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Establishment of trauma treatment teams within a regional severe trauma treatment system in China: study protocol for a national cluster-randomised trial

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ABSTRACT

Introduction The implementation of first aid processes for patients with trauma in China faces significant challenges. These challenges include long response times of prehospital first aid services, lack of information exchange between prehospital first aid services and in-hospital emergency services, lack of a professional rescue team in the majority of hospitals, and lack of standardised training for prehospital and in-hospital emergency personnel. The purpose of the trial is to guide the establishment of an urban trauma treatment system in China, highlight the construction of a trauma treatment system tailored to the Chinese context and improve levels of medical treatment by selecting approximately 100 counties across China as pilots to establish a regional trauma treatment system.

Methods and analysis A cluster-randomised controlled trial will be performed in 98 county-level research institutes. Included research institutes will be randomised into an experimental group and a control group. Patients in both experimental and control groups will receive basic treatments. A trauma treatment team will be established in the experimental group. The primary outcome measure is in-hospital mortality rate of patients. The secondary outcome measures include mortality rate of patients within 30 days after trauma attack and within 30 days after discharge, the time between arrival in the institution and receiving consultation, and the time from admission to the start of surgery. The effects of establishment of trauma treatment teams on the treatment of severe trauma will be evaluated in all counties.

Ethics and dissemination The procedures have been approved by The Medical Ethics Committee of Peking University People's Hospital (No.2017PHB098-01) and conform to the Declaration of Helsinki. Data will be collected and analysed in accordance with participant privacy laws and regulations. Results will be disseminated through policy briefs, workshops, peer-reviewed publications and conferences.

Trial registration number NCT03363880; Pre-results.

Strengths and limitations of this study

- This study will be the first to validate the critical necessity of the establishment of trauma treatment teams within a regional severe trauma treatment system in counties in China.
- The use of a cluster-randomised trial design will provide robust evidence about the effectiveness of Chinese trauma treatment system in reducing the mortality of patients with severe trauma.
- If positive results are obtained, the regional severe trauma treatment system can be replicated among all counties in China.
- All interventions are embedded within routine primary care management and practice, thus enhancing the potential scale-up of the intervention.
- Variability of hospitals from each county could be a major cofounder to bias the results of this trial.

INTRODUCTION

With the development of urban modernisation, trauma has become a significant threat to human health.[1] In China, a country with the world's largest population, the progress of urbanisation and rapid socioeconomic development has led to a rapidly growing automotive market and increasing auto ownership.[2 3] The nation has built the world's largest high-speed rail network, constructed more than 4 million km of highways and achieved a massive roll-out of electric, zero-tail, pipe-emission, two-wheeled vehicles.[4–7] As a result of these developments, the number of China's road traffic deaths has globally ranked first for the last 20 years.[8–10] Meanwhile, as a result of a rapid increase in the number of urban construction projects, the incidence of high fall injury is also high. Trauma has become the leading cause of

death and disability in China among people younger than 40 years.[11–13]

According to an investigation on the status quo of trauma treatment in China, the first aid process for trauma is plagued by various problems.[14] These include long response time in prehospital first aid services, lack of information exchange between prehospital first aid services and in-hospital emergency services, lack of a professional rescue team in the majority of hospitals, and lack of standardised training in pre-hospital and in-hospital emergency personnel.[15] With the support of major scientific projects in China, Peking University Traffic Medical Center has performed a series of traumatic research work since 2010, including exploring a standardised trauma treatment system suitable for China's national conditions, establishing standardised trauma treatment process and forming professional trauma treatment standards.[16]

According to the above-mentioned criteria, Peking University Traffic Medical Center piloted severe trauma treatment standards in 34 cities and regions in China in 2013, including Beijing and Tianjin. An early multicentre prospective study confirmed that the average prehospital first aid response time was shortened by approximately 53%, and the average in-hospital mortality rate of severe trauma victims was reduced by about 40%[17] across the 3-year study period. Trauma treatment in this pilot advanced to an international level of quality.

To further standardise and guide the establishment of an urban trauma treatment system in China, highlight the development of a trauma treatment system customised to the Chinese context and improve the quality of medical treatment, the China Trauma Treatment Union (hereinafter referred to as the 'Union') was established and approved by the Ministry of Education of China in 2016. The Union was initially cosponsored by more than 500 trauma specialists from over 100 medical institutions in China. The purpose of this Union was to increase the awareness of trauma treatment, popularise the knowledge of trauma treatment, improve the relevant regulations on severe trauma treatment, increase the treatment level of severe trauma, reduce the occurrence of severe trauma and decrease the mortality and morbidity of severe trauma. The main objective of the Union is to establish severe trauma treatment standards and a regional trauma treatment system, and it is therefore involved in many fields, including scientific research, medical treatment and policy development.[18 19]

In 2017, the first session of the Standing Committee of China Trauma Treatment Union was held in Beijing, and the China Trauma Treatment Union Charter was formulated following session discussions. Led by the China Trauma Treatment Union, Peking University Center for Trauma Medicine and Peking University People's Hospital, the 'Safe China, Hundred County Project' was launched with the cooperation of over 100 large hospitals throughout the country. This project is also launched by the National Health and Welfare Office of the State Planning Commission and by the County Construction and Administration Office of the State Ministry of Housing and Urban-Rural Development of China.

With the aim of improving trauma treatment, 100 counties will be selected to establish a closed-loop regional trauma treatment system, with the general hospital at the county level as the core of the system. Treatment services within the counties will be accessible and will standardise trauma treatment. Based on the actual situation in each county, the development of a trauma treatment system will be promoted throughout China to benefit more people. Currently, regional medical technology and resources cannot meet the increasing demand for medical treatment. The establishment of a regional trauma treatment system connected to general hospitals can promote the improvement and quality of regional medical services and public health emergency systems.[20 21]

This study is designed to establish a closed-loop regional trauma treatment system, with the general hospital in each county at the core of the system. This system will promote and standardise the training and exchange of emergency treatment, accelerate the establishment of an early warning linkage system between prehospital and in-hospital services, improve multidisciplinary cooperation for emergency treatment and standardise all aspects of critical care treatment. In this study, we will evaluate the role of establishing a trauma treatment system in the improved treatment of patients with severe trauma. This will boost China's ability to secure and treat patients with trauma, improve outcomes of treatment for patients with trauma, establish a regional trauma treatment system customised to the Chinese context and then replicate this system throughout the country.

METHODS AND ANALYSIS

A national multicentre, parallel-group, controlled, cluster-randomised superiority trial will be performed, with 100 counties in China as the randomisation units. The included counties will be randomised into the intervention arm and the control arm. A trauma treatment team will be established in the intervention arm, and no trauma treatment team will be established in the control arm. When the number of patients with trauma in each arm reaches the calculated sample size, the study will end. After the study, to enhance the control arm's rescue ability, the control arm will be supported to establish a trauma treatment team.

During the study, each hospital should submit a survey capturing data for each patient with severe trauma (online supplementary additional file 1). Randomisation will be stratified according to the level of subjects (counties, hospitals and patients with trauma) (figures 1 and 2). The in-hospital mortality rate will be compared between the two arms to investigate the effects of the establishment of the trauma treatment team on the treatment of patients with severe trauma. Randomisation stratified by county

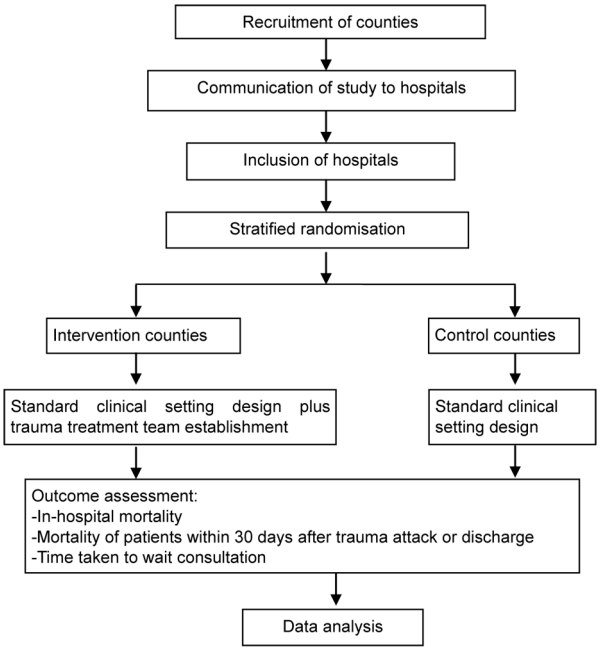

Figure 1 Trial flow chart.

will be performed in this study, as randomisation stratified by physicians or patients/caregivers is neither realistic nor practical. Physicians or patients/caregivers will not be blinded to interventions, but the trial statisticians will be blinded to grouping and interventions.

Eligibility

Eligibility criteria for counties

Inclusion criteria

- National counties and county-level administrative regions.
- Local government and health management department that have the desire and requirements to establish a standardised trauma emergency treatment system.
- Population served in the county is more than 500 000 people.
- Has a prehospital emergency treatment system.
- Trauma first aid needs: No less than 20 patients with severe trauma (Injury Severity Score (ISS) ≥16) throughout the county per month.
- Distribution of health resources:
  - Have at least one third-grade class A general hospital able to treat severe trauma.
  - Have at least four second-grade class A hospitals able to handle severe trauma.
  - Each included hospital can transfer patients to local prehospital emergency treatment centre.
  - The participating hospitals have the desire and requirements to participate in the construction of a local, regional, first aid service.

Exclusion criteria

- The region itself cannot comply with the basic requirement of the project implementation.

Withdrawal criteria

- The number of traumatic cases cannot meet the study needs during the process of project implementation.
- The mean number of patients with trauma per month across a 6-month observation period cannot meet the needs of project implementation.

Eligibility criteria for hospitals

Inclusion criteria

- Regional trauma treatment centre hospital
  - Third-grade class A hospitals.
  - With the most advanced regional treatment resources during the entire period from trauma recovery to rehabilitation.
  - Trauma doctors are on call 24 hours a day and can manage a large number of patients with severe trauma.
  - Can accommodate public health education and promotion, and provide continuous education for trauma workers.
- Regional trauma treatment pilot hospitals
  - Second-grade or third-grade hospitals.
  - With basic trauma treatment resources.
  - Trauma doctors are on call 24 hours a day and can participate in the early treatment of patients with trauma.

Exclusion criteria

- Hospitals cannot establish a trauma treatment team for any reason.

Eligibility criteria for patients with trauma

Inclusion criteria

- Patients of age >18 years.
- Patients with acute trauma occurring within 48 hours.
- Patients are transferred to trauma treatment centre hospital or trauma treatment non-centre hospital.
- Patients themselves go to or are transferred by their family members to the trauma treatment centre hospital or trauma treatment non-centre hospital.

Exclusion criteria

- Patients with trauma who are from regions not included in this study.

Randomisation and blinding

Prior to formal initiation of this study, all potentially included counties will be investigated to gather information related to basic county data, basic hospital data, first aid institutions and patients with severe trauma. The counties will be stratified into several strata according to their status quo. Randomisation will be stratified according to the following three levels: counties, hospitals and patients with trauma. Stratified randomisation will be carried out in a 1:1 ratio according to the sequence generated with SAS V.9.4 (SAS Institute). The counties at each strata will be randomly allocated to either experimental or control arms. The experimental and control arms corresponding to each

	STUDY PERIOD		
	Enrollment & Allocation	On-study	Termination
STUDY VISIT	1	2	3
TIMEPOINT	*Before admission*	*After admission*	30 days after discharge
ENROLLMENT:			
Eligibility screen		X	
Allocation		X	
INTERVENTIONS*:			
Experimental group	X	X	
Control group	X	X	
ASSESSMENTS:			
Mortality**		X	X
Time taken to wait for consultation		X	X
Response time***	X		
Referral time***	X		
Time length between admission and starting the first surgery		X	
Time length from trauma to first image examination		X	
Number of surgeries		X	
Hospital days in ICU		X	
Ventilator use time		X	
Total hospital days		X	
The expenses of treatment#	X	X	
Whole-body CT/ focused assessment with sonography		X	
Pre-hospital incubation	X		
Misdiagnosis		X	

Figure 2 Standard Protocol Items: Recommendations for Interventional Trials. *Severe trauma treatment systems involve treatment before admission, in the emergency centre and hospital. **Mortality includes in-hospital mortality, mortality within 30 days after trauma attack and mortality within 30 days after discharge. ***Response time and referral time are recorded before admission. #The expenses associated with treatment include the expenses of prehospital care, emergency care and hospitalisation treatment. ICU, intensive care unit.

strata level will be integrated together to form total experimental and control arms, respectively. Due to the nature of emergency trauma treatment, the study design will be effectively 'open label'. However, the outcome assessor will be blinded to study allocation.

Recruitment

The specific recruitment process by county is as follows:

- The recruitment notice will be delivered to the responsible persons of each county. The notice will cover the theme, purpose, contents and requirements of the recruitment. In addition, the background for establishing China's trauma treatment standard system and preliminary work as well as the working committee of 'Safe China, Hundred County Project' (ie, our study team) will be introduced.
- Each county that volunteers to participate in the trial will be chosen to participate in this study only after receiving contact from the working committee.
- The study protocol will be delivered to each county volunteer. It contains the study background, objective, design, interventions, follow-up plan, county survey scale, hospital survey scale and patient with trauma evaluation scale. If there is no special objection, the county will be considered as automatically included in the sample population.
- All second-grade class A and third-grade class A hospitals of the included county will be screened against the following inclusion and exclusion criteria. Eligible hospitals will be included in the sampling. One third-grade class A hospital from one county will be selected as the regional trauma treatment centre hospital. Based on the size of the population served, a number of second-grade class A or third-grade class A hospitals will be randomly selected as the regional trauma treatment hospitals and will be included in this study.

Intervention

In the experimental and control groups, the standard clinical setting design will be accomplished:

1. One third-grade class A general hospital in the county will be taken as the trauma treatment centre hospital,

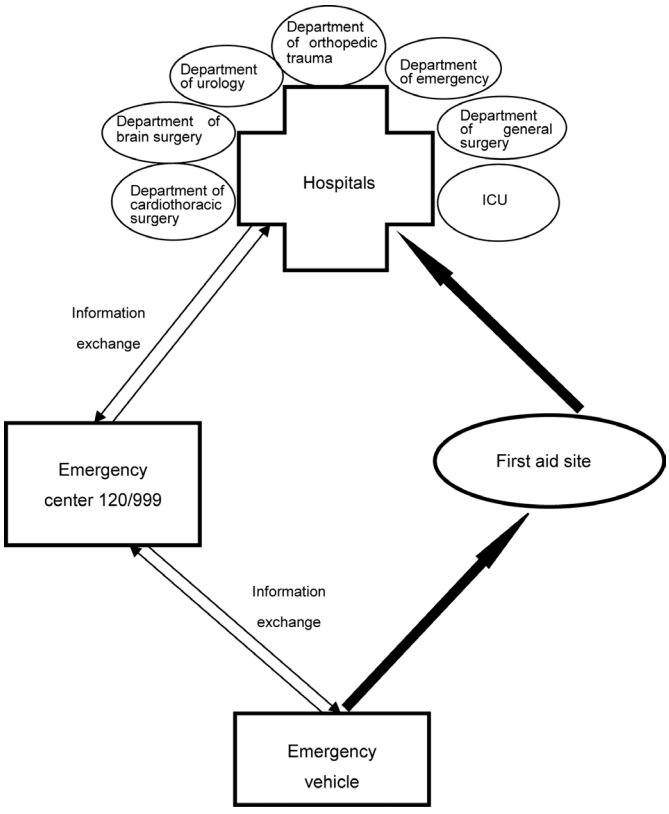

Figure 3 Schematic diagram of the information exchange system for severe trauma treatment. ICU, intensive care unit.

and four second-grade class A hospitals will be taken as trauma treatment non-centre hospitals, which form a closed-loop regional trauma treatment system.

2. Establishment of a regional information exchange (figure 3) and early warning linkage system (figure 4) for severe trauma treatment.
3. Standardised training of treatment personnel will be completed.

The precise content of the basic experimental setting is shown in figure 3.

In addition to completing the standard clinical settings, the hospitals included in the experimental arm will also establish a severe trauma treatment team, which will play a leading role during the entire treatment process. The physicians from departments of emergency, orthopaedic trauma, urology, cardiothoracic surgery, neurosurgery, general surgery, anaesthesiology and intensive care unit (ICU) will compose the severe trauma treatment team.[22] A postadmission system will be implemented for the severe trauma treatment team. All personnel with medium-grade or higher professional ranks from the above-mentioned eight departments will receive professional training regarding normalised treatment of severe trauma, and will master the principles of diagnosis and treatment of severe trauma and related medical first aid basic theory, operational skills and treatment processes. Prehospital first aid personnel will deliver the information of patient's injury to the hospital where the patient will be admitted via the information linkage system; as a result, the hospital will have fully prepared the appropriate treatment according to the patient's condition. When the hospital receives the early warning signal, the next first aid measures will be determined according to the patient's injury information. After full preparation in terms of related personnel, equipment and materials, the members of the severe trauma treatment team will arrive at the emergency room before the trauma victims arrive at the hospital. The trauma treatment team will follow the principle of 'assessment–decision–treatment–reassessment–redecision' during the treatment process.[22] As the severe trauma treatment team can perform first aid services, physical examination and diagnosis simultaneously, a prompt and effective treatment can be achieved within the shortest possible time, which can impede the progression of haemorrhagic shock, craniocerebral trauma, hernia and other dangerous outcomes.[10]

Explanation of standard clinical settings

A closed-loop regional trauma treatment system will be established with a two-level treatment mode: a large-scale third-grade class A general hospital will be the core as the trauma treatment centre hospital and regional second-grade class A hospitals as the trauma treatment non-centre hospitals.

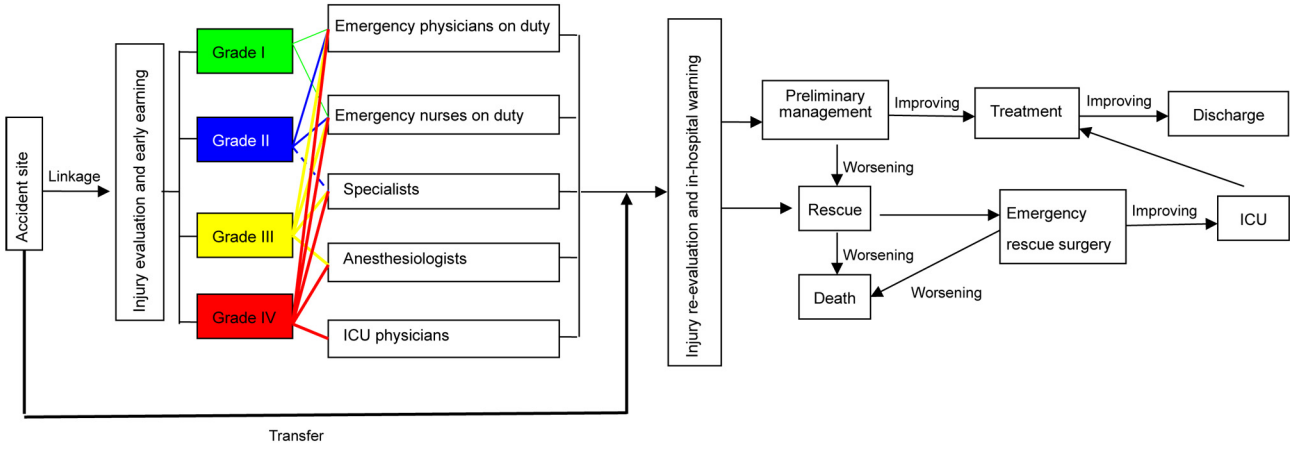

Figure 4 Prehospital and in-hospital early warning linkage system implementation flowchart. ICU, intensive care unit.

The large-scale third-grade class A general hospital with a strong rescue ability in each county will be used as the trauma treatment centre, and 4–6 second-grade hospitals surrounding the centre hospital in each county will be used as trauma treatment non-centre hospitals. The number and locations of the trauma treatment non-centre hospitals will be determined according to the condition that first aid response time can be less than 15 min and the prehospital treatment time can be less than 40 min.[18] The main responsibility of the trauma treatment centre hospital is to perform first-stage or final emergency treatment and deterministic treatment for patients with trauma with red warning signs (the early warning linkage system colour grading is shown in online supplementary additional file 2), and to perform final emergency treatment or definitive treatment for patients with trauma with yellow and blue warning signs. The general hospitals need a professional trauma treatment team and specialists from the departments of neurosurgery, orthopaedics, general surgery and radiologists should be on duty 24 hours a day. An expert committee composed of multidisciplinary experts should be established in each trauma treatment hospital or centre. The expert committee members are responsible for discussing cases of clinical death, complications and trauma treatment-related events. The committee will identify and solve new problems, offer information feedback to each related department, provide comments and suggestions regarding the cause of trauma and problems that arise in the process of treatment, regularly assess the treatment process and outcomes of severe trauma, and propose suggestions for the government, medical management and hospital administrative departments.

Establishment of regional information exchange and early warning linkage system for severe trauma treatment.

This study will establish an integrated information exchange mechanism between the accident site, emergency centre and severe trauma treatment hospital. This will include information exchange between accident site treatment providers and the emergency centre; as well as information exchange and information resource sharing between the first aid site, emergency centre and treatment hospital.

Carrying out standardised training in treatment personnel.

This study will establish a severe trauma treatment committee, and perform normalised training for trauma rescue personnel (prehospital first aid service personnel, in-hospital rescue personnel and specialised treatment personnel). Thus, a highly specialised team of severe trauma first aid experts will be established.

Outcomes

Primary outcome

- In-hospital mortality of patients with severe trauma in each county: the percentage of patients who die during hospitalisation for severe trauma.

Secondary outcomes

- Mortality of patients with severe trauma within 30 days after trauma attack: the percentage of patients who die within 30 days after trauma attack.
- Mortality of patients with severe trauma within 30 days after discharge: the percentage of admitted patients with severe trauma who die within 30 days after discharge.
- Response time before admission to the centre.
- Referral time before admission to hospital.
- Time taken while awaiting consultation: time interval from admission to consultation (ie, physicians from each department examining the patients).

Other outcomes

- The length of time from admission to the start of the first surgery for patients with severe trauma in the included county.
- The length of time from trauma to first image examination.
- The number of surgeries of patients with severe trauma in the included county.
- Hospital days in the ICU for patients with severe trauma in the included county.
- Ventilator use time for patients with severe trauma in all hospitals in the included county.
- Total hospital days for patients with severe trauma in the included county.
- The expenses of prehospital care, emergency care and hospitalisation treatment.
- Proportion of patients undergoing whole-body CT/focused assessment with sonography for trauma.
- Prehospital intubation ratio.
- Proportion of patients misdiagnosed within 24 hours of admission.
- Relationship between blood transfusion and mortality.

Sample size calculation

This study is a cluster-randomised controlled trial. Its sample size was calculated according to the following formula:

$$N_{cluster} = [1 + (m - 1) \times ICC] \times N_{simple}$$

In which m is the number of patients in the cluster, and ICC is the intraclass correlation coefficient of patients in the same cluster.[19 20] In the pilot experiment study, we selected 15 counties and collected and analysed the data regarding previous trauma rescue. Thus, in-hospital mortality rate of patients with severe trauma was calculated as 33.82%.[17] After trauma rescue team establishment, that is, the establishment of a severe trauma standardised rescue system, the in-hospital mortality rate of patients with severe trauma was reduced to 20.49%.[17] If α=0.025 and β=0.2, sample size n=442 patients per group was calculated using PASS V.11.0 software (NCSS, LLC, Utah, USA) for this randomised controlled trial. Based on an estimated ICC of 0.1, assuming that 100 cases of severe trauma were treated in each county, n=4818 patients per group are needed, which is 49 counties per group.

Data collection and management

Baseline severe trauma in-hospital mortality rate, hospital ranking, statistics of hospital medical staff, distribution of health resources and emergency checklist items will be collected. An electronic data capture system (Ziyun Trauma Emergency System, Wuxi Ziyun Medical Science and Technology Development, China) will be established. Data will be entered online into the database by each hospital, including prehospital information and emergency department information such as patients' demographic information, vital signs, initial diagnosis, ISS score and so on. When patients are admitted to the hospital, the electronic medical history system will be used. Using this system, we will be able to see all of the procedures in the hospital, including diagnosis, surgery record, medicine record, ICU record and so on. The trial database is managed by the data management team located at Peking University People's Hospital, China. The data management team has access to the final trial dataset.

At the end of the study, data integrity will be verified, the database will then be locked and all data sets will be password protected. Data analysis will be performed.

Data analysis

No interim analyses are planned, and all outcomes will be analysed following data collection. Continuous variables will be statistically described using mean and SD or median and IQR. Our primary analyses to evaluate all hypotheses will follow an intention-to-treat (ITT) approach. Data analysis will be done as per the statistical analysis plan. The X^2 test or Fisher's exact probability method will be used to compare in-hospital mortality rate of patients with severe trauma, mortality rate within 30 days after trauma and mortality rate within 30 days after discharge. The t-test or Mann-Whitney U test will be performed to compare the time taken to wait for consultation, the time length from admission to starting the first surgery, the number of surgeries, hospital days in the ICU, ventilator use time and total hospital days for patients with severe trauma.

For ITT analyses, a mixed-effect model will be used to explore whether establishing a trauma treatment team improved the prognosis of patients with trauma. The prespecified covariates to be used in the adjusted models are age, sex, systolic blood pressure, Glasgow Coma Scale and systemic inflammatory response syndrome score. SAS V.9.4 (SAS Institute) will be used for data analysis. The results will be presented as per the statistical analysis plan.

We will also complete prespecified subgroup analyses by (1) sex; (2) systemic inflammatory response syndrome (yes versus no); (3) systolic blood pressure; (4) region, (5) age and (6) response time. We will fit mixed-effect models for the primary outcome measure with the inclusion of an interaction term to examine whether establishing trauma treatment team has an impact on the prognosis of patients with trauma.

PATIENT AND PUBLIC INVOLVEMENT

Involvement of patients and the public in the development of the research question and outcome measures are not considered in this study. The patients included are all severely injured patients in the emergency department who will not participate in the recruitment, research implementation and decision-making processes and not assess the burden of the intervention. The findings will not be disseminated to patients.

ETHICS AND DISSEMINATION

Ethics

Due to the nature of the intervention, patient informed consent is not available at the trauma/rescue site. During the subsequent follow-ups and data collection, patient informed consent will be obtained. If the patient is illiterate, verbal informed consent will be obtained from the patient's legal representative. Prior to obtaining informed consent, the detail of the informed consent will be fully explained to the patient or legal representative. The conduction of the study will be overseen by an independent trial steering group, which is informed by an independent data and safety monitoring board (DSMB).

Confidentiality

Data collection and use will not be disclosed to any non-authorised persons, and will be performed in accordance with the laws and regulations regarding protection of the participants' privacy. The process of data collection will be fair and lawful. The purpose of data collection will be specific, identified and legitimate, and the collected data will not be used for other unrelated objectives. The data collected will be adequate, related and not redundant relative to the study objective. The data collected will be accurate and updated when necessary. During the study period, participants' personal information will not be obtained or disclosed to non-authorised persons, and will not be illegally destroyed, lost or altered unexpectedly. During the entire study period, the sponsors who have the right to read the participants' personal information will keep the data confidential.

Protocol modification

The study protocol modification will be signed, dated and published by Peking University People's Hospital. The study protocol will not be put into clinical practice until the medical ethics committee approval is received, unless this is necessary to avoid risk to participants. The study protocol should not be deviated from during clinical practice. When deviation exists, corresponding management will be performed. The causes and deviated contents will be recorded in the electronic case report form and original medical case notes. The study protocol deviation table and electronic case report form will be preserved in the research centre and sponsor institute.

Dissemination

Results will be disseminated through policy briefs, workshops, peer-reviewed publications, and national and

international conferences. The results of the trial will be reported according to the Consolidated Standards of Reporting Trials guidelines[19] and the Standard Protocol Items: Recommendations for Interventional Trials guidance for protocol reporting[20] (online supplementary additional file 3).

Quality assurance

1. Each link of the study will be performed in strict accordance with the protocol design. A quality control committee will be established for data collection and analysis. A quality control team and DSMB will be established prior to study commencement.
2. Before beginning the study, researchers, county chiefs, hospital chiefs and treatment staff will receive standardised training.
3. A quality control team will be established to monitor the progression of the research and be responsible for quality in study design and implementation, data collection and analysis.
4. An independent Data and Safety Monitoring Boards will be established, including two statistical professionals, two clinicians and one ethics expert. The DSMB fulfils the task of conducting security audits through real-time electronic databases and maximises the protection of potential subjects to ensure data validity and scientific integrity.

DISCUSSION

A standard system for trauma treatment has not yet been established in China, and the current situation in China differs from that in developed countries such as America, Japan and Germany. China does not have independent trauma centres, but has many three-level (highest level) general hospitals in every province and county. Hence, our aim is to build a Chinese trauma treatment system, and the establishment of a replicable trauma treatment team is a vital part of this objective.

The aim of this study is to improve critical challenges faced by Chinese healthcare services in the treatment of patients with severe trauma. As mentioned in the Introduction section, these challenges include long response times of prehospital first aid services, lack of information interchange between prehospital first aid services and in-hospital emergency services, lack of a professional rescue team in the majority of hospitals, and lack of standardised training in prehospital and in-hospital emergency personnel. This study theory is based on the 'One-Two-Three Project' which was published in *The Lancet* in 2017.[21] There are no similar studies ongoing or completed in China.

If the trauma treatment team established by this study is found to be effective in reducing in-hospital mortality of patients with trauma, this regional severe trauma treatment system can be scaled to all counties in China. This will be a significant step forward in Chinese trauma treatment. Additional research and modifications will be made to the intervention and the establishment of a regional severe trauma treatment system if the intervention is found to be ineffective and/or not feasible in real-county situations. This study will also validate a regional severe trauma treatment system that can be adapted in other contexts, including in other low-income and middle-income countries.

Trial status

We began recruitment on 1 March 2018 and expect to have completed recruitment by 30 September 2018 and completed data collection by 30 April 2019.

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Contributors B-GJ and T-BW conceived the study and participated in its design and coordination. YW drafted the manuscript. H-XL participated in the design of the study and performed the statistical analysis. Y-JZ and J-JZ participated in the study design and coordination and helped draft the manuscript. Y-HW and WH participated in the design of the study and wrote the protocol for the analysis. All authors read, revised and approved the final manuscript.

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Disclaimer Funders will have no involvement in the study design; data collection, management, analysis and interpretation; paper writing or decision to submit the paper for publication.

Competing interests None declared.

Patient consent Obtained.

Ethics approval The procedures have been approved by The Medical Ethics Committee of Peking University People's Hospital (No.2017PHB098-01) (online supplementary additional file 4) and conform to the Declaration of Helsinki. The study protocol will not be put into clinical practice until the Medical Ethics Committee approval is received, unless this is necessary to avoid risk to participants.

Provenance and peer review Not commissioned; externally peer reviewed.

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