specific price weights [39].

Unpaid productivity losses

Unpaid productivity losses will be assessed by asking patients for how many hours per week they were unable to perform their unpaid activities, such as domestic work, school and voluntary work. Dutch shadow prices will be used to value unpaid productivity [39].

Process evaluation

A process evaluation will be performed to explore the extent to which the TTCM was implemented as intended as well as the possible facilitators and barriers associated with its implementation.

The extent to which the TTCM was implemented will be explored by assessing the four process evaluation components of Linnan and Steckler, including reach, dose delivered, dose received, and fidelity [43]. *Reach* is defined as the proportion of the intended target audience that

eventually participated in the intervention (i.e. the TTCM). *Dose delivered* is defined as the number of intended units of the intervention provided (e.g. number of scheduled consultations/ treatment sessions). *Dose received* is the extent to which trauma patients actively engaged in the intervention (e.g. number of attended consultations/treatment sessions in relation to the number that was scheduled). *Fidelity* is the extent to which the intervention was delivered as planned (i.e. the extent to which the intervention protocol was followed by the various care providers). To explore these four process evaluation components, data will be collected from the intervention group participants' electronic patient records (e.g. number of secured emails, number of treatments in primary care, was the treatment according the protocol?).

Barriers and facilitators are defined as factors that hampered or enhanced the implementation of the TTCM, respectively [44]. For exploring the barriers and facilitators associated with the implementation of the TTCM, focus groups will be conducted among trauma patients (2 focus groups consisting of 5 patients each), trauma surgeons (1 focus group of 6 trauma surgeons), hospital based physical therapists (1 focus group of 5 hospital based physical therapists), and primary care network physical therapists (2 focus groups consisting of 5 primary care network physical therapists). Focus groups will be conducted at a time and location convenient to the participants. Prior to the focus groups, participants will be assured of confidentiality and will be asked to provide informed consent. The focus groups will be guided by 2 researchers, familiar with the TTCM, but not involved as care provider in the TTCM. During the focus groups, 3 round table discussions will be held; the first will be aimed at identifying possible facilitators, the second will be aimed at identifying possible barriers and the third round will be aimed at complementing and validating the barriers and facilitators identified in round one and two. During all round table discussions, a topic list will be used as a guide, but participants are allowed to discuss other topics that they consider to be of importance as well. All focus groups will be audiotaped and transcribed verbatim.

Data analysis

Descriptive statistics

Descriptive statistics will be used to compare baseline characteristics between control- and intervention group participants and participants with complete and incomplete data.

Handling missing data

Missing data are assumed to be at random and will be imputed using Fully Conditional Specification and Predictive Mean Matching [45]. An imputation model will be constructed, including variables related to the "missingness" of data, variables that predict the outcomes, and all available midpoint and follow-up cost and effect measure values. The number of imputed data sets will be determined based on the number of participants with complete cost and effect measure values [46]. All of the imputed datasets will be analysed separately as specified below. Pooled estimates were subsequently calculated using Rubin's rules [46].

Clinical effectiveness

The clinical effectiveness analyses will consist of two parts. First, the TTCMs' effectiveness in terms of HR-QOL, pain, perceived recovery, functional status and patient satisfaction compared with usual care will be explored at 3, 6 and 9 months follow-up using regression analyses. The four clusters of control patients (i.e. time after their first consultation at the outpatient clinic for trauma patients respectively 0, 3, 6 and 9 months) will be compared with the patients in the intervention group at the corresponding time points. Second, the recovery pattern of patients in of the intervention group will be studied using longitudinal data analysis in terms of HR-QOL, pain, perceived recovery, functional status and patient satisfaction during the nine-month follow-up period (and while receiving the TTCM). All of the aforementioned analyses will be corrected for confounders if necessary (e.g. age, gender, level of education). Confounding will be checked by adding the potential confounding variable to the crude models, and will subsequently be considered to be present if the regression coefficient changes by 10% or more. All of the clinical effectiveness analyses will be performed in SPSS, using a level of significance of $p<0.05$.

Economic evaluation

The economic evaluation will be performed from the societal perspective, meaning that all costs and consequences related to the intervention will be taken into account, irrespective of who pays or benefits. The mean difference in total costs between the intervention and control group will be compared to the corresponding mean difference in effects. For this, cost and effect differences will be estimated using seemingly unrelated regression analyses in order to correct for their possible correlation. To deal with the highly skewed nature of cost data, 95% CIs around the differences in costs will be estimated using the Bias Corrected and Accelerated Bootstrap method, with 5,000 replications. Incremental Cost-Effectiveness Ratios (ICERs) will be calculated by dividing the differences in costs by those in effects. To graphically illustrate the uncertainty surrounding the ICERs, bootstrapped incremental cost-effect pairs will be plotted on cost-effectiveness planes [47]. A summary measure of the joint uncertainty of costs and

effects will be presented using cost-effectiveness acceptability curves, indicating the probability of an intervention being cost-effective in comparison with the control condition for a range of willingness-to-pay values (i.e. the maximum amount of money decision-makers are willing to pay per unit of effect gained) [48]. To test the robustness of the results, various sensitivity analyses will be performed [49]. All of the economic evaluation analyses will be performed in STATA, using a level of significance of $p<0.05$.

Process evaluation

Using Nvivo, data derived from the focus groups will be analyzed in accordance to the constant comparative approach. That is, analytic categories will be inductively established by constantly comparing and checking items with the rest of the data [50]. By starting with open coding, descriptive themes and subthemes will be generated by one researcher. The final codes will subsequently be developed through discussion between two independent researchers. During these discussions, similar codes will be grouped into analytical categories and the different properties of these categories will be explored as well as the relationships between them (i.e. selective coding) [51]. Using SPSS, summary statistics will be prepared to evaluate the new care model's reach, dose delivered, dose received, and fidelity.

DISCUSSION

Traumatic fractures are common and pose a substantial economic burden to society. Nonetheless, little is currently known about how to optimally organize the post-clinical rehabilitation process for trauma patients transferred from hospital to primary care. Therefore, the TTCM for the post-clinical rehabilitation of trauma patients was developed at the VUmc, which aims to improve HR-QOL, functional outcome and patient satisfaction of trauma patients, by organizing the post-clinical rehabilitation in an innovative and more efficient way. Within the available resources, the aforementioned *modified controlled before and after design* was regarded as the most optimal research design at this stage. The study aims to provide insight into the new care models' cost-effectiveness and aims to provide clues as to how to further optimize the TTCM so it is "ready-to-implement" in other hospitals, which can possibly serve as a starting point for a future pragmatic (multicenter) controlled randomized trial. We are of the opinion that even though the applied *modified controlled before and after* design might bear on the internal validity of the current study findings (e.g. due to selection bias), it does not negate the value of its results. Another possible limitation of the proposed study might be the difficulty to identify what components of the TTCM will be responsible for (positive) effects. To illustrate, better clinical outcome could

be the result of better educated physical therapists in primary care, but could also be due to the introduction of multidisciplinary consultations at the outpatient clinic for trauma patients. In the current study, a pragmatic design will be applied, in which the TTCM is evaluated as whole. Future research will therefore be needed to provide insight into which TTCM component is accountable for which specific effect.

Despite the shortcomings of the study we aim to provide insight in organizing the post-clinical rehabilitation process for trauma patients in a more efficient way and consequently contribute to better clinical outcomes and reduced societal costs.

Funding

This project is partly funded by “Zilveren Kruis Health Insurer” (grant number Z516).

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GIDEON (59) | FELL FROM HEIGHT 1 YEAR AGO

Unstable wrist fracture and vertebral fracture

3

The Transmural Trauma Care Model (TTCM) for the rehabilitation of trauma patients is effective in improving patient related outcome measures: a non-randomized controlled trial

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BMC Health Serv Res. 2019;19(1):819

ABSTRACT

Background: The Transmural Trauma Care Model (TTCM) is a refined post-clinical rehabilitation approach, in which a multidisciplinary hospital-based team guides a network of primary care physical therapists in the treatment of trauma patients. The objective of this study was to assess the effectiveness of the TTCM compared to regular care.

Methods: A controlled-before-and-after study was performed in a level 1 trauma center. The TTCM includes four elements: 1) a multidisciplinary team at the outpatient clinic, 2) coordination and individual goal setting for each patient by this team, 3) a network of primary care physical therapists, 4) E-health support for transmural communication. Intervention group patients were prospectively followed (3, 6 and 9 months). The control group consisted of 4 clusters of patients who either had their first consultation at the outpatient clinic 0, 3, 6 or 9 months ago. Outcomes included generic- and disease-specific health-related quality of life (HR-QOL), pain, functional status, patient satisfaction, and perceived recovery. Between-group comparisons were made using linear regression analyses. The recovery pattern of intervention group patients was identified using longitudinal data analysis methods.

Results: A total of 83 participants were included in the intervention group. In the control group, 202 participants were included (68 in the baseline cluster, 26 in the 3-month cluster, 51 in the 6-month cluster, 57 in the 9-month cluster). Between-group differences were statistically significant in favor of the intervention group for disease-specific HR-QOL at 9 months, pain at 6 and 9 months, functional status at 6 and 9 months, patient satisfaction at 3, 6 and 9 months, and perceived recovery at 6 months. No significant differences were found between groups for generic HR-QOL at any time point. Generic HR-QOL, disease-specific HR-QOL, pain, and functional status significantly improved in a linear fashion among intervention group patients during the nine-month follow-up period.

Conclusions: This study provides preliminary evidence that the TTCM is effective in improving patient-related outcome measures, such as disease-specific HR-QOL, pain and functional status. A multicenter, and ideally randomized controlled trial, is required to confirm these results.

BACKGROUND

Traumatic injury-related mortality accounts for almost 10% of the global annual mortality. Moreover, major trauma accounts for the highest mortality rate among people under 40 years of age, compared to any other disease [1,2]. As a consequence, traumatic injury is responsible for the highest loss of Disability-Adjusted Life Years (DALYs) worldwide. Each year, trauma costs the global population about 300 million years of healthy life, equaling 11% of DALYs lost [3]. Furthermore, in adults younger than 45 years, major trauma is the most important cause of long-term functional limitations [4].

Many trauma patients have more than one fracture. Fractures, and those of the lower extremities in particular, significantly impact a patient's functional status and health-related quality of life (HR-QOL) [5,6]. On top of that, the economic burden of trauma to society is extensive, for example, the societal cost of an operatively treated vertebral fracture was estimated at EUR66,000 per patient [7]. Furthermore, Fakhry et al. showed that trauma patients represent a significant and increasing institutional cost, of which ICU costs per trauma patient were the largest single category [8]. During the last decades, a significant decrease in mortality has been achieved among severe trauma patients through the optimization of *pre-hospital* and *in-hospital* trauma care [9-12]. As further reductions in mortality rates are therefore expected to be trivial, the focus of trauma care has shifted from aiming to reduce mortality rates to aiming to improve trauma patients' HR-QOL and outcome [9-12]. As a consequence, HR-QOL has become one of the most important outcome measures in studies among severely injured trauma patients [13,14], whereas relatively few studies have focused on measuring HR-QOL amongst mildly to moderately injured patients [15,16].

To further improve outcome and HR-QOL among mild, moderate, and severe trauma patients, increased attention is required for optimizing the rehabilitation process after in-hospital trauma care [17-19]. Research among other patient groups indicates that an improved organization of the post-clinical rehabilitation process can lead to better outcomes [20-22]. For example, a study in patients with Parkinson's disease indicates that a post-clinical care model in which rehabilitation is organized in a network of experienced and specialized healthcare providers results in better clinical outcomes and lower costs compared to regular care models [20]. Furthermore, a feasibility study among patients with hip or knee osteoarthritis found a care model, in which primary care providers were guided by a clinical case manager, to significantly improve patients' outcome and HR-QOL [21].

Given the above, we developed a new Transmural Trauma Care Model (TTCM) for trauma patients. The core of the TTCM is a continuous feedback loop, in which a multidisciplinary hospital-based team supervises a network of primary care physical therapists.

The aim of the current study is to assess the following research questions:

1. What is the effectiveness of the TTCM on HR-QOL (generic- and disease-specific), pain, functional status, patient satisfaction and perceived recovery, compared to regular care, in trauma patients with at least one fracture?
2. What is the recovery pattern of trauma patients receiving the TTCM, during the nine-month follow-up period, regarding HR-QOL (generic- and disease-specific), pain and functional status?

METHODS

The study-protocol of the current study, with detailed descriptions of its design and methods, has been published elsewhere [23]. Alongside the present study (assessing the effectiveness of the TTCM), the *cost-effectiveness* of the TTCM was evaluated in an economic evaluation, of which the results were recently published [24]. Some parts of the method section below are overlapping with the aforementioned publications (i.e. patients, inclusion procedure, intervention- and control conditions and outcome measures). An abridged version of the earlier published study protocol, is presented below.

Design

A modified controlled-before-and-after study was conducted at the outpatient clinic for trauma patients of the Amsterdam UMC, Vrije Universiteit Amsterdam (VUmc), The Netherlands [23,24]. In a true controlled-before-and-after study both study groups are prospectively followed [25]. However, in the present study, only the intervention group was prospectively followed, while control group data were collected cross-sectionally.

From January to March 2014, control group data were collected among patients who received regular care. The control group consisted of 4 clusters of patients. The baseline, 3-month, 6-month, and 9-month clusters contained patients who had their first consultation at the outpatient clinic within one week ago, or 3 months ago, 6 months ago, and 9 months ago, respectively. All control group patients were only measured once at the time point that corresponds to the cluster they belong to.

From April to May 2014, the TTCM was implemented. Subsequently, intervention group participants were recruited from June 2014 to April 2015, after which they received care according to the TTCM. All intervention group patients were prospectively followed for 9 months with

measurements at baseline and 3, 6 and 9 months after their first consultation at the outpatient clinic. A graphical representation of the study design can be found in Figure 3.1.

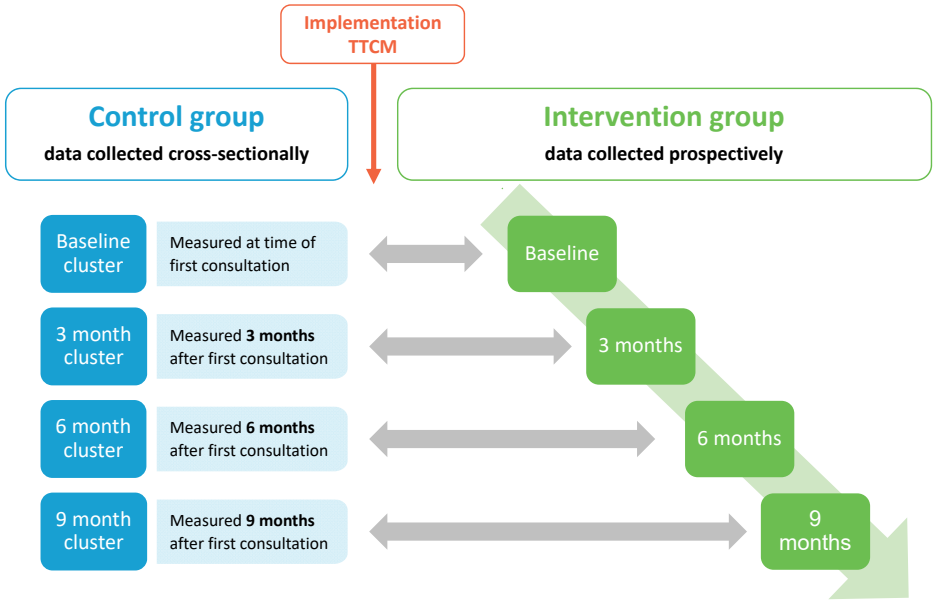


Figure 3.1 Study design.

The medical ethics committee of the VUmc assessed the present study, and decided that the Dutch Medical Research Involving Human Subjects Act (WMO) was not applicable (registered under number 2013.454). All participants gave informed consent. The trial is registered at the Dutch Trial Register (NTR5474) and adheres to CONSORT guidelines.

Patients

Operatively and non-operatively treated trauma patients were included, regardless of whether or not they were admitted to the hospital. Eligible patients had to have at least one traumatic fracture (i.e. upper and lower extremity fractures, spinal fractures, hip fractures), had to be 18 years or older, had to rehabilitate in primary care and had to be able to fill out Dutch online questionnaires. Patients were excluded if they had non-traumatic (pathological) fractures, or traumatic brain injury, or cognitive limitations. Furthermore patients were excluded if their rehabilitation occurred in a clinical tertiary care setting, or if they lived more than 30 kilometres away from the VUmc.

The recruitment procedure of potential participants took place as earlier described in the study-protocol [23,24]. Control group participants were selected from the central trauma registry of the trauma region "North West Netherlands". All sequential patients were contacted by telephone by one of the investigators and received information about the study's purpose and procedures. In- and exclusion criteria were verified by the principle investigator, after which patients were allocated to their respective cluster. Eligible patients who were willing and able to participate received an email inclosing a link to an online questionnaire. Clicking the link to the online questionnaire served as informed consent. A reminder email was send after 1 week and again after another week of non-responding. In case of patient's not replying to both emails, one of the coordinating investigators contacted the patient by telephone.

Intervention group participants were identified during their first consultation at the outpatient clinic as described in the study protocol [23,24]. Potentially eligible patients were informed about the study's purpose and procedures by one of the investigators and in- and exclusion criteria were verified. Eligible patients who were willing and able to participate received an email inclosing a link to the first online questionnaire. Clicking the link to the online questionnaire served as informed consent. A reminder email was send after 1 week and, if necessary, again after another week of non-responding. One of the coordinating investigators contacted the patient by telephone, in case of patient's not replying to both reminder emails. Then, patients were prospectively followed, with measurements at 3, 6, and 9 months follow-up.

Intervention conditions

Pre- and in-hospital trauma care was similar for both study groups, the intervention phase started at the outpatient clinic for trauma patients.

The Transmural Trauma Care Model (TTCM)

Patients in the intervention group received care according to the TTCM. A detailed description of the TTCM can be found elsewhere [23,24]. In brief, the TTCM consists of four main components:

1. *A multidisciplinary team at the outpatient clinic for trauma patients*. The team consists of a trauma surgeon and a trauma-specialized hospital-based physical therapist. The trauma surgeon evaluated the bone- and wound-healing process. The physical therapist assessed physical function.

2. *Coordination and individual goal setting for each patient by the multidisciplinary team*. The hospital-based team coordinated the patients' rehabilitation process in primary care by repeatedly defining individual goals in close cooperation with the patient. To supplement

this process, 10 rehabilitation protocols were developed for the most common fractures (e.g. hip fractures, tibial plateau fractures). These protocols were customized for each individual patient by the hospital-based physical therapist, who acted as case manager throughout the rehabilitation process.

3. *An educated and trained network of 40 specialized primary care physical therapists*. This newly developed "VUmc trauma rehabilitation network" consisted of 40 specially trained, physical therapists, all of whom worked in a primary care private practice in the region of Amsterdam [26]. Patients in the intervention group were referred to one of these specialized trauma physical therapists.

4. *Secure email traffic between the hospital-based physical therapist and the primary care physical therapist during the entire rehabilitation process*. A secured email system, developed for healthcare professionals, was connected to both the electronic patient records of the hospital-based physical therapist and the primary care physical therapist.

Regular care

Patients in the control group received regular care, during which the trauma surgeon acted as the chief consultant. The trauma surgeon performed consultations at the outpatient clinic for trauma patients, and acted independent of other health care professionals. Based on the clinical judgment of the trauma surgeon, a patient could be referred to a primary care physical therapist, but there was no standardized policy for referral of control group patients. Throughout the patients' rehabilitation in primary care, there was hardly any contact between trauma surgeon and primary care physical therapists.

Outcome assessment

An overview of all outcome measurements is provided in Table 3.1. Extensive details of the outcome measures can be found elsewhere [23,24].

Baseline characteristics

At baseline, all relevant demographic and trauma-related characteristics were measured (e.g. gender, age, medical history, ISS, the number of days between trauma and first outpatient consultation [TTO]). Baseline characteristics were collected using online questionnaires, supplemented by data derived from electronic patient records.

Table 3.1 Overview of all outcome measurements

Outcomes	Measurement Instrument	Abbreviation	Items	Item score	Interpretation
Primary outcome					
Generic HR-QOL	EQ-5D-3L	EQ-5D-3L	5	1–3	Higher utility score: better health
Secondary outcomes					
Disease-specific HR-QOL (upper extremity)	Quick Dash Score	Q-DASH	11	1–5	Sum score 0–100, higher score: less function
Disease-specific HR-QOL (lower extremity)	Lower Extremity Functional Scale	LEFS	20	0–4	Sum score 0–80, higher score: better function
Disease-specific HR-QOL (vertebral fractures)	Roland Morris Disability Score	RMDS	24	yes/no	Sum score 0–24, higher score: more disability
Disease-specific HR-QOL (multi-trauma patients)	Groningen Activity Restriction Scale	GARS	18	1–4	Sum score 18–72, higher score: more restrictions
Disease-specific HR-QOL (over-all)	Q-DASH, LEFS, RMDS, GARS	DSQOL-OA			Sum score 0–100, higher score: less function
Pain	Numeric Pain Rating Scale	NPRS	1	0–10	Higher score: more pain
Functional status	Patient Specific Function Scale	PSFS	3	100 mm VAS	Higher score: less function
Patient satisfaction	Numeric Rating Scale	NRS	3	0–10	Higher score: more satisfaction
Perceived recovery	Global Perceived Effect	GPE	1	1–7	Higher score: less recovery

Primary outcome measure

The primary outcome measure was generic HR-QOL, assessed using the EQ-5D-3L [27]. The EQ-5D-3L consists of 5 questions covering 5 health dimensions (i.e. mobility, self-care, usual activities, pain/discomfort and anxiety/depression), all of which contain 3 severity levels. Using the Dutch tariff, the participants' EQ-5D-3L health states were converted into a utility score, anchored at 0 (dead) and 1 (optimal health).

Secondary outcome measures

Secondary outcome measures were disease-specific HR-QOL, pain, functional status, patient satisfaction and perceived recovery.

Depending on the patients' specific injury type, disease-specific HR-QOL was measured using one of the following disease-specific function scales:

- The Quick Dash for patients with upper extremity fractures, consisting of 11 items, measuring physical function and symptoms on a five-point scale. The overall score ranges from 0 to 100 [28,29].
- The Lower Extremity Functional Scale (LEFS) for patients with hip fractures or other lower extremity fractures. The LEFS is a 20-item questionnaire with 5 answering options. The overall score ranges from 0 to 80 [30,31].
- The Roland Morris Disability Score (RMDS) for patients with vertebral fractures. The RMDS is a 24-item questionnaire with 2 answering categories (yes/no). The overall score ranges from 0 to 24 [32,33].
- The Groningen Activity Restriction Scale (GARS) for multi-trauma patients. The GARS is an 18-item questionnaire with 4 response categories, measuring daily activities. The overall score ranges from 18 to 72 [34,35].

An overall disease-specific HR-QOL score (DSQOL-OA) was calculated by converting the total scores of the aforementioned questionnaires to a scale from 0–100. Higher scores indicated that patients experienced more functional problems [24].

The Numeric Pain Rating Scale (NPRS) was used to measure pain. The NPRS is an 11-point scale ranging from 0 (no pain) to 10 (worst possible pain) [36].

Functional status was measured using the Patient Specific Function Scale (PSFS) [37,38]. Patients identified 3 important activities that they were having difficulty with. Per activity, they were asked to rate their present level of difficulty associated with each activity on a 0–100 mm Visual

Analogue Scale (VAS) ranging from 0 ("able to perform activity at same level as before injury or problem") to 100 ("unable to perform activity"). The activity that was first mentioned by the participants, was used for statistical analysis.

Patient satisfaction was examined on an 11-point Numeric Rating Scale (NRS) ranging from 0 (very dissatisfied) to 10 (excellent). Three patient satisfaction components related to the TTCM were evaluated: 1) the over-all treatment, 2) treatment located at the outpatient clinic, 3) collaboration between the multidisciplinary team at the outpatient clinic and the primary care physical therapist.

Perceived recovery was examined using the Global Perceived Effect (GPE) scale. The GPE quantifies a patient's subjective improvement on a 7-item scale, ranging from "worse than ever" (1) to "completely recovered" (7) [39]. Success of treatment was achieved when a patient reported 6 or 7 points meaning respectively "much improved" or "completely recovered".

Data analysis

The current data analysis section is highly comparable to the version previously described in the study protocol [23].

Descriptive statistics

Descriptive statistics were used to compare baseline characteristics between study groups.

Handling missing data

Missing data were imputed using Multiple Imputation by Chained Equations [40]. An imputation model was built, including variables predicting the outcomes, variables that are related to the "missingness" of data, and furthermore, all available midpoint and follow-up effect measure values [40]. Ten complete data sets were created in order for the loss-of-efficiency to be below 5% [41]. All of the imputed datasets were analysed separately as specified below. Rubin's rules were used to subsequently calculate Pooled estimates [41].

Clinical effectiveness

The clinical effectiveness analyses contained two parts. First, linear regression analyses were used to investigate the effectiveness of the TTCM in terms of HR-QOL (generic- and disease-specific), pain, functional status, patient satisfaction and perceived recovery compared with regular care at 3-, 6- and 9-months follow-up. For this purpose, three clusters of control patients (i.e. 3-month cluster, 6-month cluster, and 9-month cluster) were compared with the patients in

the intervention group at the corresponding time points. Second, the recovery patterns of the intervention group patients for generic- and disease-specific HR-QOL, pain and functional status during the nine-month follow-up period was studied using GLM for repeated measures [42]. All analyses were adjusted for confounders if necessary (e.g. gender, fracture region, length of stay). Confounding was examined by adding the potential confounding variable to the crude models. If the regression coefficient changed by 10% or more, the confounding variable was considered to be present. Analyses were performed in SPSS Version 22, using a level of significance of $p<0.05$.

RESULTS

Study participants

A total of 655 trauma patients were identified as being potentially eligible for participation in the control group. Of them, 453 patients were excluded for various reasons (e.g. did not performed informed consent (n=134), not willing (n=105)). The remaining 202 patients were included in the control group, of which 68 in the baseline cluster, 26 in the 3-month cluster, 51 in the 6-month cluster, and 57 in the 9-month cluster (Figure 3.2a). For the intervention group, a total of 103 potentially eligible patients were identified, of whom 20 were eventually excluded for several reasons (e.g. did not performed informed consent (n=9), no internet access (n=2)). The remaining 83 patients were included as participants in the intervention group (Figure 3.2b).

Baseline characteristics of participants in the four control group clusters and the intervention group are described in Table 3.2. The majority of these characteristics were similar among participants. However, participants in the intervention group were younger, were more frequently admitted to the hospital, and had lower extremity fractures more often than their control group counterparts.

Clinical effects

There were no relevant between-group differences in the dependent variable generic HR-QOL (primary outcome measure) at all measurement points (Table 3.3). However, the mean between-group difference in the dependent variable disease-specific HR-QOL was statistically significant in favor of the intervention group at 9 months (MD -7.96; 95% CI -14.17 to -1.75), but not at 3 and 6 months. Patients in the intervention group had statistically significant less pain at 6 (MD -0.87; 95% CI -1.44 to -0.29) and 9 months (MD -0.84; 95% CI -1.38 to -0.31) than their control group counterparts, but no difference in the dependent variable pain was found at 3 months. There was also a statistically significant difference in the dependent variable functional status favoring the

Table 3.2 Baseline characteristics (patient- and trauma-related)

Characteristics	Intervention group Mean (SD) *or* frequency (%)	Control group Cluster 1 (baseline) Mean (SD) *or* frequency (%)	Control group Cluster 2 (3-month) Mean (SD) *or* frequency (%)	Control group Cluster 3 (6-month) Mean (SD) *or* frequency (%)	Control group Cluster 4 (9-month) Mean (SD) *or* frequency (%)
N	83	68	26	51	57
Age	43.4 (15.6)	46.8 (14.3)	57.2 (16.0)	50.0 (17.4)	50.5 (17.9)
Gender (M/F)	39/44 (47/53%)	31/37 (46/54%)	13/13 (50/50%)	22/29 (43/57%)	26/31 (46/54%)
Education level					
Low	7 (8.4%)	12 (18.5%)	2 (8.3%)	5 (10.6%)	6 (11.1%)
Middle	19 (22.9%)	16 (24.6%)	4 (16.7%)	14 (29.8%)	16 (29.6%)
High	57 (68.7%)	37 (56.9%)	18 (75.0%)	28 (59.6%)	32 (59.3%)
Medical history					
None	53 (63.9%)	33 (48.5%)	14 (53.8%)	30 (60.0%)	30 (52.6%)
Chronic	14 (16.9%)	21 (30.9%)	7 (26.9%)	9 (18.0%)	13 (22.8%)
Musculoskeletal	16 (19.3%)	14 (20.6%)	5 (19.2%)	11 (22.0%)	14 (24.6%)

Trauma type					
Traffic	44 (53.0%)	26 (38.8%)	9 (34.6%)	15 (29.4%)	25 (43.9%)
Work-related	0	3 (4.5%)	3 (11.5%)	2 (3.9%)	2 (3.5%)
Fall	27 (32.5%)	13 (19.4%)	9 (34.6%)	20 (39.2%)	17 (29.8%)
Sports	11 (13.3%)	19 (28.4%)	5 (19.2%)	9 (17.6%)	9 (15.8%)
Other	1 (1.2%)	6 (9.0%)	0	5 (9.8%)	4 (7.0%)
Fracture region					
Upper extremity	31 (37.3%)	33 (48.5%)	14 (53.8%)	25 (49.0%)	25 (43.9%)
Lower extremity	41 (49.4%)	25 (36.8%)	9 (34.6%)	16 (31.4%)	19 (33.0%)
Vertebral	7 (8.4%)	0	1 (3.8%)	2 (3.9%)	1 (1.8%)
Multitrauma	4 (4.8%)	10 (14.7%)	2 (7.7%)	8 (15.7%)	12 (21.1%)
ISS (mean, SD)	7.9 (4.4)	9.1 (6.6)	7.7 (5.6)	8.9 (7.8)	8.6 (6.3)
ISS (min–max)	(4–26)	(4–34)	(4–24)	(4–43)	(4–29)
Admission hospital	62 (75.0%)	44 (65.0%)	8 (31.0%)	24 (47.0%)	29 (51.0%)
Length of stay (days)	7.1 (6.1)	8.2 (7.3)	8.4 (11.1)	10.8 (8.0)	10.0 (11.4)
Surgery	53 (64.0%)	36 (53.0%)	5 (19.0%)	22 (43.0%)	21 (37.0%)
TTO (days)*	24.3 (14.3)	15.9 (13.1)	11.5 (15.9)	16.0 (15.8)	14.6 (14.7)

* TTO = Time between Trauma and first Outpatient consultation.

Table 3.3 Treatment effects for primary and secondary outcomes

Outcomes	Intervention group Mean (SD)	Control group Mean (SD)	Treatment effect (crude) MD (95% CI)	Treatment effect (adjusted) MD (95% CI)	Adjusted for*
Primary outcome					
HR-QOL (EQ-5D-3L)					
Baseline	0.65 (0.21)	0.70 (0.19)	-0.05 (-0.11 to 0.02)	-0.03 (-0.10 to 0.04)	Age, TTO**, admission hospital, surgery
3 months	0.78 (0.16)	0.85 (0.13)	-0.07 (-0.14 to 0.01)	-0.083 (-0.17 to 0.01)	Age, TTO, fracture region
6 months	0.82 (0.13)	0.81 (0.19)	0.01 (-0.05 to 0.08)	0.051 (-0.02 to 0.12)	Gender, trauma type, TTO, admission hospital, surgery
9 months	0.85 (0.13)	0.81 (0.19)	0.04 (-0.02 to 0.10)	0.06 (-0.01 to 0.12)	Age, medical history, TTO
Secondary outcomes					
Disease-specific HR-QOL (DSQOL-OA)					
Baseline	55.60 (21.35)	50.61 (22.26)	4.99 (-1.88 to 11.86)	3.65 (-3.37 to 10.67)	Age, medical history, TTO, fracture region, admission hospital, surgery
3 months	29.56 (20.06)	26.16 (23.35)	3.44 (-5.21 to 12.09)	0.36 (-8.85 to 9.58)	Age, medical history, fracture region, admission hospital, surgery, length of stay
6 months	22.66 (20.01)	20.21 (20.09)	2.45 (-3.91 to 8.82)	-3.65 (-10.38 to 3.08)	Age, medical history, trauma type, TTO, fracture region, ISS, admission hospital, surgery
9 months	17.63 (15.74)	20.45 (21.00)	-2.82 (-8.41 to 2.77)	-7.96 (-14.17 to -1.75)	Age, medical history, TTO, fracture region, admission hospital, surgery
Pain (NPRS)					
Baseline	2.84 (1.85)	2.83 (1.93)	0.01 (-0.60 to 0.62)	0.34 (-0.36 to 1.04)	Gender, age, education, medical history, trauma type, TTO, fracture region, ISS, admission hospital, surgery
3 months	1.95 (1.26)	2.54 (1.64)	-0.59 (-1.20 to 0.02)	-0.38 (-1.07 to 0.32)	TTO, admission hospital, surgery
6 months	1.63 (1.33)	2.31 (2.09)	-0.68 (-1.26 to -0.11)	-0.87 (-1.44 to -0.29)	Trauma type
9 months	1.34 (1.11)	2.19 (2.01)	-0.84 (-1.38 to -0.31)	-0.84 (-1.38 to -0.31)	None

Functional status (PSFS)					
Baseline	65.90 (28.89)	58.15 (37.10)	6.84 (-3.69 to 17.37)	5.90 (-5.45 to 17.24)	Education, medical history, fracture region
3 months	26.71 (26.82)	34.00 (35.72)	-7.29 (-19.32 to 4.74)	-2.02 (-15.82 to 11.76)	Medical history, trauma type, TTO, fracture region, admission hospital, length of stay
6 months	18.49 (22.06)	29.64 (25.43)	-11.15 (-18.66 to -3.64)	-16.49 (-24.39 to -8.60)	Trauma type, TTO, admission hospital, surgery
9 months	18.39 (22.36)	34.39 (30.74)	-16.00 (-24.09 to -7.90)	-20.68 (-29.20 to -12.16)	TTO, surgery
Patient satisfaction (total treatment)					
Baseline	7.84 (1.48)	7.32 (2.01)	0.53 (-0.03 to 1.08)	0.60 (0.04 to 1.16)	Education
3 months	8.10 (0.99)	7.17 (1.43)	0.93 (0.38 to 1.47)	0.77 (0.13 to 1.42)	TTO, admission hospital, surgery, length of stay
6 months	8.09 (1.35)	7.44 (2.04)	0.64 (0.07 to 1.22)	0.53 (-0.07 to 1.13)	Admission hospital
9 months	8.09 (1.57)	7.77 (1.18)	0.32 (-0.19 to 0.82)	0.24 (-0.29 to 0.76)	Surgery
Patient satisfaction (outpatient clinic)					
Baseline	7.76 (1.57)	7.33 (2.01)	0.43 (-0.15 to 1.00)	0.56 (-0.02 to 1.15)	Education, medical history
3 months	7.73 (1.55)	7.41 (1.66)	0.31 (-0.37 to 1.00)	0.15 (-0.64 to 0.95)	Medical history, TTO, fracture region, admission hospital, surgery, length of stay
6 months	7.98 (1.46)	7.50 (1.92)	0.48 (-0.09 to 1.05)	0.39 (-0.25 to 1.03)	Trauma type, fracture region, admission hospital, surgery
9 months	8.22 (1.41)	7.71 (1.36)	0.51 (0.03 to 0.98)	0.44 (-0.08 to 0.95)	Age, TTO, surgery
Patient satisfaction (collaboration)					
Baseline	7.16 (2.00)	5.77 (2.57)	1.39 (0.39 to 2.39)	1.25 (0.24 to 2.25)	Trauma type
3 months	7.40 (1.31)	5.61 (2.19)	1.79 (0.93 to 2.66)	1.61 (0.72 to 2.51)	TTO
6 months	7.65 (1.53)	5.86 (2.48)	1.78 (1.03 to 2.53)	1.78 (1.03 to 2.53)	None
9 months	7.51 (2.03)	6.13 (2.35)	1.39 (0.65 to 2.12)	1.20 (0.42 to 1.97)	Admission hospital, surgery

* The baseline characteristics mentioned in this column were confounders (changed the regression coefficient with 10% or more).

** TTO = Time between Trauma and first Outpatient consultation (days).

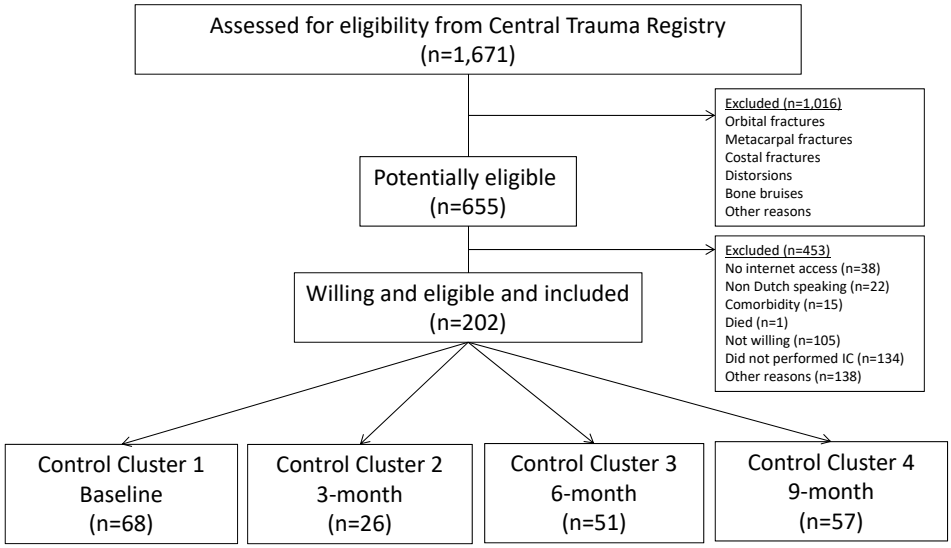


Figure 3.2a Enrollment of control group participants.

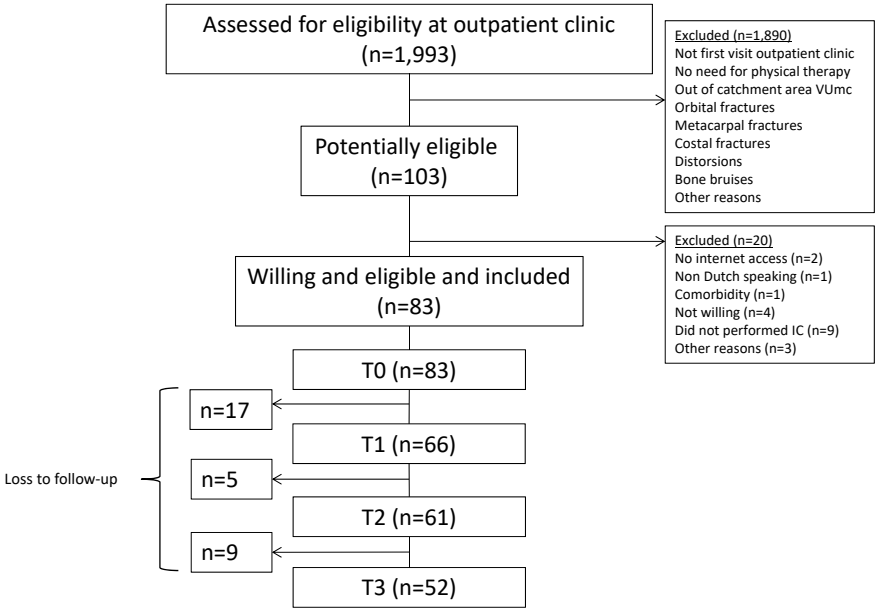


Figure 3.2b Enrollment of intervention group participants.

intervention group at 6 months (MD -16.49; 95% CI -24.39 to -8.60) and 9 months (MD -20.68; 95% CI -29.20 to -12.16), but not at 3 months. Furthermore, participants in the intervention group were statistically significant more satisfied with their total treatment at 3 months (MD 0.77; 95% CI 0.13 to 1.42), but not at 6 and 9 months. At all of the time points, patients in the intervention group were statistically significant more satisfied with the collaboration between primary and secondary care (3 months = MD 1.61; 95% CI 0.72 to 2.51, 6 months = MD 1.78; 95% CI 1.03 to 2.53, and 9 months = MD 1.20; 95% CI 0.42 to 1.97). However, no statistically significant differences were found at any time point for the dependent variable patient satisfaction regarding the treatment at the outpatient clinic (Table 3.3).

Based on the Global Perceived Effect, 74.6%, 78.3%, and 84.6% of the intervention group patients were “completely recovered” or “much improved” at 3, 6, and 9 months, respectively. Of the control group patients, 53.8%, 53.3% and 75% were “completely recovered” or “much improved” at these time points. At 6 months this effect was statistically significant (OR 3.35; 95% CI 1.32 to 8.49) (Table 3.4).

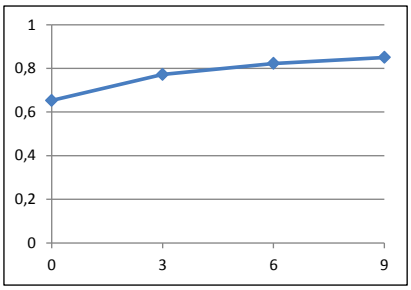
Table 3.4 Treatment effect for global perceived effect (“completely recovered” or “much improved”)

GPE succes	Succes% Intervention group	Succes% Control group	Treatment effect (crude) OR (95% CI)	Treatment effect (adjusted) OR (95% CI)	Adjusted for*
3 months	74.6	53.8	2.37 (0.85 to 6.62)	2.39 (0.69 to 8.20)	Age, fracture region, length of stay
6 months	78.3	53.3	2.99 (1.24 to 7.23)	3.35 (1.32 to 8.49)	Fracture region
9 months	84.6	75.0	1.16 (0.46 to 2.95)	1.21 (0.45 to 3.28)	Medical history, TTO**

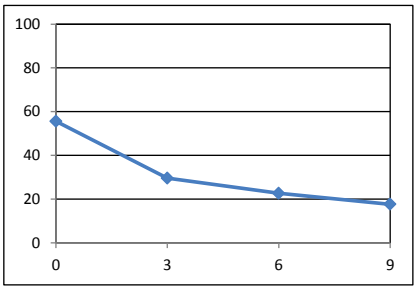
* The baseline characteristics mentioned in this column were confounders (changed the regression coefficient with 10% or more).
** TTO = Time between Trauma and first Outpatient consultation (days).

Recovery pattern of patients in the intervention group

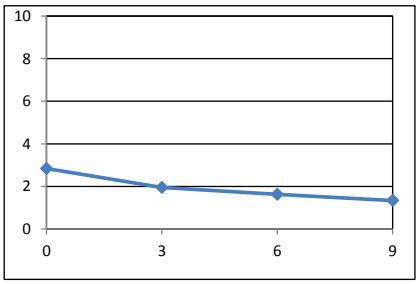
During the nine-month follow-up period, generic HR-QOL (F=18.43; p=0.000), disease-specific HR-QOL (F=6.18; p=0.001), pain (F=17.16; p=0.000), and functional status (F=65.05; p=0.000) statistically significantly improved in a linear fashion among intervention group patients (Figure 3.3a, 3.3b, 3.3c and 3.3d).



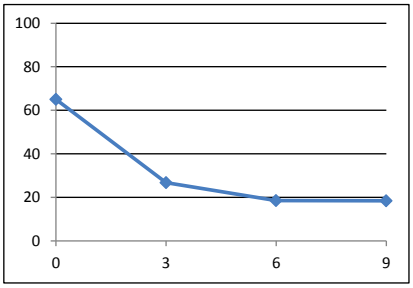
a: Generic HR-QOL (EQ-5D-3L)



b: Disease-specific HR-QOL (DSQOL-OA)



c: Pain (NPRS)



d: Functional status (PSFS)

Figure 3.3 Longitudinal follow-up intervention group.

DISCUSSION

Traumatic injury poses a substantial economic burden to society. However, little is currently known about how to optimally organize the post-clinical rehabilitation process of trauma patients. Therefore, the current study developed and evaluated the TTCM, the first transmural care model for the rehabilitation of trauma patients in primary care [9,10,23].

Important study findings and comparison with the literature

Our results indicate that the TTCM statistically significantly improved disease-specific HR-QOL, functional status, patient satisfaction and perceived recovery, and reduced pain among mild, moderate and severe trauma patients. It is important to mention, however, that even though no statistically significant effects were found for generic HR-QOL, the identified mean difference can be regarded as clinically relevant at 6 months (MD 0.051; 95% CI -0.02 to 0.12) and 9 months (MD 0.055; 95% CI -0.01 to 0.12). To illustrate, estimates of the minimal clinical important difference (MCID) for the EQ-5D range from 0.03 among patients with low back pain [43], to 0.52 in patients with recurrent lumbar stenosis [44]. In light of this finding it is also important to bear in mind

that the current study was not powered to detect a clinically meaningful difference in generic HR-QOL due to its explorative nature.

Strengths and limitations

The present study population covers a broad range in trauma patients, with an ISS ranging from 4 to 43. This is an important strength, as the majority of studies only included major trauma patients with an ISS >16 [4,14,45]. Since our study population includes mild, moderate and severely injured patients, the TTCM is likely to be effective in the entire group of trauma patients. However, future research is necessary to examine whether several subgroups of trauma patients respond in different ways on the TTCM.

A second important strength of this study is its clinical relevance as well as the fact that it was the first to develop and evaluate a transmural care model for the post-clinical rehabilitation of trauma patients. Other strengths include its use of a broad spectrum of measurement instruments, covering all domains of the International Classification of Functioning, Disability and Health (ICF) [46], its use of validated questionnaires, as well as its pragmatic design (i.e. daily practice was resembled as much as possible).

The study also had some limitations. Even though the applied modified controlled-before-and-after design was regarded as the most optimal research design within the available resources, it is susceptible to many kinds of bias. Examples of such kinds of bias are selection bias, recall bias, regression to the mean, the Hawthorne effect, and repeat testing bias. Of them selection bias is probably most likely, meaning that the study groups have a different composition regarding various etiological factors. A multicenter randomized controlled trial would therefore be the next step in order to study the TTCM's effectiveness more robustly. In spite of the fact the all participating trauma patients met the same inclusion criteria, we observed some baseline differences in age (intervention group patients were younger) and admission to hospital (75% of intervention group patients were admitted to the hospital, compared to 51% in control group). Based on the recommendations of de Boer et al. we decided not to statistically test baseline differences across study groups [47]. They postulate that statistically testing of baseline differences ignores the fact that the prognostic strength of a variable is also important when the interest is in e.g. adjustment for confounding. On top of that, our study was not powered to detect relevant differences at baseline, so possibly relevant differences may also turn out not to be statistically significant. Nonetheless, if we found the addition of a certain baseline variable to change the regression coefficient by more than 10%, they were added to the final models. Another potential limitation was the absence of a sample size calculation. We based the sample size on

our estimate of the number of patients that could potentially be included within the time frame and financial constraints of this study. A sample size calculation is preferable in future research, to make sure that the study is not underpowered to detect clinically meaningful effect differences. Another limitation is the fact that we were not able to identify what components of the TTCM were responsible for the positive effects. To illustrate, the better functional outcomes could be the result of an improved communication strategy between the multidisciplinary hospital team and the primary care physical therapist. On the other hand, the better outcomes may have been the result of a better educated and more experienced network of primary care physical therapists. It would be interesting to identify the critical ingredient of this relatively complex intervention. One might also argue, however, that the sum is greater than the individual parts and therefore there is probably no such thing as a critical ingredient. Future research can possibly provide more insight into whether separate TTCM components are accountable for specific effects.

CONCLUSIONS

This study provides preliminary evidence that the TTCM is effective in improving patient-related outcome measures, such as disease-specific HR-QOL and functional status. A multicenter, and ideally randomized controlled trial, is required to confirm these results.

Funding

This project is partly funded by “Zilveren Kruis Health Insurer” (grant number Z516).

Acknowledgements

We thank all trauma patients who participated in the study. Furthermore we thank the participating trauma surgeons and physical therapists for their willingness to change their approach.

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METTE (60) | FRONTAL CAR CRASH SOME YEARS AGO

Shattered femoral fracture and fractures of the foot

4

Cost-effectiveness of the Transmural Trauma Care Model (TTCM) for the rehabilitation of trauma patients

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Int J Technol Assess Health Care. 2019;35(4):307-16

ABSTRACT

Objectives: To assess the societal cost-effectiveness of the Transmural Trauma Care Model (TTCM), a multidisciplinary transmural rehabilitation model for trauma patients, compared to regular care.

Methods: The economic evaluation was performed alongside a before-and-after study, with a convenience control group measured only afterwards, and a 9-month follow-up. Control group patients received regular care and were measured before implementation of the TTCM. Intervention group patients received the TTCM and were measured after its implementation. The primary outcome was generic health-related quality of life (HR-QOL). Secondary outcomes included disease-specific HR-QOL, pain, functional status and perceived recovery.

Results: Eighty-three trauma patients were included in the intervention group and 57 in the control group. Total societal costs were lower in the intervention group than in the control group, but not statistically significantly so (EUR-267; 95% CI: EUR-4,175 to 3,011). At 9 months, there was no statistically significant between-group differences in generic HR-QOL (0.05; 95% CI-0.02 to 0.12) and perceived recovery (0.09; 95% CI -0.09 to 0.28). However, mean between-group differences were statistically significantly in favor of the intervention group for disease-specific HR-QOL (-8.2; 95% CI -15.0 to -1.4), pain (-0.84; 95% CI -1.42 to -0.26), and functional status (-20.1; 95% CI -29.6 to -10.7). Cost-effectiveness acceptability curves indicated that if decision-makers are not willing to pay anything per unit of effect gained, the TTCM has a 0.54–0.58 probability of being cost-effective compared with regular care. For all outcomes, this probability increased with increasing values of willingness-to-pay.

Conclusion: The TTCM may be cost-effective compared with regular care, depending on the decision-makers willingness to pay and the probability of cost-effectiveness that they perceive as acceptable.

BACKGROUND

Traumatic injury is the leading cause of death during the first four decades of life, accounts for 9.6% of global mortality [1,2] and causes the biggest loss of Disability-Adjusted Life Years (DALYs) compared to any other disease [3]. Traumatic injury disproportionately affects younger individuals and, as a consequence, accounts for the highest amount of lost productive years of life [4]. While the direct medical costs of traumatic injury are substantial, its economic burden is particularly high for employers. To illustrate, in the United States, the total cost of fatal unintentional injury was estimated at about USD84 billion, of which the largest share was due to lost productivity (i.e. about USD83 billion) [4]. In the Netherlands, the total cost of trauma (intentional and unintentional) was estimated to be EUR6 billion, of which EUR2.6 billion were direct medical costs and EUR3.4 billion were lost productivity costs [5].

During the last three decades, an improved organization of acute trauma care has led to a 15–25% decrease in mortality [6-8]. As further improvements in survival rates are likely to be relatively small, the focus of trauma care has moved from reducing mortality to improving quality of life and outcome [9]. A possible means for improving trauma patients' health-related quality of life (HR-QOL) and outcome may be the optimization of their rehabilitation process. We therefore developed the Transmural Trauma Care Model (TTCM), which aims to improve the organization, content, and quality of the trauma patients' rehabilitation process. The TTCM consists of a continuous feedback loop, in which a multidisciplinary hospital-based team supervises a network of primary care physical therapists in the treatment of trauma patients [10]. Effectiveness analyses showed that, among trauma patients with at least one fracture, the TTCM resulted in better patient outcomes, such as disease-specific HR-QOL, pain and functional status, compared to regular care (Wiertsema et al., unpublished data).

As healthcare resources are restricted, trauma systems should not only be effective in improving patient outcomes, but also provide "good value for money". The latter is assessed in an economic evaluation, which provides insight into a treatment's additional cost per additional unit of health gained [11]. Up until now, relatively few economic evaluations evaluated the cost-effectiveness of trauma systems [12-14], and those aimed at the rehabilitation phase in particular. Therefore the current economic evaluation aimed to assess the cost-effectiveness of the TTCM for generic HR-QOL from a societal perspective compared to regular care. In a secondary analysis, the intervention's cost-effectiveness for disease-specific HR-QOL, pain, functional status, and perceived recovery was assessed.

METHODS

The study protocol has been published elsewhere [10]. A summary is given below.

Design

The economic evaluation was conducted alongside a before-and-after study with a convenience control group measured only afterwards. This clinical trial was conducted at the outpatient clinic of a level-1 trauma center (Amsterdam UMC, location VUmc, Amsterdam, The Netherlands) [15]. In contrast to a *true* controlled-before-and-after study, only the intervention group was prospectively followed, while control group data were collected cross-sectionally. That is, the trial's control group consisted of 4 independent clusters of patients who either had their first consultation at the outpatient clinic 0, 3, 6 or 9 months ago. After implementation of the TTCM, one cluster of intervention group patients was prospectively followed and measured directly after their first consultation at the outpatient clinic (i.e. baseline), and after 3, 6 and 9 months (Figure 4.1). In order to capture all costs flowing from the intervention under study, the analytic time frame of an economic evaluation typically needs to be longer than that of an effectiveness study [16]. Therefore, in the present economic evaluation, only the 9-month control cluster was compared to the intervention group. The 9-month control cluster will be further referred to as the control group.

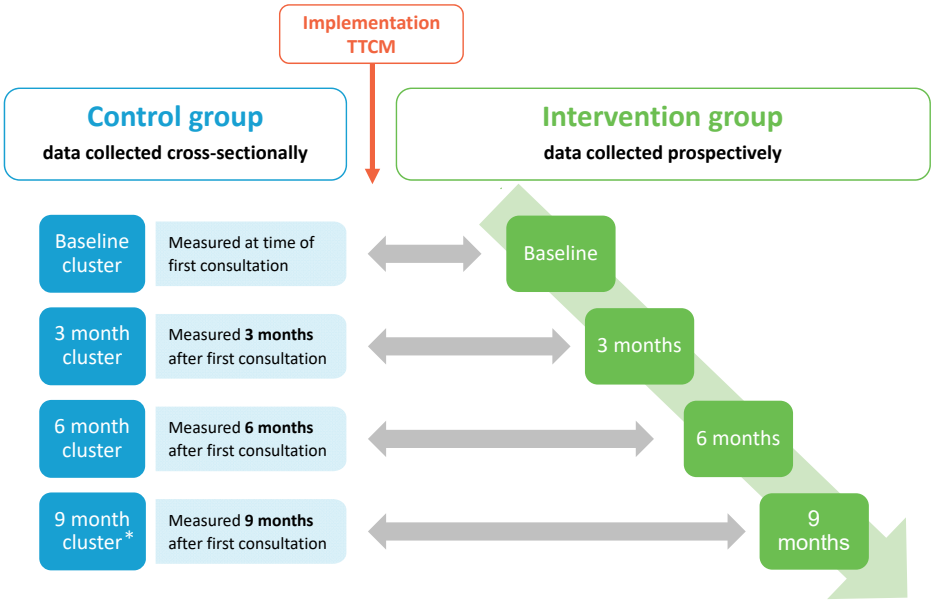

Figure 4.1 Study design of the modified controlled before and after study.
* Cost data of control group patients in the 9-month cluster will be used for economic evaluation.

The medical ethics committee of the VUmc decided that the Dutch Medical Research Involving Human Subjects Act (WMO) was not applicable to the present study (registered under number 2013.454). All participants gave informed consent. The trial is registered at the Dutch Trial Register (NTR5474).

Participants

Surgically as well as conservatively treated trauma patients were included. Eligible trauma patients had at least one traumatic fracture, were aged ≥18 years, rehabilitated in the primary care setting and were able to fill out online questionnaires in Dutch. Patients were excluded if they met any of the following criteria: traumatic brain injury, pathological (non-traumatic) fractures, cognitive limitations, rehabilitation in a tertiary care facility or living outside the catchment area of the VUmc.

Control group patients were identified from the central trauma registry of the trauma region "North West Netherlands" and were contacted by phone by one of the investigators. They received further information about the study, after which the principle investigator verified the in- and exclusion criteria and patients were assigned to their specific cluster (based on the time elapsed since their first consultation). Eligible patients who were willing to participate received an email containing a link to the online questionnaire. Patients who did not respond within one week received a maximum of two reminder emails. If the patient did not reply to both emails, one of the coordinating investigators contacted the patient by phone.

Intervention group patients were identified during their first consultation at the outpatient clinic. During this consultation, patients were informed about the study by one of the investigators and in- and exclusion criteria were verified. In the week following the first consultation, patients who were willing and eligible to participate, received an email containing a link to the first online questionnaire. Subsequently, patients were prospectively followed and received additional online questionnaires at 3-, 6- and 9-month follow-up. Patients who did not respond within one week, received a maximum of 2 reminder emails. If the patient did not reply to both emails, one of the coordinating investigators contacted the patient by phone.

Intervention conditions

Pre- and in-hospital trauma care remained unchanged and was the same for the intervention group and the control group.

The Transmural Trauma Care Model (TTCM)

Patients in the intervention group received care according to the TTCM [10]. The TTCM combined the following components:

1. *A multidisciplinary team consisting of a trauma surgeon and a highly-specialized hospital-based trauma physical therapist at the outpatient clinic for trauma patients*. The trauma surgeon acted as the chief consultant, the physical therapist assessed physical function and acted as case manager throughout the rehabilitation process. During a shared-decision making process the surgeon, physical therapist and patient determined whether and when physical therapy in primary care was required.

2. *Coordination and individual goal setting for each patient by this hospital-based team in combination with treatment according to customized protocols*. The hospital-based team coordinated the patients' rehabilitation process by repeatedly defining individual goals with the patient during the rehabilitation period. For the purpose of the TTCM, 10 rehabilitation protocols were developed for the most common fractures (e.g. hip fractures, tibial plateau fractures).

3. *A network of 40 specialized primary care physical therapists*. This so called "VUmc trauma rehabilitation network" consisted of 40 physical therapists covering the region of Amsterdam (www.traumarevalidatie.nl) (17). The 40 primary care physical therapists participating in the trauma network were trained and educated during a two-day course led by trauma surgeons and hospital-based physical therapists, specialized in trauma care.

4. *E-health support for transmural communication between the hospital-based trauma physical therapist and the primary care physical therapist*. The hospital-based physical therapist and the primary care physical therapist communicated repeatedly throughout the rehabilitation process using secured email (especially developed for health care professionals).

Regular care

Patients in the control group received regular post-clinical care during which the trauma surgeon acted as the chief consultant and performed the post-clinical consultations, unaccompanied by any allied health care professionals. The trauma surgeon decided whether and when physical therapy in primary care was needed. During a patients' rehabilitation, there was no regular contact between the surgeon and the primary care physical therapist.

Outcome measures

Various demographic and trauma-related characteristics were assessed for all patients (e.g. age, gender, medical history, ISS, time between trauma and first outpatient consultation [TTO]). These characteristics were collected using online questionnaires, supplemented by data derived from electronic patient records.

The primary outcome was generic HR-QOL. Secondary outcomes included disease-specific HR-QOL, pain, functional status, and perceived recovery. In the intervention group, outcome measures were assessed at 0, 3, 6 and 9 months after patients' first consultation at the outpatient clinic. In the control group, outcome measures were solely assessed at 9 months after the patients' first consultation at the outpatient clinic.

Generic HR-QOL was measured using the EQ-5D-3L [18]. Using the Dutch tariff, the participants' EQ-5D-3L health states were converted into a utility score, anchored at 0 (dead) and 1 (optimal health). As control group participants were only measured once, we were not able to estimate quality adjusted life years and include them as an outcome measure in the current economic evaluation. Nonetheless, generic HR-QOL can still be regarded as a preference-based measure, as utility values were based on the preferences of the Dutch population.

Disease-specific HR-QOL was measured using four disease-specific function scales, appropriate to the patients' specific injury type. The Quick Dash score was filled out by patients with fractures of the upper extremity [19,20]. The Lower Extremity Functional Scale (LEFS) was used in patients with hip fractures or other lower extremity fractures [21,22]. The Roland Morris Disability Score (RMDS) was filled out by patients with vertebral fractures [23,24]. The Groningen Activity Restriction Scale (GARS) was used in multi-trauma patients [25]. An overall disease-specific HR-QOL score was calculated by converting the overall scores of the four abovementioned questionnaires to a scale from 0–100, with higher scores representing more functional problems.

Pain was measured using an 11-point numeric pain rating scale (NPRS), ranging from 0 (no pain) to 10 (worst possible pain) [26].

Functional status was measured using the Patient Specific Function Scale (PSFS) [27,28]. Patients had to identify 3 important activities that they are having difficulty with and were requested to rate their current level of difficulty associated with each activity on an 0–100 mm visual analogue scale (VAS) ranging from 0 ("able to perform activity at same level as before injury or problem") to 100 ("unable to perform activity"). Only the activity that was first mentioned by the patient was used in the economic evaluation.

Perceived recovery was measured using the Global Perceived Effect (GPE) scale. Patients were asked to rate how much their condition has improved or deteriorated since their trauma on a 7-item scale [29]. Success of treatment was achieved when a patient reported to being "completely recovered" or "much improved".

Cost measures

Costs were measured from a societal perspective, including intervention, health care, absenteeism, presenteeism and unpaid productivity costs. Intervention costs included all costs related to the additional time investments of the hospital-based trauma physical therapist (estimated at 15 minutes per outpatient clinic consultation) and the specialized primary care physical therapist (estimated at 5 minutes per outpatient clinic consultation), as well as the cost of hosting and maintaining the transmural communication system. The costs associated with the TTCM's development (e.g. training costs) were excluded, as these costs will become negligible after implementing the intervention broadly [30,31]. All other cost categories were assessed using online cost questionnaires, supplemented by hospital records if available (e.g. for imaging procedures). In order to cover the complete duration of follow-up, recall periods of the online questionnaires varied between treatment groups and measurement points. For the intervention group, 3-month recall periods were used at baseline, 3, 6 and 9 months follow-up and costs were added together to get an estimate of the total costs during the 9-month follow-up period. For the control group, a recall period of 9 months was used at 9-month follow-up.

Health care utilization included 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 were used to value health care costs [31]. Medication use was valued using the G-standard of the Dutch Society of Pharmacy [32].

Absenteeism was assessed using the "PROductivity and DISease Questionnaire" (PRODISQ). Patients were asked to report their total number of sick leave days [33]. Absenteeism was valued using age- and gender-specific price weights [31].

Presenteeism was defined as reduced productivity while at work and was assessed using the World Health Organization Health and Work Performance Questionnaire [34]. Presenteeism was valued using age- and gender-specific price weights [31].

Unpaid productivity losses were 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. A

recommended Dutch shadow price was used to value unpaid productivity. The Dutch shadow price was calculated in accordance with the opportunity good method and was estimated to be EUR12.50 per hour in 2009 [31].

All costs were presented in Euros and converted to the same reference year (i.e. 2014) using consumer price indices. Discounting of costs was not necessary due to the 9-month follow-up period [11].

Data analysis

Descriptive statistics

Descriptive statistics were used to compare baseline characteristics between intervention and control group participants.

Handling missing data

Missing data were imputed using Multiple Imputation by Chained Equations [35]. Two imputation models were constructed, including one for the intervention group and one for the control group. Both imputation models included variables related to the "missingness" of data, variables that predicted the outcomes, and all available midpoint and follow-up cost and effect measure values [35]. Ten complete data sets were created in order for the loss-of-efficiency to be below 5% [36]. Imputed datasets were analysed separately as specified below, after which pooled estimates were calculated using Rubin's rules [36].

Economic evaluation

Cost-effectiveness analyses were performed according to the intention-to-treat principle. Cost and effect differences were estimated using seemingly unrelated regression analyses in order to correct for their possible correlation. Cost and effect differences were corrected for confounders. Confounding was checked by adding the potential confounding variable to the crude models, and was subsequently considered to be present if the regression coefficient changed by 10% or more. To deal with the highly skewed nature of cost data, 95% CIs around the differences in costs were estimated using the Bias Corrected and Accelerated Bootstrap method, with 5,000 replications. Incremental Cost-Effectiveness Ratios (ICERs) were calculated by dividing the differences in costs by those in effects. To graphically illustrate the uncertainty surrounding the ICERs, bootstrapped incremental cost-effect pairs were plotted on cost-effectiveness planes [37]. A summary measure of the joint uncertainty of costs and effects was presented using Cost-Effectiveness Acceptability Curves (CEACs), which indicate the probability of an intervention

being cost-effective in comparison with the control condition for a range of willingness-to-pay values (i.e. the maximum amount of money decision-makers are willing to pay to gain one extra unit of effect) [38]. Two one-way structural sensitivity analyses were performed to test the robustness of the results; 1) applying the healthcare perspective (i.e. only costs accruing to the Dutch healthcare system were included), and 2) excluding presenteeism costs [11]. All analyses were performed in STATA, using a level of significance of $p<0.05$.

RESULTS

Study participants

Eighty-three trauma patients were enrolled in the intervention group and 57 in the control group (Supplementary Figure S4.1). Most baseline characteristics were similar among intervention and control group patients. However, patients in the intervention group were slightly younger, were more frequently admitted to a hospital, received surgery more frequently, and had a longer time between trauma and their first outpatient consultation than their control group counterparts (Table 4.1). A total of 107 patients (76%) had complete effect data at nine months follow-up (i.e. 52 intervention group patients and 55 control group patients) and 62 patients (44%) had complete cost data on all measurement points (i.e. 17 intervention group patients and 45 control group patients).

Effectiveness

At 9 months, there was no statistically significant difference in the primary outcome generic HR-QOL between the intervention group and control group. As for the secondary outcomes, mean between-group differences were statistically significantly in favor of the intervention group for disease-specific HR-QOL, pain and functional status, but not for perceived recovery (Table 4.2).

Costs

On average, the cost of the TTCM was EUR272 (SEM=EUR4) per patient. Secondary healthcare, presenteeism, and total societal costs were lower in the intervention group than in the control group, while primary healthcare, medication, absenteeism and unpaid productivity costs were higher in the intervention group than in the control group. Of them, only the difference in secondary healthcare costs was statistically significant (Table 4.3).

Table 4.1 Baseline characteristics (patient- and trauma-related)

Characteristics	Intervention group Mean (SD) or frequency (%)	Control group Mean (SD) or frequency (%)
N	83	57
Age	43.4 (15.6)	50.5 (17.9)
Gender (M/F)	39/44 (47/53%)	26/31 (46/54%)
Education level		
Low	7 (8.4%)	6 (11.1%)
Middle	19 (22.9%)	16 (29.6%)
High	57 (68.7%)	32 (59.3%)
Medical history		
None	53 (63.9%)	30 (52.6%)
Chronic	14 (16.9%)	13 (22.8%)
Musculoskeletal	16 (19.3%)	14 (24.6%)
Trauma type		
Traffic	44 (53.0%)	25 (43.9%)
Work-related	0	2 (3.5%)
Fall	27 (32.5%)	17 (29.8%)
Sports	11 (13.3%)	9 (15.8%)
Other	1 (1.2%)	4 (7.0%)
Fracture region		
Upper extremity	31 (37.3%)	25 (43.9%)
Lower extremity	41 (49.4%)	19 (33.0%)
Vertebral	7 (8.4%)	1 (1.8%)
Multitrauma	4 (4.8%)	12 (21.1%)
ISS	7.9 (range 4–26, SD 4.4)	8.6 (range 4–29, SD 6.3)
Admission hospital	62 (75.0%)	29 (51.0%)
Length of stay (days)	7.1 (6.1)	10.0 (11.4)
Surgery	53 (64.0%)	21 (37.0%)
TTO (days)*	24.3 (14.3)	14.6 (14.7)

* TTO = Time between Trauma and first Outpatient consultation.

Economic evaluation

Primary outcome: generic HR-QOL

The main analysis results for generic HR-QOL indicated that the TTCM dominated regular care (i.e. less costly and more effective) (Table 4.2). The CEAC in Supplementary Figure S4.2 indicates that the TTCM has a 0.58 probability of being cost-effective compared with usual care if decision-makers are not willing to pay anything per utility gained, increasing to a maximum of 0.90 at a willingness-to-pay of EUR55,000/utility gained.

Table 4.2 Differences in pooled mean costs and effects (95% CI), incremental cost-effectiveness ratios, and the distribution of incremental cost-effect pairs around the quadrants of the cost-effectiveness planes

Analysis	Intervention group N	Control group N	Outcome	ΔC (95% CI)* EUR	ΔE (95% CI)** Points	ICER EUR/point	Distribution CE-plane (%)			
							NE[1]	SE[2]	SW[3]	NW[4]
Main analysis Imputed dataset	83	57	Generic HR-QOL (0–1)	-237 (-4,286 to 3,285)	0.05 (-0.02 to 0.12)	-4,453	40.7	53.4	2.2	3.7
	83	57	Disease-specific HR-QOL (0–100)	-232 (-4,342 to 3,167)	-8.2 (-15.00 to -1.40)	28	39.6	53.5	2.0	5.0
	83	57	Pain (0–10)	-190 (-4,140 to 3,284)	-0.84 (-1.42 to -0.26)	225	45.1	54.7	0.0	0.1
	83	57	Perceived recovery (0–1)	-192 (-4,348 to 3,112)	0.09 (-0.09 to 0.28)	2,087	36.9	48.2	0.9	0.6
	83	57	Functional status (0–100)	-345 (-4,372 to 3,121)	-20.1 (-29.60 to -10.70)	17	42.7	57.3	0.0	0.0
One-way sensitivity analysis 1 Healthcare perspective	83	57	Generic HR-QOL (0–1)	-491 (-2,700 to 393)	0.05 (-0.02 to 0.12)	19	24.3	69.5	0.4	0.2
	83	57	Disease-specific HR-QOL (0–100)	-466 (-2,698 to 317)	-8.2 (-15.00 to -1.40)	57	21.0	68.1	5.1	5.9
	83	57	Pain (0–10)	-490 (-2,780 to 391)	-0.84 (-1.44 to -0.25)	580	26.4	73.5	0.1	0.0
	83	57	Perceived recovery (0–1)	-454 (-2,570 to 412)	0.09 (-0.08 to 0.25)	5,725	20.1	62.8	10.4	6.7
	83	57	Functional status (0–100)	-511 (-2,749 to 391)	-20.1 (-29.60 to -10.70)	25	24.5	74.5	0.0	0.0
One-way sensitivity analysis 2 Excluding presenteeism	83	57	Generic HR-QOL (0–1)	339 (-4,237 to 4,216)	0.05 (-0.02 to 0.12)	6,371	52.0	42.1	1.7	4.2
	83	57	Disease-specific HR-QOL (0–100)	351 (-4,222 to 4,152)	-8.2 (-15.00 to -1.40)	-43	50.6	41.6	2.0	5.7
	83	57	Pain (0–10)	373 (-4,142 to 4,179)	-0.84 (-1.44 to -0.25)	-441	56.9	42.9	0.0	0.1
	83	57	Perceived recovery (0–1)	393 (-4,327 to 4,283)	0.09 (-0.08 to 0.25)	4,328	48.9	36.4	6.2	8.5
	83	57	Functional status (0–100)	224 (-4,340 to 4,045)	-20.1 (-29.60 to -10.70)	-11	54.7	45.3	0.0	0.0

[1] Refers to the northeast quadrant of the CE-plane, indicating that the intervention is more effective and more costly than usual care.

[2] Refers to the southeast quadrant of the CE-plane, indicating that the intervention is more effective and less costly than usual care.

[3] Refers to the southwest quadrant of the CE-plane, indicating that the intervention is less effective and less costly than usual care.

[4] Refers to the northwest quadrant of the CE-plane, indicating that the intervention is less effective and more costly than usual care.

Please note that the mean cost differences differ across outcomes. This is due to the use of Seemingly Unrelated Regression analyses, in which cost and effect differences are corrected from their possible correlation.

* Cost differences were corrected for medical history, surgery, paid work (y/n) and number of working hours/week.

** Effect differences were corrected for age, medical history, TTO (Generic HR-QOL); age, medical history, TTO, fracture region, admission hospital, surgery (Disease-specific HR-QOL); none (Pain); medical history, TTO (Perceived recovery) and TTO, surgery (Functional status).

Table 4.3 Mean costs per participant in intervention- and control group and mean cost differences between groups during the 9-month follow-up period

Cost category	Intervention group N=83 Mean (SEM) EUR	Control group N=57 Mean (SEM) EUR	Mean cost difference Unadjusted (95% CI) EUR	Mean cost difference Adjusted (95% CI) EUR
Intervention	272 (4)	0 (0)	272 (257 to 278)	270 (264 to 277)
Healthcare	2,397 (174)	3,003 (639)	-606 (-2,821 to 218)	-953 (-3,854 to 168)
Primary healthcare	1,138 (108)	925 (152)	212 (-175 to 559)	56 (-440 to 494)
Secondary healthcare	1,216 (112)	2,005 (567)	-789 (-2,853 to -119)	-1,010 (-3,696 to -67)
Medication	44 (14)	74 (21)	-29 (-90 to 14)	1 (-65 to 87)
Absenteeism	7,052 (1,253)	3,419 (1,149)	3,633 (503 to 6,292)	595 (-3,072 to 3,564)
Presenteeism	2,692 (559)	2,274 (533)	418 (-937 to 1,679)	-565 (-1,769 to 666)
Unpaid productivity	1,408 (250)	1,214 (273)	194 (-483 to 880)	283 (-645 to 1,305)
Total	13,822 (1,261)	9,910 (1,475)	3,912 (-457 to 6,860)	-267 (-4,175 to 3,011)

Secondary outcomes: disease-specific HR-QOL, pain, perceived recovery, and functional status
The main analysis results for disease-specific HR-QOL indicated that the TTCM dominated regular care (i.e. less costly and more effective) (Table 4.2). Please note that a lower score in disease-specific HR-QOL indicates an improvement. The CEAC in Supplementary Figure S4.2 indicates that the TTCM has a 0.55 probability of being cost-effective compared with regular care if decision-makers are not willing to pay anything per 1-point improvement in disease-specific HR-QOL, increasing to 0.95 at a willingness-to-pay of EUR700/point improvement.

The main analysis results for pain indicated that the TTCM dominated regular care (i.e. less costly and more effective) (Table 4.2). Please note that a lower pain score indicates an improvement. The CEAC in Supplementary Figure S4.2 indicates that the TTCM has a 0.54 probability of being cost-effective compared with regular care if decision-makers are not willing to pay anything per 1-point improvement in pain, increasing to 0.95 at a willingness-to-pay of EUR3,500/point improvement.

The main analysis results for perceived recovery indicated that the TTCM dominated regular care (i.e. less costly and more effective) (Table 4.2). The CEAC in Supplementary Figure S4.2 indicates that the TTCM has a 0.54 probability of being cost-effective compared with regular care if decision-makers are not willing to pay anything per recovered patient, increasing to a maximum of 0.85 at a willingness-to-pay of EUR50,000/recovered patient.

The main analysis results for functional status indicated that the TTCM dominated regular care (i.e. less costly and more effective) (Table 4.2). Please note that a lower score in functional status indicates an improvement The CEAC in Supplementary Figure S4.2 indicates that the TTCM has a 0.57 probability of being cost-effective compared with regular care if decision-makers are not willing to pay anything per point improvement in functional status, increasing to 0.95 at a willingness-to-pay of EUR125/point improvement.

One-way sensitivity analyses

When the healthcare perspective was applied, the mean difference in total costs was larger than in the main analysis (e.g. EUR-491 versus EUR-237 for general HR-QOL), and still in favor of the intervention group. This resulted in higher probabilities of the TTCM being cost-effective compared with the main analysis (Table 4.2). When excluding presenteeism costs, total costs were higher in the intervention group than in the control group. This finding was in contrast to the main analysis, and resulted in lower probabilities of the TTCM being cost-effective (Table 4.2).

DISCUSSION

Traumatic injury is the most important cause of long-term functional limitations in adults younger than 45 years [39] and poses a substantial economic burden to society [40]. As healthcare resources are restricted, trauma systems should not only be effective in improving patient outcomes, but also provide "good value for money". Therefore, the current economic evaluation aimed to assess the cost-effectiveness of the TTCM for generic HR-QOL from a societal perspective compared to regular care. In a secondary analysis, the intervention's cost-effectiveness for disease-specific HR-QOL, pain, functional status, and perceived recovery was assessed.

Main findings

Results indicated that the TTCM statistically significantly improved disease-specific HR-QOL and functional status, and reduced pain, compared with regular care. Between-group differences in generic HR-QOL, perceived recovery, and total costs were in favour of the intervention group as well, but not statistically significantly so. On average, the TTCM dominated regular care for all outcomes. CEACs indicated that if decision-makers are not willing to pay anything per unit of effect gained, the TTCM has a 0.54–0.58 probability of being cost-effective compared with usual practice. For all outcomes, this probability increased to relatively high levels with increasing values of willingness-to-pay (e.g. to 0.95 at a willingness-to-pay of EUR700/point improvement on a NRS). However, as it is unknown what decision-makers are currently willing-to-pay per unit of effect gained, strong conclusions cannot be made about the cost-effectiveness of the TTCM. Nonetheless, decision-makers need to understand the role that rehabilitation, job retraining, and injury prevention play in dealing with the tremendous economic impact of traumatic injury to society and they can use the present results to consider whether the TTCM provides "good value for money" at an acceptable probability of cost-effectiveness.

Comparison with the literature

Even though extensive research has been done on the quality and organization of pre- and in-hospital trauma care, relatively few economic evaluations have evaluated the cost-effectiveness of regionalized trauma systems [12-14], and those aimed at the rehabilitation phase in particular. A recent study assessed the cost-effectiveness of several care pathways for inpatient rehabilitation in severe trauma patients [41]. All participants were treated in a specialized trauma hospital, but the group that rehabilitated in an in-hospital rehabilitation center, had a significantly shorter length of stay (LOS) compared to the group that rehabilitated in an external rehabilitation center. However, this was a retrospective cohort study that solely used LOS as a proxy for resource

consumption and therefore cannot be considered as a full economic evaluation. Furthermore, a Dutch study evaluated an integrated inpatient 'Fast Track' rehabilitation service for multi-trauma patients. No significant effect differences were observed between the intervention and control group and results of the scheduled economic evaluation have not yet been published [42]. Another study evaluated the cost-effectiveness of three inpatient rehabilitation modalities (i.e. physically orientated, geriatrically orientated and routine treatment) in patients with hip fractures. Considering total costs one year after trauma, physically orientated rehabilitation showed to be more cost-effective than routine treatment. Though it was a robust study, the results were not generalizable to other trauma patients [43]. To the best of our knowledge the present study is the first to evaluate the cost-effectiveness of a transmural care model for the post-clinical rehabilitation of trauma patients.

Strengths and weaknesses of the study

Important strengths of this study are the fact that it was the first to evaluate the cost-effectiveness of a new multidisciplinary transmural rehabilitation model for trauma patients, its use of a control group and its pragmatic design (i.e. daily practice is resembled as much as possible). Also, the study population covers a broad range in trauma patients (ISS ranging from 4 to 43). This is an important strength, as the majority of studies assessing HR-QOL, functional outcomes and costs after trauma, included only major trauma patients with an ISS>16 [39,44,45] or trauma patients with specific injuries (e.g. hip fractures or vertebral fractures) [46]. As our study population represents the whole spectrum from mild to severely injured trauma patients, the results are likely to be generalizable to the total trauma patient population (except patients with traumatic brain injury, which were excluded in this study). However, future research is necessary to explore whether specific trauma patient subgroups respond in a different way on the TTCM.

The study also had some limitations. First, a controlled-before-and-after design, with a convenience control group measured only afterwards, was regarded as the most optimal research design within the available resources and within the possibilities of clinical practice. However, such non-randomized study designs are inherently susceptible to many types of bias, such as selection bias, recall bias, regression to the mean, the Hawthorne effect, and repeat testing bias [47]. Most likely in the present study is the occurrence of selection bias, meaning that the control group and intervention group are likely to differ in known and unknown etiological factors. As a consequence, it is not possible to rule out the possibility that the current findings are biased by baseline differences in group characteristics, and those that we were not able to measure due to the current study design in particular [15]. Even though we were able to correct for some of them in our analyses, a randomized controlled design or an observational design

with a propensity score matched control group would have likely produced more valid results. Amongst others, this is evidenced by the fact that after correcting the total cost difference for medical history, surgery, paid work, and working hours it changed from being positive to negative, albeit not statistically significant in both cases. Another potential form of bias is the possible influence of recall bias due to the use of retrospective questionnaires with varying recall periods. The assumption is that a longer recall period increases the change of recall bias due to difficulties in recollecting facts and events after an elongated period of time. As control group patients were asked to remember their resource use during the last 9 months instead of during the last 3 months (which was the case for the intervention group), one might argue that the costs of the control group have a higher probability of being *underestimated* than those of the intervention group. However, as total societal costs were higher in the control group than in the intervention group, it seems unlikely that the use of retrospective questionnaires severely biased our results. A second shortcoming of the present study was the inability to include quality adjusted life years in the current economic evaluation, since utilities of the control group were only measured at one single time point. A third shortcoming is the relatively short time horizon of the clinical trial. Short time horizons are common in trial-based economic evaluations, as longer follow-ups are typically not feasible within a trial setting. One should bear in mind, however, that an intervention's cost-effectiveness observed within a trial may be substantially different from its longer-term cost-effectiveness. To deal with this limitation, the intervention's longer-term cost-effectiveness can be estimated using modelling techniques [48].

Finally and inherent to all economic evaluations, is the fact that the current results may not be generalizable to other countries due to differences in healthcare systems across countries. Also, despite extensive efforts to limit the amount of missing data, 56% of all participants had some missing cost data and 24% had some missing effect data. Although missing data are generally unavoidable in clinical studies and economic evaluations in particular, and multiple imputation techniques were used for filling in missing values, a complete dataset would have produced more valid and reliable results.

Implications for practice and further research

Decision-makers can use the present results to consider whether the TTCM provides "good value for money" at an acceptable probability of cost-effectiveness. Implementation of the TTCM in other level-1 trauma centers could be considered in the future, though a multicenter controlled trial would be required to confirm the present results.

CONCLUSION

The TTCM may be cost-effective compared with regular care, depending on the decision-makers willingness to pay and the probability of cost-effectiveness that they perceive as acceptable. However, a multicenter, and ideally randomized controlled trial, would be preferred to fortify the results of this pragmatic study.

Funding

This project is partly funded by "Zilveren Kruis Health Insurer" (grant number Z516).

Acknowledgements

We thank all trauma patients who participated in the study. Furthermore we thank Frank Duijff and Sander Assendelft from FysioRoadmap for their ongoing support and technical assistance during the project. Finally we thank Milou Rossenaar for her help with the cost-effectiveness analyses as a part of her graduation thesis.

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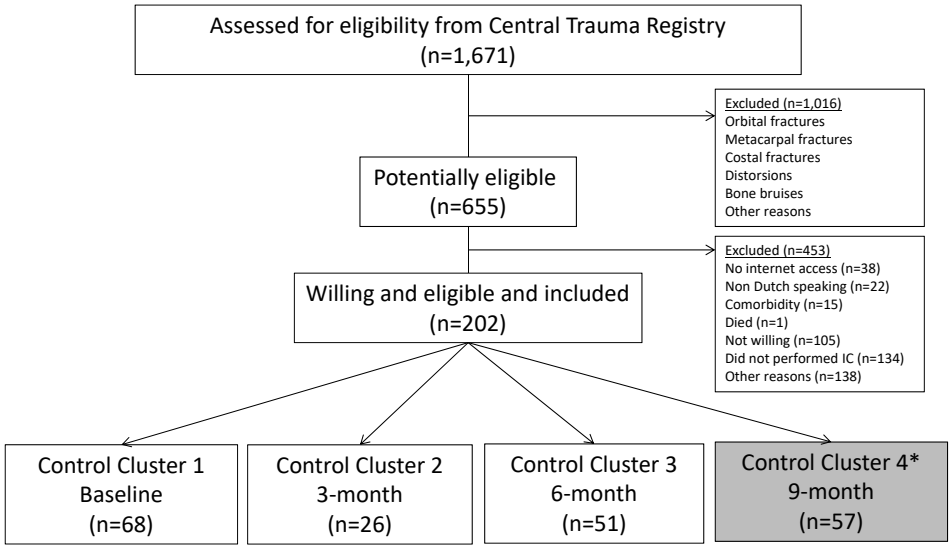
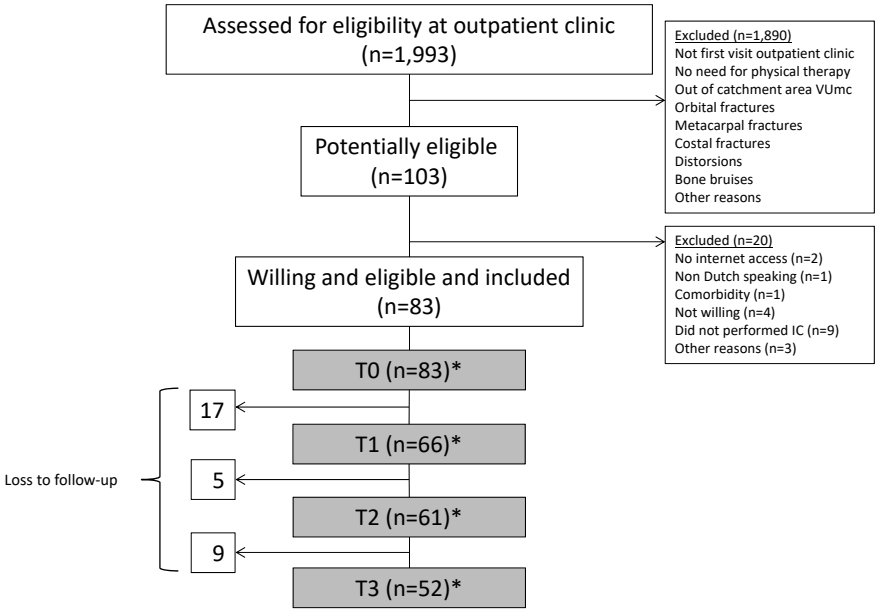
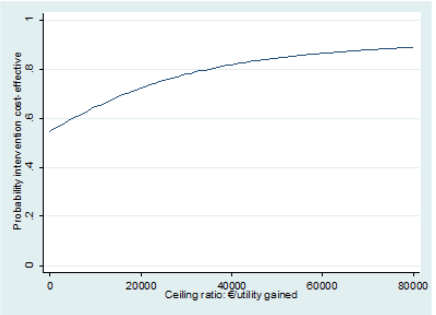
SUPPLEMENTARY FILES



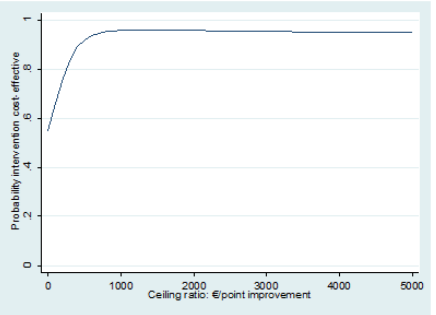
Supplementary Figure S4.1a Enrollment of control group participants.
* Cost data of patients in cluster 4 were used for economic evaluation.



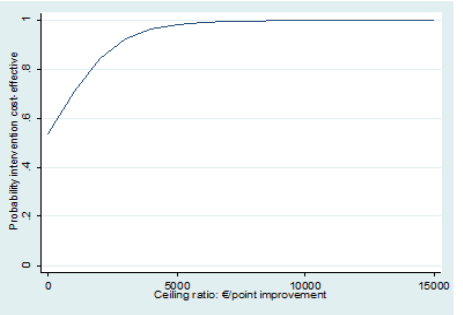
Supplementary Figure S4.1b Enrollment of intervention group participants.
* Cost data of all patients in the intervention group were used for economic evaluation.



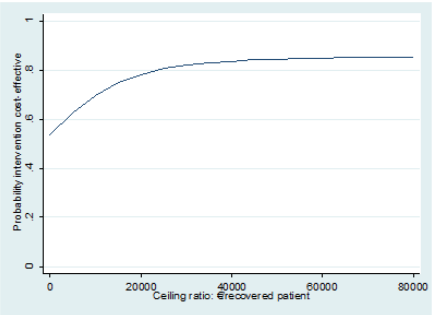
a: CEAC indicating the probability of the TTCM being cost-effective in comparison with usual care for different values (€) of willingness to pay per utility gained (EQ5D-3L).



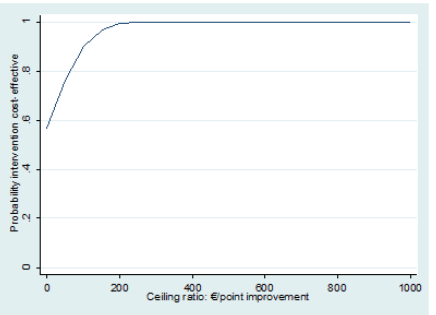
b: CEAC indicating the probability of the TTCM being cost-effective in comparison with usual care for different values (€) of willingness to pay per 1-point improvement in disease-specific HR-QOL (DSQOL-OA).



c: CEAC indicating the probability of the TTCM being cost-effective in comparison with usual care for different values (€) of willingness to pay per 1-point improvement in pain (NPRS).



d: CEAC indicating the probability of the TTCM being cost-effective in comparison with usual care for different values (€) of willingness to pay per recovered patient.



e: CEAC indicating the probability of the TTCM being cost-effective in comparison with usual care for different values (€) of willingness to pay per point improvement in functional status (PSFS).

Supplementary Figure S4.2 Cost-Effectiveness Acceptability Curves (CEACs).

Photo: Judith van Beek

DORE (24) | SCOOTER ACCIDENT 2 YEARS AGO

Knee luxation, lower leg fracture with associated vascular and neurological damage

5

Implementation of the Transmural Trauma Care Model (TTCM) for the rehabilitation of trauma patients: a process evaluation

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ABSTRACT

Objective: The Transmural Trauma Care Model (TTCM) is an advanced rehabilitation model for trauma patients with at least one fracture. This study aimed to explore the extent to which the TTCM was implemented as intended and to identify barriers and facilitators associated with its implementation.

Methods: This mixed-method process evaluation was conducted alongside a controlled-before-and-after study. The extent to which the TTCM was implemented as intended was quantitatively evaluated by assessing its reach, dose delivered, dose received, and fidelity. To explore the barriers and facilitators associated with the implementation of the TTCM, qualitative data were collected by conducting homogeneous focus groups among trauma patients, trauma surgeons, hospital-based physical therapists (HBPT) and primary care network physical therapists (PCNPT). A framework method was used for analyzing the focus groups. In doing so, the "constellation approach" was used to categorize barriers and facilitators into three categories; i.e. structure, culture, and practice.

Results: The TTCM's reach was 81%, its dose delivered was 99% and 100%, and its dose received was 95% and 96% for the multidisciplinary TTCM consultation hours at the outpatient clinic for trauma patients and the primary care network physical therapists, respectively. Fidelity scores, indicating the extent to which the intervention protocol was followed by the care providers, ranged from 66% to 93% (e.g. whether a secured email was sent from the HBPT to the PCNPT after each multidisciplinary TTCM visit and vice versa). Various barriers and facilitators were identified. An important facilitator at the structural level was the "use of a secured email system". The "absence of reimbursement for the HBPT at the outpatient clinic" was identified as a main barrier at the structural level. At the cultural level, the "shared decision-making process at the outpatient clinic" was identified as a facilitator and the fact that "care providers sometimes contradict each other" as a barrier. At the practical level, an "increased level of knowledge and skills" was identified as a facilitator and the "absence of awareness of the TTCM in other relevant departments" as a barrier.

Conclusion: This process evaluation showed that the TTCM was largely implemented as intended. Furthermore, various facilitators and barriers were identified that need to be considered when implementing the TTCM broadly. Some differences were found among stakeholders, but in general, they were of the opinion that if the barriers were overcome and a good working balance was achieved, the quality of care and patient satisfaction were likely to improve significantly after implementing the TTCM.

BACKGROUND

Traumatic injury accounts for 9.6% of global mortality [1-3] and major trauma in particular, was found to be the most important cause of long-term functional limitations in adults younger than 45 years [4]. Traumatic injury mainly affects younger individuals and, as a consequence, accounts for the highest number of lost productive years of life compared with other conditions [5]. During the last two decades, mortality due to traumatic injury has decreased considerably with 15–25% [6-8]. Consequently, the focus of trauma care has moved from reducing mortality to improving quality of life and outcome, which in turn resulted in a growing interest in improving the quality of trauma rehabilitation [9].

To improve the rehabilitation process of trauma patients, we developed and implemented the Transmural Trauma Care Model (TTCM) at a level-1 trauma center in the Netherlands. The TTCM is an advanced rehabilitation model, consisting of a continuous feedback-loop, in which a multidisciplinary hospital-based team supervises a network of primary care network physical therapists (PCNPT) during the rehabilitation process of trauma patients [10]. Evidence on the effectiveness and cost-effectiveness of the TTCM compared to regular care has been published elsewhere [11,12]. Results showed that the TTCM was associated with better patient outcomes and that it may be considered cost-effective compared with regular care, depending on the decision-makers' willingness to pay and the probability of cost-effectiveness that they perceive as acceptable.

It is recommended to conduct a process evaluation alongside clinical trials, as process evaluations can provide important information for interpreting their results [13-16]. On top of that, process evaluation results can be used to further improve the intervention and to facilitate the transition of research evidence into clinical practice [17,18]. In the field of trauma treatment and trauma rehabilitation, process evaluations are hardly performed. One mixed-method study assessed the relationship between participant-related factors and adherence to osteoporosis medication, vitamin D supplementation, and participation in physical activity in older patients with fragility fractures [19]. Moreover, a recent focus group study among trauma patients suggested that inadequate aftercare negatively influenced trauma patients' perceived quality of life at least one year after trauma [20]. It is noteworthy, that the majority of patients participating in this study were aged >65 and that, to the best of our knowledge, process evaluations in younger patients with traumatic injury are lacking.

Even though results suggest that the TTCM could improve patient outcomes and healthcare efficiency [11,12], it is less clear how to implement this model in practice. Amongst others, it is unknown how the TTCM could be implemented in other trauma regions with their own

structures, cultural norms and values, and practical routines [21]. These considerations led us to perform a process evaluation to assess the following research questions:

1. What is the reach, dose delivered, dose received, and fidelity of the TTCM?
2. What are the barriers and facilitators associated with the implementation of the TTCM?

METHODS

Design

This process evaluation was conducted alongside a clinical trial evaluating the effectiveness and cost-effectiveness of the TTCM compared with regular practice using a modified controlled-before-and-after design [22]. The clinical trial was conducted at the outpatient clinic for trauma patients of a level-1 trauma center (Amsterdam UMC, location VUmc, Amsterdam, The Netherlands). In this study, operatively and non-operatively treated trauma patients with at least one fracture, aged 18 years or older, were included. The trial is registered at the Dutch Trial Register (NTR5474). The medical ethics committee of Amsterdam UMC, location VUmc, decided that the Dutch Medical Research Involving Human Subjects Act (WMO) was not applicable to the present study (registered under number 2013.454). All participants gave informed consent.

This process evaluation uses a mixed-methods design. That is, quantitative process evaluation data were collected from the intervention group participants' electronic patient records to assess the TTCM's reach, dose delivered, dose received, and fidelity. Additionally, qualitative data were collected by conducting focus groups among various stakeholders to explore the barriers and facilitators related with the implementation of the TTCM.

The Transmural Trauma Care Model

Below, the TTCM is briefly described. A more detailed description of the TTCM is provided elsewhere [10]. The TTCM consists of four components, all of which are inextricably linked to one another.

1. *A multidisciplinary TTCM consultation hour at the outpatient clinic for trauma patients by a trauma surgeon and a trauma-specialized hospital-based physical therapist (HBPT)*. During the trauma patients' outpatient visits, the trauma surgeon evaluated the bone- and wound-healing process and acted as the chief consultant. The HBPT assessed physical function and acted as case manager throughout the rehabilitation process. During a shared-decision

making process, the trauma surgeon, HBPT and patient determined whether and when physical therapy in primary care was required.

2. *Coordination and individual goal setting for each patient by the multidisciplinary hospital-based team*. The hospital-based team coordinated the patients' rehabilitation process in primary care by repeatedly defining individual treatment goals in close cooperation with the patient. To support this process, 10 rehabilitation protocols were developed for the most common fractures (e.g. hip fractures, tibial plateau fractures). These protocols were customized for each individual patient by the HBPT.

3. *A network of specialized primary care physical therapists*. This "Network Trauma Rehabilitation VUmc" consisted of 40 PCNPTs all of whom worked in a primary care practice in the region of Amsterdam and were specifically trained to rehabilitate trauma patients (www.traumarevalidatie.nl).

4. *Secure email traffic between the hospital-based physical therapist and the primary care network physical therapist*. A secured email system ("Zorgmail"), developed for healthcare professionals, was linked to both the electronic patient records of the HBPT and the PCNPT, so that regular communication was guaranteed throughout the rehabilitation process.

Quantitative assessment

The extent to which the TTCM was implemented as intended was explored by assessing four process evaluation components of Linnan and Steckler, including its *reach*, *dose delivered*, *dose received*, and *fidelity* [23]. *Reach* is defined as the proportion of the intended target audience that participated in the intervention (i.e. the proportion of potentially eligible trauma patients that eventually participated in the TTCM during the clinical trial period). *Dose delivered* is defined as the number of units of the intervention delivered (i.e. the proportion of intended multidisciplinary TTCM consultation hours that eventually took place at the outpatient clinic and the proportion of included TTCM participants that was eventually referred to a PCNPT). *Dose received* is the extent to which trauma patients actively engaged in the intervention (i.e. the proportion of included TTCM participants that eventually visited their scheduled multidisciplinary TTCM appointment at the outpatient clinic and the proportion of included TTCM participants that eventually visited the PCNPT they were referred to). *Fidelity* is defined as the extent to which the intervention was delivered as planned (i.e. the extent to which the intervention protocol was followed by the various care providers). Various fidelity scores were assessed (e.g. whether a secured email was sent from the HBPT to the PCNPT after each multidisciplinary TTCM visit and vice versa). A complete overview of all fidelity scores can be found in Table 5.1. To explore the four process

evaluation components, data were collected from the patients' electronic patient records (e.g. the number of secured emails, the use of standardized referral forms, the setting of individual functional goals) and from the care providers' schedules.

Qualitative assessment

Barriers and facilitators are defined as "factors that hampered or enhanced the implementation of an intervention", respectively [24]. For exploring the barriers and facilitators associated with the implementation of the TTCM, homogeneous focus groups were conducted among trauma patients, trauma surgeons, HBPTs, and PCNPTs. Participants were selected purposively. This sampling method allows researchers to use their own judgement to select individuals who are able to provide in-depth information pertaining to the research questions. We choose for focus groups instead of in-depth interviews, because more in-depth information can be obtained from a group context, in which members influence each other ("the whole is greater than the sum of its parts) [25,26]. Another strength of focus groups is that they provide access to shared social meaning and norms and how these are enacted [27]. We opted for homogeneous focus groups to avoid existing professional and/or personal hierarchy structures (e.g. between surgeons and physical therapists and patients) to influence the results. Homogeneous focus groups create a save environment, in which participants are more likely to speak free and open [28]. Focus groups were conducted at a time and location convenient to the participants. Prior to the focus groups, participants were assured of confidentiality and were asked to provide informed consent. Focus groups were guided by two experienced qualitative researchers who were familiar with the TTCM, but were not involved in the TTCM as care provider. During each focus group, three round table discussions were held; the first aimed to identify possible facilitators, the second aimed to identify possible barriers, and the third aimed to complement and validate the barriers and facilitators identified in round one and two. During all round table discussions, a topic list was used as a guide.

Every round started by asking participants to independently write down facilitators and barriers on post-it's to frame the personal perspective of the participants and avoid groupthink. Subsequently, participants were free to discuss all topics they considered important. All focus groups were audiotaped and transcribed verbatim.

Data preparation and analysis

Quantitative analysis

To assess the reach, dose delivered, dose received, and fidelity of the TTCM, summary statistics were prepared using SPSS.

Qualitative analysis

Focus group data were analyzed using the framework method. This is a hierarchical, matrix-based method for ordering and synthesizing qualitative data [29,30]. The framework method enables systematic exploration of the data while simultaneously maintaining an effective and transparent examination path [31]. In this study, an "analytical framework" was constructed iteratively from the research aims, existing literature, and the data derived from the focus groups. For constructing the analytical framework, the "constellation perspective" as described by Van Raak was used as theoretical framework [21]. The constellation approach will be described briefly below, followed by a stepwise description of the way the framework method was used for analyzing the data.

The constellation approach as theoretical framework

The constellation approach has its origins in organizational research, and assumes that a healthcare system consists of so-called constellations, defined as "*a set of interrelated practices and relevant, interrelated, structuring elements that together both define and fulfill a function in the larger system*". The needs of healthcare systems are diverse and therefore the system consists of a multitude of nested complementing and competing constellations and (sub)constellations [32]. Within a constellation there is a continuous interaction between the three elements of the "structure, culture and practice triplet", introduced by Rotmans and Loorbach in 200933 and adapted by Van Raak (Figure 5.1) [21]. These elements are:

Structure

Structure consists of the physical structures and resources, enforced regulations and legal rights, economic resources and other material elements that structure behavior within a constellation.

Culture

Culture refers to the paradigms, norms and values and other immaterial elements that structure behavior in practices.

Practice

Practice involves the typical routines on the operational level, which are undertaken by the actors within the constellation.

Actors are the individuals (e.g. patients, physicians, managers), or groups (e.g. insurance companies, departments) that work or act in a certain constellation. Please notice that actors are not part of a constellation, but shape its culture and structure (and vice versa) through practice.

For the TTCM, several nested constellations can be recognized, for example, the outpatient clinic for trauma patients on the one hand and the primary care network practices on the

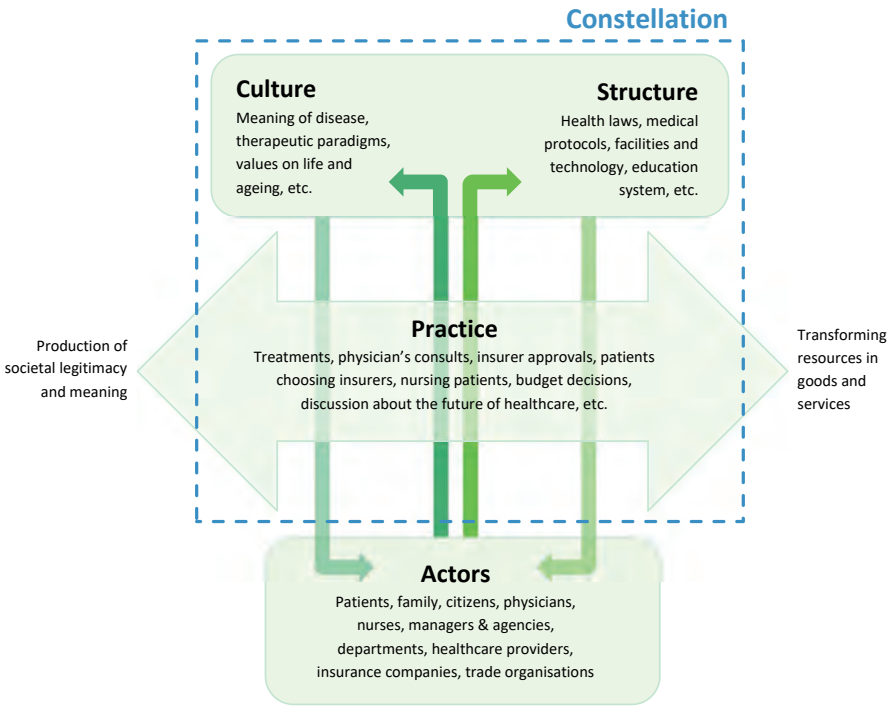

Figure 5.1 The interaction between the three elements of the "structure culture and practice triplet" within a constellation [21].

other hand. Moreover, both the hospital and the primary care network practices are part of a bigger constellation, in which insurers, and policy-makers act in a certain structure and culture. Dynamics, such as those created by the implementation of the TTCM provide an opportunity for change. When the change process leads to a fundamental shift in structure, culture, and practice, a transition of the constellation has occurred. In general, the driving force of change is the sense of urgency for change by "*key actors*" within a constellation [32]. These actors initiate and push for change on the structural, cultural, and practical level [34]. To achieve a transition the relevant actors need to develop a collective sense of urgency to change and they need to develop new competences (knowledge, attitude and skills). Scaling up involves implementing the results of niche experiments in the existing structure, culture and practice [35].

Stepwise procedure of the framework method to construct an analytical framework

We constructed an "analytical framework" iteratively from the literature and the focus group data. For building this analytical framework, the "constellation perspective" as described above was used as "theoretical framework". The *first* step of the framework method [30] consisted

of a verbatim "transcription" of the audiotaped focus groups, followed by the *second* step which was "familiarization" with the data by listening and rereading the transcripts. The *third* step was "coding", and was aimed at classifying the data in such a way that it can be compared systematically with other parts of the data set. For this purpose, all transcripts were manually coded line by line by applying a paraphrase or label to relevant parts of the text (the "code"), using Microsoft Word. We started with open coding, meaning that anything that could be possibly relevant, was coded independently by two of the researchers, SW and MD. Subsequently, both researchers independently generated descriptive themes and subthemes. The *fourth* step was the "development of an analytical framework", in which codes were grouped into categories on the structural, cultural, and practical level of the theoretical framework (i.e. the constellation approach). Subsequently, the final codes were developed through discussion between the two researchers. During these discussions, similar codes were grouped into main topics and subtopics in order to identify important themes (i.e. selective coding), resulting in the initial analytical framework. Then, both researchers independently coded all remaining transcripts of the focus groups using the initial framework. Subsequently, they met again and following discussion, revised the initial framework to incorporate new and refined codes. The process of refining, applying, and refining the analytical framework was repeated until no new codes were generated.

Note that the process of developing the analytical framework was a combined deductive and inductive approach. On the one hand pre-selected themes and codes of Van Raaks' theoretical framework were used (deductive), while on the other hand, themes and codes were generated from our own data (inductive). The final framework consisted of 16 themes, clustered into six categories (facilitators and barriers on the structural, cultural or practical level, respectively). In the *fifth* step, called "indexing", both researchers systematically went through each transcript again, highlighting each meaningful passage of text and selecting and attaching an appropriate code from the final analytical framework. At this stage, each code was assigned an abbreviation for easy identification (e.g. FST1 = Facilitator Structural Theme 1). Indexing involves the comparison of data within and between focus groups.

The *sixth* step is called "charting", in which a spreadsheet was used to generate a framework matrix. During this stage, data are summarized by category and subsequently categorized into the matrix, followed by adding illustrative and interesting quotes from participants in the focus groups. During the *seventh* step, "interpretation of the data", the framework matrix was used to interpret the data together with some notes that were made during the focus groups and the coding process. This interpretation process was an iterative process and relied on a consultation between both researchers about the relevance and strength of a theme. The intensity, frequency, persuasiveness, and contrast with which statements were made by the participants, determined

the value that was given to them. To ensure rigor and credibility of the findings, another researcher (JvD) reviewed the generated matrix and checked whether the selected quotes were of relevance to the themes. Disagreements were resolved by discussion. To guarantee quality of study reporting, the COREQ checklist was used (COnsolidated criteria for REporting Qualitative research) [36].

RESULTS

Quantitative results

An overview of the quantitative results of the process evaluation are presented in Table 5.1 and will be briefly discussed below.

Table 5.1 Process evaluation components, definitions and scores

Component	Definition	Score (%)
Reach	The proportion of potentially eligible trauma patients that eventually participated in the TTCM during the clinical trial.	80.6
Dose delivered	The proportion of intended multidisciplinary TTCM consultation hours that eventually took place at the outpatient clinic for trauma patients.	99.3
	The proportion of included TTCM participants that was eventually referred to a primary care network physical therapist.	100.0
Dose received	The proportion of included TTCM participants that eventually visited their scheduled multidisciplinary TTCM appointment at the outpatient clinic for trauma patients.	95.1
	The proportion of included TTCM participants that eventually visited the primary care network physical therapist they were referred to.	96.4
Fidelity	The use of the standardized referral form for the primary care network physical therapist.	89.2
	Secured email was send from the hospital-based physical therapist to the primary care network physical therapist after each multidisciplinary TTCM visit.	92.8
	Secured email was send from the primary care network physical therapist to the hospital-based physical therapist prior to each multidisciplinary TTCM visit.	75.9
	Individual functional goals were set for the patient by the multidisciplinary hospital-based team during each multidisciplinary TTCM visit.	89.2
	Specific feedback from the primary care network physical therapist to the hospital-based team whether the functional goals have been achieved or not (and why).	66.3

Reach

Of the 1,993 trauma patients that were assessed for eligibility at the outpatient clinic for trauma patients between June 2014 and April 2015, 103 potentially eligible patients were identified. Reasons for not being eligible included (amongst others) sprains, orbital fractures, bone bruises or no need for physical therapy. Of the potentially eligible patients, 20 were excluded, because they did not provide informed consent (n=9), had no internet access (n=2), were not willing to participate (n=4), had other reasons (n=5). The remaining 83 patients were allocated to the TTCM (Figure 5.2). The reach of the TTCM was therefore 80.6% (83/103).

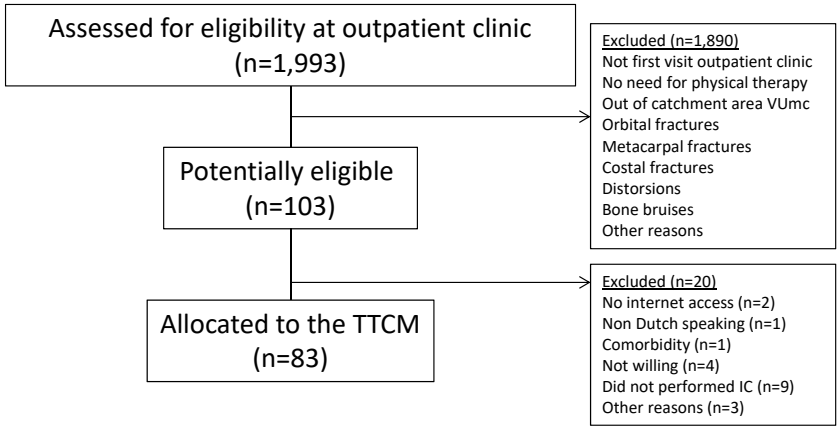

Figure 5.2 Reach of the TTCM.

Dose delivered

During the intervention period, 544 multidisciplinary TTCM consultation hours at the outpatient clinic were scheduled. During four of these multidisciplinary TTCM consultation hours, the HBPT was absent due to personnel shortage (n=1), illness of a care provider (n=2), and scheduling problems (n=1). Thus, the dose delivered of the multidisciplinary TTCM consultation hours was 99.3% (540/544). During the intervention period, all of the 83 TTCM participants were referred to a PCNPT. Thus the dose delivered of primary care network physical therapy was 100%.

Dose received

During the intervention period, all of the 83 TTCM participants visited at least two of their scheduled multidisciplinary TTCM appointments at the outpatient clinic. The mean number of actual visits per participant was 4.7 (range 2–10). In total, 407 multidisciplinary TTCM appointments were scheduled, of which 387 visits eventually took place. Participants did not show up or canceled their appointment due to not having complaints anymore (n=4), being ill (n=10),

and other reasons (n=6). Thus, the dose received of the multidisciplinary TTCM visits was 95.1% (387/407). The proportion of participants that eventually visited the PCNPT they were referred to, was 80 out of 83, which made the dose received of this component of the TTCM 96.4%.

Fidelity

The extent to which the intervention protocol was followed by the various care providers was expressed in terms of several fidelity scores, all of which are shown in Table 5.1. Fidelity scores ranged from 66.3% (i.e. specific feedback from the PCNPT to the HBPT whether functional goals were achieved) to 92.8% (i.e. secured email was sent from HBPT to the PCNPT after each visit).

Qualitative results

Participants

In total, 28 potential participants were purposively selected and invited to take part in the focus groups, including six trauma patients, six trauma surgeons, five HBPTs, and 11 PCNPTs. Of them, two trauma patients, two trauma surgeons, one HBPT, and one PCNPT declined to participate due to several reasons (e.g. not willing, not available). Finally, five homogeneous focus groups (FGs) took place, consisting of four trauma patients (FG1), four trauma surgeons (FG2), four HBPTs (FG3), and 10 PCNPTs (FG4 and FG5).

Barriers and facilitators associated with the implementation of the TTCM

Various barriers and facilitators associated with the implementation of the TTCM were identified. (Table 5.2).

In general, stakeholders perceived the TTCM to be an improvement from usual care, enhancing both the quality and efficiency of care. However, differences were observed among stakeholders. Below, identified barriers and facilitators will be discussed per level of the constellation approach separately. First, similarities and differences between the various stakeholders will be described, followed by the within-group differences per focus group.

Structural level

On the structural level, six overarching themes were identified, which were categorized into facilitators and barriers (Table 5.2). During all focus groups, the "*communication structure of the TTCM*", including its use of a secured email system and standard referral forms, was mentioned as an important improvement compared with usual care.

> "Yes, the referral form has become a lot more efficient. Which makes the care better. But certainly more efficient." (trauma surgeon)

The most frequently mentioned barrier on the structural level was "*the absence of reimbursement for the HBPT at the outpatient clinic*". This is identified as an important barrier because it seriously hampers broader implementation of the TTCM. Another facilitator that was mentioned by all focus groups on the structural level was the "*availability of guidelines for the most common fractures*". Some participants, however, thought that "*these guidelines are too detailed and do not apply in case of a deviant course in fracture healing*".

Different structural aspects of the TTCM were considered more or less important by the various stakeholders. Trauma surgeons, for example, were pleased with the fact that there now was "*a clear infrastructure and clear working agreements at the outpatient clinic*". They liked, for example, that they could briefly discuss the list of patients prior to the multidisciplinary TTCM consultation hour with the HBPT. They did mention, however, that feedback from the PCNPTs sometimes lingered with the HBPT and did not reach them. For the HBPTs, the "*absence of reimbursement for the HBPT at the outpatient clinic*" was the most important barrier, and was also mentioned as a barrier by most of the other stakeholders. Another frequently mentioned barrier by the HBPTs was "*the occurrence of software failures*". PCNPTs indicated to be very satisfied with the "*use of a standardized referral form*" and with the fact that "*the network practice receives an email from the HBPT when a new trauma patient is referred*". Furthermore, they highly appreciated the "*functional goals they received from the HBPT for trauma patients after each visit at the outpatient clinic*".

> "The next goal was very clear for everyone, for the surgeon, for the patient, for the physical therapist in the hospital and for us. If that succeeds, we continue to the next goal and otherwise it will be evaluated and adjusted. This is a very clear structure, making the process very satisfying for everyone." (PCNPT)

Patients were most satisfied with the fact that "*the HBPT sets functional goals for trauma patients after each visit at the outpatient clinic*". This functional goal setting provided the trauma patients with clear expectations on their recovery and their expected outcome.

The within-group differences on the structural level were negligible, meaning that the participants of one homogeneous focus group agreed on most themes and subthemes.

Cultural level

On the cultural level, five overarching themes were identified, which were further specified in subthemes, categorized into facilitators and barriers (Table 5.2). During all focus groups, the "*shared decision-making process at the outpatient clinic*" was mentioned as an important facilitator for the implementation of the TTCM. Another theme that was frequently mentioned during all focus groups was the "*contact between the HBPT and PCNPT*" with "*the possibility of low-threshold contact between HBPT and PCNPT via email and telephone, in addition to the structural forms of communication*" as most mentioned facilitator.

> "Yes, you are now being encouraged to contact the hospital, the threshold has been lowered enormously." (PCNPT)

The most mentioned barrier by all focus groups was that sometimes "*care providers contradict each other*".

> "You really have to achieve that balance, it is true that if you are very comfortable, you reinforce each other. But it is not good if the patient feels that we do not agree with each other." (trauma surgeon)

Some differences between the focus groups were noteworthy. Trauma surgeons, for example, emphasized the importance of the "*awareness of professional boundaries*", meaning that they perceived it to be important that the healthcare providers who are present during the outpatient consultations are aware of the boundaries of their own discipline. They sometimes found it hard to strike a balance in co-working with the physical therapist at the outpatient clinic. After an adequate balance was achieved, trauma surgeons were of the opinion that the quality of care and patient satisfaction increased significantly, and working closely with a HBPT became one of the most important assets of the TTCM.

> "I also like that you can deliberate together, not out of uncertainty, but the fact that the hospital physical therapist is actively involved in the decision making process positively affects the patient." (trauma surgeon)

The HBPT also perceived the "*awareness of responsibilities and leadership*" to be important. For them, it was at times complicated to adapt to their new role and position within the existing hierarchal culture of the hospital. Despite these challenges, the most important asset of the

TTCM according to the HBPTs was the fact that "*care providers at the outpatient clinic now act as a team and are unambiguous*".

> "You must be able to adapt to the situation and to various trauma surgeons." (HBPT)

PCNPTs most frequently indicated that they now felt like "*a substantial part of the care chain*". That is, they now perceived themselves as a member of the trauma patients' treatment team instead of working solitary, which was the case before implementation of the TTCM. Another facilitator that was frequently mentioned by the PCNPTs was "*the possibility of low-threshold contact between HBPTs and PCNPTs via email and telephone, in addition to the structural forms of communication*".

Trauma patients were very pleased with the existence of a "*shared decision-making process at the outpatient clinic*". For them, the experience of being involved in the decision-making process, and having a voice in formulating their own functional goals was of great importance. This is evidenced by the following quote of a participating patient:

> "I really liked having a voice in formulating my own goals. During the visits there was time to think and talk about what is important to me, that I wanted to play tennis again. And whether it was actually achievable what I wanted. It really helped me to discuss these issues with the surgeon and the physical therapist." (patient)

However, some of the trauma patients indicated to have "*received conflicting statements regarding prognosis by doctors who do not work according to the TTCM*", including those working at the emergency department or trauma ward of the hospital. This was therefore considered to be an important barrier to the implementation of the TTCM.

Within the focus groups there were only minor differences among stakeholders. For example, some HBPTs indicated to prefer working with the same trauma surgeon every week, while others preferred to work with various trauma surgeons. The same applied for the trauma surgeons.

Practical level

On the practical level, five overarching themes were identified, which were further specified in subthemes, categorized into facilitators and barriers (Table 5.2). All healthcare providers indicated that they liked their "*increased level of knowledge and skills*" resulting from working with the TTCM. That is, many of them repeatedly stated that they learned a lot from the other healthcare providers they collaborated with.

Table 5.2 Facilitators and barriers expressed by care-providers and patients regarding the implementation of the TTCM, related to structure, culture and practice. Quotes of trauma patients (P), trauma surgeons (T), hospital-based physical therapists (HBPT) and primary care network physical therapists (PCNPT).

Level	Theme	Facilitator	Barrier	Illustrative quote
Structure	Communication structure	• Use a secured email system from file to file between primary and secondary care (and vice versa) • Use a standardized template for the secured email • Use a standardized referral form • The network practice receives an email from the HBPT when a new trauma patient is referred • The HBPT sets functional goals for trauma patients after each visit at the outpatient clinic	• Feedback from PCNPT lingers with HBPT and does not reach trauma surgeon. • The standardized email template is too standardized	• "There is a lot of regular e-mail contact between the hospital physical therapist and the network physical therapist but that does not always reach us." (T) • "Yes, the referral form has become a lot more efficient. Which makes the care better. But certainly more efficient." (T) • "The next goal was very clear for everyone, for the surgeon, for the patient, for the physical therapist in the hospital and for us. If that succeeds, we continue to the next goal and otherwise it will be evaluated and adjusted. This is a very clear structure, making the process very satisfying for everyone." (PCNPT)
	Infrastructure and working agreements at the outpatient clinic	• Trauma surgeon and HBPT prepare the consultation hour individually • Trauma surgeon and HBPT briefly discuss the patients prior to the consultation hour • Trauma surgeon and HBPT work in regular couples	• The occurrence of software failures • The incompatibility of electronic patient records in primary- and secondary care	• "I am usually fifteen minutes / half an hour earlier to look at the difficult cases. It would be nice if they (the HBPT) were already there." (T) • "For your own expertise it is good to work with multiple trauma surgeons, but in the context of efficiency and work relationship it is better to work in regular couples." (HBPT)

	Financial structures	• Let the network practices pay an annual fee for education and accreditation	• The absence of reimbursement for the HBPT at the outpatient clinic	• "What worries me even more is the uncertainty how the network will survive without money. Because it takes a lot of time and a lot of effort to take good care of our network." (HBPT)
	Organization of the primary care network	• Having an appropriate and up to date website	• Patients are not treated by the trained PCNPT, due to inadequate logistic pathways within the network practice	• "Yes, that's partly our fault. I think we have around 19 physical therapists working in our practice and sometimes trauma patients are scheduled with a non-trauma physical therapist. That is a logistic problem." (PCNPT)
	Training and education	• Organize a two-day training for the PCNPTs prior to joining the network • Organize regular meetings for PCNPTs and the complete hospital team (e.g. twice a year) • Request accreditation for PCNPTs and HBPTs		• "I can imagine that we organize theme meetings with the network physical therapists twice a year to discuss specific topics concerning our patient category, which also makes them more involved." (T)
	Guidelines	• Availability of guidelines for the most common fractures	• Guidelines are too detailed and do not apply in case of deviant course in fracture healing	• "Yes, the protocols are so incredibly concrete that you can only use it for one specific condition. You cannot longer use it in case of a slightly different fracture or a deviate course of the recovery." (PCNPT)

Table 5.2 continues on next page.

Table 5.2 *Continued*

Level	Theme	Facilitator	Barrier	Illustrative quote
Culture	Awareness of responsibilities and leadership	• Shared decision making process at the outpatient clinic • Care providers share responsibility for treatment options • Care providers at the outpatient clinic act as a team and are unambiguous	• There is ambiguity about ownership in the consultation room • Care providers contradict each other	• "I really liked having a voice in formulating my own goals. During the visits there was time to think and talk about what is important to me, that I wanted to play tennis again. And whether it was actually achievable what I wanted. It really helped me to discuss these issues with the surgeon and the physical therapist." (P) • "You really have to achieve that balance, it is true that if you are very comfortable, you reinforce each other. But it is not good if the patient feels that we do not agree with each other." (T) • "I also like that you can deliberate together, not out of uncertainty, but the fact that the hospital physical therapist is actively involved in the decision making process positively affects the patient." (T) • "You must be able to adapt to the situation and to various trauma surgeons." (HBPT) • "I think you should be able to express what you stand for at the outpatient clinic, what your vison is… of course well substantiated, but you should not be too anxious to say what you think…" (HBPT)

Awareness of professional boundaries	• Care providers at the outpatient clinic (trauma surgeon and HBPT) take professional boundaries into account	• Care providers go across the boundaries of their profession	• "We are usually on the same line about normal content. That may vary, but we do manage that. But it is a problem if they come outside their domain." (T) • "Discomfort arises when the hospital physical therapist makes a statement about non physical therapy topics." (T) • "Once, the physical therapist was not present during my visit. The advises the surgeon gave me about walking with crutches were not really clear for me at that point." (P)
Job satisfaction	• Increased job satisfaction for all care providers		• "It's just really nice to work this way." (HBPT)
Contact between HBPT and PCNPT	• The possibility of low-treshold contact between HBPT and PCNPT via email and telephone, in addition to the structural forms of communication • The PCNPTs feeling to be a substantial part of the care chain		• "Yes, I am really happy that the network physical therapist can easily contact the hospital physical therapist." (P) • "The primary care physical therapist finds us quicker and easier than before in case they have an acute problem with a patient." (HBPT) • "Yes, you are now being encouraged to contact the hospital, the threshold has been lowered enormously." (PCNPT)

Table 5.2 continues on next page.

Table 5.2 *Continued*

Level	Theme	Facilitator	Barrier	Illustrative quote
	Patients' experience	• Large acceptance of care outcome by the patients due to clear expectation management • Patients experience a clear treatment plan and-strategy • Patients experience it as positive to be treated by a specialized PCNPT, having a high level of knowledge and skills • Patients are satisfied with care	• Receiving conflicting statements regarding prognosis by doctors who do not work according to the TTCM (e.g. emergency department)	• "Yes, patients receive better care. At least, that is what we usually hear; that they are satisfied with the care." (T) • "Yes, there is more focus on the everyday things that patients have to deal with." (T) • "The doctor at the emergency department told me very crudely, that I would never regain full function again." (P) • "Nobody told me that such a simple fracture could affect my daily live in such an enormous way." (P)
Practice	Practical concerns at the outpatient clinic	• Availability of a separate consultation room for the HBPT • Trauma surgeon and HBPT work overlapping at outpatient clinic	• The HBPT who acts as case manager, is poorly accessible by telephone for PCNPT	• "I really didn't have to wait long, it was my turn quickly." (P) • "Usually, the hospital physical therapist continues to explain exercises and then I start up with the next patient." (T) • "The surgeon spends less time with a patient, he can proceed with the next patient, while I give some extra advices." (HBPT) • "For example, I see a patient who comes for wound control without the hospital physical therapist. She does something behind the computer or already examines a new patient with a knee distorsion, and then I walk in later." (T)

	Practical concerns at the primary care network	• In total there is a higher amount of referrals for members of the network	• The presence of quality differences between PCNPTs (both in terms of knowledge and equipment) • The absence of a social media platform for HBPTs and PCNPTs • The lack of guarantee on a high number of referrals	• "I think the quality of the connected network practices still varies, and that is regrettable, because the patients expect a lot from such a practice." (HBPT)
	Quality and efficiency of care	• Due to the specialized primary care network, some patients can rehabilitate at home instead of in a clinical rehabilitation setting • Patients with simple fractures receive compact advises from HBPT and do not need a referral to a PCNPT	• Absence of awareness of the TTCM in other relevant departments in the hospital (e.g. emergency department)	• "Well, we have to realize that we are doing something very special. This is the future of healthcare." (PCNPT)
	Workload	• Lower administrative workload for trauma surgeon	• High administrative workload for HBPT	• "That means that you have to prepare well, and that preparation takes quite a lot of time. So the TTCM takes more time than just being present at the outpatient clinic." (HBPT)
	Knowledge	• Increased level of knowledge and skills • PCNPTs have increased expertise in trauma rehabilitation because they treat more trauma patients • Trauma surgeon and HBPT at outpatient clinic learn from each other's field		• "Yes, I have seen a lot of ankle fractures lately and I noticed that I now have a better view of the course and whether it deviates or not. I recognize certain patterns. I used to have more difficulties with that before." (PCNPT)

Stakeholders differed in terms of the practical aspects of the TTCM that they considered to be of importance. Trauma surgeons and HBPTs were of the opinion that the "*availability of a separate consultation room for the HBPTs*" would improve their way of working. Then, the physical therapist could examine patients (e.g. for function-control or instructions), while the trauma surgeon could proceed to the next patient.

> "For example, I see a patient who comes for wound control without the hospital physical therapist. She does something behind the computer or already examines a new patient with a knee distorsion, and then I walk in later." (trauma surgeon)

Trauma surgeons also indicated to have a "lower administrative workload" due to the TTCM, as the HBPT was now responsible for the communication with the PCNPTs.

HBPTs, on the other hand, experienced a "*higher administrative workload at the outpatient clinic*". That is, all HBPTs indicated that their workload increased due to their new role as case manager, but that working according to the TTCM also gave them energy because they perceived it to be inspiring.

> "That means that you have to prepare well, and that preparation takes quite a lot of time. So the TTCM takes more time than just being present at the outpatient clinic." (HBPT)

The PCNPTs also indicated to have an "*increased level of knowledge and skills*" and "*increased expertise in trauma rehabilitation*" due to their involvement in the TTCM. As a consequence, they highly enjoyed working according to the TTCM.

> "Yes, I have seen a lot of ankle fractures lately and I noticed that I now have a better view of the course and whether it deviates or not. I recognize certain patterns. I used to have more difficulties with that before." (PCNPT)

For them however, "*the lack of guarantee on a high number of referrals*" was an important barrier, because they prefer a continuous amount of new referrals, perceived from a business perspective. For trauma patients, an important barrier was the "*absence of awareness of the TTCM at other relevant departments in the hospital (e.g. emergency department)*". As a consequence, they sometimes received conflicting information regarding their treatment and prognosis from physicians from other departments.

> "The doctor at the emergency department told me very crudely, that I would never regain full function again." (patient)

The within-group differences were small for the trauma surgeons and HBPTs. For the PCNPTs, within-group differences were small as well, but depending of the number of new referrals they received during the intervention period, they were more or less satisfied with the TTCM. The within-group differences for trauma patients were negligible.

DISCUSSION

The present paper describes the results of a process evaluation exploring the extent to which the TTCM, an advanced rehabilitation model for trauma patients, was implemented as intended, and identifying barriers and facilitators associated with its implementation.

Results showed that the TTCM was largely implemented as intended, with a moderate reach (81%), a high dose delivered (99% and 100%) and high dose received (95% and 96%) for the multidisciplinary TTCM consultation hours at the outpatient clinic and the primary care network physical therapists, respectively. Moderate to high fidelity scores were found (66% to 93%), indicating the extent to which the intervention protocol was followed by the care providers. The fidelity scores regarding the secured email traffic from the PCNPTs to the HBPT provided the most room for improvement. That is, in 24% of the cases no secure email was sent to the hospital and in 34% of cases it was not clearly reported whether functional goals of the patient were achieved or not.

Focus groups indicated that on the structural level, the "communication structure of the TTCM" was found to be an important theme, expressed in several facilitators, e.g. the "use of a secured email system". The "absence of reimbursement for the HBPT at the outpatient clinic" was identified as a main barrier at the structural level. At the cultural level, the existence of a "shared decision making process at the outpatient clinic" was found to be an important facilitator, and the fact that "care providers sometimes contradict each other" to be a barrier. At the practical level, the "increased level of knowledge and skills" was an important facilitator and the "absence of awareness of the TTCM in other relevant departments" was recognized as a barrier. In general, stakeholders were of the opinion that if the barriers were overcome, the quality of care and patient satisfaction were likely to improve significantly after implementing the TTCM.

Comparison with the literature

In trauma surgery and trauma rehabilitation, process evaluations are rare, and therefore an appropriate substantive comparison with the literature is difficult to perform. However, process evaluations have been described in adjoining fields. For example, we found a mixed-method study in older patients with fragility fractures assessing the relationship between patient-related factors and adherence to "healthy bone advices" (i.e. taking osteoporosis medication, and participate in physical activity). The qualitative interviews in this study suggested that feedback from case managers helped participants understand the underlying cause of their fragility fracture and helped them to adhere to the advices [19]. We found similar results regarding the role of the HBPT, who acted as case manager. Next to other components of the TTCM, having an appropriate case manager was found to be a crucial factor for successful implementation of the TTCM. Another process evaluation, which was conducted alongside a randomized controlled trial, evaluated the implementation of RESPOND [37]. This is a telephone-based falls prevention program including person-centered education and goal setting, designed for older patients visiting an emergency department after a fall, but not necessarily with a fracture. The results from this process evaluation, in which focus groups were held with participants and interviews were conducted with clinicians, provided detailed information to guide future implementation of RESPOND. One of the main findings was that implementation of the intervention was facilitated by the use of "positive and personally relevant health messages" [37]. Parts of the RESPOND intervention program are comparable with the TTCM (e.g. personal goalsetting), whereas the scope of the TTCM differed from RESPOND (i.e. trauma rehabilitation versus prevention). Furthermore, a recently published focus group study among trauma patients, aiming to describe their perceived quality of life at least one year after trauma, found that inadequate aftercare negatively influenced the trauma patients' perceived quality of life.20 In contrast to the present study, however, this focus group study was of descriptive nature and was not aimed at identifying facilitators and barriers of an intervention. While the aforementioned process evaluations are meaningful and important in their own field, they differ in terms of their design, population and intervention and are therefore not entirely comparable. However, they all confirm or suggest that various elements of an intervention such as the TTCM, aiming to improve rehabilitation and outcome after (major) trauma, are of great importance and that its implementation should be evaluated quantitatively as well as qualitatively, as we did in this study.

Strengths and limitations

This study has several strengths. First, to the best of our knowledge, this is one of the first studies to apply qualitative research methods in the field of trauma rehabilitation. The use of a mixed-

methods approach enabled us to assess both the implementation of the TTCM as well as its associated barriers and facilitators [38]. Second, we chose for five homogeneous focus groups, including a broad range of stakeholders, which had several advantages. That is, five is the optimal number of focus groups for analysis according to the literature [39]. It is important for a broad range of stakeholders to have a voice in the focus groups in order to obtain a maximum amount of information necessary to optimize the possible implementation of the TTCM. Moreover, the use of homogenous focus groups created a save environment, in which participants were most likely to speak free and open [28]. Third, data derived from the focus groups were analyzed systematically, using a well-founded theoretical model (i.e. the framework method) [29,30]. This method enabled a systematic exploration of the data, while simultaneously maintaining an effective and transparent examination path [31]. Finally, to optimize the implementation of the TTCM, reflection meetings for the HBPTs were held during the implementation phase of the TTCM. These meetings were valuable in gaining insight to their new role, and in matching professional responsibilities and borders.

The study also had some limitations. Participants of the focus groups were purposively selected and participated voluntarily, which may have resulted in participants being more content with the TTCM than the average care provider and/or trauma patient. This could have resulted in an overestimation of positive opinions regarding the TTCM, especially in the focus group with trauma patients (FG5). Another limitation is the absence of healthcare decision-makers and insurers in the focus groups, we therefore lack input from a relevant group of stakeholders regarding the theme “financial structures” on the structural level. Furthermore, we probably could have obtained more detailed information if we had conducted interviews in addition to the focus groups, since in-depth interviews can provide more detailed information on specific topics [25].

Implications for future implementation and further research

Information derived from the current process evaluation can be used to further improve the TTCM and to enable the transition of research evidence into clinical practice [17,18]. The TTCM seems feasible in practice and was implemented as intended for nearly all participants (i.e. appropriate reach, dose delivered, dose received and fidelity). Important needs for a successful implementation of the TTCM were “having an appropriate communication structure” and “reimbursement for the HBPT at the outpatient clinic” on the structural level, the presence of a “shared decision-making process at the outpatient clinic” on the cultural level, and an “increased level of knowledge and skills” on the practical level. Additionally, we know from the literature that other important needs for successfully scaling up and deepening of a new practice include: 1) the establishment of coalitions among strategically chosen parties; 2) transparent organizational

structures; 3) a clear division of responsibilities; 4) a change in mind set; and 5) an appropriate legal and financial framework [35,40]. When we specify these needs, complemented with the results of the current process evaluation, the following recommendations for implementation and scaling up of the TTCM can be made:

1. Form a steering group with all stakeholders to take everyone's interests into account.
2. Describe clear organizational structures for care providers at the outpatient clinic and for primary care network physical therapists (e.g. communication pathways and templates for standardized documentation).
3. Describe duties and responsibilities of the participating care providers in a manual and organize training courses for the primary care network physical therapists.
4. Organize reflection meetings with stakeholders (homogeneous as well as heterogeneous) per trauma center and respect local differences.
5. Arrange an appropriate and structural embedded reimbursement system for the hospital-based physical therapist, who acts as case manager within the TTCM.

As mentioned above, an important limitation of the current study is the lack of input from healthcare decision-makers and insurers. Their input is important because a structurally embedded reimbursement system for the HBPT is required for a successful implementation of the TTCM. Consequently, a final recommendation for future research is to include these stakeholders in the focus groups, or to conduct semi-structured interviews with them to obtain a complete overview of facilitators and barriers for implementation of the TTCM.

CONCLUSION

This process evaluation showed that the TTCM was largely implemented as intended. Various barriers and facilitators were found to be associated with the implementation of the TTCM. Moreover, some differences were found among stakeholders, but in general, they were of the opinion that if the barriers were overcome and a good working balance was achieved, the quality of care and patient satisfaction would improve significantly after implementing the TTCM.

Funding

This project is partly funded by "Zilveren Kruis Health Insurer" (grant number Z516).

Acknowledgements

We thank all trauma patients and care providers who participated in the study. Furthermore we thank Vincent van Vliet for transcription of the audiotaped data and for collecting the quantitative data as a part of his graduation thesis. Finally we thank Dr. Gogem Topcu, an experienced qualitative researcher from the School of Medicine, University of Nottingham, for giving very valuable advices in applying the framework method on our data. Adopting this method consolidated the rigor of the analysis and the credibility of our findings.

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BOB (26) | SCOOTER ACCIDENT 3 YEARS AGO

Open fracture of the lower leg

6

Which fracture and treatment-related factors are associated with disease-specific HR-QOL, functional outcome, and societal costs in trauma patients?

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ABSTRACT

Background: The presence of one or more comorbidities, multiple injuries, and age have been found to be associated with functional outcome and quality of life in trauma patients. However, the associations between fracture and treatment-related factors (e.g. fracture type and surgical technique) and disease-specific health-related quality of life (HR-QOL), functional outcomes and societal costs at longer-term follow-up are not well known. Therefore, the aim of the present study was to assess which fracture and treatment-related factors are associated with disease-specific HR-QOL, functional outcome, and societal costs in trauma patients with at least one fracture 9 months after their first outpatient visit.

Methods: The current study was embedded within the TTCM-trial. Trauma patients with at least one fracture were considered eligible. Data on the fracture and treatment-related factors surgery (yes/no), fracture type (intra-articular/extra-articular), fracture localization (upper extremity/lower extremity/other), and fracture treatment (intramedullary nail/ open reduction internal fixation [ORIF]/conservatively) were collected at baseline. Data on outcomes were collected 9 months after baseline. OLS regression analyses were performed to assess the association of each fracture and treatment-related factor (i.e. independent variables) with disease-specific HR-QOL, functional outcome, and societal costs (i.e. dependent variables), while correcting for receiving the TTCM (yes/no), the case-mix variables age, gender, and comorbidity, and for the other independent fracture and treatment-related factors.

Results: In total, 140 trauma patients were included in the analysis. Having a fracture of the lower extremity was found to be associated with a lower disease-specific HR-QOL after 9 months compared to the reference category patients (i.e. patients with a vertebral fracture or multi-trauma patients) (MD 10.09; 95% CI 2.18 to 18.00). Having an upper extremity fracture was associated with a better functional outcome compared to patients from this reference category (MD -19.12; 95% CI -31.65 to -6.59). Having had a surgery instead of conservative treatment was associated with lower societal costs. On the other hand, being treated with ORIF was associated with higher societal costs. Fracture type was not associated with any of the outcomes.

Conclusions: Of the investigated fracture and treatment-related factors, a fracture of the lower extremity was associated with lower disease-specific HR-QOL and a fracture of the upper extremity was associated with better functional outcome, both compared to the reference category. Surgical treatment was associated with lower societal costs compared to conservative treatment. However, ORIF was associated with higher societal costs when compared to conservative treatment, whereas intramedullary nailing was not. Future studies should focus on confirming these associations and understanding their underlying mechanisms in order to be able to design effective initiatives to improve trauma patients' HR-QOL and functional outcome and to reduce their societal costs.

BACKGROUND

Traumatic injury is a major global health problem and one of the main causes of death and disability worldwide [1,2]. They cost the global population about 300 million years of healthy life per year [3]. On top of that, traumatic injuries are associated with high healthcare and societal costs, and are one of the five most costly medical conditions worldwide [4,5]. In recent years, mortality rates due to traumatic injury decreased significantly, mainly as a result of a better quality and organization of care [6]. Consequently, however, a growing number of trauma patients suffer from long-term disability [3,7-9], which in turn has a significant impact on their health-related quality of life, functional outcome, and costs [10-13].

Well-known predictors of long-term disability after trauma are the presence of one or more comorbidities [14], multiple injuries [15], frailty [16], and age [17,18]. Furthermore, it is recognized that severity of the injury, the presence of a comorbidity and having a fracture of the lower extremity predict higher healthcare costs [19,20]. However, associations between fracture and treatment-related factors, such as fracture type and surgical techniques, and outcomes, such as disease-specific health-related quality of life (HR-QOL), functional outcomes, and costs, are not well known [21-23]. This is important because trauma patients extensively differ with respect to the impact and origin of their trauma, which may, in turn, impact the severity of their injuries, their treatment, and hence their recovery [24].

Studies assessing the association between fracture and treatment-related factors and disease-specific HR-QOL, functional outcome, and costs are rare, and those that have been conducted provide conflicting results. To illustrate, some studies found the occurrence of intra-articular fractures, a higher ISS, and having multiple fractures to be associated with poorer functional outcomes and a reduced disease-specific HR-QOL compared with patients not having these characteristics [25-27], while other studies did not find any of these associations [28-30]. Moreover, it remains unclear whether the type of fracture treatment (i.e. nailing or plating) is associated with disease-specific HR-QOL, functional recovery, and/or costs [23].

Given the aforementioned uncertainties in combination with the increasing number of surviving trauma patients, there is a need to better understand the association between fracture and treatment-related factors and outcomes, such as disease-specific HR-QOL, functional outcome, and costs. Knowledge about these associations could help clinicians in achieving better patient outcomes and providing more cost-effective healthcare. Therefore, the current study aimed to assess which fracture and treatment-related factors are associated with disease-specific HR-QOL, functional outcome, and costs in trauma patients 9 months after their first outpatient visit.

METHODS

Study design

To assess which fracture and treatment-related factors are associated with disease-specific HR-QOL, functional outcome, and societal costs, data of the TTCM-trial were used. This trial was performed at a Dutch level-1 trauma center (Amsterdam UMC, location VUmc). The TTCM-trial is a controlled-before-and-after study that aimed to evaluate the cost-effectiveness of the Transmural Trauma Care Model (TTCM) compared with usual care. The TTCM is a multidisciplinary transmural rehabilitation model for trauma patients aiming to improve patient outcomes by optimizing the organization and quality of trauma patients' rehabilitation process [31]. In contrast to a true controlled-before-and-after study, only the intervention group was prospectively followed in the TTCM-trial, while control group data were collected cross-sectionally. That is, the TTCM-trial's control group consisted of 4 independent clusters of patients, who were either measured at baseline, 3, 6, or 9 months after their first consultation at the outpatient clinic for trauma patients. More details on the TTCM-trial's design and results can be found elsewhere [31-33]. For the purpose of the current study, only the participating trauma patients' baseline and 9-month follow-up data of both the intervention group participants and the 9-month control cluster participants were used. The medical ethics committee of the VUmc approved the present study and decided the Dutch Medical Research Involving Human Subjects Act (WMO) was not applicable (registered under number 2013.454). Written informed consent was obtained from all participants, and the TTCM-trial was conducted according to the Declaration of Helsinki.

Patients

More detailed information on the recruitment strategy can be found elsewhere [31]. In brief, both operatively and non-operatively treated trauma patients were included, irrespective of whether or not they were admitted to the hospital. To be eligible for the TTCM-trial, patients had to meet the following inclusion criteria: having at least one traumatic fracture, being aged 18 years or older, and being able to fill out online questionnaires. Patients were excluded if they met any of the following criteria: pathological fractures, traumatic brain injury, cognitive limitations, not speaking Dutch, rehabilitation process in a tertiary care facility, living outside the catchment area of the hospital.

Independent variables

Independent variables consisted of both fracture and treatment-related factors as well as case-mix variables for which the analyses were corrected. All of these variables were based on data

from the national trauma registry and electronic patient files and will be discussed into more detail below.

Fracture and treatment-related factors

- Surgery (yes/no): For every patient it was defined whether he or she underwent surgery or whether he or she was treated conservatively.
- Fracture type (intra-articular/extra-articular): Every fracture was assessed by a radiologist and classified as either being an intra-articular or an extra-articular fracture. Intra-articular fractures were defined as all fractures involving a joint space, whereas extra-articular fractures as all fractures not involving a joint space. All vertebral fractures were classified as intra-articular fractures.
- Fracture localization (upper extremity/lower extremity/other): For every patient, it was assessed whether they had one or more fractures located in one single extremity. If so, they were categorized as either having an upper extremity fracture or a lower extremity fracture. Patients with vertebral fractures and multi-trauma patients (i.e. having at least fractures in two or more regions) were referred to as "other" in the current study and served as reference category.
- Fracture treatment (intramedullary nail/open reduction internal fixation [ORIF]/conservatively): For every patient, their fracture treatment was classified as either involving an intramedullary nail, an ORIF, or being conservative. Conservatively treated patients served as reference category.

Case-mix variables

Data on the following case-mix variables were collected: age (years), gender (male/female) and comorbidity (none/chronic illness/musculoskeletal disease). Additionally, for every participant it was described whether they received the TTCM intervention or not in order to be able to correct for the fact that the current data were collected as part of a controlled trial.

Dependent variables

Dependent variables consisted of disease-specific HR-QOL, functioning, and societal costs. All of them were assessed using online questionnaires administered 9 months after the trauma patients' first visit at the outpatient clinic for trauma patients. All of these dependent variables will be discussed into more detail below.

Disease-specific HR-QOL

Depending on the diagnosis, patients were asked to complete one of the following standardized Patient-Reported Outcome Measures (PROMS) assessing disease-specific HR-QOL:

- Patients with upper extremity fractures: The Disabilities of the Arm, Shoulder and Hand questionnaire (QuickDASH). The Dutch version of the QuickDASH is a shortened version of the 30-item DASH and consists of 11 items (five-point scale) with higher scores indicating more complaints/limitations. The Quick-DASH can be used instead of the DASH with similar precision in upper extremity disorders [34]. The QuickDASH is performing well with substantial evidence supporting reliability and validity [35].
- Patients with lower extremity fractures: The Lower Extremity Functional Scale (LEFS). The LEFS is a questionnaire containing 20 questions about a person's ability to perform everyday tasks. The maximum score is 80 with a higher score indicating better function. The LEFS is a valid tool compared to the SF-36 [36] with fair-to-good accuracy in discriminating between participants with and without improvement [37].
- Patients with multiple fractures and/or more locations: The Groningen Activity Restriction Scale (GARS). The GARS is an 18-item questionnaire with four response categories, measuring the degree of self-reliance of people. The severity of functional limitations can be mapped out using the instrument in which higher scores indicate more limitations in everyday activities. The psychometric properties of the GARS are very good in patients with rheumatoid arthritis and older adults [38-42].
- Patients with vertebral fractures: The Roland Morris Disability Questionnaire (RMDQ). This questionnaire is a self-administered disability measure consisting of 24 items, containing two answering categories (yes/no). The overall score ranges from 0 to 24 in which higher scores indicates greater levels of disability. The Dutch RMDQ showed good reliability in patients with chronic low back pain, with an ICC of 0.91 [43].

An overall disease-specific HR-QOL score (DSQOL-OA) was calculated by converting the total scores of the questionnaires mentioned above to a scale from 0–100, with higher scores representing more functional problems (and thus a lower disease-specific HR-QOL).

Functional outcome

Functional outcome was measured using the Patient-Specific Function Scale (PSFS) [44]. Patients had to identify three important activities that they are having difficulties with and were asked to rate their current level of difficulty associated with each activity on a 0–100 mm visual analog

scale (VAS) ranging from 0 ("able to perform activity at same level as before injury or problem") to 100 ("unable to perform activity"). Only the activity that was first mentioned by the patient was used for analysis. Note that higher scores represent more functional problems. The PSFS showed good reliability and responsiveness in various patient groups with musculoskeletal disorders (e.g. in patients with chronic low back pain [45] and patients after a total knee arthroplasty [46]).

Societal costs

Societal costs included TTCM, health care, absenteeism, presenteeism, and unpaid productivity costs. TTCM costs included all costs related to implementing and administering the TTCM (i.e. on average, EUR272 per patient (SEM=4)) [47,48]. All other cost categories were assessed using online cost questionnaires, supplemented by hospital records if available (e.g. for imaging procedures). Costs were measured for the complete 9-month follow-up duration using three 3-monthly questionnaires with 3-month recall periods and one 9-monthly questionnaire with a 9-month recall period for the intervention and control group, respectively. Health care utilization included 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 were used to value health care costs [48]. Medication use was valued using the G-standard of the Dutch Society of Pharmacy [49]. Absenteeism was assessed using the "PROductivity and DISease Questionnaire" (PRODISQ). Patients were asked to report their total number of sick leave days [50]. Absenteeism was valued using age- and gender-specific price weights [48]. Presenteeism was defined as reduced productivity while at work and was assessed using the "World Health Organization Health and Work Performance Questionnaire" (WHO-HPQ) [34]. Presenteeism was valued using age- and gender-specific price weights as well [48]. Unpaid productivity losses were 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. A recommended Dutch shadow price was used to value unpaid productivity [48]. All costs were presented in Euros and converted to the same reference year (i.e. 2014) using consumer price indices. Discounting of costs was not necessary due to the 9-month follow-up period [51].

Data analysis

Descriptive statistics were used to describe patient characteristics and fracture and treatment-related factors at baseline. Missing data were imputed using multivariate imputation by chained equations [52]. The imputation model included variables related to the "missingness" of data, all fracture and treatment-related factors and case-mix variables as well as all available midpoint

and follow-up disease-specific HR-QOL, functional outcome, and cost measure values [52]. Ten complete data sets were created in order for the loss-of-efficiency to be below 5% [53].

Ordinary Least Squares regression analyses were performed to assess the association of each fracture and treatment-related factor (i.e. independent variables: surgery, fracture type, fracture localization and fracture treatment) with disease-specific HR-QOL, functional outcome, and societal costs (i.e. dependent variables). To deal with the highly skewed nature of cost data, 95% confidence intervals were estimated using Bias Corrected and Accelerated Bootstrapping, with 5,000 replications, when societal costs were the dependent variable. For the three dependent variables, the following four models were performed:

- Model 1:
  Crude analysis, meaning that the dependent variable in question was only regressed upon one of the independent variables.
- Model 2:
  Adjusted for receiving the TTCM (yes/no).
- Model 3:
  Adjusted for receiving the TTCM (yes/no) and for the case-mix variables age, gender, and comorbidity.
- Model 4:
  Adjusted for receiving the TTCM (yes/no), for the case-mix variables, and for the other independent fracture and treatment-related factors.

Please note that model 4 serves as the final model, whereas models 1 to 3 were run and presented to show the impact of the various independent variables on the study results.

Statistical analyses were performed using IBM SPSS Statistics for Windows version 26.0 (IBM Corporation) for the dependent variables disease-specific HR-QOL and functional outcome and STATA version 12 for the dependent variable societal costs. Statistical significance was set at $p>0.05$.

RESULTS

Patients

A total of 3,664 trauma patients was assessed for eligibility. Most of them turned out to be not eligible because they did not have a fracture or had a minimal fracture of for example, the orbita, costa or digit. Of the remaining 758 potentially eligible patients, 473 were excluded for various reasons,

including them not being willing to participate and not having access to the internet. Another 145 patients were excluded from the analyses, because they did not belong to the intervention or the 9-month control cluster of the TTCM-trial. The remaining 140 patients were included as participants in the present study. Further details on the enrollment procedure (including reasons for exclusion and loss to follow-up) can be found in the publication regarding the cost-effectiveness of the TTCM, in which the same dataset was used for analyses [33]. An overview of all patient characteristics and fracture and treatment-related factors of the included participants can be found in Table 6.1.

Disease-specific HR-QOL

Table 6.2 provides an overview of all models assessing the association between fracture and treatment-related factors and disease-specific HR-QOL. In the final model, which is corrected for having had the TTCM (yes/no), the case-mix variables, and the other fracture and treatment-related factors, having a fracture of the lower extremity was found to be statistically significantly associated with a lower disease specific HR-QOL after 9 months compared with having a vertebral fracture or multi-trauma (Model 4: 10.09; 95% CI 2.18 to 18.00). Please note that this beta is positive, because higher scores indicate a lower disease-specific HR-QOL. None of the other fracture and treatment-related factors were found to be associated with disease-specific HR-QOL after 9 months in the final model (Table 6.2).

Functional outcome

Table 6.3 provides an overview of all models assessing the association between fracture and treatment-related factors and functional outcome. In the final model, having an upper extremity fracture was associated with a better functional outcome compared to having a vertebral fracture or multi-trauma (Model 4: -19.12; 95% CI -31.65 to -6.59). Please note that this beta is negative, because higher scores indicate a lower functional outcome. None of the other fracture and treatment-related factors were found to be associated with functional outcome after 9 months in any of the models (Table 6.3).

Societal costs

Table 6.4 provides an overview of all models assessing the association between fracture and treatment-related factors and societal costs. In the final model, having had a surgery was found to be statistically significantly associated with lower societal costs during the patients' first 9 months after their first visit at the outpatient trauma clinic compared to conservative treatment (Model 4:-1,770; 95% CI:-3,276 to -433). Furthermore, fracture treatment with ORIF was statistically

significantly associated with higher societal costs compared to conservative treatment (Model 4: 1,651; 95% CI: 245 to 3,237), whereas fracture treatment with an intramedullary nail was not. The variables fracture type and fracture localization were found to be not associated with societal costs (Table 6.4).

Table 6.1 Patient characteristics, trauma characteristics and outcomes

	Patient characteristic Mean (SD) or frequency (%)	All participants (N=140)
Case-mix variables	Age (years)	46.3 (16.8)
	Gender (male)	65 (46.4%)
	Comorbidity	
	None	83 (59.3%)
	Chronic illness	27 (19.3%)
	Musculoskeletal disease	30 (21.4%)
	Received TTCM (yes)	83 (59.3%)
	ISS*	8.2 (range 4–29, SD 5.2)
	Trauma type	
	Traffic	69 (49.3%)
	Work-related	2 (1.4%)
	Fall	44 (31.4%)
	Sport	20 (14.3%)
	Other	5 (3.6%)
Fracture and treatment-related factors	Surgery (yes)	74 (52.9%)
	Fracture type	
	Intra articular	115 (82.1%)
	Extra articular	25 (17.9%)
	Fracture localization	
	Single upper extremity	56 (40.0%)
	Single lower extremity	60 (42.9%)
	Vertebral fracture(s)	8 (5.7%)
	Multi-trauma	16 (11.4%)
	Fracture treatment	
	Intramedullary nail	15 (10.7%)
	ORIF**	59 (42.1%)
	Conservatively	66 (47.1%)
Outcomes at 9 months	Disease-specific HR-QOL (DSQOL-OA)*** Range 0–100 (higher score: lower HR-QOL)	18.8 (16.5)
	Functional outcome (PSFS)**** Range 0–100 (higher score: less function)	25.0 (25.3)
	Societal costs in Euros [mean (SEM)]	5,047 (422)

* ISS: Injury Severity Score;
** ORIF: Open Reduction Internal Fixation;
*** DSQOL-OA: Disease Specific Quality of Life Overall;
**** PSFS: Patient-Specific Function Scale.

Table 6.2 The association between fracture and treatment-related factors with **disease-specific HR-QOL**

Fracture and treatment-related factors	Model 1 Crude B (95% CI)	Model 2 Adjusted for TTCM B (95% CI)	Model 3 Adjusted for TTCM and case-mix variables B (95% CI)	Model 4 Adjusted for TTCM, case-mixed variables, and the other fracture and treatment-related factors B (95% CI)
Surgery (ref: no)**				
Yes	-3.64 (-9.11 to 1.83)	-4.71 (-10.37 to 0.94)	-4.23 (-9.88 to 1.41)	-1.75 (-7.59 to 4.09)
Fracture type (ref: extra-articular) ***				
Intra-articular	-1.07 (-8.27 to 6.12)	-1.19 (-8.38 to 6.01)	0.41 (-7.01 to 7.84)	2.06 (-5.93 to 10.06)
Fracture localization (ref: other) ***				
Upper extremity	-0.06 (-7.72 to 7.60)	0.35 (-7.28 to 7.99)	0.63 (-6.99 to 8.26)	0.09 (- 8.22 to 8.40)
Lower extremity	8.79 (1.20 to 16.38)	9.77 (2.13 to 17.41)	10.31 (2.63 to 17.99)	10.09 (2.18 to 18.00)
Fracture treatment (ref: cons.)***				
Intramedullary nail	0.27 (-9.02 to 9.56)	1.63 (-7.85 to 11.11)	1.29 (-8.35 to 10.93)	-4.14 (-14.51 to 6.23)
ORIF*	4.50 (-1.30 to 10.30)	5.45 (-0.50 to 11.36)	4.88 (-1.03 to 10.79)	2.69 (-3.29 to 8.68)

* ORIF: Open Reduction Internal Fixation;
** Not corrected for “fracture treatment” in model 4 because of a too high level of collinearity;
*** Not corrected for “surgery” in model 4 because of a too high level of collinearity.

Table 6.3 The association between fracture and treatment-related factors with **functional outcome**

Fracture and treatment-related factors	Model 1 Crude B (95% CI)	Model 2 Adjusted for TTCM B (95% CI)	Model 3 Adjusted for TTCM and case-mix variables B (95% CI)	Model 4 Adjusted for TTCM, case-mixed variables, and the other fracture and treatment-related factors B (95% CI)
Surgery (ref: no)**				
Yes	-1.85 (-10.26 to 6.56)	-6.50 (-14.75 to 1.76)	-6.76 (-15.20 to 1.68)	-3.25 (-11.98 to 5.48)
Fracture type (ref: extra-articular) ***				
Intra-articular	-1.72 (-12.65 to 9.20)	-2.37 (-12.78 to 8.05)	-2.22 (-13.26 to 8.82)	3.28 (-8.73 to 15.30)
Fracture localization (ref: other) ***				
Upper extremity	-19.64 (-31.32 to -7.96)	-18.13 (-29.28 to -6.99)	-18.89 (-30.33 to -7.44)	-19.12 (-31.65 to -6.59)
Lower extremity	-12.10 (-23.67 to -0.54)	-8.55 (-19.70 to 2.69)	-9.03 (-20.56 to 2.50)	-10.04 (-21.97 to 1.89)
Fracture treatment (ref: cons.)***				
Intramedullary nail	1.73 (-12.63 to 16.09)	7.89 (-5.99 to 21.76)	8.89 (-5.55 to 23.33)	2.69 (-13.01 to 18.39)
ORIF*	1.88 (-7.07 to 10.83)	6.17 (-2.54 to 14.87)	6.28 (-2.58 to 15.15)	3.34 (-5.68 to 12.36)

* ORIF: Open Reduction Internal Fixation;

** Not corrected for “fracture treatment” in model 4 because of a too high level of collinearity;

*** Not corrected for “surgery” in model 4 because of a too high level of collinearity.

Table 6.4 The association between fracture and treatment-related factors with **costs** (in Euros)

Fracture and treatment-related factors	Model 1 Crude B (95% CI)	Model 2 Adjusted for TTCM B (95% CI)	Model 3 Adjusted for TTCM and case-mix variables B (95% CI)	Model 4 Adjusted for TTCM, case-mixed variables, and the other fracture and treatment-related factors B (95% CI)
Surgery (ref: no)**				
Yes	-1,884 (-3,656 to -570)	-1,884 (-3,656 to -561)	-1,879 (-,3678 to -518)	-1,770 (-3,276 to -433)
Fracture type (ref: extra-articular) ***				
Intra-articular	-867 (-6,690 to 1,346)	-886 (-6,589 to 1,337)	-475 (-,5448 to 1,752)	-622 (-4,143 to 1,449)
Fracture localization (ref: other) ***				
Upper extremity	-1,891 (-3,846 to -113)	-1,923 (-,3881 to -141)	-1,763 (-3,665 to 157)	-1,652 (-3,694 to 406)
Lower extremity	-1,170 (-3,160 to 1,193)	-1,245 (-3,266 to 1,530)	-898 (-2,914 to 2,377)	-1,567 (-3,529 to 772)
Fracture treatment (ref: cons.)***				
Intramedullary nail	3,543 (352 to 13,794)	3,728 (99 to 14,359)	3,654 (-191 to 13,934)	3,507 (-105 to 12,390)
ORIF*	1,537 (206 to 2,927)	1,646 (249 to 3,212)	1,702 (270 to 3,348)	1,651 (245 to 3,237)

* ORIF: Open Reduction Internal Fixation;
** Not corrected for “fracture treatment” in model 4 because of a too high level of collinearity;
*** Not corrected for “surgery” in model 4 because of a too high level of collinear.

DISCUSSION

Traumatic injury, and fractures in particular have a serious impact on patients' everyday life, work and social activities [11,54] and poses a substantial economic burden to society [2,3]. Studies conducted to investigate the association between specific fracture and treatment-related factors (e.g. fracture type, surgical techniques) and disease-specific health-related quality of life (HR-QOL) and functional outcomes are rare and give conflicting results [25-30]. Moreover, the association of these factors with costs remains unclear. Therefore, the present study aimed to assess the association between fracture and treatment-related factors with disease-specific HR-QOL, functional outcome, and societal costs.

Study findings

This study found fracture localization to be associated with disease-specific HR-QOL and functional outcome after 9 months, and the variables surgery and fracture treatment to be associated with societal costs during the first 9 months after the trauma patients' first visit at the outpatient trauma clinic. To illustrate, lower extremity fracture patients' disease-specific HR-QOL after 9 months was 10.09 points higher on a 0–100 scale (i.e. indicating a lower disease-specific HR-QOL) than that of patients with a vertebral fracture or multi-trauma). Furthermore, patients with an upper extremity fracture scored 19.12 points lower on a 0–100 scale (i.e. indicating a better functional outcome) than patients with a vertebral fracture or multi-trauma. Moreover, the societal costs of trauma patients who had surgery were on average EUR1,770 lower during the first 9 months after their first visit at the outpatient clinic for trauma patients compared to trauma patients who did not undergo surgery. ORIF, on the other hand, was associated with on average EUR1,651 higher societal costs compared to conservative treatment, and intramedullary nailing was not significantly associated with societal costs. Fracture type was not found to be associated with disease-specific HR-QOL, functional outcome, and societal costs.

Most of the identified associations were in the expected direction, with for example fractures of a lower extremity being associated with less favorable outcomes after 9 months, such as a lower disease specific HR-QOL. However, it is noteworthy that surgery patients were found to have lower societal costs during the first 9 months after their first outpatient visit compared to trauma patients who did not undergo surgery. When interpreting these findings, one should bear in mind that surgery costs were not included in our societal cost estimate, because they occurred prior to the patients first outpatient visit. The finding that trauma patients who underwent surgery have lower societal costs after their first outpatient visit compared to those who did not, might be explained by the fact that one of the most important goals of a surgery

is achieving a situation, in which a patient can start exercising at an earlier stage, which may in turn lead to a quicker return to work and thus a decrease in societal costs.

Comparison with the literature

Even though extensive research has been done on functional outcome and costs after major trauma [3,7-9,54], relatively few studies assessed which fracture and treatment-related factors are associated with disease-specific HR-QOL, functional outcome, and/or societal costs. Earlier studies that did assess one or more of these associations mostly included patients suffering from a specific type of fracture, instead of a broad range of fractures. To illustrate, Alexandridis et al. found various radiographic characteristics (e.g. Bohlers' angle) of calcaneal fractures to be statistically significantly associated with HR-QOL, patient satisfaction, and complication rate [26] and Souer et al. found similar associations for intra-articular and extra-articular radial fractures with impairment and disability [28]. Moreover, a recent Dutch study found ORIF (i.e. volar plating) to be associated with lower societal costs when compared to conservative treatment (i.e. plaster immobilization) in patients with an extra-articular distal radial fracture [55], whereas we found the opposite result. Differences in study population (i.e. patients with a distal radial fracture versus all kinds of fractures) and study design (i.e. randomized controlled trial versus non randomized controlled trial) might explain this difference in results.

Other authors only assessed the association of one trauma or fracture-related factor with a relatively small number of outcomes. For example, Chiu et al. assessed the association between fracture localization and a couple of outcomes (e.g. physical capacity and psychological well-being), including HR-QOL. They found fracture localization to be associated with HR-QOL, with hip fractures being associated with the smallest improvements in physical HR-QOL during the first year after treatment. This is in contrast to our finding that upper extremity fractures were associated with the lowest disease-specific HR-QOL values. This difference might be explained by the fact that HR-QOL was conceptualized and measured differently in both studies (i.e. physical HR-QOL assessed using the WHO HR-QOL versus disease-specific HR-QOL assessed using different PROMS) and because both studies were conducted in different countries (i.e. Taiwan versus the Netherlands) [29]. Another recent study found ORIF to result in better functional outcomes compared to intramedullary nailing in patients with a shaft fracture of both forearm bones, whereas we found both to result in similar outcomes [23]. This difference in results might be due to differences in the study population (i.e. patients with a shaft fracture of both forearm bones in particular versus all kinds of fractures) and country (i.e. South Korea versus the Netherlands).

Strengths and limitations

The present study population included a broad range of trauma severity levels with an ISS ranging from 4 to 29. This is a strength, as our results are therefore generalizable to mild, moderate, and severe trauma patients, whereas the results of most other studies are only generalizable to multi-trauma patients who generally have an ISS>16 [54,56]. Another factor that improved the generalizability of our findings is that we included all kinds of fractures, whereas previous studies typically focused on one specific type of fracture, such as a proximal humeral fracture [25]. Another strength is our use of a wide range of outcomes instead of only one single outcome measure.

Our study also had some limitations. First, our follow-up period was limited to 9 months, which is slightly shorter than the usual follow-up period when assessing functional outcome in trauma patients (up to 36 months) [57,58]. Second, we had a relatively small study population of 140 participants. Consequently, we could not perform additional subgroup analyses to assess whether associations differ between subgroups (e.g. for older versus younger, or severely versus mildly injured trauma patients). Moreover, only 8 vertebral fracture and 16 multi-trauma patients were included. Consequently, the vertebral fracture patient group was too small to treat it as a separate fracture localization category in our analyses. Therefore, we decided to use an "other" group, including both vertebral fracture and multi-trauma patients, as reference category. This is not optimal, as disease-specific HR-QOL, functional outcome, and societal costs might differ between vertebral fracture and multi-trauma patients. However, we do not expect our decision to combine both groups of patients into one reference category to have severely biased our results, as a post-hoc analysis indicated that the associations for fracture localization did not extensively change when excluding vertebral fracture patients from our analyses (data not shown). Third, despite our efforts to limit the amount of missing data, we had some missing cost data and some missing effect data. Although missing data are generally unavoidable in clinical studies and we used multiple imputation techniques to fill in missing values, a complete dataset would have produced more valid and reliable results. A last limitation is the fact that the current study used clinical trial data, instead of data of large cohort of consecutive trauma patients. Hence, the study results might be influenced by the fact that some patients received the TTCM as well as the relative small sample size that is typical for a clinical trial. The possible influence of some patients receiving the TTCM was handled by correcting for receiving the TTCM in the final models. Moreover, we do not expect our study to be severely underpowered, because we even found statistically significant associations for the dependent variable societal costs, which typically requires relatively large sample sizes due to its highly skewed nature.

Future recommendations

As indicated above, the sample size of our study was relatively small. To be able to perform stratified analyses (e.g. among older versus younger trauma patients), and to treat multi-trauma and vertebral fractures as a separate category for the variable trauma localization, a bigger dataset would be required. Such a dataset is ideally collected as part of a cohort study, instead of a study assessing the effectiveness and/or cost-effectiveness of a particular healthcare intervention, and preferably has a follow-up duration of more than 9 months. To achieve this, working together with other level-1 trauma centers is probably essential, because more trauma patients could then be included during the same time frame. Future studies might also focus on understanding the mechanisms underlying the identified associations. For example, if it is known what factors cause lower extremity fracture patients to have lower disease-specific HR-QOL after 9 months, we might develop and/or implement initiatives to improve trauma patients' longer-term disease-specific HR-QOL. A possible example of such an initiative might be the development of tailored rehabilitation pathways for different types of trauma patients, but further research into this area is needed to establish this.

CONCLUSION

Of the investigated fracture and treatment-related factors, a fracture of the lower extremity was associated with lower disease-specific HR-QOL and a fracture of the upper extremity was associated with better functional outcome, both compared to the reference category. Surgical treatment was associated with lower societal costs compared to conservative treatment. However, ORIF was associated with higher societal costs when compared to conservative treatment, whereas intramedullary nailing was not. Future studies should focus on confirming these associations and understanding their underlying mechanisms in order to be able to design effective initiatives to improve trauma patients' HR-QOL and functional outcome and to reduce their societal costs.

Funding

This project is partly funded by "Zilveren Kruis Health Insurer" (grant number Z516).

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GERDINA (77) | FOOT RAN OVER BY A BUS 10 MONTHS AGO

Crush injury left foot

7

Effectiveness and cost-effectiveness of the Transmural Trauma Care Model (TTCM) investigated in a multicenter trial with a controlled-before-and-after design: a study protocol

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Physiother Res Int. 2021;26(2):e1894

ABSTRACT

Objective: The rehabilitation of trauma patients in primary care is challenging, and there are no guidelines for optimal treatment. Also, the organization of care is not well-structured. The Transmural Trauma Care Model (TTCM) has been developed in the Netherlands, aiming to improve patient outcomes by optimizing the organization and quality of the rehabilitation process in primary care. A recent feasibility study showed that implementation of the TTCM at a Dutch level-one trauma center was feasible, patient outcomes were improved, and costs were reduced. The current study aims to assess the effectiveness and cost-effectiveness of the TTCM as compared to usual care in a multicenter trial.

Methods: A multicenter trial with a controlled before-and-after design will be performed at ten hospitals in the Netherlands. First, participating hospitals will include 322 patients in the control group, receiving usual care as provided in these specific hospitals. Subsequently, the TTCM will be implemented in all participating hospitals, and hospitals will include an additional 322 patients in the intervention group. The TTCM consists of a multidisciplinary team at the outpatient clinic (trauma surgeon and hospital-based physical therapist), an educated and trained network of primary care trauma physical therapists, and structural communication between them. Co-primary outcomes will investigate generic and disease-specific health-related quality of life. Secondary outcomes will include pain, patient satisfaction, perceived recovery, and patient-reported physical functioning. For the economic evaluation, societal and healthcare costs will be measured. Measurements will take place at baseline and after 6 weeks, 3, 6, and 9 months. Analyses will be based on the intention-to-treat principle. Missing data will be handled using longitudinal data analyses in the effect analyses and by multivariate imputation in the economic evaluation.

Conclusion: This trial with a controlled before-and-after design will give insight into the effectiveness and cost-effectiveness of the TTCM in a multicenter trial.

INTRODUCTION

Trauma-related injury is one of the most common causes of death and disability worldwide [1]. Globally, trauma accounts for 9.6% of mortality in patients under 40 years of age [2]. In older age groups, it is one of the most important causes of death, behind cardiovascular disease and cancer [3,4]. In addition, trauma negatively influences a patient's physical functioning and health-related quality of life (HR-QOL) [5-8]. Since trauma patients are typically relatively young, the associated loss of Disability-Adjusted Life Years (DALYs) is higher than in any other disease [1]. To illustrate, each year, traumatic injuries cost an estimated 300 million years of healthy life, translating into 11% of DALYs experienced worldwide [1].

The economic burden of trauma is high, and traumatic injuries rank among the five most costly medical conditions [9]. Globally, the lifetime cost of traumatic injuries has been estimated at $406 billion, of which the majority is due to increased absenteeism and lost productivity at work [9-11]. In the Netherlands, 79,573 patients were treated at trauma centers in 2017, and the total societal costs of traumatic injuries were estimated at EUR3.5 billion (EUR210/capita and EUR4,300/patient) [12,13].

An improved organization of pre- and in-hospital trauma care has led to a 9% to 25% decrease in mortality among severe trauma patients [14-17]. As further improvements in survival rates are likely to be small, the focus of trauma care shifted to other relevant outcomes of trauma, such as reduced morbidity, improved functioning, increased health-related quality of life and reduced costs [18-20]. Due to trauma's significant clinical and economic impact, there has also been an increased interest in its rehabilitation process to improve patients' generic and disease-specific quality of life. After discharge from a hospital, the majority of Dutch trauma patients rehabilitate in primary care (mostly treated by a physical therapist), and communication between primary and secondary care is minimal [21]. However, the organization of post-clinical trauma rehabilitation in primary care is challenging, and there are no (inter)national guidelines available [22]. Consequently, severe gaps exist between trauma patients' transition from hospital to their home situation and return to society. For instance, research shows both, under- and overtreatment of trauma patients by non-experienced physical therapists in primary care and there is a lack of assessment of trauma patients' physical functioning at the outpatient clinic [22-26].

The Transmural Trauma Care Model (TTCM) has been developed in the Netherlands, aiming to improve patient outcomes by optimizing the organization and quality of the rehabilitation process in primary care [27]. A recent feasibility study found implementation of the TTCM at a Dutch level-one trauma center to be feasible, improve patient outcomes and patient satisfaction, and reduce costs [21,28]. However, due to some of the shortcomings of this feasibility (e.g. control group

measured only afterward, one hospital), a larger study is needed to obtain more reliable data on the effectiveness and cost-effectiveness of the TTCM. Therefore, a prospectively followed control group will be included in this study and patients will be recruited at several participating hospitals (both University medical centers and regional hospitals), increasing the representativeness of the study population and thereby the generalizability of the results. Moreover, during the feasibility study, the implementation of the TTCM was evaluated and adjusted by means of a process evaluation [27]. This has led to substantive and logistical improvements to the TTCM, which will all be incorporated in this study, for example, a manual describing clear organizational structures, duties and responsibilities of the participating care providers, and the inclusion of the entire range of severity of fracture(s) treated by the trauma surgeon independent of where they will rehabilitate. Please note that in contrast to the feasibility study, patients rehabilitating in tertiary care will now be included.

Therefore, this study aims to assess the effectiveness and cost-effectiveness of the improved version of the TTCM as compared to usual care in a multicenter trial with a true controlled before-and-after design. Given the current situation of the Dutch healthcare system and the complexity of the intervention this design was considered to be the most optimal design for assessing the (cost)-effectiveness of the TTCM, which will be described in detail below.

We hypothesize that the TTCM improves generic and disease-specific health-related quality of life and that it is cost-effective compared to usual care from both the healthcare and the societal perspective.

METHODS

Study design

The effectiveness and cost-effectiveness of the TTCM compared to usual care will be evaluated in a multicenter trial with a controlled before-and-after design.

Inclusion procedures will be identical for both study groups and will take place during the patients' first consultation with a trauma surgeon at the outpatient clinic of the participating hospitals. Per hospital, a local research assistant will be responsible for the selection of potentially eligible patients and the daily coordination of the trial. Potentially eligible patients will be selected by the local research assistant prior to their first consultation with the trauma surgeon. The trauma surgeon will subsequently inform potentially eligible patients about the study during their first consultation. If patients are interested in participating, they will be asked to meet the local

research assistant to get further oral and written information about the study. After re-assessing the patients' eligibility, patients can sign the informed consent form after a minimum reflection period of 1 hour. If patients prefer a more extended reflection period, they will be contacted by phone by the local research assistant at a date and time convenient to the patient. After receiving the patients' signed informed consent form, patients will be included in the study. They will receive an e-mail containing a link to the baseline questionnaire through a secured e-mail system following the General Data Protection Regulation (Dutch: Algemene verordening gegevensbescherming).

During the inclusion period for the control group, 322 patients will be recruited, and they will receive usual care and will be followed for a total of nine months. After this control period, the TTCM will be implemented in all of the participating hospitals during a so-called implementation phase. The research team of Amsterdam UMC, location VUmc will coordinate and supervise the implementation process. Implementation procedures will be hospital-specific, taking into account local differences, to guarantee a successful implementation [29,30]. Subsequently, during the inclusion period for the intervention group, 322 patients will be recruited and they will receive the TTCM. Follow-up of the intervention group will also be nine months. A graphical representation of the study design is provided in Figure 7.1. Due to the nature of the intervention, blinding of participants is not possible.

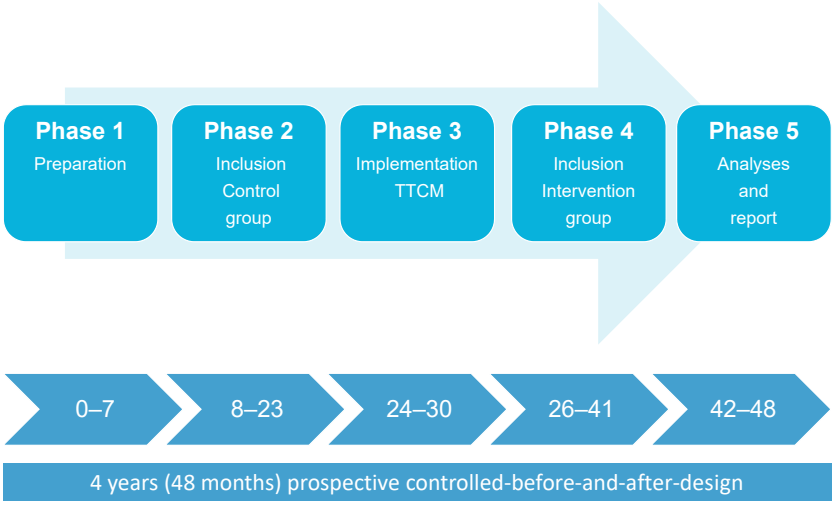

Figure 7.1 Study design.

Population

Patients older than 16 years with one or more fracture(s) as a result of a trauma, who have received medical treatment at an emergency department or have been admitted to a hospital will be invited to participate. Patients with traumatic brain injury, pathological fractures, severe psychopathology, cognitive limitations, insufficient knowledge of the Dutch language, as well as patients living in an institution or refusing to sign informed consent and second opinions will be excluded. Please note that in contrast to the feasibility study, patients rehabilitating in tertiary care will now be included.

Treatment conditions

In this trial, pre- and in-hospital trauma care will remain unchanged and will be in line with the Dutch guidelines for the network of acute care (Landelijk Netwerk Acute Zorg) [31]. In brief, these guidelines recommend the existence of good national and regional network(s) consisting of involved chain partners and professionals to promote the optimal accessibility of acute care. Acute care takes place within the whole care chain that starts with the emergency call and ends with the rehabilitation process. Eleven Dutch hospitals have been designated as trauma centers, and form the backbone of the national network. These trauma centers are an important platform for the coordination of acute care chains in their region.

Control group

Control group patients will receive usual rehabilitation care as provided by the participating hospitals prior to the implementation of the TTCM. Usual care may slightly differ across hospitals, and trauma surgeons perform post-clinical consultations individually. Based on the clinical judgment of the trauma surgeon, a patient might be referred to a physical therapist in primary care, but there is no standardized policy for these referrals, nor is there a network of specialized primary care trauma physical therapists and communication between primary and secondary care is minimal [21]

Intervention group

Patients in the intervention group will receive the TTCM, as developed and described earlier (21). In the TTCM, a multidisciplinary team consisting of a trauma surgeon and a specialized, hospital-based physical therapist will examine patients during their first outpatient consultations and will coordinate their rehabilitation process.

The TTCM consists of four main elements [21]:

1. Intake and follow-up consultations by a multidisciplinary team at the outpatient clinic.
   This team consists of a trauma surgeon and a specialized hospital-based physical therapist. The trauma surgeon is responsible for medical procedures (e.g. indicating surgery, fracture- and wound-healing), whereas the physical therapist will assess physical function (e.g. mobility).

2. Coordination and individual goal setting.
   The hospital team will coordinate the rehabilitation process, and the hospital-based physical therapist will act as a case manager throughout the rehabilitation process. Following a shared decision-making process, treatment goals will be formulated at a functional level for each patient. Besides, ten previously developed rehabilitation protocols for the most common fractures will support this process.

3. An educated and trained network of primary care trauma physical therapists.
   The 'trauma rehabilitation primary care physical therapy network' will consist of 20 to 40 physical therapists, per hospital, depending on the size and catchment area of the specific hospital. All network physical therapists will receive a three-day training program which content is validated by the central research team. The training will focus on fracture treatment, fracture rehabilitation, and recognizing complications. Furthermore, the working agreements within the TTCM will be explained during the course. In addition, internal training days and network meetings will take place regularly.

4. Secured e-mail traffic between hospital-based physical therapists and network physical therapists.
   A secured e-mail system will enable a well-structured interaction between hospital-based physical therapists and network physical therapists, allowing them to exchange patient data more efficiently and in a safe way according to agreed timeframes.

Sample size calculation

To detect a difference in generic quality of life of 0.057 [SD=0.15] as measured by the EQ-5D-5L with α=0.025, a power=90%, an Intracluster Correlation Coefficient of ICC=0.01, assuming an expected cluster size of 50, and an anticipated drop-out of 20%, 322 patients will be needed per group, equaling a total of 644 patients. We will assess the difference found between the two groups from the perspective of a clinically relevant difference. Based on previous publications [32,33], we assume that 0.057 [SD=0.15] is the minimum clinical relevant difference for health-related quality of life. A between-group difference of 10% in improvement of disease-specific

quality of life is assumed to be clinically relevant. If one of the co-primary outcomes shows a clinically relevant difference in favor of the intervention, TTCM will be considered effective. Therefore, we accounted for multiple testing of the two co-primary outcomes by using an α of 0.025 [34]. It should be noted, however, that all available outcome measurements will be taken into account when interpreting the results.

Outcomes

At baseline, various relevant patient and trauma characteristics will be measured, including:

Patient characteristics

Age (years), gender (woman/man), educational level (low/middle/high), country of birth, medical history (none/chronic illness/musculoskeletal disease), self-reliance (independent/dependent), marital status (living together/alone), personal injury claim (injury process: yes/no), illness perceptions and patient expectations (Somatic Pre-Occupation and Coping Questionnaire [SPOC questionnaire]). The SPOC is a questionnaire assessing the impact of patients' beliefs on functional recovery, and consists of 27 questions in four domains, including somatic complaints, coping, energy, and optimism. The SPOC questionnaire is a valid measurement of illness beliefs and attitudes in patients with lower extremity injuries and is highly predictive of their long-term functional recovery [35,36].

Trauma characteristics

Injury Severity Score (ISS) [37], type of trauma (traffic/fall/sport), fracture region (upper extremity fracture/lower extremity fracture/vertebral fracture/multi-trauma), fracture typing (open/closed, intraarticular/ extra-articular, stable/ unstable, comminutive (yes/no), peripheral nerve injury (yes/no), multiple fractures within one region (yes/no), weight-bearing policy (full weight-bearing/ partially weight-bearing/ non weight-bearing), treatment (operatively/conservatively), length of hospital stay (days), discharge destination (home/home with support/institution).

Follow-up measures will include co-primary outcomes, secondary outcomes, and cost measures, including:

Co-primary outcomes

The co-primary outcomes are generic and disease-specific quality of life. Co-primary outcomes will be measured at baseline, 6 weeks, 3 months, 6 months, and 9 months.

Generic quality of life will be measured using the EQ-5D-5L. Utility values ranging from 0 (equivalent to death) to 1 (full health) will be estimated using the Dutch tariff [38]. For the economic evaluation, quality-adjusted life-years (QALYs) will be calculated using linear interpolation between measurement points.

Depending on the diagnosis, disease-specific quality of life will be measured using one of the following four standardized Patient-Reported Outcome Measures [PROMS]:

- Upper extremity: QuickDASH DLV (Disabilities of the Arm, Shoulder, and Hand) [39,40];
- Lower extremity: Lower Extremity Functional Scale (LEFS) [41];
- Multiple fractures and/or more locations: Groningen Activity Restriction Scale (GARS) [42,43];
- Vertebral fractures: The Roland Morris Disability Questionnaire (RMDQ) [44,45].

An overall score of the disease-specific quality of life PROMS is calculated by converting the overall scores of the aforementioned questionnaires to a scale from 0–100, with higher scores representing less functional problems.

Secondary outcomes

Secondary outcomes include functional status (Patient-Specific Functional Scale PSFS), pain (11-point NPRS), patient satisfaction (11-point NRS), perceived recovery (7-point Global Perceived Effect Scale) and patient-reported health based on physical functioning (PROMIS-PF SF (-UE)). All secondary outcomes will be measured at baseline, after 3 months, 6 months, and 9 months. A detailed description of the outcomes, including references, can be found in Appendix 7.1.

Societal and health care costs

For the economic evaluation, societal and healthcare costs will be estimated. Societal costs include intervention, healthcare, informal care, unpaid productivity, absenteeism, and presenteeism costs. Healthcare costs only include costs accruing to the formal Dutch healthcare sector. Resource use data will be collected using cost questionnaires administered at baseline, 3, 6, and 9 months follow-up. All costs will be valued in accordance with the Dutch Manual of Costing [46].

A detailed description of the co-primary and secondary outcomes, as well as the measurement and valuation of societal and healthcare costs, can be found in Appendix 7.1. An overview of all outcome measurements is provided in Table 7.1.

Table 7.1 Assessments and follow-up moments

	Pre- consultation	Baseline	6 weeks	3 months	6 months	9 months
Intake surgeon (diagnosis)		X				
Intake local research assistant (inclusion and exclusion criteria)	X	X				
Patient and trauma characteristics (CRF)		X				
Illness perceptions patient expectations (SPOC)		X				
Co-primary outcomes						
Generic quality of life (EQ-5D-5L)		X	X	X	X	X
Disease-specific quality of life (QuickDASH DLV, LEFS, GARS, RMDQ)		X	X	X	X	X
Secondary outcomes						
Patient-Specific Functional Scale (PSFS)		X		X	X	X
Numeric Pain Rating Scale (NPRS)		X		X	X	X
Patient satisfaction (NRS)		X		X	X	X
Global Perceived Effect Scale (GPE)		X		X	X	X
Patient-Reported Outcomes Measurement Information System (PROMIS-PF SF 10a and PROMIS-PF-UE 7a)		X		X	X	X
Societal and healthcare costs		X		X	X	X

Process evaluation

To evaluate the implementation of the TTCM, a mixed-method process evaluation will be performed. Quantitative data contribute to understanding why and if an intervention (i.e. TTCM) has its intended impact [47]. By using qualitative data, stakeholders' experiences including barriers and facilitators, may be reviewed in more detail to modify the TTCM for future implementation.

Following the recommendations of Linnan and Steckler, quantitative data on the TTCM's reach, dose delivered, dose received, and fidelity will be collected from electronic patient records [48].

These data will be registered in the control group using the following process variables: number of post-clinical consultations of the trauma surgeon, discharge location (home/rehabilitation setting), referral to primary care yes or no and if so number of sessions attended by a patient at the primary care physical therapist. In the intervention group the following process variables will be registered: is the outpatient consultation provided by a trauma surgeon and a physical therapist (yes/no), discharge location (home/rehabilitation setting), referral to primary care yes or 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), agreed timeframes of e-mails exchanged between hospital physical therapist and network physical therapist apprehended (yes/no) and the number of sessions attended by a patient at the primary care physical therapist.

For the qualitative part of the process evaluation, focus groups and semi-structured interviews with stakeholders (e.g. patients, trauma surgeons, physiotherapists, insurance representatives) will take place to identify possible facilitators and barriers associated with the implementation of the TTCM. Focus groups and interviews will be analyzed using a framework method [49,50] with data mapped onto different levels of the 'constellation perspective" (i.e. structure, culture, practice) (Van Raak, 2010).

Data analysis

Analyses will be based on the intention-to-treat principle. Missing data will be handled using longitudinal data analyses for clinical outcomes and using Multivariate Imputation by Chained Equations (MICE) for the economic evaluation.

Clinical outcomes

The TTCM's effect on both co-primary outcomes will be analyzed using a linear mixed model using the participants' responses at baseline, at 6 weeks, 3 months, 6 months, and 9 months. In these analyses, the hospital level, as well as that of the patient and time of measurement,

will be taken into account. The effects of interest are the difference between groups at each time point, as well as the overall effect of the TTCM over time. The non-randomized nature of the study will be accounted for using propensity score weights [51,52]. Propensity scores are defined as the "*conditional probability of receiving a treatment given the patients' pre-treatment characteristics*". In this study, propensity scores will be calculated based on the patients' baseline characteristics that differed between groups and those that will be associated with the patients' baseline primary effect measure values. The estimated propensity scores will be used as sampling weights in the analyses. Continuous secondary outcomes will be analyzed, as outlined above. For dichotomous secondary outcomes, we will use a generalized mixed model (logit link) with the same multilevel structure, and the effects of interest are the difference between groups at each time point as well as the overall effect of the TTCM over time. Again, the non-randomized nature of the trial will be accounted for using propensity score weights.

Economic evaluation

To account for the possible clustering of data, cost and effect differences will be estimated using linear mixed models. Within these analyses, the non-randomized nature of this study will again be accounted for using propensity score weights, but now propensity scores will be calculated based on the patients' baseline characteristics that differ between groups and those that are associated with the patients' baseline primary effect and cost measure values. To deal with the highly skewed nature of cost data, 95% CIs around the differences in costs will be estimated using Bias Corrected and Accelerated bootstrapping, with 5,000 replications. Incremental Cost-Effectiveness Ratios (ICERs) will be calculated by dividing the difference in costs by that in QALYs (cost-utility) and in co-primary outcomes (cost-effectiveness). Bootstrapped incremental cost-effect pairs will be plotted on cost-effectiveness planes [53]. A summary measure of the joint uncertainty of costs and effects will be presented using Cost-Effectiveness Acceptability Curves (CEACs) [54]. One-way sensitivity analyses will be performed to test the robustness of the results. The assumptions being varied in these sensitivity analyses will be determined over the course of the study. Analyses will be performed in STATA, using a level of significance of $p<0.025$.

DISCUSSION

The current study is a comprehensive multicenter study, albeit non-randomized, aimed at assessing the effect of the TTCM, a patient-centralized multidisciplinary outpatient rehabilitation model, compared to usual care in patients with at least one fracture due to trauma.

Comparison with literature

A review of multidisciplinary rehabilitation in multiple trauma patients emphasized the lack of high-quality studies on the effectiveness of rehabilitation [22]. Also, there is uncertainty about the recommended questionnaires in trauma patients and a core outcome set of questionnaires for trauma patients is missing. Hoffmann et al. (2014) stated that there is no general classification for measuring disability or health outcomes following trauma [26].

Strengths and limitations

Following the recommendation of Hoffman et al. to use the ICF as a framework for measuring health outcomes among trauma patients, we will use a comprehensive measurement strategy to describe the whole range of trauma's impact on function, disability, and health including all relevant domains of the International Classification of Functioning, Disability and Health [55]. In this study, we will include trauma patients in ten hospitals from different regions in the Netherlands. Furthermore, we will include the entire range of severity of fracture(s) treated by the trauma surgeon, independent of where they will rehabilitate. As a consequence, we expect the results to be generalizable to the general Dutch (trauma patient) population. Furthermore, we will perform a process evaluation to analyze all perspectives of the implementation.

However, there are also some methodological considerations. From a methodological point of view, a randomized controlled trial would have been the most optimal design for assessing the (cost-)effectiveness of the TTCM. Given the current situation of the Dutch healthcare system and the complexity of the intervention, however, such a design was not feasible for several reasons. First, the TTCM is organized at a hospital level, making it impossible to randomize individual trauma patients. Second, for a true randomization "effect", and in order to be able to use the appropriate statistical analyses for cluster RCTs, at least 30 clusters should be included [56]. In our case, that would have meant that we needed to perform the study in at least 30 hospitals, which was financially and practically not feasible given the constrains of this study. Third, suitable hospitals were less inclined to participate in the proposed study if they would have been randomized across study conditions, because one of their main reasons for participation was the prospective implementation of the TTCM. Some researchers may argue that a stepped wedge design may have been used to overcome this barrier, but we were of the opinion that such a design would have led to contamination, because many patients in the control group would have then likely received some of their follow-up consultations after their hospital started providing the TTCM. Moreover, there is (some) overlap in the catchment areas of the participating hospitals (and therefore in primary care networks of specialized primary care trauma physical therapists).

This may lead to even more contamination if the 2 hospitals with overlapping catchments areas deliver both treatment conditions at the same time. Given these considerations, we decided to use a controlled before-and-after design instead. To minimize the possibility of selection bias, we decided to collect data on a large number of patient and trauma characteristics at the baseline [57] and to adjust for relevant patient and trauma characteristics in the analysis using propensity score weight [51,52].

A second limitation of the study could be its impossibility to identify which element of the TTCM is responsible for possible effects since the TTCM as a whole will be evaluated. Therefore we will perform a mixed-methods process evaluation contribute to understanding why an intervention (i.e. TTCM) has its intended impact' and in which domain this went as planned or not [47].

Implications for physiotherapy practice

This research will provide insight into the effectiveness and cost-effectiveness of the TTCM. We expect the results to be generalizable to the general Dutch (trauma patient) population. Data will be analyzed in 2023. If found to be (cost-)effective, the TTCM can be implemented nationally, and the rehabilitation of patients with at least one fracture due to trauma will be more efficient and effective.

Ethics approval and consent to participate

The medical ethics committee of the VUmc assessed the present study (registered under number A2019.459 (2019.419)). Before participation, all participants will provide informed consent according to the Declaration of Helsinki.

Funding

This project is funded by ZonMw (grant number 80-85200-98-91009).

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APPENDIX 7.1

Primary outcomes

The co-primary outcomes are generic and disease-specific quality of life. Both co-primary outcomes will be measured at baseline, 6 weeks, 3 months, 6 months, and 9 months.

Generic quality of life

Generic quality of life will be measured using the EQ-5D-5L, which consists of five questions representing five health dimensions; mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Using the Dutch tariff, the patients' EQ-5D-5L health states will be converted into a utility score ranging from 0 (dead) to 1 (full health). For the economic evaluation, quality-adjusted life-years (QALYs) will be calculated using linear interpolation between measurement points. The EQ-5D shows excellent psychometric properties in trauma patients with one or more fractures [1,2].

Disease-specific quality of life

Depending on the diagnosis, disease-specific quality of life will be measured using one of the following four standardized PROMS:

- Upper extremity: QuickDASH DLV (Disabilities of the Arm, Shoulder, and Hand)
  The Disabilities of the Arm, Shoulder and Hand (QuickDASH) questionnaire is a shortened version of the 30-item DASH [3]. The results of Gummesson et al. indicate that the QuickDASH can be used instead of the DASH with similar precision in upper extremity disorders [4]. The QuickDASH consists of 11 items of symptoms and limitations of activities. The central issue here is the degree of complaints or restrictions throughout upper extremity during the past week. The patient answers the questions based on a 5-point scale with higher scores indicating more complaints/limitations. This test is performing well with substantial evidence supporting reliability and validity [5].

- Lower extremity: Lower Extremity Functional Scale (LEFS)
  The Lower Extremity Functional Scale (LEFS) is a questionnaire containing 20 questions about a person's ability to perform everyday tasks. The maximum score is 80. The lower the score, the more significant the disability. The LEFS is a valid tool as compared to the SF-36 [6] with fair-to-good accuracy in discriminating between participants with and without improvement [7].

- Multiple fractures and/or more locations: Groningen Activity Restriction Scale (GARS)
  The Groningen Activity Restriction Scale (GARS) is a scale for measuring the degree of self-reliance of people. Eighteen items relating to activities of daily living are included in the

questionnaire. The severity of a disability can be mapped out using the instrument in which higher scores indicate more limitations in everyday activities. The psychometric properties of the GARS are very good in patients with rheumatoid arthritis and older adults [8-12].

- Vertebral fractures: The Roland Morris Disability Questionnaire (RMDQ)
  This questionnaire is a self-administered disability measure in which higher numbers reflect greater levels of disability on a 24-point scale. The Dutch RMDQ showed excellent reliability in patients with chronic low back pain, with an ICC of 0.91. Calculating limits of agreement to quantify the stability, a large amount of natural variation (+/- 5.4) is relative to the total scoring range of 0 to 24 [13-15].

An overall disease-specific quality of life score of the PROMS is calculated by converting the overall scores of the aforementioned questionnaires to a scale from 0–100, with higher scores representing less functional problems.

Secondary outcomes

Patient-specific Functional Scale (PSFS)

The Patient-Specific Functional Scale (PSFS) is a self-reported, patient-specific outcome measure designed to assess functional change, primarily in patients presenting with musculoskeletal disorders. Patients are asked to identify three to five important activities they are unable to perform or are having difficulty with as a result of their problem. In addition to identifying the activities, patients are asked to rate, on an 11-point scale, the current level of difficulty associated with each activity (0 = impossible, 10 = possible). The PSFS is a valid, reliable, and responsive outcome measure for patients with a large number of clinical presentations [16,17].

Numeric pain rating scale (NPRS)

The Numeric Pain Rating Scale (NPRS) is a measure of subjective intensity of pain in adults. The 11-point numeric scale ranges from '0' (no pain) to 10 ("worst pain imaginable"). The patients are asked to indicate the numeric value on the segmented scale that best describes their pain intensity. There is an excellent correlation between NPRS and Visual Analog Scale (VAS) in a hospital/ emergency population (r=0.094, 95% CI=0.93–0.95) [18].

Patient satisfaction (11-point NRS)

The patient satisfaction questionnaire is a questionnaire containing five questions about patient satisfaction components related to the TTCM: 1) total treatment, 2) treatment at the outpatient clinic, 3) treatment in primary care, 4) collaboration between practitioners from the hospital team

and 5) collaboration between the hospital team and the primary care physical therapist. Patient satisfaction is scored using an 11-point numeric rating scale ranging from 0 (very dissatisfied) to 10 (excellent).

Perceived recovery (7-point Global Perceived Effect Scale)

Based on the Global Perceived Effect (GPE), the patient's opinion about its recovery is measured. The GPE consists of one item that needs to be answered on a 7-point scale. Intraclass correlation coefficient values of 0.90–0.99 indicate excellent reproducibility of the GPE scale [19].

Patient-Reported Outcomes Measurement Information System (PROMIS-PF SF 10a or PROMIS-PF-UE 7a)

The Patient-Reported Outcomes Measurement Information Systems (PROMIS-PF SF 10a or PROMIS-PF-UE 7a) are instruments measuring patient-reported health based on physical functioning and physical functioning of the upper extremity. The questionnaires show good psychometric properties for cross-sectional use within different (patient) populations [20,21].

Choice of measurement of patient-reported health depends on trauma location:

- lower extremity/ vertebral fractures/ multiple fractures, more locations: PROMIS-PF SF 10a
- upper extremity: PROMIS-PF-UE 7a

Economic evaluation

For the economic evaluation, societal as well as healthcare costs will be estimated. 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 will be micro-costed to accurately estimate the real costs of the intervention to the health system and society [22]. 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) will be 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 [23].

Health care utilization includes the use of primary care (e.g. consultations with 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 will be used to value healthcare utilization [23]. Medication use is valued using information from the website http://www.medicijnkosten.nl. Absenteeism will be assessed by asking patients to

report their total number of sick leave days [24]. Absenteeism will be valued using gender-specific price weights [23)] Presenteeism is defined as reduced productivity while at work [25], will be measured using items from the WHO-HPQ and the iPCQ, and will be valued using gender-specific price weights [23]. Unpaid productivity losses will be 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 will be assessed by asking patients how many hours per week, they received help from family or friends. A recommended Dutch shadow price will be used to value unpaid productivity and informal care [23]. All costs will be presented in Euros and will be converted to the same reference year using consumer price indices. Discounting of costs is not necessary due to the 9-month follow-up period [26].

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MARTIJN (40) | MOTORCYCLE ACCIDENT 2 YEARS AGO

Pelvic, femoral and upper extremity fractures

8

General discussion

INTRODUCTION

This thesis described the development and evaluation of the Transmural Trauma Care Model (TTCM) that aimed to improve trauma patients' outcomes after mild, moderate or severe injury by refining the organization and quality of their rehabilitation process. The primary aim of this thesis was to assess the effectiveness and cost-effectiveness of the TTCM within a controlled-before-and-after study. Secondary aims included the assessment of the implementation of the TTCM by exploring its reach, dose delivered, dose received, and fidelity, supplemented by identifying possible barriers and facilitators associated with its implementation. Furthermore, an additional study was conducted aimed at assessing the association of various fracture and treatment-related factors (e.g. fracture treatment, fracture localization and fracture type) with disease-specific HR-QOL, functional outcome, and societal costs. In this general discussion, the main findings will be summarized and discussed followed by some methodological considerations regarding the internal and external validity of the findings. Finally, recommendations for clinical practice and future research will be presented, completed by a general conclusion of the thesis.

MAIN FINDINGS

Study protocol

Chapter 2 described the development of the TTCM, complemented by a detailed description of the study design of the controlled-before-and-after study, which was aimed at assessing the effectiveness and cost-effectiveness of the TTCM compared to regular care, and a general outline of the process evaluation. The TTCM is an advanced transmural rehabilitation model for trauma patients, aiming to improve patient outcomes and reduce costs by optimizing the organization, content, and quality of the rehabilitation process. The TTCM consists of four components, namely: 1) a multidisciplinary team at the outpatient clinic for trauma patients consisting of trauma surgeon and hospital-based physical therapist, 2) coordination and individual functional goal setting for each patient by the multidisciplinary hospital-based team, 3) a network of specialized primary care physical therapists, and 4) secured email traffic between the hospital-based physical therapist and the primary care network physical therapist. In the controlled-before-and-after study, trauma patients with at least one fracture who received the TTCM at the outpatient clinic of Amsterdam UMC, location VUmc, were compared with trauma patients who did not (i.e. regular care). Patients receiving the TTCM were prospectively followed for 9 months, whereas the control group consisted of 4 independent clusters of patients, who were either measured at baseline, 3, 6, or 9 months after their first consultation at the outpatient clinic.

Effectiveness of the TTCM

The effectiveness study in *chapter 3* provides preliminary evidence that the TTCM is effective in improving patient-related outcome measures, such as disease-specific HR-QOL, functional status, and patient satisfaction among mild, moderate and severe trauma patients with at least one fracture compared with regular care. To illustrate, mean satisfaction about the collaboration between primary and secondary care was nearly 2 points higher on a 10-point scale at 6 months (MD 1.78; 95% CI 1.03 to 2.53) for patients treated with the TTCM compared to patients receiving regular care. Furthermore, the mean difference for functional status at 9 months was nearly 21 points on a 100-points scale, favoring the TTCM group patients (MD -20.68; 95% CI -29.20 to -12.16). Patients in the intervention group had statistically significant less pain at 6 and 9 months than their control group counterparts (6 months: MD -0.87; 95% CI -1.44 to -0.29 and 9 months: MD -0.84; 95% CI -1.38 to -0.31). No difference in generic HR-QOL, measured with the EQ-5D-3L, was found at any time point between TTCM group patients and control group patients. It is worth mentioning, however, that the identified mean differences on the EQ-5D-3L can possibly be regarded as clinically relevant at 6 months (MD 0.051; 95% CI -0.02 to 0.12) and 9 months (MD 0.055; 95% CI -0.01 to 0.12), since both are comparable with estimates of the minimal clinical important differences (MICD) for the EQ-5D that were found in other patients with musculoskeletal disorders (i.e. ranging from 0.03 among patients with low back pain to 0.52 in patients with recurrent lumbar stenosis [1,2].

Cost-effectiveness of the TTCM

The results of the economic evaluation in *chapter 4* indicated that secondary healthcare costs and presenteeism costs were lower among patients treated with TTCM compared with those receiving regular care, while primary healthcare, medication, absenteeism, and unpaid productivity costs were higher among patients treated with TTCM compared with those receiving regular care. Total societal costs were lower among patients treated with TTCM compared with those receiving regular care, suggesting that implementation of the TTCM-on average- results in lower costs to society as a whole. However, of these aggregate and disaggregate cost differences, only the difference in secondary healthcare costs was statistically significant. For generic as well as disease-specific HR-QOL, pain, perceived recovery, and functional status, TTCM dominated the control condition, meaning that-on average- TTCM was less costly and more effective than usual practice. When considering the joint uncertainty surrounding costs and effects, the results imply that if decision-makers are not willing to pay anything per unit of effect gained, the TTCM has a relatively low probability of being cost-effective compared to usual practice (i.e. 0.54–0.58). However, this probability increased for all outcomes to relatively high levels with increasing values

of willingness-to-pay (e.g. to 0.95 at a willingness-to-pay of EUR700/point improvement on the NRS). Since it is unknown what decision-makers are actually willing-to-pay per unit of effect gained for the outcomes included in the analyses, we cannot make strong conclusions about the cost-effectiveness of the TTCM compared with usual practice. Nonetheless, the results of the present thesis can be used by decision-makers to consider whether they think that the TTCM provides "good value for money" at an acceptable probability of cost-effectiveness.

Process evaluation

Chapter 5 described the results of the process evaluation and showed that the TTCM was largely implemented as intended, with a moderate reach (81%), a high dose delivered, and a high dose received (95% to 100%). Moderate to high fidelity scores were found (66% to 93%), indicating the extent to which the intervention protocol was followed by the care providers. Additionally, various facilitators and barriers were identified that need to be considered when implementing the TTCM broadly. Focus groups among patients and health care providers indicated that the "communication structure of the TTCM" was found to be an important theme, expressed in several facilitators, such as "the use of a secured email system" and "the use of a standardized referral form". Other frequently mentioned facilitators were the "shared decision making process at the outpatient clinic" and an "increased level of knowledge and skills". For example, patients were satisfied to be involved in setting their own functional goals for their rehabilitation and care providers indicated to have learned from each other because of an increased level of collaboration due to the implementation of the TTCM. The "absence of reimbursement for the hospital-based physical therapists at the outpatient clinic" was identified as one of the most important barriers to the implementation of the TTCM. This indicates that it was hard to find resources for the additional physical therapist at the outpatient clinic, most likely because it was a new position, unknown by most of the decision-makers. Other barriers that are worth mentioning here, were the fact that "care providers sometimes contradict each other" and the "absence of awareness of the TTCM in other relevant departments of the hospital" (e.g. nurses and doctors at the emergency ward were not familiar with the TTCM and provided incomplete information).

Association of fracture characteristics with HR-QOL, functional outcome and costs

Chapter 6 described the results of the study assessing the association between various fracture and treatment-related factors with disease-specific HR-QOL, functional outcome, and societal costs. This study was conducted using data of the TTCM trial. For the purpose of this association study, the participating trauma patients' baseline and 9-month follow-up data of both the intervention group participants and the 9-month control cluster participants were

used. Ordinary Least Squares regression analyses were performed to assess the association of various fracture and treatment-related factors (i.e. surgery, fracture type, fracture localization and fracture treatment as independent variables) with respectively disease-specific HR-QOL, functional outcome, and societal costs (i.e. dependent variables), corrected for receiving the TTCM (yes/no), the case-mix variables age, gender and comorbidity, and the other independent fracture and treatment-related factors. Having a fracture of the lower extremity was found to be associated with a lower disease-specific HR-QOL after 9 months compared to patients with a vertebral fracture or multi-trauma (MD 10.09; 95% CI 2.18 to 18.00). Having an upper extremity fracture was associated with a better functional outcome compared to patients from the reference category (MD -19.12; 95% CI -31.65 to -6.59). Having had a surgery instead of conservative treatment was associated with lower societal costs. On the other hand, being treated with ORIF (open reduction internal fixation) instead of conservative treatment was associated with higher societal costs, whereas intramedullary nailing was not. Fracture type (i.e. intra-articular or extra-articular) was found not to be associated with disease-specific HR-QOL, functional outcome, and societal costs.

Study protocol of the multicenter trial

Chapter 7 described the study protocol of the multicenter trial that was initiated, funded and designed based on the results of *chapter 3, 4, 5 and 6* of this thesis. This multicenter trial aims to assess the effectiveness and cost-effectiveness of an improved version of the TTCM compared to regular care in 10 Dutch hospitals using an improved design (i.e. both the intervention and control group are now prospectively followed). Main improvements made to the TTCM were broadening it to tertiary care (i.e. rehabilitation centers and homes for the elderly with a geriatric rehabilitation setting) and involving healthcare decision-makers at an earlier stage to discuss the reimbursement for the hospital-based physical therapists at the outpatient clinic.

METHODOLOGICAL CONSIDERATIONS

Various choices in the methodology of the presented studies and their limitations should be taken into account when interpreting their results. Most of the methodological issues have been discussed in the previous chapters, however some general remarks can be made and will be discussed below.

The most important methodological issues of this thesis are related to the controlled-before-and-after study design as well as the pragmatic set-up of the TTCM trial presented in *chapter*

3 and 4. The controlled-before-and-after study design has the potential to adversely affect the internal validity of the study findings [3], whereas the pragmatic set-up, in which daily practice was resembled as much as possible, facilitates the generalizability of the trial results to daily practice (i.e. external validity) [4]. Both of these issues will therefore be discussed into more detail below, followed by some additional methodological considerations regarding the TTCM trial, the process evaluation described in *chapter 5* and the study assessing the association between various fracture and treatment-related factors with outcomes (*chapter 6*).

Study design, bias and internal validity

At the start of the TTCM trial, the controlled-before-and-after design was regarded as the most optimal research design within the available resources [5]. However, it was clear from the beginning, that measuring 4 independent control-clusters (i.e. baseline, 3, 6 or 9 months after patients' first visit at the outpatient clinic) and comparing these clusters with one prospectively followed intervention group, would probably adversely affect the internal validity of the study findings. We considered the possibility of prospectively following a control group for 9 months prior to the implementation of the TTCM, but this was not possible due to the limited time frame and resources of the study. Moreover, randomization of participants was not possible, because the TTCM was implemented at the entire outpatient clinic for trauma patients at the same time, and therefore we could not create a control condition within our hospital. A cluster randomized controlled trial and a stepped wedged design were also considered, but both of these options were not possible given the previously mentioned constraints. In the multicenter trial, for which more resources were available, we made improvements to the design by using both a prospectively followed intervention and control group and we collected extensive baseline data in both groups to adjust for the possible influence of "selection bias" resulting from a non-randomized design using propensity score weights [6].

The applied controlled-before-and-after design was susceptible to several kinds of bias. Examples of such kinds of biases are *selection bias*, *repeat testing bias*, *regression to the mean*, *the Hawthorne effect*, and *recall bias*. The most relevant biases to our study will be discussed in more detail below. First, selection bias was the most likely to occur, meaning that results might be biased due to the control clusters and intervention group having a different composition regarding various etiological factors [3]. Of the factors that we did measure, we observed some meaningful baseline differences in age (i.e. mean age 43 years versus 50 years for intervention group patients and control group patients respectively) and admission to hospital (75% of intervention group patients were admitted to the hospital, compared to an average of 51% in the four control group clusters). In our analyses, we tried to deal with possible confounding factors by adjusting for factors that changed the regression

coefficients by more than 10%. One should bear in mind, however, that there might always be unmeasured factors that differ across both groups, for which the analyses have not been corrected because it was simply not possible. Second, *repeat testing bias and regression to the mean* are two types of bias that possibly occurred in our study, and if so, then specifically affected patients in the intervention group due to the repeated measurements in this group (i.e. the same questionnaires at baseline, 3, 6 and 9 months). Repeat testing bias occurs when patients remember the questions and try to perform better the next time they have to fill in the same question, however this bias is most likely to occur in performance based questionnaires and physical performance tests, whereas in our study questionnaires were aimed at registering actual functioning instead of "performing better" [3,7]. Regression to the mean is a statistical phenomenon that means that extreme outliers tend to become less extreme with repeated measurements. As our control group was measured more than once this might have occurred in our study as well [8]. Third, the *Hawthorne effect*, meaning that patients' awareness of being a study subject positively affects their behavior and sense of well-being, possibly occurred in our study [9]. Our control group patients were only measured once and did not receive an intervention, whereas our intervention group was prospectively followed and received the TTCM. Therefore we expect this effect to be slightly bigger in our intervention group. However, the extent to which this effect differed between both groups is unclear. Moreover, patients and care providers could not be blinded, due to the content of the intervention. This may, similar to the Hawthorne effect, have led to an overestimation of the treatment effect of the TTCM. That is, patients knew which group they were in and what the aim of the study was and may therefore have given more positive answers. Fourth, we used retrospective cost-questionnaires with varying recall periods for the purpose of our economic evaluation, which may have led to *recall bias*. That is, the control group patients were asked to remember their resource use during the last 9 months, whereas intervention group patients were only asked to remember their resource use during the last 3 months. As the probability of recall bias increases with increasing recall periods one might expect the possible influence of recall bias to be bigger in the intervention group as compared to the control group. However, as total societal costs were higher in the control group than in the intervention group, it seems unlikely that the use of retrospective questionnaires severely biased our results by underestimating costs in the control group. Note that, for all clinical outcomes, the possible effect of recall bias is similar for both intervention group and control group and therefore not a noteworthy issue.

Pragmatic set up and generalizability (external validity)

The pragmatic set-up of the study, in which daily practice was resembled as much as possible may facilitate the generalizability of our results to daily practice [4]. Moreover, the use of a broad

range of trauma severity levels in our study probably increases the generalizability of the TTCM to all kinds of trauma patients. However, it is also important to mention that our study population was rather small and was only recruited from one level-1 trauma center in the Netherlands, Amsterdam UMC (location VUmc). It is therefore not possible to draw strong conclusions about the generalizability of the current findings to other trauma centers and/or specific subgroups of trauma patients. Nonetheless we assume the results to have a fair chance of being generalizable to other academic hospitals with a similar population of trauma patients and a similar working atmosphere. However, the multicenter trial should bring more insight into the generalizability to all kinds of hospitals. We therefore included ten trauma centers from different regions of the Netherlands in the multicenter trial, including seven level-1 trauma centers and three level-2 trauma centers. Among these 10 participating hospitals are 4 academic hospitals, 5 supra-regional hospitals and 1 small regional hospital.

Another point which is inherent to all economic evaluations, is the fact that its results may not be generalizable to other countries due to differences in healthcare and social security systems across countries [10]. To illustrate, in the Netherlands most healthcare costs are borne by the government and/or by health insurance companies, whereas healthcare in the UK is mainly provided through the NHS (National Health Service) and freely available for all residents of the UK. However, under very strict conditions for recalculating costs, results of economic evaluations can be generalized from one country to another. These conditions include for example, a detailed description of the intervention and the resources, allocation of costs to various parties and detailed knowledge of the healthcare systems in the original studies [11].

Time horizon

Our follow-up period was limited to 9 months, which is shorter than the usual follow-up period when assessing functional outcome in trauma patients [12,13]. Such time horizons are typically longer than 9 months, because multi-trauma patients in particular, reach their optimal functional level somewhere between one and two years after their initial trauma [14]. However, this is not the case for mild and moderate trauma patients, who in general, recover more rapidly. This resulted in studies with a shorter follow-up period to measure functional outcome, for example Keene et al. used a 6-month follow-up period in patients with an unstable ankle fracture [15]. Though it is worth mentioning that many studies measuring (functional) outcome in trauma patients are of retrospective nature [16,17]. Furthermore, some might argue that our 9-month follow-up is probably not long enough to cover all costs and effects flowing from the intervention program (i.e. the TTCM), which is of importance when performing an economic evaluation [4]. Ideally, the time frame necessary to cover all costs is generally longer than the follow-up

needed to examine the effectiveness of an intervention [18]. To illustrate, trauma patients' functioning can be at an acceptable level after 9 months, even when they have not yet been fully returned to work. If this is the case, the total societal costs of the intervention will likely be underestimated, because the cost of not returning to work even after achieving an acceptable level of functioning will then not be included in the analyses. To rule out such an underestimation of the total societal costs a longer follow-up period would have been preferable. However, since the majority of our study population consisted of mild and moderately injured trauma patients we do not expect the total societal costs to be severely underestimated and hence we feel that the 9-month follow-up period is of acceptable duration. Therefore, we also decided to use this follow-up period in the multicenter trial.

Study population and sample size

Our study population covers a broad range of trauma severity levels, with an ISS ranging from 4 to 43 in patients with at least one fracture. Most previous studies assessing functional outcome after trauma mainly include major trauma patients with an ISS>16 and/or patients with only one specific type of fracture instead of trauma patients in general [19-22]. The results of the TTCM trial are therefore probably generalizable to mild, moderate, as well as severe trauma patients, whereas the results of previous studies were not. This is important because the TTCM is aimed at optimizing and refining the rehabilitation process for every single trauma patient, irrespective of their level of severity and type of trauma.

Our study population was relatively small and not based on an a priori sample size calculation, which possibly made the study underpowered for some factors. For the multicenter trial we therefore performed a sample size calculation based on a clinically relevant difference of 10% for disease-specific HR-QOL and 0.057 for generic HR-QOL between the intervention and control group, resulting in a required sample size of 644 participants. As a consequence of our relatively small study population, we were also not able to perform additional subgroup analyses to assess whether effects and associations differed between subgroups, however the sample size of the multicenter trial will probably offer us the opportunity to do so.

Methodological issues regarding the process evaluation

Until now, well set-up process evaluations are rare in trauma research in general and in trauma rehabilitation research more specifically. In *chapter 5* we used the "framework method" for analyzing the focus group data. This is a hierarchical, matrix-based method for ordering and synthesizing qualitative data, first described by Ritchie [23] and further developed by Gale et

al. [24]. In doing so, we were able to build a valuable matrix, in which facilitators and barriers were presented in a structured and systematic way. Using such a well-founded theoretical model for analyzing the data was one of the strengths of our process evaluation along with the use of a mixed-methods approach, in which qualitative as well as quantitative data were collected. On the one hand, qualitative data provided detailed insight into which factors facilitated or hampered the implementation of the TTCM, whereas quantitative data had the advantage of precisely measuring to which extent implementation succeeded or not. The most important methodological limitation of our process evaluation was the fact that patients were purposively selected, meaning that researchers used their own judgement to select individuals who are able to provide in-depth information related to the research questions. This may have resulted in an overestimation of positive opinions about the TTCM. Another limitation is the absence of healthcare decision-makers and insurers in the focus groups. As a consequence, we lack input from a relevant group of stakeholders regarding the financial issues in transmural healthcare systems like the TTCM, in which different types of financial structures and insurances are present (i.e. in primary and secondary care). Lacking input from healthcare decision-makers and insurers turned out to be one of the main problems when setting up our multicenter trial described in *chapter 7* and they will therefore be present in the multi center trial's process evaluation.

Methodological issues regarding the study assessing the association of fracture and treatment-related factors with outcomes

For assessing the association of fracture characteristics with disease-specific HR-QOL, functional outcome, and societal costs, we used data of the TTCM trial. However, using trial data is not optimal for studies assessing the association between independent variables other than that of an intervention versus a control. To gain more insight into the associations of fracture and treatment-related factors with disease-specific HR-QOL, functional outcome, and societal costs, a longitudinal cohort study would therefore be advised, with a follow-up duration of at least two years [13]. This two-year time frame is based on the ability to identify characteristics associated with long-term health status. Next to fracture and treatment-related factors, numerous sociodemographic elements should be taken into account when assessing the complex interaction with (functional) outcomes [25]. In *chapter 6*, however, we were only able to correct for the case-mix variables age, gender and co-morbidities. This was due to the fact that we had to rely on EPD data for this variables. Larger datasets containing a larger variety of sociodemographic variables will therefore be necessary. Such datasets will also offer more opportunities for subgroup analyses and might also give insight in understanding the mechanisms underlying the identified associations.

RECOMMENDATIONS FOR FUTURE RESEARCH

Most of the recommendations for future research have been discussed in *chapter 3 to 7* as well as during the previous section of this general discussion. In brief, future studies aimed at assessing the effectiveness and cost-effectiveness of an intervention like the TTCM, are advised to use a pragmatic design as well, in which the circumstances under which the intervention took place is comparable with routine practice to improve the generalizability of their results (4). Moreover, a randomized controlled design would be the most optimal design from a methodological point of view when analyzing the effectiveness and/or cost-effectiveness of an intervention such as the TTCM. However, this was not feasible in the study described in *chapter 3 and 4* as well as in our multicenter study and will likely be not feasible in most other studies aiming to assess the cost-effectiveness of complex integrated care models that are developed based on empirical findings from daily practice. A "second best" is probably the use of a controlled-before-and-after design, such as our multicenter trial. However, to deal with the non-randomized nature of such a study it will be necessary to collect data on a large number of patient and trauma characteristics at baseline and to adjust for them in the analysis using propensity score weights [6,26].

In the TTCM trial we were not able to identify what components of the TTCM were responsible for the positive effects. That is, it remains unclear whether these effects were the result of an improved communication between primary and secondary care and/or whether they were the result of a better educated and more experienced network of primary care physical therapists. Future research, like our multicenter trial, can possibly provide more insight into whether specific TTCM components are accountable for specific effects and to assess which component works best for which type of trauma patient. However, we should also keep in mind that the multicenter trial will probably show that the strength of the TTCM is its integrated nature and that such thing as a critical ingredient does not exist in this rather complex intervention. Similar conclusions were also made in another study, assessing the cost-effectiveness of a complex intervention aimed at improving quality of care for frail older adults and subsequently improve their quality of life. This intervention included an integrated care model consisting of various integrated care components, like a geriatric assessment and tailored care plan, and multidisciplinary team consultations [27].

Another recommendation for future research is to include input from healthcare decision-makers and insurers when planning future studies aimed at implementing care models, like the TTCM. In our case this may this have led to better financial structures in general and reimbursement for the physical therapist at the outpatient clinic system in particular. Finally, as indicated above, a longitudinal cohort study with a larger sample size, more information on the sociodemographic characteristics of the study population and a follow-up duration of at least two years would

be advised to gain more insight in associations of fracture and treatment-related factors with disease-specific HR-QOL, functional outcome, and societal costs [13]. Larger datasets will also offer more opportunities for subgroup analyses and might also give the possibility of building models to predict (functional) outcomes.

RECOMMENDATIONS FOR CLINICAL PRACTICE

Based on the results described in this thesis, the TTCM seems feasible in practice and we found preliminary evidence that it is effective in improving patient-related outcome measures, such as disease-specific HR-QOL, functional status and patient satisfaction among mild, moderate and severe trauma patients. Since it is unknown what decision-makers are actually willing-to-pay per unit of effect, however, we cannot make strong conclusions about the cost-effectiveness of the TTCM compared with usual practice. As indicated above, information derived from this thesis was used to further improve the TTCM and to set up the multicenter trial aimed to assess the effectiveness and cost-effectiveness of an improved version of the TTCM compared to regular care, on a wider scale and using an improved design. Therefore, we do not recommend an immediate nationwide implementation of the TTCM, because resources are scarce and should not be used before stronger evidence on the effectiveness and cost-effectiveness of the TTCM is available [18]. We expect the first results of the current multicenter trial on TTCM's effectiveness and cost-effectiveness in 2023. Information from the multicenter study will be important for healthcare decision-makers and politicians and will help them with deciding whether or not a broad implementation of the TTCM provides good "value for money" and if so, in building an appropriate legal and financial framework for this complex transmural healthcare intervention.

However, based on the findings of the process evaluation described in *chapter 5*, we can already give some valuable and useful practical recommendations for the local implementation of the TTCM. Some of these recommendations have already been embedded in the multicenter trial and are described above and some of the recommendations are more relevant to future clinical practice. For a complete overview, all needs and recommendations for the possible nationwide implementation of the TTCM will be listed below (improvements already made to the TTCM in the context of the multicenter trial are marked with a *).

- Form a steering group with all stakeholders to take everyone's interests into account.
- Clearly describe clear organizational structures for care providers at the outpatient clinic and for primary care network physical therapists (e.g. communication pathways and templates for standardized documentation).*

- Clearly describe duties and responsibilities of the participating care providers in a manual.*
- Organize training courses for the multidisciplinary teams at the outpatient clinic and for the primary care network physical therapists.*
- Organize reflection meetings with the local stakeholders (homogeneous as well as heterogeneous) during the implementation period.
- Arrange an appropriate and structural embedded reimbursement system for the hospital-based physical therapist, who acts as case manager within the TTCM.
- Structure verbal and written information for trauma patients with minor fractures in brochures, so these type of patients probably do not need additional physical therapy in primary care.*
- Develop several rehabilitation pathways for mild, moderate and severe trauma patients respectively (but be aware that the main goal and strength of the TTCM is the individually tailored rehabilitation path).*
- Extent the network with physical therapists working in rehabilitation centers and geriatric rehabilitation settings.*

To complete this section, we would like to express our wish of developing a nationwide network of trauma physical therapists, united in Network Trauma Rehabilitation Netherlands (NTN). Initiatives of building such an overarching organization are currently being developed in cooperation with several stakeholders (e.g. the Dutch network of acute care (Landelijk Netwerk Acute Zorg). Finally, it could be valuable to translate the TTCM to other patient groups, with a similar variability in severity and patient characteristics and being dependent of physical therapy for their rehabilitation (i.e. patients with complicated orthopedic problems or patients with acquired neurological disorders). For these patient groups, an improved coordination of their rehabilitation process and an improved communication structure between primary and secondary care might also be valuable. Please note that for some specific patient groups similar integrated care models already exist in the Netherlands (e.g. for patients with Parkinson's disease and one recently developed for COPD patients). Although there are overlapping aspects, these care models differ from the TTCM, especially when it comes to the strict communication structure and the focus on individual functional goalsetting, which are main issues within the TTCM [28,29]. Collaboration with initiators of other integrated care models could help further developing these care models by learning from each other's experiences.

GENERAL CONCLUSIONS

In conclusion, this thesis shows that the TTCM seems feasible in practice and we found preliminary evidence that it is effective in improving patient-related outcome measures, such as disease-specific HR-QOL, functional status and patient satisfaction among mild, moderate and severe trauma patients. Strong conclusions about the cost-effectiveness of the TTCM cannot be made, since it is unknown what decision-makers are willing-to-pay per unit of effect gained for the outcomes included in the analyses. Furthermore, lessons learned from the TTCM trial and its process evaluation were used to further improve the TTCM and to set up a multicenter trial aimed to assess the effectiveness and cost-effectiveness of an improved version of the TTCM compared to regular care, on a wider scale and using an improved study design. Results of this multicenter trial are expected in 2023 and will hopefully contribute to an individually tailored rehabilitation path for every single trauma patient in the Netherlands, supervised by closely connected care providers in primary and secondary care.

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FRANK (52) | BOTH LEGS TRAPPED IN A BUS ACCIDENT

Open lower leg fractures left and right

Summary
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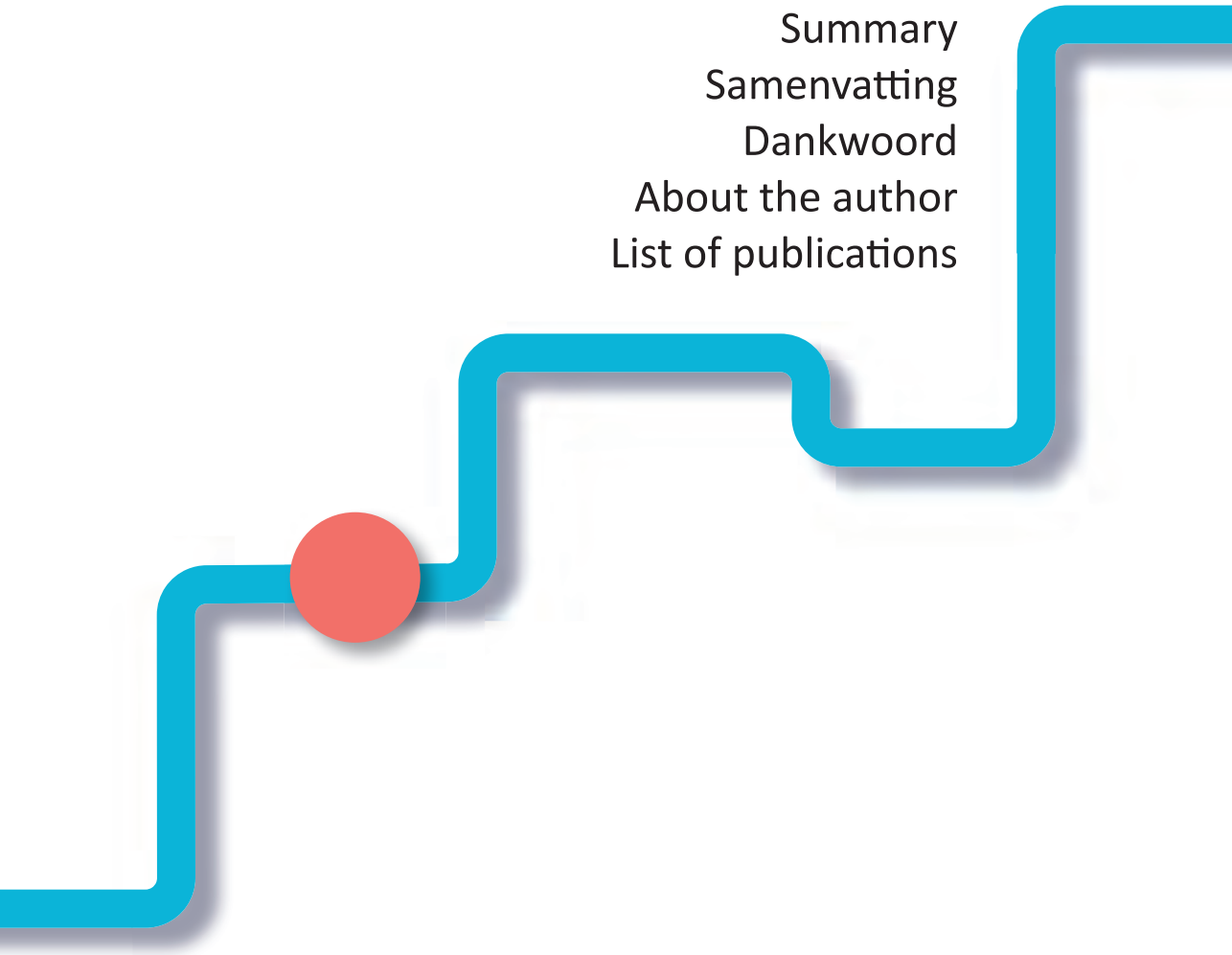

SUMMARY

Traumatic injury is one of the main causes of death and disability worldwide and poses a substantial economic burden to society. Traditionally, the organization of trauma care focused more on pre-hospital and in-hospital care than on the rehabilitation phase, because the trauma patients' survival was its first and most important goal. Since the organization of acute trauma care has improved and mortality due to traumatic injury has decreased, the focus of trauma care has shifted from reducing mortality to improving quality of life and outcome. This in turn resulted in a growing interest in improving the quality of trauma rehabilitation, which is the main focus of this thesis.

Most trauma patients have one or more fractures due to their trauma. Trauma patients' treatment depends on their fracture characteristics and other patient-related characteristics, such as age, comorbidity, health status, and activity level prior to the injury. Treatment can be conservative (e.g. with plaster or a limited weight-bearing policy) or surgical, which in most cases means intramedullary nailing or internal fixation with plates and screws. Trauma recovery generally proceeds in four phases, i.e. 1) the acute treatment phase, 2) the rehabilitation phase, 3) the adaption phase, and 4) the stable end situation. For physical therapists who treat trauma patients, it is important to deal with each phase of the recovery process in an appropriate way. In doing so, they will be able to give – within a certain margin – an estimate of a trauma patient's length and outcome of the rehabilitation process. This is important, because it is recognized that managing trauma patients' expectations is a critical element of their rehabilitation process and is necessary to achieve an optimal outcome. After being discharged from a hospital, the majority of Dutch trauma patients rehabilitates with the help of a primary care physical therapist. However, there is a lack of programs and guidelines for the rehabilitation of trauma patients following their medical treatment (i.e. in primary care), and it seems to be a rather unexplored area. Although it is recognized that post-clinical care organized in primary care networks of experienced and specialized healthcare providers results in better clinical outcomes, this was typically lacking for trauma patients prior to the start of this study.

To bridge this gap, we developed and evaluated the Transmural Trauma Care Model (TTCM), an advanced transmural rehabilitation model for mild, moderate and severe trauma patients, aiming to improve patient outcomes and reduce costs by optimizing the organization, content, and quality of the rehabilitation process. The TTCM consists of four components, all of which are linked to one another, i.e. 1) a multidisciplinary team at the outpatient clinic for trauma patients, 2) coordination and individual functional goal setting for each patient by the multidisciplinary hospital-based team, 3) a network of specialized primary care physical therapists, and 4) secured

email traffic between the hospital-based physical therapist and the primary care network physical therapist.

The primary aim of this thesis was to assess the effectiveness and cost-effectiveness of the TTCM within a controlled-before-and-after study. Secondary aims included the assessment of the implementation of the TTCM by exploring its reach, dose delivered, dose received, and fidelity, supplemented by identifying possible barriers and facilitators associated with its implementation. Additionally, data collected in the context of this study were used to explore the association of specific trauma- and fracture related factors with disease-specific HR-QOL, functional outcome, and costs and to further improve the TTCM.

Chapter 2 described the development of the TTCM, complemented by a detailed description of the study design of the controlled-before-and-after study, which – as indicated above – was aimed at assessing the effectiveness and cost-effectiveness of the TTCM compared to regular care. Furthermore, a general outline of the process evaluation was given. In the controlled-before-and-after study, trauma patients with at least one fracture who received the TTCM at the outpatient clinic of Amsterdam UMC, location VUmc, were compared with trauma patients who did not (i.e. regular care).

Chapter 3 investigated the effectiveness of the TTCM compared to regular care among trauma patients, in terms of health-related quality of life (HR-QOL), functional outcome, pain and patient satisfaction. Preliminary evidence was provided that the TTCM is effective in improving patient-related outcome measures, such as disease-specific HR-QOL, functional status, and patient satisfaction among mild, moderate, and severe trauma patients with at least one fracture compared with regular care. For example, the mean difference for functional status at 9 months was nearly 21 points on a 100-points scale, favoring the TTCM group. Furthermore, patients in the intervention group suffered from statistically significant less pain at 6 and 9 months than their control group counterparts.

Chapter 4 described the results of the economic evaluation and indicated that secondary healthcare costs and presenteeism costs were lower among patients treated with TTCM compared with those receiving regular care. On the other hand, primary healthcare, medication, absenteeism, and unpaid productivity costs were higher among patients treated with TTCM compared with those receiving regular care. Total societal costs were lower among patients treated with TTCM compared with those receiving regular care, suggesting that implementation of the TTCM – on average – results in lower costs to society as a whole. However, only the difference in secondary healthcare costs was statistically significant. For generic as well as disease-specific HR-QOL, pain, perceived recovery, and functional status, TTCM dominated the

control condition, meaning that – on average – TTCM was less costly and more effective than usual practice. These results imply that if decision-makers are not willing to pay anything per unit of effect gained, the TTCM has a relatively low probability of being cost-effective compared to usual practice (i.e. 0.54–0.58). However, this probability increased for all outcomes to relatively high levels with increasing values of willingness-to-pay. However, since it is unknown what decision-makers are actually willing-to-pay per unit of effect gained for the outcomes included in the analyses, we cannot make strong conclusions about the cost-effectiveness of the TTCM compared with usual practice.

Chapter 5 described the results of the process evaluation and showed that the TTCM was largely implemented as intended, with a moderate reach (81%), a high dose delivered, and a high dose received (95% to 100%). Moderate to high fidelity scores were found (66% to 93%). Fidelity scores indicate the extent to which the intervention protocol was followed by the care providers. Additionally, various facilitators and barriers were identified that need to be considered when implementing the TTCM broadly. Focus groups among patients and health care providers indicated that the "communication structure of the TTCM" was found to be an important theme, expressed in several facilitators, such as "the use of a secured email system" and "the use of a standardized referral form". Other frequently mentioned facilitators were the "shared decision-making process at the outpatient clinic" and an "increased level of knowledge and skills". The "absence of reimbursement for the hospital-based physical therapists at the outpatient clinic" was identified as one of the most important barriers to the implementation of the TTCM. Another important barrier was the "absence of awareness of the TTCM in other relevant departments of the hospital".

Chapter 6 described the results of the study assessing the association between various fracture and treatment related factors with disease-specific HR-QOL, functional outcome, and societal costs. This study was conducted using data of the TTCM trial. For the purpose of this association study, the participating trauma patients' baseline and 9-month follow-up data of both the intervention group participants and the 9-month control cluster participants were used. Having a fracture of the lower extremity was found to be associated with a lower disease-specific HR-QOL after 9 months compared to patients with a vertebral fracture or multi-trauma. Having an upper extremity fracture was associated with a better functional outcome compared to patients from the reference category. Having had surgery instead of conservative treatment was associated with lower societal costs. Fracture type (i.e. intra-articular or extra-articular) was found not to be associated with disease-specific HR-QOL, functional outcome, and societal costs.

Chapter 7 described the study protocol of the multicenter trial that was initiated, funded, and designed based on the results of *chapter 3, 4, 5* and *6* of this thesis. This multicenter trial aims to assess the effectiveness and cost-effectiveness of an improved version of the TTCM compared to regular care in 10 Dutch hospitals using an improved design (i.e. both the intervention and control group are prospectively followed). Main improvements made to the TTCM were broadening it to tertiary care (i.e. rehabilitation centers and homes for the elderly with a geriatric rehabilitation setting) and involving healthcare decision-makers at an earlier stage to discuss the reimbursement for the hospital-based physical therapists at the outpatient clinic.

Chapter 8 presents an extensive discussion of our studies, the choices we made with respect to their methodology as well as their limitations that should be taken into account when interpreting the results. The most important methodological issues of this thesis are related to the controlled-before-and-after study design as well as the pragmatic set-up of the TTCM trial. The controlled-before-and-after study design has the potential to adversely affect the internal validity of the study findings, whereas the pragmatic set-up, in which daily practice was resembled as much as possible, facilitates the generalizability of the trial results to daily practice. Additionally, various methodological issues regarding the process evaluation and the study assessing the association between various fracture and treatment related factors with outcomes were discussed. This chapter was completed with recommendations for further research and a complete overview of valuable and useful practical recommendations for the local implementation of the TTCM.

In conclusion, this thesis shows that the TTCM seems feasible in practice and we found preliminary evidence that it is effective in improving patient-related outcome measures, such as disease-specific HR-QOL, functional status and patient satisfaction among mild, moderate and severe trauma patients. Strong conclusions about the cost-effectiveness of the TTCM cannot be made, since it is unknown what decision-makers are willing-to-pay per unit of effect gained for the outcomes included in the analyses. Furthermore, lessons learned from the TTCM trial and its process evaluation were used to further improve the TTCM and to set up a multicenter trial aimed to assess the effectiveness and cost-effectiveness of an improved version of the TTCM compared to regular care, on a wider scale and using an improved study design. Results of this multicenter trial are expected in 2023 and will hopefully lead to a nationwide implementation of the TTCM and thus contribute to an individually tailored rehabilitation path for every single trauma patient in the Netherlands.

SAMENVATTING

Achtergrond

Traumatisch letsel is letsel als gevolg van een ongeval en is één van de belangrijkste doodsoorzaken wereldwijd. Daarnaast heeft een groot aantal traumapatiënten last van (blijvende) beperkingen in fysiek functioneren. Traumatische letsels leiden tot hoge medische en niet medische (verzuim) kosten en zijn derhalve een substantiële economische last voor de samenleving. Historisch gezien richt de traumazorg zich vooral op de acute fase, dat wil zeggen de acute opvang "op straat", snel vervoer naar het juiste ziekenhuis en een adequate behandeling tijdens de ziekenhuisopname. Voor de revalidatiefase was minder aandacht, het overleven van de patiënt stond immers voorop. De organisatie van acute traumazorg is in de laatste decennia echter sterk verbeterd en het sterftecijfer als gevolg van een trauma is als direct gevolg daarvan met 15–25% gedaald. De aandacht kon daarom worden verlegd van het terugdringen van mortaliteit naar het verhogen van de kwaliteit van leven van traumapatiënten en het verbeteren van hun functionele uitkomsten. Dit heeft weer gezorgd voor een groeiende interesse in het optimaliseren van het revalidatieproces van traumapatiënten, wat het onderwerp is, dat in dit proefschrift centraal staat.

De meeste traumapatiënten hebben één of meerdere breuken, welke adequaat behandeld dienen te worden. De behandeling hangt af van de specifieke kenmerken van de breuk, maar ook van patiëntspecifieke factoren, zoals leeftijd, comorbiditeit, gezondheid en de mate van activiteit voorafgaand aan het letsel. De behandeling kan conservatief zijn (bijvoorbeeld met gips of een beleid van beperkt belasten) of chirurgisch, bijvoorbeeld met een mergpen of fixatie met platen en schroeven. Het herstel na een (ernstig) trauma verloopt doorgaans in vier fasen: 1) de acute behandeling, 2) de revalidatiefase, 3) de adaptatiefase, en 4) de stabiele eindsituatie. Voor fysiotherapeuten is het tijdens de behandeling van traumapatiënten belangrijk om in elke fase van het herstel accuraat te handelen. Ervaren en geschoolde traumafysiotherapeuten zullen – binnen zekere marges – een schatting kunnen geven van zowel de duur als de uitkomst van het revalidatieproces van de traumapatiënt. Dit is relevant omdat verwachtingsmanagement bij traumapatiënten een cruciaal element is tijdens hun revalidatieproces en noodzakelijk voor een optimaal verloop. Na ontslag uit het ziekenhuis revalideert het merendeel van de Nederlandse traumapatiënten met behulp van een eerstelijns fysiotherapeut. Niettemin lijkt de revalidatie van traumapatiënten met fracturen in de eerste lijn betrekkelijk onbekend terrein; specifieke programma's en richtlijnen voor de revalidatie van traumapatiënten zijn schaars, terwijl deze voor het acuut medisch handelen wel bestaan. Hoewel wordt erkend dat post-klinische zorg die is georganiseerd in eerstelijns netwerken van ervaren en gespecialiseerde zorgverleners betere functionele resultaten oplevert (bijvoorbeeld voor patiënten met de ziekte van Parkinson), ontbreekt dit soort zorg voor traumapatiënten.

Om deze kloof te dichten hebben we in Amsterdam UMC, locatie VUmc, het Transmurale Trauma Care Model (TTCM) ontwikkeld en geëvalueerd. Het TTCM is een geavanceerd transmuraal revalidatiemodel voor traumapatiënten, dat zowel toepasbaar is op licht- als zwaargewonde patiënten. Het doel van dit revalidatiemodel is het verbeteren van de functionele uitkomsten van de traumapatiënt en het reduceren van zorg- en verzuimkosten door het optimaliseren van de organisatie, de inhoud en de kwaliteit van het revalidatieproces. Het TTCM bestaat uit vier componenten die onlosmakelijk met elkaar verbonden zijn: 1) een multidisciplinair team op de polikliniek voor traumapatiënten (bestaande uit traumachirurg en klinisch fysiotherapeut), 2) coördinatie van de revalidatie en het stellen van individuele functionele doelen voor elke patiënt door het multidisciplinaire ziekenhuisteam, 3) een netwerk van gespecialiseerde eerstelijns fysiotherapeuten, en 4) beveiligd e-mailverkeer tussen de fysiotherapeut in het ziekenhuis en de eerstelijns fysiotherapeut.

Het hoofddoel van dit proefschrift was het onderzoeken van de effectiviteit en kosteneffectiviteit van het TTCM in een gecontroleerde voor-na studie. Een nevendoelstelling was het onderzoeken van de implementatiegraad van het TTCM. Dat wil zeggen, in hoeverre werd het revalidatiemodel geïmplementeerd zoals gepland en wat waren factoren die de implementatiegraad positief dan wel negatief beïnvloedden? Daarnaast werden de data uit dit onderzoek gebruikt om de associatie te onderzoeken tussen specifieke fractuurkenmerken en drie afhankelijke uitkomsten (ziektespecifieke kwaliteit van leven, functionele uitkomst en maatschappelijke kosten).

Samenvatting per hoofdstuk

Hoofdstuk 2 beschrijft het ontstaan en de ontwikkeling van het TTCM en geeft een gedetailleerde beschrijving van het studieprotocol van de gecontroleerde voor-na studie, die als doel had de effectiviteit en kosteneffectiviteit van TTCM in vergelijking met reguliere zorg te onderzoeken in traumapatiënten met tenminste één fractuur. Ook wordt de opzet van de kwalitatieve studie (procesevaluatie) in dit hoofdstuk beschreven.

Hoofdstuk 3 beschrijft de effectiviteit van het TTCM in vergelijking met reguliere zorg in traumapatiënten met tenminste één fractuur op de uitkomsten kwaliteit van leven, functie, pijn en patiënttevredenheid. Voorlopig bewijs werd verkregen dat het TTCM effectief was in vergelijking met reguliere zorg in traumapatiënten met tenminste één fractuur voor patiëntgerelateerde uitkomstmaten, zoals ziektespecifieke kwaliteit van leven, functie en patiënttevredenheid. Zo toonde de resultaten van de lineaire regressieanalyse bijvoorbeeld na 9 maanden een significant verschil van 21 punten in het voordeel van de TTCM-groep aan (op een schaal van 100 punten) voor functionele status. Bovendien hadden patiënten in de interventiegroep op zes

en negen maanden na inclusie statistisch significant minder pijn dan patiënten die reguliere zorg kregen.

Hoofdstuk 4 beschrijft de resultaten van de economische evaluatie en laat zien dat de tweedelijns gezondheidszorgkosten lager zijn voor de groep die behandeld is volgens het TTCM vergeleken met patiënten die niet volgens het TTCM behandeld werden. Ook de "ervaren effectiviteit" op de werkvloer was hoger voor de TTCM-groep en de daaraan gerelateerde kosten daarom lager. Aan de andere kant bleken de kosten voor eerstelijns gezondheidszorg hoger in de TTCM-groep vergeleken met de groep die reguliere zorg kreeg en was het ziekteverzuim hoger in de TTCM-groep evenals de kosten voor het niet kunnen uitvoeren van onbetaald werk. De totale maatschappelijke kosten bleken echter lager te zijn in de TTCM-groep dan in de controlegroep, wat lijkt te betekenen dat het TTCM gemiddeld gezien leidt tot lagere kosten voor de maatschappij als geheel. Opgemerkt moet worden dat van de bovengenoemde verschillen in kosten alleen het verschil in tweedelijns gezondheidszorgkosten significant was. Voor andere uitkomstmaten, te weten ziektespecifieke kwaliteit van leven, pijn, ervaren herstel en functie, domineerde de TTCM-groep de controlegroep, wat gemiddeld genomen betekent dat het TTCM minder kost en effectiever is dan reguliere zorg. Kosteneffectiviteitscurves geven aan dat wanneer beslissers in de zorg niet bereid zijn om een bedrag per punt verbetering op de uitkomstschalen te investeren, de kans klein (te weten 0.54 tot 0.58) is dat het TTCM kosteneffectief is ten opzichte van reguliere zorg. Deze kansen stijgen echter fors voor elke uitkomstmaat bij een toegenomen bereidheid tot betalen door de beslissers in de zorg. Omdat niet bekend is wat beslissers in de zorg daadwerkelijk willen betalen per punt verbetering op de uitkomstschalen is het vooralsnog niet mogelijk sterke conclusies te trekken over de kosteneffectiviteit van het transmurale revalidatiemodel TTCM ten opzichte van reguliere zorg.

Hoofdstuk 5 toont de resultaten van de procesevaluatie en laat zien dat de implementatie van TTCM grotendeels verliep zoals we hadden beoogd, zo was het bereik van het TTCM 81%, en werd de interventie in 95% tot 100% van de gevallen daadwerkelijk geleverd. De interventieprotocollen en werkafspraken werden redelijk tot goed nageleefd door de diverse zorgverleners met scores van 66% tot 93%. Bovendien werden door middel van homogene focusgroepen onder patiënten en zorgprofessionals factoren geïdentificeerd die de implementatiegraad van het TTCM positief dan wel negatief beïnvloedden. Duidelijk werd dat de "communicatiestructuur binnen het TTCM" een belangrijk thema is, zo werd bijvoorbeeld "het gebruik van een beveiligd e-mailsysteem" en "het gebruik van een gestandaardiseerd verwijzingsformulier" als positief ervaren door zorgverleners in zowel de eerste als tweede lijn. Andere frequent genoemde sterke punten van het TTCM waren "het gezamenlijke besluitvormingsproces in de polikliniek" en het "hogere niveau van kennis en vaardigheden door binnen TTCM te werken". Het "ontbreken van financiële middelen

voor de klinisch fysiotherapeut op de polikliniek" werd als belangrijke hindernis genoemd voor de implementatie van TTCM. Een andere vaak genoemde barrière was "de onbekendheid met TTCM op andere afdelingen van het ziekenhuis, zoals bijvoorbeeld de SEH".

Hoofdstuk 6 beschrijft de resultaten van het onderzoek waarin de associatie onderzocht werd tussen specifieke fractuurkenmerken en drie afhankelijke uitkomsten (ziektespecifieke kwaliteit van leven, functionele uitkomst en maatschappelijke kosten), waarbij gecorrigeerd werd voor het ontvangen van de interventie (TTCM) en voor diverse case-mix variabelen (o.a. leeftijd en geslacht). Voor dit onderzoek werden data van interventiegroepdeelnemers en deelnemers uit het 9-maanden controlecluster uit de eerder genoemde gecontroleerde voor-na studie gebruikt. Van al deze deelnemers werden baselinegegevens en de follow-up data op 9 maanden gebruikt voor analyse. Het hebben van een breuk in de onderste extremiteit bleek geassocieerd te zijn met een lagere ziektespecifieke kwaliteit van leven ten opzichte van de patiënten in de referentiecategorie (met een wervelfractuur of meerdere letsels). Daarentegen bleek het hebben van een fractuur in de bovenste extremiteit juist met een betere functionele uitkomst geassocieerd te zijn in vergelijking met de referentiecategorie. Tenslotte vonden we dat operatief ingrijpen geassocieerd werd met lagere maatschappelijke kosten ten opzichte van conservatieve behandeling. Type fractuur (intra- of extra-articulair) bleek met geen van de uitkomsten geassocieerd te kunnen worden.

Hoofdstuk 7 beschrijft het onderzoeksprotocol van de multicenterstudie die werd geïnitieerd, gefinancierd en ontworpen op basis van de resultaten van *hoofdstuk 3, 4, 5* en *6* van dit proefschrift. De multicenterstudie heeft als doel de effectiviteit en kosteneffectiviteit van een verbeterde versie van het TTCM te onderzoeken ten opzichte van reguliere zorg in tien Nederlandse ziekenhuizen. We maken daarbij gebruik van een geoptimaliseerd onderzoeksdesign. Dit betekent dat nu zowel de interventiegroep als de controlegroep prospectief wordt gevolgd, terwijl in de effectiviteits- en kosteneffectiviteitsstudies die in de eerdere hoofdstukken van dit proefschrift beschreven worden, slechts de interventiegroep prospectief werd gevolgd. Verbeteringen binnen het TTCM maakten het revalidatiemodel ook functioneel in de derde lijn (revalidatiecentra en instellingen met een geriatrische revalidatie-afdeling). Ook werden meerdere stakeholders, zoals beleidsmakers en beslissers in de zorg, in een eerder stadium betrokken waardoor bijvoorbeeld het gebrek aan financiële middelen voor de klinisch fysiotherapeut op de polikliniek een serieus aandachtspunt werd.

Hoofdstuk 8 geeft een overzicht van de belangrijkste bevindingen van ons onderzoek, en gaat in op de methodologische keuzes die we gemaakt hebben. De beperkingen die gepaard gaan met deze keuzes worden besproken, evenals de belangrijkste punten waarvan men zich bewust moet

zijn bij het interpreteren van de resultaten. De voornaamste methodologische issues hebben betrekking op het design van de gecontroleerde voor-na studie en daarnaast de pragmatische aanpak van de TTCM-trial. Het gekozen design beïnvloedt mogelijk de interne validiteit van onderzoeksresultaten op een negatieve manier, terwijl de pragmatische aanpak, waarin de alledaagse praktijk zoveel mogelijk werd benaderd, mogelijk de generaliseerbaarheid van de resultaten positief beïnvloedt.

De methodologische beschouwingen worden afgesloten met het kritisch bespreken van de methodiek en de resultaten van respectievelijk de procesevaluatie en de studie waarin de associatie onderzocht werd tussen specifieke fractuurkenmerken en drie afhankelijke uitkomsten (ziektespecifieke kwaliteit van leven, functionele uitkomst en maatschappelijke kosten). Tot slot worden aanbevelingen voor vervolgonderzoek gedaan en wordt een overzicht gegeven van praktisch toepasbare aanbevelingen voor de klinische praktijk en het implementeren van het TTCM in andere ziekenhuizen en regio's.

Conclusie

Concluderend toont dit proefschrift aan dat het implementeren van TTCM praktisch haalbaar is. Daarnaast is er voorlopig bewijs gevonden dat TTCM effectief is in vergelijking met reguliere zorg in traumapatiënten met tenminste één fractuur voor wat betreft patiëntgerelateerde uitkomstmaten, zoals ziektespecifieke kwaliteit van leven, functie en patiënttevredenheid. Sluitende conclusies over de kosteneffectiviteit van TTCM kunnen niet worden getrokken, omdat niet bekend is wat beslissers in de zorg daadwerkelijk willen betalen per punt verbetering op de diverse uitkomstmaten.

Tot slot werd lering getrokken uit de beschreven trialresultaten en uit de resultaten van de procesevaluatie. De gevonden verbeterpunten werden gebruikt om het TTCM verder te optimaliseren. Vervolgens werd een multicenterstudie opgezet om op een grotere schaal en met een verbeterd design de effectiviteit en kosteneffectiviteit van de geoptimaliseerde TTCM-versie te kunnen onderzoeken. De resultaten van de multicenterstudie worden in 2023 verwacht en zullen hopelijk leiden tot landelijke implementatie van TTCM en op die manier bijdragen aan individueel maatwerk en een optimaal revalidatietraject voor elke traumapatiënt in Nederland.

DANKWOORD

Dit project is begonnen met een praktische vraag vanuit de spreekkamer: “hoe bieden we traumapatiënten een optimale revalidatie, zonder onnodige vertraging en met een duidelijk doel”. Dat de vraag beantwoord is, dat er een proefschrift ligt, dat ons zorgmodel inmiddels breed gedragen wordt en dat we vervolgonderzoek doen in de vorm van een multicenterstudie, is dankzij de inzet van velen. Al deze mensen wil ik op deze plek danken voor hun inspanningen, vertrouwen en geduld.

Allereerst wil ik **de patiënten** bedanken die belangeloos hebben meegewerkt aan dit onderzoek in een moeilijke fase van hun leven. Dankzij jullie inzet en input kunnen we niet alleen de traumapatiënten uit Amsterdam UMC een betere revalidatie bieden, maar de komende jaren gaan we hopelijk deze zorg voor alle traumapatiënten in Nederland beschikbaar maken. Speciale dank aan **Co**, **Steve**, **Gideon**, **Mette**, **Dore**, **Bob**, **Gerdina**, **Martijn** en **Frank** voor de foto’s die jullie mij hebben gestuurd van jullie “optimale functie” na een lange revalidatie. Het proefschrift is door jullie beeldverhalen echt gaan leven.

De uiterst gevarieerde samenstelling van ons TTCM projectteam maakte dat de bijeenkomsten nooit saai waren. Een mix van sportfanaten, creatieve geesten, gastronomen en muziekliefhebbers, met als grootste gemene delers een tomeloze ambitie en hart voor de patiënt:

Edwin Geleijn, collega, vriend, sparringpartner, en natuurlijk paranimf. Wat begon als een leuk idee tijdens één van onze geanimeerde woon-werk fietstochtjes, groeide uit tot een volwassen zorgmodel en dito onderzoek. Jouw lef en innovatieve inborst en mijn inhoudelijke drive bleek een gouden combinatie. We werkten van meet af aan hard aan dit project en namen nooit een blad voor de mond en dat was heerlijk werken. Dit resultaat hebben we samen bereikt en daar ben ik je dankbaar voor.

Hanneke van Dongen, copromotor, ik had me geen betere dagelijkse begeleider kunnen wensen; snel, slim, accuraat, maar bovenal ontspannen en grappig. We gaven elkaar ruimte, maar pakten ook op hoog tempo door als het moest. Jouw input heeft dit proefschrift op alle vlakken naar een hoger niveau getild. Je kennis van methodologie, statistiek en economische evaluaties is onmisbaar geweest voor het onderzoek en dan ben je ook nog eens een taalkundig wonder. Heel veel dank en ik hoop dat jullie nog vaak in onze “tuin” komen plonzen met de kleine man!

Frank Bloemers, copromotor, heel veel dank voor jouw enthousiasme. Je hebt je vanaf de allereerste dag van dit project ten volle ingezet om de nieuwe aanpak van de grond te krijgen. Keer op keer brak je een lans voor een multidisciplinaire aanpak, steeds beredenerend vanuit het belang van de traumapatiënt. Jouw mailtjes, telefoontjes en aanwezigheid op de vele

bijeenkomsten openden deuren en slingerden de motoren aan. Ik hoop de laatste schakel van de traumaketen samen met jou verder op de kaart te zetten in Nederland.

Raymond Ostelo en **Vincent de Groot**, promotoren, dank voor jullie inzet en input op vele momenten. Jullie weten gas te geven op het moment dat het nodig is en los te laten als dat effectiever blijkt. Ik vond dat prettig werken en heb veel van jullie geleerd. **Raymond**, dank dat jij direct enthousiast en vol vertrouwen instapte, toen Edwin jou een aantal jaar geleden vroeg om het wetenschappelijk fundament onder onze plannen te leggen. En geweldig dat jouw inspanningen er toe hebben geleid dat er nu een multicenterstudie loopt. **Vincent**, heel fijn dat jij bereid was om ondanks je drukke werkzaamheden als tweede promotor op te treden. Jouw snelle, effectieve en constructieve manier van werken heeft de gang erin gehouden en op cruciale momenten tot goede beslissingen geleid. Daarnaast heb je mijn persoonlijke ambities en groei volop ondersteund in je rol als afdelingshoofd.

De leden van de beoordelingscommissie, prof.dr. K.D.P.W.B. Nanayakkara, prof.dr. I.B. Schipper, prof.dr. J.E. Bosmans, prof.dr. P.J. van der Wees en prof.dr. C.K. van der Sluis, dank ik hartelijk voor het vlot en kritisch lezen van mijn proefschrift. Dat de onderzoeken en het transmurale zorgmodel vanuit zo'n breed perspectief beoordeeld zijn, waardeer ik zeer.

Rosalie Huijsmans, als mijn directe leidinggevende heb je dit onderzoek en mijn persoonlijke ontwikkeling altijd gesteund. Het was fijn zo'n krachtige persoonlijkheid achter me te hebben staan. Ik denk dat jij een van de weinigen bent, die het volledige "kleurenspectrum" dat tijdens dit onderzoek de revue heeft gepasseerd, kan overzien. Jouw inlevingsvermogen is groot en je tactische zetten zijn vrijwel altijd raak. Ik dank je voor alles wat je in de afgelopen jaren voor me hebt gedaan en betekend.

Mijn vakgroep, mijn buddy's. Jullie geduld, flexibiliteit en incasseringsvermogen was groot en onmisbaar. De afgelopen jaren zijn veel vakgroep-uren naar dit onderzoek gegaan. Voor ons allemaal een enorme investering, maar ook een prachtig gezamenlijk product, waaraan iedereen op zijn eigen manier heeft bijgedragen. Hiervoor wil ik jullie persoonlijk bedanken:

Maaike Schothorst coördineerde de dataverzameling en pleegde honderden telefoontjes, ik heb heel veel waardering en respect voor je precisie, vasthoudendheid en inzet op de traumapoli's. **Josien Jongejan** wist keer op keer op keer op creatieve wijze onderzoeksuren vrij te plannen, dank voor al het puzzelen, de groene bril en je grote hart. **Pauline Manni**, sparringpartner en sportmaatje, wat werk je hard en wat waardeer ik je inzet en doorzettingsvermogen. Waar anderen stoppen ga jij door. Wat vaker samen een rondje hardlopen in het bos zou misschien goed zijn voor ons beiden! **Lydia Köster** en **Bouke Hepkema**, jullie weten niet beter dan dat er een

fysiotherapeut naast de traumachirurg zit op de poli, maar zo gewoon is dat niet in Nederland. Mede dankzij jullie inzet en harde werken kunnen we verder bouwen! In jullie zie ik jonge collega's die niet bang zijn om in het diepe te springen en vol enthousiasme nieuwe uitdagingen zoeken en aangaan. Ik ben trots op jullie. **Madelon Fennet**, fijn dat je ons bent komen versterken!

Laurens Migchelsen, onze pater familias en mijn goede vriend! Jij symboliseert voor mij de hele vakgroep. Ik vind het geweldig dat je je voor de volle 100% hebt ingezet om dit project tot een succes te maken. Toen we net begonnen op de traumapoli's was dat best spannend en het is mooi om te zien dat deze nieuwe werkwijze je zoveel plezier geeft. Ik ben blij dat je namens de hele vakgroep mijn paranimf wilt zijn.

Op deze plek wil ik ook twee oud-collega's bedanken die aan de wieg van mijn ontwikkeling als traumafysiotherapeut hebben gestaan. **Rik van Hooff** heeft mij alle fijne kneepjes van het vak bijgebracht en gaf mij veel ruimte om met vallen en opstaan te leren wat traumarevalidatie echt betekent. Ik had me geen betere mentor kunnen wensen. **Karin Hekman**, samen kwamen we het "ortho-traumateam" versterken met onze ambities en dromen, wat was het leuk samenwerken en wat hebben we een hoop bereikt. Jij bouwde Schoudernetwerk Nederland en bent inmiddels eigenaar van een florerende praktijk. En zowaar lees je nu het dankwoord van mijn proefschrift ☺.

Julia Ratter, wat hebben we een geluk met jou als promovenda op de TTCM-Trial! Het is ongelooflijk hoe jij je vastbijt in dit onderzoek. Je gaat recht op je doel af. Ondanks onverwachte pandemische tegenslagen en bureaucratische vertragingen lig je gewoon op schema en loopt de trial als een trein. Dank voor je vrolijkheid en inzet en ik kijk uit naar de resultaten van de TTCM-Trial en natuurlijk naar jouw proefschrift.

Al mijn andere collega's van de afdeling revalidatiegeneeskunde wil ik natuurlijk ook bedanken. Wat een leuke afdeling hebben we, zoveel disciplines bij elkaar! Er is veel wederzijdse belangstelling en support, "in good times and bad times". Fijn dat ik bij jullie hoor. In het bijzonder dank ik **alle fysio's** en **oud-fysio's van de andere vakgroepen** (neuro, inspanning en kinderen). Er gaat veel veranderen, maar ik hoop dat de verbondenheid blijft!

Maartje Terra, **Leo Geeraedts**, **Jaap Deunk**, **Charlotte Lameijer**, **Wietse Zuidema** en **Frank Bloemers**, traumachirurgen van Amsterdam UMC, locatie VUmc! Ik dank jullie voor de bereidheid in het diepe te springen en fysiotherapeuten toe te laten in de spreekkamer. Voor iedereen was het in eerste instantie wennen en bijschaven, met af en toe een gezonde discussie, maar bovenal samenwerken aan de beste nabehandeling voor onze patiënten. Inmiddels zetten jullie je volop in als ambassadeur van onze werkwijze. Altijd bereid om een scholing te verzorgen of te participeren in onze infofilm. En zoals Wietse treffend in deze film zei: "uiteindelijk is de patiënt de winnaar".

Alle fysiotherapeuten van Netwerk Traumarevalidatie VUmc wil ik enorm bedanken! De brug tussen de eerste en tweede lijn is geslagen. Patiëntenbelang stond altijd voorop, jullie open, positieve en leergierige houding bleek geweldig goed te werken, 1000 keer beter dan iedere fysiotherapeut op zijn eigen eiland!

Heleen Beckerman, jouw bijdrage aan het effectartikel was waardevol. Professioneel heb je me stukken verder geholpen en je aanmoedigingen waardeer ik enorm. **Marianne Donker**, jij hebt mij begeleid bij het schrijven van het leukste artikel uit dit proefschrift. Je kennis van verandermanagement maakt de procesevaluatie goed leesbaar én bruikbaar in de praktijk. **Gogem Topcu**, from the University of Nottingham, it was very inspiring to meet you! I learned a lot and you encouraged me to bring my qualitative research skills to a higher level. I look forward to work together again in our multicenter study.

Michael Wijnberg, **Milou Rossenaar** en **Vincent van Vliet** leverden als studenten een substantiële bijdrage aan het onderzoek. Veel dank voor jullie inzet en goed te zien en te horen dat jullie alle drie goed terecht gekomen zijn als respectievelijk huisarts, kosteneffectiviteitsexpert en collega-fysiotherapeut. Waar zo'n stage al niet goed voor is!

Dankzij het enthousiasme van **Frank Duijff**, het arbeidsethos en de oneindige ICT-kennis van **Sander Assendelft** is de studie van de grond gekomen. Het was naast effectief, vooral heel leuk en enerverend om met FysioRoadmap samen te werken!

Frans Lanting van het Nederlands Paramedisch Instituut wil ik bedanken voor de effectieve en goede samenwerking. De cursus "Traumachirurgie en Fractuurbehandeling" blijft onverminderd populair bij fysiotherapeuten, dus voorlopig zijn we nog niet van elkaar af en daar ben ik blij om.

Asako Takahashi en **Regina The** van Zorgkeuzelab, het was inspirerend om samen met jullie en de werkgroep de keuzehulp "herstel na botbreuk" te schrijven. En **Asako** wat heb je de afbeeldingen in mijn proefschrift mooi gemaakt, dank je wel voor je hulp en tips!

Renate Siebes en **Wendy Schoneveld** hebben geweldig werk afgeleverd met de layout en de cover van het proefschrift. Super hoe jullie mijn vage ideeën tot een perfect eindresultaat hebben gesmeed.

Familie en vrienden, ik geloof dat ik niet heel veel ins & outs van dit onderzoek heb gedeeld met jullie. Voor mij was het "gewoon werk" en daarnaast was er vooral het "echte leven" om met jullie te delen.

Lieve **pa** en **ma**, ik ben blij dat we dit feest samen kunnen vieren en dank jullie voor een mooie, avontuurlijke jeugd, waarin ik alle kansen kreeg en heb geleerd dat niks onmogelijk is. Heel fijn

dat nu de kinderen zo genieten van de logeerpartijtje en gezelligheid bij opa en oma. **Selma** en **Emo**, lieve zus en broer! Ondanks onze drukke levens en jonge gezinnen weten we elkaar altijd te vinden, dank dat jullie er voor mij zijn. **Selma**, tijdens het schrijven van dit proefschrift heb je me vaak wijze raad gegeven, heel veel dank daarvoor! Mijn lieve **tante Joke** ben ik dankbaar, je huis staat altijd voor ons open en zolang ik me kan herinneren kom ik logeren en doen we leuke dingen samen. Fijn dat ik af en toe een paar dagen kon komen schrijven tussen je "juttersvondsten".

Lieve **Reinold**, wat missen we **Jacobine**, maar wat ben ik blij dat onze gezinnen zo verbonden zijn. Ik vergeet nooit meer de intense en liefdevolle tijd waar we doorheen zijn gegaan, **Jac** blijft voor altijd in ons hart. **Jacco** en **Wendy** dank voor onze vriendschap die niet veel woorden nodig heeft, maar staat als een huis.

Vriendinnen uit Maastricht, dat we elkaar nog steeds zien, spreken en appen in allerlei samenstellingen zegt genoeg. Het was een prachttijd en jullie zijn prachtmeiden met prachtgezinnen! Laten we maar snel weer eens een feestje vieren **Marion**, **Martine**, **Ineke**, **Inge** en **Pia**.

Twee proefschriften, twee sportcarrières, drie kinderen, en bijna 20 jaar samen. En nog steeds één. Natuurlijk. Ergens vol voor gaan is ons niet vreemd. Gelukkig is het klip en klaar dat ons gezin altijd op 1 staat. Daarom hoeft er in dit dankwoord ook niet gezegd te worden dat er nu maar eens tijd moet komen voor elkaar, voor de kinderen, voor ontspanning, voor reizen, voor sporten, of voor wat dan ook. We plukken de dag. Elke dag opnieuw is het fijn thuiskomen bij jou. Dank je wel lieve **Daniël**, voor wie je bent, voor wat je doet, voor wat je me gegeven hebt, voor alles.

Mijn lieve **Rink**, grote jongen, wat ben ik trots (en stiekem een beetje jaloers) op jouw toewijding en inzet bij alles wat je doet. Of het nu school of sport betreft, jij gaat er vol voor en bent ook nog eens heel gezellig en behulpzaam! **Saartje**, mijn lieve stoere meisje, wat werk je hard en wat ben je al zelfstandig. Je houdt ons bij de tijd en we genieten volop van de sociale manier waarop je in het leven staat. Je stevent af op een mooie voetbalcarrière en papa en mama zijn beretrots op je! **Siem**, mijn lieve dondersteen, wat geef jij ons een plezier. Voor scherpe observaties en goede grappen moeten we bij jou zijn. Heerlijk om er zo'n creatieve en ondernemende jongen bij te hebben die ongeremd hutten bouwt, buiten speelt en een hoofd vol weetjes heeft.

ABOUT THE AUTHOR

Suzanne Wiertsema was born on October 6th, 1971 in Nieuwegein and moved to Mierlo when she was 5 years old. She attended secondary school at the Strabrecht College in Geldrop (VWO), where her fascination for athletics, human movement, and health has its origin. She graduated in 1990 and was repeatedly kept from attending Medical School due to the numerus fixus rules of that time. She started studying Health Sciences at Maastricht University instead and received a Master's Degree in 1995 with specializations in Human Movement Sciences and Epidemiology. However, clinical practice continued to draw her attention and from 1995 to 1998 she therefore combined working as a research assistant at VU University (EMGO+ Institute, LASA study) with studying Physical Therapy at the Utrecht University of Applied Sciences. After some short episodes of working in primary care practices, she started working at the department of Physical Therapy of the VU University Medical Centre (VUmc) in 1999. From the beginning, Suzanne was intrigued by trauma patients and their rehabilitation, she liked the challenges of working in a level-1 trauma center with its wide variety in patients. During her study and early working years she never lost her passion for athletics and from 1999–2005 she combined working at VUmc with a life as a semiprofessional athlete, which led to national titles in cross-country running (2002) and duathlon (2003) and participation in various international tournaments. The following years she further developed and sharpened her scientific and teaching skills, always directly related to her work as clinical physical therapist on the trauma ward. Together with her mentor in trauma rehabilitation, Rik van Hooff, she developed a three-day course for post-graduate physical therapists with special interest in trauma surgery and trauma rehabilitation. This course is still embedded within the Dutch Institute of Allied Health Care (NPi) and since 2014 Suzanne is fully responsible for the program. In 2013, Suzanne collaborated with her colleague Edwin Geleijn and trauma surgeon Frank Bloemers to develop the Transmural Trauma Care Model (TTCM). They received a grant from Zilveren Kruis Health Insurer in 2014 to perform a feasibility study on the cost-effectiveness of the TTCM. They expanded their team with Raymond Ostelo and Hanneke van Dongen to gain more expertise on methodological and health economic issues. The results of the feasibility study were used to further improve the TTCM and to set up a multicenter trial which is currently running (PhD student Julia Ratter) and granted by ZonMw. Suzanne is combining her work as clinical physical therapist with working as supervisor on this multicenter study and is responsible for implementing the TTCM in the participating hospitals. She is married to historian, teacher and writer Daniël Rewijk and they have three children, Rink, Saartje and Siem.

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13. Ratter J, Pellekooren S, **Wiertsema SH**, van Dongen JM, Geleijn E, de Groot V, Bloemers FW, Jansma E, Ostelo RWJG. Content validity and measurement properties of the Lower Extremity Functional Scale in patients with fractures of the lower extremities: a systematic review. Submitted.

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