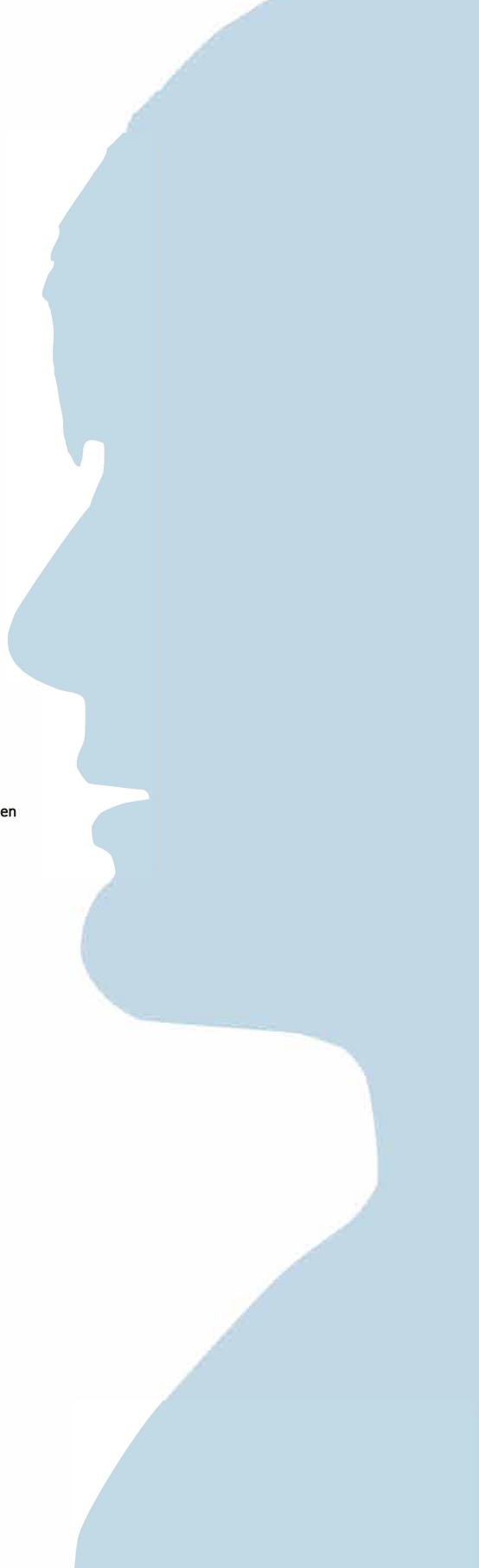
Improving Trauma Rehabilitation

Broadening and Upscaling the Transmural Trauma Care Model: clinical effects, challenges, and opportunities

Julia Ratter

„Wir können einem System nicht unseren Willen aufzwingen. Wir können darauf hören, was das System uns wissen lässt, und dabei entdecken, wie seine Eigenschaften und unsere Wertvorstellungen im Zusammenspiel etwas viel Besseres hervorbringen können. Wir können Systeme weder beherrschen noch sie enträtseln. Aber wir können mit ihnen tanzen."

(Donella Meadows, Die Grenzen des Denkens, 5. 244)



Improving Trauma Rehabilitation and Upscaling the Transmural Trauma Care Model:

Clinical Effects, Challenges, and Opportunities

Julia Ratter

This PhD 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 printing of this thesis was financially supported by the Scientific College Physical Therapy (WCF) of the Royal Dutch Society for Physical Therapy (KNGF), the Dutch Institute of Allied Health Care (NPi) and Amsterdam Movement Sciences Research Institute.

The studies described in this thesis were funded by ZonMw (grant number: 80-85200-98-91009).

Cover design and layout:	© Elke Ratter, erdesign
Thesis design and layout:	Anna Bleeker, persoonlijkproefschrift.nl
Printed by	Proefschriftspecialist.nl
ISBN:	978-94-93330-77-1
DOI:	http://doi.org/10.5463/thesis.610

VRIJE UNIVERSITEIT

Improving Trauma Rehabilitation and Upscaling the Transmural Trauma Care Model:

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ACADEMISCH PROEFSCHRIFT

ter verkrijging van de graad Doctor aan
de Vrije Universiteit Amsterdam,
op gezag van de rector magnificus
prof.dr. J.J.G. Geurts,
in het openbaar te verdedigen
ten overstaan van de promotiecommissie
van de Faculteit der Geneeskunde
op donderdag 23 mei 2024 om 11.45 uur
in een bijeenkomst van de universiteit,
De Boelelaan 1105

door

Julia Ratter

geboren te Bergisch Gladbach, Duitsland

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TABLE OF CONTENTS

CHAPTER 1

General introduction

INTRODUCTION

Major trauma is one of the leading causes of death and invalidity worldwide (1, 2). In the Netherlands, 71,623 patients were treated at trauma centers in 2020, of which the majority (92%) were mildly or moderately injured (Injury Severity Score (ISS) ≤ 15), while eight percent were critically injured patients (ISS ≥ 16) (3). It is noteworthy that the number of major trauma patients significantly declined during the first COVID-19 peak in 2020, likely due to the restrictive regulations of society (4).

Trauma causes a relatively high number of disability-adjusted life years (DALYs) (5-7), which is due to the fact that relatively many young people suffer a trauma, which can in turn have large long-term impacts on physical and mental health. Besides the physical and mental health burden of trauma, trauma negatively influences a patients' social functioning and health-related quality of life (HR-QOL) (8-11). To illustrate, research has demonstrated that individuals who have experienced trauma frequently experience persistent pain, reduced mobility, and functional limitations (9, 10). Furthermore, they often report lower health-related quality of life, increased psychological distress, and higher rates of disability (12, 13).

The economic burden of trauma is high, and traumatic injuries rank among the five most costly medical conditions worldwide (14). In the Netherlands, the total societal costs of traumatic injuries were estimated at €3.5 billion in 2017 (€210/capita and €4300/patient; (15, 16)). The cost of traumatic injuries is expected to increase during the upcoming decades due to the current aging population (1, 16-20).

Organization of trauma care

Trauma care encompasses the entire care chain, starting from the emergency call and extending to the rehabilitation process. In the Netherlands, eleven designated trauma centers serve as the backbone of the national network and play a crucial role in coordinating the delivery of acute care. The hospitals are categorized into three levels for the management of trauma patients. Level 3 hospitals are capable of treating isolated injuries, such as ankle or hip fractures. Level 2 hospitals can also accommodate critically ill patients, but may not have all necessary facilities. Level 1 hospitals can provide 24/7 care for all severely injured patients. Prehospital healthcare providers, such as ambulance personnel or Mobile Medical Teams, are trained to make the appropriate choice regarding which hospital the patient should be transported to. The system follows a well-established approach, with emergency medical services providing prompt assessment and transportation to trauma centers. A multidisciplinary team comprising trauma surgeons, anesthesiologists, radiologists, and nurses provides coordinated care. The effectiveness of this tiered system has been extensively researched over the past years. The findings of these studies have further validated the importance of a well-organized trauma care system and provided valuable insights for continuous improvement and refinement (21, 22). The Dutch guidelines for trauma care emphasize the importance of establishing national and regional networks involving various stakeholders and professionals to ensure optimal accessibility of acute care services.

However, the organization of trauma rehabilitation in primary care is challenging, and there are no (inter)national guidelines available (23). Consequently, severe gaps exist between trauma patients' transition from hospital to their home situation and their return to society. Therefore, there is an increased interest in improving trauma rehabilitation in recent years (2, 24, 25).

The Transmural Trauma Care Model

To improve trauma rehabilitation, the Transmural Trauma Care Model (TTCM) was developed in 2014 at Amsterdam UMC, location VUmc, the Netherlands (26). The TTCM is a multidisciplinary and patient-centered transmural rehabilitation model, consisting of four interlinked components (Figure 1):

1) Intake and follow-up joint consultations by a multidisciplinary team at the outpatient clinic for trauma patients: During the trauma patients' outpatient visits, the trauma surgeon evaluates the bone and wound healing process and acts as the chief consultant. A hospital-based physiotherapist (HBP) assesses physical function and acts as a case manager throughout the rehabilitation process.
2) Coordination and individual goal setting: The hospital-based team coordinates the patients' rehabilitation process in primary (and sometimes tertiary care) by repeatedly defining individual treatment goals in close cooperation with the patient.
3) A network of specialized network physiotherapists (NPs): Patients are referred to the Dutch Network Trauma Rehabilitation, which consists of specifically trained network physiotherapists (www.traumarevalidatie.nl).
4) Secured e-mail traffic between hospital-based physiotherapists and network physiotherapists: Hospital-based and network physiotherapists communicate rehabilitation goals and results through a secure email system throughout the patients' rehabilitation process.

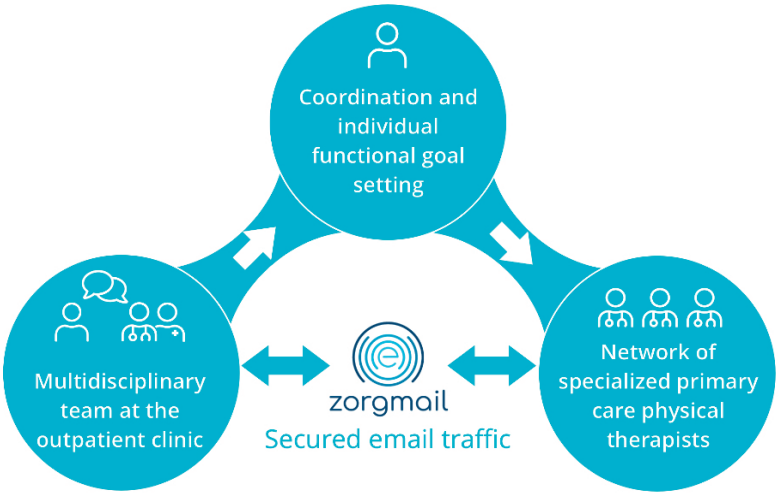

Figure 1 The Transmural Trauma Care Model

Broadening and upscaling of healthcare interventions

In a pilot study, implementation of the TTCM at a Dutch Level 1 trauma center was found to be feasible and had the potential to improve patient outcomes and satisfaction and to reduce costs (26-28). Based on the results of this pilot study, the TTCM was further developed. For instance, a comprehensive manual was created to outline the organizational structures, to delineate the duties and responsibilities of the involved care providers, and to ensure the inclusion of fractures of varying severity treated by trauma surgeons, irrespective of the subsequent rehabilitation setting. Moreover, unlike the pilot study, patients undergoing rehabilitation in tertiary care settings were now also incorporated into the model. These adaptations aimed to enhance the effectiveness and applicability of the TTCM by encompassing a broader range of trauma patients and optimizing the transition between acute trauma care and rehabilitation.

After the favorable outcomes observed in the pilot study, the TTCM had to be evaluated on a larger scale to generate higher quality evidence regarding its (cost-)effectiveness. For that, it had to be upscaled, meaning that the innovative and small-scale TTCM needed to be expanded and replicated to reach more hospitals (29). Upscaling healthcare interventions is an essential step in improving healthcare, because more people can be reached by increasing the scale at which interventions are implemented. Upscaling healthcare interventions can also lead to improved quality and effectiveness of care as well as an increased access to healthcare services. However, upscaling healthcare interventions is a challenging endeavor, as it requires an unstained commitment of resources and capacity to ensure their cost-effectiveness and sustainability. Furthermore, healthcare interventions must be adapted to the local context, which requires in-depth understanding of the local context and the capacity to adjust the intervention accordingly. To ensure that healthcare interventions are successfully upscaled, capacity must be available to implement them, which requires the development of skills and capacity within the healthcare system (30-32). Dynamics, such as those created by the implementation of the TTCM, provide an opportunity for change (33-35). For the TTCM, however, it was unknown how it could be implemented successfully in other Dutch hospitals, all of which have their own structures, cultural norms/values, and practical routines. Therefore, it is recommended to conduct process evaluations alongside clinical trials, as their results can help further improve the (implementation of an) intervention and hence facilitate the transition of research evidence into clinical practice (34, 36). On top of that, they can provide important information for interpreting the clinical trial's results (37, 38).

Transmural care and challenges in financing

Transmural care, such as the TTCM, addresses the increasing burden of (chronic) diseases and aims to improve patients' health-related quality of life (2, 24, 25) and to reduce health service costs and utilization. Please note that various terms are sometimes used interchangeable with transmural care, such as integrated care, shared care, managed care, and the widely known concepts of comprehensive care and disease management (39).

Transmural care aims to overcome service fragmentation, enabling better coordinated and more continuous care (40).

In the Netherlands, health services have historically been strictly divided into primary and secondary care (41, 42). In addition, there are specialized institutions for the mentally and physically disabled, for the elderly, for home care, and rehabilitation (43). These institutions are also known as tertiary care. The fragmentation caused by this organizational specialization is exacerbated by compartmentalized reimbursement arrangements (44), i.e., the existence of separate funding streams and payment mechanisms for different sectors and providers. The lack of coordination and continuity across these fragmented components hinders the provision of comprehensive and efficient healthcare services. Therefore, the integration of care needs to occur at three different levels: 1) the macro-level, where policies and regulatory mechanisms can be developed to integrate primary, secondary, and tertiary care; 2) the meso-level, where strategic plans and coordination mechanisms for managerial functions can be formulated (e.g. organization and professional integration based on shared competencies, roles, responsibilities, and accountability, and 3) the micro-level, which includes the coordination of care plans and the integration of health services across primary, secondary and tertiary care settings. At the micro-level, professionals work collaboratively to ensure that patients receive the most appropriate care and treatment (45). In the case of the TTCM, this concerns the joint consultations of a multidisciplinary team at the outpatient clinic for trauma patients and the collaboration with specialized network physiotherapists to work on individual treatment goals in close cooperation with the patient throughout the patient's rehabilitation process.

Previous research indicates, however, that it is challenging to fund transmural care models, such as the TTCM, due to the strict separation between the outpatient clinics of hospitals, i.e. secondary care, and their affiliated physiotherapy networks in the Netherlands, i.e. primary and tertiary care (46). Financial constraints like these can pose significant barriers to scaling up interventions since obtaining additional funding or efficiently allocating existing funds can be time-consuming and detrimental to the intervention's success. Despite the potential of transmural care to improve patient outcomes and reduce costs, there has been limited research into how to bridge the traditional and financial boundaries between primary and secondary care sectors, and it is unclear what barriers and facilitators are to facilitate a successful financing and hence implementation of transmural care models. Therefore, it is still challenging to upscale a transmural care model, such as the TTCM, and to create a sustainable system for funding and communication for the TTCM (41, 42, 47). Moreover, it is essential to investigate and identify the factors that impede or facilitate the integration of care across these sectors, including the financial considerations involved. Such research can provide insights into strategies to overcome the existing challenges and promote the adoption of transmural care approaches, ultimately leading to improved patient outcomes and more cost-effective healthcare delivery.

Aims of the thesis

This thesis describes the upscaling of the TTCM. The primary aim of this thesis was to assess the (cost-) effectiveness of the TTCM within a multicenter trial. Secondary aims included the investigation of the barriers and facilitators of the upscaling of the TTCM and identifying possibilities for funding transmural care models, such as the TTCM. By exploring the association between fracture and treatment-related factors versus disease-specific HR-QOL, functional outcome, and societal costs in trauma patients, this thesis also aims to identify opportunities for content improvement in the TTCM. Finally, by conducting a systematic review about the content validity and the measurement properties of the Lower Extremity Functional Scale, this thesis aims to provide guidance for improving the measurement of functional status in patients with lower extremity fractures, an important part of the target population of the TTCM.

Outline of the thesis

Chapter 2 describes the study protocol of a multicenter trial with a controlled before-and-after design to assess the effectiveness and cost-effectiveness of the Transmural Trauma Care Model.

Chapter 3 describes the preliminary results of the multicenter trial evaluating the effectiveness of the TTCM compared to the usual care in patients with trauma with a six months follow-up period.

Chapter 4 describes the process evaluation of the barriers and facilitators associated with the upscaling of the TTCM.

Chapter 5 presents the results of a case study assessing barriers and facilitators from different stakeholders' perspectives that influence the funding of transmural care models in the Netherlands.

Chapter 6 presents the results of a study assessing the association between fracture and treatment-related factors versus disease-specific HR-QOL, functional outcome, and societal costs in trauma patients.

Chapter 7 presents the results of a systematic review about the content validity and measurement properties of the Lower Extremity Functional Scale in patients with fractures of the lower extremities.

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

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CHAPTER 2

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

Julia Ratter, Suzanne H Wiertsema, Johanna M van Dongen, Edwin Geleijn, Raymond WJG Ostelo, Vincent de Groot, Frank W Bloemers

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 €3.5 billion (€210/capita and €4300/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.

The trial is scheduled at seven level 1 trauma centers and three level 2 trauma centers in the Netherlands, of which one regional hospital (Zaans Medisch Centrum), five supra-regional hospitals (Haaglanden Medisch Centrum, HagaZiekenhuis, Noordwest Ziekenhuisgroep Alkmaar, Reinier de Graaf Ziekenhuis, Spaarne Gasthuis) and four academic hospitals (LUMC Leiden, Radboudumc Nijmegen, UMC Amsterdam, location AMC, Maastricht UMC+). Amsterdam UMC, location VUmc will coordinate the trial, but will not include patients because the TTCM is already implemented at its trauma center as usual care.

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 1. Due to the nature of the intervention, blinding of participants is not possible.

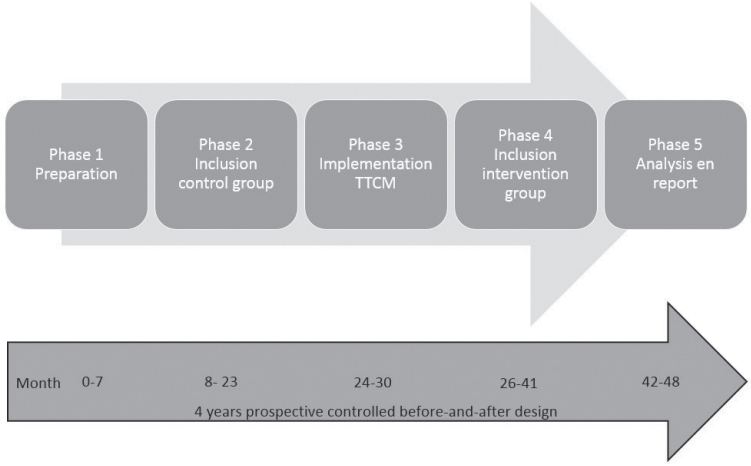

Figure 1 A graphical representation of the study design

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, intra-articular/ 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 all outcomes, including references, can be found in Appendix 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 1. An overview of all outcome measurements is provided in Table 1.

Table 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 and 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 health 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, and 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, and practice) (51).

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 (52, 53). 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 5000 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 (54). A summary measure of the joint uncertainty of costs and effects will be presented using Cost-Effectiveness Acceptability Curves (CEACs) (55). 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. (26) 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 (56). 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 (57). 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 catchment 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 baseline (58) and to adjust for relevant patient and trauma characteristics in the analysis using propensity score weight (52, 53).

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.

Abbreviations:

CRF: Case Report Form, DALY: Disability-adjusted life years, DASH: Disabilities of the arm, shoulder and hand (questionnaire), EQ-5D-5L: Measurement general HR-QOL (questionnaire), GARS: Groningen Activity Restriction Scale (questionnaire), GPE: Global Perceived Effect Scale (questionnaire), LEFS: Lower Extremity Functional Scale (questionnaire), HR-QOL: Health-related quality of life, ICERs: Incremental Cost-Effectiveness Ratios, iMCQ: Medical Consumption Questionnaire, iPCQ: Productivity Cost Questionnaire, ISS: Injury Severity Score, METc: Medical research ethics committee, NRS: Numeric rating scale, NPRS: Numeric pain rating scale, PROMS: Patient-Reported Outcome Measures, PROMIS: Patient-Reported Outcomes Measurement Information System, PROMIS-PF SF 10a: Patient-Reported Outcomes Measurement Information System physical functioning short form 10a, PROMIS-PF-UE 7a: Patient-Reported Outcomes Measurement Information System physical functioning upper extremity 7a, QALYs: Quality-adjusted life-years, PSFS: Patient-Specific Functional Scale, TTCM: Transmural Trauma Care Model, VAS: Visual Analog Scale

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.

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APPENDIX 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 ((59, 60)).

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 (39). The results of Gummesson et al. indicate that the QuickDASH can be used instead of the DASH with similar precision in upper extremity disorders (40). 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 (61).
- 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 [41] with fair-to-good accuracy in discriminating between participants with and without improvement [62].
- 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 (42, 43, 62-64).

- 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 (44, 45, 65).

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 (66, 67).

Numeric pain rating scale (NPRS)
The Numeric Pain Rating Scale (NPRS) is a measure of the 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) (68).

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 (69).

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 (70, 71). 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 (72). 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 (73).

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 (73). 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 (74). Absenteeism will be valued using gender-specific price weights (73). Presenteeism is defined as reduced productivity while at work (75), will be measured using items from the WHO-HPQ and the iPCQ, and will be valued using gender-specific price weights (73). 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 (73). 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 (76).

CHAPTER 3

Preliminary effectiveness of the Transmural Trauma Care Model (TTCM)

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Under embargo

ABSTRACT

Objective: To assess the preliminary effectiveness after 6 months follow-up, of the Transmural Trauma Care Model (TTCM), a multidisciplinary transmural rehabilitation model for trauma patients compared with usual care in ten Dutch hospitals.

Methods: A controlled before-and-after multicenter trial was performed to assess the effectiveness of the TTCM. Co-primary outcomes were generic and disease-specific health-related quality of life (QOL). For general and disease-specific QOL, between-group differences of 0.057 and 10% were assumed to be clinically relevant, respectively. Secondary outcomes were patient-specific functional status, pain, patient satisfaction, perceived recovery, and patient-reported health based on physical functioning. Measurements took place at baseline and after 6 weeks, 3, and 6 months. Data were analyzed using longitudinal data analyses on multiply imputed data.

Results: 206 trauma patients were included in the intervention group and 322 in the control group. Of them, 384 patients (73%) had complete data. Although there were no statistically significant *overall* between-group differences for the co-primary outcomes generic QOL (0.02; 97.5%CI: 0.00 to 0.04; scale -0.446 to 1.000) and disease-specific QOL (1.7; 97.5%CI: -0.4 to 3.5; scale 0 to 100) during the complete duration of the 6 month follow-up period, the mean-between group differences in generic and disease-specific QOL were statistically significantly and in most cases clinically relevantly in favor of the intervention group *at 3- and 6-months* follow-up. Statistically significant *overall* between-group differences in favor of the intervention group were found for the secondary outcomes patient satisfaction, and patient-reported health based on physical functioning, but not for the other secondary outcomes.

Conclusion: During the complete 6-month follow-up period, generic and disease-specific QOL were similar among patients receiving the TTCM and usual care. However, at 3 and 6 months follow-up TTCM patients exhibited higher levels of generic and disease-specific QOL than their usual care group counterparts. The secondary outcomes patient satisfaction and patient-reported health based on physical functioning exhibited a similar positive trend, but this was not observed for the other secondary outcomes. The results of this preliminary analysis are not conclusive and are currently under embargo. Further comprehensive analysis incorporating complete follow-up data is required to validate the current effectiveness findings of the TTCM. The final results are expected to be available at the beginning of 2024.

INTRODUCTION

Traumatic injury is a leading cause of mortality, morbidity, and disability, and ranks among the most prevalent and costly medical conditions (1-3). In the United States, for example, traumatic injuries were among the top 10 causes of death for all age groups in 2019, and their economic cost was estimated at $4.2 trillion, including $327 billion in medical care, $69 billion in work loss, and $3.8 trillion in the value of statistical life (i.e. a monetary estimate of the collective value placed on mortality risk reduction as derived in research studies through revealed preferences) and quality of life losses (4).

Next to the economic burden of traumatic injuries, they negatively influence a patient's physical functioning and health-related quality of life (HR-QOL) (5-7). That is, fractures of the hip, spine, and/or pelvis can lead to chronic pain and mobility limitations, reducing a patient's ability to perform daily activities, which in turn might negatively impact their HR-QOL (8, 9). Fractures of the shoulder, wrist, and/or hand can also have a significant impact on physical functioning, particularly in terms of dexterity and fine motor skills (10). Again, this can affect a patient's ability to work and engage in leisure activities, and hence their HR-QOL.

Due to traumatic injuries' significant clinical and economic impact there has been an increased interest in improving its rehabilitation process (11, 12). As part of these efforts, the Transmural Trauma Care Model (TTCM) has been developed at the Amsterdam UMC, the Netherlands. The TTCM is a multidisciplinary and patient-centered transmural rehabilitation care model, consisting of: 1) joint consultations by a multidisciplinary team at the outpatient clinic for trauma patients; 2) coordination and individual goal setting; 3) a network of specialized network physiotherapists (NPs); and 4) secured email traffic between hospital-based physiotherapists and NPs.

A recent pilot study found the implementation of the TTCM at a Dutch Level 1 trauma center to be feasible and to improve patient outcomes and satisfaction (13). However, due to some of the methodological shortcomings of this pilot study (e.g., single center, control group was not prospectively followed), a multicenter study was set up to obtain more reliable estimates of the (cost-)effectiveness of the TTCM (14). In this chapter, we report on a preliminary effectiveness analysis of the 6 months follow-up data of our multicenter trial comparing the TTCM with usual care in ten Dutch hospitals. While the 6 months follow-up provides valuable insights into the initial outcomes, it is important to acknowledge that a full analysis of the effectiveness and cost-effectiveness at the 9 months follow-up is not included in this thesis for several reasons. The main reason is that the 9 months follow-up data was still being collected and processed at the time of completing this thesis, making it unavailable for comprehensive analysis. Future analyses will delve into the extended follow-up period and present a more comprehensive understanding of the sustained impact and cost-effectiveness of the TTCM over a more extended duration, ensuring a robust evaluation

of its efficacy in improving patient outcomes and optimizing resource allocation. These comprehensive analysis will be submitted to a scientific journal for publication.

METHOD

Design

In this preliminary analysis, 6-month follow-up data of the TTCM multicenter trial were available in April 2023 and were used. The TTCM multicenter trial had a controlled before-and-after design and took place at seven Level-1 trauma centers and three Level 2 trauma centers in the Netherlands, of which one regional hospital (Zaans Medisch Centrum), five supra-regional hospitals (Haaglanden Medisch Centrum, HagaZiekenhuis, Noordwest Ziekenhuisgroep Alkmaar, Reinier de Graaf Ziekenhuis, and Spaarne Gasthuis), and four University Medical Centers (LUMC Leiden, Radboudumc Nijmegen, Amsterdam UMC, location AMC, Maastricht UMC+). Since January 2020**,** participating hospitals included patients in the control group, receiving usual care as provided in these specific hospitals. Since February 2021, the TTCM was implemented in all participating hospitals and hospitals included patients in the intervention group. The research team at Amsterdam UMC, location VUmc, coordinated and supervised the implementation process. During the complete study period, pre- and in-hospital trauma care remained unchanged and were in line with the Dutch guidelines for the network of acute care (15). 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 on which this study is focused. The TTCM is a multidisciplinary and patient-centered transmural rehabilitation care model, in which a multidisciplinary hospital-based team guides a specialized network of primary and tertiary care trauma physiotherapists throughout the rehabilitation process of the patient. A more detailed description of the intervention can be found below.

The medical ethics committee of Amsterdam UMC, assessed and approved the multicenter trial (registered under number A2019.459 [2019.419]). The study was conducted in accordance with the Declaration of Helsinki. Before participation, all participants provided written informed.

Participants

Patients were eligible if they were aged 16 years and above, had one or more fracture(s) as a result of a trauma, and received medical treatment at an emergency department or were admitted to one of the participating hospitals. 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 were excluded. Please note that in contrast to the pilot study, patients rehabilitating in tertiary care were included as well.

Intervention condition

The TTCM is a multidisciplinary and patient-centered, well-structured rehabilitation care model, and consists of four interlinked components (Figure 1):

1) Intake and follow-up joint consultations by a multidisciplinary team at the outpatient clinic for trauma patients: During the trauma patients' outpatient visits, the trauma surgeon evaluates the bone and wound healing process and acts as the chief consultant. A hospital-based physiotherapist (HBP) assesses physical function and acts as a case manager throughout the rehabilitation process.
2) Coordination and individual goal setting: The hospital-based team coordinates the patients' rehabilitation process in primary (and sometimes tertiary care) by continuously defining individual treatment goals in close cooperation with the patient.
3) A network of specialized network physiotherapists (NPs): Patients are referred to the Dutch Network Trauma Rehabilitation, which consists of specifically trained NPs (www.traumarevalidatie.nl).
4) Secured email traffic between HBP and NPs: HBPs and NPs communicate rehabilitation goals and results through a secure email system throughout the patients' rehabilitation process.

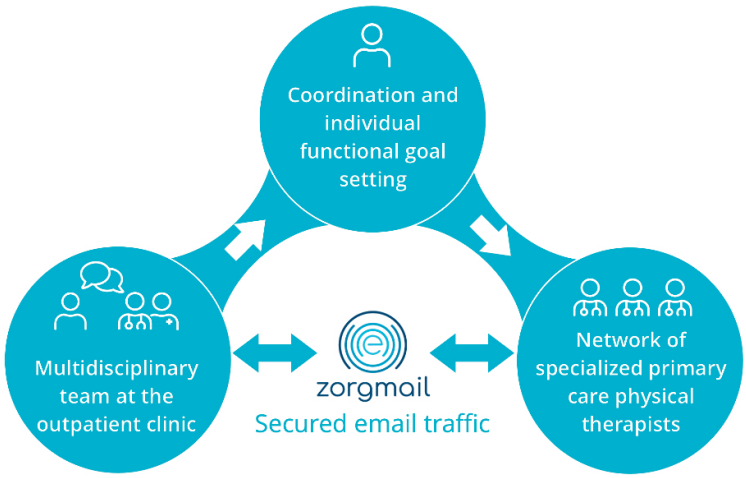

Figure 1 TTCM

Control condition

Control group patients received usual rehabilitation care as provided by the participating hospitals prior to the implementation of the TTCM. Usual care may slightly differ across hospitals, but most trauma surgeons performed post-clinical consultations individually. Based on their clinical judgment, patients were then referred to a physiotherapist in primary or tertiary care, but there was no standardized policy for these referrals, nor was there a highly structured network of specialized primary care trauma physiotherapists and communication between primary and secondary care was minimal (16).

Outcome measures
At baseline, various demographic and trauma-related characteristics (e.g., age, gender, medical history, Injury Severity Score [ISS], trauma type, time between trauma and first outpatient consultation), illness perceptions, and patient expectations (Somatic Pre-Occupation and Coping Questionnaire [SPOC Questionnaire]) (17, 18) were assessed. These characteristics were collected using online questionnaires, supplemented by data derived from electronic patient records.

Co-primary outcomes
Co-primary outcomes were generic and disease-specific quality of life (QOL). Co-primary outcomes were measured at baseline, 6 weeks as well as 3 and 6 months using online questionnaires.

Generic QOL was measured using the EQ-5D-5L, which consists of five questions representing five health dimensions (i.e., mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), all of which can be scored using five severity levels (i.e. mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). Using these data, utility values ranging from 0 ("equivalent to death") to 1 ("full health") were estimated using the Dutch tariff (19).

Depending on the diagnosis, disease-specific QOL was measured using one of the following four standardized Patient-Reported Outcome Measures:

- *Upper extremity*: QuickDASH DLV (disabilities of the arm, shoulder, and hand) (20, 21). The QuickDASH questionnaire consists of 11 items assessing symptoms and limitations of activities. The overall QuickDASH score ranges from 0 to 100, with higher scores indicating more limitations (Institute for work and health, 22).
- *Lower extremity*: Lower Extremity Functional Scale (23). The Lower Extremity Functional Scale (LEFS) is a questionnaire containing 20 questions about a person's ability to perform everyday tasks. The overall LEFS score ranges from 0 to 80, with higher scores indicating less significant limitations.
- *Multiple fractures and/or more locations*: Groningen Activity Restriction Scale (24, 25). 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 overall score of the GARS ranges from 18 to 72, with higher scores indicating more limitations in everyday activities.
- *Vertebral fractures*: The Roland Morris Disability Questionnaire (26, 27). The Roland Morris Disability Questionnaire (RMDQ) is a self-administered disability measure. The overall score of the RMDQ ranges from 0 to 24, with higher scores indicating more limitations in everyday activities.

As all of these questionnaires have different scales, an overall disease-specific QOL score was calculated by converting the overall scores of the aforementioned four questionnaires to a scale from 0 to 100 where higher scores representing less functional problems.

Secondary outcomes
All secondary outcomes were measured at baseline and after 3 and 6 months.

Patient-specific Functional Scale (PSFS): The Patient-Specific Functional Scale (PSFS) used to measure functional status is a self-reported, patient-specific outcome measure. Patients are asked to identify and prioritize three to five important activities that they are unable to perform or that they 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) (28). For the current preliminary analysis, the most important activity was analyzed.

Numeric pain rating scale (NPRS): The Numeric Pain Rating Scale (NPRS) is a subjective pain intensity measure. 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 (29).

Patient satisfaction (11-point NRS): Patient satisfaction was assessed using a one-item question about the patients' overall satisfaction with their treatment. Patient satisfaction was measured using an 11-point numeric rating scale ranging from 0 (very dissatisfied) to 10 (excellent).

Perceived recovery (7-point Global Perceived Effect Scale): Perceived recovery was measured using the Global Perceived Effect (GPE), comprising a question about patients' sense of being recovered, on a 7-point scale (30). The patients' answers to the questions were dichotomized into "successful recovered" and "not successfully recovered".

Patient-reported health based on physical functioning: The Patient-Reported Outcomes Measurement Information Systems are questionnaires about patient-reported health status, specifically focusing on physical functioning (PROMIS-PF 10a) and physical functioning of the upper extremity (PROMIS-PF-UE 7a) (31, 32). Choice of measurement of patient-reported health depends on trauma location:

- lower extremity/ vertebral fractures/ multiple fractures, more locations: patient-reported health status, specifically focusing on physical functioning (PROMIS-PF 10a physical functioning)
- upper extremity: patient-reported health based on physical functioning for upper extremities (PROMIS-PF-UE 7a upper extremity)

Note that we used the names PROMIS-PF 10a physical functioning and PROMIS-PF-UE 7a upper extremity for better readability in this manuscript.

After the total raw score for the measure has been calculated, the applicable score conversion table can be used to translate the total raw score into a T-score for each participant. The T-score rescales the raw score into a standardized score with a mean of 50 and a standard deviation (SD) of 10 (33).

Sample size calculation

To detect a difference in generic QOL 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 were needed per group, equaling a total of 644 patients.

Data analysis

Analyses were performed according to the intention to treat principle. Baseline characteristics were compared between the two groups using descriptive statistics. To handle the non-randomized nature of the study, propensity scores were calculated based on the patients' baseline characteristics that differed between groups at baseline, and those that were associated with the patients' baseline primary effect measure values (i.e. age, gender, BMI, smoking, medical history, educational level, ISS, coping) using the pscore package in STATA. Then, co-primary and secondary outcomes were analyzed using linear (for continuous outcomes) and logistic (for dichotomous outcomes) mixed models for repeated measurements at 6 weeks (co-primary outcomes), 3, and 6 months (co-primary and secondary outcomes). Both overall treatment effects during the complete duration of follow-up and treatment effects per time point (using time by treatment interactions) were estimated. Three different models were built; 1) a model with a two-level structure (i.e., patient, time) where the outcome's values was regressed upon the treatment indicator, the outcome's baseline value if available, and the propensity score; 2) a model with a three-level structure (i.e. patient, time, hospital) with the same dependent and independent variables as model 1, and 3) a model with a three-level structure (i.e. patient, time, hospital) with the same dependent and independent variables as model 1, but then on multiple imputed data. For this, data were imputed using Multivariate Imputation by Chained Equations and Predictive Mean Matching (MICE-PMM). In total, 10 imputed datasets were generated, all of which were analyzed as outlined above, after which their results were pooled using Rubin's rules (34). Please note that model 3 serves as the final model, whereas model 1 and 2 were run and presented to show the impact of the various model specifications on the study results.

The effects of interest are the overall effect of the TTCM over time, as well as the difference between groups at each time point (14). For general and disease-specific QOL, a between-group difference of 0.057 (35, 36) and 10% were assumed to be clinically relevant, respectively. P-value of <0.0025 and <0.05 was considered statistically significant for the co-primary and secondary outcomes, respectively. We accounted for multiple testing (i.e., the fact that this study has two co-primary outcomes) using the aforementioned α of 0.025 (37). If one of the co-primary outcomes showed a clinically relevant difference in favor of the

intervention, TTCM was considered effective. It should be noted, however, that all available outcome measurements were taken into account when interpreting the results. Analyses were performed using SPSS V.28.0 and STATA V.17.0.

RESULTS

Population

A total of 528 patients were included in the study, of which 322 patients in the control group and 206 patients in the intervention group. Among patients meeting the inclusion criteria, the most important reasons for not participating were "refusing to sign informed consent", and "no internet access/e-mail address" (Figure 2). Most baseline characteristics were similar between control and intervention group patients. However, patients in the intervention group were slightly older, 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 1). All of these characteristics were highly correlated with the patients' ISS, which was in turn used to estimate their propensity score. A total of 384 patients (73%) had complete effect data during the 6 months follow-up (Figure 2).

Adherence to the trial protocol

The sample size (n=528) was less than the intended 644, which was mainly due to the COVID-19 pandemic. This reduction in sample size can be attributed to several pandemic-related factors, such as staff shortages and staff changes in project management.

Table 1 Baseline characteristics of the study population

	Characteristics ***Mean (SD)* or *frequency (%)***	***Control group***	***Intervention group***	***All (n=528)***
Patient characteristics	N	322	206	528
	Age (years)	52.17 (17.47)	55.76 (15.97)	53.57 (16.98)
	Gender (male)	159 (46.2%)	100 (46.5)	242 (45.8%)
	Country of birth the Netherlands (yes) [n (%)]	290 (90.1%)	178 (86.4%)	468 (88.6%)
	Educational level			
	Low	203 (63%)	125 (60.7%)	328 (62.1%)
	Middle	74 (23%)	54 (26.2%)	128 (24.2%)
	High	45 (14%)	27 (13.1%)	72 (13.6%)
	Medical history: none (yes) [n (%)]	134 (41.6%)	93 (45.1%)	227 (43%)
	Smoking (yes) [n (%)]	53 (16.5%)	25 (12,1%)	78 (14.8%)
	Body Mass Index (self-reported weight/height^2)	25.84 (4.61)	25.99 (4.31)	25.89 (4.49)
	Personal injury claim (yes) [n (%)]	32 (9.9%)	12 (5.8%)	44 (8.3%)
	Basic and additional health insurance (yes) [n (%)]	239 (74.2%)	151 (73.3%)	390 (73.9%)
	SPOC Questionnaire (Somatic Pre-Occupation and Coping Questionnaire)	96.41 (20.05)	95.28 (20.0)	95.97 (20.02)
Pre-trauma mobility	Walking mobility >1km (yes) [n (%)]	294 (91.3%)	193 (93.7%)	487 (92.2%)
	Ability climbing stairs (yes) [n (%)]	312 (96.9%)	202 (98.1%)	514 (97.3%)
	Use of walking aids (yes) [n (%)]	10 (3.1%)	6 (2.9%)	16 (3%)
Fracture-related factors	Trauma type			
	Fall	125 (38.8%)	109 (52.9%)	234 (44.3%)
	Traffic	110 (34.2%)	59 (28.6%)	169 (32%)
	Other	35 (10.9%)	13 (6.3%)	48 (9.1%)

Table 1 Continued

	Characteristics *Mean (SD)* or *frequency (%)*	*Control group*	*Intervention group*	*All (n=528)*
	Sports	26 (8.1%)	21 (10.2%)	47 (8.9%)
	Work-related	17 (5.3%)	4 (1.9%)	21 (4%)
	Violence	9 (2.8%)	0	9 (1.7%)
	ISS (mean, SD, min-max)	5.07 (3.3, 1-34)	5.96 (4.4, 1-41)	5.4 (3.8, 1-41)
	Fracture region			
	Upper extremity	186 (57.8%)	112 (54.4%)	298 (56.4%)
	Lower extremity	115 (35.7%)	78 (37.9%)	193 (36.6%)
	Vertebral	8 (2.5%)	3 (1.5%)	11 (2.1%)
	Multitrauma	13 (4%)	13 (6.3%)	26 (4.9%)
Treatment-related factors	Admission hospital (yes) [n (%)]	107 (33.2%)	93 (45.1%)	200 (37.9%)
	Length of stay (days)	1.5 (3.68)	2.37 (5.1)	1.85 (4.3)
	Fracture treatment			
	Surgery (yes) [n (%)]	111 (34.5%)	115 (55.8%)	226 (42.8%)
	Weight-bearing policy[1]			
	full weight-bearing [n (%)]	63 (19.6%)	24 (11.7%)	87 (16.5%)
	partially weight-bearing [n (%)]	90 (28%)	23 (11.2%)	113 (21.4%)
	non weight-bearing [n (%)]	169 (52.5%)	158 (76.7%)	327 (61.9%)
	Time between trauma and first outpatient consultation (days)	15.59 (35.96)	19.77 (18.51)	19.23 (17.77)

[1] The weight-bearing policy after trauma is an aspect of treatment-related factors/fracture management and can involve a full, partial, or non-weight-bearing approach. For the upper extremity, for example, a partially weight-bearing approach may be wearing a sling.

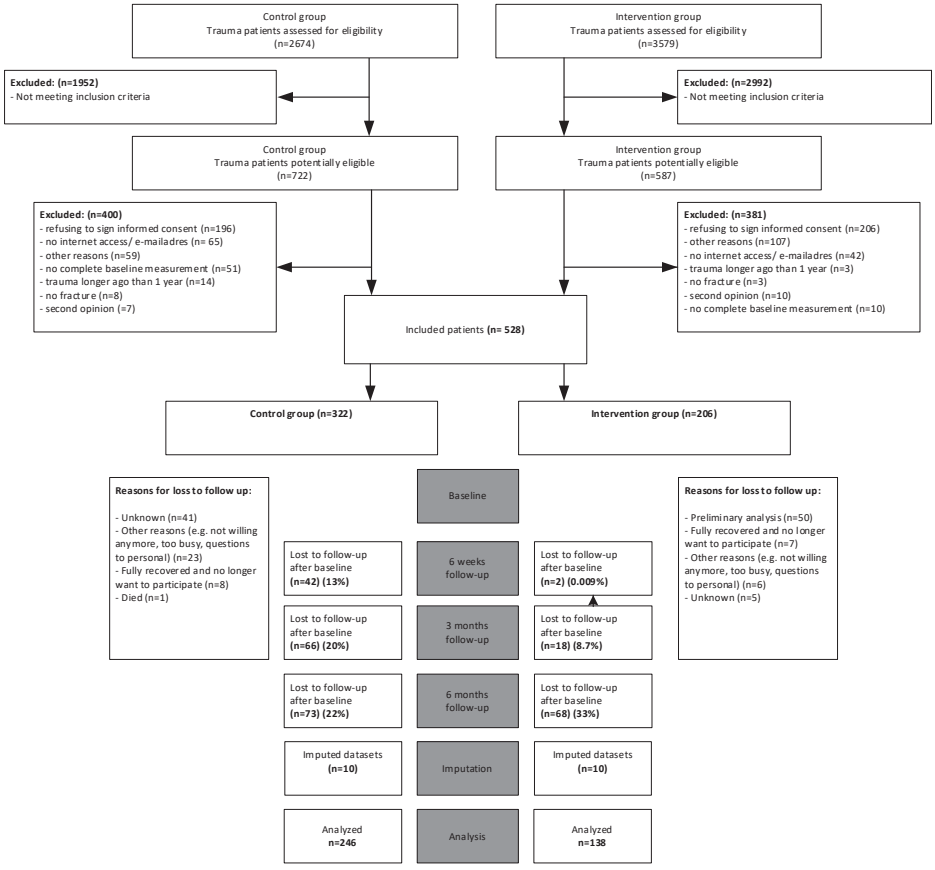

Figure 2 Flow diagram of participants in the study

Clinical effects

Co-primary outcomes

The overall effect between both groups during the *complete duration of the* 6 months of follow-up was neither statistically significantly nor clinically relevantly different. The final model (i.e., model 3 in Table 2) showed that generic QOL was statistically significantly higher in the intervention group compared with the control group *at 3 and 6 months*, but not at 6 weeks. Of the statistically significant differences, only that at 6 months (0.06; 97.5%CI:0.03 to 0.1) was also clinically relevant (i.e. ≥0.057). The final model (i.e. model 3 in Table 2) showed that disease-specific QOL was statistically significantly higher in the intervention group compared with the control group at 3 and 6 months, but not at 6 weeks. Both statistically significant differences were also clinically relevant (i.e., ≥2.6 [10% of the improvement in the control group]).

Secondary outcomes

Statistically significant *overall* between-group differences in favor of the intervention group were found for the secondary outcomes, patient satisfaction (0.2; 95%CI:0.03 to 0.40), and PROMIS-PF 10a physical functioning (1.5; 95%CI:0.03 to 2.89), but not for physical functioning (i.e. Patient-Specific Functional Scale) **(**-0.01; 95%CI:-0.33 to 0.31), pain (-0.4; 95%CI:-0.6 to -0.1), PROMIS-PF 7a upper extremities **(**0.3; 95%CI:-1.69 to 2.20), and self-perceived recovery (0.2; 95%CI: -0.01 to 0.5). Moreover, at some time points, statistically significant differences in favor of the intervention group were found for PROMIS-PF 10a physical functioning, patient satisfaction, and self-perceived recovery. For pain, statistically significant overall between-group differences and between-group differences at all of the separate measurement points were found in favor of the control group, but all of these differences were relatively small (for example -0.6; 95%CI: -1.0 to -0.2 at 6 months).

Table 2 Treatment effects for co-primary and secondary outcomes (statistically significant results are bold marked)

	Control group Mean (SD)	**Intervention group** Mean (SD)	**Treatment effect** MD (97.5% CI) Model 1 with a two-level structure (i.e., patient, time)	**Treatment effect** MD (97.5% CI) Model 2 with a three-level structure (i.e., patient, time, hospital)	**Treatment effect** MD (97.5% CI) Model 3 (mixed model on imputed dataset)
Co-primary outcomes					
Generic QOL (EQ-5D-5L)					
Overall effect			*0.02 (0.00 to 0.05)*	*0.02 (0.00 to 0.05)*	*0.02 (0.00 to 0.04)*
Baseline	*0.6 (0.3)*	*0.6 (0.3)*			
6 weeks	*0.8 (0.2)*	*0.7 (0.3)*	*-0.01 (-0.05 to 0.04)*	*0.00 (-0.05 to 0.04)*	*-0.01 (-0.04 to 0.03)*
3 months	*0.8 (0.2)*	*0.8 (0.2)*	*0.05 (0.00 to 0.09)*	***0.05 (0.01 to 0.09)***	***0.05 (0.001 to 0.07)***
6 months	*0.8 (0.2)*	*0.9 (0.1)*	***0.07 (0.03 to 0.11)***	***0.07 (0.03 to 0.11)***	***0.06 (0.03 to 0.10)***
Disease-specific HR-QOL (DS-HR-QOL, 0-100)					
Overall effect			*1.4 (-0.6 to 3.3)*	*1.4 (-0.4 to 3.3)*	*1.7 (-0.4 to 3.5)*
Baseline	*55.6 (24.5)*	*51.9 (25.4)*			
6weeks	*66.4 (21.1)*	*64.9 (21.9)*	*0.5 (-2.1 to 3.2)*	*0.5 (-2.3 to 3.4)*	*0.3 (-2.6 to 2.6)*
3 months	*71.1 (19.8)*	*72.7(19.2)*	*2.6 (-0.3 to 5.4)*	*2.6 (-0.3 to 5.5)*	***3.4 (0.2 to 5.3)***
6 months	*75.5 (18.6)*	*78.0 (15.8)*	***3.4 (0.3 to 6.5)***	***3.4 (0.3 to 6.6)***	***3.8 (0.9 to 6.7)***

Table 2 Continued

	Control group Mean (SD)	**Intervention group** Mean (SD)	**Treatment effect** MD (95% CI) Model 1 with a two-level structure (i.e., patient, time)	**Treatment effect** MD (95% CI) Model 2 with a three-level structure (i.e., patient, time, hospital)	**Treatment effect** MD (95% CI) Model 3 (mixed model on imputed dataset)
Physical functioning Patient-Specific Functional Scale (NRS 0-10)					
Overall effect			-0.07 (-0.4 to 0.3)	-0.09 (-0.4 to 0.2)	-0.01 (-0.33 to 0.31)
Baseline	7.3 (2.6)	7.5 (2.5)			
3 months	4.9 (3.0)	5.3 (2.8)	0.1 (-0.4 to 0.6)	0.1 (-0.4 to 0.6)	0.26 (-0.27 to 0.79)
6 months	4.3 (3.1)	4.0 (3.0)	**-0.5 (-1.0 to -0.02)**	-0.5 (-1.0 to 0.02)	-0.42 (-0.91 to 0.08)
Pain (NRS 0-10)					
Overall effect			**-0.3 (-0.6 to - 0.1)**	**-0.4 (-0.6 to -0.1)**	**-0.4 (-0.6 to -0.1)**
Baseline	4.5 (2.5)	4.5 (2.3)			
3 months	3.1 (2.5)	2.6 (2.1)	**-0.6 (-0.9 to - 0.2)**	**-0.6 (-0.9 to -0.2)**	**-0.4 (-0.8 to -0.1)**
6 months	2.5 (2.4)	2.2 (2.2)	**-0.5 (-0.9 to -0.2)**	**-0.5 (-0.9 to -0.2)**	**-0.6 (-1.0 to -0.2)**
Patient satisfaction (NRS 0-10)					
Overall effect			**0.2 (0.02 to 0.35)**	**0.2 (0.02 to 0.35)**	**0.2 (0.03 to 0.40)**
Baseline	7.9 (1.5)	7.9 (1.8)			
3 months	7.7 (1.6)	8.0 (1.7)	**0.3 (0.01 to 0.54)**	**0.3 (0.01 to 0.54)**	**0.3 (0.02 to 0.58)**
6 months	7.7 (1.8)	8.1 (1.8)	**0.4 (0.08 to 0.65)**	**0.4 (0.07 to 0.65)**	**0.4 (0.02 to 0.72)**

Table 2 Continued

	Control group Mean (SD)	**Intervention group** Mean t-scores (SE)	**Treatment effect** MD (95% CI) Model 1 with a two-level structure (i.e., patient, time)	**Treatment effect** MD (95% CI) Model 2 with a three-level structure (i.e., patient, time, hospital)	**Treatment effect** MD (95% CI) Model 3 (mixed model on imputed dataset)
Patient-reported health based on physical functioning for upper extremities (PROMIS-PF 7a upper extremity)					
Overall effect			0.8 (-0.60 to 2.18)	0.8 (-0.67 to 2.24)	0.3 (-1.69 to 2.20)
Baseline	33.0 (10.5)	30.5 (9.3)			
3 months	41.6 (11.5)	40.5 (9.7)	0.3 (-1.56 to 2.15)	0.3 (-1.59 to 2.20)	-0.5 (-4.0 to 3.04)
6 months	44.1 (10.7)	45.2 (9.8)	**2.3 (0.34 to 4.31)**	**2.4 (0.33 to 4.38)**	0.5 (-3.13 to 4.15)
Patient-reported health based on physical functioning (PROMIS-PF 10a physical functioning)					
Overall effect			-0.2 (-1.57 to 1.25)	0.1 (-1.36 to 1.61)	**1.5 (0.03 to 2.89)**
Baseline	33.2 (7.0)	32.2 (6.7)			
3 months	43.4 (9.1)	42.8 (8.5)	0.2 (-1.47 to 1.94)	0.3 (-1.39 to 2.09)	**3.3 (0.82 to 5.71)**
6 months	46.1 (9.8)	46.1 (8.2)	1.0 (-0.82 to 2.88)	1.2 (-0.71 to 3.04)	1.4 (-2.07 to 4.84)
Self-perceived recovery ***** (NRS 1-7) Success is 1 & 2 = "completely recovered" or "much improved"					
Overall effect			0.2 (-0.04 to 0.5)	0.2 (-0.04 to 0.5)	0.2 (-0.01 to 0.5)
Baseline	33.2% (107/322)	28.1% (58/206)			
3 months	73.4% (185/252)	79.5% (147/185)	**0.7 (0.07 to 1.4)**	**0.7 (0.06 to 1.4)**	**0.8 (0.08 to 1.4)**
6 months	80.9% (199/246)	87.7% (121/138)	**0.9 (0.07 to 1.7)**	**0.9 (0.1 to 1.7)**	0.8 (-0.05 to 1.6)

* SE= Standard Error on T-score metric

DISCUSSION

Main findings

Even though there were no statistically significant *overall between-group differences* for the co-primary outcomes generic and disease-specific QOL during the 6 month follow-up period, both were statistically significantly and - in most cases - clinically relevantly higher in the intervention group compared with the control group *at 3- and 6-months follow-up*. Of the secondary outcomes, only the overall between-group differences in pain, PROMIS-PF 10a, physical functioning, and patient satisfaction were statistically significant. Note that, in contrast to PROMIS-PF 10a physical functioning and patient satisfaction, statistically significant overall between-group differences and between-group differences at each follow-up were found in favor of the control group for pain. As for the latter, however, the differences were relatively small, for example, a between-group difference at 6 months of -0.6; 95%CI: -1.0 to -0.2. As the current study is only based on part of the data and 6-months instead of 9-months follow-up, further analyses are warranted, which will be done after the last follow-up measurement. The final results are expected to be available in 2024.

Interpretation of the preliminary results

The current findings suggest that patients who received the TTCM had a higher disease-specific and generic QOL at 3- and 6 months follow-up. Even though these findings are encouraging, it is important to exercise caution due to the various limitations of this preliminary analysis, including the shorter follow-up duration (i.e., 6 instead of 9 months) and relative incompleteness of the data. Hence, further analysis utilizing more complete and 9-month follow-up data is necessary.

If we compare our results at 6-month follow-up, they are in line with those of the pilot study by Wiertsema et al. (16), suggesting that TTCM had a bigger effect on generic and disease-specific QOL compared with usual care. We/one should bear in mind, however, that we analyzed our data using a mixed model and estimated the overall effect during follow-up. In the pilot study, however, we were only able to estimate the difference in effects at certain time points due to the lack of prospectively collected control group data. Moreover, the degree to which certain parts of the TTCM were implemented differed from the study of Wiertsema [2021], i.e., reimbursement of TTCM, accreditation of the network, exchange of patient information, and joint outpatient consultations were significantly lower in the present multicenter study. For example, in our study, outpatient trauma consultations were only provided jointly in ≤50% of the participating hospitals, and generally only for a limited proportion of the outpatient consultations and/or a limited period (38). This was not the case in the pilot study, where most outpatient consultations were provided jointly (39). This omission was largely due to the COVID-19 pandemic, which coincided with the implementation process and abruptly changed care priority and delivery, delaying others like the upscaling of the TTCM (40, 41). Please note that the current study also experienced problems due to the COVID-19 pandemic. To illustrate, funding negotiations for the HBP at

the joint outpatient clinic for trauma patients were temporarily halted in the Netherlands (38, 42), training and network sessions had to be organized online, resulting in less personal interactions (43, 44), and fewer trauma patients visited the outpatient clinic.

Strengths and weaknesses of the study

The study population in our research encompassed a wide spectrum of trauma patients, with ISS ranging from 1 to 41. This is a notable strength of our study, as most previous studies investigating HR-QOL and functional outcomes after trauma have focused only on major trauma patients with ISS>16 (45) or specific types of injuries, such as hip fractures (46). By including a diverse range of trauma patients, our results are applicable to mild, moderate, and severe trauma cases, making them more generalizable. Another strength of our study is the use of a comprehensive measurement strategy that captures the complete impact of trauma on function, disability, and health, encompassing all relevant domains of the International Classification of Functioning, Disability, and Health (47). This approach allows for a more comprehensive and accurate assessment of the outcomes of interest, providing a more robust and comprehensive picture of the effects of trauma on patients' well-being. In order to minimize social desirability bias and enhance the internal validity of the data, we employed self-administration of questionnaires in our study, combined with information extracted from electronic patient records of the hospitals. This approach reduces the potential for bias that may arise from social desirability or interviewer influence and strengthens the reliability and validity of our findings by utilizing objective data from electronic patient records, specifically for the baseline measurement.

The study also had several limitations. Firstly, the sample size (n=528) was lower than the a priori calculated required sample size (n=644), which was mainly due to the COVID-19 pandemic. This may have limited our ability to detect significant effect differences between the groups; however, given the results, this is likely to have had a negligible impact. Additionally, at the time of the preliminary analysis, a substantial proportion of patients had incomplete effect data, because the follow-up measurements were still ongoing. To address this, a mixed model was performed on a multiply imputed dataset. This could, however, have introduced potential bias, as the imputed data may not accurately capture the true values of the missing measurements, leading to potential under- or overestimation of the results. We are therefore continuing follow-up measurements and will report the final analysis in a peer-reviewed scientific journal in the near future. Another limitation of the study is the relatively short follow-up period of 6 months, which may not be sufficient for capturing the full recovery trajectory of trauma injuries, particularly fractures, which can have a natural recovery component lasting longer than half a year (48, 49). However, the mean between-group difference in disease-specific QOL favored the intervention group at 6 months, and the final analysis will include 9 months follow-up data to provide a more comprehensive assessment of the intervention's effects. Furthermore, the study utilized propensity scores as a method to address confounding; however, propensity scores have inherent limitations as well. They rely on the assumption of no unmeasured confounding, which may not

always be valid. Moreover, if not properly implemented or validated, propensity scores can introduce selection bias into the study results, potentially impacting the internal validity of the findings (50). Therefore, caution should be exercised when interpreting the results.

CONCLUSION

Even though there were no statistically significant *overall* between-group differences for the co-primary outcomes generic and disease-specific QOL during the 6 month follow-up period, both were statistically significantly and clinically relevantly higher in the intervention group compared with the control group *at 3- and 6-months follow-up*. Caution is advised when interpreting these results, and a more comprehensive analysis with more complete, and 9-month follow-up data is necessary to validate the current effectiveness results of the TTCM.

Acknowledgments
We thank all trauma patients who participated in the study. Furthermore, we thank all local research assistants, physiotherapists, and trauma surgeons for their willingness to change their approach.

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CHAPTER 4

Barriers and facilitators associated with the upscaling of the Transmural Trauma Care Model: a qualitative study

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BMC Health Serv Res. 2024;24(1):195.

ABSTRACT

Background: To assess the barriers and facilitators associated with upscaling the Transmural Trauma Care Model (TTCM), a multidisciplinary and patient-centred transmural rehabilitation care model.

Methods: Semi-structured interviews were conducted with eight trauma surgeons, eight hospital-based physiotherapists, eight trauma patients, and eight primary care physiotherapists who were part of a trauma rehabilitation network. Audio recordings of the interviews were made and transcribed verbatim. Data were analysed using a framework method based on the "constellation approach". Identified barriers and facilitators were grouped into categories related to structure, culture, and practice.

Results: Various barriers and facilitators to upscaling were identified. Under structure, barriers and facilitators belonged to one of five themes: "financial structure", "communication structure", "physical structures and resources", "rules and regulations", and "organisation of the network". Under culture, the five themes were "commitment", "job satisfaction", "acting as a team", "quality and efficiency of care", and "patients' experience". Under practice, the two themes were "practical issues at the outpatient clinic" and "knowledge gained".

Conclusion: The success of upscaling the TTCM differed across hospitals and settings. The most important prerequisites for successfully upscaling the TTCM were adequate financial support and presence of "key actors" within an organisation who felt a sense of urgency for change and/or expected the intervention to increase their job satisfaction.

BACKGROUND

Major trauma is one of the leading causes of death and disability (1, 2). Typically, trauma patients are relatively young and the sustained injuries not only adversely affect health and wellbeing (3), but also result in a high number of disability-adjusted life years (DALYs) (4-6). In addition to the human impact of traumatic injuries, their economic impact can also be substantial (7). For example, an estimate of the total societal cost of traumatic injuries in the Netherlands in 2017 was €3.5 billion (8, 9). Increased levels of absenteeism and lost productivity while being at work (i.e., presenteeism) account for the majority of these costs (10).

In recent decades, the optimisation of pre- and in-hospital trauma care has led to a notable decline in trauma-related morality rates and evolved to such an extent that further reductions in mortality are expected to be marginal (11). As such, the focus of both trauma care and research has shifted towards improving the rehabilitation process (2, 12-14). To illustrate, Brooke et al. (15) compared the effect of early consultation with a rehabilitation physician and pain management, physiotherapy, psychological treatment, and further specialist referrals (i.e., early rehabilitation intervention) with usual care in patients who were in motor vehicle accidents. The findings showed that early rehabilitation intervention resulted in significant improvements in pain and earlier return to previous activities. Bouman et al. (16) investigated the effect of coordinated care by a trauma surgeon and a rehabilitation physician (i.e. so-called fast-track rehabilitation) for patients with multiple trauma. The results showed that fast-track rehabilitation led to faster recovery in functional status during six months of follow-up.

To improve the rehabilitation process of patients with traumatic injuries in the Netherlands, the Transmural Trauma Care Model (TTCM) was developed. The TTCM consists of the following four features: 1) A joint outpatient consultation with a trauma surgeon and a hospital-based physiotherapist (HBP); 2) Rehabilitation care provided by a physiotherapist belonging to network of specialised primary and tertiary care trauma physiotherapists (referred to as network physiotherapist [NPs] in the Dutch setting); 3) Continuous alignment of treatment goals between the multidisciplinary hospital team and specialised NPs, and 4) Encrypted and continuous email contact between HBPs and NPs throughout the patients' rehabilitation process.

A pilot study showed that implementing the TTCM in a Dutch Level-1 trauma centre was feasible, had the potential to improve patient outcomes and patient satisfaction, and may reduce costs (17, 18). However, two key challenges were ensuring that information sharing between primary care (e.g., general practitioners and physiotherapy practices) and secondary care (e.g., hospital-based care services) providers was consistent and timely, and funding for the HBPs was arranged. Based on these findings, the original TTCM was updated and recently implemented in a larger number of hospitals with the aim of evaluating

TTCM's effectiveness and cost-effectiveness (19). This process of expanding and replicating an innovative pilot project in more and different hospitals is known as "upscaling", and is a complex process that depends heavily on context (20-23). Currently, it is not known if the TTCM can be implemented successfully in Dutch hospitals that were not involved in its initial development. Therefore, this study aims to assess the barriers and facilitators associated with successful upscaling TTCM in the Netherlands.

METHODS

Study design and setting

This study was conducted alongside a multicentre trial that aims to evaluate the effectiveness and cost-effectiveness of TTCM in nine Dutch hospitals (19). The research team at Amsterdam UMC, location VUmc, coordinated and supervised the implementation of the TTCM at each site. The implementation process involved using procedures tailored to each hospital's respective context (24, 25). The methods for conducting the current process evaluation were based on those described in Wiertsema et al. (18) and the guideline for evaluating implementations in healthcare (26). The study was reported according to the COnsolidated criteria for REporting Qualitative research (COREQ) checklist (27) (Supplementary file 1).

Participant recruitment

Participants were purposively selected from the nine hospitals involved in the aforementioned multicentre trial. The relevant stakeholders that were represented included trauma surgeons, NPs, HBPs, and patients. Three researchers (JR/SW/JvD) were responsible to recruiting participants. The recruitment procedure involved contacting potential participants via email or telephone, explaining the study purpose and procedures, and inviting them to participate in the study. Care was taken to include healthcare providers and patients who were positive about the TTCM as well as those who were not. If potential participants were willing to participate and gave informed consent, an in-person interview was scheduled at a time and location convenient to the participants. An interview by video conferencing was also an option.

Data collection

Data were collected using semi-structed interviews. These interviews were conducted by a two- or three-person team, consisting of a (3rd-year) student enrolled in a Bachelor of Health Sciences degree program at the VU University and one or two researchers (JR/RO/JvD/SW). The professional and academic backgrounds of the researchers were as follows: clinical epidemiology (JR/RO), human movement sciences (JvD/SW), physiotherapy (JR/SW/RO), or health technology assessment (JvD). Two researchers (JvD/SW) were experienced in conducting qualitative research (19, 28, 29) and all four student interviewers had successfully completed coursework on qualitative research and interviewing methods. Before the formal interviews were conducted, all interview team members were trained on procedures.

In sum, interviews were guided by a topic list and an audio recording was made (30). Topic lists were based on the literature, a theoretical framework (see section on data analysis), and previous experience (18). During the interview phase of the study, the topic list was adjusted based on knowledge and experience from previous interviews and adapted to the stakeholder in question (28)(Supplementary file 2). The interview procedure involved one researcher leading the interview, while the other(s) probed areas for further questioning, kept track of the topic list, and made notes. Researcher objectivity was optimised by keeping a reflective diary (29). To enhance the data's trustworthiness, a member check was performed after each interview by sending the participants a brief summary of the interview and its transcript (31). The interviews were conducted between April 2022 and August 2022.

Data analysis

Descriptive statistics were used to analyse participant characteristics (i.e., age, gender, stakeholder, and if applicable, years of professional experience, experience with TTCM [yes/no], type of injury, and time since discharge) and the degree to which certain parts of the TTCM were implemented/upscaled (i.e., reimbursement of the HBP, joint outpatient consultations, the exchange of patient information, accreditation of the network). For this, the following variables were described and compared between university medical centres and supra-regional hospitals: reimbursement of the HBPs (i.e., completely, partially, or not), care providers acted as a team (i.e., completely, partially, or no), information exchange between primary and secondary care (i.e., yes/no), and accreditation (i.e., was arranged for the network activities, yes/no).

Data from the interviews were analysed using a framework method, a hierarchical, matrix-based method for ordering and synthesising qualitative data (32). Our theoretical framework was based on the "constellation approach", which assumes that a healthcare system consists a set of interrelated practices and relevant, interrelated, structuring elements that define and fulfill a function in the more extensive system as in a constellation (22). Within a constellation, there is a continuous interaction between the "structure, culture and practice triplet" (Figure 1). A more detailed description of the constellation approach can be found in Supplementary file 3.

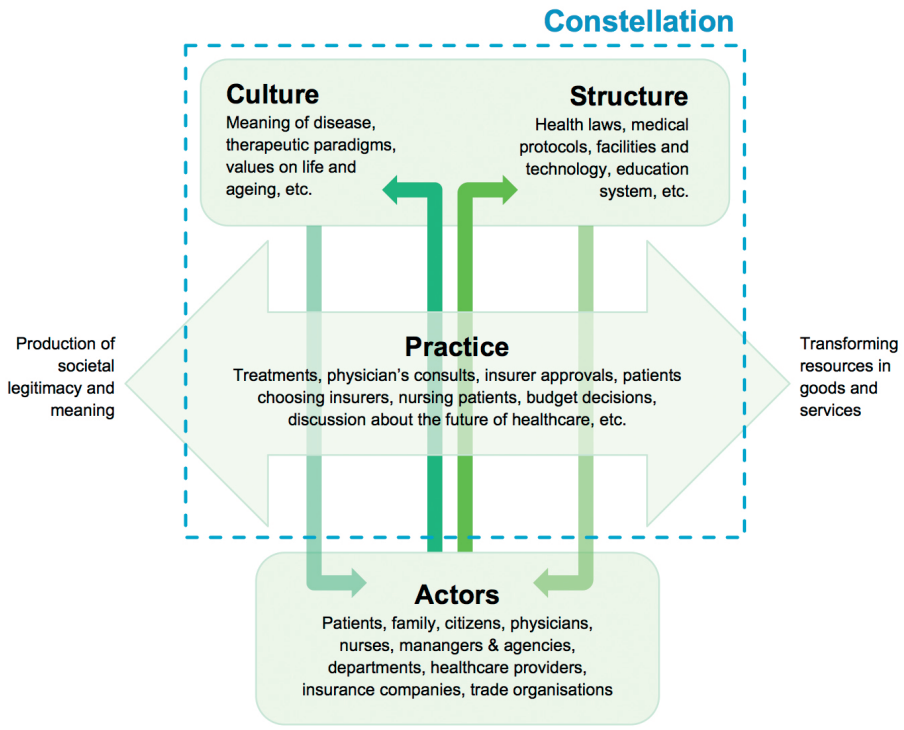

Figure 1 The interaction between the three elements of the 'structure culture and practice triplet' within a constellation (22).

The applied framework method consists of seven steps. First, we transcribed the recorded interviews verbatim (IE/RM/AG/JK). Second, we familiarised ourselves with the content in the interviews by listening to the audio recordings and rereading the transcripts (IE/RM/AG/JK/JR). Third, we labelled text fragments relevant to the research question by relevant codes (open coding)(IE/RM/AG/JK and JR). Fourth, we developed a working analytical framework by grouping codes according to structure, culture, and practice categories of the constellation approach (IE/RM/AG/JK/JR). We developed final codes by applying an iterative process of refining through discussion until the criterion of saturation (i.e., no novel codes emerged from subsequent iterations) was met (JR/RO/JvD). Our approach to identifying themes and codes was both deductive and inductive: we used themes and codes defined by Wiertsema et al. (18) as a starting point (deductive), while new themes and codes were generated from the data (inductive). Fifth, working in pairs, we systematically reread each transcript, highlighted each meaningful text passage, and selected and attached an appropriate code from the final analytical framework (IE/RM/AG/JK/JR/JvD). Sixth, we charted the data by generating a framework matrix in which data were summarised by category and stakeholder group, categorised into the matrix, followed by adding illustrative quotes from participants to the matrix (IE/RM/AG/JK/JR). Lastly, we used the framework matrix to interpret the data together with the interview/coding notes. Two researchers (JR/

JvD) assessed the "value" of the participants' statements based on the intensity, frequency, persuasiveness, and contrast with which they were made. To ensure rigour and credibility, two other researchers (SW/RO) reviewed the generated matrix and checked whether the selected quotes were relevant to the themes. Disagreements were resolved by discussion. All steps were conducted using word-processing software. Quotes were translated from Dutch to English by an English native speaker and were edited slightly to make them more readable without losing their meaning.

RESULTS

Participants and setting

A total of 33 stakeholders were invited to participate; however, one trauma surgeon declined the invitation due to limited availability. In the end, 32 interviews (31 via Zoom/ Microsoft Teams; one in-person) were conducted with eight trauma surgeons, eight NPs, eight HBPs, and eight patients. Five (63%) of the trauma surgeons, seven (88%) NPs, and four (50%) HBPs worked at a university medical centre. Six patients (75%) were treated at a university medical centre. The healthcare providers' professional experience ranged from 2 to 40 years (mean=11.78; SD=10.09) and their experience with the TTCM ranged from 1 to 54 months (mean=15.19; SD=11.13)(Table 1).

Barriers and facilitators

Stakeholders shared the belief that the TTCM held the potential to improve both the quality and efficiency of trauma rehabilitation. Nonetheless, various barriers and facilitators associated with the upscaling of the TTCM were identified for each category of the constellation approach and are discussed below. Similarities and differences between the various stakeholders also were observed. An overview of all themes, sub-themes, and illustrative quotes are presented in Table 3.

Of the participating hospitals, one had successfully arranged reimbursement for the HBP at the outpatient trauma clinic, three had partially arranged it, and five had not made any arrangements for reimbursement. Additional findings on the extent to which the TTCM was implemented are summarised in Table 2.

Table 1 Characteristics participants

Gender	Age (years)	Professional experience (month)	Experience TTCM (month)	Affiliation with one of the participating University Medical Centers or supra-regional hospitals	Stakeholder	Kind of injury	Time since discharge (month)
female	26	0- 5	20-25	supra-regional hospital	HBP	not applicable	not applicable
male	30	0- 5	20-25	University Medical Center	HBP	not applicable	not applicable
female	41	10-15	30	supra-regional hospital	HBP	not applicable	not applicable
male	25	0- 5	10-15	University Medical Center	HBP	not applicable	not applicable
male	63	40-45	5-10	University Medical Center	HBP	not applicable	not applicable
female	29	5-10	15-20	supra-regional hospital	HBP	not applicable	not applicable
female	45	20-25	15-20	University Medical Center	HBP	not applicable	not applicable
female	25	0- 5	30-35	supra-regional hospital	HBP	not applicable	not applicable
male	47	10-15	5-10	supra-regional hospital	trauma surgeon	not applicable	not applicable
male	53	15-20	15-20	University Medical Center	trauma surgeon	not applicable	not applicable
male	37	0- 5	15-20	University Medical Center	trauma surgeon	not applicable	not applicable
male	38	5-10	5-10	supra-regional hospital	trauma surgeon	not applicable	not applicable
male	38	5-10	15-20	University Medical Center	trauma surgeon	not applicable	not applicable
male	50	10-15	5-10	University Medical Center	trauma surgeon	not applicable	not applicable
male	39	5-10	0-5	supra-regional hospital	trauma surgeon	not applicable	not applicable
male	39	0- 5	15-20	University Medical Center	trauma surgeon	not applicable	not applicable
male	65	not applicable	not applicable	University Medical Center	patient	Collarbone fracture and torn tendons by making a rollover	0-5
female	55	not applicable	not applicable	supra-regional hospital	patient	Both wrists fractured, both sides radius and ulna fractured by slipping on a frozen puddle	5-10

Table 1 Continued

Gender	Age (years)	Professional experience (month)	Experience TTCM (month)	Affiliation with one of the participating University Medical Centers or supra-regional hospitals	Stakeholder	Kind of injury	Time since discharge (month)
female	60	not applicable	not applicable	University Medical Center	patient	Fractured shoulder/upper arm due to slipping	0-5
male	54	not applicable	not applicable	University Medical Center	patient	Fractured left fibula and right shoulder	0-5
male	59	not applicable	not applicable	University Medical Center	patient	Fall with fracture of the back part of the foot	5-10
male	48	not applicable	not applicable	supra-regional hospital	patient	Right shoulder fracture due to skiing at low speed	0-5
male	48	not applicable	not applicable	University Medical Center	patient	Six broken ribs, a broken wrist, a broken hip, and a broken tibia plateau due to a bike accident	5-10
male	67	not applicable	not applicable	University Medical Center	patient	Broken little finger due to black out and fall on a grate	0-5
male	50	25-30	10-15	supra-regional hospital	NP	not applicable	not applicable
male	38	10-15	5-10	University Medical Center	NP	not applicable	not applicable
male	35	5-10	10-15	supra-regional hospital	NP	not applicable	not applicable
male	50	25-30	50-55	University Medical Center	NP	not applicable	not applicable
male	29	5-10	10-15	University Medical Center	NP	not applicable	not applicable
male	54	30-35	10-15	supra-regional hospital	NP	not applicable	not applicable
female	31	5-10	10-15	University Medical Center	NP	not applicable	not applicable
female	49	10-15	5-10	supra-regional hospital	NP	not applicable	not applicable

Table 2 Degree of implementation

Participating hospital and affiliated networks	Complete reimbursement of the HBP at the outpatient trauma clinic	Partial reimbursement of the HBP at the outpatient trauma clinic	No reimbursement of the HBP at the outpatient trauma clinic	Completely 'Acting as a team' at the outpatient clinic for trauma patients'	Partially 'Acting as a team' at the outpatient clinic for trauma patients'	No 'Acting as a team' at the outpatient clinic for trauma patients'	Exchange of patient information/data between the networks and hospitals (and vice versa) arranged	Accreditation of network activities is arranged
University Medical Centers	0/4	2/4	2/4	1/4	1/4	2/4	2/4	1/4
Supra-regional hospitals	1/5	1/5	3/5	0/5	2/5	3/5	2/5	2/5

Table 3 Facilitators (F) and barriers (B) expressed by care providers and patients regarding the implementation of the TTCM, related to structure, culture and practice. Quotes are from trauma patients (P), trauma surgeons (T), hospital-based physiotherapists (HBP), and network physiotherapists (NP)

Level	Theme	Subtheme	Facilitator	Barrier	Stakeholders	Illustrative quote
Structure	Communication structure	Encrypted email system	Use of an encrypted email system between hospitals and network practices	Electronic patient records in hospitals and network practices are often incompatible	· Trauma surgeons · Hospital-based physiotherapists · Network physiotherapists	B: 'The problem are the electronic patient record systems. They aren't communicating with each other. That's where the problem lies.' (R17, NP)
						B: 'I'm not sure why exactly, but I think my emails from ZorgDomein are not being received.' (R24, NP)
						F: 'It's of course ideal for the network that you can simply send it digitally and securely.' (R13, HBP)
			Use of a standardized template for the encrypted email	Standardized template is not implemented in the appropriate software	· Hospital-based physiotherapists · Network physiotherapists	B: 'There are still some difficulties. Initially, the communication was supposed to be via e-mail, but there still seem to be some issues. I believe it's being run by the hospital, but the system isn't fully functional yet.' (R19, NP)
						F: 'It's a standardized list that we fill in, which is very nice because it's faster and easier. We don't have to rush through things. In principle, you can send it in straight away. The process costs you very little time.' (R12,HBP)

Table 3 Continued

Level	Theme	Subtheme	Facilitator	Barrier	Stakeholders	Illustrative quote
				(Changes in) dates and times of the patients' outpatient appointments are not automatically communicated to the NP/HBP	· Network physiotherapists	B: 'It does cause some stress or [extra] work because we have to keep track of the patients' outpatient arrangements or when they need to go for a checkup. And then you still have to write a transfer report.' (R23, NP)
	Financial structure	Reimbursement	Reimbursement for the HBP at the outpatient clinic for trauma patients has been arranged	Reimbursement for the HBP at the outpatient clinic for trauma patients has not been arranged	· Trauma surgeons · Hospital-based physiotherapists	B: 'Look, one has to pay. It's all about budgeting and whether the department says it won't reimburse or pay for it. It has nothing to do with a lack of space. I think it's really a matter of finances.' (R5, T)
						F: '… things started in November [2021] [start implementation phase February 2021], when all financing had been arranged. That's when we launched the outpatient clinic.' (R12, HBP)
	Physical structures and resources	Availability of rooms and/or computers	Sufficient consultation rooms available	Insufficient consultation rooms available	· Trauma surgeons · Hospital-based physiotherapists	F: 'Well, the clinic is so big and has so many rooms available that's not a problem.' (R13, HBP)
						B: 'It would be more helpful if they [HBP] were there with us. Only in terms of actual rooms, there's no physical space available. So that's, of course, a pity. Yes, that's a problem at our hospital, in my opinion. This must improve if you want to get the most out of it.' (R4, T)
				Too few computers available	· Hospital-based physiotherapists	B: 'We can't type at the same time as the doctor because they're often behind the computer. So, we often have to do that on the side (after the consultation). This can be quite time-consuming.' (R14, HBP)
	Rules and regulations		Patients are free to choose their care providers	The lack of guarantee to a high number of referrals for the network physiotherapists	· Trauma surgeons · Network physiotherapists · Patients	B: 'But we ended up training so many therapists in [name of city]. But if you compare the number of patients per trained therapist in [name of city], I think it's [referrals] very little.' (R21, NP)
						F: 'No, just unrestrained. I didn't at all feel controlled or anything.' (R32, P)

Table 3 Continued

Level	Theme	Subtheme	Facilitator	Barrier	Stakeholders	Illustrative quote
						F: '… the patient can choose a physiotherapist himself.' (R4, T)
				Benchmark (a regulatory tool) limits the number of treatments	Network physiotherapists	B: 'Yes, in some cases I'd prefer to see certain people three times a week. But I don't because my treatment index limits what I can offer.' (R18, NP)
				Reimbursement through the basic insurance package is limited	· Network physiotherapists	B: 'One thing that's sometimes inconvenient is that the health insurance policy only covers treatment lasting half a year when there are cases when you really do need more time.' (R24, NP)
						B: 'If you don't have supplementary insurance, you'll have to pay for the first twenty treatments. And if the initial phase includes treatments at home, then this can run up to around 40 euros per treatment. So, after the €285 deductible excess, you'd have to pay an additional €800, more or less. For some people, that's a lot of money. Occasionally people say, well, I'll use my supplementary insurance, and I'll see what happens. That also happens. And of course this, well… sometimes this, unfortunately, has an impact on the initial goal or the recovery process.' (R18, NP)
	Organisation of the network	Accreditation		Accreditation of the network activities has not been arranged	· Network physiotherapists	B: 'The meetings have yet to be accredited, so at the moment, it's completely voluntarily.' (R21, NP)
		Training and education	Being part of the network is free of charge	Training for the NPs is a prerequisite for joining the network and costs money (e.g. because they had to close the practice)	· Network physiotherapists	B: 'The only investment we had to make is to take a course… [I] watched some presentations by trauma surgeons. I think it cost more than six hundred euros. And the annoying thing was, this wasn't possible during the weekend, so I also had to take three days off. So I also lost three days' revenue because I had to close [my practice] for three days.' (R17, NP)
						F: 'No, no, the only investment we had to make is that we had to take a course.' (R17, NP)

Table 3 Continued

Level	Theme	Subtheme	Facilitator	Barrier	Stakeholders	Illustrative quote
			The fact that the training was online due to the Covid-19 pandemic made participating more feasible from a logistical perspective	The fact that the training was online due to the Covid-19 pandemic resulted in fewer possibilities for personal interaction	· Network physiotherapists	F/B: 'Everything took place online, so it was all a bit detached and impersonal during this Corona time. I think this was a plus, especially considering the travel time to the north of the country. But if you want more interaction, I think one should arrange live or face-to-face meetings.' (R18, NP)
			The duration of the training was good	The training could have been shorter	· Network physiotherapists	B: 'As far as I am concerned, the training could easily have been completed in two days.' (R17, NP)
						F: 'Yes, I thought the duration [of the course] was okay. I think three days was in itself good as a basis.' (R18, NP)
			Content of the training was of added value for the treatment of patients with trauma	Training lacked some topics/content relevant to the treatment of trauma patients	· Network physiotherapists	B: 'Maybe the psychological aspect of the trauma process could also be looked at a little more. This doesn't always receive the same amount of attention.' (R20, NP)
						B: 'My biggest problem was that I found the second training quite bad, to be honest. This was because there was a lot of overlap between what the various doctors said.' (R22, NP)
						F: 'Yes, to some degree. You learn to look more critically at things, especially at the burden you may be placing on your patients. So in this sense, certainly.' (R17, NP)
		Website	Having an appropriate and up-to-date website	More information about the NPs (e.g. expertise) on the website would be useful	· Patients	B: 'It would be useful to provide a description of the specialties of the physiotherapists on the list that's handed out.'(R25, P)
Culture	Commitment	Commitment at the hospital	High intrinsic motivation of TTCM teams and colleagues of other relevant departments (e.g.: trauma surgery, rehabilitation medicine)	Low intrinsic motivation of TTCM teams and colleagues of other relevant departments (eg: traumasurgery, rehabilitation medicine)	· Hospital-based physiotherapists	B: 'If they can tackle it at the front-end, so to speak so that also my colleagues [could be involved] and not just me. This way, it will also 'come to life' more, also in the department. I think this is one area where we could improve.' (R10, HBP)

Table 3 Continued

Level	Theme	Subtheme	Facilitator	Barrier	Stakeholders	Illustrative quote
						B: 'We have a surgeon who is very enthusiastic about it. But he communicated very little about it with other surgeons [from other departments].' (R9, HBP)
						B: '… it's a logistical issue involving your work, so to speak. You have to take, well, your colleagues have to grant you the space to take the time you need to be there.' (R11, HBP)
						F: 'I've noticed that if you build something together from scratch [network], you're inclined to make sure it's a success; maybe just take those extra steps, call again, or send an e-mail or describe things in more detail…' (R10, HBP)
		Commitment at the network	High intrinsic motivation of the participating network physiotherapists to be part of a network	Low intrinsic motivation of the participating network physiotherapists to be part of a network	· Network physiotherapists	B: 'Honestly, I feel I need to say that… well, many people currently involved in the trauma network didn't join because they are interested in trauma patients. They seem more interested in just being part of a network.' (R22, NP)
						F: 'You have a group of therapists who are motivated to do something with it. Otherwise, you wouldn't follow the training.' (R21, NP)
	Acting as a team	Contact trauma surgeons and hospital-based physiotherapists	Care providers at the outpatient clinic act as a team during the joint consultations	Care providers work separately from each other during the outpatient consultations	· Trauma surgeons · Hospital-based physiotherapists · Patients	B: 'So, three times people [the trauma surgeon and the HBP] came by, and I just sat there alone in that room, and that felt strange… […] they each came by and sent the other over, but they never visited me at the same time. Well, I just sat in that chair and wondered: 'What now?'' (R26, P)
						B: 'We don't have fixed days when we're present at the trauma clinic because the surgeons don't want us in the room with them. So yes, we have a separate room.' (R9, HBP)

Table 3 Continued

Level	Theme	Subtheme	Facilitator	Barrier	Stakeholders	Illustrative quote
						F: 'It was a shared effort. The surgeon explained what had taken place and what he had done [during the surgery], and the physiotherapist indicated what I can do. Of course, there was also the treatment by another physiotherapist affiliated with the trauma [network].' (R29, P)
						F: '... Yeah, as colleagues among colleagues, it all ran very smoothly. There just didn't seem to be any [professional] borders getting in the way.' (R12, HBP)
						F: 'And I also like is that you immediately have more eyes, and they looked at them [the trauma patients] with a slightly different view. Look, we do a trick during the operation, then our work is done for the most important part. So in that.... we are also very often dependent on the physiotherapist's work.' (R4, T)
			Awareness of responsibilities, leadership, and professional boundaries: care providers at the outpatient clinic (trauma surgeon and HBP) take professional boundaries into account		· Trauma surgeons	F: 'So, there's this patient where I still have to look at the wound to see if the fracture isn't healing properly yet, and the physiotherapist then takes a bit of a step back. So it's clear to us what our responsibilities are.' (R2, T)
		Contact between network and hospital team	The possibility of low-threshold contact between network and hospital team	Inconsistent feedback loop between network and hospital team	· Trauma surgeons · Hospital-based physiotherapists · Network physiotherapists · Patients	B: 'Sometimes, the feedback sent from primary care to us is a bit lacking. And, of course, we [only] see what takes place at the outpatient clinic. So, I don't know how people perform their exercises at home, and I don't always know if what people tell me in the doctor's office is the actual truth. This is why I think feedback is so important. This is where we should establish a smoother or better feedback loop.' (R3, T)
						F: 'The advantage of having a physiotherapist is that you can just contact them, and they can then easily contact the trauma surgeon.' (R20, NP)

Table 3 Continued

Level	Theme	Subtheme	Facilitator	Barrier	Stakeholders	Illustrative quote
						F: 'It's easier when the physiotherapist [HBP] is there because they can then take over that task, thus bridging the gap in communication.' (R1, T)
						B: 'Only what I understood from my physiotherapist. He had questions regarding certain pains I have at the moment. But these haven't been answered yet. It's been two weeks now, and I have no explanation for this yet.' (R29, P)
						F: 'The times I was in contact with them were very pleasant. We could just talk to each other, as colleagues. So, I think the cooperation is very balanced.' (R23, NP)
						F: 'I think it's a big plus for patient satisfaction or patient friendliness.' (R4, T)
	Quality and efficiency of care	Contact between care providers and patients	Care providers think that the TTCM, which amongst others, improved the level of contact between different care-provides, enhances the quality and efficiency of care		· Trauma surgeons · Hospital-based physiotherapists · Network physiotherapists	F: 'I think that good collaboration between primary and secondary care can reduce that kind of risk, improve cooperation, and also improve the speed and agility of care.' (R21, NP)
						F: 'You are able to provide more efficient outpatient services.' (R2, T)
						F: '[Yes, excellent, very nice.] I think good cooperation between primary and second care [the TTCM] is greatly lacking within the Dutch healthcare system.'(R21, NP)
		Workload	Lower administrative workload for trauma surgeon		· Trauma surgeons	F: 'I think the administrative workload has decreased, even for surgeons.' (R2, T)
		Applicability of the TTCM	Presence of a hospital-based physiotherapist at the joint consultations is particularly useful – and of added value - for complex injuries	The HBP does not have an added value at the joint consultations for every patient	· Trauma surgeons · Hospital-based physiotherapists	B: 'No, [multidisciplinary collaboration] is not always an equally useful contribution for [trauma patients].' (R4, T)

Table 3 Continued

Level	Theme	Subtheme	Facilitator	Barrier	Stakeholders	Illustrative quote
						F: 'For certain patient categories, yes, especially regarding more complex cases, such as patients receiving multidisciplinary treatment or patients with multiple injuries. I think that's the most important thing.' (R8, T)
						F: 'Yes, I just think it [the TTCM] should happen nationwide, especially in large trauma centers with patients dealing with multiple trauma.' (R5, T)
	Patient experience		Patients receive a clear treatment plan	Patient is not aware of what has been communicated between hospital-based physiotherapists and network physiotherapists	· Patients	F: 'I do know that my physiotherapist [network physiotherapist] sent feedback to the hospital's physiotherapist before the final interview with the doctor.' (R30, P)
			Patients feel heard	Care providers sometimes contradict each other	· Hospital-based physiotherapists · Patients	B: 'Doctors and physiotherapists don't go well together. That's often the old practice, especially in the Netherlands. While it's precisely the combination of recovery and [a focus on] the body – actually moving and building things up again – that can help.' (R30, P)
						B: 'So, the physiotherapist who released me from the hospital gave me a schedule with exercises. But when I eventually had a consultation with the hand physiotherapist, they never referred to those exercises at all. They gave me completely different exercises, from which I benefitted much more.' (R26, P)
						F: 'No, no, they certainly heard me, and it was an empathetic conversation. I wasn't sent away by anyone, and I was given the time I needed. So I didn't get kicked out, no.' (R25, P)

Table 3 Continued

Level	Theme	Subtheme	Facilitator	Barrier	Stakeholders	Illustrative quote
						F: 'Now that I've been through this whole process, I have to say that my confidence in the Dutch healthcare system has increased. Not that I had little faith in it, but I eventually felt supported by the fact that all this [collaboration between care providers] is possible. Yeah, so it gave me courage.' (R26, P)
			Patients are satisfied with the care that they received	Patients feel like the care process was somewhat rushed	· Patients	B: 'I had the feeling that things were being rushed, that it was just hectic. I understand that, I'm busy too sometimes. But, well…' (R26, P)
						F: 'I do have the feeling that going to the physiotherapist at a relatively early stage ensured that my shoulder soon regained freedom [of movement], and I suffered less in the long term.' (R30, P)
						F: 'Yes, I liked the joint consultation with the physiotherapist and doctor, trauma doctor, or surgeon. Also because they could respond to each other, which they did. So when one of them said something, another immediately gave an answer, which gave clarity to what, why, and how. So yes, it was very clear.' (R27, P)
	Job satisfaction		Care providers indicated that they were more satisfied with their job after the implementation of the TTCM		· Trauma surgeons · Hospital-based physiotherapists · Network physiotherapists	F: 'Well, at [hospital], I'm just super happy with how things are going. And I'm also very satisfied with the meetings.' (R24, NP)
						F: 'So yes, they are just two different specializations present in one place at the same time. And I'm personally very excited about this.' (R3, T)
						F: 'So it's, well, actually, I'd rather spend my full twenty-six hour working week just working with TTCM.' (R11, HBP)
						F: 'So that just makes it a really fun group. Let me put it this way: it makes it all just a little more satisfying.' (R20, NP)

Table 3 Continued

Level	Theme	Subtheme	Facilitator	Barrier	Stakeholders	Illustrative quote
Practice	Practical issues at the outpatient clinic		Sufficient consultation rooms available	Insufficient consultation rooms available	· Trauma surgeons · Hospital-based physiotherapists	B: 'It would be more helpful if they [HBP] were there with us. Only, in terms of actual rooms, there's no physical space available. So that's of course, a pity. Yes, that's a problem at our hospital, in my opinion. This must improve if you want to get the most out of it.' (R4, T)
						B: '…if there are any additional questions, or if I think, well, I'd actually like to spend some more time with them, I don't currently have the time or space for that as things are.' (R16, HBP)
						F: 'Well, the outpatient clinic is so big and has so many rooms available that's not really a problem.' (R13, HBP)
				Too few computers available	· Hospital-based physiotherapists	B: 'We can't type at the same time as the doctor because they're often behind the computer. So, we often have to do that on the side (after the consultation). This can be quite time-consuming.' (R14, HBP)
	Knowledge gained	Knowledge exchange between care providers	Trauma surgeons and hospital-based physiotherapists at outpatient clinic learn from each other's field/profession		· Network physiotherapists · Trauma surgeons · Hospital-based physiotherapists	F: 'Of course, we bring along the know-how of the injury and exactly what kind of surgery we've performed (if we operated). So that is our know-how. But they really take care of the movement issues and really know how the physiotherapist works in the network practice. [So, they can do that, yes, they can do that too, they may be talking at that level]. I think that's an advantage.' (R6, T)
			Network physiotherapists gain knowledge and expertise in trauma rehabilitation		· Trauma surgeons	F: 'Insight into the various fracture treatments has improved, and this knowledge actually expands via the network.' (R2, T)

Table 3 Continued

Level	Theme	Subtheme	Facilitator	Barrier	Stakeholders	Illustrative quote
						F: 'Well, through the trauma network, you can refer more directly to physiotherapists who are involved with trauma patients. So it's no longer enough to send a patient with an ankle fracture to go to the nearest general physiotherapist, who may have never or only incidentally dealt with trauma patients and doesn't know what to do.' (R1, T)
						F: 'What you also realise when you share knowledge with each other, is that this increases my insight into how they work, and I think it also effects the physiotherapist's insight into how we think as surgeons.' (R2, T)

STRUCTURE CATEGORY

With regards to the structure category, five themes were identified: "communication structure", "financial structure", "physical structures and resources", "rules and regulations", and "organisation of the network". Each theme was associated with its unique barriers and/or facilitators.

Communication structure refers to the exchange of patient information between primary and secondary care. Typically, this takes place via an encrypted email system (i.e., ZorgMail) that allows healthcare providers to send and receive messages, documents, and images securely. The use of this system was perceived as both a facilitator and a barrier. On one hand, communication was sometimes hampered by incompatibility between a given hospital's electronic patient record system and that of a network or a primary care practice, resulting in extra work (i.e., healthcare providers had to write separate emails instead of the information being automatically transferred). One NP noted:

> *'The problem are the Electronic Patient Record Systems. They aren't communicating with each other.'(R17,NP)*

Some HBPs considered alternative encrypted email systems (e.g., ZorgDomein), but these systems had similar incompatibility issues. If, however, the electronic patient record system and the encrypted email system were compatible, the communication structure was perceived as a facilitator.

Financial structure refers to the reimbursement of HBPs. The lack thereof was deemed an critical barrier to implementing TTCM by all healthcare providers. One trauma surgeon noted:

> *'…. It's all to do with budgeting and whether the department says it won't reimburse or pay for it. It has nothing to do with a lack of space. I think it's really a matter of finances.'(R5,T)*

In hospitals that were successful in securing full reimbursement for the HBP, HBPs were able to be present during all joint outpatient trauma consultations. In most hospitals, however, only partial reimbursement could be achieved (e.g., as in for a limited proportion of the consultations and/or for a limited period); thus, joint outpatient trauma consultations were performed inconsistently or offered only temporarily.

Physical structures and resources refers to the availability of adequate rooms and number of computers to conduct joint consultation. Trauma surgeons and HBPs noted that the implementation of the TTCM was sometimes hampered by a lack of adequate rooms and/or an insufficient number computers. In some hospitals, the problem of insufficient resources was pronounced by the wish of trauma surgeons to work separately from HBPs, and hence

requiring two rooms per consultation. In other hospitals, the number and size of rooms was simply insufficient. One trauma surgeon noted, for example, that the presence of a HBP meant that there was no longer space for a medical resident.

Rules and regulations refer to existing rules and regulations that impacted the implementation of the TTCM. NPs frequently mentioned that the number of TTCM patients they received was relatively low, because of the freedom to choose, some patients disregarded the referral to a network practice. Additionally, regulatory issues, such as "benchmarking" and "reimbursements" limited the number of physiotherapy sessions per patient. "Benchmarking" refers to the Dutch healthcare performance index that compares the average number of sessions per patient across physiotherapy practices. While the aim of this index is to monitor efficiency, some insurance companies use this index as leverage during contract negotiations with physiotherapy practices and/or audits. For physiotherapy practices, this can translate into less money per session, which in turn negatively impacts treatment decisions (33). One NP indicated, for example, that even if he/she wanted to treat a certain patient three times a week, he/she would not do so, because of the benchmark. Moreover, the number of physiotherapy sessions that is reimbursed through the Dutch basic insurance package is limited. That is, physiotherapy sessions following a hospital admission are only reimbursed after the 20th session and within the one year following discharge. Even though people have the option to purchase supplemental insurance that would cover physiotherapy sessions prior to the 20th session, only 35% of the Dutch population has this coverage (34).

The organisation of the network refers to the set-up, content, website, and accreditation of the network. Physiotherapists were eligible to join a TTCM network after completing an online training on how to provide care according to the TTCM. Due to the COVID-19 pandemic, training sessions were organised online, which was perceived as both a facilitator and a barrier. Most NPs appreciated the convenience of not having to travel for training; however, they also noted a reduction in opportunities for personal interaction and networking. The number and duration of the training sessions differed between networks, and depended on the participating networks' prior experience.

Most hospitals (n=7) had not yet arranged accreditation for their network. NPs perceived this as a barrier, as it rendered the status of their participation in the network as being voluntary. Consequently, when they had to temporarily close their practice to attend network activities, such as training sessions, it resulted in a loss of income. In general, healthcare providers and patients were positive about the TTCM website and believed that up-to-date websites can strengthen a network/intervention. One patient noted, however, that he/she would have liked the website to contain more content about the NPs, such as their expertise.

CULTURE CATEGORY

Five overarching themes were identified: “commitment”, “acting as a team”, “quality and efficiency of care”, “patients’ experience”, and “job satisfaction”.

Commitment was the most common theme identified from the interviews and the most contributions came from healthcare providers. This theme refers to their, as well as their colleagues’, intrinsic motivation to work according to the TTCM. A high level of “commitment” was perceived as a facilitator, while a lack thereof was perceived as a barrier. Most healthcare providers were committed and felt some responsibility for the successful implementation of the TTCM. Some HBPs, however, noted that their direct colleagues and/or colleagues from other departments (e.g., trauma surgery) were less committed. In their opinion, this was detrimental to the successful implementation of the TTCM.

Acting as a team refers to the “contact between trauma surgeons and hospital-based physiotherapists at the outpatient trauma clinic” and the “contact between the network and the hospital team.” In the hospitals with an inconsistent presence of a HBP during outpatient trauma consultations, both types of contact were affected negatively. In some cases, contact between trauma surgeons and HBPs was limited due to trauma surgeons, contrary to what was intended, expressing the desire to work separately from the HBPs. As one HBP noted:

> *‘We don’t have fixed days when we’re present at the trauma clinic, because the surgeons don’t want us in the room with them. So yes, we have a separate room.’(R9,HBP)*

Patients also noted that some of their outpatient consultations were not provided jointly by a trauma surgeon and HBP, which they perceived as a barrier.

Patients and NPs also reported problems with the communication between the hospital team and NPs. As one patient noted:

> *‘..what I understood from my physiotherapist… He had questions regarding certain pains I have at the moment [for the hospital team]. But these haven’t been answered yet. It’s been two weeks now and I have no explanation for this as yet.’(R29,P)*

If consultations were provided jointly and an effective communication channel was in place, stakeholders perceived the improved levels of communication between primary care and secondary care as a critical facilitator. When working together, trauma surgeons and HBPs indicated that they were respectful of professional boundaries and that their respective responsibilities were clear. That is, they believed that they complemented each other in terms of knowledge and expertise. Also, most trauma surgeons indicated that their communication with the NPs (via the HBPs) had improved since implementing the TTCM.

NPs, on their part, indicated that their contact with the hospital had improved and they believed that they played a more significant role in the rehabilitation process of patients with traumatic injuries.

Quality and efficiency of care refers the belief among healthcare providers and patients that the TTCM could enhance the quality and efficiency of trauma care. A trauma surgeon noted:

> *'You are able to provide more efficient outpatient services.' (R2, T)*

Some healthcare providers indicated, however, that "the applicability of the TTCM" was not always clear. Specifically, they found it challenging to anticipate when and if the presence of a HBP would contribute value to a particular patient's treatment. Trauma surgeons believed that HBPs provided significant added value for patients with complex injuries. In addition, trauma surgeons frequently mentioned that they experienced a "lower administrative workload" since the implementation of the TTCM, because they were no longer responsible for the communicating with NPs.

Patient experience refers to the patients' experience and satisfaction with the TTCM. In some hospitals, patients reported "feeling rushed" or "not feeling heard". In most of these hospitals, however, HBPs were inconsistently and/or only temporarily present during the outpatient trauma consultations. Some patients also indicated they were unaware of what had been communicated between the hospital and their NP, and/or noticed that "care providers contradicted each other". As one patient noted:

> *'So, the physiotherapist who released me from the hospital gave me a schedule with exercises. But when I eventually had a consultation with the hand physiotherapist, they never referred to those exercises at all. They gave me completely different exercises, which I benefitted much more from.'(R26,P)*

Job satisfaction refers to the anticipated or experienced effect that working according to the TTCM had on the healthcare providers' job satisfaction after its implementation. One trauma surgeon was particularly enthusiastic about his/her increased collaboration with HBPs:

> *'So yes, they are just two different specialisations present in one place at the same time. And I'm personally very excited about this.'(R3,T)*

A HBP noted that he/she would prefer to spend his/her entire work week treating patients according to the TTCM.

PRACTICE CATEGORY

Two overarching themes were identified, i.e. "practical issues at the outpatient clinic" and "knowledge gained".

Practical issues at the outpatient clinic refers to the fact that some HBPs and trauma surgeons experienced some practical problems/issues while working with the TTCM. An important practical issue was the lack of appropriate consultation rooms. In some cases, there was a shortage of consultation rooms at their outpatient clinic, which became pronounced when trauma surgeons wanted to work separately from HBPs. In others, there was insufficient space in the available consultation rooms to allow both a HBP and medical resident to be present with the patient, and/or to place enough computers for each healthcare provider to enter notes simultaneously.

> *'We can't type at the same time as the doctor because they're often behind the computer. So, we often have to do that on the side (after the consultation). This can be quite time-consuming.' (R14, HBP)*

Knowledge gained refers to the fact that most healthcare providers indicated that they gained expertise in treating patients with traumatic injuries since working according to the TTCM. As one trauma surgeon noted:

> *'What you also realise when you share knowledge with each other, is that this increases my insight into how they work, and I think it also affects the physiotherapist's insight into how we think as surgeons.'(R2,T)*

DISCUSSION

Main findings

This study identified various barriers and facilitators associated with the upscaling of the TTCM. Under the structure category of the "constellation approach", the main barriers to upscaling the TTCM were "communication structure" (i.e., incompatibility of electronic patient records), "financial structure" (i.e., absence of reimbursement for the HBP), "physical structures and resources" (i.e., unavailability of rooms/computers), "rules and regulations", and "the organisation of the network" (e.g., online training). Under culture, the presence of "commitment" and "acting as a team during the consultations" were perceived as facilitators and the lack thereof as barriers. In some hospitals, contact between trauma surgeons and HBPs and between the hospital team and NPs was suboptimal and considered a barrier. In hospitals where contact between healthcare providers was improved, the improvement appeared to coincide with two perceived facilitators: increased level of "job satisfaction" and a "lower administrative workload for the trauma surgeons". Under the practice category, "practical issues at the outpatient clinic" (e.g., inadequate or insufficient consultation

rooms) was perceived as a barrier. With regards to "knowledge gained", most healthcare providers indicated that they appreciated the fact that their expertise in treating patients with traumatic injuries increased since working according to the TTCM. Most stakeholders, including patients, believed that if the barriers were overcome, the TTCM could significantly improve trauma rehabilitation.

Comparison with the literature and recommendations for practice

In line with the pilot study, we found that most stakeholders, including patients, believed that the TTCM could significantly improve trauma rehabilitation if implemented successfully. Many of the identified barriers and facilitators were in line with those of the pilot study (18). In both studies, the inability to refer Dutch patients to a designated healthcare provider was identified as a barrier. This interferes with patients with traumatic injuries from receiving treatment from physiotherapists specialised in trauma rehabilitation (i.e. NPs), and impedes effective collaboration between primary and secondary care. Another barrier that was identified in both studies was the challenge stakeholders faced with arranging reimbursement for HBPs. The main reason for this difficulty arises from the entrenched financial boundaries between primary and secondary care in the Netherlands, which have also impeded the reimbursement of various other transmural care models (35, 36). Bloemen-Vrencken et al. (37), for example, found that organisational and financial constraints interfered with the implementation of a transmural care model for spinal cord injury patients. In the pilot study, efforts to secure funding for the entire TTCM were not successful either, however, full reimbursement for the HBP was arranged by adjusting the pricing of medical specialist care (i.e., the trauma surgeon). We planned on using the same funding strategy in the current multicentre trial, but this was not feasible due to the suspension of negotiations amid the COVID-19 pandemic. This unforeseen circumstance further complicated the intricate challenge of navigating financial and organisational obstacles in the implementation of transmural care. Consequently, outpatient trauma consultations were performed jointly in less than 50% of the participating hospitals, and generally only for a limited proportion of the scheduled consultations and/or a limited period. Another notable discrepancy between the current multicentre trial and the pilot study was the reluctance of certain trauma surgeons to collaboratively conduct outpatient consultations in the present study; this was not the case in the pilot study. This discrepancy is likely explained by the "not-invented-here syndrome", that is, the tendency of people and organisations to avoid things they did not create themselves (38, 39). Such an attitude can act as a barrier to upscaling (healthcare) interventions (40). Indeed, findings from other studies indicate that "key actors", "ownership", and "leadership engagement" (i.e., commitment, involvement, and accountability of leaders with the implementation) are conditional requirements for change management, and upscaling activities in particular (35, 36, 40). Therefore, it is crucial for trauma surgeons, who frequently hold leadership positions in hospitals (41, 42), to serve as "key actors" during the implementation and/or scaling of the TTCM. In an ideal situation, this would be established along with strong support from highly committed HBPs. This might be achieved by providing comprehensive training programs to trauma surgeons, HBPs, and

NPs; fostering a culture of collaboration and shared responsibility; and establishing clear communication channels between stakeholders. Furthermore, it is crucial for the overall leadership of a hospital to champion the implementation of a new healthcare intervention, as a supportive organisational environment is a critical success factor for effective implementation and/or upscaling (43, 44). Another barrier that impacted the upscaling of the TTCM is the fact that many of the electronic patient record systems used in Dutch hospitals are incompatible with the available encrypted email systems. This incompatibility severely complicates communication between primary and secondary care providers, which is an integral part of TTCM and many other transmural care initiatives. Indeed, the challenges of compatibility between electronic patient record systems and encrypted email systems have been identified in a systematic review (45) and emphasises the necessity for standardised communication platforms between primary and secondary care (45-47).

Strengths and limitations

This process evaluation had several strengths. First, we used a theoretical framework to construct an analytical framework that enabled a systematic exploration of the data. Second, all stakeholders groups who provided treatment according to the TTCM were represented in the study. We made deliberate efforts to include participants from diverse hospitals and networks (including those that were who were positive as well as negative about the TTCM) to enhance the transferability of the results. Third, the credibility of data was improved by performing a member-check (31) and keeping a reflective diary (29). Finally, to optimise reliability and reproducibility, the role of the researcher, the location, the order of the questions, and the description of the coding were described as precisely as possible (29).

The study also had some limitations. Participants were purposively selected, potentially introducing a bias in the sample towards individuals were more positive about the TTCM than the average healthcare provider or patient. Given that the sample is skewed towards individuals who express higher satisfaction with the TTCM compared to the average healthcare provider or patient, the bias may lead to an overestimation of the observed facilitators. Furthermore, we did not include representatives of other healthcare professionals, such as nurses or orthopedic casting specialists, who might have also been affected by the implementation and/or upscaling of the TTCM. Future research endeavors may benefit from interviewing individuals at different departments to capture a more comprehensive perspective. Furthermore, data were obtained through interviews with researchers involved in the development and/or evaluation of the TTCM, which may have caused “social desirability bias”. Consequently, participants may have overstated their positive experiences with the implementation of or working according to the TTCM. For future research, we therefore recommend researchers to obtain additional data through other methods, such as surveys or focus groups (preferably conducted by researchers who are not involved with the TTCM). Third, it is essential to acknowledge the fact the current study only assessed the barriers and facilitators associated with the upscaling of the TTCM during a period of nine months. However, upscaling procedures in the context of healthcare

transitions may unfold over more extended periods(23, 52). As such, we may have missed some barriers and facilitators and/or the identified barriers and facilitators may have been experienced more intensely by the stakeholders due to the fact that implementation process had just started.

CONCLUSION

Various barriers and facilitators were found to determine the success of upscaling the TTCM in Dutch hospitals. While many of these barriers and facilitators were similar to those identified in the pilot study, some were notably different. The different findings emphasise that implementation of healthcare interventions and upscaling requires attention to context and the importance of the "not-invented-here syndrome". The most important prerequisites for successfully upscaling the TTCM were adequate financial support and the presence of "key actors" within an organisation who felt a sense of urgency for change and/or expected the intervention to increase their job satisfaction.

List of abbreviations

DALYs: disability-adjusted life years, TTCM: Transmural Trauma Care Model, HBP: hospital-based physiotherapist, NP: network physiotherapist, Amsterdam UMC: Amsterdam University Medical Center, VUmc: VU medisch centrum, COREQ: COnsolidated criteria for REporting Qualitative research checklist, JR: Julia Ratter, SW: Suzanne Wiertsema, JvD: Johanna van Dongen, IE: Ilham Ettahiri, RM: Robin Mulder, AG: Anne Grootjes, JK: Julia Kee, RO: Raymond Ostelo, SD: Standard Deviation, P: patient, T: trauma surgeon, R: respondent, F: facilitators, B: barriers, Coronavirus disease 2019: COVID-19 pandemic

Acknowledgments

We thank all trauma patients and care providers (Haaglanden Medisch Centrum, HagaZiekenhuis, Noordwest Ziekenhuisgroep Alkmaar, Reinier de Graaf Ziekenhuis, Spaarne Gasthuis, LUMC Leiden, Radboudumc Nijmegen, Amsterdam UMC, location AMC, and Maastricht UMC+) who participated in the study. We thank also Sidney Rubinstein for the translation of the quotes.

SUPPLEMENTARY FILE 1

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist
For further information about the COREQ guidelines, please see Tong et al., 2017: https://doi.org/10.1093/intqhc/mzm042

No.	Item	Description	Section #
Domain 1: Research team and reflexivity			
Personal characteristics			
1.	Interviewer/facilitator	Which author/s conducted the interview or focus group?	Methods, Data preparation, page 4
2.	Credentials	What were the researcher's credentials? *E.g. PhD, MD*	Methods, Data preparation, page 4
3.	Occupation	What was their occupation at the time of the study?	Methods, Data preparation, page 4
4.	Gender	Was the researcher male or female?	not stated
5.	Experience and training	What experience or training did the researcher have?	Methods, Data preparation, page 4
Relationship with participants			
6.	Relationship established	Was a relationship established prior to study commencement?	Methods, Data preparation, page 4
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? *E.g. Personal goals, reasons for doing the research*	Relevant information was disseminated in the introduction of the interviewer
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? *E.g. Bias, assumptions, reasons and interests in the research topic*	Relevant information was disseminated in the introduction of the interviewer
Domain 2: Study design			
Theoretical framework			
9.	Methodological orientation and theory	What methodological orientation was stated to underpin the study? *E.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis*	Methods, Data analysis, page 5, Supplementary file 3
Participant selection			
10.	Sampling	How were participants selected? *E.g. purposive, convenience, consecutive, snowball*	Methods, Data preparation, page 4

11.	Method of approach	How were participants approached? *E.g. face-to-face, telephone, mail, email*	Methods, Data preparation, page 4
12.	Sample size	How many participants were in the study?	Results, page 6
13.	Non-participation	How many people refused to participate or dropped out? What were the reasons for this?	Results, page 6
Setting			
14.	Setting of data collection	Where was the data collected? *E.g. home, clinic, workplace*	Results, page 6
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	No, but not specifically stated

SUPPLEMENTARY FILE 2

1.1 Topiclist trauma surgeon

Introduction

Personal questions
- Age
- How long have you been working as a trauma surgeon?
- Where do you currently work?
- How long have you been working according to the TTCM?
- What do you know about the TTCM?

If not familiar with the TTCM: Briefly explain.

Open questions
- What is your personal experience with the TTCM?
- What is your role within the TTCM trial?
- What are your responsibilities?
- Have you been directly involved in the implementation of the TTCM?
- What is your role regarding the TTCM which has recently been implemented in [name hospital]?
- How do you experience your working compared to before TTCM? (workload, quality of care for the patients)
- Which tasks are going well?
- Why are they going well (examples facilitators)?
- What tasks are still a challenge (examples barriers)?
- Can you elaborate on why ... is still a challenge?
- What do you think would be a solution for this?
- How do you experience the cooperation with the hospital-based physiotherapists?
- When can interprofessional collaboration lead to problems (explanation, examples)
- How do you experience the cooperation with primary/ tertiary care physiotherapists?
- How does this cooperation work in practice?
- Do you have confidence in the TTCM (why yes/no)?
- Tips/tops?
- In your opinion, should other hospitals in the Netherlands implement TTCM?
- What barriers and facilitators do you expect?
- What problems do you expect/what problems could TTCM eliminate?
- If you could give the model a score on a scale of 0-10, what would this be?

1.2 Topiclist patients

Introduction
- Thank you for taking the time for this interview. There will be no judgments and it is considered to be a neutral conversation.
- Brief explanation of TTCM and explanation of the purpose of the research and the interview
- What are the barriers and facilitators of the implementation of the TTCM, with respect to patients?
- Informed consent questions, emphasize anonymity
- Questions before we begin?

Personal questions
- Age
- Gender
- What injury did you suffer and how did this happen?
- When did this happen?
- How long have you been treated using the TTCM model?
- In which hospital have you being treated?

Open questions
1. Experience
- What is your personal experience with the TTCM model?
- How do you feel about the hospital- based physiotherapist?
    - Is he/she always present?
    - Does he/she take a lot of initiative in the consultations (relative to the surgeon)?
2. How would you describe the cooperation in the consultation room between the trauma surgeon and the hospital-based physiotherapist?
    - Were you referred to a network physiotherapist in your living area?
    - Did you experience the choice options you were given when being referred as a free choice?
    - To the best of your knowledge, is there contact between the hospital and the physical therapy practice during your treatment?
    - What was the transition from the hospital to the physical therapy practice like?
    - How do you experience the physiotherapist's treatments?
    - Does the advice you receive from the physiotherapist outside the hospital match with the advice given in the hospital?
    - How is the treatment going?
3. Barriers and facilitators:

Are there any negative factors that you have noticed during your treatment according to the TTCM model?
    - Why do you see this as a negative factor?
    - Can you explain this in more detail?
    - Where do you think this is due to? (Yourself, the physiotherapist, the organisation?)

- Would you have liked this to be different? (If so, how? Maybe give examples)

Would insurance reimbursement be a factor for you to continue the pathway?
- For example, would you stop earlier than advised by the physiotherapist?
- if your treatments were not reimbursed (anymore)?

Possible barriers: cooperation, materials, space, hours, time, contact researchers, location

Facilitators:
Are there any positive factors that you have noticed during your treatment according to the TTCM model?
- Why do you see this as a positive factor?
- How has this helped you in your care process?

Possible facilitators: collaboration, materials, space, hours, time, contact care providers, location
Other questions:
4. Do you have any other points you would like to make about the TTCM?
5. What is your level of satisfaction, on a scale of 1 - 10?

1.3 Topiclist hospital-based physiotherapists and network physiotherapists

Introduction

Personal questions
- Age
- Time working as a hospital-based physiotherapist/ network physiotherapist?
- Time working with TTCM?
- Since when has TTCM been implemented at the hospital/practice?

Open questions
Question 1: What is your personal experience with the TTCM?
- As a hospital-based physiotherapist/ network physiotherapist, what is your personal experience with the TTCM which has recently been implemented in [name hospital/practice]?
- How do you experience working according to the TTCM?
- What are your tasks within the TTCM?
- Have you been directly involved in the implementation of the TTCM?
- What is your role regarding the TTCM which has recently been implemented in [name hospital/practice]?

Question 2:
- How do you experience your working compared to before TTCM? (workload, quality of care for the patients)

Facilitators:
- What advantages do you experience while working according to the TTCM?

- What makes these factors conducive?
- Which tasks are going well?
- Why are they going well (examples facilitators)?
- What positive experiences have you had with the TTCM?
- Where do you think this is due to (the organization, yourself, the trauma surgeon or physiotherapist)

Examples: Contact, resources, materials, space, money, hours, time, training, contact researchers, location

Barriers:
- What negative experiences have you had with the TTCM?
- Why do you see this as a negative experience?
- What disadvantages do you experience while working according to the trauma rehabilitation network?
- What tasks are still a challenge (examples barriers)?
- What do you think would be a good solution for these barriers?
- What do you think this is due to? (yourself, the trauma surgeon, hospital-based physiotherapist/ network physiotherapist, organization)

Examples: Contact, resources, materials, space, money, hours, time, training, contact researchers, location
- What could you do to counter/diminish this negative experience? And what could be your role in this?
- Can you elaborate on why ... is still a challenge?
- What do you think would be a solution for this?
- How do you experience the contact with the physiotherapists?
- When can interprofessional collaboration lead to problems (explanation, examples)
- Do you have confidence in the TTCM (why yes/no)?
- Tips/tops?

Question 3:
- Do you notice any difference in terms of quality of trauma care after implementation of the TTCM compared to regular care as before implementation?
- If so/ If applicable, what difference do you notice and to what extent do you think your new role as a hospital-based physiotherapist in this model affects this?

Question 4:
- How do you find the contact with the trauma surgeons?
- How is the communication with the trauma surgeons?
- Did you ever have contact with trauma surgeons prior to implementation?
- If so, how often and how was that contact?

Question 5:

- How do you find the contact with the hospital-based physiotherapists/network physiotherapists?
- How is the communication going?
- Is email traffic about the patient going smoothly?
- What tool is used for your communication?
- Are the emails you receive clear?
- Is a standard format used?

Question 6:
- How do you feel the contact as a hospital-based physiotherapists/ network physiotherapists goes with the patients within the TTCM ?
- Do you have enough contact with the patient?
- Does advice arrive well and clearly to the patient?

If applicable: Question 7:
- How do you feel the post-clinical consultations are done together with the trauma surgeon and patient?
- How often are those consultations scheduled?
- Do you find that your advice can help both the trauma surgeon and the patient?
- Regarding the establishment of individual treatment goals, how does this involve collaboration with the trauma surgeon and patient?
- Are treatment recommendations drawn up together with the trauma surgeon and do you complement each other in this?
- As you know, the TTCM consists of four major components ((1) A joint outpatient consultations by a multidisciplinary team consisting of a trauma surgeon and a hospital-based physiotherapist (HBP); 2) Coordination and individual goal-setting; 3) A network of specialized network physiotherapists (NPs); and 4) Secured email traffic between HBPs and NPs.))
- Which component do you think is most relevant and where do you think the most growth lies?

Question 8:
- What would you recommend in terms of further scaling up TTCM in the other Dutch hospitals?
- Do you think that other hospitals can also start to benefit from it and that the TTCM should therefore be scaled up?
- If the TTCM is going to be implemented in other hospitals, what would you advise hospital-based physiotherapists to make the implementation of the TTCM as successful as possible?

Closing questions:
- Do you have anything to add to the interview, or important points I forgot to ask?
- Do you still have enough time for other patients?
- if applicable: Do you have to pay to participate in the trauma rehabilitation network?
- How do you experience the mental aspect of trauma care in the trauma rehabilitation network/the TTCM

SUPPLEMENTARY FILE 3

Constellation approach

This approach assumes that a healthcare system consists of so-called constellations, i.e., a set of interrelated practices and relevant, interrelated structuring elements that define and fulfill a function in the more extensive system (22). To meet their diverse needs, healthcare systems consist of many nested complementing and competing constellations and (sub) constellations (22). Within a constellation, there is a continuous interaction between the three elements of the 'structure, culture, and practice triplet' (22). 'Structure' consists of physical structures and resources, enforced regulations and legal rights, economic resources, and other material elements that structure behavior within a constellation (e.g., compatibility of electronic patient records). 'Culture' refers to the paradigms, norms and values, and other immaterial elements that structure behavior in practice (e.g., the willingness of different departments working together at the outpatient clinic). 'Practice' involves the typical operational routines which the actors within the constellation undertake. Actors are individuals (e.g., patients, physicians, managers) or groups (e.g., insurance companies, departments) who work or act in a particular constellation. For the TTCM, several nested constellations can be recognized, for example, the outpatient clinic for trauma patients on the one hand and the primary/tertiary care network practices on the other hand. Moreover, both hospital and primary/tertiary care network practices are part of a bigger constellation in which insurers and policymakers act in a particular structure and culture. Dynamics, such as those created by the upscaling 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. The driving force of change is the sense of urgency for change by 'key actors' within a constellation (59). These actors initiate and push for change on the structural, cultural, and practical levels (60). To achieve a transition, the relevant actors need to develop a collective sense of urgency to change and develop new competencies (knowledge, attitudes, and skills). Scaling up involves implementing the results of niche experiments in the existing structure, culture, and practice (18, 59, 61).

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CHAPTER 5

Barriers and facilitators of funding transmural care models in the Netherlands: a case study in trauma rehabilitation

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Under revision

ABSTRACT

Objective: Transmural care can improve patient outcomes and reduce costs, but limited research exists on bridging the financial boundaries between primary and secondary care. This process evaluation aimed to identify barriers and facilitators of funding a transmural care model in the Netherlands, specifically the Transmural Trauma Care Model (TTCM).

Methods: Semi-structured interviews with relevant stakeholder were conducted, and a framework method and the constellation approach were used to analyze them.

Results: Stakeholders indicated that it was hard to arrange funding for the TTCM, and for secondary allied healthcare professionals in particular. Stakeholders proposed eight funding models, of which a model where - in case of the TTCM - the hospital-based physiotherapist was funded by increasing the price of the outpatient consultation of the trauma surgeon seemed most feasible. Other important challenges included 'the fragmentation of care' and 'a lack of commitment'.

Conclusion: It is difficult to fund transmural care models as a whole, and secondary care activities performed by allied healthcare professionals in particular. A funding model where the latter are funded by increasing the price of medical specialist care seemed most feasible. When arranging funding, it is important to have dedicated key actors, and a dedicated medical specialist in particular.

INTRODUCTION

Worldwide, policymakers face the challenge of ensuring high-quality healthcare within a limited budget. Providing high-quality care requires effective collaboration between different echelons, including primary and secondary care providers (1, 2). Innovative healthcare interventions and reforms are constantly being implemented to ensure that high-quality care ensured (3, 4). In the 1990s, for example, the Dutch healthcare system focused on integrating primary and secondary healthcare services and encouraging so-called 'transmural care' between these traditionally separated sectors.

Transmural care aims to provide seamless, integrated care, while recognizing the interconnectedness of all stages and sectors of care and the importance of coordinated care, supporting individuals throughout their entire care process (5). Various terms for transmural care are used interchangeably, e.g., integrated care, shared care, managed care, comprehensive care, and disease management (6). Integration of care can take place at three levels: 1) macro-level, where policies and regulatory mechanisms are developed to integrate primary, secondary, and tertiary care; 2) meso-level, where strategic plans and coordination mechanisms for managerial functions are formulated to facilitate the integration of care, and 3) micro-level, where healthcare professionals work collaboratively to ensure that the patient receives the most appropriate care (7).

Recently, several studies assessed the implementation of transmural care models, most of which concluded that more guidance on organizational issues, such as the traditional and financial boundaries between primary and secondary care, and appropriate funding are needed (8-11). In a recent pilot study, our research group found that implementing a transmural care model for Dutch trauma patients, i.e., Transmural Trauma Care Model (TTCM), was feasible and had the potential to improve patient outcomes and to reduce costs (12). Currently, the (cost-)effectiveness of an updated version of the TTCM is being evaluated at nine Dutch hospitals (13), offering us the opportunity to investigate the barriers and facilitators associated with funding transmural care models in the Netherlands.

METHOD

Study design and setting

This process evaluation was conducted alongside a multicenter trial (13) and builds on the experiences of previous process evaluations and the guideline for evaluating implementations in healthcare (14, 15). The COREQ checklist was followed (16). The study took place in the Dutch healthcare system. A description of this system can be found in Supplementary file 1.

The Transmural Trauma Care Model

The TTCM has been developed at the Amsterdam UMC and consists of four interlinked components (Figure 1):

1) Intake and follow-up joint consultations by a multidisciplinary team at the outpatient clinic for trauma patients: During the trauma patients' outpatient visits, the trauma surgeon evaluates the bone and wound healing process and acts as the chief consultant. A hospital-based physiotherapist (HBP) assesses physical function and acts as a case manager throughout the rehabilitation process.
2) Coordination and individual goal setting: The hospital-based team coordinates the patients' rehabilitation process in primary (and sometimes tertiary care) by continuously defining individual treatment goals in close cooperation with the patient.
3) A network of specialized network physiotherapists (NPs): Patients are referred to the Dutch Network Trauma Rehabilitation, which consists of specifically trained NPs (www.traumarevalidatie.nl).
4) Secured email traffic between HBP and NPs: HBPs and NPs communicate rehabilitation goals and results through a secure email system throughout the patients' rehabilitation process.

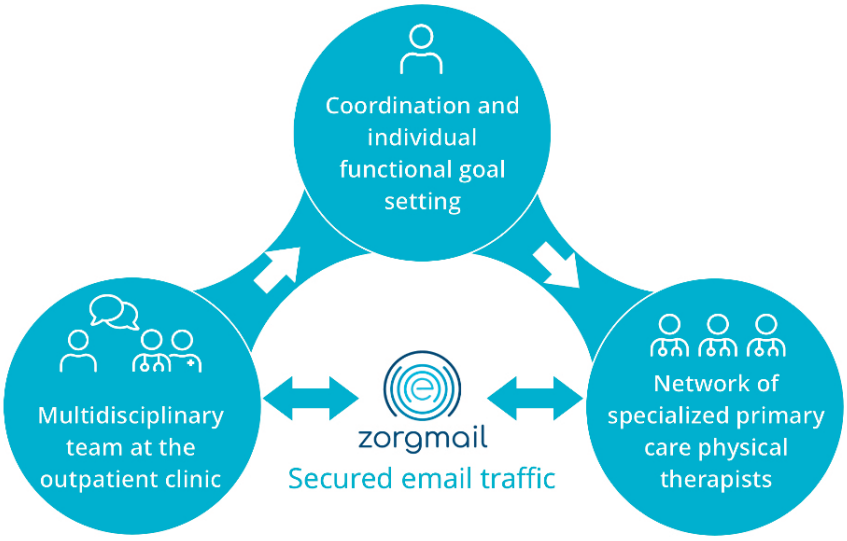

Figure 1 The Transmural Trauma Care Model

Data preparation

Data were collected through semi-structured interviews. Participants were purposively selected (17-19). Special efforts were made to include stakeholders acting on the "health insurance market" (e.g., health insurer), "healthcare purchasing market" (e.g. health insurer, health providers), "healthcare provision market" (e.g. health providers), and the government (e.g. "National Health Care Institute")(Supplementary file 1). Patients were

not included, because they are unlikely to provide detailed information about healthcare funding. Interviews were conducted at a time and location (physically/online) convenient to the participants. The interviews were conducted by an intern (SB), accompanied by at least one research team member (JR/JvD). One researcher conducted the interview. The others probed areas for further questioning, kept track of the topic list, and made notes. Interviews were audiotaped and transcribed verbatim (20). Throughout the study, "objectivity" was optimized by keeping a reflective diary (21). A topic list was used, which was based on the literature, professional experience, previous process evaluations (15, 22), and a theoretical framework, and was adjusted throughout the study and adapted to the specific stakeholder (see Supplementary file 2) (23-25). Before the interviews, stakeholders gave written informed consent. To enhance "trustworthiness", a member check was performed per interview by sending the participants an interview summary and its transcript (26).

Data analysis

Data were analyzed using the hierarchical, matrix-based framework method (20, 27). Our theoretical framework was based on the 'constellation approach'(see Supplementary file 3) (28).

This study iteratively created an 'analytical framework' by following *seven* steps, using word-processing software. *First*, the interviews were transcribed verbatim (SB/JR). *Second*, familiarization with the interviews was achieved by listening to the audio recordings and rereading the transcripts (SB/JR). *Third*, text fragments were labeled by relevant codes (open coding)(SB/JR/JvD). *Fourth*, codes were grouped into categories on the structural, cultural, and practical levels of the constellation approach (SB/JR/JvD). *Fifth*, final codes were developed and refined through discussions with two other researchers (RO/SW). *Sixth*, a framework matrix was generated (SB/JR/JvD/BS), meaning that data were summarized per category, categorized into a matrix, and linked to relevant quotes. *Seventh*, the framework matrix was used to interpret the data. To ensure "rigor" and "credibility", other researchers (RO/SW) reviewed the generated matrix and checked whether the selected quotes were relevant to the themes. Disagreements were resolved by discussion.

RESULTS

Ten stakeholders were invited to participate, of whom one declined (a trauma surgeon). Three interviews were conducted physically and six online. On average, the interviews lasted 40 minutes. The stakeholder's characteristics can be found in Table 1.

Table 1 Overview of the stakeholders' characteristics

Gender	Position	Affiliation	Market
Male	Health insurer (paramedical care and medical specialist rehabilitation care)	Health insurance	Health insurance market
Male	Medical advisor	National Health Care Institute	On behalf of the government
Male	Trauma surgeon	Supra-regional hospital	Health purchasing market
Female	Analyst and account manager in healthcare contracting	University Medical Center	Health purchasing market
Male	Healthcare innovator	University Medical Center	Healthcare provision market/ Health purchasing market
Female	Hospital-based allied healthcare manager	University Medical Center	Health purchasing market
Male	Hospital-based allied healthcare manager	University Medical Center	Health purchasing market
Male	Hospital-based allied healthcare manager	Supra-regional hospital	Health purchasing market
Male	Hospital-based allied healthcare manager	Supra-regional hospital	Health purchasing market

Barriers and facilitators

Stakeholders indicated it to be hard to fund transmural care models, such as the TTCM. Most believed funding for secondary care activities to be the main bottleneck (i.e., HPB). Below, the identified barriers and facilitators are discussed per level of the constellation approach (Table 2).

Table 2 Barriers (B) and facilitators (F) expressed by policymakers and healthcare providers regarding funding transmural care models in the Netherlands, related to structure, culture, and practice.

Level	Theme	Subtheme	Facilitator	Barrier	Stakeholders	Illustrative quote
Structure	Financial structure Proposed funding models: Funding for the complete TTCM	Non regular declaration code (Dutch= Facultatieve prestatie)	More control for health insurers over healthcare costs, as healthcare products specified in packages	· Permission is needed from the Dutch Healthcare Authority (NZA) to be able to offer such a care package to insurers · No guarantee that insurers buy such a care package · Hospital care is generally more expensive than primary care and is not in line with the promotion of 'the right care in the right place' · Health insurers felt that they would be financing twice [first for the HBP to do his/her regular work, and second for the same HBP to be part of the joint outpatient clinic]. · Fragmentation of care	· healthcare innovator (HI) · hospital-based allied healthcare manager (HBAHM) · analyst and account manager in healthcare contracting (AAMH)	· B: 'You have to get permission from the Dutch Healthcare Authority to offer such a care package to insurers.' (HI) · B: 'And insurers can choose to procure the 'non-regular declaration code'. And then it turned out that the insurers did not want to do so.' (HBAHM) · B: 'The Dutch Healthcare Authority approved the non-regular declaration code for TTCM.' (HBAHM) · B: 'Health insurers objected to this [purchasing the 'non regular declaration code'] because they felt that they would be financing twice[first for the HBP to do his/her regular work, and second for the same HBP to be part of the joint outpatient clinic].' (HBAHM) · B: 'That is very complicated, because this [primary and secondary care] are different [financial] entities [...] very complicated due to the fragmentation.' (AAMH)
		Integrated funding	· More transparency over costs due to healthcare products specified in the packages · Promotes cooperation between chain partners in primary care (i.e., a multidisciplinary group of care providers in primary care)	· Cooperation between chain partners is not procedurally regulated and concerns solely chain partners in primary care · Traditional and financial boundaries between primary, secondary and tertiary care	· healthcare insurer (HCP) · heads of the paramedical service of a hospital (HBAHM)	· B: 'I know that there was 'integrated funding' in the past. However, traditional and financial boundaries make it difficult to organise.' (HBAHM)

Table 2 Continued

Level	Theme	Subtheme	Facilitator	Barrier	Stakeholders	Illustrative quote
	Proposed funding models: Funding hospital-based physiotherapists in particular	Increasing Diagnosis Treatment Combination (DTC) price	· Increasing the DTC price seems easy and transparent · The health insurer must invest in developments and chain care is on their agenda to support · Physiotherapy at the outpatient clinic is part of hospital care and therefore it should also be included in the DTC	· DTC negotiations were halted due to COVID-19 pandemic · If TTCM saves costs in the long term, the financing can be obtained from the hospital's own budget · Not regulated nationally (e.g., DTC prices need to be negotiated separately per insurer) · Fragmentation of care within the hospital (i.e., trauma surgery other department than rehabilitation medicine) · Quantification of the work of HBP at the outpatient clinic is required for DTC transparency but provides additional administration	· healthcare innovator (HI) · healthcare insurer (HCP) · analyst and account manager healthcare contracting (AAMH) · medical advisor of the National Health Care Institute (MAZIN) · hospital-based allied healthcare manager (HBAHM)	· F: 'I think this [increasing the DTC price] is the easiest way.' (HI) · F: 'The most logical thing is to make one package price for this and just increase the DTC slightly.' (HCP) · F: 'I find it [increasing DTC] a very pleasant way because it is very transparent.' (HBAHM) · B: 'If you look at the HBP who helps the trauma surgeon with the treatment goals, you could say that he/she is an extension of specialist care and should thus be included in the DTC.' (MAZIN) · F:'"Increasing the DTCs is a solution. However, I would quantify that. How many hours per patient does such a HBP [at the TTCM outpatient clinic] put in? And what does that mean for the DTC? And relate that to what it delivers.' (HCP) · B: 'You have one DTC, but it has different prices because you make agreements with each insurer about what the price is for that particular DTC.' (AAMH) · F: 'We managed to get it [funding of the HBP] arranged within the DTC prices.' (HBAHM)
		Declaration within medical specialist care contracts		· Officially not allowed · At the expense of the additional insurance · Additional costs for the patient if he/she does not have additional insurance	· healthcare insurer (HCP)	· B: 'It is not officially allowed (...). And suppose you declare the hospital-based physiotherapy via this. In that case, it is at the expense of the additional insurance [plan] (...) if patients do not have additional insurance, they will still have to pay those costs themselves.' (HCP)
		Inclusion of allied healthcare providers (e.g., HBP and NP) in the basic health insurance package	· The costs for physiotherapy are relatively cheap and costs remain affordable	· Funding systems are challenging due to traditional and financial boundaries between primary, secondary, and tertiary care · If TTCM saves costs in the long term, the financing can also be obtained from the hospital's own budget · Evaluation of an intervention's cost-effectiveness is necessary before the products are included in the basic health insurance	· hospital-based allied healthcare manager (HBAHM) · healthcare innovator (HI) · healthcare insurer (HCP) · trauma surgeon (TS)	· F: 'And perhaps our only advantage is that physiotherapy is relatively cheap compared to the cost of chemotherapy or a medical specialist.' (HBAHM) · B: 'Well, that is a well-known very difficult [...] the bottleneck is that it is cost-effective [...] so you don't need any extra money because you already get it out yourself.' (TS)

Table 2 Continued

Level	Theme	Subtheme	Facilitator	Barrier	Stakeholders	Illustrative quote
		"Primary Care Plus" (Dutch: Anderhalvelijnszorg)	· Possibly lower costs	· No structural agreements yet for "Primary Care Plus" · "Primary Care Plus" more related to primary care than to secondary and tertiary care · Trauma surgeons and HBP cannot typically work in primary care due to feasibility concerns	· healthcare insurer (HCP)	· B: 'I think "Primary Care Plus" sounds less logical here.' (HCP)
		Use of internal funds (e.g. hospital)	· There are sometimes internal funds through research and/or innovation projects · Hospitals have to distribute money from the health insurer themselves, so they can choose to partially give more money to physiotherapy	· Scarcity of financial resources at the hospital level · The final hospital budget is allocated during the year, what makes the planning difficult	· hospital-based allied healthcare manager (HBAHM) · healthcare innovator (HI) · trauma surgeon (TS)	· B: 'After a few months, you hear your budget for the current year.' (HBAHM) · B/F: 'The hospital distributes money behind the scenes.' (TS)
		Use of external funds (e.g., municipalities, health insurers)	· Shared-ownership facilitates financing and vice versa	· Local agreements are not automatically transferable to all hospitals · Health insurance funds much less due to the COVID-19 pandemic.	· hospital-based allied healthcare manager (HBAHM) · analyst and account manager healthcare contracting (AAMH)	· F: 'That worked out due to [name health insurer]'s innovation funds and shared efforts, as they co-developed the new transmural care model.' (HBAHM) · B: 'There is no guarantee that this will work for other hospitals.' (AAMH) · F: 'The budget of the health insurers of our hospital is frozen in 2021 due to COVID-19 pandemic.' (HBAHM)
	Organisation structure	Organisation hospital		· Fragmentation of care and logistics within a hospital means that several managers must be consulted to reach an agreement · If a hospital does not have one major health insurer, discussions must be held with several health insurers	· hospital-based allied healthcare manager (HBAHM)	· B: 'Unfortunately, physiotherapy is not the same department in our hospital as trauma surgery. So yes, you have to talk to them and together arrange reimbursement.' (HBAHM) · B: 'Yes, both departments [trauma surgery and physiotherapy] said that it [TTCM] was good. However, ... we [department of trauma surgery] are not going to pay for them [the HBPs].' (HBAHM) · B: 'Our hospital's largest health insurance company provides about 25% of the total budget. (...) So our purchasing department has to work with various health insurers to arrange financing for all trauma patients.' (HBAHM)

Table 2 Continued

Level	Theme	Subtheme	Facilitator	Barrier	Stakeholders	Illustrative quote
	Physical structure		· The smaller the outpatient clinic [the fewer HBPs are scheduled], the less money is needed	· The larger the outpatient clinic for trauma patients, the more money is needed to schedule a HBP at the outpatient clinic for trauma patients	· healthcare innovator (HI)	· B: 'They may have one or two trauma outpatient clinics, so the costs are manageable. While other hospitals [...] have 12 trauma outpatient clinics, which has a lot more impact on the costs....' (HI)
Culture	Hierarchy		· Relatively high level of influence of medical specialists within a hospital	· Allied healthcare providers' have relatively low level of influence within a hospital	· healthcare innovator (HI) · hospital-based allied healthcare manager (HBAHM)	· B: 'I'm too low in the hierarchy to be able to set that up [reimbursement of the HBP].' (HBAHM) · B/F: 'Because then you notice that a medical specialist has a lot more power.' (HI)
	Commitment and responsibility		· Dedicated key actors · Local ownership · Context important	· Scarcity of personnel and time · Not-invented-here syndrome	· healthcare innovator (HI) · hospital-based allied healthcare manager (HBAHM)	· F: 'We know how the implementation works in one center. So we build it from scratch with motivated people.' (HI) · B: 'They suffer from the 'not-invented-here syndrome'. So they avoid things they haven't created themselves.' (HI)
	Current developments in the Dutch healthcare system		· Transition from production-driven agreements to agreements that incentivize quality and appropriate care · Promotion of the government (e.g. "the right care at the right place", "appropriate care" (Dutch= Zinnige zorg))	· Agreements between hospitals and health insurers production-driven	· analyst and account manager in healthcare contracting (AAMH)	· B: 'The agreements you make with insurers are often production-driven. So the more production you run, the more money you get.' (AAMH) · B/F: 'There is a transition in the Netherlands. We are actually moving towards: Less is more.' (AAMH)

Quotes are from a healthcare innovator (HI), one trauma surgeon (TS), one medical advisor of the National Health Care Institute (MAZIN), one healthcare insurer (purchasing paramedical care and medical specialist rehabilitation care) (HCP), one analyst and account manager in healthcare contracting (AAMH), and four hospital-based allied healthcare managers (HBAHM)

STRUCTURAL-LEVEL

Three themes were identified: “proposed funding models”, “organizational structure”, and “physical structure”.

Proposed funding models refer to the funding models that stakeholders came up. The first two models (i.e. “non-regular declaration code”, “integrated funding”) were aimed at arranging funding for the *complete TTCM*, all others were primarily aimed at arranging funding for the *HBP*.

1. Non-regular declaration code (Dutch: Facultatieve prestatie) refers to funding the *complete TTCM* through a so-called non-regular declaration code. Such codes allow healthcare providers and health insurers to tackle financial bottlenecks that cannot easily be solved using an existing declaration code. Healthcare providers and healthcare insurers can then jointly request a new declaration code at the Dutch Healthcare Authority (29). For the TTCM, a non-regular declaration code would imply that all parts are funded through a single code, which health insurers can include it in their procurement contracts. After approval, other parties can also declare/reimburse the healthcare product using the same code. A hospital-based allied healthcare manager indicated that their application for a non-regular declaration code was approved for the TTCM, but that healthcare insurers eventually decided not to procure it:

> *‘And insurers can choose to procure the “non-regular declaration code”. And then it turned out that the insurers did not want to do so.’*

Some stakeholders believed that this was due to the health insurers being afraid to then fund certain services twice, e.g., the HBP to perform his/her regular tasks and for taking part in the joint TTCM consultations. Moreover, while a non-regular declaration code could fund the complete TTCM at once, it would still be hard to distribute funds across care sectors.

2. Integrated funding (Dutch: Integraal pakket) refers to funding the *complete TTCM* through an integrated package. For this, an optional declaration code must be jointly requested by healthcare providers in primary and secondary care, and a healthcare insurer (29). In contrast to a non-regular declaration code, however, integrated funding typically only involves chain partners in primary care (e.g., general practitioners, physiotherapists, and other allied healthcare professionals). For transmural care models, integrated funding has been challenging to organize due to existing boundaries between care sectors and the lacking of procedural regulation.

3. Increasing the Diagnosis Treatment Combination price refers to funding the HBP in particularly, by increasing the DTC price for the outpatient consultation of the trauma

surgeon. All participating stakeholders considered this to be relatively easy and transparent. An advisor of the Dutch National Health Care Institute noted:

> *'If you look at the HBP who helps the trauma surgeon with the treatment goals, you could say that he/she is an extension of specialist care and should thus be included in the DTC.'*

A frequently mentioned barrier to this model was that DTC prices have to be negotiated per insurer and are negotiated only annually. A health insurer indicated that it would be relatively hard to determine the necessary price increase, as it is unclear how many hours a HBP invests per TTCM patient. Although one hospital successfully arranged funding for the HBP through this model, most others did not, partly because DTC negotiations were halted during the COVID-19 pandemic.

4. Declaration within medical specialist care contracts refers to funding the HBP through a yearly financial agreement between hospitals and health insurers, where certain in-hospital (allied) healthcare services are reimbursed through the same system as their primary care counterparts. For the TTCM, this would mean that HBPs would be funded similarly to NPs.

The most important barrier to this model is legality, because similar declarations mostly concern outpatient consultations with individual (allied) healthcare providers, instead of joint consultations (e.g., HBP and trauma surgeon). Moreover, the patient's health insurance plan must then cover physiotherapy, meaning that patients need to have additional insurance that covers all physiotherapy sessions or have to bear the costs themselves.

5. Including all allied healthcare (e.g., HBP and NP) in the basic health insurance package refers to funding the HBP and NP through the basic healthcare insurance package. A facilitator of this funding model is that physiotherapy is relatively cheap. A hospital-based allied healthcare manager mentioned, for example:

> *'… our only advantage is that physiotherapy is relatively cheap compared to the cost of chemotherapy, a new drug, or a medical specialist.'*

Despite the relatively low cost of physiotherapy, its cost-effectiveness still needs to be established. Two stakeholders mentioned that they were concerned that if the TTCM would turn out to be cost-effective from the hospital perspective, health insurers might demand hospitals to pay for the extra expenses themselves.

6. *"Primary Care Plus" (Dutch: Anderhalvelijnszorg)* refers to an existing funding model where a combination of primary and secondary healthcare is funded through the basic health insurance package. With this model, however, secondary healthcare providers typically work in primary care (e.g., at a general practice), meaning that the trauma surgeon and HBP

would have to work in primary care as well, which was deemed infeasible. Additionally, no structural agreements currently exist regarding *"Primary Care Plus"*.

7. Internal funds refers to funding the HBP through cash flows within hospitals; e.g., through in-hospital innovation funds. Such internal funds are regularly available, but stakeholders indicated that the budgeting of these funds is often not timely and transparent. Some stakeholders also indicated that it is challenging to arrange long-term internal funding, because such funds are typically allocated on a yearly basis. Hence, even though internal funds can be relatively easily arranged, they do not seem to be future-proof.

8. External funds refers to funding the HBP through external funds; e.g., innovation funds of municipalities or health insurers. External funds can be requested without the government's intervention, but do not offer long-term funding either. They can, however, create shared ownership between a hospital and health insurer/municipality, which might, in turn, facilitate both structural implementation and funding. However, as many external funds are based on agreements between hospitals and health insurers/municipalities, they are not easily transferable across hospitals. Moreover, health insurers have spent less on external funds in recent years due to the COVID-19 pandemic.

Organisational structure refers to the organisational structure of a hospital. Here, the most important barrier was the fragmentation of care and the lack of communication between healthcare providers and departments. According to the stakeholders, fragmentation of care is of particular concern to the TTCM, as HBPs and trauma surgeons typically work at different departments, each with different cash flows and logistics. Consequently, several managers must be consulted and convinced before being able to reach funding agreements. A hospital-based allied healthcare manager noted:

> *'Yes, both departments [trauma surgery and physiotherapy] said that it [TTCM] was good. However, …. we [trauma surgery] are not going to pay for them [the HBPs].'*

Another frequently mentioned barrier was that Dutch hospitals must make contract agreements with each health insurer separately.

Physical structure refers to the size of the outpatient clinic (in terms of space and employees), which directly influences the complexity and amount of money required for implementing the TTCM. One healthcare innovator noted:

> *'They may have one or two trauma outpatient clinics, so the costs are manageable. While other hospitals […] have 12 .., which has a lot more impact on the costs….'*

CULTURAL-LEVEL

Three themes were identified: “hierarchy”, “commitment and responsibility”, and “current developments in the Dutch healthcare system”.

Hierarchy refers to the difference in the influence that medical specialists (e.g., trauma surgeons) and allied healthcare providers (e.g., HBP) have within a hospital. Stakeholders perceived allied healthcare providers’ relatively small influence to be an important barrier. A hospital-based allied healthcare manager noted:

> *‘I’m too low in the hierarchy to be able to arrange that [reimbursement of the HBP].’*

Stakeholders also noted, however, that the relatively large influence of medical specialists can be used as an advantage.

Commitment and responsibility refer to the degree of commitment and responsibility that stakeholders feel for arranging funding for the TTCM. Some stakeholders emphasized that achieving a sense of local ownership and understanding of the context (e.g., local cultural and political factors) play a significant role in fostering commitment and responsibility, and hence in arranging funding for the TTCM. However, the scarcity of personnel and time and the so-called ‘not-invented-here syndrome’ were perceived as important barriers. A healthcare innovator noted:

> *‘They suffer from the “not-invented-here syndrome”. So they avoid things that they haven’t created themselves.’*

Current developments in the Dutch healthcare system refers to the current shift from volume-based to value-based healthcare procurement. Stakeholders thought that volume-based agreements encourage health providers to focus on the quantity of services provided rather than their quality, which in turn hampered acquiring funding for the TTCM. An analyst and account manager in healthcare contracting noted:

> *‘The agreements you make with insurers are often production-driven. So the more production you run, the more money you get.’*

Stakeholders indicated, however, that the current shift towards value-based healthcare agreements might eventually alleviate this barrier.

PRACTICAL-LEVEL

No themes were identified.

DISCUSSION

Main findings

It is hard to arrange funding for transmural care models, e.g., the TTCM. Most stakeholders perceived funding for secondary care activities performed by allied healthcare professionals to be the main bottleneck (i.e., HPB). Stakeholders proposed eight funding models, of which two were aimed at funding the complete TTCM and six the HBP in particular. A funding model where secondary care activities (i.e., HBP) are funded by increasing the DTC price of medical specialist care (i.e., trauma surgeon) seemed most feasible and future-proof. Other important challenges included 'the fragmentation of care' and 'a lack of commitment'.

Comparison with the literature

Several identified barriers and facilitators are consistent with those of other studies. For example, Bloemen-Vrencken et al. (11) found that implementation of a transmural care model for spinal cord injury people was hampered by organizational and financial constraints, and prevailing social attitudes. Researchers that assessed the implementation of a transmural palliative care consultation service also found a need for more guidance on organizational issues and appropriate funding (9). Baker et al. (30) found that financial and organizational barriers can impede funding of transmural care and, thus, highlighted the importance of leadership in their successful implementation.

Recommendations for practice

The current study identified eight potential funding models. Two models were aimed at funding the complete TTCM, which seems difficult to organise due to strict boundaries between care sectors (31, 32). Funding HBPs through the same system as their primary care counterparts seems sub-optimal as well, as this would mean that patients either need to have additional insurance or have to bear the costs themselves. Including HPBs in the basic health insurance package also seems infeasible, as physiotherapy funding is still a highly debated topic in the Netherlands (33). While using internal or external funds seems feasible, it only offers a solution in the short-term. The most feasible funding model seems to be increasing the DTC price of medical specialist care (i.e., trauma surgeon). Although one hospital was successful in doing so, most others were not, because DTC negotiations were halted during the COVID-19 pandemic (34). Nevertheless, DTC negotiations are anticipated to be started again.

The Dutch Ministry of Health, Welfare, and Sports is also studying a funding model for transmural care models, i.e., *"Sectoroverstijgende betaaltitel"* [in Dutch]. Such a model would allow for a single payment mechanism for healthcare providers of different sectors and is expected to improve access to transmural care and to reduce costs. However, the barriers and facilitators associated with this new model still need to be assessed (35). In the meantime, transmural care activities performed by secondary allied healthcare professionals can be funded by increasing the DTC price for medical specialist care (28, 36).

Strengths and limitations

Our study had several strengths. First, its qualitative approach yielded in-depth information (37). Second, the use of a theoretical framework (38) enabled the systematic exploration of the data. Third, credibility was improved by performing a member-check (26). There were also some limitations. First, data were obtained through interviews, which may have caused 'social desirability bias'. Second, participants were purposively selected, which may have made them more knowledgeable and/or positive about transmural care models.

CONCLUSION

It is difficult to fund transmural care models as a whole, and secondary care activities performed by allied healthcare professionals in particular. A funding model where the latter are funded by increasing the price of medical specialist care seemed most feasible. When arranging funding, it is important to have dedicated key actors, and a dedicated medical specialist in particular.

SUPPLEMENTARY FILE 1: THE DUTCH HEALTHCARE SYSTEM

The Dutch healthcare system

The Dutch healthcare system is best compared to that of Belgium, Germany, and Switzerland. These countries recently shifted from a system with a hierarchical structure to one with more opportunities for insurers and providers to be more entrepreneurial (34). In 2006, the Dutch government implemented provider competition in its healthcare system (39). This reform established regulated competition between healthcare insurers, insured individuals, and healthcare providers on three different markets: (1) the healthcare insurance market, (2) the healthcare provision market, and (3) the healthcare purchasing market, all of which are linked to one another (Figure 2). The government and the Dutch Healthcare Authority monitor and regulate these markets (40).

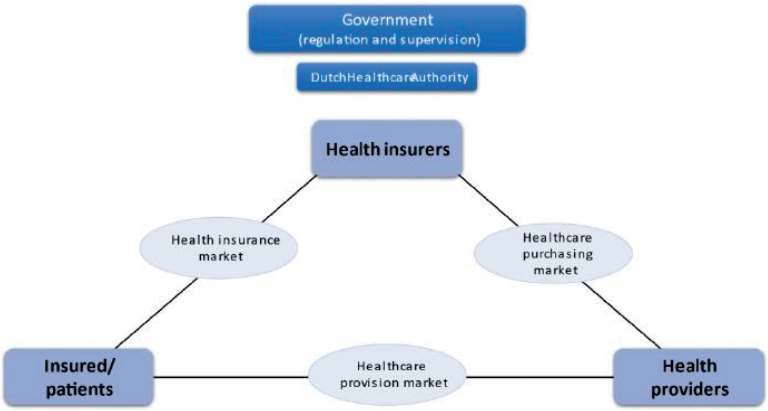

Figure 2 The Dutch healthcare system, adopted from Kroneman et al. (41).

The Dutch healthcare reform aimed to provide universal access to high-quality healthcare that was both affordable and based on solidarity (39, 40). The basic health insurance package covers all costs for the General Practitioner, most medications, and hospital costs, while for most of the services covered a front-end deductible (€385 in 2021) and, for some services, additional copayments are required. With regard to physiotherapy following hospital admission, sessions are only covered by the basic health insurance package after the 20th session up to one year following discharge. However, individuals can purchase an additional health insurance plan that covers part of the initial 20 sessions (42). The average premium of such a plan was equal to €30/month in 2021.

In the Netherlands, hospital payment rates are determined mostly through negotiations between health insurers and hospitals regarding prices, quality, and volumes. Most payments occur through the diagnosis-treatment combination (DTC, Dutch: DBC) system (43), which is similar to a diagnosis-related group approach in the United States (44). A DTC is a registry of diagnosis, treatment, and costs of in- and outpatient services provided by hospitals, for which prospectively fixed amounts are charged per episode of care. Each DTC

has its own price. In the Netherlands, insurers and hospitals can negotiate prices freely and contract selectively for 20% of the 4,500 DTCs (45).

Due to the financial crisis in 2013, the government announced a cost-saving measure, i.e. "the right care at the right place" (34), which aimed to avoid expensive care by replacing relatively expensive in-hospital or outpatient care (i.e. secondary care) with care delivered closer to individuals' homes (i.e. primary and transmural care) (46).

SUPPLEMENTARY FILE 2: TOPIC GUIDE

Introduction
Brief explanation of the TTCM. Depending on who is being talked to, a longer explanation may be given.
Explain the purpose of the interview: "What are the barriers and facilitators associated with funding the Transmural Trauma Care Model, specifically funding the hospital-based physiotherapist at the outpatient clinic of the trauma surgeon"
Important to briefly discuss results of the pilot study, where funding was identified as an important bottleneck: (Link: https://www.sciencedirect.com/science/article/pii/S1836955321000977?via%3Dihub)
Confirm the informed consent procedure.

Questions
1. What is your personal experience with the TTCM?/ with the funding of transmural care models? (Depending on the stakeholder)
2. To what extent do you influence/involve yourself in the process of funding transmural care models? (Depending on the stakeholder)
3. What role do you play related to the TTCM?/ funding of transmural care models? (Depending on the stakeholder) What are your tasks? What are your responsibilities?
4. Can you explain which parts of the TTCM intervention (would) require(d) funding? (Depending on the stakeholder)
5. What steps have you taken to secure financing?/ What steps need to be taken to fund transmural care models, such as the TTCM? (Depending on the stakeholder)
6. Did you manage to get funding for the TTCM? (If applicable)
If yes: How did you manage to do so? Is the funding structural or temporary? What does the funding look like? Where does the funding come from? Is it internal or external?
If temporarily: When will it end? And then how does it continue?
If structural: Is there an "end date" or does it continue "indefinitely"?
If not: What do you think is (still) needed to complete the financing? Can you give more insights about the barriers?
7. What factors helped/would help to get the TTCM/transmural care model funded? (Depending on the stakeholder)
8. What factors would be/have you found to be limiting? (Depending on the stakeholder)

Optional

9. If the current multicenter trial shows that the TTCM is effective and cost-effective, how do you think the TTCM should be implemented/funded nationwide, and why?
10. Which, if any, barriers and facilitators do you expect?

SUPPLEMENTARY FILE 3: CONSTELLATION APPROACH

The constellation approach assumes that a healthcare system consists of so-called constellations, *"a set of interrelated practices, and relevant, interrelated, structuring elements that together both define and fulfill a function in a larger societal system in a specific way"* (38). Within a constellation, there is continuous interaction between the elements of the "structure", "culture", and "practice" triplet (Figure 3). "Structure" consists of physical structures and resources, enforced regulations and legal rights, economic resources, and other material elements that structure behavior within a constellation. "Culture" refers to the paradigms, norms and values, and other immaterial elements that structure behavior in practices. "Practice" involves the typical operational routines that the constellation actors undertake. Actors are individuals (e.g., healthcare providers, patients) or groups (e.g., health insurance companies) who act in a particular constellation. For the TTCM, the hospital and the outpatient clinic for trauma patients are part of a bigger constellation in which health insurers and policymakers act in a particular structure and culture. For funding a transmural care model, it is essential to have detailed insight into the stakeholders and the nested complementing and competing (sub)constellations involved in that care model (47).

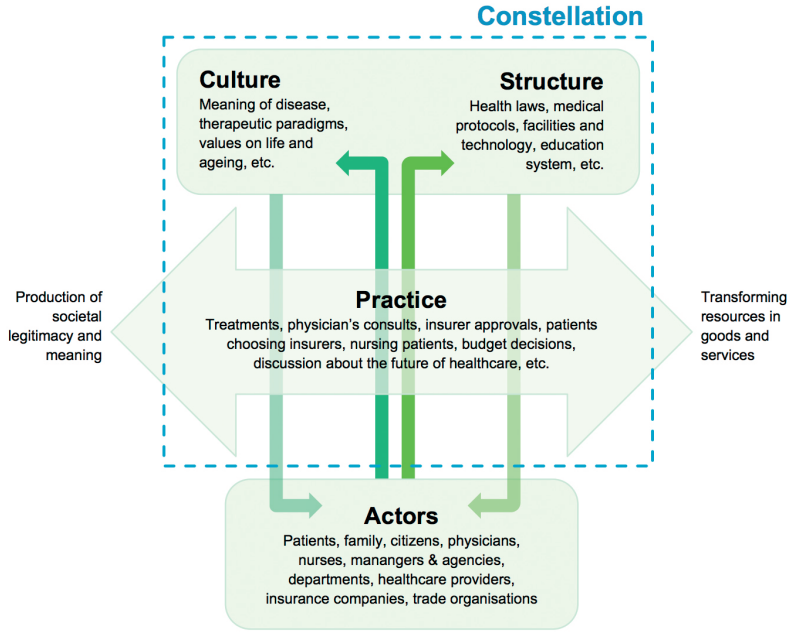

Figure 3 The interaction between the three elements of the 'structure, culture, and practice triplet' within a constellation (38).

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CHAPTER 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), 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 (yes/no) 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 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 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 that 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

Participants to the TTCM-trial were recruited from a Dutch level-1 trauma center (Amsterdam UMC, location VUmc). 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 (5-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 patients 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, €272 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 physiotherapist) 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) (48). 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 5000 replications, when societal costs were the dependent variable. For the three dependent variables, the following four models were performed:

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

Disease-specific HR-QOL

Table 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 2).

Functional outcome

Table 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 3).

Table 1 Patient and trauma characteristics and outcomes

	Patient characteristic	All participants (N = 140)
Case-mix variables	Age (years) [mean (SD)]	46.3 (16.8)
	Gender (male) [n (%)]	65 (46.4)
	Comorbidity [n (%)]	
	none	83 (59.3)
	chronic illness	27 (19.3)
	musculoskeletal disease	30 (21.4)
	Received TTCM (yes) [n (%)]	83 (59.3)
	ISS* [mean (SD)]	8.2 (5.2)
	Trauma type [n (%)]	
	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) [n (%)]	74 (52.9)
	Fracture type [n (%)]	
	intra articular	115 (82.1)
	extra articular	25 (17.9)
	Fracture localization [n (%)]	
	single upper extremity	56 (40.0)
	single lower extremity	60 (42.9)
	vertebral fractures(s)	8 (5.7)
	multi-trauma	16 (11.4)
	Fracture treatment [n (%)]	
	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 indicating lower HR-QOL) [mean (SD)]	18.8 (16.5)
	Functional outcome (PSFS****, range 0-100, higher score indicating more functional problems) [mean (SD)]	25.0 (25.3)
	Societal costs in Euros [mean (SEM)]	5047 (422)

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

Table 2 The association of 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 3 The association of 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 4 The association of fracture and treatment related factors with costs

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	-1884 (-3656 to -570)	-1884 (-3656 to -561)	-1879 (-3678 to -518)	-1770 (-3276 to -433)
Fracture type (ref: extra-articular) ***				
Intra-articular	-867 (-6690 to 1346)	-886 (-6589 to 1337)	-475 (-5448 to 1752)	-622 (-4143 to 1449)
Fracture localization (ref: other) ***				
Upper extremity	-1891 (-3846 to -113)	-1923 (-3881 to -141)	-1763 (-3665 to 157)	-1652 (-3694 to 406)
Lower extremity	-1170 (-3160 to 1193)	-1245 (-3266 to 1530)	-898 (-2914 to 2377)	-1567 (-3529 to 772)
Fracture treatment (ref: cons.)***				
Intramedullary nail	3543 (352 to 13794)	3728 (99 to 14359)	3654 (-191 to 13934)	3507 (-105 to 12390)
ORIF*	1537 (206 to 2927)	1646 (249 to 3212)	1702 (270 to 3348)	1651 (245 to 3237)

* 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

Societal costs

Table 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: -1770; 95%CI: -3276 to -433). Furthermore, fracture treatment with ORIF was statistically significantly associated with higher societal costs compared to conservative treatment (Model 4: 1651; 95%CI: 245 to 3237), 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 4).

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 having 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 having a vertebral fracture or multi-trauma. Moreover, the societal costs of trauma patients who had surgery were on average €1,770 lower during the first 9 months after their first visit at the outpatient clinic for trauma patients compared to trauma patients who did not underwent surgery. However, ORIF was associated with on average €1,651 higher societal costs, compared to conservative treatment, whereas intramedullary nailing was not significantly associated with costs. Fracture type was not found to be associated with disease-specific HR-QOL, functional outcome, and societal costs.

Most of these associations were in the expected direction, with 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 costs after their first outpatient visit compared to those who did can likely 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 possibly leads to a quicker return to work and thus a decrease in total societal costs.

Comparison with the literature

Even though extensive research has been done on functional outcome and costs after major trauma, 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, one 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 opposite results. Differences in study population (i.e. patients with a distal radial fracture versus all kinds of fractures) and study design might explain this difference in results.

Other authors only assessed the association of trauma or fracture-related factor with a relatively small number of outcomes. For example, Chiu et al. only 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 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 43. 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 category in our analyses. Therefore, we decided to use an "other" group, including both vertebral fracture and multi-trauma patients, as reference category for the independent variable fracture localization. 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 (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 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 and it might be underpowered. The possible influence of some patients receiving the TTCM was handled by correcting for receiving the TTCM in the final models. 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. amongst 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. Which 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 be included. 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 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 (yes/no) 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.

Abbreviations:
VUmc: VU University Medical Center**,** TTCM: Transmural Trauma Care Model**,** HR-QOL: Health-Related Quality Of Life, ORIF: Open Reduction Internal Fixation**,** NTR: The Netherlands National Trial Register, ISS: Injury Severity Score, PROMS: Patient Reported Outcome Measures, LEFS: Lower Extremity Functional Scale, GARS: Groningen Activity Restriction Scale, RMDS: Roland Morris Disability Score, PSFS: Patient Specific Function Scale

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CHAPTER 7

Content validity and measurement properties of the Lower Extremity Functional Scale in patients with fractures of the lower extremities: a systematic review

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J Patient Rep Outcomes. 2022;6(1):11.

ABSTRACT

Background: Fractures of lower extremities are common trauma-related injuries, and have major impact on patients' functional status. A frequently used Patient-Reported Outcome Measure (PROM) to evaluate patients' functional status with lower extremity fractures is the Lower Extremity Functional Scale (LEFS). However, there is no systematic review regarding content validity and other measurement properties of the LEFS in patients with lower extremity fractures.

Methods: A search was performed in PubMed, Embase, Scopus, and Cochrane Library from inception until November 2020. Studies on development of the LEFS and/or the evaluation of one or more measurement properties of the LEFS in patients with lower extremity fractures were included, and independently assessed by two reviewers using COSMIN guidelines.

Results: Seven studies were included. Content validity of the LEFS was rated 'inconsistent', supported by very low quality of evidence. Structural validity was rated 'insufficient' supported by doubtful methodological quality. Internal consistency, measurement error, and responsiveness were rated 'indeterminate' supported by inadequate to adequate methodological quality. The methodological quality of the construct validity (hypotheses testing) assessment was rated as 'inadequate'.

Conclusion: The LEFS has several shortcomings, the lack of sufficient content validity being the most important one as content validity is considered the most crucial measurement property of a PROM according to the COSMIN guidelines. In interpreting the outcomes, one should therefore be aware that not all relevant aspects of physical functioning may be accounted for in the LEFS. Further validation in a well-designed content validity study is needed, including a clearly defined construct and patient involvement during the assessment of different aspects of content validity.

PLAIN ENGLISH SUMMARY

Bone fractures of the lower extremities are a common injury. During rehabilitation it is essential to evaluate how patients experience their physical functioning, in order to monitor the progress and to optimize treatment. To measure physical functioning often questionnaires (also known as Patient Reported Outcome Measures) are used, such as the Lower Extremity Functional Scale (LEFS). However, it is not clear if the LEFS actually measures physical function, and if its other measurement properties are sufficient for using this questionnaire among patients with fractures in the lower extremities. Therefore, we systematically searched and assessed scientific papers on the development of the LEFS (i.e., its ability to measure physical functioning), and papers on the performance of the LEFS with regard to several measurement properties to identify possible factors that may cause measurement errors. Hereby we have assessed the quality of the studies included. Our main finding was that the LEFS may not measure all aspects of physical function. Given the low quality of the papers included in our study, these findings come with considerable uncertainty. As the LEFS was developed more than 20 years ago, it may not represent physical functioning as we currently conceptualize this. Therefore, we recommend to perform a study in which the content of the LEFS will be evaluated by experts in the field as well as patients, and modify the questionnaire as needed.

BACKGROUND

Fractures of the lower extremities are a common injury. Moreover, as life expectancy is generally increasing and the risk of osteoporotic fractures typically grows with age, lower extremity fractures are a rising source of morbidity, particularly in the elderly population (1-3). In younger patients, fractures are more frequently sustained from high-energy or sports-related trauma (4-6). Although data on the worldwide incidence of fractures are scarce and oftentimes outdated, studies suggest that their worldwide incidence ranges from 9.0 to 22.8 fractures per 1000 person-years (7, 8), and fractures of the lower limb account for approximately one third of all fractures (9-11).

Fractures of the lower extremities have a major impact on patients' functional status (5, 10, 12-14). Due to a variation of types of injury and treatment and the variation in the natural recovery process of traumatic fractures patients with fractures typically differ from patients with other lower extremity dysfunction, for instance rheumatism.

After traumatic injury, maximizing patients' recovery relies heavily on optimizing their functional status and minimizing their symptoms (15-17). Using a validated Patient-Reported Outcome Measure (PROM) helps identify and address these outcomes in clinical practice (18, 19). PROMs are designed to quantify the patients' health, health-related quality of life, or functional status without interpretation of the patients' response by a clinician (14, 20-22).

A frequently used PROM to examine the functional status of patients with lower extremity fractures is the Lower Extremity Functional Scale (LEFS) (23, 24). The LEFS is a self-administered questionnaire containing 20 questions about a person's ability to perform everyday tasks. The scale ranges from 0 to 80, with higher scores indicating better function.

Two systematic reviews have assessed the measurement properties of the LEFS (24, 25). Although these systematic reviews concluded that the LEFS had good reliability, validity, and responsiveness (24, 25), no comprehensive assessment on content validity was performed, and none of these studies focused on the measurement properties of the LEFS in patients with fractures of the lower extremities in particular (26). Therefore, this study aimed to systematically review the literature to evaluate the content validity and other measurement properties of the LEFS in patients with fractures of the lower extremities in accordance with the COSMIN methodology for systematic reviews of Patient-Reported Outcome Measures (PROMs) (26).

METHODS

This review was conducted in accordance with the COSMIN methodology for systematic reviews of Patient-Reported Outcome Measures (PROMs) (26). A protocol was written *a priori* and was registered prospectively in PROSPERO (registration number: CRD42020184557).

Data sources and study selection

A search was performed in PubMed (including Medline), Embase, Scopus, and the Cochrane Library from inception until November 2020. The initial search was conducted together with an experienced clinical librarian (EJ) on 27 May, and updated on 3 November 2020. The search strategies are presented in Appendix **1.** Additionally, a forward citation search was performed in Google Scholar, and references of included studies were cross-checked.

Eligible studies had to report on the development of the LEFS or the evaluation of one or more measurement properties of the LEFS in patients with at least one fracture of the lower extremities. As content validity is considered the most crucial measurement property of a PROM (27), we decided to include the original development study of the LEFS, irrespective of the study population, which is in line with the COSMIN methodology for systematic reviews of Patient-Reported Outcome Measures (PROMs) (26). According to the guideline of Prinsen et al. (28) 'content validity is defined as 'the degree to which the content of an instrument is an adequate reflection of the construct to be measured' is the first measurement property that should be assessed when selecting an instrument, as it allows making a link between the content of the instrument and that of the construct to be measured.'

Studies reporting on all other measurement properties had to have a study sample consisting largely of patients with at least one fracture of the lower extremity (≥75% of the sample) (26).

No timing criteria for the fractures of the lower extremities were used as inclusion criteria. Studies published in any language were eligible for inclusion, in accordance with the COSMIN methodology for systematic reviews of Patient-Reported Outcome Measures (PROMs) (26). Studies that used the LEFS as an outcome measure or studies that used the LEFS to assess another instrument's measurement properties were excluded (26).

Records retrieved by the search were independently assessed for eligibility by two reviewers (JR, SP). The initial selection was based on title and abstract. Potentially eligible studies were assessed by obtaining the full-text to confirm eligibility. Discrepancies between reviewers were reviewed, and consensus was achieved by discussion.

Data extraction and quality assessment

Data on the characteristics of the study population (i.e., sample size, age, gender, proportion of total sample consisting of fracture patients, location fracture, treatment, time since fracture/treatment) and instrument administration (i.e., setting, country, language) were extracted by one reviewer (JR) and checked by a second reviewer (SP). A customized data extraction form was developed for this purpose, based on the COSMIN guidelines (26). The methodological quality of the included studies was assessed by two independent reviewers (JR, SP), using the COSMIN Risk of Bias (RoB) checklist (26).

This checklist included ten separate boxes with standards for individual assessment of PROM development (box 1), and for nine measurement properties (box 2- 10) according to the COSMIN taxonomy which is based on the COSMIN guidelines (26). The order and structure of evaluating the measurement properties were in line with the COSMIN methodology for systematic reviews of Patient-Reported Outcome Measures (PROMs) (26), i.e.:

- *Content validity*: PROM development (not a measurement property, but taken into account when evaluating content validity) and content validity;
- *Internal structure*: structural validity, internal consistency, Cross-cultural validity/ measurement invariance;
- *Remaining measurement properties*: reliability, measurement error, criterion validity, hypotheses testing for construct validity, responsiveness (29).

In our protocol we had included the evaluation of all measurement properties. However, none of the included studies evaluated cross-cultural validity and criterion validity and therefore these measurement properties were not further evaluated.

The assessment of *content validity* required slightly different steps than assessing *internal structure* and the *remaining measurement properties*, both of which will be discussed in more detail below.

To assess the LEFS's *content validity,* the COSMIN guideline for systematic reviews of PROMs (26) as well as an additional guideline for evaluating the content validity of PROMs were used (27), and the three following steps were conducted:

1) Evaluation of the quality of the PROM development: The quality of the PROM development was evaluated by two independent reviewers (JR, SP), using the COSMIN Risk of Bias checklist box 1, which consists of two parts (quality of the PROM design, quality of a cognitive interview study or other pilot test).
2) Evaluation of the quality of all additional content validity studies on the PROM (if available): If available, the quality of additional content validity studies was evaluated using the COSMIN Risk of Bias checklist box 2, concerning relevance, comprehensiveness, and comprehensibility of the PROM.
3) Evaluation of the content validity of the PROM, based on the quality and results of the available studies and the PROM itself against the ten criteria for good content validity: In this step, the content validity of the PROM was rated by two independent reviewers (JR, SP), based on a summary of all available evidence on the PROM development and additional content validity studies, if available. In addition, according to the COSMIN guideline (27), the reviewers rated the content of the PROM themselves hereby using additional literature linking ICF categories on to the LEFS (30).

To assess the LEFS's *internal structure* and the *remaining measurement properties,* the three following steps were conducted:

1) Methodological quality assessment: The methodological quality of the included studies was assessed by two independent reviewers (JR, SP), using the COSMIN Risk of Bias (RoB) checklist (26). The studies' methodological quality was assessed per measurement property separately. That is, per measurement property, only the boxes pertaining to that measurement property were used. Each box consists of four or more items, all of which were rated on a 4-point rating scale (i.e., "very good", "adequate", "doubtful", or "inadequate"). The studies' overall score per measurement property was equal to the lowest rated item of the respective box (i.e., "the worst score counts" principle). Discrepancies between reviewers were discussed and solved by consensus.
2) Measurement property assessment: The results of every single study on a specific measurement property (e.g., ICC or weighted Kappa) were extracted and subsequently rated according to the updated criteria for good measurement properties as being "sufficient", "insufficient" or "indeterminate" (26), as stated in the COSMIN guideline (26).
3) Summarizing and grading the evidence: In our protocol we had included "quantitatively pooling of the results" and "grading the evidence of all available studies in accordance with the GRADE approach". However, based on the included studies, we were not able to perform these steps due to insufficient homogeneity in both statistical analysis and study population, and the inconsistency of results of all available studies per measurement property (26).

Results

Identified studies

The search yielded 2,170 records, equaling 1173 potentially relevant studies after removing duplicates. After initial screening, 67 full texts were obtained. The final selection included seven studies. Reasons for excluding studies included were: no full-text available (n=2), wrong study population (e.g. musculoskeletal disorders) (n=48) and wrong study design (e.g. studies that used the LEFS as an outcome measure or studies that used the LEFS to assess another instrument's measurement properties) (n=10). More details of the search are presented in Figure 1.

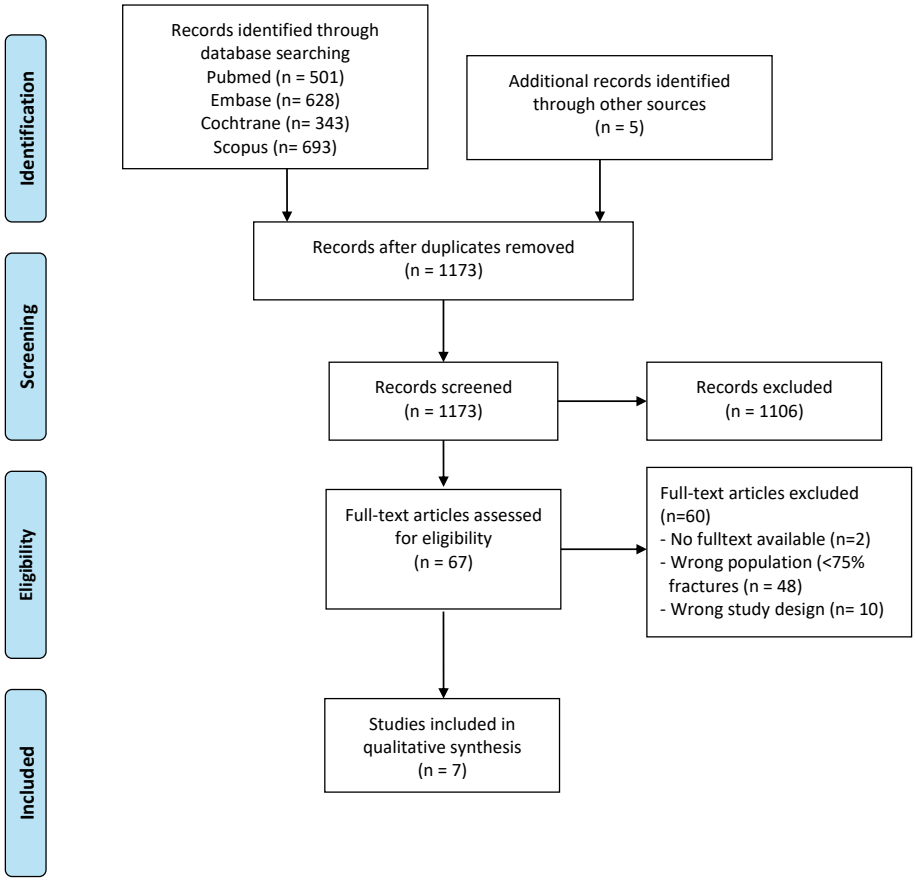

Figure 1 PRISMA flow diagram

Study characteristics

Sample sizes of the included studies varied from 20 (31) to 567 patients (32). The mean age of the patients ranged from 38.0 (31) to 57.5 years (32), and 50.3% (33) to 70.0% (31) of the patients were female. These figures are based on the descriptive statistics where we rely

on the reported numbers as published in the included studies. The setting in which the measurement properties of the LEFS were assessed differed between studies and included a physical therapy clinic (23), a (teaching) hospital (32, 34, 35), a rehabilitation department (31, 33), and records from a national electronic database on post-operative patients (36). The LEFS was assessed in four languages, including English (23, 33), Norwegian (32), Chinese (31), and Finnish (34-36). All included studies met the criterion of having at least 75% subjects with a fracture of the lower extremity, except for Binkley et al.'s (23) development study, where only 10.2% had a lower extremity fracture. Furthermore, Hsu et al. (31) included patients with ankle fractures and a group of age- and sex-matched healthy controls. This study was included because more than 75% of the fracture patient group had a fracture of the lower extremities. The LEFS was administered directly after (surgical) treatment (23) until several years after trauma (31-36). Fractures were located in different lower extremities regions, mostly the ankle/foot region (23, 31-36). More details on the characteristics of the studies are presented in Table 1.

Seven studies were included, including one study that evaluated the development of the LEFS (23). No additional content validity studies were identified. Five studies (32-36) evaluated structural validity, four studies (32-35) evaluated internal consistency, two studies (32, 34) evaluated reliability, two studies (32, 35) evaluated measurement error, and three studies (31, 32, 34) evaluated construct validity (i.e. hypotheses testing). One study (33) evaluated two aspects of responsiveness (i.e. hypotheses testing: comparison with other outcome measurement and hypotheses testing: before and after intervention). None of the studies evaluated cross-cultural validity and criterion validity and therefore were not further evaluated.

Table 1 Characteristics of the studies

	Population				Fracture characteristics			Instrument administration		
Studies in alphabethic order	N	Age Mean (SD, range) yr	Gender % female	Fracture (% of total sample)	Location fracture(s)	Treatment surgical/ non-surgical	Time since fracture/ treatment	Setting	Country	Language
Binkley, Stratford (23)	107	Mean 44 (SD 16.2)	54.2%	10.2%	knee, thigh, foot, ankle	unclear	6 (0-250) weeks since onset	Physical therapy clinics	United States and Canada	English
Garratt, Naumann (32)	959 (returned: 567)	Mean 57.5 (Range 22.2-91.2)	56.8%	100%	ankle (Weber A 2.6%, Weber B 67.5%, Weber C 27.5%)	operative fixation of closed ankle fractures	> 3 years after treatment	2 hospitals in SE Norway	Norway	Norwegian
Hsu, Tsai (31)	20	Median 38.0 (IQR 18.0)	70%	50% (100% cases)	ankle	cast immobilization ± open reduction and internal fixation	4 months (median) after fracture	Rehabilitation department of a teaching hospital	Taiwan	Chinese
Lin, Moseley (33)	306	Mean 45.1 (SD 15.7)	50.3%	100%	ankle	56.3% surgical	within 7 days of cast removal	Outpatient physical therapy departments of 3 teaching hospitals, outpatient orthopedic clinic of 2 teaching hospitals	Australia	English
Ponkilainen, Tukiainen (36)	165	Mean 54.6 (SD 19.7)	54.5%	95.5% trauma (n = 156), infection (n = 6), tumor (n = 2) or osteoarthritis (n = 1)	ankle (n=133), hindfoot (n=16), midfoot (n=7), forefoot (n=3) or more locations (n = 6)	ankle fracture osteosynthesis, removal of implants from foot or ankle, tibiotalar joint fusion	averagely 4 years (range from 1 month to 10 years) after surgery	Database	Finland	Finnish
Repo, Tukiainen (34)	166	Mean 55.0 (SD 16.0)	53%	90%	ankle, foot	100% surgical	4 years (0-14) time since surgery	Helsinki University Hospital	Finland	Finnish
Repo, Tukiainen (35)	182	Mean 55.0 (SD 16.0)	53.5%	89%	ankle, foot	100% surgical	3.2 years (9.6) since surgery	Helsinki University Hospital	Finland	Finnish

Methodological quality and measurement property assessment

PROM development and content validity

One study was identified on the development and initial assessment of the LEFS (23), whereas no additional studies were identified on the content validity of the LEFS. A clear description of the construct that the LEFS sets out to measure was missing from the identified development study, and the LEFS' conceptual framework was unclear. Moreover, no cognitive interview or pilot test was performed in which patients were asked about the comprehensiveness and comprehensibility of the LEFS. Therefore, all of these items were scored as 'inadequate'. As the PROM development's overall methodological quality was rated 'inadequate' an 'indeterminate' rating was given for relevance, comprehensiveness and comprehensibility.

Seven studies were included, including one study that evaluated the development of the LEFS (23). No additional content validity studies were identified. Five studies (32-36) evaluated structural validity, four studies (32-35) evaluated internal consistency, two studies (32, 34) evaluated reliability, two studies (32, 35) evaluated measurement error, and three studies (31, 32, 34) evaluated construct validity (i.e. hypotheses testing). One study (33) evaluated two aspects of responsiveness (i.e. hypotheses testing: comparison with other outcome measurement and hypotheses testing: before and after intervention). None of the studies evaluated cross-cultural validity and criterion validity and therefore were not further evaluated.

Table 2 Content validity assessment

		Development study	Rating of reviewers	OVERALL RATINGS	QUALITY OF EVIDENCE
Score: + = sufficient; - = insufficient; ? = indeterminate; ± = inconsistent		+ / - / ± / ?	+ / - / ± / ?	+ / - / ± / ?	High, moderate, low, very low
		consensus	consensus	consensus	
Relevance					
1	Are the included items relevant for the construct of interest?[1]	?	+		
2	Are the included items relevant for the target population of interest?[1]	?	+		
3	Are the included items relevant for the context of use of interest?[1]	?	+		
4	Are the response options appropriate?	?	+		
5	Is the recall period appropriate?	?	+		
	RELEVANCE RATING (+ / - / ± / ?)	**?**	**+**	**+**	
Comprehensiveness					
6	Are all key concepts included?	?	±		
	COMPREHENSIVENESS RATING (+ / - / ± / ?)	**?**	**±**	**±**	
Comprehensibility					
7	Are the PROM instructions understood by the population of interest as intended?	?			
8	Are the PROM items and response options understood by the population of interest as intended?	?			
9	Are the PROM items appropriately worded?		+		
10	Do the response options match the question?		+		
	COMPREHENSIBILITY RATING (+ / - / ± / ?)	**?**	**+**	**+**	
	CONTENT VALIDITY RATING (+ / - / ± / ?)	**?**	**±**	**±**	**very low**

[1] These criteria refer to the construct, population, and context of use of interest in the systematic review

Methodological quality and measurement property assessment

PROM development and content validity

One study was identified on the development and initial assessment of the LEFS (23), whereas no additional studies were identified on the content validity of the LEFS. A clear description of the construct that the LEFS sets out to measure was missing from the identified development study, and the LEFS' conceptual framework was unclear. Moreover, no cognitive interview or pilot test was performed in which patients were asked about the comprehensiveness and comprehensibility of the LEFS. Therefore, all of these items were scored as 'inadequate'. As the PROM development's overall methodological quality was rated 'inadequate' an 'indeterminate' rating was given for relevance, comprehensiveness and comprehensibility.

In accordance with the COSMIN guidelines, the content validity of the LEFS was then rated subjectively by the reviewers (26). Reviewers rated both relevance and comprehensibility as 'sufficient' and comprehensiveness as 'inconsistent'. The latter was due to the fact that reviewers found that probably not all key concepts regarding patients with fractures of the lower extremities were included in the development of the LEFS. ICF categories *d4 mobility* (e.g. movement with equipment and using transportation such as a bike or public transport) and *d5 self-care* (e.g. toileting and caring for body parts) may not be sufficiently covered. Hence, the LEFS' content validity was 'inconsistent', supported by a very low level of evidence. The rating of the PROM development study's results against the ten criteria for good content validity is provided in Table 2.

Structural validity

In accordance with the COSMIN methodology for systematic reviews of Patient-Reported Outcome Measures (PROMs) 'structural validity conceptualizes the degree to which the scores of a PROM are an adequate reflection of the dimensionality of the construct to be measured ' (26).

Five studies (32-36) evaluated the structural validity of the LEFS. The methodological quality of the structural validity assessment was rated as 'doubtful' in four of these studies (32-34, 36). This was mainly due to insufficient reporting. The remaining study (35) was rated 'adequate'. The assessment of the methodological quality of the included studies using the COSMIN RoB checklist is provided in Table 3. Studies that included classical test theory (CTT) were assessed based on the use and outcomes of the comparative fit index (CFI) or Tucker-Lewis index (TLI). Studies that included IRT/Rasch analyses were assessed bases on the assumptions of no violation of unidimensionality, local independence and monotonicity, and an adequate model fit. One study (36) found the LEFS to measure a unidimensional construct, based on "principal component (PC) analysis". Four studies (32-35) found it to measure a multidimensional construct, based on "TLI" (32), "IRT" (33, 35), respectively "maximum likelihood factor analysis with oblimin rotation" (34). The structural validity is insufficient because the results of the different studies do not give a convincing picture of the unidimensionality of the LEFS. Therefore the structural validity of the LEFS was rated 'insufficient'. The rating of the results of every single study on a measurement property against the updated criteria for good measurement properties is provided in Table 3.

Table 3 Methodological quality and assessment measurement properties

	structural validity		internal consistency		reliability	
	risk of bias	**assessment measurement properties** [1]	**risk of bias**	**assessment measurement properties**	**risk of bias**	**assessment measurement properties**
Garratt, Naumann (32)	doubtful	CFA: LEFS unidimensional TLI = 0.99, RMSEA= 0.091; LEFS multidimensional TLI=1.00, RMSEA 0.073 TLI waarde (+), RMSAE waarde (?)	inadequate	Cronbach's alpha (scale) α=0.96 sufficient structural validity (?) , Cronbach's alpha (+)	adequate	test-retest ICC 0.91 (+)
Hsu, Tsai (31)						
Lin, Moseley (33)	doubtful	IRT: criteria followed Z- standardized statistic less than 2.0 or ≥ 2.0 (-): 3 items failed to conform to Rasch expectations; no further information reported (?)	inadequate	Baseline Cronbach's alpha α= 0.92, short-term follow-up α= 0.94, medium-term follow-up α= 0.90 sufficient structural validity (?) , Cronbach's alpha (+)		
Ponkilainen, Tukiainen (36)	doubtful	Correlation LEFS scores with 15D total score 0.67 (0.57- 0.74), LEFS and FIT index 0.44 (0.31- 0.57), LEFS and VAS general health -0.66 (-0.76 to -0.55) (?)				
Repo, Tukiainen (34)	doubtful	Maximum likelihood factor analysis with oblimin rotation: LEFS loads on two factors, no further information reported (?)	inadequate	Cronbach's alpha (scale) α=0.96 sufficient structural validity (?) , Cronbach's alpha (+)	adequate	test-retest ICC 0.93 (95% CI, 0.91-0.95) (+)
Repo, Tukiainen (35)	adequate	IRT: unideminsionality not violated (+)	inadequate	Cronbachs alpha α=0.95 sufficient structural validity (?) , Cronbach's alpha (+)		
	measurement error		**hypotheses testing for construct validity** *			
	risk of bias	**assessment measurement properties**	**risk of bias**	**assessment measurement properties**		
Garratt, Naumann (32)	adequate	SDC individual 12.49, SDC group 0.93, MIC not defined (?)	inadequate	Spearman correlation LEFS and OMAS 0.86, LEFS and SEFAS -0.84, LEFS and SF-36 physical function 0.85, LEFS and EQ-5D index 0.73, ASA classification -.026 *		
Hsu, Tsai (31)			inadequate	Correlation LEFS scores with walking speed (r = 0.60, p = 0.044) and step length (r = 0.68, p = 0.021) *		
Lin, Moseley (33)						
Ponkilainen, Tukiainen (36)						
Repo, Tukiainen (34)	adequate	SEM 4.1, MIC not defined (?)	inadequate	Spearman correlation LEFS and 15D total index r= 0.66, FIT index physical activity r= 0.46, LEFS and VAS Foot and ankle pain at rest r=-0.5, LEFS and VAS Foot and ankle pain during activity r= -0.69, LEFS and VAS Foot and ankle stiffness r= 0.62 *		
Repo, Tukiainen (35)						

Table 3 Continued

	responsiveness construct approach (i.e. hypotheses testing: comparison with other outcome measurement)		responsiveness construct approach (i.e. hypotheses testing: before and after intervention)	
	risk of bias	**assessment measurement properties**	**risk of bias**	**assessment measurement properties**
Garratt, Naumann (32)				
Hsu, Tsai (31)				
Lin, Moseley (37)	inadequate	Guyatt responsiveness ratio: short-term 1.99, medium-term 1.74; External criterion for improvement= the global perceived effect scale (?)	inadequate	Effect size short-term 1.92, medium-term 3.33; standardized response mean short-term 1.91, medium-term 2.95 (?)
Ponkilainen, Tukiainen (36)				
Repo, Tukiainen (34)				
Repo, Tukiainen (35)				

[1] "+" = sufficient, " –" = insufficient, "?" = indeterminate

* authors have decided not to rate this property due to unclear construct of the LEFS

Abbreviations:

ASA classification: ASA (American Society of Anesthesiologists) physical status classification system, CFA: confirmatory factor analysis, IRT: item response theory, MIC: minimally important change, TFI: Tucker-Lewis Index, RMSEA: Root means square error of approximation, SDC: Smallest detectable change, OMAS: Olerund Molander Ankle Score, VAS: Visual analog scale

Internal consistency

Internal consistency refers to "the degree of the interrelatedness among the items" (26). The risk of bias in a study on internal consistency depends on the available evidence for structural validity because unidimensionality is a prerequisite for the interpretation of internal consistency analyses (i.e. Cronbach's alpha's). Therefore, the quality of evidence for internal consistency cannot be higher than the quality of evidence for structural validity (26). Four studies (32-35) assessed the internal consistency of the LEFS. The methodological quality of all of these studies was rated 'inadequate'. The assessment of the methodological quality of the included studies using the COSMIN RoB checklist is provided in Table 3. The included studies calculated a Cronbach's alpha, all of which were 0.90 (33) or higher (32, 34). Even though this suggests that the items of the LEFS have relatively high internal consistency, the LEFS was found not to measure a unidimensional construct in one of the included studies (35). The internal consistency of the LEFS was therefore rated as 'indeterminate' as outlined in the COSMIN guideline and was supported by three studies of lower methodological quality as well (32-34).

Reliability

Two studies (32, 34) assessed the test-retest reliability of the LEFS. The methodological quality of the reliability assessment in both included studies was rated as 'adequate'. The assessment of the methodological quality of the included studies using the COSMIN RoB checklist can be found in Table 3. The time interval between the first and the second measurement was on average 2.5 weeks (34), respectively six weeks (32). Garratt (32) found the test-retest ICC of the LEFS to be 0.91, based on a two-way mixed effects model with absolute agreement. A weighted kappa was used for assessing individual item reliability (32). Repo et al. (34) found a ICC of 0.93 (95% CI, 0.91- 0.95), based on a two-way mixed model with absolute agreement. Both of these ICCs indicate that the reliability of the LEFS is 'sufficient' (Table 3).

Measurement error

According to the COSMIN guideline, "measurement error refers to the systematic and random error of an individual patient's score that is not attributed to true changes in the construct to be measured." (26) When applying the criteria for good measurement error, information is needed on the Smallest Detectable Change (SDC) or Limits of Agreement (LoA), as well as on the Minimal Important Change (MIC) (26). Two studies (32, 35) assessed the measurement error of the LEFS. The methodological quality of both of these two studies was rated as 'adequate'. The assessment of the methodological quality of the included studies using the COSMIN RoB checklist is provided in Table 3. Garratt et al. (32) found a smallest detectable change of 12.49. The minimal important change was not defined. Repo et al. (35) reported a Standard Error of Measurement of 4.1. In their study, the minimal important change was not defined. Consequently, the measurement error of the LEFS was rated as 'indeterminate' (Table 3).

Construct validity (hypotheses testing)
According to the COSMIN guideline, construct validity has 3 subsections, one of them being hypotheses testing. This refers to "the degree to which the scores of a PROM are consistent with hypotheses (for instance with regard to internal relationships, relationships to scores of other instruments, or differences between relevant groups) based on the assumption that the PROM validly measures the construct to be measured." (26) According to the COSMIN guideline the risk of bias of studies comparing the PROM to comparison instruments was completed (26).

Three studies (31, 32, 34) evaluated the construct validity (hypotheses testing) of the LEFS. The methodological quality of the construct validity (hypotheses testing) assessment was rated as 'inadequate' for all included studies (Table 3). Due to an unclear definition of the construct the LEFS purports to measure, we did not further assess hypotheses testing for construct validity and did not apply criteria for good measurement properties.

Responsiveness
Responsiveness refers to "the ability of a PROM to detect change over time in the construct to be measured", according to the COSMIN guideline (26). One study (33) evaluated two aspects of responsiveness (i.e. hypotheses testing: comparison with other outcome measurement and hypotheses testing: before and after intervention). The methodological quality of the responsiveness assessment was rated as 'inadequate' for the included study. The assessment of the methodological quality of the included study using the COSMIN RoB checklist can be found in Table 3. The responsiveness of the LEFS was rated as 'indeterminate' as outlined in the COSMIN guideline.

DISCUSSION

Main findings
This study found the content validity of the LEFS to be 'inconsistent', which was supported by very low quality evidence. One study was identified on the development and initial assessment of the LEFS (23), whereas no additional studies were identified on the content validity of the LEFS. A clear description of the construct that the LEFS sets out to measure was missing from the identified development study, and the LEFS' conceptual framework was unclear. Moreover, a study of 'adequate' methodological quality showed that the LEFS has a multidimensional construct (35). The internal consistency of the LEFS was therefore rated as 'indeterminate' as outlined in the COSMIN guideline and was supported by three studies of lower methodological quality as well (32-34). The reliability was rated 'sufficient' (32, 34), based on two studies of adequate methodological quality. Measurement error was rated 'indeterminate' (32, 34), based on two studies of adequate methodological quality. Responsiveness was rated 'indeterminate' (33), based on one study of inadequate methodological quality. Given the lack of clarity on the construct the LEFS aims to measure, hypotheses testing for construct validity was not assessed.

Interpretation of the findings

As content validity is considered the most crucial measurement property of a PROM (27), it is of utmost importance that the construct a PROM sets out to measure, and the theoretical grounds which it is based on are clear. The development study of the LEFS did not include a clearly defined construct, and was based on an older version of the World Health Organization's model of disability and handicap (38), instead of the nowadays used more dynamic model of health in which health is defined as a process with a positive concept emphasizing social and personal resources, as well as physical capacities (39). Therefore, the LEFS may not measure a patients' physical functioning as we currently conceptualize this. Also, no appropriate cognitive interview was performed during the development or during additional validation studies, making it difficult to assess the relevance, comprehensiveness, and comprehensibility (e.g., ICF categories *d4 mobility* and *d5 self-care*) of the LEFS. For this reason, the LEFS encounters shortcomings regarding its content validity. We do acknowledge that the LEFS was developed many years before the COSMIN criteria, and the introduction of the dynamic model of health (34), however, we would like to endorse the fact that PROMS need to be fit for purpose when evaluating current health care. As no high quality evidence supported insufficient content validity of the LEFS, further assessment of the individual measurement properties was conducted in accordance with the COSMIN methodology for systematic reviews of Patient-Reported Outcome Measures (PROMs) (26). Although internal structure and the remaining measurement properties can be assessed, these measurement properties are directly or indirectly related to the content validity of the LEFS. Therefore, their interpretation is strongly dependent on the quality of the content validity of the LEFS. By assessing these measurement properties, a thorough overview of strengths and weaknesses of the LEFS was obtained which can facilitate the further development of this frequently used instrument.

Comparison with the literature

Until now, the literature on the content validity, structural validity, internal consistency, reliability, measurement error, and construct validity (hypotheses testing) of the LEFS in patients with fractures of the lower extremity has not yet been summarized and/or critically appraised using the updated COSMIN criteria. Nonetheless, two previous systematic (24, 40) reviews assessed the reliability, validity, and responsiveness of the LEFS in patients with a range of musculoskeletal disorders. In contrast to our findings, the systematic review of Mehta et al. (24) found the reliability, validity, and responsiveness of the LEFS to be good (24) and rated more than half of the included studies as being of very good to excellent methodological quality. These differences could be explained by differences in the definition of the concept of content validity and other assessment criteria (i.e., MacDermid (41)) instead of using the updated COSMIN guidelines. The study of Shultz et al. (40) did evaluate the responsiveness of the LEFS by using the COSMIN guidelines. However, this study included patients with any condition associated with the lower leg, ankle, or foot, instead of patients with fractures of the lower extremities in particular. They found a lack of consistency for reporting responsiveness among recovery measures used in the lower leg, ankle, or foot studies. Our systematic review results also differ from Morris et al. (25),

who assessed outcome measurements following tibia fractures and found the measurement properties of the LEFS to be good. Nevertheless, the authors also stated that if only the fracture patients were considered in the validation studies, all studies would score poorly on the COSMIN checklist, which is in line with the findings of the current review.

Strengths and limitations

This study included a comprehensive methodological assessment of the LEFS in accordance with the COSMIN methodology for systematic reviews of Patient-Reported Outcome Measures (PROMs) (26), and thereby rated all properties in the appropriate order (i.e., content validity first), based on well-defined criteria. This study focused on the use of the LEFS patients with fractures of the lower extremity in particular, which differ from patients with other lower extremity dysfunctions. Furthermore, patients with fractures of the lower extremity are a rising source of morbidity associated with a major impact on patients' functional status and health-related quality of life. This is important because measurement properties are context-dependent and have to be evaluated in the context of interest (24). A possible limitation may be the settings in which the measurement properties of the LEFS were assessed. As only one study (23) included patients that were treated in a primary care setting the generalizability of our findings may be limited for patients that are treated in primary care, such as patients that have sustained a fracture longer ago, or who have a simpler injury.

Another possible limitation may be the small sample sizes of the included studies, in combination of the small amount of the studies we retrieved on the different measurement properties. Although the COSMIN guideline provides the opportunity to pool the results of studies with small sample sizes on several measurement properties (i.e. internal consistency, measurement error, hypothesis testing for construct validity and responsiveness), this is not accounted for in our study as pooling was not feasible (26). However, in the assessment of the measurement properties content validity and structural validity, we did account for small sample sizes, according to the COSMIN guideline.

Furthermore, another possible limitation may be the strict inclusion criteria of only including studies, of which at least 75% of the study sample had a lower extremity fracture. This may be why we did not identify additional content validity studies of the LEFS and were not able to include all measurement properties, such as criterion validity and cross-cultural validity. We did consider including studies performed in (slightly) different populations because such studies could provide evidence on the PROM's comprehensibility and (although perhaps to a lesser extent) its relevance and comprehensiveness. However, as our main focus was to investigate the measurement properties of the LEFS in patients with fractures of the lower extremity, instead of all patients with musculoskeletal disorders of the lower extremity, we eventually opted not to do so. Another possible limitation may be our findings' generalizability, as the included studies mostly assessed the LEFS in patients with fractures in the ankle and foot region (23, 31-36). This could make our systematic review results less generalizable to the whole population of patients with fractures of the lower extremity,

such as hip, ankle and/or tibial fractures which form a substantial part of all fractures of the lower extremities. Another point that can be made is the inclusion of studies that assessed the LEFS in four languages, including English (23, 33), Norwegian (32), Chinese (31), and Finnish (34-36). Nevertheless, no studies assessing cross-cultural validity in patients with fractures of the lower extremities could be identified.

Implications for practice

In interpreting the scores of the LEFS, one should therefore be aware that not all relevant aspects of physical functioning may be accounted for, such as mobility and self-care. It is not clear if patients find the LEFS comprehensive and perceive the items as relevant and comprehensible. Although the LEFS is often used to assess progress and recovery in treating patients with fractures, no evidence was found to endorse the use of the LEFS in doing so.

Implications for research

The LEFS needs to be further validated in a well-designed content validity study, which includes a clearly defined construct and involves patients during assessing the different aspects of content validity (i.e., relevance, comprehensiveness, and comprehensibility).

CONCLUSION

Although the LEFS is a well-known, frequently used, and easily applicable PROM, there are limitations in the development. This led to an 'inconsistent' rating for content validity of the LEFS, which was supported by very low evidence. Moreover, there is 'adequate' evidence that shows that the LEFS has a multidimensional construct, leading to an 'indeterminate' rating for internal consistency. In interpreting the scores of the LEFS, one should therefore be aware that not all relevant aspects of physical functioning may be accounted for, such as mobility and self-care. For this reason, the LEFS encounters shortcomings regarding its content validity according to the COSMIN guideline (27). We acknowledge that the LEFS was developed many years before the COSMIN criteria, and the introduction of the dynamic model of health (34), however, we do endorse the fact that PROMS need to be fit for purpose when evaluating current health care. Further validation in a well-designed content validity study is needed, which includes a clearly defined construct and a qualitative part in which not only professionals but also patients with different types of fractures are involved during assessing the different aspects of content validity (i.e., relevance, comprehensiveness, and comprehensibility).

Acknowledgments

We want to thank Dr. Caroline Terwee, Department of Epidemiology and Data science (Amsterdam UMC, location VUmc), for advice in the evaluation according to the COSMIN guidelines.

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APPENDIX 1

Searchstring PubMed (including Medline)

LEFS[tiab] OR "lower extremity functional scale"[tiab] OR "lower extremity FS"[tiab] OR "LE functional scale"[tiab] OR "lower extremity scale"[tiab]

Searchstring Embase

LEFS:ti,ab,kw OR "lower extremity functional scale":ti,ab,kw OR "lower extremity FS":ti,ab,kw OR "LE functional scale":ti,ab,kw OR "lower extremity scale":ti,ab,kw

Searchstring Scopus

LEFS OR "lower extremity functional scale" OR "lower extremity FS" OR "LE functional scale" OR "lower extremity scale"

Searchstring Cochrane

LEFS OR "lower extremity functional scale" OR "lower extremity FS" OR "LE functional scale" OR "lower extremity scale"

CHAPTER 8

General discussion

INTRODUCTION

This thesis described the upscaling and evaluation of the Transmural Trauma Care Model (TTCM). The TTCM's clinical effects, challenges, and opportunities were investigated to provide knowledge to support decision-making by care providers, patients, and policymakers. The primary aim of the thesis was to assess the (cost-)effectiveness of the TTCM within a multicenter trial. Secondary aims included the investigation of the barriers and facilitators of the upscaling of the TTCM and its financing. Additionally, data from a previous study were used to explore the association between fracture and treatment-related factors versus disease-specific HR-QOL, functional outcome, and societal costs in trauma patients. Finally, by conducting a systematic review about the content validity and measurement properties of the Lower Extremity Functional Scale, this thesis aimed to provide guidance for improving the measurement of functional status in patients with lower extremity fractures, an important part of the target population of the TTCM.

The main findings of the thesis will be summarized and discussed in this General Discussion, followed by some methodological considerations and recommendations for clinical practice and future research, and ending with a general conclusion.

MAIN FINDINGS

Study protocol

Chapter 2 described the study protocol of a multicenter trial with a controlled before-and-after design that aimed to assess the (cost-)effectiveness of the TTCM. In brief, the TTCM is a multidisciplinary and patient-centered transmural rehabilitation care model, in which a multidisciplinary hospital-based team guides a specialized network of primary care trauma physiotherapists throughout the rehabilitation process of the patient. Within this trial, control group patients received usual rehabilitation care as provided by the participating hospitals prior to the implementation of the TTCM. Usual care slightly differed across hospitals, but generally, trauma surgeons provided the post-clinical consultations unaccompanied by other healthcare professionals. Moreover, based on the clinical judgment of the trauma surgeon, trauma patients were referred to a physiotherapist in primary care, but there was no standardized policy for these referrals, nor was there a highly structured network of specialized primary care trauma physiotherapists in the catchment area of the participating hospitals, and there was no structured communication between primary and secondary care which was consequently minimal. Patients in the intervention group received the TTCM.

Short-term effectiveness of the Transmural Trauma Care Model

Chapter 3 presented a preliminary analysis of data from the aforementioned multicenter trial assessing the (cost-)effectiveness of the TTCM compared to usual care in trauma patients. This preliminary analysis was aimed at assessing the 6-month clinical effectiveness the TTCM. Please note that a significant number of patients had incomplete effect data at

the time of analysis, because the follow-up measurements were still ongoing. While there were no statistically significant between-group differences in the co-primary outcomes generic and disease-specific quality of life during the complete 6 months of follow-up, both measures were found to be statistically and clinically significantly higher in the intervention group compared to the control group at both the 3 and 6 months follow-up time points. However, it is important to exercise caution when interpreting these results, as a more comprehensive analysis incorporating more complete, and also 9-month follow-up, data is required to validate the current findings. Additionally, a comprehensive cost-effectiveness analysis is yet to be conducted, as cost data were not available at the time of the preliminary analysis either. Both the 9-month effectiveness and cost-effectiveness results are expected at the beginning of 2024.

Challenges with upscaling the TTCM

Chapter 4 described the results of a process evaluation assessing the barriers and facilitators associated with the upscaling of the TTCM. In the multicenter trial, the success of upscaling the TTCM highly differed across hospitals and settings, which seemed to be related to the issue of whether or not hospitals were able to arrange funding for one or more hospital-based physiotherapist(s) and the commitment of key actors within the organization (e.g. trauma surgeons). Other factors that were found to impact the successful implementation of the TTCM were the experience of an 'increased job satisfaction', the 'lower administrative workload for trauma surgeon', and 'more experience with and knowledge of treating trauma patients since working with the TTCM'. One should bear in mind, however, that the COVID-19 pandemic might have played an important role during the implementation of the TTCM. That is, due to the pandemic, various implementation efforts, such as coaching and training the healthcare professionals as well as setting up the network, had to take place online, which may have hampered the fostering of a sense of ownership and commitment amongst the key actors and healthcare professionals.

Challenges with financing transmural care

Chapter 5 presented the results of a process evaluation to identify barriers and facilitators influencing the funding of transmural care models in the Netherlands, and the TTCM in particular. In line with *chapter 4,* the results of *chapter 5* showed that it is difficult to fund transmural care models, and it seemed harder to fund transmural care activities performed by allied healthcare professionals in secondary care than in primary care. Various possible funding models were discussed by the interviewees, of which the most feasible funding model was thought to be including the cost of the allied healthcare providers to the diagnosis-treatment combination (DTC, Dutch: DBC) system price for the outpatient consultation of the trauma surgeon. During the course of the multicenter trial, however, DTC negotiations were temporarily halted due to the COVID-19 pandemic. Other factors that were deemed to be important for a successful funding of the TTCM are the presence of dedicated key actors, and a dedicated medical specialist in particular, a sense of local ownership, and a good understanding of the context (e.g. local cultural and political factors).

Further improvements and valorization

Chapter 6 aimed to assess the association between fracture and treatment-related factors versus outcomes, such as disease-specific HR-QOL, functional outcome, and costs. Therefore data of the pilot study of the TTCM-trial were used. The results suggest that fracture localization was associated with disease-specific HR-QOL and functional outcome after nine months. That is, lower extremity fractures were associated with less favorable outcomes after 9 months, and upper extremity fractures were associated with better functional outcome compared to the reference category (i.e. patients with a vertebral fracture or multi-trauma patients). Future studies should focus on confirming these associations in a broader range of trauma patient populations to help clinicians achieve better patient outcomes and provide more cost-effective healthcare.

Chapter 7 described a systematic review of the Lower Extremity Functional Scale (LEFS), a Patient-Reported Outcome Measure (PROM) to evaluate lower extremity fracture patients' functional status. We found that the LEFS has several shortcomings, including inconsistent content validity, lack of clarity regarding the construct being measured, and limited evidence supporting its measurement properties. Of them, the lack of sufficient content validity was considered most important, as content validity is the most crucial measurement property of a PROM according to the COSMIN guidelines. More specifically, no appropriate cognitive interview was performed during the development or validation of the LEFS, making it difficult to assess the relevance, comprehensiveness, and comprehensibility of the questionnaire. Since the LEFS was developed more than 20 years ago, there is a possibility that it may not fully represent physical functioning as we currently conceptualize it. In light of this, we recommend conducting a study in which the content of the LEFS is evaluated by experts in the field as well as patients, allowing for the necessary modifications to be made to the questionnaire. It is also important to note that when interpreting the outcomes of the LEFS, one should be aware that not all relevant aspects of physical functioning may be accounted for in the questionnaire. Therefore, future research should strive to develop an updated and more comprehensive measure that captures the various dimensions of physical functioning in patients with lower extremity fractures.

METHODOLOGICAL CONSIDERATIONS

When interpreting the results of the studies presented in this thesis, it is important to consider the choices made in their set-up and their respective limitations. While many methodological issues have already been discussed in the respective chapters, others warrant further exploration and will be discussed into greater detail below.

Controlled before-and-after trial

Within this thesis, the effectiveness of the TTCM was assessed using a non-randomized study design, i.e. a controlled before-and-after trial. 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. This is because the randomization of study participants across intervention conditions then ensures a balanced distribution of both known and unknown confounding factors, minimizing bias and allowing for a more reliable assessment of the intervention's impact (1). Such a design, however, was not feasible for assessing the (cost-)effectiveness of the TTCM for several reasons. First, the TTCM is organized at a hospital level, making it impossible to randomize individual trauma patients, all of whom were recruited at specific hospitals. Second, for a true randomization "effect", and in order to be able to use the appropriate statistical analyses for cluster randomized controlled trials, at least 30 clusters should be included (2). 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. Moreover, even if we would have been able to recruit 30 hospitals, only a relatively small subset of them would have been classified as a level 1 trauma center, simply because there are only 11 level 1 trauma centers in the Netherlands. This would have been a problem for our trial, because most severe trauma patients – who typically rehabilitate in primary care, and hence would be eligible for the TTCM - are treated at a level 1 trauma center. Third, during the set-up of the study, we noticed that suitable hospitals were less inclined to participate if they would have the chance of being randomized to a control condition that would not get the TTCM, because one of their main reasons for participation was the prospective implementation of the TTCM. Combined with the more practical considerations discussed above, this has led to our decision of using a controlled before-and-after design for assessing the (cost-)effectiveness of the TTCM.

Before-and-after trials are a type of quasi-experimental, non-randomized, study design, in which the (cost-)effectiveness of interventions is assessed by comparing outcomes before and after their implementation. However, there are several methodological considerations that must be taken into account when using such a study design. First, more advanced statistical techniques are needed to address the possible influence of selection bias. In the current, preliminary analysis, we used propensity score weights for this purpose (3, 4). However, propensity scores have inherent limitations as well, including the fact that they are reliant on the assumption of no unmeasured confounding, which may not always be valid, and the proper specification of the model for estimating the patients' propensity scores. For the final (cost-)effectiveness analyses of the TTCM trial it might therefore be advisable to assess the possible added value of more advanced methods, such as propensity score matching, genetic matching, G-computation, and/or Targeted Maximum Likelihood Estimation (5).

Another methodological consideration is the potential influence of temporal trends that may have occurred independent of the intervention. This is a particular concern because control group patients were measured between January 2020 and June 2022, while the measurement of all intervention group patients started in September 2021 and is expected to end in December 2023. It is possible that these different time periods are related to different seasons, and hence different types of fractures (e.g. more skying-related fractures during the winter) as well as advancements in treatments, changes in treatment protocols,

clinical practice, and/or resource availability that could have independently impacted the outcomes as well. There is in turn a possibility that our results are influenced to some extent by these factors, because even though we were, and will be, able to correct for a broad range of possible individual-level confounding factors (e.g. age, gender, BMI, smoking, medical history, educational level, ISS, coping), more system-level confounding factors (e.g. the intensity of the COVID pandemic) are hard to correct for. Probably the most important system-level confounding factors in our study are related to the COVID-19 pandemic. The control group, for example, was measured between January 2020 and June 2022, i.e. during the early stages of the COVID-19 pandemic and its subsequent waves. During this time, the Netherlands experienced strict lockdown measures. In contrast, the intervention group was measured between September 2021 and is expected to end in December 2023, which represented a later phase of the pandemic, during which the Netherlands had already implemented vaccination campaigns, allowing for a higher percentage of the population to be immunized against COVID-19.

Some researchers may also argue that a stepped-wedge design could have been used to overcome the aforementioned barriers. We were of the opinion, however, that such a design would have led to contamination between patients visiting the same outpatient trauma departments, 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. While it is theoretically possible to address this concern by initiating the follow-up period only after the last follow-up of the control group had been completed, such an approach would have significantly lengthened the duration of the study, which was not feasible given the constrained time and resources available. On top of that, there was (some) overlap in the catchment areas of the participating hospitals (and therefore in the affiliated networks), which may have led to even more contamination if the two hospitals with overlapping catchments areas delivered both treatment conditions at the same time.

Missing data

As in every clinical trial, some patients had missing cost and/or effect data on one or more measurement points. To illustrate, in *chapter 3,* 27% of the population had some missing data. This is a concern because patients with missing data might differ from those with complete data, and hence the missingness of data should be corrected for in the analyses. In *chapter 3* missing data were addressed using both mixed models fitted by maximum likelihood estimation and Multivariate Imputation by Chained Equations and Predictive Mean Matching (MICE-PMM) methods. Even though some studies suggest that combining both is not necessary when analyzing clinical effects, we did opt for doing so for several reasons (6-8). First, the addition of multiple imputation allowed us to add different covariates to the imputation and analysis model, which in turn may have improved the handling of missing values that were dependent on variables other than those included in the analysis model. Second, due to the preliminary nature of the current analyses, some patients in the dataset had missing baseline variables and/or only complete data at one

measurement point. When only using a mixed models, these patients would have been excluded from the analyses, whereas they are retained when combining mixed models with MICE-PMM, which in turn results in an increase in statistical power.

Qualitative studies

The studies presented in *chapter 4* and *chapter 5* used a qualitative design with semi-structured interviews. Following the guidelines of qualitative designs, we aimed to ensure methodological rigor (9). One aspect of methodological rigor that we prioritized was reflexivity, meaning that we acknowledged our own biases and assumptions and actively reflected on their potential influence on data collection, analysis, and interpretation throughout the research process. We did so by engaging in continuous, collaborative, and multifaceted practices through which researchers self-consciously critique, appraise, and evaluate how their subjectivity and context influence the research processes (10, 11). We engaged a variety of practices such as journaling, peer debriefing and critical reflection to promote reflexivity. By maintaining awareness of our subjective perspectives, we strived to mitigate their impact on data collection, analysis, and interpretation. Another aspect that we considered was contextualization, which means that we recognized the significance of understanding and capturing the social, political, and cultural contexts that shaped our participants' experiences. We actively engaged with these contexts, seeking to comprehend their influence and interpret our findings accordingly. A last aspect was transferability, meaning that we aimed to enhance credibility and validity by providing detailed descriptions of our research design, methods, and analytical processes. We did so to facilitate the assessment of how our findings may apply to other contexts or settings. Furthermore, the use of a theoretical framework enabled the systematic exploration of the acquired data (12), which in turn helped to identify the challenges and opportunities associated with the implementation, upscaling, and funding of the TTCM. Moreover, data were collected and analyzed iteratively, meaning that the topic list was adjusted multiple times based on feedback provided by participants and researchers themselves during the study and adapted to the specific stakeholder (13, 14). This approach allowed for a more in-depth understanding of the challenges and opportunities associated with the implementation, upscaling, and funding of the TTCM.

Probably the most important methodological limitation of our qualitative studies was the fact that researchers used their own judgement to select individuals who they thought were are able to provide information related the research questions (i.e. purposive sampling). This is an often used recruitment strategy in qualitative research. Nonetheless, by relying on our personal judgment, we may have inadvertently introduced a bias towards individuals who align with our own perspectives or preconceived notions, thereby limiting the diversity of perspectives represented in the study. By using this approach we may have also overlooked some valuable insights that could have been provided by individuals who were not initially identified as potential participants. Consequently, the findings of our qualitative studies may be limited in their ability to capture the full range of perspectives and experiences

relevant to the research questions. To mitigate this limitation, future qualitative studies should consider employing more systematic and objective participant selection methods, such as random sampling or stratified sampling, to ensure a more representative and comprehensive exploration of the research topic (15). Another limitation is the possible influence of social desirability bias, because respondents may have been inclined to provide socially desirable responses during an interview, potentially leading to distorted or biased results (16). Furthermore, we had originally planned to conduct focus groups as an additional method to explore the barriers and facilitators related to the implementation and funding of the TTCM. An advantage of focus groups is that they allow for collective insights and discussions among participants, fostering a dynamic exchange of perspectives and potentially uncovering group consensus or disagreements. However, unforeseen challenges arose due to pandemic-related delays in data collection and analysis. As a result, we were unable to execute this aspect of the study and had to solely rely on semi-structured interviews that were often conducted through video conferencing tools, such as Microsoft Teams or Zoom. As a consequence, the data collected may not be as diverse as originally intended and may not fully represent the views of all stakeholders involved in the Dutch healthcare system.

Another limitation is the unavailability of quantitative process evaluation data at the time of this thesis. Quantitative process evaluation is an essential component of a mixed-methods design, as it provides valuable insights into the "actual" implementation and delivery of the intervention (17). In our case, the quantitative data for the process evaluation will be collected from the electronic patient records of the participants in the intervention group at the end of the study period. These data will enable the assessment of various aspects, including the reach of the intervention (i.e., the proportion of eligible participants who received the intervention), the dose delivered (i.e., the extent to which the intervention was implemented as intended), the dose received (i.e., the extent to which participants engaged with and received the intervention components), and fidelity (i.e., adherence to the intervention protocol) (18). The absence of these implementation indicators at the time of finishing this thesis limits the comprehensive evaluation of the intervention's delivery and impact.

Possible impact of the COVID-19 pandemic

Possible impact of the COVID-19 pandemic on trauma patients and research in general
The COVID-19 pandemic also had a significant impact on the treatment of patients with a traumatic injury. The fact that many healthcare resources had to be quickly re-allocated towards the pandemic response (e.g., prioritizing COVID-19 testing and treatment, establishing COVID-19 dedicated units) has led to the cancellation of many elective surgeries and the closure of some outpatient trauma clinics (19, 20). Amongst others, this has resulted in delays in the treatment of non-COVID-19 related injuries, including many traumatic injuries (21-23). Moreover, during lockdowns, there was a significant decrease in the number of motor vehicle accidents, as there were fewer motor vehicles on the roads

(24). To illustrate, a report from the Department for Transport Great Britain found that road casualties decreased in line with the decrease in road traffic during the national lockdowns. In contrast, however, there was an increase in the number of injuries resulting from falls, domestic accidents, and domestic violence as individuals spent more time at home (25). This is illustrated by a study of van Aert et al. (23) who examined the effects of the COVID-19 pandemic during the first lockdown in the Netherlands on the number of trauma-related admissions, trauma severity, and treatment. They found that, even though there was an increase in the severity of traumatic injuries, the number of trauma-related admissions decreased and treatments were more frequently delayed (23). Moreover, after lockdowns, as individuals began to return to work and re-engage in outdoor activities, there was an increase in the number of sports-related injuries, such as fractures and sprains (26) and there was a resurgence in traffic accidents as people began to travel more frequently. The pandemic also had a psychological impact on patients with traumatic injuries, particularly those who were isolated from their families and support systems due to quarantine measures. Overall, the COVID-19 pandemic has had a significant impact on the treatment of patients with traumatic injury, and it is crucial to continue to monitor and adapt to these changes to ensure that patients receive the care they need. For example, a study by Herrera-Escobar et al. found that the COVID-19 pandemic had a negative impact on the recovery of trauma patients, emphasizing the importance of being aware of the pandemic's impact on injured patients, while directing focused efforts towards improving long-term outcomes in this already vulnerable population (27).

It should be noted that, during the course of the studies presented in this thesis, the COVID-19 pandemic also had a profound impact on scientific research across the world, and the current project in particular. The restrictions on travel, physical distancing requirements, and the closure of many research facilities disrupted ongoing experiments and led to delays in data collection and analysis. Additionally, many scientists have had to divert their attention and resources towards studying the virus and developing vaccines, which has resulted in a slowdown of research in other areas. On top of that, the COVID-19 pandemic had a significant impact on the funding landscape for research and healthcare projects. That is, due to the urgent need for resources to address the pandemic, many funding agencies and healthcare sectors have been compelled to reallocate their funding towards COVID-19 related research and healthcare. As a consequence, numerous research projects unrelated to COVID-19 have been left without the necessary financial support (28, 29).

Possible impact of the COVID-19 pandemic on this study in particular

As briefly noted above, the COVID-19 pandemic also had a profound impact on the current project. In our specific case, the suspension of the DTC negotiations (i.e. the reimbursement of the HBP) made it very hard for the participating hospitals to arrange funding for the hospital-based physiotherapists, which - as part of the TTCM - had to be present during the joint consultations with the trauma surgeon to guide the patients' further rehabilitation

trajectory in primary care. In most of the participating hospitals, this hampered the successful implementation of the TTCM.

Also, the COVID-19 pandemic hindered our ability to fully meet the requirements of a tailored (i.e. hospital specific) implementation strategy. Amongst others, we had to shift from providing all coaching, network, and training sessions in-person to providing them online, which in turn resulted in fewer opportunities for personal interactions with the local key actors. Moreover, when people are not able to meet face-to-face, it can be more difficult to build up a relationship and establish trust. This can lead to misunderstandings and miscommunications that can negatively impact the quality of communication and collaboration between the actors involved (30). However, we used certain strategies to mitigate this issue. For example, when using video conferencing tools, such as Microsoft Teams, we used breakout rooms to facilitate small group discussions and encourage participation from all members, which in turn can help build relationships and establish trust between the actors involved. Nevertheless, the importance of personal interaction in change management (i.e. an increased cooperation between hospital-based care and primary care and joint consultations by a multidisciplinary team at the outpatient clinic for trauma patients), and the possible impact of the lack thereof in our study, should not be underestimated (31, 32). This is because when change initiatives are accompanied by meaningful personal interaction, employees feel valued, and supported, leading to higher levels of engagement and commitment to the change process. This engagement can then translate into a more seamless adoption of new practices, reduced resistance, and improved overall performance. Moreover, by fostering a culture of open communication, trust, and collaboration, organizations can lay the foundation for long-term growth and adaptability, as individuals become more receptive to future changes and contribute to the ongoing success of the organization. Ultimately, by prioritizing personal interaction in change management, organizations can create a positive and empowering environment that facilitates successful transformations and drives sustainable organizational development (33-35).

Clinical relevance

When interpreting the results of the current preliminary findings both their statistical significance and clinical relevance ought to be considered. Statistically significant results indicate that the observed effect is unlikely to have occurred by chance alone. However, statistical significance does not necessarily imply clinical relevance. Clinical relevance refers to the perceived importance of the observed effect in terms of patient care. Therefore, it is important to consider both statistical significance and clinical relevance when interpreting study results (36, 37). In our case, we deemed a difference for HR-QOL of 0.057 (SD = 0.15) and a between-group difference of 10% in improvement of disease-specific QOL to be clinically relevant for health-related and disease-specific QOL, respectively. By setting these parameters, we aimed to provide a-priori insights into the clinical interpretation of our findings and their implications for patient well-being. It is important to realize that cutoff points for clinical relevance are a much debated issue. Predefining these cutoff points is

important, something we therefore also did prior to the commencement of our study. A criticism on our predetermined cutoff points could be that they were solely based on literature and expert opinion and hence that patients did not play a decisive role (38). One should be aware, however, that patients were involved in the studies that we based our cutoff points on.

IMPLICATIONS FOR FUTURE RESEARCH AND CLINICAL PRACTICE

Recommendations for future research

Most of the recommendations for future research have been discussed *in chapters 3 to 7* as well during the previous sections of this general discussion. An examples of such a recommendation is to obtain additional data through other methods, such as surveys and/or focus groups, to reduce the risk of social desirability bias. We also want to emphasize the importance, as well as the challenges and recommendations, of implementation research. Research on the implementation of healthcare models aims to identify strategies to effectively and efficiently implement evidence-based care models into practice (39). Implementation research is important, and should ideally be incorporated in every pragmatic trial, because it helps to understand and work within real-world conditions, rather than trying to control for these conditions and/or to remove their influence on causal effects. It recognizes that people need to be ready for change and that creating optimal conditions for an intervention is crucial to its maintenance. Therefore, implementation science is fundamental to the design of successful interventions (40). Therefore, the researcher-in-residence model could provide pragmatic strategies for a sustainable implementation of complex interventions in a variety of contexts (41). Research-in-residence models involve embedding a dedicated researcher within the organization or community where the intervention is taking place. This researcher works closely with stakeholders, collects real-time data, and engages in ongoing collaboration to adapt and refine the intervention as needed. Such models facilitate a deep understanding of local context and allow for rapid feedback, making them valuable tools in the field of implementation science (41, 42).

As described in *chapter 7,* the LEFS is a questionnaire that measures the physical functioning of patients with lower extremity disorders. However, it is important to note that not all relevant aspects of physical functioning seem to be accounted for in the questionnaire, such as mobility and self-care. Moreover, it is not clear if patients find the LEFS comprehensive and perceive the items as relevant and comprehensible. Therefore, we recommend to further validate the LEFS in a well-designed content validity study, which includes a clearly defined construct and involves patients during assessing the different aspects of content validity (i.e., relevance, comprehensiveness, and comprehensibility). As soon as the construct is more clear, the LEFS can be cross-validated with the PROMIS questionnaires for upper extremities. Furthermore, we recommend investigating the measurement properties of the PROMIS questionnaires, in particular the PROMIS CAT (i.e. computer adaptive testing),

in trauma patients for future research. It is important to note, that comparable research has already begun (43).

Recommendations for clinical practice

Based on the process evaluations described in *chapter 4 and 5* we can already give some valuable and useful recommendations for implementing transmural care models, such as the TTCM, and for funding them. Furthermore, the importance of an interprofessional collaboration, as a part of our transmural model, is emphasized.

Implementation of transmural care models

Transmural care models, such as the TTCM, often involve complex interventions, and their successful implementation depends on a variety of factors, including the characteristics of the model, the context of the implementation, and the individuals involved in the implementation process. Therefore, it is of great importance that all these factors are assessed (44). To facilitate a successful implementation of the TTCM, we conducted a comprehensive assessment of the factors that could impact its success. This involved examining the characteristics of the TTCM, including its components, mechanisms, and expected outcomes. Based on this, we developed an implementation toolkit (i.e. an implementation manual with checklists, training courses, website for patients and professionals, information movie and digital channels). Such a toolkit is important because evidence indicates that individuals are more likely to adopt new behaviors in implementation trajectories if they have a specific plan for how to do so (45-47). In the future, the developed implementation toolkit can be used by healthcare professionals and other stakeholders who would like to implement the TTCM. It is important to acknowledge that this toolkit would still need to be tailored to the specific context and needs of the participating stakeholders, and their environment. Additionally, it is imperative to recognize the necessity of regularly updating this toolkit, similar to the update of a website, to ensure that the toolkit remains current and relevant. Adequate administrative support, including financial resources, should thus be reserved to facilitate such ongoing updates and optimizations.

Funding of transmural care models

As mentioned before, one of the main barriers to the implementation of the TTCM was the funding of transmural care models as a whole, and the funding of transmural care activities performed by allied healthcare professionals in secondary care in particular. At the moment, Dutch hospitals can use the information derived from the case study described in *chapter 5* to negotiate funding for transmural care activities performed by allied healthcare professionals in secondary care (i.e. in the case of the TTCM, the HBP working on the joint consultations with the trauma surgeon). This case study suggests that increasing the DTC price of medical specialist care is likely to result in the most sustainable model for funding allied healthcare activities performed in secondary care. While awaiting the final results of the TTCM trial, we recommend hospitals to do so.

If the physiotherapists' activities cannot be fully funded, or if there is insufficient commitment from local stakeholders, it may be necessary to re-evaluate the feasibility of continuing the current funding strategy. In such cases, it would be prudent to consider de-implementing the physiotherapists' activities and to redirect resources towards other areas of need. However, before resorting to de-implementation, hospitals may consider alternative funding sources for transmural care activities performed by allied healthcare professionals as described in *chapter 5*. Ultimately, the decision to continue or de-implement the physiotherapists' activities should be based on a thorough assessment of the feasibility, (cost-)effectiveness, and sustainability of the TTCM, as well as the availability of adequate funding and support from local stakeholders. Regarding the further upscaling and continuation of the network, two ZonMw subsidized upscaling coaches have started to safeguard the future of this national network and we recommend to continue this activity.

Interprofessional collaboration

The importance of interprofessional collaboration should not be underestimated, as it is essential for improving patient care and healthcare outcomes (48, 49). In our case, the partnership between a trauma surgeon and a hospital-based physiotherapist during the joint outpatient consultations demonstrates the significance of such a collaboration. By bringing together professionals from different disciplines, interprofessional collaboration allows for a comprehensive and integrated approach to patient management (50). As described in *chapter 4*, the collaboration between the trauma surgeon and the hospital-based physiotherapist fosters the exchange of knowledge, expertise, and skills. This collaborative effort ensures that patients benefit from diverse clinical insights and treatment strategies, rather than being limited to a single perspective. Furthermore, interprofessional collaboration ideally also extends beyond the hospital setting, involving the collaboration between the hospital and a network of primary care physiotherapists. Such a collaboration facilitates a seamless transition of care from the hospital to the community, thereby ensuring continuity and coordinated support for trauma patients. In the context of the TTCM, the hospital and primary care physiotherapists work together to provide ongoing rehabilitation and monitor progress through information sharing and regular communication. Collaboration between the hospital and primary care settings allows for a more comprehensive and patient-centered approach. It recognizes the importance of the continuity of care and the need for a multidimensional support system. Overall, interprofessional collaboration in trauma care facilitates a seamless continuum of care. Recent systematic reviews, conducted by Doornebosch et al. (51), Rawlinson et al. (52), and Wei et al. (53), have shed light on interprofessional collaboration and the barriers hindering its implementation. These reviews have identified obstacles that are largely consistent with the barriers observed in *chapter 4 and 5*. Rawlinson et al. [2021] concluded that these obstacles are generic factors, i.e., not specific to any particular group or discipline, emphasizing the need to address them comprehensively. Based on the findings of the process evaluation *in chapter 4* we recommend to pay attention towards facilitating a successful interprofessional collaboration. To achieve this, efforts should focus on developing clear communication

channels and compatible electronic patient records. Additionally, fostering a culture of mutual respect, trust, and understanding among healthcare professionals is essential. By actively addressing the barriers and implementing (interprofessional) evidence-based strategies, healthcare organizations can create an environment that supports seamless interprofessional collaboration. Ultimately, such a collaborative approach will enhance patient care by facilitating streamlined communication, reducing duplications, and providing consistent and coordinated advice across different care providers and disciplines.

GENERAL CONCLUSIONS

This thesis described the upscaling and evaluation of the TTCM. The TTCM's clinical effects, challenges, and opportunities were investigated to provide knowledge to support decision-making by care providers, patients, and policymakers. The results of the process evaluation in *chapter 4* showed that a successful upscaling of the TTCM requires some key prerequisites, including adequate financial support, active engagement of committed key actors who value change and improved work satisfaction, establishment of local ownership, and a thorough understanding of the local cultural and political context. *Chapter 5* showed that the most feasible funding model for the TTCM was including the cost of the secondary allied healthcare providers to the DTC system price for the outpatient consultation of the trauma surgeon. The results of the preliminary analysis of the effectiveness of the TTCM presented in *chapter 3* seem promising, but are not conclusive and are currently under embargo. A comprehensive analysis is pending and is expected to be completed by the beginning of 2024. This analysis will include a thorough (cost-)effectiveness assessment and an extended 9-month follow-up period. This thesis also examined the impact of fracture- and treatment-related factors on quality of life, functional outcome, and societal costs in trauma patients (*chapter 6*) and assessed the measurement properties of the LEFS (*chapter 7*), a frequently used instrument to assess functional status in patients with lower extremity fractures. The results of these two chapters can be used to improve care for trauma patients, and those with lower extremity fractures in particular, thereby also benefiting the TTCM's target population.

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SUMMARY

Traumatic injuries, defined as injuries resulting from a traumatic event such as a motor vehicle accident, fall, or violence, represent a significant global health burden. Traumatic injuries encompass a wide range of severities, ranging from minor wounds to life-threatening incidents, and can have profound consequences for the affected individuals and society. They not only result in immediate physical pain and disability but also have long-term consequences that can significantly impact the quality of life for survivors. On top of that, the economic burden of trauma is high, and traumatic injuries rank among the five most costly medical conditions worldwide. Also, these costs are expected to increase during the upcoming decades due to the aging population.

The effectiveness of trauma care systems has been extensively researched over the past years. Due to decreased trauma-related mortality, the focus has shifted towards improving trauma survivors' quality of life and long-term functional outcomes. Amongst others, this is done by aiming to improve the organization of trauma rehabilitation and streamlining care between primary and secondary care. The Transmural Trauma Care Model (TTCM) was developed at Amsterdam UMC, the Netherlands, to bridge this gap between these two care sectors. The TTCM is a multidisciplinary and patient-centered transmural rehabilitation care model, consisting of 1) joint consultations by a multidisciplinary team at the outpatient clinic for trauma patients; 2) coordination and individual goal setting; 3) a network of specialized network physiotherapists (NPs) and 4) secured email traffic between hospital-based physiotherapists and NPs.

The primary aim of this thesis was to assess the (cost-)effectiveness of the TTCM compared with usual care. Secondary aims included the investigation of the barriers and facilitators of the upscaling and financing of the TTCM, exploring the association of fracture- and treatment-related factors and disease-specific HR-QOL, functional outcome, and societal costs in trauma patients, and assessing the measurement properties of the Lower Extremity Functional Scale (i.e., a functional outcome scale, used for patients with lower extremity fractures).

Chapter 2 described the study protocol of the multicenter trial that aimed to assess the (cost-)effectiveness of the TTCM. Within this trial, control group patients received the usual rehabilitation care provided by the participating hospitals before implementing the TTCM. Patients in the intervention group received the TTCM. Co-primary outcomes included generic and disease-specific health-related quality of life. Secondary outcomes included pain, patient satisfaction, perceived recovery, and patient-reported physical functioning. For the economic evaluation, societal and healthcare costs were measured at baseline and after 6 weeks, 3, 6, and 9 months.

Chapter 3 presented a preliminary analysis of the multicenter trial described in *Chapter 2*. This preliminary analysis was primarily aimed at determining the 6-month effectiveness

of the TTCM. Even though there were no statistically significant overall between-group differences for the co-primary outcomes generic and disease-specific QOL during the complete 6-month follow-up period, both were statistically significantly and, in most cases, clinically relevantly higher in the intervention group compared with the control group at 3- and 6-months follow-up. Additional analysis incorporating 9 months of follow-up data is required to determine whether this trend continues. Additionally, a comprehensive cost-effectiveness analysis has not yet been conducted, as cost data were not available at the time of the preliminary analysis. Both the 9-month effectiveness and cost-effectiveness results are expected at the beginning of 2024.

Chapter 4 described a process evaluation assessing the barriers and facilitators associated with the upscaling of the TTCM. This study consisted of semi-structured interviews. The participants, who were purposively selected, represented stakeholders relevant to the four interlinked components of the TTCM: trauma surgeons, network physiotherapists (NPs working in primary and tertiary care), HBPs, and patients. Participants for the study were selected from care providers and patients involved in the multicenter trial and hence had experience with upscaling the TTCM. Various barriers and facilitators were identified (e.g., 'increased job satisfaction,' 'lower administrative workload for a trauma surgeon,' and 'more experience with and knowledge of treating trauma patients since working with the TTCM'). Moreover, the successfulness of upscaling the TTCM was found to highly differ across hospitals and settings, which seemed to be related to the issue of whether or not hospitals were able to arrange funding for one or more hospital-based physiotherapist(s) and the commitment of key actors within the organization (e.g., trauma surgeons).

Chapter 5 described a qualitative study assessing barriers and facilitators associated with arranging funding for transmural care models in the Netherlands, particularly the TTCM. Semi-structured interviews with relevant stakeholders were conducted, and a framework method was used for the analysis, during which the 'constellation approach' was used to categorize barriers and facilitators into three categories: structure, culture, and practice. The interviewees discussed various possible funding models, of which the most feasible one seemed to include the cost of the secondary allied healthcare providers in the diagnosis-treatment combination (DTC, Dutch: DBC) of relevant medical specialist care. In the case of the TTCM, this would be the DTC of the trauma surgeon. During the multicenter trial, however, DTC negotiations were temporarily halted due to the COVID-19 pandemic. Other factors that were deemed necessary for the successful funding of transmural care models, such as the TTCM, are the presence of dedicated key actors, and dedicated medical specialists in particular, a sense of local ownership, and a good understanding of the context (e.g., local cultural and political factors).

Chapter 6 assessed the association between fracture- and treatment-related factors versus disease-specific HR-QOL, functional outcome, and societal costs in trauma patients. This study used data from intervention group participants and participants from the 9-month

control group from a previously mentioned controlled before and after study. Data on the fracture- and treatment-related factors of surgery, fracture type, fracture localization, and fracture treatment 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 with disease-specific HR-QOL, functional outcome, and societal costs while correcting for receiving the TTCM, the case-mix variables age, gender, and comorbidity, and for the other independent fracture and treatment-related factors. The results suggest that fracture localization was associated with disease-specific HR-QOL and functional outcomes after nine months. Lower extremity fractures were associated with less favorable outcomes after 9 months, and upper extremity fractures were associated with better functional outcomes than the reference category (i.e., patients with a vertebral fracture or multi-trauma patients).

Chapter 7 assessed the measurement properties of the LEFS, a Patient-Reported Outcome Measure (PROM), to evaluate lower extremity fracture patients' functional status. This systematic review was conducted in accordance with the COSMIN methodology for systematic reviews of PROMs. Eligible studies had to report on the development of the LEFS or the evaluation of one or more measurement properties of the LEFS in patients with at least one fracture of the lower extremities. A total of 7 studies were included. The LEFS was found to have several shortcomings, including inconsistent content validity, lack of clarity regarding the measured construct, and limited evidence supporting its measurement properties. The lack of sufficient content validity was considered the most important, as content validity is a PROM's most crucial measurement property according to the COSMIN guidelines.

Discussion

In Chapter 8, the main findings were discussed and interpreted, and recommendations for research and practice were presented. In conclusion, this thesis aimed to evaluate the (cost-)effectiveness of the TTCM compared to usual care in trauma patients in a multicenter trial. Unfortunately, due to – amongst others – the COVID-19 pandemic, follow-up of the study is still ongoing; hence, we could only perform a preliminary effectiveness analysis. Even though the results of this analysis seem promising, they are inconclusive, and further strong conclusions about the (cost-)effectiveness of the TTCM can only be made after completing the follow-up and performing the 9-month (cost-)effectiveness analyses. When implementing the TTCM, we would recommend facilitating a successful interprofessional collaboration and arranging a sustainable funding structure for the hospital-based physiotherapist by adding those costs to the DTC of the trauma surgeon. We recommend further validating the Lower Extremity Functional Scale (LEFS) in a well-designed content validity study and, in the meantime, investigating the measurement properties of the Patient-Reported Outcomes Measurement Information System (PROMIS) questionnaires, particularly the PROMIS CAT (i.e., computer adaptive testing), in trauma patients.

SAMENVATTING

Traumatisch letsel is letsel veroorzaakt door een onverwachte gebeurtenis, zoals bijvoorbeeld een verkeersongeval, een val of geweld. Zij vertegenwoordigen een aanzienlijk deel van de wereldwijde gezondheidslast. Traumatische letsels omvatten een breed spectrum en lopen uiteen van kleine wonden tot levensbedreigende incidenten, en kunnen derhalve grote gevolgen hebben voor getroffen individuen en de samenleving als geheel. De economische, maatschappelijke en individuele last is hoog. Traumatische letsels veroorzaken niet alleen onmiddellijke fysieke pijn en beperkingen, maar kunnen ook langdurige gevolgen voor de kwaliteit van leven hebben. Daarnaast is de economische last van traumatisch letsel hoog, traumatische letsels behoort tot de vijf meest kostbare medische aandoeningen wereldwijd. Bovendien zullen deze kosten naar verwachting in de komende decennia toenemen als gevolg van de steeds ouder wordende bevolking.

De effectiviteit van verschillende traumazorgsystemen is de afgelopen jaren uitgebreid onderzocht en verbeterd en sterfte als gevolg van een ongeval daalde daardoor met wel 16 %. Door de daling van het sterftecijfer verschoof de aandacht naar de kwaliteit van leven en het functioneren van de overlevende patiënten. Als gevolg daarvan was er ook meer aandacht voor het revalidatieproces. De organisatie van traumarevalidatie is echter uitdagend en er bestaat een grote kloof tussen ziekenhuis en het ontslag naar de thuissituatie. Om deze kloof te dichten is het Transmurale Trauma Care Model (TTCM) ontwikkeld. Het TTCM is een transmuraal revalidatiemodel voor traumapatiënten dat als doel heeft om functionele uitkomsten te verbeteren en zorg- en verzuimkosten te reduceren door het optimaliseren van de organisatie, inhoud en kwaliteit van het revalidatieproces. Het TTCM bestaat uit vier componenten die onlosmakelijk met elkaar verbonden zijn 1) intake en vervolgconsulten door een multidisciplinair team op de polikliniek voor traumapatiënten (bestaande uit traumachirurg en ziekenhuisfysiotherapeut); 2) coördinatie van de revalidatie en het stellen van individuele functionele doelen; 3) netwerk van gespecialiseerde fysiotherapeuten in de eerstelijn en in GRZ- en revalidatie-instellingen; 4) beveiligd e-mailverkeer tussen de ziekenhuisfysiotherapeuten en de netwerkfysiotherapeuten.

Het primaire doel van dit proefschrift was om de (kosten-)effectiviteit van het TTCM te onderzoeken binnen een multicenteronderzoek. Nevendoelen waren het onderzoeken van factoren die de opschaling van het TTCM positief dan wel negatief beïnvloedden en het identificeren van opties om een transmuraal zorgmodel, zoals het TTCM te financieren. Daarnaast werden de data uit het pilotonderzoek gebruikt om de associatie van fractuur- en behandelinggerelateerde factoren met drie afhankelijke uitkomsten (ziektespecifieke kwaliteit van leven, functionele uitkomst en maatschappelijke kosten) bij traumapatiënten te onderzoeken. Ten slotte is er door middel van een systematische review getracht de validiteit en meeteigenschappen van de Lower Extremity Functional Scale, een vragenlijst voor het meten van functionele status bij patiënten met fracturen aan de onderste extremiteit, te onderzoeken.

Samenvatting per hoofdstuk

Hoofdstuk 2 beschrijft het onderzoeksprotocol van het multicenteronderzoek met een gecontroleerd voor-en-na-ontwerp dat als doel had de effectiviteit en kosteneffectiviteit van het TTCM te onderzoeken. Daarnaast wordt in hoofdstuk 2 de opzet van de procesevaluatie nauwgezet beschreven. Binnen dit onderzoek ontvangen patiënten in de controlegroep de gebruikelijke revalidatiezorg die door de deelnemende ziekenhuizen wordt gegeven voordat het TTCM wordt geïmplementeerd. De gebruikelijke zorg verschilt enigszins tussen ziekenhuizen, maar over het algemeen bieden traumachirurgen de poliklinische afspraken aan zonder begeleiding van andere zorgverleners. Op basis van het klinische oordeel van de traumachirurg worden traumapatiënten doorverwezen naar een fysiotherapeut in de eerstelijnszorg of revalideerden in GRZ- en revalidatie-instellingen. Er is echter geen gestandaardiseerd beleid voor deze verwijzingen, noch is er een gestructureerd netwerk van gespecialiseerde fysiotherapeuten in de eerstelijnszorg of GRZ- en revalidatie-instellingen. Patiënten in de interventiegroep ontvangen TTCM. Co-primaire uitkomsten zijn generieke en ziektespecifieke gezondheidsgerelateerde kwaliteit van leven. Secundaire uitkomsten zijn pijn, patiënttevredenheid, ervaren herstel en door de patiënt gerapporteerd fysiek functioneren. Voor de economische evaluatie worden de maatschappelijke kosten en de kosten voor de gezondheidszorg gemeten op de basislijn en na 6 weken, 3, 6 en 9 maanden.

Hoofdstuk 3 presenteert een voorlopige analyse van het multicenteronderzoek naar de klinische effectiviteit van het TTCM in vergelijking met de reguliere zorg bij traumapatiënten na 6 maanden. Hoewel er geen statistisch significante verschillen tussen de groepen waren voor generieke en ziektespecifieke kwaliteit van leven gedurende de gehele periode van 6 maanden, waren beide statistisch significant en, in de meeste gevallen, klinisch relevant hoger in de interventiegroep in vergelijking met de controlegroep op 3 en 6 maanden. Om te beoordelen of deze trend zich voortzet, is een aanvullende analyse op 9 maanden nodig. Een aanzienlijk aantal patiënten had onvolledige effectgegevens op het moment van de huidige analyse, aangezien de metingen nog gaande waren. Bovendien moet er nog een uitgebreide kosten-effectiviteitsanalyse worden uitgevoerd, omdat de kostengegevens niet beschikbaar waren op het moment van de voorlopige analyse. Zowel de resultaten van de effectiviteit na 9 maanden als de kosteneffectiviteit worden begin 2024 verwacht.

Hoofdstuk 4 beschrijft de resultaten van een procesevaluatie die belemmerende en bevorderende factoren beschrijft, die verband houden met de opschaling van het TTCM. De procesevaluatie bestond uit semigestructureerde interviews. De deelnemers vertegenwoordigden de patiënten en de betrokken zorgverleners (traumachirurgen, ziekenhuisfysiotherapeuten en netwerkfysiotherapeuten werkzaam in zowel de eerstelijnszorg als in GRZ- en revalidatie-instellingen). Diverse belemmeringen en bevorderende factoren werden geïdentificeerd (bijvoorbeeld ‘meer werkplezier’, ‘minder administratieve last voor de traumachirurg’ en ‘meer ervaring en kennis over de behandeling van traumapatiënten sinds het werken met het TTCM’). Er werd geconcludeerd dat het succes van het opschalen van het TTCM sterk verschilde tussen ziekenhuizen

en instellingen, wat te maken leek te hebben met de vraag of ziekenhuizen al dan niet aanvullende financiering konden regelen voor ziekenhuisfysiotherapeut(en) op de polikliniek traumachirurgie. Daarnaast speelde de betrokkenheid van sleutelfiguren binnen de organisatie (bijv. traumachirurgen) een grote rol bij succesvolle implementatie.

Hoofdstuk 5 presenteert de resultaten van een casestudy die als doel had om positieve en negatieve factoren te identificeren die van invloed zijn op de financiering van transmurale zorgmodellen in Nederland, met als voorbeeld het TTCM. Er werden semigestructureerde interviews met relevante stakeholders gehouden en voor de analyse werd een raamwerkmethode gebruikt, waarbij de 'constellatiebenadering' werd gebruikt om de positieve en negatieve factoren in drie categorieën te verdelen: structuur, cultuur en praktijk. De geïnterviewden bespraken verschillende mogelijke financieringsmodellen. Het meest haalbare financieringsmodel bleek om de kosten van de ziekenhuisfysiotherapeuten op te nemen in de diagnose-behandelcombinatie (DBC) systeemprijs voor het poliklinische consult van de medische specialist. Tijdens het multicenteronderzoek weden de DBC-onderhandelingen helaas tijdelijk stopgezet vanwege de COVID-19-pandemie. Andere factoren die noodzakelijk leken voor een succesvolle financiering van het TTCM zijn de aanwezigheid van toegewijde sleutelfiguren, met name toegewijde medisch specialisten, een gevoel van lokaal eigenaarschap van de TTCM en een goed begrip van de context (bijv. lokale culturele en politieke factoren).

Hoofdstuk 6 presenteert de resultaten van het onderzoek naar de associatie van fractuur- en behandelingsgerelateerde factoren en drie afhankelijke uitkomsten (ziektespecifieke kwaliteit van leven, functionele uitkomst en maatschappelijke kosten) bij traumapatiënten met ten minste één fractuur 9 maanden na hun eerste poliklinische bezoek. Voor dit onderzoek werden data van interventiegroepdeelnemers en deelnemers uit de 9 maanden controlegroep uit een eerder genoemde gecontroleerde voor- en na studie gebruikt. OLS-regressieanalyses werden uitgevoerd om de associatie van elke fractuur- en behandelingsgerelateerde factor met ziektespecifieke kwaliteit van leven, functionele uitkomst en maatschappelijke kosten te beoordelen, terwijl er werd gecorrigeerd voor zowel het ontvangen van de TTCM als diverse case-mixvariabelen (bijvoorbeeld leeftijd, geslacht en comorbiditeit). De resultaten suggereren dat fractuurlokalisatie geassocieerd was met ziektespecifieke kwaliteit van leven en functionele uitkomsten na 9 maanden. Fracturen aan de onderste extremiteit waren geassocieerd met minder gunstige uitkomsten na 9 maanden, en fracturen aan de bovenste extremiteit waren geassocieerd met betere functionele uitkomsten dan de referentiecategorie (d.w.z. patiënten met een wervelfractuur of multitraumapatiënten).

Hoofdstuk 7 presenteert de resultaten van een systematische review over de inhoudsvaliditeit en andere meeteigenschappen van de Lower Extremity Functional Scale (LEFS), een vragenlijst om de functionele status van patiënten met een fractuur van de onderste extremiteit te evalueren. De LEFS heeft verschillende tekortkomingen, waaronder

inconsistente inhoudsvaliditeit, onduidelijkheid over het gemeten construct en beperkt bewijs ter ondersteuning van de meeteigenschappen. Het ontbreken van voldoende inhoudsvaliditeit werd als de belangrijkste beschouwd, aangezien inhoudsvaliditeit volgens de COSMIN richtlijnen de meest cruciale meeteigenschap van een vragenlijst is. De vraag hierbij is, of je meet wat je moet meten.

In *Hoofdstuk 8* worden de belangrijkste bevindingen besproken en geïnterpreteerd, en aanbevelingen voor onderzoek en praktijk gepresenteerd. Concluderend was het doel van dit proefschrift om de (kosten)effectiviteit van de TTCM te evalueren in vergelijking met de gebruikelijke zorg voor traumapatiënten in een multicenter onderzoek. Helaas is de follow-up van het onderzoek, onder andere vanwege de COVID-19-pandemie, nog steeds gaande. er konden daarom alleen voorlopige effectiviteitsanalyse uitgevoerd worden. Hoewel de resultaten van deze analyse veelbelovend lijken, leiden ze nog niet tot sluitende conclusies. Deze kunnen pas worden getrokken na voltooiing van de follow-up en de uitvoering van (kosten)effectiviteitsanalyses over een periode van negen maanden.

Wij raden aan bij de implementatie van de TTCM de nadruk te leggen op het bevorderen van succesvolle interprofessionele samenwerking en het tot stand brengen van een duurzame financieringsstructuur voor de ziekenhuisfysiotherapeut, binnen de DBC van de traumachirurg. Verder raden we aan om de Lower Extremity Functional Scale (LEFS) verder te valideren in een kwalitatief goed inhoudsvaliditeitsonderzoek, en in de tussentijd de meeteigenschappen van de Patient-Reported Outcomes Measurement Information System (PROMIS)-vragenlijsten te onderzoeken, met name de PROMIS CAT (computeradaptief testen), bij traumapatiënten.

DANKWOORD

Met een flinke dosis enthousiasme en op mijn eigen 'Julia-manier' begon ik vijf jaar geleden aan mijn promotietraject. Geïnspireerd door vernieuwende ideeën en met de vastberadenheid om er voor de volle 100 procent voor te gaan, startte ik aan deze uitdagende reis. Gelukkig hoefde ik dit avontuur niet alleen te doorlopen, en daarvoor wil ik graag mijn oprechte dank uitspreken aan iedereen die mij heeft ondersteund, gesteund en aangemoedigd.

Allereerst wil ik alle patiënten, de deelnemende centra en mijn promotieteam bedanken. Zonder jullie inzet was dit proefschrift niet tot stand gekomen.

Beste **patiënten**, ik wil jullie van harte danken voor jullie deelname aan ons onderzoek. Jullie inzet heeft ons in staat gesteld om het onderzoek te voltooien en bevindingen te publiceren. We hopen dat we samen de zorg voor patiënten na een ongeluk hebben kunnen verbeteren.

Een multicenteronderzoek kan natuurlijk niet zonder de medewerking van de deelnemende ziekenhuizen. Beste lokale **coördinatoren, traumachirurgen en hoofden paramedische dienst**, ik ben ontzettend dankbaar dat jullie mee hebben gedaan met ons onderzoek. Jullie bijdrage heeft ons in staat gesteld om de traumarevalidatie in Nederland verder te verbeteren en patiënten een nog betere nazorg te bieden.

Mijn bijzondere dank gaat naar de lokale coördinatoren in de deelnemende ziekenhuizen **Milou, Laura (AUMC), Judith (LUMC), Indy, Tjarda, (Radboudumc) Yvonne (MUMC), Jolijn (NWZ), Tessa (Haga), Renate (ZMC), *Peter* †, Valerie (RDDG), Dennis, Natasha (HMC) en Bas (SG)**.

Jullie hebben niet alleen alle data verzameld en de lokale netwerken opgezet; dankzij jullie doorzettingsvermogen en motivatie hebben jullie ook collega's kunnen enthousiasmeren voor TTCM. Samen met collega's uit jullie ziekenhuizen hebben jullie dit project gedragen. Ik hoop dat jullie en jullie patiënten hier iets aan hebben over gehouden. Veel dank!!!

De traumachirurgen die het onderzoek en TTCM als ambassadeur hebben gesteund verdienen ook een speciale vermelding: **Kees-Jan, Boj (NWZ), Sven (HMC), Maarten (RDDG), Peter, Tim (AUMC), Robert Jan (ZMC), Martijn (MUMC), Inger (LUMC), Alexander (Haga), Gerben (SG), Michael (Radboudumc)**, dank voor jullie inzet.

Ook veel dank aan alle andere betrokken traumafysiotherapeuten en leidinggevenden van de deelnemende ziekenhuizen: **Wilfred, Eric (LUMC), Roy, Niels, Alex, Rob (MUMC), Iris, Xaviera, Jasper, Wim (RDDG), Stephan, Lotte, Frank, Frans (Haga), Jolanda, Erik (NWZ), Frank (Radboudumc), Ad (ZMC), Daniël, Sophie (HMC), Jessie, Nienke, Yvonne (SG)**.

En aan alle fysiotherapeuten van het **Netwerk Traumarevalidatie Nederland**: Bedankt voor jullie geweldige bijdrage, samenwerking en fantastische inzet! Op naar landelijke dekking van het mooie netwerk dat tijdens deze trial is opgezet.

Zoals jullie zien zijn er heel veel enthousiaste mensen die hebben geholpen TTCM te implementeren. Gevaarlijk aan het noemen van namen is dat je altijd iemand vergeet. Ik weet dat ik vast niet iedereen bij naam heb genoemd, maar ik wil alle geweldige mensen die hebben bijgedragen aan de implementatie van TTCM enorm bedanken. Zonder jullie was dit avontuur niet zo fantastisch geweest.

Beste **promotieteam**, ik wil jullie graag bedanken voor de steun die jullie mij hebben gegeven bij het schrijven van dit proefschrift. Jullie deskundigheid, begeleiding en advies waren van onschatbare waarde bij het onderzoek en het schrijfproces.

Raymond Ostelo, mein Doktorvater, ich möchte mich aufrichtig für deine Unterstützung und dein Engagement bei meiner Dissertation bedanken. Ich war nicht immer geduldig, aber du hast dich nicht aus der Ruhe bringen lassen. Du hast nicht nur deine Fachkenntnisse eingebracht, sondern auch deine Erfahrung und Weisheit, die ich bei meiner Arbeit sehr zu schätzen gelernt habe. Durch deine Kritik an meiner Arbeit hast du mir geholfen, meine Forschungsmethoden zu überdenken und zu verbessern, was letztendlich zu einer erheblichen Verbesserung meiner Arbeit geführt hat. Auch deine Bereitschaft, meine Ideen zu unterstützen und zu ermutigen, hat mir die Motivation gegeben, mein Ziel zu erreichen. Vielen Dank dafür.

Frank Bloemers, promotor, heel veel dank voor jouw enthousiasme, jouw passie voor de gezondheidszorg en jouw deskundigheid van het vak. Je stond altijd klaar om te helpen (ook voor olifantenbaby's, Ajacieden en nog zo veel meer patiënten die blij met jou kunnen zijn).

Suzanne Wiertsema, copromotor, je hart op de goede plek en een echte expert in ons vak. Je hebt mij niet alleen geholpen met je kennis, maar ook met je onvoorwaardelijke steun. Jouw pionierschap, doorzettingsvermogen en gedrevenheid hebben mij geïnspireerd om door te zetten en mijn best te doen. Als hard werkende collega's kwamen wij helaas maar eenmalig in het genot van een gezamenlijk hardloopevent, maar ik kijk uit naar meer gezamenlijke momenten.

Hanneke van Dongen, copromotor, zonder jou als mijn copromotor was mijn promotietraject niet hetzelfde geweest (als het dan überhaupt al af was geweest ;-)) Ik ben dankbaar voor je snelle, slimme en geduldige begeleiding; altijd beschikbaar met constructieve feedback. In lijn met de wijsheid van lego.com, waarbij je je droom opbouwt, steen voor steen, wil ik jou van harte bedanken voor het helpen vormgeven van de constructie van mijn wetenschappelijke reis.

Edwin Geleijn, innovator en creatieveling, ik heb veel van jou kunnen leren. Gelukkig heb ik jou op de squashbaan nog een klein beetje weerstand kunnen bieden.

De leden van de **beoordelingscommissie**, dr. Charlotte Lameijer, prof.dr. Martijn Poeze, prof. dr. Ton Lenssen, dr. Marike van der Schaaf, dr. Harald Miedema en dr. Femke van Nassau, wil ik hartelijk danken voor het kritisch lezen van mijn proefschrift.

Graag bedank ik hier ook de andere collega's en medeauteurs van de in dit proefschrift opgenomen wetenschappelijke publicaties.

Vincent de Groot, afdelingshoofd van de revalidatieafdeling, dank voor jouw inzet en jouw constructieve, efficiënte en scherpzinnige manier van werken. Terwijl ik soms een week over een wetenschappelijk probleem heb nagedacht, wist jij het antwoord al voordat ik de vraag had gesteld.

Marianne Donker, universitair docent Gezondheidswetenschappen, en specialist kwalitatieve onderzoeksmethoden aan de Vrije Universiteit, dank voor jouw specifieke kennis, feedback en scherpe blik. Jouw feedback op de artikelen heb ik erg gewaardeerd. Wanneer gaan we thee drinken?

Sylvia Pellekooren, mattie, kanjer, duizendpoot. Ongelofelijk hoe veel goed werk je binnen korte tijd kunt verrichten. ZonMw heeft echt geluk met jou!

Benjamin Salampessy, adviseur Risicoverevening at Zorginstituut Nederland, wat weet jij veel over de Nederlandse gezondheidszorg. Dank dat je deze kennis met mij wilde delen.

Anne, Ilham, Julia, Robin, Sarah en Shadi, voormalige stagiaires gezondheidswetenschappen, wat hebben jullie hard gewerkt binnen jullie stages! Heel erg bedankt voor jullie inspanningen.

De fysio trauma vakgroep (voormalig locatie VUmc): **Lydia, Josien, Maaike, Madelon, Pauline, Bouke, Laurens**, altijd druk met patiënten werk op hoog niveau, maar gelukkig tussendoor tijd om mij te helpen, vraag en antwoord te staan, of een bakje koffie samen te doen. Dank jullie wel! Ook alle andere fysio collega's van de afdeling revalidatiegeneeskunde wil ik graag bedanken. Mijn bijzondere dank gaat aan **Laura** en **Milou.**

Datamanagement VUmc, **Cüneyt**, dank je voor de leerzame, leuke en interessante TTCM meetings, je input en geduld met die je ordening in de data hebt gebracht en jouw vakkennis met die je elk probleem hebt kunnen oplossen. Koffie?

Dankzij vele fijne collega's en goede sfeer, lekker gebak en spelletjes bij het 't Refpunt heb ik met veel plezier gewerkt op de afdeling revalidatiegeneeskunde in het Amsterdam UMC, locatie VUmc.

Mijn kamergenoten en collega's onderzoek, bedankt voor jullie gezelligheid, vele kopjes koffie, fanatieke spelavonden of sportuitjes. Mijn kamergenoten: **Marijke (dank je wel dat je mijn paranimf bent!), Kirsten (ja ja @ Jim: "Kürsten"), Jim, Niels, Maaike, Eline, Wilmar, Charlotte, Karen**, **Helga** dank jullie voor het luisterend oor, gezelligheid en goede discussies. Collega's onderzoek: **Elvira, Arianne, Marjolein, Marjolein, Nina, Laura, Lara, Tim, Emma, Elza, Mique, Koen, Wouter**, **Marjolein** ik wil jullie allen bedanken voor de geweldige tijd op de afdeling. Hoewel we aan verschillende projecten werkten, hebben we leuke, leerzame, en gekke gesprekken gehad. Dank voor jullie fantastische bijdrage (en mij laten winnen met squashen) en succes in de toekomst. **Juul en Romain**, mijn "opvolgers", ik wens jullie een geweldig Phd traject toe, geniet er niet met mate van! **Boas**, kritische sparringpartner, harde werker en ook nog eens een goede hardloper- petje af!

Al mijn andere collega's van de afdeling revalidatiegeneeskunde en de VU: **Larissa, Rosalie, Heleen, Helga, Monique, Manon, Anneke, Ellis en Appie**, bedankt voor jullie geduld en gastvrijheid.

Ook mijn collega's van Amsterdam Movement Sciences (AMS) wil ik graag danken: **Richard, Sicco, Erwin, Solveig, Mirjam, Mirjam, Wendy, Vincent, Idsart, Marieke, Marike, Esther, Karin, Annemieke, Thomas, Fieke, Elza, Annemieke, Lisa, Babette, Lotte**, **Guido.**

Graag wil ik mijn dankbaarheid uitdrukken jegens de **Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO)** en de onderzoekers van de projecten die ik begeleid. Jullie toewijding aan wetenschappelijk onderzoek en jullie voortdurende inzet voor het bevorderen van kennis, innovatie en toepassing zijn bewonderenswaardig. Dank jullie wel voor jullie warme ontvangst, geduld en enthousiasme.

Hartelijk dank aan mijn partner, familie, vrienden, en al degenen die mij hebben geholpen bij de totstandkoming van dit proefschrift. Zonder jullie steun en aanmoediging was deze prestatie nooit mogelijk geweest. En omdat jullie er zijn. Ook naast de fulltime baan als PhD student heb ik vele fantastische jaren gehad samen met jullie.

Armin, ik wil je heel erg bedanken voor alles wat je voor me hebt gedaan. Je bent lief, slim en begripvol (of je luistert gewoon niet ;-)). Je bent een geweldige partner, mijn steun en toeverlaat en ik waardeer jou en jouw onvoorwaardelijke liefde, geduld en begrip enorm. Je hebt me geholpen om mezelf te zijn en om mijn doelen te bereiken (wat waren de doelen nog weer? ;-)). Dankzij jou ben ik een betere versie van mezelf geworden. Ik hou van jou.

Mum, was waren unsere letzten Jahre heftig, anders, besonders, krass (wie sagt man das im Deutschen?). Du hast dich nicht unter kriegen lassen und hast dich immer wieder aufgerappelt- so stark! Mit deinen kreativen Fähigkeiten hast du dieses Buch gestaltet und ihm das gewisse I-Tüpfelchen gegeben. Danke! Wann fliegen wir nach Tallinn auf den Spuren van Hoeps & Toes? ***Volker†***, *-pa-*, auch wenn du nicht mehr da bist, wenn ich meine Dissertation verteidigen muss, bin ich sicher, dass du stolz auf mich wärest.

Patrick, Rosi und Co, klein aber fein. Gemeinsam bilden wir eine einzigartige Familie, die ich sehr schätze. Wie Rosi so treffend sagt: "Unkraut vergeht nicht".

Jake en Ben, ik weet dat jullie dit niet willen horen/lezen, maar toch ga ik het schrijven. Dank dat jullie zijn zoals jullie zijn, en ik blijf graag de cognitieve en sportieve uitdagingen met jullie aangaan, steeds weer lerend en groeiend (behalve mijn kennis rond voetbal dan).

Rozema-Sijbrandij-clan en aanhang, dank jullie wel voor de gezelligheid, lange Paasweekenden (Lisanne, Amber, Wietske en Nynke wanneer gaan we weer galopperen door de Friese bossen?) en de warme herinneringen die we hebben gedeeld.

Klaus, Ulla, Ricci und Tilda, vielen Dank für die leckere Schokolade, entspannenden Saunengänge, Shakespeare Theaterstücke und Festivals.

Bedankt **Cindy, Daniel, James, Marion, Anneke** en **Arie**! Jullie zijn de beste buren ooit!

Ed, vakidioot, inspirator, (wandel-)maat, vriend, bedankt dat je er altijd voor me bent, en mij blijft inspireren.

Lies, **paranimf**, urenlange wandelingen, eindeloze gesprekken, en daaruit voortvloeiende verdwalingen, gezamenlijke sporten, dansfeestjes en nog veel meer. Ik ben je enorm dankbaar dat je er altijd voor me bent. Dank je wel voor al je liefde en support. Je bent de beste!

Ingrid, jouw broek heeft onze gezamenlijke hardloopmomenten laten beginnen. Wat een fantastische tijd die ik nooit zou willen missen. Inmiddels aangevuld door windsurfen, paardrijden, eetuitjes, bios, autorijden, VR rooms, geitenyoga en nog zo veel meer. Wanneer gaan we weer samen voor de halve marathon? **Rik,** later begonnen met hardlopen dan wij en nu veel sneller en op langere afstanden ("zo'n type"). Zo leuk, dat we dit gezamenlijk kunnen beleven (Armin: '*Sinds wanneer is hardlopen leuk?*' [zegt hij nadat hij ongetraind 10km met ons heeft gelopen]).

Kerstin, wir haben so viele Erfahrungen und Erinnerungen miteinander geteilt und du warst trotz des Abstandes da. Ich hoffe, dass unsere Freundschaft für immer bestehen bleibt.

Dede, mein externes Gehirn für Erinnerungen seit dem Kindergarten. Sorry, das ich nicht bei deiner Hochzeit sein konnte! Grüß mir den Rest des Clans, ihr seid echt toll zusammen!

Patricia, natuur, puur, samen en buiten spelen beschrijven onze trailrunning momenten. Zo fijn jou te hebben mogen leren kennen en ik hoop dat we nog veel gezamenlijke momenten gaan beleven.

Jojo, vakvrouw en ontwikkelaar, je passie waarmee jij voor jouw patiënten klaarstaat is zo enorm bijzonder en waardevol. Je doortastende manier van doorvragen en spiegelen is zo kostbaar. **Lisette**, je bent een topper en onze (spelletjes-)avonden blijven onvergeten. Beide, bedankt voor alle mooie en gezellige momenten die ik met jullie heb mogen delen.

Timo, squashmaat, doorzetter, de beste rally's die ik nooit wil gaan missen. Nu heb ik gelukkig weer wat meer tijd om jou weerstand te bieden.

Annebel, samen nogal wat verhalen meegemaakt waar we gelukkig om konden huilen (van het lachen) en ik ben blij dat we deze bijzondere momenten samen hebben kunnen delen.

Anneke, nadat ik vanuit Zwitserland naar Nederland verhuisde begon ik als jouw collega in het revalidatiecentrum. Nauwelijks Nederlands (menigeen zou zeggen, niks verandert ;-)), cultuur- en culinaire schok (patat met pindakaassaus?). Jij hebt je niet gek laten maken door mij maar mij de mooie dingen van Nederland laten zien (ter paard ;-)).

ABOUT THE AUTHOR

Curriculum Vitae

Julia Ratter was born on November 29, 1982, in Bergisch Gladbach (Germany), and grew up in a small village near Cologne. In 2002, she completed her pre-university secondary education at the Gymnasium Odenthal. She then pursued Physiotherapy at HAN University of Applied Sciences, earning her Bachelor of Science degree in 2006. Driven by curiosity and adventurousness, she relocated to Switzerland, where she worked as a physiotherapist and junior researcher at the University Hospital of Bern. Despite Switzerland being a leading country in top-quality higher education and an early adopter of the Bologna Process and the Lisbon Recognition Convention, providing limited opportunities for specialization in the physiotherapy research master's program, she returned to the Netherlands in 2010. Julia studied Evidence-Based Practice at the University of Amsterdam, receiving her Master's Degree in 2013. Alongside her education and specializations, she worked full-time as a physiotherapist, primarily in a hospital setting, but she also gained experience working in primary and tertiary care. In 2019, Julia commenced her PhD under the supervision of Prof. dr. Raymond WJG Ostelo, Prof.dr. Vincent de Groot, Prof.dr. Frank W Bloemers, Dr. Johanna M van Dongen, and Dr. Suzanne H Wiertsema at the Department of Rehabilitation Medicine. Simultaneously, she continued her role as a clinical physiotherapist at Amsterdam UMC, location VUmc. The onset of the Covid-19 pandemic redirected her attention to different tasks within her PhD trajectory, including supporting physiotherapy colleagues in Covid-19 wards. Furthermore, she was PhD representative in the board of AMS Musculoskeletal Health and coordinator for RehabNet Amsterdam of AMS Rehabilitation and Development. Collaborating with experts from various fields energizes her. In 2023, she started working at the department of applied and engineering sciences of NWO (Dutch research council) in Utrecht, alongside completing her doctoral trajectory in her free time. She is analytically strong, structured, and well-organized. Or just German "grundanständig und korrekt". She lives with Armin Rozema and five cats.

PORTFOLIO

PhD training	Year	ECTS
Courses and workshops		
Sportvoeding	2023	0.1
Economic evaluation	2022	6
Webinar Traumanight 'Bekkenfracturen'	2022	0.1
Research integrity course	2020	2
Webinars Cochrane	2020	0.4
Data Science: R Basics	2020	0.71
Writing a Data Management Plan	2020	1
Workshop Multiple baseline single case design en R	2019	0.2
Writing a scientific article	2019	3
Traumachirurgie en fractuurbehandeling	2019	0.85
BROK	2019	1.5
Research methods: Biostatistics and advanced epidemiology	2011	1
Conferences and symposia		
Traumadagen (presenter)	2023	0.2
AMS P5 symposium (presenter)	2023	0.2
KNGF Dag van de Fysiotherapeut 2022 (poster)	2022	0.2
MSG Symposium 2022 (presenter poster pitch)	2022	0.2
Annual Meeting 2022 Amsterdam Movement Sciences (presenter poster)	2022	1.1
Annual Meeting 2021 Amsterdam Movement Sciences	2021	0.2
Academic day NVZF	2021	0.2
Netherlands Research Integrity Symposium	2020	0.12
Amsterdam Movement Sciences PhD day 2020	2020	0.2
Amsterdam Movement Sciences PhD day 2019	2019	0.2
Traumadagen	2019	0.57
Refereerbijeenkomst revalidatieartsen, VUmc	2019	0.1
Other activities		
Co-set up and execution of 2 and 3-day NPi training courses: Implementation of TTCM Network Trauma Rehabilitation	2021	6.5
VERSA Project of the Vrije Universiteit Amsterdam: Training social skills, cognitive flexibility, creativity, and critical thinking	2021	3
External work placements with a company in The Netherlands, Sint Maartenskliniek, with a publication	2019	2
Coordinator RehabNet Amsterdam	2021-2023	6
Board and Committee positions Amsterdam Movement Sciences AMS		
Organizing committee AMS P5 symposium "From research to implementation"	2023	0.1
Organizing committee AMS P5 symposium "Rehabilitation: Assessment and intervention"	2021	0.1

PhD representative of the board of AMS Musculoskeletal Health	2019- 2023	2
Organizing committee Annual Meeting AMS 2022	2022	0.3
Organizing committee Annual Meeting AMS 2021	2021	0.3
Organizing committee Annual Meeting AMS 2020	2020	0.25
Jury committee best poster awards Annual Meeting AMS 2020	2020	0.25
Supervising		
One student, BSc, Gezondheidswetenschappen; sectie Doelmatigheidsonderzoek	2023	1
Four students, BSc, Gezondheidswetenschappen; sectie Doelmatigheidsonderzoek	2022	1
One student, BSc, Gezondheidswetenschappen; sectie Doelmatigheidsonderzoek	2021	1
One student, Circulation practitioner	2019	1.29

List of publications

Publications for this thesis	
Ratter J, Wiertsema S, Ettahiri I, Mulder R, Grootjes A, Kee J, et al. Barriers and facilitators associated with the upscaling of the Transmural Trauma Care Model: a qualitative study. BMC Health Serv Res. 2024;24(1):195.	2024
Barriers and facilitators of funding transmural care models in the Netherlands: a case study in trauma rehabilitation	under revision
Which fracture and treatment-related factors are associated with disease-specific HR-QOL, functional outcome, and societal costs in trauma patients?	submitted
Preliminary effectiveness of the Transmural Trauma Care Model (TTCM)	under embargo
Ratter J, Pellekooren S, Wiertsema S, van Dongen JM, Geleijn E, de Groot V, et al. Content validity and measurement properties of the Lower Extremity Functional Scale in patients with fractures of the lower extremities: a systematic review. J Patient Rep Outcomes. 2022;6(1):11.	2022
Ratter J, Wiertsema S, van Dongen JM, Geleijn E, Ostelo R, de Groot V, et al. Effectiveness and cost-effectiveness of the Transmural Trauma Care Model investigated in a multicenter trial with a controlled before-and-after design: A study protocol. Physiother Res Int. 2021.	2021
Other publications	
Interprofessionele samenwerking binnen de paramedische (leefstijl)-zorg: Waarom is dit zo moeilijk realiseerbaar en hoe kunnen we dit verbeteren? Nederlandse tijdschrift voor leefstijlgeneeskunde	2023
Rikkert ME, van Rood Y, de Roos C, Ratter J, van Hout M. The effect of Eye Movement Desensitizaton and Reprocessing on tinnitus. Trauma focussed treatment (EMDR) in patients with tinnitus related distress- a multicenter clinical trial. European Journal of Psychotraumatology 2018; 9 (1).	2018
Ratter J, Radlinger L, Lucas C. Several submaximal exercise tests are reliable, valid and acceptable in people with chronic pain, fibromyalgia or chronic fatigue: a systematic review. Journal of Physiotherapy 2014; 60(3): 144-150.	2014
Gessel van A, Ratter J. Fysieke training in de oncologische palliatieve fase. Oedemius 2013; 4: 13.	2013
Ratter J, Benz D, Oberli A, Radlinger L. Nordic Walking mit psychosomatischen Patienten- Ziele, Machbarkeit und Effekte. Praxis Physiotherapie 2009; 4:58- 62.	2009

„Wenn du ein Schiff bauen willst,
dann rufe nicht die Menschen zusammen,
um Holz zu sammeln, Aufgaben zu verteilen und
die Arbeit einzuteilen, sondern lehre sie die
Sehnsucht nach dem grossen, weitem Meer."

(Antoine de Saint-Exupéry)

Amsterdam Movement Sciences

VU VRIJE UNIVERSITEIT AMSTERDAM

Amsterdam UMC University Medical Centers

Amsterdam Movement Sciences conducts scientific research to optimize physical performance in health and disease based on a fundamental understanding of human movement in order to contribute to the fulfillment of a meaningful life.