Received: 24 April 2020 | Revised: 7 December 2020 | Accepted: 25 December 2020

DOI: 10.1002/pri.1894

RESEARCH ARTICLE

WILEY

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

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Funding information

ZonMw, Grant/Award Number: 80-85200-98-91009

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 the quality of the rehabilitation process in primary care. A recent feasibility study showed that implementation of the TTCM at a Dutch Level 1 trauma center was feasible, patient outcomes were improved, and costs were reduced. This study aims to assess the effectiveness and cost-effectiveness of the TTCM compared to the usual care in a multicenter trial.

Methods: A multicenter trial with a controlled before-and-after design will be performed at 10 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.

KEYWORDS
cost-effectiveness, fractures, multicenter, rehabilitation, trauma

Trial registration: Trial registration number: NL8163 The Netherlands National Trial Register (NTR). Registered 16-11-2019.

1 | INTRODUCTION

Trauma-related injury is one of the most common causes of death and disability worldwide (Murray et al., 2012). Globally, trauma accounts for 9.6% of mortality in patients younger than 40 years of age (Simon & King, 2019). In older age groups, it is one of the most important causes of death, behind cardiovascular disease and cancer (GBD 2017 Mortality Collaborators, 2018; Nickson, 2015). In addition, trauma negatively influences a patient's physical functioning and health-related quality of life (HR-QOL; Kendrick et al., 2011; Kruithof et al., 2018; van der Sluis, Eisma, Groothoff, & ten Duis, 1998; Stalp et al., 2002). Since trauma patients are typically relatively young, the associated loss of disability-adjusted life years (DALYs) is higher than in any other disease (Murray et al., 2012). To illustrate, each year, traumatic injuries cost an estimated 300 million years of healthy life, translating into 11% of DALYs experienced worldwide (Murray et al., 2012).

The economic burden of trauma is high, and traumatic injuries rank among the five most costly medical conditions (Velopulos et al., 2013). 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 (Corso, Finkelstein, Miller, Fiebelkorn, & Zaloshnja, 2015; Geraerds et al., 2019; Velopulos et al., 2013). 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; LTN, 2018; Polinder et al., 2016).

An improved organization of pre- and in-hospital trauma care has led to a 9%–25% decrease in mortality among severe trauma patients (Lansink & Leenen, 2007; MacKenzie et al., 2006; de Munter et al., 2017; Nathens, Jurkovich, Rivara, & Maier, 2000). 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 HR-QOL, and reduced costs (Celso et al., 2006; Haas et al., 2009; de Munter et al., 2019). 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 QOL. 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 (Wiertsema, et al., 2019a). However, the organization of postclinical trauma rehabilitation in primary care is challenging, and there are no (inter)national guidelines available (Khan, Amatya, & Hoffman, 2012). 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 (Franche & Krause, 2002; Hoffman et al., 2014; Kempen, Scaf-Klomp, Ranchor, Sanderman, & Ormel, 2001; Khan et al., 2012; Mock et al., 2000).

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 (Wiertsema et al., 2017). A recent feasibility study found implementation of the TTCM at a Dutch Level 1 trauma center to be feasible, improve patient outcomes and patient satisfaction, and reduce costs (Wiertsema, et al., 2019a; Wiertsema, et al., 2019b). 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 (Wiertsema et al., 2017). 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 compared to the 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 HR-QOL and that it is cost-effective compared to usual care from both the healthcare and the societal perspective.

2 | METHODS

2.1 | 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, and 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 the study groups and will take place during the patients' first consultation with a trauma surgeon at the outpatient clinic of the participating hospitals. In each 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 reassessing the patients' eligibility, patients can sign the informed consent form after a minimum reflection period of 1 h. 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 9 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, considering local differences, to guarantee a successful implementation (Aitken et al., 2008; Perry et al., 2019). 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 9 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.

2.2 | 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.

2.3 | 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, 2015). 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.

2.4 | 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 postclinical 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 (Wiertsema, et al., 2019a).

2.5 | Intervention group

Patients in the intervention group will receive the TTCM, as developed and described earlier (Wiertsema, et al., 2019a). 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 (Wiertsema, et al., 2019a):

(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).

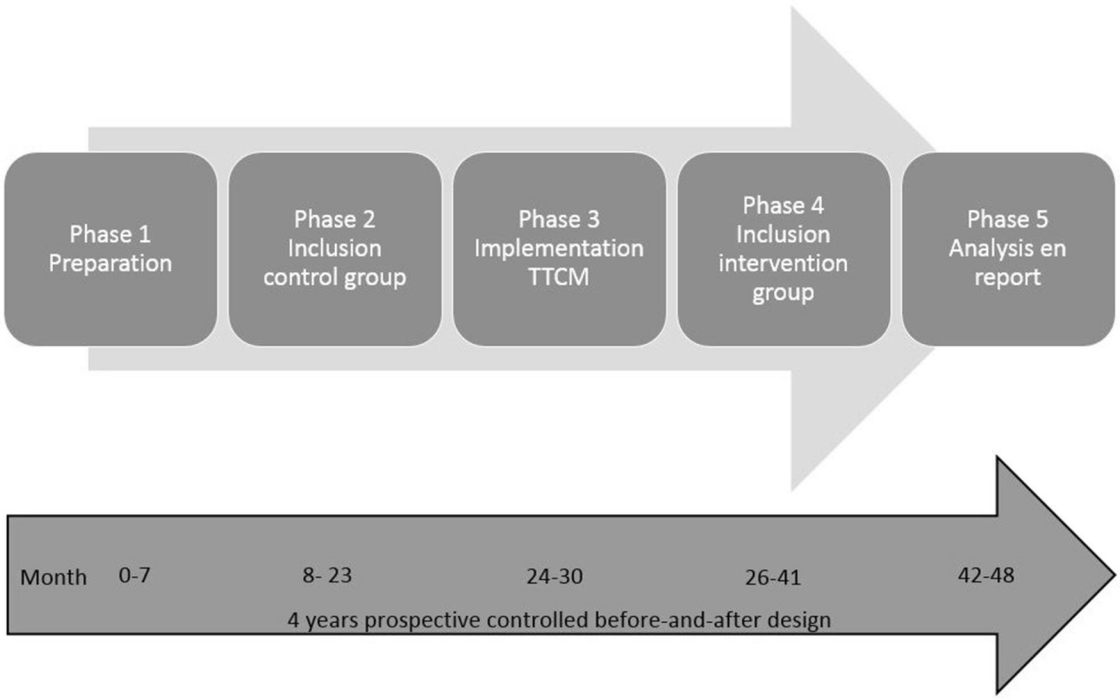

FIGURE 1 Flowchart of the transmural trauma care model study

(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, 10 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 20–40 physical therapists, per hospital, depending on the size and catchment area of the specific hospital. All network physical therapists will receive a 3-day training program whose 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.

2.6 | 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 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 (Luo, Johnson, & Coons, 2010; Walters & Brazier, 2005), we assume that 0.057 (SD = 0.15) is the minimum clinical relevant difference for HR-QOL . A between-group difference of 10% in improvement of disease-specific QOL 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 (EMA, 2016). It should be noted, however, that all available outcome measurements will be taken into account when interpreting the results.

2.7 | Outcomes

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

2.7.1 | 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 (Busse et al., 2012; Reininga et al., 2015).

2.7.2 | Trauma characteristics

Injury severity score (Baker, O'Neill, Haddon, & Long, 1974), type of trauma (traffic/fall/sport), fracture region (upper-extremity fracture/lower-extremity fracture/vertebral fracture/multitrauma), 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/nonweight-bearing), treatment (operatively/conservatively), length of hospital stay (days), and discharge destination (home/home with support/institution).

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

2.7.3 | Co-primary outcomes

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

Generic QOL 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 (Versteegh et al., 2016). For the economic evaluation, quality-adjusted life-years (QALYs) will be calculated using linear interpolation between measurement points.

Depending on the diagnosis, disease-specific QOL 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) (Gummesson, Ward, & Atroshi, 2006; Hudak, Amadio, & Bombardier, 1996)
- Lower extremity: Lower Extremity Functional Scale (Binkley, Stratford, Lott, & Riddle, 1999)
- Multiple fractures and/or more locations: Groningen Activity Restriction Scale (Jansen, Steultjens, Holtslag, Kwakkel, & Dekker, 2010; Kempen, Miedema, Ormel, & Molenaar, 1996)
- Vertebral fractures: The Roland Morris Disability Questionnaire (Roland & Morris, 1983a, 1983b)

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 to 100, with higher scores representing less functional problems.

2.8 | Secondary outcomes

Secondary outcomes include functional status (Patient-Specific Functional Scale), 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, 6, and 9 months. A detailed description of the outcomes, including references, can be found in Appendix S1.

2.9 | Societal and healthcare 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 (van Roijen, Bouwmans, Kanters, & Tan, 2015).

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 S1. An overview of all outcome measurements is provided in Table 1.

2.10 | 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 (Suman, Schaafsma, Bamarni, van Tulder, & Anema, 2017). 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 (Linnan, 2002).

These data will be registered in the control group using the following process variables: number of postclinical consultations of

TABLE 1 Assessments and follow-up moments

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

Abbreviations: CRF, case report form; DASH, disabilities of the arm, shoulder and hand (questionnaire); GARS, Groningen Activity Restriction Scale (questionnaire); LEFS, Lower Extremity Functional Scale.

the trauma surgeon, discharge location (home/rehabilitation setting), referral to primary care (yes/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/no), is the standardized referral form used (yes/no), are the functional goals described (yes/no), are e-mails exchanged between hospital physical therapist and network physical therapist (yes/no), agreed timeframes of e-mails exchanged between hospital physical therapist and network physical therapist apprehended (yes/no), and the number of sessions attended by a patient at the primary care physical therapist.

For the qualitative part of the process evaluation, focus groups and semi-structured interviews with stakeholders (e.g., patients, trauma surgeons, physiotherapists, insurance representatives) will take place to identify possible facilitators and barriers associated with the implementation of the TTCM. Focus groups and interviews will be analyzed using a framework method (Gale, Heath, Cameron, Rashid, & Redwood, 2013; Ritchie, 2003) with data mapped onto different levels of the "constellation perspective" (i.e., structure, culture, practice; Van Raak, 2010).

2.11 | 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 for the economic evaluation.

2.12 | 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, 6, 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 nonrandomized nature of the study will be accounted for using propensity score weights (Austin, 2011; McCaffrey et al., 2013). Propensity scores are defined as the "conditional probability of receiving a treatment given the patients' pretreatment 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 nonrandomized nature of the trial will be accounted for using propensity score weights.

2.13 | 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 nonrandomized 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% confidence intervals around the differences in costs will be estimated using bias corrected and accelerated bootstrapping, with 5000 replications. Incremental cost-effectiveness ratios 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 (Gomes, 2012). A summary measure of the joint uncertainty of costs and effects will be presented using cost-effectiveness acceptability curves (Fenwick, O'Brien, & Briggs, 2004). 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 $p < 0.025$.

3 | DISCUSSION

This study is a comprehensive multicenter study, although nonrandomized, 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.

3.1 | Comparison with literature

A review of multidisciplinary rehabilitation in multiple trauma patients emphasized the lack of high-quality studies on the effectiveness of rehabilitation (Khan et al., 2012). Also, there is uncertainty about the recommended questionnaires in trauma patients and a core outcome set of questionnaires for trauma patients is missing. Hoffman et al. (2014) stated that there is no general classification for measuring disability or health outcomes following trauma.

3.2 | Strengths and limitations

Following the recommendation of Hoffman et al. (2014) 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 (ICF, 2019). In this study, we will include trauma patients in 10 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 randomised controlled trials, at least 30 clusters should be included (Leyrat, Morgan, Leurent, & Kahan, 2018). 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 two hospitals with overlapping catchments areas deliver both treatment conditions at the same time. Given these considerations, we decided to use a controlled before-and-after design instead. To minimize the possibility of selection bias, we decided to collect data on a large number of patient and trauma characteristics at the baseline (CDC, 2001) and to adjust for relevant patient and trauma characteristics in the analysis using propensity score weight (Austin, 2011; McCaffrey et al., 2013).

A second limitation of this 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 (Suman et al., 2017).

3.3 | 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.

ACKNOWLEDGMENTS

This study received funding from ZonMw (80-85200-98-91009). The authors would like to thank Dr. Gogem Topcu, Programme Manager (NEuRoMS), University of Nottingham for advice in the qualitative analysis.

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

ETHICS STATEMENT

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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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

How to cite this article: Ratter J, Wiertsema S, van Dongen JM, 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;26:e1894. https://doi.org/10.1002/pri.1894