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Feasibility of a Cluster Randomised Trial on the Effect of Trauma Life Support Training: A Pilot Study in India

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Complete List of Authors:	Gerdin Wärnberg, Martin ; Karolinska Institutet, Department of Global Public Health; Karolinska University Hospital, Perioperative Medicine and Intensive Care Basak, Debojit; Seth Sukhlal Karnani Memorial Hospital; Institute of Postgraduate Medical Education and Research Berg, Johanna; Karolinska Institutet, Department of Global Public Health; Skånes universitetssjukhus Malmö, Emergency Medicine, Department of Internal and Emergency Medicine Chatterjee, Shamita; Seth Sukhlal Karnani Memorial Hospital, Department of Surgery; Institute of Postgraduate Medical Education and Research Felländer-Tsai, Li; Karolinska Institutet, Department of Clinical Science Intervention and Technology (CLINTEC); Karolinska University Hospital, Department of Reconstructive Orthopedics Ghag, Geeta; HBT Medical College and Dr RN Cooper Municipal General Hospital, Department of Surgery Juillard, Catherine; University of California Los Angeles, Division of General Surgery, Department of Surgery, David Geffen School of Medicine Khajanchi, Monty; Seth GS Medical College and KEM Hospital, Department of Surgery Khan, Tamal; All India Institute of Medical Sciences New Delhi Nandu, Vipul; HBT Medical College and Dr RN Cooper Municipal General Hospital, Department of Surgery Roy, Nobhojit; The George Institute for Global Health India, Program for Global Surgery and Trauma; Karolinska Institutet, Department of Global Public Health Singh, Rajdeep; Maulana Azad Medical College, Surgery Soni, Kapil; All India Institute of Medical Sciences, Critical Care Strömmer, Lovisa; Karolinska Institutet, Department of Clinical Science, Intervention and Technology (CLINTEC); Karolinska Institutet, Department of Global Public Health
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Dear Editor and Reviewers,

Thank you for your second review of our manuscript and for allowing us to submit a minor revision. We have addressed all of the comments and provided a detailed response below. In addition, we have revised the introduction to account for recent publications on trauma life support training.

On behalf of all the authors,

Martin Gerdin Wärnberg, MD, PhD Department of Global Public Health Karolinska Institutet Stockholm, Sweden

Response to Reviewer 1, Dr. Feroze Sidhwa, San Joaquin General Hospital:

Q1 Improvements in patient outcomes could take much longer than a few months to manifest, and may also be dependent on a certain level of training being achieved in the unit. These limitations should be addressed.

> R1 We agree, especially some outcomes may take substantially longer than the follow up of one month. We have added a note to the discussion section to address this.

Q2 "The principal investigator at each hospital selected the units for training." How? Was this based on who conducts the trauma resuscitation?

> R2 Only units involved in the trauma resuscitation were eligible for training. The principal investigator selected the units based on their own mandate to involve the units in the study.

Q3 How do you know the accuracy of ICD-10 coding at these hospitals?

> R3 The project officers conducting the ICD-10 coding have been trained using the WHO module on ICD-10 coding and their coding reviewed by the research team in previous projects.

Q4 Faculty not being included in the study because they are not typically directly involved in the initial management of trauma patients will be a major factor limiting generalizability of the findings. This cannot be helped and not every trial can be generalizable to the entire universe, but this should be noted in future conclusions and limitations.

> R4 Good point. We have a highlighted this in the appropriate section in the discussion.

Q5 "We initially planned to use simple random sampling to select the units to be trained, but for pragmatic reasons this decision was left to the site principal investigator." Does this mean that the site principal investigator decided what kind of sampling to use, or that they decided on what units to be trained instead of using any kind of randomization?

> R5 The principal investigator at each site decided what units to be trained instead of randomising these units. We have clarified this in the manuscript.

Q6 An “error in the data uploading process” that led to 1/10th of the data being collected in two out of seven clusters is very alarming. Isn’t it possible this data uploading process error wasn’t a source of random error? For example maybe it drastically reduced the data available from the two most incompetent clusters, regardless of training status? Unless this issue is addressed it would be a major source of potential error in a larger trial. This was mentioned briefly in the conclusion but I would encourage the authors to make clear that they understand that this is an issue of grave concern for the accuracy of the study.

R6 We agree that this is a major concern that cannot be allowed to happen in a full-scale trial. We have strengthened the language in the discussions section accordingly.

Q7 Overall this is a very useful pilot study and I hope the larger study will shed light on some important questions in the trauma world.

R7 Thank you very much and we agree.

Feasibility of a Cluster Randomised Trial on the Effect of Trauma Life Support Training: A Pilot Study in India

Trauma life support training Effectiveness Research Network (TERN) collaborators

Trial registration

This pilot study was registered with ClinicalTrials.gov (reg. no NCT05417243).

Corresponding author

Martin Gerdin Wärnberg, MD, PhD (MGW)

Department of Global Public Health
Karolinska Institutet
171 77 Stockholm
Sweden

martin.gerdin@ki.se
+46 708 53 95 98 (mobile)

Authors (in alphabetical order by last name)

Debojit Basak, MS (DB)

Project Research Scientist, Institute of Post Graduate Medical Education and Research, Kolkata, India.

Johanna Berg, MD (JB)

Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden.

Emergency Medicine, Department of Internal and Emergency Medicine, Skåne University Hospital, Malmö, Sweden.

Shamita Chatterjee, MBBS, MS (SC)

Department of Surgery, Institute of Post Graduate Medical Education and Research, Kolkata, India.

Li Felländer-Tsai, MD, PhD (LFT)

Division of Orthopaedics and Biotechnology, Department of Clinical Science Intervention and Technology (CLINTEC), Karolinska Institutet, Stockholm, Sweden.

Department of Reconstructive Orthopedics, Karolinska University Hospital, Stockholm, Sweden.

Geeta Ghag, MBBS, MS (GG)

Department of Surgery, HBT Medical College And Dr. R N Cooper Municipal General Hospital, Mumbai, India.

Catherine Juillard, MD, MPH (CJ)

Division of General Surgery, Department of Surgery, David Geffen School of Medicine at UCLA, Los Angeles, California, United States of America.

Monty Khajanchi, MBBS, MS (MK)

Seth G. S. Medical College and K.E.M. Hospital, Mumbai, India.

Tamal Khan, MSc (TK)

Senior Research fellow, All India Institute of Medical Sciences, New Delhi, India.

Vipul Nandu, MBBS, MS (VN)

Department of Surgery, HBT Medical College And Dr. R N Cooper Municipal General Hospital, Mumbai, India.

Nobhojit Roy, MBBS, MS, PhD (NR)

Program for Global Surgery and Trauma, The George Institute of Global Health, New Delhi, India.

Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden.

Rajdeep Singh, MBBS, MS (RS)

Department of Surgery, Maulana Azad Medical College, New Delhi, India.

Kapil Dev Soni, MBBS, MD (KDS)

Critical and Intensive Care, JPN Apex Trauma Center, All India Institute of Medical Sciences, New Delhi, India.

Lovisa Strömmer, MD, PhD (LS)

Division of Surgery and Oncology, Department of Clinical Science, Intervention and Technology (CLINTEC), and Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden.

Nonauthor contributors

Anirban Chatterjee (AC)

Department of Orthopaedic Sciences, Medica Superspecialty Hospital, Kolkata, India.

Marie Hasselberg (MH)

Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden.

Debabrata Kundu (DK)

Department of Surgery, Medical College Kolkata, Kolkata, India.

Anurag Mishra (AM)

Department of Surgery, Maulana Azad Medical College, New Delhi, India.

Arun Prasad (AP)

Department of Surgery, Indraprastha Apollo Hospitals, New Delhi

Harris Solomon (HS)

Department of Cultural Anthropology and the Duke Global Health Institute, Duke University, Durham, USA.

Megha Tandon (MT)

Department of Surgery, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, India.

Keywords

Trauma management, Accident and emergency medicine, Education and training.

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The funding sources had no role in the design of this study nor during its execution, analyses, interpretation of the data, or decision to submit the results.

Abstract

Objective The aim was to assess the feasibility of conducting a cluster randomised controlled trial comparing the effects of Advanced Trauma Life Support (ATLS) and Primary Trauma Care (PTC) with standard care on patient outcomes.

Design This was a pilot pragmatic three-armed parallel, cluster randomised, controlled trial conducted between April 2022 and February 2023. Patient were followed up for 30 days.

Setting The study setting was tertiary care hospitals across metropolitan areas in India.

Participants Adult trauma patients and residents managing these patients were included.

Interventions ATLS or PTC training was provided for residents in the intervention arms.

Main Outcomes and Measures The outcomes were the consent rate, lessons to follow up rate, missing data rates, differences in the distribution between observed data and data extracted from medical records, and the resident pass rate.

Results Two hospitals were randomised to the ATLS arm, two to the PTC arm, and three to the standard care arm. We included 376 patients and 22 residents. The percentage of patients who consented to follow up was 77% and the percentage of residents who consented to receive training was 100%. The loss to follow up rate was 14%. The pass rate was 100%. Overall, the amount of missing data for key variables was low. The data collected through observations were similar to data extracted from medical records, but there were more missing extracted data.

Conclusions Conducting a full-scale cluster randomised controlled trial comparing the effects of ATLS, PTC, and standard care on patient outcomes appears feasible, especially if such a trial would use data and outcomes available in medical records.

Trial Registration ClinicalTrials.gov (reg. no NCT05417243)

Strengths and limitations of this study

- Prospective data collection with direct observations made by dedicated research officers.
- A lack of a priori defined success criteria and thresholds for feasibility outcomes.
- The use of sealed envelopes potentially compromised allocation concealment.
- Heterogeneity of the participating centers may affect the study estimates and introduce bias.

Introduction

Trauma, defined as a clinical entity composed of physical injury and the associated response of the body, causes 4.3 million deaths every year[1]. Several trauma life support training programmes have been developed to improve the early management of patients in hospitals by providing a structured framework for assessment and treatment[2–7].

Advanced Trauma Life Support (ATLS) and Primary Trauma Care (PTC) are the most established trauma life support training programmes[8,9]. Both programmes improve provider knowledge and skills[2,4], and while most observational studies associate them with reduced mortality[10–20], some report associations with increased mortality[21,22].

There are no controlled trials of the effect of ATLS or PTC on patient outcomes, and no trials evaluating any trauma life support training programme in a general trauma population[2–7]. However, a recent cluster randomised trial found that the rural trauma team development course reduced mortality in patients with motorcycle injuries[23].

Systematic reviews call for controlled trials of ATLS and PTC[2–4], but large scale cluster randomised trials can be complex. We therefore conducted a pilot study with the aim to assess the feasibility of a cluster randomised controlled trial comparing the effects of ATLS and PTC with standard care on outcomes in adult trauma patients.

Methods

Protocol Deviations

Protocol deviations are mentioned where relevant in this manuscript, but a list of all deviations is also included as Supplementary Material S1 for completeness.

Trial Design

We piloted a three-armed cluster randomised controlled trial[24]. The trial included a standard care arm and two intervention arms, ATLS and PTC training. We planned to collect data for four months in all three arms, first during a one month observation phase, followed by a three-month intervention phase (or continued observation in the standard care arm). The actual data collection period varied across clusters depending on the timing of the training, to ensure a minimum of three months of data collection in the intervention clusters post-training. We included a one month observation phase to evaluate the feasibility of comparing patient outcomes both as absolute differences between the intervention phases, and as differences in changes from baseline. In the published protocol, we also aimed to estimate probable effect sizes and other parameters needed for sample size calculations for a full-scale trial[24]. However, we revised this aim in light of current guidance on the conduct and reporting of pilot trials[25].

Study Setting

We conducted this pilot study in seven tertiary hospitals across metropolitan areas in India, where neither ATLS, PTC, nor any other established trauma life support training program is routinely taught. Details about each cluster are provided in Supplementary Table S1. We initially intented to include six hospitals as clusters, but added a seventh hospital when management expressed interest, as we had the budget to accommodate the request. These seven hospitals represented a convenience sample that fulfilled the inclusion criteria, and had existing connections to the research team.

Eligibility Criteria for Cluster and Participants

Clusters

We defined a cluster as a tertiary care hospital in metropolitan areas in India that admit more than 400 adult patients with trauma annually, and has operation theatres, X-ray, CT, and ultrasound facilities, and blood bank available around the clock. In each cluster, we trained one or more units of physicians providing trauma care in the emergency department. To be eligible, units could have no more than 25% of their physicians with previous training in either ATLS, PTC, or similar training programmes. Residents who had received training in the last five years were considered trained. The 25% threshold was determined through consensus within the research team, to balance feasibility and the risk of contamination. The principal investigator at each hospital selected the units for training. We randomised at the hospital level to avoid contamination between the intervention and standard care arms.

Residents

We trained resident doctors undertaking speciality training in surgery or emergency medicine who managed trauma patients in the emergency department, and were expected to remain in the participating hospitals for at least one year after training. Consent was obtained from the residents in each intervention arm before ATLS or PTC training. In the published protocol, we stated that only surgical residents would be trained. However, in some of the participating hospitals, emergency medicine residents led the initial resuscitation and management of trauma patients, and we therefore included them in the training.

Patients

We included persons aged 15 years or older who presented to the emergency department at participating hospitals with a history of trauma when a designated unit was on duty. A history of trauma was defined as having any of the external causes of morbidity and mortality listed in block V01-Y36, chapter 20 of the International Classification of Disease version 10 (ICD-10) codebook as the reason for presentation.

Standard Care

Standard care varies across hospitals in India, but most surgical and emergency medicine departments in India organise their physicians into units. These units include both faculty members and residents, who are assigned a specific day of the week to work in the emergency department. Trauma patients are initially assessed by residents in these units, who also resuscitate patients, perform interventions and refer patients for imaging or other investigations. Compared with settings that adopt a trauma team approach, nurses and other healthcare professionals are involved to a limited extent during initial management. We did not collect data on how standard care varied between the participating hospitals.

Intervention

In each intervention arm, residents from one or two units were trained in either ATLS or PTC at the beginning of the three month intervention phase. For the purpose of this pilot study, our target was to train at least 75% of residents in each unit. Faculty members were not trained, because they are typically not directly involved in the initial management of trauma patients. ATLS training was conducted at an ATLS certified training centre in Mumbai and PTC training was conducted in New Delhi. Both trainings were conducted according to their respective standard curriculum[8,9], and we did not modify or adapt the delivery or content of these programmes during this pilot study.

The provider courses of both programmes take place across two days, and focus on the assessment, resuscitation and stabilisation of trauma patients, with adaptions for different patient populations. Teaching is based on case discussions and skill stations. There are several important differences between the two programmes. The ATLS course focuses more on inter-hospital patient transfers and includes a greater emphasis on the trauma team[8]. In contrast, the PTC course focuses on trauma care in the low resource setting[9]. The ATLS programme is run by the American College of Surgeons and requires a participant fee, whereas the PTC programme is run by the UK-based PTC Foundation and is provided free of charge.

Feasibility Outcomes

Our feasibility outcomes were as follows:

- Consent rates of patients and residents. This was defined as the percentage of patients or residents who consented to be included, out of the total number of eligible patients or residents.
- Loss to follow-up rate. This applied only to patients and was defined as the percentage of patients among all included patients who did not complete the 30 day follow up.
- Missing data rate. This applied to each outcome and variable and was defined as the percentage of missing values.
- Differences in distributions between directly observed data and data extracted from medical records. Distribution refers to summary statistics and directly observed data refers to data collected by project officers while observing the delivery of care.

This outcome applied to all variables that could be reasonably expected to be present in the medical records. To reduce workload, these data were extracted from a convenience sample of patients only.

- Pass rate. This applied only to residents in the intervention arms and was defined as the percentage of residents who passed the training programme, among all residents who received training.

We did not prespecify criteria to determine whether to proceed with a full-scale trial.

Sample Size

We aimed to include at least two clusters per arm to avoid basing conclusions on single centres. We also aimed to train at least two units per intervention cluster to evaluate the logistics of sending residents for training. We did not conduct a formal power calculation for this pilot, as the primary purpose of the study was to assess the feasibility of the trial logistics and research methods. We anticipated variation in the number of patients included per cluster depending on hospital patient volume.

Participant Timeline and Inclusion

Patients

Incoming patients were screened for eligibility and consented, if they were conscious and able to provide consent. For unconscious patients, consent was provided by a patient representative. These patients reaffirmed this proxy consent, upon regaining consciousness. Patients who did not regain consciousness remained included based on their representative's consent. We followed up patients at 24 hours and at 30 days after arrival at the emergency department. The follow-up period for each patient was therefore one month.

Residents

Participating units were screened for eligibility once the hospitals confirmed participation. All residents in these units were approached for consent to training if their hospital was randomised to one of the intervention arms. The protocol stated that residents would be approached for consent before randomisation, but this proved not to be feasible. Instead, we asked residents for consent after the hospitals were randomised but before training. Training took place approximately one month after study initiation in that hospital. We initially planned to use simple random sampling to select the units to be trained, but for pragmatic reasons the decision on which units to train was left to the site principal investigator. The number of residents trained in each intervention cluster varied based on the unit size.

Allocation and Blinding

We used simple randomisation implemented using sealed envelopes to allocate sites to the trial arms. It was not possible to blind investigators, residents or patients to the intervention. Data analysts were not blinded.

Data Collection

The planned data collection period was four months. However, the actual period varied across clusters depending on the timing of the training, to ensure a minimum of three months of data collection after the training in the intervention clusters. Research officers collected data on all patients who presented on the days and shifts when participating residents were assigned to trauma care. The research officers observed care, interviewed residents and patients, and extracted data from hospital records. Admitted patients were followed up for complications and other in-hospital outcome measures. Patients who were not admitted or who were discharged before the end of the study were followed up by telephone for mortality and quality-of-life.

Variables

Research officers collected data on demographics, vital signs, management details including imaging and surgery, and details of any injury sustained. All injuries were coded according to the International Classification of Diseases version 10 (ICD-10). Based on these codes, we calculated the Injury Severity Score (ISS) using the R package `icdpicr`[26]. The ISS is a widely used measure of injury severity and ranges from 0 to 75, with a cut-off score of 16 often used to define major trauma and 75 representing unsurvivable trauma. We also collected data on potential outcomes for the full-scale trial, including 30-day and in-hospital mortality, complications and health related quality of life (assessed using the EQ-5D-3L). We did not calculate an EQ-5D-3L index score, because no Indian value set is currently available[27]. We also attempted to collect data on cause of death. A list of variables is available in Supplementary Table S2.

Patient and Public Involvement

We conducted community consultations with patients, their caregivers, patient groups, and resident doctors to inform the selection of outcome measures and implementation of the full-scale trial. Results of these consultations are published separately[28]. We initially planned to distribute periodic surveys to residents and follow them up 30 days after training, but this was later changed to end-of-study interviews to allow for richer data (not published).

Data Monitoring

Weekly online meetings were held to monitor study progress and data collection. One interim analysis was conducted approximately halfway through the study, and it was decided to complete the study, as residents and patients were consenting to be included in the study and key variables including mortality, could be collected. A formal data monitoring committee was not used.

Statistical Methods

All analyses were conducted using R version 4.5.0 (2025-04-11) statistical software[29]. Feasibility outcomes and other data were analysed using descriptive statistics and no

formal hypothesis testing was performed. Initially, we planned to analyse feasibility outcomes at both the overall and individual cluster levels, but the sample sizes in individual clusters were too small to generate meaningful results. Quantitative variables are summarised as medians and interquartile ranges. Qualitative variables are presented as absolute numbers and percentages. Additional analyses performed according to the original protocol are available as additional online material[30].

Ethics and Dissemination

We were granted research ethics approval from the institutional ethics committees at each participating hospital. For each hospital, the approvals were HBTMC/266/SURGERY for Dr R N Cooper Municipal General Hospital in Mumbai, IEC(II)/OUT/134/2022 for Seth GS Medical College and KEM Hospital in Mumbai, ICC/214/22/20/05/2022 for Lokmanya Tilak Municipal Medical College and General Hospital, CREC/2022/FEB/1(ii) for MEDICA Superspeciality Hospital in Kolkata, MC/KOL/IEC/NON-SPON/1217/11/21 for Medical College, Kolkata, NRSMC/IEC/93/2021 for Nilratan Sircar Medical College & Hospital in Kolkata, and finally IEC-03/2022-2332 for the Postgraduate Institute of Medical Education and Research, Chandigarh.

Results

We included 376 trauma patients from seven clusters between April 2022 and February 2023. The data collection period and the number of patients included per month per cluster are shown in Figure 1. Owing to an error in the data uploading process, data were available only for one and three months in two clusters respectively. The standard care arm included 202 patients, the ATLS arm included 44 patients, and the PTC arm included 130 patients. A total of 22 residents were trained, seven in ATLS and 15 in PTC.

The study flow diagram is shown in Figure 2, and patient sample characteristics across trial arms are shown in Table 1. Extended patient sample characteristics are shown in Supplementary Table S2. Overall, 86 (23%) patients were females, the median (interquartile range, IQR) age was 33 (24, 46) years, and the median ISS (IQR) was 4 (1, 8). These prognostic factors differed between the trial arms. A total of 32 (10%) patients died within 30 days of arrival at the emergency department, and 29 (8%) patients died in the hospital.

After training, a total of 22 (16%) patients in the standard care arm died within 30 days, compared with 1 (4%) patient in the ATLS arm and 3 (5%) patients in the PTC arm. The corresponding rates for in-hospital mortality were 19 (12%), 1 (4%), and 3 (4%) for the standard care, ATLS and PTC arms, respectively.

Outcomes

The percentage of patients who consented to follow-up was 77% and the percentage lost to follow-up was 14%. The missing data rate ranged from 0% to 50%, with details for selected variables shown in Table 1 and in Supplementary Table S2. The variables with the largest

amount of missing data were the cost of treatment, complications and cause of death, also reported in Supplementary Table S2.

Differences in distributions between directly observed data and data extracted from medical records for selected variables collected through observation or interviews are shown in Table 2. Overall, the data were similarly distributed, but there were considerably more missing values in the data extracted from medical records than in the directly observed data.

The percentage of residents who consented to training was 100% and the pass rate was also 100%.

Discussion

We demonstrated that it is feasible to conduct and collect data for a cluster randomised controlled trial comparing ATLS with PTC and standard care. The missing data rate was low for key variables. However, some variables had very high missing data rates and may not be feasible to include in a full-scale trial, or may require different data collection methods. The missing data rate was substantially higher when data were extracted from medical records rather than directly observed, although the distributions were similar. Thus suggests that data collected from medical records are reliable even if they are less complete. To increase the completeness of data extracted from the medical records, a full-scale trial should limit the number of variables extracted from medical records and emphasise the importance of having these variables recorded to the participating hospitals.

All-cause 30-day mortality data were missing for 14% of patients. This rate may be high, especially compared to, for example, the CRASH-2 and REACT-2 trials, which reported missing primary outcomes for fewer than 0.01% of patients[31,32]. Like many other trauma trials, both CRASH-2 and REACT-2 used in-hospital mortality as their primary outcome measure, whereas we attempted to follow patients after discharge. Our missing data rate for in-hospital mortality was only 1%, which is comparable to those in previous trials. Following patients after discharge is notoriously challenging in this setting, and the full-scale trial may need to focus on in-hospital mortality as the primary outcome.

During this pilot study we deviated from the protocol in several ways. The most significant deviation was a revision of the study aim, as we initially intended to estimate potential effect sizes and other parameters to help sample size calculations for a full-scale trial, in addition to assessing the feasibility outcomes. However, current guidance advises against using pilot studies to estimate effect sizes, as the usefulness of these estimates is questionable[25,33]. We therefore chose to report patient outcomes descriptively. Another significant deviation was the training of emergency medicine residents. We originally planned to train only surgical residents, but trauma management routines varied between participating hospitals, and we adapted to local routines. A full-scale study will need to accommodate this variation as part of the protocol.

There are several significant limitations of this pilot study and, therefore, additional lessons to be learned and factored into the design of a full-scale trial. First, the patient

volumes at some of the participating hospitals were lower than expected. A careful assessment of patient volumes as part of the screening process should be included for a full-scale trial. Second, data on complications and causes of death were almost universally missing. Collecting data on these variables will require alternative methods, as these were not explicitly described in the medical records and autopsy reports were not readily available. Third, we did not collect detailed data on the standard care at each hospital. These data should be collected as part of the screening process for a full-scale trial. Fourth, we used sealed envelopes for randomisation, which increases the risk of bias and errors. A full-scale trial should use a computer-generated randomisation system. Fifth, we did not blind the data analysts, but recommend doing so in a full-scale trial. Sixth, we assessed a large number of potential outcomes, and a full-scale trial should focus on the most relevant outcomes. Seventh, the follow-up period was only one month, and changes in some of the outcomes may take longer than that to manifest. The effect on the outcomes is also likely to depend on the adherence to the training, which is not assessed in this pilot study. Finally, owing to a data uploading error, limited data were available from two clusters. At the time of data collection, network and other technical issues were present in some of the clusters, which could explain this error. Regardless, this is a major concern that must be mitigated in a full-scale trial by using a more robust data collection system with local offline backups and careful centralised monitoring.

Previous studies on the effects of ATLS or PTC training on patient outcomes have been observational or quasi-experimental without a control group, with heterogeneous results[35]. Most suggest that these programmes are associated with improved outcomes, although not all report significant effects[10–20]. In contrast, some studies have shown potential associations with increased mortality[21,22]. We observed fewer deaths in the intervention arms than in the standard care arm. This difference may have resulted from the randomisation process with a small number of heterogeneous clusters, highlighting the importance of taking varying cluster sizes into account when designing a full-scale trial.

A full-scale trial remains ethically justifiable after this pilot study, considering that it was never powered to detect meaningful differences in clinical outcomes. In addition, educating physicians in trauma life support through programmes such as ATLS and PTC is considered standard care in many settings, but this approach has been criticised for being costly and for propagating outdated practices[36]. Several systematic reviews have called for trials in settings where these programmes are not routinely implemented[2–4]. In recognition of their widespread use and high face validity, a stepped-wedge design in which all clusters receive the intervention but at randomised time points may be the best trial design. With regards to generalisability, the study was conducted in India, and the results are likely to be generalisable to other settings with similar trauma care systems. The findings may be less generalisable to settings where senior faculty are more directly involved in the initial management of trauma patients, as these were not trained in this pilot study.

Our study represents the first published attempt to pilot a controlled trial evaluating the effect of ATLS and PTC on patient outcomes. We conclude that a full-scale cluster randomised trial is feasible after incorporating the lessons of this pilot study.

Contributorship statement

MGW conceived the study, performed the analysis and drafted and revised the manuscript. AG, AM, CJ, DKV, HS, JB, KDS, LFT, LS, MH, MK, NR, PB, PP, RS, SD, and VK contributed to the design of the study. MGV, DKV, KDS, and MK drafted the first version of the protocol. AG, HS, and SD drafted the first version of the patient and public involvement activities. JB and PP drafted the first versions of the data management sections and wrote the data management plan. PB and PP drafted the first versions of the statistical analysis section. AG, AM, CJ, DKV, HS, JB, KDS, LFT, LS, MH, MGW, MK, NR, PB, PP, RS, SC, SD, and VK contributed to the refinement of the protocol. DB, JB, SC, LFT, GG, MK, TK, CJ, NR, RS, KDS, LS and VP interpreted the results and revised the manuscript. AR, AC, C, DK, GG, MK, MT, VK and VP are representatives of the participating hospitals. MGW is the guarantor.

Competing Interests

Several authors are ATLS and/or PTC instructors.

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Data Sharing Statement

The code for the analysis is released publicly on GitHub (https://github.com/martingerdin/tern-pilot). The final anonymised dataset is available from the corresponding author upon request.

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Figure Legends

Figure 1: Number of patients included per cluster per month. Owing to an error in the data uploading process, data were available for only one and three months in two clusters respectively.

Figure 2: Study flow diagram. Abbreviations: ATLS, Advanced Trauma Life Support; PTC, Primary Trauma Care.

Tables

Table 1. Patient sample characteristics.

Characteristic	**Standard care** N = 202	**ATLS** N = 44	**PTC** N = 130	**Overall** N = 376
Age, years, median (IQR)	35 (25, 47)	40 (30, 57)	30 (22, 38)	33 (24, 46)
Elderly (Age ≥ 65 years), n (%)	15 (7%)	6 (14%)	5 (4%)	26 (7%)
Sex, n (%)				
Male	160 (79%)	33 (75%)	97 (75%)	290 (77%)
Female	42 (21%)	11 (25%)	33 (25%)	86 (23%)
Dominating injury type, n (%)				
Penetrating	13 (6%)	3 (7%)	1 (1%)	17 (5%)
Blunt	189 (94%)	41 (93%)	129 (99%)	359 (95%)
Blunt multisystem trauma, n (%)	2 (1%)	2 (5%)	6 (5%)	10 (3%)
Severe traumatic brain injury, n (%)	10 (5%)	1 (2%)	5 (4%)	16 (4%)
Missing	1	0	0	1
Shock (SBP ≤ 90 mmHg), n (%)	4 (2%)	2 (5%)	4 (3%)	10 (3%)
Missing	7	3	4	14
Respiratory rate, breaths per minute, median (IQR)	20 (18, 22)	21 (20, 24)	21 (20, 24)	20 (19, 23)
Missing	7	0	5	12
Oxygen saturation, %, median (IQR)	98 (97, 99)	98 (97, 99)	98 (98, 99)	98 (97, 99)
Missing	1	1	0	2
Heart rate, beats per minute, median (IQR)	86 (80, 96)	87 (73, 100)	90 (76, 104)	86 (78, 100)
Missing	1	1	1	3
Systolic blood pressure, mmHg, median (IQR)	123 (112, 135)	124 (113, 131)	122 (111, 136)	123 (112, 135)
Missing	7	3	4	14
Glasgow Coma Scale, median (IQR)	15 (15, 15)	15 (15, 15)	15 (15, 15)	15 (15, 15)
Missing	2	1	0	3
Injury Severity Score, median (IQR)	1 (1, 8)	4 (1, 5)	4 (1, 8)	4 (1, 8)
Missing	37	5	35	77
In-hospital mortality, n (%)	21 (11%)	1 (2%)	7 (5%)	29 (8%)
Missing	2	1	0	3
30 day mortality, n (%)	23 (13%)	1 (3%)	8 (7%)	32 (10%)
Missing	29	4	20	53

Abbreviation: ATLS = Advanced Trauma Life Support; PTC = Prehospital Trauma Care; SBP = systolic blood pressure

Missing data counts are only shown for variables with missing values. The absence of a count indicates complete data.

Table 2. Differences in distributions between directly observed data and data extracted from medical records, for selected variables collected through observation or interview in a convenience sample of patients.

Characteristic	**Directly observed** N = 55	**Medical records** N = 55
Age, years, median (IQR)	34 (27, 48)	34 (25, 50)
Missing	0	22
Sex, n (%)		
Female	10 (18%)	6 (18%)
Male	45 (82%)	27 (82%)
Missing	0	22
Dominating injury type, n (%)		
Blunt	52 (95%)	29 (91%)
Penetrating	3 (5%)	3 (9%)
Missing	0	23
Respiratory rate, breaths per minute, median (IQR)	21 (18, 24)	18 (16, 20)
Missing	0	37
Oxygen saturation, %, median (IQR)	98 (98, 99)	98 (97, 100)
Missing	0	29
Heart rate, beats per minute, median (IQR)	85 (80, 98)	87 (84, 93)
Missing	0	19
Systolic blood pressure, mmHg, median (IQR)	123 (112, 136)	118 (110, 128)
Missing	1	18

Feasibility of a Cluster Randomised Trial on the Effect of Trauma Life Support Training: A Pilot Study in India

Trauma life support training Effectiveness Research Network (TERN) collaborators

Trial registration

This pilot study was registered with ClinicalTrials.gov (reg. no NCT05417243).

Corresponding author

Martin Gerdin Wärnberg, MD, PhD (MGW)

Department of Global Public Health
Karolinska Institutet
171 77 Stockholm
Sweden

martin.gerdin@ki.se
+46 708 53 95 98 (mobile)

Authors (in alphabetical order by last name)

Debojit Basak, MS (DB)

Project Research Scientist, Institute of Post Graduate Medical Education and Research, Kolkata, India.

Johanna Berg, MD (JB)

Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden.

Emergency Medicine, Department of Internal and Emergency Medicine, Skåne University Hospital, Malmö, Sweden.

Shamita Chatterjee, MBBS, MS (SC)

Department of Surgery, Institute of Post Graduate Medical Education and Research, Kolkata, India.

Li Felländer-Tsai, MD, PhD (LFT)

Division of Orthopaedics and Biotechnology, Department of Clinical Science Intervention and Technology (CLINTEC), Karolinska Institutet, Stockholm, Sweden.

Department of Reconstructive Orthopedics, Karolinska University Hospital, Stockholm, Sweden.

Geeta Ghag, MBBS, MS (GG)

Department of Surgery, HBT Medical College And Dr. R N Cooper Municipal General Hospital, Mumbai, India.

Catherine Juillard, MD, MPH (CJ)

Division of General Surgery, Department of Surgery, David Geffen School of Medicine at UCLA, Los Angeles, California, United States of America.

Monty Khajanchi, MBBS, MS (MK)

Seth G. S. Medical College and K.E.M. Hospital, Mumbai, India.

Tamal Khan, MSc (TK)

Senior Research fellow, All India Institute of Medical Sciences, New Delhi, India.

Vipul Nandu, MBBS, MS (VN)

Department of Surgery, HBT Medical College And Dr. R N Cooper Municipal General Hospital, Mumbai, India.

Nobhojit Roy, MBBS, MS, PhD (NR)

Program for Global Surgery and Trauma, The George Institute of Global Health, New Delhi, India.

Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden.

Rajdeep Singh, MBBS, MS (RS)

Department of Surgery, Maulana Azad Medical College, New Delhi, India.

Kapil Dev Soni, MBBS, MD (KDS)

Critical and Intensive Care, JPN Apex Trauma Center, All India Institute of Medical Sciences, New Delhi, India.

Lovisa Strömmer, MD, PhD (LS)

Division of Surgery and Oncology, Department of Clinical Science, Intervention and Technology (CLINTEC), and Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden.

Nonauthor contributors

Anirban Chatterjee (AC)

Department of Orthopaedic Sciences, Medica Superspecialty Hospital, Kolkata, India.

Marie Hasselberg (MH)

Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden.

Debabrata Kundu (DK)

Department of Surgery, Medical College Kolkata, Kolkata, India.

Anurag Mishra (AM)

Department of Surgery, Maulana Azad Medical College, New Delhi, India.

Arun Prasad (AP)

Department of Surgery, Indraprastha Apollo Hospitals, New Delhi

Harris Solomon (HS)

Department of Cultural Anthropology and the Duke Global Health Institute, Duke University, Durham, USA.

Megha Tandon (MT)

Department of Surgery, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, India.

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Abstract

Objective The aim was to assess the feasibility of conducting a cluster randomised controlled trial comparing the effects of Advanced Trauma Life Support (ATLS) and Primary Trauma Care (PTC) with standard care on patient outcomes.

Design This was a pilot pragmatic three-armed parallel, cluster randomised, controlled trial conducted between April 2022 and February 2023. Patient were followed up for 30 days.

Setting The study setting was tertiary care hospitals across metropolitan areas in India.

Participants Adult trauma patients and residents managing these patients were included.

Interventions ATLS or PTC training was provided for residents in the intervention arms.

Main Outcomes and Measures The outcomes were the consent rate, lessons to follow up rate, missing data rates, differences in the distribution between observed data and data extracted from medical records, and the resident pass rate.

Results Two hospitals were randomised to the ATLS arm, two to the PTC arm, and three to the standard care arm. We included 376 patients and 22 residents. The percentage of patients who consented to follow up was 77% and the percentage of residents who consented to receive training was 100%. The loss to follow up rate was 14%. The pass rate was 100%. Overall, the amount of missing data for key variables was low. The data collected through observations were similar to data extracted from medical records, but there were more missing extracted data.

Conclusions Conducting a full-scale cluster randomised controlled trial comparing the effects of ATLS, PTC, and standard care on patient outcomes appears feasible, especially if such a trial would use data and outcomes available in medical records.

Trial Registration ClinicalTrials.gov (reg. no NCT05417243)

Strengths and limitations of this study

- Prospective data collection with direct observations made by dedicated research officers.
- A lack of a priori defined success criteria and thresholds for feasibility outcomes.
- The use of sealed envelopes potentially compromised allocation concealment.
- Heterogeneity of the participating centers may affect the study estimates and introduce bias.

Introduction

Trauma, defined as a clinical entity composed of physical injury and the associated response of the body, causes 4.3 million deaths every year[1]. Several trauma life support training programmes have been developed to improve the early management of patients in hospitals by providing a structured framework for assessment and treatment[2–47].

~~The proprietary~~ Advanced Trauma Life Support (ATLS) and ~~low-cost alternative~~ Primary Trauma Care (PTC) are ~~two widely~~the most established trauma life support training programmes[8,9]. Both programmes ~~with over a million physicians trained in over 80 countries[5,6]. Observational~~improve provider knowledge and skills[2,4], and while most observational studies ~~indicate that these programmes may improve patient outcomes[7–21]; but there is~~ associate them with reduced mortality[10–20], some report associations with increased mortality[21,22].

There are no ~~high quality evidence from~~ controlled trials ~~to~~of the effect of ATLS or PTC on patient outcomes, and no trials evaluating any trauma life support ~~this[2–4,22–24]~~training programme in a general trauma population[2–7]. However, a recent cluster randomised trial found that the rural trauma team development course reduced mortality in patients with motorcycle injuries[23].

~~Several studies, including at least two randomised studies[25,26], have shown that ATLS is associated with improved knowledge and skills among providers[2]. Observational evidence also suggests that PTC also leads to improved provider skills[4]. The missing link is whether this improved knowledge and skill set translates into measurably improved patient outcomes.~~

Systematic reviews ~~have called~~call for controlled trials ~~in settings where these programmes are not routinely implemented[2]~~of ATLS and PTC[2–4], ~~as conducting such effectiveness trials in settings where they are part of the standard of care is not feasible. Many of these settings are in low- and middle income countries, where trial logistics~~but large scale cluster randomised trials can be ~~more challenging.~~

complex. We therefore conducted a pilot study with the aim to assess the feasibility of a cluster randomised controlled trial comparing the effects of ATLS and PTC with standard care on outcomes in adult trauma patients.

Methods

Protocol Deviations

Protocol deviations are mentioned where relevant in this manuscript, but a list of all deviations is also included as Supplementary Material S1 for completeness.

Trial Design

We piloted a three-armed cluster randomised controlled ~~trial[27]~~trial[24]. The trial included a standard care arm and two intervention arms, ATLS and PTC training. We planned to collect data for four months in all three arms, first during a one month observation phase, followed by a three-month intervention phase (or continued observation in the standard care arm). The actual data collection period varied across clusters depending on the timing of the training, to ensure a minimum of three months of data collection in the intervention clusters post-training. We included a one month observation phase to evaluate the feasibility of comparing patient outcomes both as absolute differences between the intervention phases, and as differences in changes from baseline. In the published protocol, we also aimed to estimate probable effect sizes and other parameters needed for sample size calculations for a full-scale ~~trial[27]~~trial[24]. However, we revised this aim in light of current guidance on the conduct and reporting of pilot ~~trials[28]~~trials[25].

Study Setting

We conducted this pilot study in seven tertiary hospitals across metropolitan areas in India, where neither ATLS, PTC, nor any other established trauma life support training program is routinely taught. Details about each cluster are provided in Supplementary Table S1. We initially intented to include six hospitals as clusters, but added a seventh hospital when management expressed interest, as we had the budget to accommodate the request. These seven hospitals represented a convenience sample that fulfilled the inclusion criteria, and had existing connections to the research team.

Eligibility Criteria for Cluster and Participants

Clusters

We defined a cluster as a tertiary care hospital in metropolitan areas in India that admit more than 400 adult patients with trauma annually, and has operation theatres, X-ray, CT, and ultrasound facilities, and blood bank available around the clock. In each cluster, we trained one or more units of physicians providing trauma care in the emergency department. To be eligible, units could have no more than 25% of their physicians with previous training in either ATLS, PTC, or similar training programmes. Residents who had received training in the last five years were considered trained. The 25% threshold was determined through consensus within the research team, to balance feasibility and the risk of contamination. The principal investigator at each hospital selected the units for training. We randomised at the hospital level to avoid contamination between the intervention and standard care arms.

Residents

We trained resident doctors undertaking speciality training in surgery or emergency medicine who managed trauma patients in the emergency department, and were expected to remain in the participating hospitals for at least one year after training. Consent was obtained from the residents in each intervention arm before ATLS or PTC training. In the

published protocol, we stated that only surgical residents would be trained. However, in some of the participating hospitals, emergency medicine residents led the initial resuscitation and management of trauma patients, and we therefore included them in the training.

Patients

We included persons aged 15 years or older who presented to the emergency department at participating hospitals with a history of trauma when a designated unit was on duty. A history of trauma was defined as having any of the external causes of morbidity and mortality listed in block V01-Y36, chapter 20 of the International Classification of Disease version 10 (ICD-10) codebook as the reason for presentation.

Standard Care

Standard care varies across hospitals in India, but most surgical and emergency medicine departments in India organise their physicians into units. These units include both faculty members and residents, who are assigned a specific day of the week to work in the emergency department. Trauma patients are initially assessed by residents in these units, who also resuscitate patients, perform interventions and refer patients for imaging or other investigations. Compared with settings that adopt a trauma team approach, nurses and other healthcare professionals are involved to a limited extent during initial management. We did not collect data on how standard care varied between the participating hospitals.

Intervention

In each intervention arm, residents from one or two units were trained in either ATLS or PTC at the beginning of the three month intervention phase. For the purpose of this pilot study, our target was to train at least 75% of residents in each unit. Faculty members were not trained, because they are typically not directly involved in the initial management of trauma patients. ATLS training was conducted at an ATLS certified training centre in Mumbai and PTC training was conducted in New Delhi. Both trainings were conducted according to their respective standard ~~curriculum~~[5,6]curriculum[8,9], and we did not modify or adapt the delivery or content of these programmes during this pilot study.

The provider courses of both programmes take place across two days, and focus on the assessment, resuscitation and stabilisation of trauma patients, with adaptions for different patient populations. Teaching is based on case discussions and skill stations. There are several important differences between the two programmes. The ATLS course focuses more on inter-hospital patient transfers and includes a greater emphasis on the trauma ~~team~~[5]team[8]. In contrast, the PTC course focuses on trauma care in the low resource ~~setting~~[6]setting[9]. The ATLS programme is run by the American College of Surgeons and requires a participant fee, whereas the PTC programme is run by the UK-based PTC Foundation and is provided free of charge.

Feasibility Outcomes

Our feasibility outcomes were as follows:

- Consent rates of patients and residents. This was defined as the percentage of patients or residents who consented to be included, out of the total number of eligible patients or residents.
- Loss to follow-up rate. This applied only to patients and was defined as the percentage of patients among all included patients who did not complete the 30 day follow up.
- Missing data rate. This applied to each outcome and variable and was defined as the percentage of missing values.
- Differences in distributions between directly observed data and data extracted from medical records. Distribution refers to summary statistics and directly observed data refers to data collected by project officers while observing the delivery of care. This outcome applied to all variables that could be reasonably expected to be present in the medical records. To reduce workload, these data were extracted from a convenience sample of patients only.
- Pass rate. This applied only to residents in the intervention arms and was defined as the percentage of residents who passed the training programme, among all residents who received training.

We did not prespecify criteria to determine whether to proceed with a full-scale trial.

Sample Size

We aimed to include at least two clusters per arm to avoid basing conclusions on single centres. We also aimed to train at least two units per intervention cluster to evaluate the logistics of sending residents for training. We did not conduct a formal power calculation for this pilot, as the primary purpose of the study was to assess the feasibility of the trial logistics and research methods. We anticipated variation in the number of patients included per cluster depending on hospital patient volume.

Participant Timeline and Inclusion

Patients

Incoming patients were screened for eligibility and consented, if they were conscious and able to provide consent. For unconscious patients, consent was provided by a patient representative. These patients reaffirmed this proxy consent, upon regaining consciousness. Patients who did not regain consciousness remained included based on their representative's consent. We followed up patients at 24 hours and at 30 days after arrival at the emergency department. The follow-up period for each patient was therefore one month.

Residents

Participating units were screened for eligibility once the hospitals confirmed participation. All residents in these units were approached for consent to training if their hospital was randomised to one of the intervention arms. The protocol stated that residents would be approached for consent before randomisation, but this proved not to be feasible. Instead,

we asked residents for consent after the hospitals were randomised but before training. Training took place approximately one month after study initiation in that hospital. We initially planned to use simple random sampling to select the units to be trained, but for pragmatic reasons ~~this~~the decision on which units to train was left to the site principal investigator. The number of residents trained in each intervention cluster varied based on the unit size.

Allocation and Blinding

We used simple randomisation implemented using sealed envelopes to allocate sites to the trial arms. It was not possible to blind investigators, residents or patients to the intervention. Data analysts were not blinded.

Data Collection

The planned data collection period was four months. However, the actual period varied across clusters depending on the timing of the training, to ensure a minimum of three months of data collection after the training in the intervention clusters. Research officers collected data on all patients who presented on the days and shifts when participating residents were assigned to trauma care. The research officers observed care, interviewed residents and patients, and extracted data from hospital records. Admitted patients were followed up for complications and other in-hospital outcome measures. Patients who were not admitted or who were discharged before the end of the study were followed up by telephone for mortality and quality-of-life.

Variables

Research officers collected data on demographics, vital signs, management details including imaging and surgery, and details of any injury sustained. All injuries were coded according to the International Classification of Diseases version 10 (ICD-10). Based on these codes, we calculated the Injury Severity Score (ISS) using the R package ~~*icdpicr*[29]~~*icdpicr*[26]. The ISS is a widely used measure of injury severity and ranges from 0 to 75, with a cut-off score of 16 often used to define major trauma and 75 representing unsurvivable trauma. We also collected data on potential outcomes for the full-scale trial, including 30-day and in-hospital mortality, complications and health related quality of life (assessed using the EQ-5D-3L). We did not calculate an EQ-5D-3L index score, because no Indian value set is currently ~~available~~[30]available[27]. We also attempted to collect data on cause of death. A list of variables is available in Supplementary Table S2.

Patient and Public Involvement

We conducted community consultations with patients, their caregivers, patient groups, and resident doctors to inform the selection of outcome measures and implementation of the full-scale trial. Results of these consultations are published ~~separately~~[31]separately[28]. We initially planned to distribute periodic surveys to residents and follow them up 30 days after training, but this was later changed to end-of-study interviews to allow for richer data (not published).

Data Monitoring

Weekly online meetings were held to monitor study progress and data collection. One interim analysis was conducted approximately halfway through the study, and it was decided to complete the study, as residents and patients were consenting to be included in the study and key variables including mortality, could be collected. A formal data monitoring committee was not used.

Statistical Methods

All analyses were conducted using R version 4.5.0 (2025-04-11) statistical ~~software[32]~~software[29]. Feasibility outcomes and other data were analysed using descriptive statistics and no formal hypothesis testing was performed. Initially, we planned to analyse feasibility outcomes at both the overall and individual cluster levels, but the sample sizes in individual clusters were too small to generate meaningful results. Quantitative variables are summarised as medians and interquartile ranges. Qualitative variables are presented as absolute numbers and percentages. Additional analyses performed according to the original protocol are available as additional online ~~material[33]~~material[30].

Ethics and Dissemination

We were granted research ethics approval from the institutional ethics committees at each participating hospital. For each hospital, the approvals were HBTMC/266/SURGERY for Dr R N Cooper Municipal General Hospital in Mumbai, IEC(II)/OUT/134/2022 for Seth GS Medical College and KEM Hospital in Mumbai, ICC/214/22/20/05/2022 for Lokmanya Tilak Municipal Medical College and General Hospital, CREC/2022/FEB/1(ii) for MEDICA Superspeciality Hospital in Kolkata, MC/KOL/IEC/NON-SPON/1217/11/21 for Medical College, Kolkata, NRSMC/IEC/93/2021 for Nilratan Sircar Medical College & Hospital in Kolkata, and finally IEC-03/2022-2332 for the Postgraduate Institute of Medical Education and Research, Chandigarh.

Results

We included 376 trauma patients from seven clusters between April 2022 and February 2023. The data collection period and the number of patients included per month per cluster are shown in Figure 1. Owing to an error in the data uploading process, data were available only for one and three months in two clusters respectively. The standard care arm included 202 patients, the ATLS arm included 44 patients, and the PTC arm included 130 patients. A total of 22 residents were trained, seven in ATLS and 15 in PTC.

The study flow diagram is shown in Figure 2, and patient sample characteristics across trial arms are shown in Table 1. Extended patient sample characteristics are shown in Supplementary Table S2. Overall, 86 (23%) patients were females, the median (interquartile range, IQR) age was 33 (24, 46) years, and the median ISS (IQR) was 4 (1, 8).

These prognostic factors differed between the trial arms. A total of 32 (10%) patients died within 30 days of arrival at the emergency department, and 29 (8%) patients died in the hospital.

After training, a total of 22 (16%) patients in the standard care arm died within 30 days, compared with 1 (4%) patient in the ATLS arm and 3 (5%) patients in the PTC arm. The corresponding rates for in-hospital mortality were 19 (12%), 1 (4%), and 3 (4%) for the standard care, ATLS and PTC arms, respectively.

Outcomes

The percentage of patients who consented to follow-up was 77% and the percentage lost to follow-up was 14%. The missing data rate ranged from 0% to 50%, with details for selected variables shown in Table 1 and in Supplementary Table S2. The variables with the largest amount of missing data were the cost of treatment, complications and cause of death, also reported in Supplementary Table S2.

Differences in distributions between directly observed data and data extracted from medical records for selected variables collected through observation or interviews are shown in Table 2. Overall, the data were similarly distributed, but there were considerably more missing values in the data extracted from medical records than in the directly observed data.

The percentage of residents who consented to training was 100% and the pass rate was also 100%.

Discussion

We demonstrated that it is feasible to conduct and collect data for a cluster randomised controlled trial comparing ATLS with PTC and standard care. The missing data rate was low for key variables. However, some variables had very high missing data rates and may not be feasible to include in a full-scale trial, or may require different data collection methods. The missing data rate was substantially higher when data were extracted from medical records rather than directly observed, although the distributions were similar. Thus suggests that data collected from medical records are reliable even if they are less complete. To increase the completeness of data extracted from the medical records, a full-scale trial should limit the number of variables extracted from medical records and emphasise the importance of having these variables recorded to the participating hospitals.

All-cause 30-day mortality data were missing for 14% of patients. This rate may be high, especially compared to, for example, the CRASH-2 and REACT-2 trials, which reported missing primary outcomes for fewer than 0.01% of ~~patients[34,35].~~ patients[31,32]. Like many other trauma trials, both CRASH-2 and REACT-2 used in-hospital mortality as their primary outcome measure, whereas we attempted to follow patients after discharge. Our missing data rate for in-hospital mortality was only 1%, which is comparable to those in previous trials. Following patients after discharge is notoriously challenging in this setting, and the full-scale trial may need to focus on in-hospital mortality as the primary outcome.

During this pilot study we deviated from the protocol in several ways. The most significant deviation was a revision of the study aim, as we initially intended to estimate potential effect sizes and other parameters to help sample size calculations for a full-scale trial, in addition to assessing the feasibility outcomes. However, current guidance advises against using pilot studies to estimate effect sizes, as the usefulness of these estimates is ~~questionable[28,36].~~questionable[25,33]. We therefore chose to report patient outcomes descriptively. Another significant deviation was the training of emergency medicine residents. We originally planned to train only surgical residents, but trauma management routines varied between participating hospitals, and we adapted to local routines. A full-scale study will need to accommodate this variation as part of the protocol.

There are several significant limitations of this pilot study and, therefore, additional lessons to be learned and factored into the design of a full-scale trial. First, the patient volumes at some of the participating hospitals were lower than expected. A careful assessment of patient volumes as part of the screening process should be included for a full-scale trial. Second, data on complications and causes of death were almost universally missing. Collecting data on these variables will require alternative methods, as these were not explicitly described in the medical records and autopsy reports were not readily available. Third, we did not collect detailed data on the standard care at each hospital. These data should be collected as part of the screening process for a full-scale trial. Fourth, we used sealed envelopes for randomisation, which increases the risk of bias and errors. A full-scale trial should use a computer-generated randomisation system. Fifth, we did not blind the data analysts, but recommend doing so in a full-scale trial. Sixth, we assessed a large number of potential outcomes, and a full-scale trial should focus on the most relevant outcomes. Seventh, the follow-up period was only one month, and changes in some of the outcomes may take longer than that to manifest. The effect on the outcomes is also likely to depend on the adherence to the training, which is not assessed in this pilot study. Finally, owing to a data uploading error, limited data were available from two clusters. At the time of data collection, network and other technical issues were present in some of the clusters, ~~and should~~which could explain this error. Regardless, this is a major concern that must be mitigated in a full-scale trial by using a more robust data collection system with local offline backups and careful centralised monitoring~~.~~

Previous studies on the effects of ATLS or PTC training on patient outcomes have been observational or quasi-experimental without a control group, with heterogeneous ~~results[8]~~results[35]. Most suggest that these programmes are associated with improved outcomes, although not all report significant ~~effects[7,9,10,12,14–18,]~~effects[10–20,21]. In contrast, some studies have shown potential associations with increased ~~mortality[13,19]~~mortality[21,22]. We observed fewer deaths in the intervention arms than in the standard care arm. This difference may have resulted from the randomisation process with a small number of heterogeneous clusters, highlighting the importance of taking varying cluster sizes into account when designing a full-scale trial.

A full-scale trial remains ethically justifiable after this pilot study, considering that it was never powered to detect meaningful differences in clinical outcomes. In addition, educating physicians in trauma life support through programmes such as ATLS and PTC is considered standard care in many settings, but this approach has been criticised for being costly and

for propagating outdated ~~practices[37]~~practices[36]. Several systematic reviews have called for trials in settings where these programmes are not routinely implemented[2–4]. In recognition of their widespread use and high face validity, a stepped-wedge design in which all clusters receive the intervention but at randomised time points may be the best trial design. With regards to generalisability, the study was conducted in India, and the results are likely to be generalisable to other settings with similar trauma care systems. The findings may be less generalisable to settings where senior faculty are more directly involved in the initial management of trauma patients, as these were not trained in this pilot study.

Our study represents the first published attempt to pilot a controlled trial evaluating the effect of ~~trauma life support training~~ATLS and PTC on patient outcomes. We conclude that a full-scale cluster randomised trial is feasible after incorporating the lessons of this pilot study.

Contributorship statement

MGW conceived the study, performed the analysis and drafted and revised the manuscript. AG, AM, CJ, DKV, HS, JB, KDS, LFT, LS, MH, MK, NR, PB, PP, RS, SD, and VK contributed to the design of the study. MGV, DKV, KDS, and MK drafted the first version of the protocol. AG, HS, and SD drafted the first version of the patient and public involvement activities. JB and PP drafted the first versions of the data management sections and wrote the data management plan. PB and PP drafted the first versions of the statistical analysis section. AG, AM, CJ, DKV, HS, JB, KDS, LFT, LS, MH, MGW, MK, NR, PB, PP, RS, SC, SD, and VK contributed to the refinement of the protocol. DB, JB, SC, LFT, GG, MK, TK, CJ, NR, RS, KDS, LS and VP interpreted the results and revised the manuscript. AR, AC, C, DK, GG, MK, MT, VK and VP are representatives of the participating hospitals. MGW is the guarantor.

Competing Interests

Several authors are ATLS and/or PTC instructors.

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Data Sharing Statement

The code for the analysis is released publicly~~.~~ on GitHub (*https://github.com/martingerdin/tern-pilot*). The final anonymised dataset is available from the corresponding author upon request.

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Figure Legends

Figure 1: Number of patients included per cluster per month. Owing to an error in the data uploading process, data were available for only one and three months in two clusters respectively.

Figure 2: Study flow diagram. Abbreviations: ATLS, Advanced Trauma Life Support; PTC, Primary Trauma Care.

Tables

Table 1. Patient sample characteristics.

Characteristic	**Standard care** N = 202	**ATLS** N = 44	**PTC** N = 130	**Overall** N = 376
Age, years, median (IQR)	35 (25, 47)	40 (30, 57)	30 (22, 38)	33 (24, 46)
Elderly (Age ≥ 65 years), n (%)	15 (7%)	6 (14%)	5 (4%)	26 (7%)
Sex, n (%)				
Male	160 (79%)	33 (75%)	97 (75%)	290 (77%)
Female	42 (21%)	11 (25%)	33 (25%)	86 (23%)
Dominating injury type, n (%)				
Penetrating	13 (6%)	3 (7%)	1 (1%)	17 (5%)
Blunt	189 (94%)	41 (93%)	129 (99%)	359 (95%)
Blunt multisystem trauma, n (%)	2 (1%)	2 (5%)	6 (5%)	10 (3%)
Severe traumatic brain injury, n (%)	10 (5%)	1 (2%)	5 (4%)	16 (4%)
Missing	1	0	0	1
Shock (SBP ≤ 90 mmHg), n (%)	4 (2%)	2 (5%)	4 (3%)	10 (3%)
Missing	7	3	4	14
Respiratory rate, breaths per minute, median (IQR)	20 (18, 22)	21 (20, 24)	21 (20, 24)	20 (19, 23)
Missing	7	0	5	12
Oxygen saturation, %, median (IQR)	98 (97, 99)	98 (97, 99)	98 (98, 99)	98 (97, 99)
Missing	1	1	0	2
Heart rate, beats per minute, median (IQR)	86 (80, 96)	87 (73, 100)	90 (76, 104)	86 (78, 100)
Missing	1	1	1	3
Systolic blood pressure, mmHg, median (IQR)	123 (112, 135)	124 (113, 131)	122 (111, 136)	123 (112, 135)
Missing	7	3	4	14
Glasgow Coma Scale, median (IQR)	15 (15, 15)	15 (15, 15)	15 (15, 15)	15 (15, 15)
Missing	2	1	0	3
Injury Severity Score, median (IQR)	1 (1, 8)	4 (1, 5)	4 (1, 8)	4 (1, 8)
Missing	37	5	35	77
In-hospital mortality, n (%)	21 (11%)	1 (2%)	7 (5%)	29 (8%)
Missing	2	1	0	3
30 day mortality, n (%)	23 (13%)	1 (3%)	8 (7%)	32 (10%)
Missing	29	4	20	53

Abbreviation: ATLS = Advanced Trauma Life Support; PTC = Prehospital Trauma Care; SBP = systolic blood pressure

Missing data counts are only shown for variables with missing values. The absence of a count indicates complete data.

Table 2. Differences in distributions between directly observed data and data extracted from medical records, for selected variables collected through observation or interview in a convenience sample of patients.

Characteristic	**Directly observed** N = 55	**Medical records** N = 55
Age, years, median (IQR)	34 (27, 48)	34 (25, 50)
Missing	0	22
Sex, n (%)		
Female	10 (18%)	6 (18%)
Male	45 (82%)	27 (82%)
Missing	0	22
Dominating injury type, n (%)		
Blunt	52 (95%)	29 (91%)
Penetrating	3 (5%)	3 (9%)
Missing	0	23
Respiratory rate, breaths per minute, median (IQR)	21 (18, 24)	18 (16, 20)
Missing	0	37
Oxygen saturation, %, median (IQR)	98 (98, 99)	98 (97, 100)
Missing	0	29
Heart rate, beats per minute, median (IQR)	85 (80, 98)	87 (84, 93)
Missing	0	19
Systolic blood pressure, mmHg, median (IQR)	123 (112, 136)	118 (110, 128)
Missing	1	18

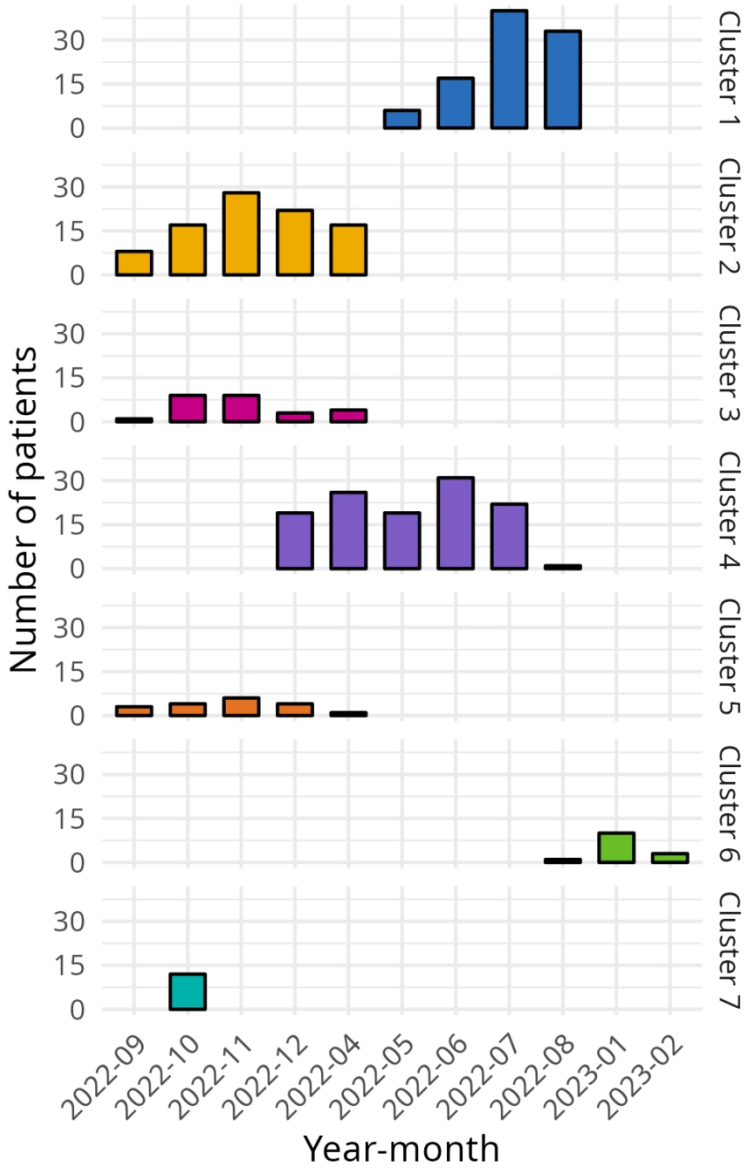

Figure 1. Number of patients included per cluster per month. Owing to an error in the data uploading process, data were available for only one and three months in two clusters respectively.

215x330mm (118 x 118 DPI)

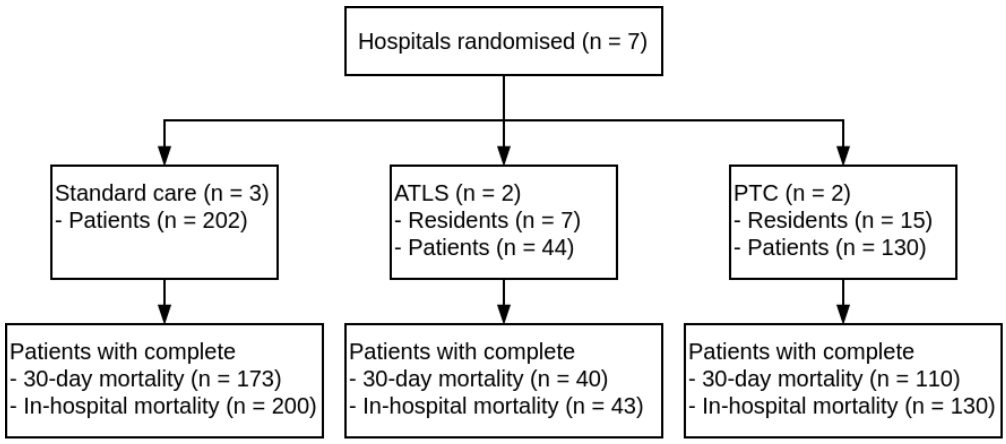

Figure 2. Study flow diagram. Abbreviations: ATLS, Advanced Trauma Life Support; PTC, Primary Trauma Care.

311x146mm (72 x 72 DPI)

Supplementary Material

Feasibility of a Cluster Randomised Trial on the Effect of Trauma Life Support Training: A Pilot Study in India

Trauma life support training Effectiveness Research Network (TERN) collaborators

Table of Contents

S1 Protocol Deviations

Trial Registration

We intended to register our trial with Clinical Trials Registry - India (CTRI), but because of a communication error in the management group this was only attempted after the trial has started including patients, and CTRI only accept prospective registrations. We intend to register the full scale trial with both ClinicalTrials.gov and CTRI.

Aim

In the original protocol, we also aimed to estimate probable effect sizes and other measures needed for the sample size calculations of a full-scale trial, but we revised this aim in the light of current guidance on the conduct and reporting of pilot trials

Number of Participating Clusters

We recruited seven hospitals as clusters instead of six, as a seventh hospital expressed interest and we had the budget to accommodate this request. We therefore assigned two centres each to the intervention arms and three centres to the control arm.

Resident Participants

We included emergency medicine residents in addition to surgical residents.

Periodic surveys of residents

We did not distribute periodic surveys to the participating residents but discussed challenges and suggestions that they had regarding the scheduling or implementation of the training programs.

Follow up of residents

We stated that resident participants would be followed up 30 days after training, but revised this to follow them up after the end of the study period.

Data collection from records

We decided to extract data from medical records only for a convenience sample of patients to reduce the research officers' workload.

Selection of units for training

We planned to use simple random sampling to select units if there were more than two eligible units in a hospital but instead the hospital principal investigator decided which units to train.

Timing of resident consent

We had initially planned to ask residents for consent before randomisation, but because of logistical issues the units were only finalised after the hospitals had been randomised. Residents were therefore approached for consent after randomisation but before training.

Analysis level of feasibility outcomes

We had planned to analyse feasibility outcomes on both an overall and individual cluster level, but we only analysed them on an overall level, because the sample sizes in individual clusters were too small to generate meaningful results.

Patient outcomes across subgroups

Because of small numbers in the pre-specified subgroups men, women, blunt multisystem trauma, penetrating trauma, shock, severe traumatic brain injury and elderly we decided to report only descriptive data on these subgroups.

Table S1. Cluster characteristics

Cluster	City	Beds	Type
Dr R N Cooper Municipal General Hospital	Mumbai	600	Public
Seth GS Medical College and KEM Hospital	Mumbai	1800	Public
Lokmanya Tilak Municipal Medical College and General Hospital	Mumbai	1850	Public
MEDICA Superspeciality Hospital	Kolkata	300	Private
Medical College	Kolkata	2140	Public
Nilratan Sircar Medical College & Hospital	Kolkata	1910	Public
Postgraduate Institute of Medical Education and Research	Chandigarh	1400	Public

Table S2. Extended patient sample characteristics

Characteristic	Before training				After training				Overall
	Standard care N = 41[1]	**ATLS** N = 16[1]	**PTC** N = 57[1]	**Overall** N = 114[1]	**Standard care** N = 161[1]	**ATLS** N = 28[1]	**PTC** N = 73[1]	**Overall** N = 262[1]	**N = 376**[1]
Age, years	32 (23, 46)	46 (30, 61)	30 (22, 38)	33 (23, 46)	35 (26, 47)	37 (30, 55)	30 (22, 38)	34 (25, 45)	33 (24, 46)
Elderly (Age ≥ 65 years)	3 (7%)	3 (19%)	3 (5%)	9 (8%)	12 (7%)	3 (11%)	2 (3%)	17 (6%)	26 (7%)
Sex									
Male	36 (88%)	10 (63%)	44 (77%)	90 (79%)	124 (77%)	23 (82%)	53 (73%)	200 (76%)	290 (77%)
Female	5 (12%)	6 (38%)	13 (23%)	24 (21%)	37 (23%)	5 (18%)	20 (27%)	62 (24%)	86 (23%)
Dominating injury type									
Penetrating	3 (7%)	2 (13%)	0 (0%)	5 (4%)	10 (6%)	1 (4%)	1 (1%)	12 (5%)	17 (5%)
Blunt	38 (93%)	14 (88%)	57 (100%)	109 (96%)	151 (94%)	27 (96%)	72 (99%)	250 (95%)	359 (95%)
Blunt multisystem trauma	0 (0%)	1 (6%)	3 (5%)	4 (4%)	2 (1%)	1 (4%)	3 (4%)	6 (2%)	10 (3%)
Severe traumatic brain injury	3 (8%)	0 (0%)	3 (5%)	6 (5%)	7 (4%)	1 (4%)	2 (3%)	10 (4%)	16 (4%)
Missing	1	0	0	1					1
Shock (SBP ≤ 90 mmHg)	0 (0%)	1 (7%)	0 (0%)	1 (1%)	4 (3%)	1 (4%)	4 (6%)	9 (4%)	10 (3%)
Missing	3	1	1	5	4	2	3	9	14
Respiratory rate, breaths per minute	20 (18, 21)	22 (20, 24)	21 (19, 23)	20 (18, 22)	20 (18, 22)	21 (19, 24)	22 (20, 25)	21 (19, 23)	20 (19, 23)
Missing	4	0	3	7	3	0	2	5	12
Oxygen saturation, %	98 (98, 99)	98 (96, 99)	98 (97, 98)	98 (97, 99)	98 (97, 99)	98 (97, 99)	98 (98, 99)	98 (98, 99)	98 (97, 99)
Missing	1	1	0	2					2
Heart rate, beats per minute	86 (80, 97)	94 (74, 106)	90 (79, 104)	88 (80, 100)	85 (80, 95)	86 (73, 97)	90 (74, 105)	86 (78, 100)	86 (78, 100)
Missing	1	0	1	2	0	1	0	1	3
Systolic blood pressure, mmHg	126 (116, 130)	128 (113, 150)	123 (115, 138)	124 (115, 133)	123 (112, 136)	124 (113, 130)	120 (110, 136)	123 (111, 136)	123 (112, 135)
Missing	3	1	1	5	4	2	3	9	14
Glasgow Coma Scale	15 (15, 15)	15 (15, 15)	15 (15, 15)	15 (15, 15)	15 (15, 15)	15 (15, 15)	15 (15, 15)	15 (15, 15)	15 (15, 15)
Missing	1	1	0	2	1	0	0	1	3
Injury Severity Score	1 (1, 4)	4 (1, 25)	4 (2, 16)	4 (1, 14)	4 (1, 9)	4 (1, 4)	4 (1, 5)	4 (1, 6)	4 (1, 8)

Characteristic	Before training				After training				Overall
	Standard care N = 41[1]	**ATLS** N = 16[1]	**PTC** N = 57[1]	**Overall** N = 114[1]	**Standard care** N = 161[1]	**ATLS** N = 28[1]	**PTC** N = 73[1]	**Overall** N = 262[1]	**N = 376**[1]
Missing	5	2	18	25	32	3	17	52	77
In-hospital mortality	2 (5%)	0 (0%)	4 (7%)	6 (5%)	19 (12%)	1 (4%)	3 (4%)	23 (9%)	29 (8%)
30 day mortality	1 (3%)	0 (0%)	5 (10%)	6 (6%)	22 (16%)	1 (4%)	3 (5%)	26 (12%)	32 (10%)
Missing	3	2	8	13	26	2	12	40	53
24 hour mortality	1 (2%)	0 (0%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)
Missing	0	2	5	7	7	2	8	17	24
Self-ambulatory at discharge	37 (95%)	11 (92%)	47 (96%)	95 (95%)	135 (99%)	24 (100%)	68 (97%)	227 (98%)	322 (97%)
Missing	2	4	8	14	24	4	3	31	45
Return to work	12 (41%)	5 (83%)	31 (74%)	48 (62%)	56 (53%)	11 (58%)	40 (70%)	107 (59%)	155 (60%)
Missing	12	10	15	37	56	9	16	81	118
Pulmonary complication	0 (0%)	0 (0%)	1 (2%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)
Missing	2	6	11	19	33	5	10	48	67
Septic complication	1 (3%)	0 (0%)	2 (4%)	3 (3%)	1 (1%)	0 (0%)	2 (3%)	3 (1%)	6 (2%)
Missing	1	6	12	19	33	5	10	48	67
Renal failure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Missing	1	5	11	17	32	5	10	47	64
Coagulopathy	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)	1 (0%)	1 (0%)
Missing	1	6	12	19	32	5	10	47	66
Need for reexploration or resurgery	0 (0%)	0 (0%)	1 (2%)	1 (1%)	3 (3%)	0 (0%)	1 (2%)	4 (2%)	5 (2%)
Missing	1	4	10	15	42	6	10	58	73
Failure of conservative management	0 (0%)	0 (0%)	1 (2%)	1 (1%)	2 (2%)	2 (8%)	1 (2%)	5 (2%)	6 (2%)
Missing	2	10	11	23	44	3	12	59	82
EQ-5D mobility at discharge									
I have no problems in walking	24 (62%)	8 (67%)	34 (83%)	66 (72%)	73 (62%)	16 (89%)	55 (92%)	144 (73%)	210 (73%)
I have some problems in walking	7 (18%)	1 (8%)	5 (12%)	13 (14%)	22 (19%)	2 (11%)	3 (5%)	27 (14%)	40 (14%)
I am confined to bed	8 (21%)	3 (25%)	2 (5%)	13 (14%)	23 (19%)	0 (0%)	2 (3%)	25 (13%)	38 (13%)
Missing	2	4	16	22	43	10	13	66	88
EQ-5D self-care at discharge									

Characteristic	Before training				After training				Overall
	Standard care N = 41[1]	**ATLS** N = 16[1]	**PTC** N = 57[1]	**Overall** N = 114[1]	**Standard care** N = 161[1]	**ATLS** N = 28[1]	**PTC** N = 73[1]	**Overall** N = 262[1]	**N = 376**[1]
I have no problems with self-care	23 (59%)	7 (58%)	33 (80%)	63 (68%)	59 (50%)	12 (67%)	51 (85%)	122 (62%)	185 (64%)
I have some problems bathing or dressing myself	6 (15%)	2 (17%)	5 (12%)	13 (14%)	36 (31%)	2 (11%)	5 (8%)	43 (22%)	56 (19%)
I am unable to bathe or dress myself	10 (26%)	3 (25%)	3 (7%)	16 (17%)	23 (19%)	4 (22%)	4 (7%)	31 (16%)	47 (16%)
Missing	2	4	16	22	43	10	13	66	88
EQ-5D usual activities at discharge									
I have no problems in performing my usual activities	21 (54%)	6 (50%)	31 (76%)	58 (63%)	55 (47%)	11 (61%)	51 (85%)	117 (60%)	175 (61%)
I have some problems in performing my usual activities	11 (28%)	3 (25%)	6 (15%)	20 (22%)	45 (38%)	4 (22%)	5 (8%)	54 (28%)	74 (26%)
I am unable to perform my usual activities	7 (18%)	3 (25%)	4 (10%)	14 (15%)	18 (15%)	3 (17%)	4 (7%)	25 (13%)	39 (14%)
Missing	2	4	16	22	43	10	13	66	88
EQ-5D pain/discomfort at discharge									
I have no pain or discomfort	13 (33%)	4 (33%)	14 (34%)	31 (34%)	30 (25%)	9 (50%)	39 (65%)	78 (40%)	109 (38%)
I have moderate pain or discomfort	16 (41%)	8 (67%)	26 (63%)	50 (54%)	41 (35%)	9 (50%)	18 (30%)	68 (35%)	118 (41%)
I have extreme pain or discomfort	10 (26%)	0 (0%)	1 (2%)	11 (12%)	47 (40%)	0 (0%)	3 (5%)	50 (26%)	61 (21%)
Missing	2	4	16	22	43	10	13	66	88
EQ-5D anxiety/depression at discharge									
I am not anxious or depressed	31 (79%)	6 (50%)	30 (73%)	67 (73%)	108 (92%)	15 (83%)	57 (95%)	180 (92%)	247 (86%)
I am moderately anxious or depressed	7 (18%)	6 (50%)	10 (24%)	23 (25%)	8 (7%)	3 (17%)	3 (5%)	14 (7%)	37 (13%)
I am extremely anxious or depressed	1 (3%)	0 (0%)	1 (2%)	2 (2%)	2 (2%)	0 (0%)	0 (0%)	2 (1%)	4 (1%)
Missing	2	4	16	22	43	10	13	66	88
EQ-5D mobility at 30 day follow-up									

Characteristic	Before training				After training				Overall
	Standard care N = 41[1]	**ATLS** N = 16[1]	**PTC** N = 57[1]	**Overall** N = 114[1]	**Standard care** N = 161[1]	**ATLS** N = 28[1]	**PTC** N = 73[1]	**Overall** N = 262[1]	**N = 376**[1]
I have no problems in walking	20 (65%)	4 (67%)	39 (91%)	63 (79%)	79 (77%)	16 (80%)	57 (98%)	152 (84%)	215 (83%)
I have some problems in walking	4 (13%)	1 (17%)	3 (7%)	8 (10%)	17 (17%)	4 (20%)	0 (0%)	21 (12%)	29 (11%)
I am confined to bed	7 (23%)	1 (17%)	1 (2%)	9 (11%)	6 (6%)	0 (0%)	1 (2%)	7 (4%)	16 (6%)
Missing	10	10	14	34	59	8	15	82	116
EQ-5D self-care at 30 day follow-up									
I have no problems with self-care	22 (71%)	5 (83%)	39 (91%)	66 (83%)	81 (79%)	16 (80%)	56 (97%)	153 (85%)	219 (84%)
I have some problems bathing or dressing myself	2 (6%)	1 (17%)	2 (5%)	5 (6%)	15 (15%)	2 (10%)	0 (0%)	17 (9%)	22 (8%)
I am unable to bathe or dress myself	7 (23%)	0 (0%)	2 (5%)	9 (11%)	6 (6%)	2 (10%)	2 (3%)	10 (6%)	19 (7%)
Missing	10	10	14	34	59	8	15	82	116
EQ-5D usual activities at 30 day follow-up									
I have no problems in performing my usual activities	22 (71%)	6 (100%)	39 (91%)	67 (84%)	83 (81%)	15 (75%)	55 (95%)	153 (85%)	220 (85%)
I have some problems in performing my usual activities	6 (19%)	0 (0%)	2 (5%)	8 (10%)	12 (12%)	3 (15%)	1 (2%)	16 (9%)	24 (9%)
I am unable to perform my usual activities	3 (10%)	0 (0%)	2 (5%)	5 (6%)	7 (7%)	2 (10%)	2 (3%)	11 (6%)	16 (6%)
Missing	10	10	14	34	59	8	15	82	116
EQ-5D pain/discomfort at 30 day follow-up									
I have no pain or discomfort	23 (74%)	4 (67%)	33 (77%)	60 (75%)	81 (79%)	16 (80%)	50 (86%)	147 (82%)	207 (80%)
I have moderate pain or discomfort	8 (26%)	2 (33%)	9 (21%)	19 (24%)	19 (19%)	4 (20%)	8 (14%)	31 (17%)	50 (19%)
I have extreme pain or discomfort	0 (0%)	0 (0%)	1 (2%)	1 (1%)	2 (2%)	0 (0%)	0 (0%)	2 (1%)	3 (1%)
Missing	10	10	14	34	59	8	15	82	116
EQ-5D anxiety/depression at 30 day follow-up									

Characteristic	Before training				After training				Overall
	Standard care N = 41[1]	**ATLS** N = 16[1]	**PTC** N = 57[1]	**Overall** N = 114[1]	**Standard care** N = 161[1]	**ATLS** N = 28[1]	**PTC** N = 73[1]	**Overall** N = 262[1]	**N = 376**[1]
I am not anxious or depressed	30 (97%)	6 (100%)	37 (86%)	73 (91%)	97 (95%)	17 (85%)	56 (97%)	170 (94%)	243 (93%)
I am moderately anxious or depressed	1 (3%)	0 (0%)	5 (12%)	6 (8%)	4 (4%)	3 (15%)	2 (3%)	9 (5%)	15 (6%)
I am extremely anxious or depressed	0 (0%)	0 (0%)	1 (2%)	1 (1%)	1 (1%)	0 (0%)	0 (0%)	1 (1%)	2 (1%)
Missing	10	10	14	34	59	8	15	82	116
Patient satisfaction									
Very satisfied	26 (67%)	9 (64%)	37 (73%)	72 (69%)	97 (70%)	19 (79%)	66 (94%)	182 (78%)	254 (76%)
Somewhat satisfied	9 (23%)	5 (36%)	8 (16%)	22 (21%)	20 (14%)	3 (13%)	4 (6%)	27 (12%)	49 (15%)
Somewhat dissatisfied	3 (8%)	0 (0%)	2 (4%)	5 (5%)	13 (9%)	1 (4%)	0 (0%)	14 (6%)	19 (6%)
Very dissatisfied	1 (3%)	0 (0%)	4 (8%)	5 (5%)	8 (6%)	1 (4%)	0 (0%)	9 (4%)	14 (4%)
Missing	2	2	6	10	23	4	3	30	40
Number of hospitalizations for this injury	0 (0%)	1 (17%)	3 (6%)	4 (4%)	6 (5%)	0 (0%)	0 (0%)	6 (3%)	10 (3%)
Missing	2	10	8	20	34	3	11	48	68
EQ-5D health state at discharge	50 (3, 90)	60 (40, 90)	80 (60, 90)	75 (40, 90)	50 (4, 80)	65 (50, 80)	90 (79, 100)	70 (5, 90)	70 (10, 90)
Missing	10	5	16	31	48	10	19	77	108
EQ-5D health state at 30 day follow-up	10 (7, 100)	100 (60, 100)	100 (89, 100)	99 (70, 100)	83 (9, 100)	83 (70, 100)	100 (95, 100)	100 (45, 100)	100 (50, 100)
Missing	14	10	15	39	61	8	17	86	125
Cost of treatment	14,000 (500, 53,000)	7,000 (0, 14,000)	2,025 (500, 11,000)	3,000 (500, 15,000)	2,500 (500, 25,000)	5,000 (0, 15,000)	1,500 (200, 3,000)	2,000 (299, 13,000)	2,000 (500, 14,000)
Missing	23	14	18	55	90	21	21	132	187

[1]Median (Q1, Q3); n (%)

PROTOCOL: Does trauma life support training improve patient outcomes?

A pilot cluster randomised controlled trial

Version: 2021-05-25 (#1621970441)

Contents

1 Introduction

Trauma, defined as the clinical entity composed of physical injury and the body's associated response, causes 4.5 millions deaths every year.[1] Trauma is the top cause of death in children and young adults aged between 5 and 29 years. In addition, almost 10% of the global burden of disease is due to trauma.

Trauma care is time sensitive and early management of life or limb threatening conditions is crucial. Several trauma life support training programs have been developed to improve the early management of patients as they arrive at hospital by providing a structured framework to assessment and treatment.[2–4]

The proprietary Advanced Trauma Life Support (ATLS) is the most established trauma life support training program and more than one million doctors in over 80 countries have been trained in the program.[5] Uptake in low- and middle income countries (LMIC) has been slow, potentially due to high costs.[4]

The free Primary Trauma Care (PTC) program is the most widely spread alternative program. The goal of PTC is to improve trauma care in LMIC.[6] PTC has been endorsed by the World Health Organization (WHO).[7]

Despite these training programs being widely used there are no published controlled trials showing that they improve patient outcomes.[2–4] There is level 1 evidence that these programs improve provider skills and some observational data suggesting that they also improve patient outcomes.

We will perform a pilot study that aims to assess the feasibility of conducting a cluster randomised controlled trial comparing ATLS and PTC with standard care. The objectives of this pilot study will be to:

- Estimate probable effect sizes on patient outcomes associated with ATLS and PTC compared with standard care, as a basis for future sample size calculations.
- Assess the feasibility of collecting data on primary and secondary outcomes, such as mortality, in-hospital complications, length of stay, and quality of life.
- Assess how the effect sizes and directions of these effects of ATLS and PTC differ across clinically important subgroups.

2 Methods

2.1 Trial design

This study will pilot a pragmatic three-armed parallel, cluster randomised, controlled trial.

2.2 Participants

There will be two groups of participants: patients and resident doctors.

Patient participants

Adults (15 years or older) who present to the emergency department at participating hospitals with a history of trauma. History of trauma is here defined as having any of the external causes of morbidity and mortality listed in block V01-Y36, chapter XX of the International Classification of Disease version 10 (ICD-10) codebook as reason for admission. We will explore intervention effects across the following clinical subgroups: men, women, blunt multisystem, penetrating, shock, severe traumatic brain injury, and elderly.

Resident doctor participants

Resident doctors doing their specialty training in surgery or emergency medicine, who manage trauma patients in the emergency department, and who are expected to remain in the participating hospitals for at least on year. One or two units' doctors will be selected from each hospital. One unit consists of at least three faculty and three to twelve residents who are posted in the emergency department duty on fixed days of the week.

To be eligible, units should have a maximum of 25% of the doctors trained in either ATLS, PTC, or similar training program. We will select the units by conducting a prior survey to ascertain this criteria. Those residents who have received training in the last five years will be considered as trained. Consent will be sought from the trainees in each of these groups before they undergo the ATLS or PTC training.

Clusters

Indian tertiary care hospitals that admit 400-800 adult patients with trauma each year. We randomise on the cluster (hospital) level to avoid contamination between intervention and control arms. To be eligible for inclusion hospitals have to provide the following services round the clock: operation theatres, X-ray, CT, and ultrasound facilities, and blood bank. In addition the baseline admission rate should be more than 35 adult patients with major trauma per month.

Interventions

There will be two intervention groups, ATLS and PTC training, and one control group, standard care. In each intervention group one or two units' residents and faculty on call per hospital providing emergency care to trauma patients will be trained in either ATLS or PTC. For the purpose of this pilot study, we will target to train a minimum of 75% of doctors in each unit. If unit members drop out or change units after training but before data collection is completed we will conduct additional training if needed to meet the 75% criterion.

The ATLS training will be conducted in the nearest ATLS certified training centre in India. The PTC training will be arranged in hospital/s which have been randomized to the PTC arm. These courses will be conducted over a period of 2.5 to 3 days. The residents certified "pass" will be considered as trained in respective courses.

The control group provides standard care with no intervention. We will ensure that less than 25% of the total doctors in the control arm are trained in any trauma life support course (ATLS or PTC or similar).

2.3 Data Collection

Data collection will begin after the training has been delivered. A one month variability in the date when data collection is started between hospitals will be accepted. Each participating hospital will have a dedicated research officer to collect data. The research officers will have a masters in a health science field and should have experience in data collection. Because participating doctors are assigned designated days for trauma care for a period of 6 months, data will be collected during those particular days when these trauma courses trained doctors are present in the emergency department.

Data will be collected for a period of minimum three to four months after training. The research officers will collect data of all patients, who present with trauma in the surgical bay during the duty hours of the research officers. Those patients who are admitted will be followed up for complications and other outcome measures like length of stay. Those patients who are not admitted will be followed up for mortality outcomes and quality of life outcomes.

The research officer will administer the study information and informed consent (consent will only be sought for data collection including follow up) to the patient, or the patient's relatives as appropriate, once the patient is stabilised. They will continue to collect data once they have received the consent.

Details of data of those patients/relatives not willing to give consent will be removed from the analysis. The number of patients who opt out from data collection will be collected, as well as limited data on their age and sex. Patients will be followed up in the ward regularly for the various outcome variables. They will also be followed up telephonically after they have been discharged.

2.4 Variables

The project officers will collect data on demographics, time of injury to arrival at the participating hospital, time to recording vital signs, vital signs, and times to and details of imaging and surgery. Details of any injury sustained will be collected and we will calculate injury severity scores using these details.

2.5 Outcomes

Our primary outcome is all cause mortality within 30 days from arrival to the emergency department. All outcomes pertain to the individual patient level.

Our secondary outcomes are:

- All cause mortality within 24 hours from arrival to the emergency department.
- Time to death during follow up.
- Presumed cause of death as judged by the treating physician.
- Adherence to the WHO trauma care checklist.
- Fluids for resuscitation in first one hour in patients.
- Massive transfusion, defined as four or more units of packed red blood cells, plasma or platelets transfused within the first 24 hours after arrival to the emergency department.
- Time to surgery.
- Time to intubation.
- Time to CT scan.
- Ventilator free days.
- ICU free days.
- Pulmonary complications.
- Septic shock.
- Renal failure.
- Coagulopathy.
- Length of stay.
- Quality of life.
- Number of hospitalizations.
- Return to work.
- Need for re-exploration.
- Failure of conservative management.
- Patient satisfaction.
- Cost of treatment.
- Self-ambulatory.
- Residents' confidence in managing trauma patients.

2.6 Randomization

We will prepare six sealed envelopes of which one representative from each pilot site will draw one. The content of the envelope will dictate what trial arm (ATLS, PTC, or standard care) the pilot site will be in.

2.7 Sequence generation

There will be two pilot sites in each trial arm.

2.8 Allocation concealment mechanism

Allocation will be based on clusters.

2.9 Implementation

The random allocation sequence will be generated by the project management, who also enrol clusters. Representatives from the pilot sites will draw from the sealed envelopes during a common meeting. Patient participants will be included if they present during the project officers shift. Resident participants are enrolled if they are in the units selected for training. We will use random sampling to select units if there are more than two eligible units in a hospital. For patient participant consent for follow up is sought after randomisation from patients or patient relatives as appropriate. For resident participants consent is sought before randomisation from the residents.

2.10 Blinding (masking)

Participating clusters will not be blinded to the intervention.

2.11 Sample size

Each of these units from one hospital see 2-4 trauma patients per week. If we select a minimum one unit per hospital then each cluster will get 4-6 patients per week and 16-20 patients per month. Over a period of 3 months we expect each of the hospitals to have 39-60 patients. With a 10% attrition rate we assume each hospital to have 35-54 patients over a period of 3 months.

3 Participant Information Sheets and Informed Consent Forms

Starts on the next page.

3.1 Patient Information Sheet - English

You are being invited to participate in a research study. Before your data can be included in this data bank the purpose of the data collection must be explained to you, and you must be given the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the informed consent form. You will be given a copy of this document to take home with you.

Protocol Title Trauma Training Effectiveness Pilot Study

Principal Investigator [ADD NAME OF PRINCIPAL INVESTIGATOR HERE]

Purpose of the research study

We are currently conducting research in this hospital to study the feasibility of assessing the effect of trauma life support training programs on care and outcome of patients with injury. We ask you to participate in this study because you presented to this hospital after having an injury.

Study procedures and visit schedule

If you agree to participate, we will:

- Store health data registered in your hospital records and vital signs recordings from the emergency department
- Contact you in person or by telephone for follow ups to obtain information about your health status at the following times:
  - On arrival at the emergency department and wards till you are discharged
  - On hospital discharge
  - 24 hours after arrival to the hospital
  - 30 days after arrival to the hospital

When you arrived at the hospital, we recorded some basic parameters such as your age, gender, and how you were injured. We also recorded health data such as blood pressure, heart rate, oxygen levels, respiratory rate, surgical care and treatment provided. During your stay, we will record periodically health data, the investigations and treatment that you have undergone.During the follow-up calls, we may ask you details about your health and general information on returning back to your normal life and experience of the injury in your life. If you want complete information regarding all the parameters that were recorded, please do not hesitate to ask, and we will be happy to inform you.

Should you wish that your data is deleted from the study, you may please tell us now or contact us using the contact information provided below. The results of the study may be used for research that can be published as scientific articles; however, it will not be possible to identify you by reading any article that may result from this data bank. Further, data from this project will be combined with data from other hospitals that use the same system and shared for other researchers and individuals to use, but it will not be possible to identify you using that data. Research on the data without identifiers may seek to answer other questions than those stated above.

Withdrawal from study

Participation in this study is completely voluntary. Even if you agree to participate now you are free to withdraw at any time without giving any reason for doing so. Withdrawing will not affect your ordinary treatment or the care given to you. To withdraw contact any of the contact persons using the contact information provided. Note that we can only delete data from the data collected in this hospital. We cannot delete data once it has been de-identified because we will not be able to tell from whom the data came.

Possible risks, discomforts and inconveniences

We have not been able to identify any major risks associated with participating in this study. Even if you agree to participate now you are free to withdraw at any time without giving any reason for doing so. You are free to withdraw at that point, or at any time using the contact information provided below.

Potential benefits

This research may help to improve the care of injured patients. Although this study will not affect the care you are given in this hospital at this time, your participation will contribute to medical knowledge, and may improve care for you if you are injured again in the future care for others that are injured.

Subject's rights

Your participation in this study is entirely voluntary. Your questions will be answered clearly and to your satisfaction. In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you will be informed in a timely manner by the Principal Investigator or his/her representative.

Confidentiality of study and medical records

The results of this research may be published as a scientific article; however, it will not be possible to identify you by reading any article that may result from this work. Further, data from this project will be combined with data from other hospitals that use the same system and shared for other researchers and individuals to use, but it will not be possible to identify you using that data.

Also, Regulatory Agencies, Institutional Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you are authorizing such access to your study and medical records.

Costs of participation

No charge will be levied on you if you take part in this study. You will not receive any compensation for participating in this study.

Research related injury and compensation

Due to the nature of this project, it is unlikely to cause any research related injury. The hospital will provide medical care for any problems that may arise during this study.

Whom to contact if you have questions

If you have questions regarding this study and your rights, or in the case of any injuries sustained during this project, you may contact the Principal Investigator.

3.2 Patient Information Sheet - Hindi | रोगी सूचना पत्र

आपको एक शोध अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है। इससे पहले कि आपकी जानकारी को इस डेटा बैंक में शामिल किया जा सके डेटा संग्रह का उद्देश्य आपको समझाया जाना चाहिए, और आपको प्रश्न पूछने का मौका दिया जाना चाहिए। कृपया यहां दी गई जानकारी को ध्यान से पढ़ें। यदि आप भाग लेने के लिए सहमत हैं, तो कृपया सूचित सहमति फॉर्म पर हस्ताक्षर करें। आपको अपने साथ घर ले जाने के लिए इस दस्तावेज की एक प्रति दी जाएगी।

प्रोटोकॉल शीर्षक

प्रमुख अन्वेषक

अनुसंधान अध्ययन का उद्देश्य

हम वर्तमान में चोटिल रोगियों की देखभाल और परिणाम पर ट्रामा लाइफ सपोर्ट ट्रेनिंग प्रोग्राम के प्रभाव का आकलन करने की व्यवहार्यता का अध्ययन करने के लिए इस अस्पताल में अनुसंधान का आयोजन कर रहे हैं। हम आपको इस अध्ययन में भाग लेने के इसलिए पूछते हैं क्योंकि चोट लगने के बाद आप इस अस्पताल में आये हैं।

अध्ययन प्रक्रियायें और भेंट अनुसूची

यदि आप भाग लेने के लिए सहमत हैं, हम:

- अस्पताल के रिकॉर्ड में पंजीकृत स्वास्थ्य डेटा और आपातकालीन विभाग से महत्वपूर्ण संकेत रिकॉर्डिंग स्टोर करें। - निम्नलिखित समय में आप के स्वास्थ्य स्थिति के बारे में जानकारी प्राप्त करने के लिए फॉलो अप के लिए व्यक्तिगत या टेलीफोन द्वारा आपसे संपर्क करते है:

- आपातकालीन विभाग और वार्डों में आगमन पर और जब तक आप को छुट्टी ना मिले - अस्पताल के डिस्चार्ज पर - अस्पताल पहुंचने के 24 घंटे बाद - अस्पताल पहुंचने के 30 दिन बाद

जब आप अस्पताल पहुंचे, तो हमने कुछ बुनियादी मापदंडो जैसे आपकी उम्र, लिंग और आप कैसे घायल हुए। हमने रक्तचाप, हृदय गति, ऑक्सीजन का स्तर, श्वसन दर, शल्य चिकित्सा देखभाल और प्रदान किए गए उपचार जैसे स्वास्थ्य डेटा को भी दर्ज किया। आपके अस्पताल में ठहरने के दौरान, हम समय-समय पर स्वास्थ्य डेटा, आपकी की गई जांच और उपचार को रिकॉर्ड करेंगे। फॉलोअप कॉल के दौरान, हम आपसे आपके सामान्य जीवन में वापस लौटने और आपके जीवन में चोट के अनुभव के बारे में आपके स्वास्थ्य और सामान्य जानकारी के बारे में विवरण पूछ सकते हैं।

क्या आप चाहते हैं कि आपका डेटा अध्ययन से हटा दिया जाए, आप कृपया हमें अब बता सकते हैं या नीचे दी गई संपर्क जानकारी का उपयोग करके हमसे संपर्क कर सकते हैं। अध्ययन के परिणामों का उपयोग अनुसंधान के लिए किया जा सकता है जिसे वैज्ञानिक लेखों के रूप में प्रकाशित किया जा सकता है; हालांकि, इस डेटा बैंक से परिणाम देने वाले किसी भी लेख को पढ़कर आपकी पहचान करना संभव नहीं होगा। इसके अलावा, इस परियोजना से डेटा को अन्य अस्पतालों के डेटा के साथ जोड़ा जाएगा जो एक ही प्रणाली का उपयोग करते हैं और उपयोग करने के लिए अन्य शोधकर्ताओं और व्यक्तियों के लिए साझा करते हैं, लेकिन उस डेटा का उपयोग करके आपकी पहचान करना संभव नहीं होगा। पहचानकर्ताओं के बिना डेटा पर अनुसंधान ऊपर बताए गए लोगों की तुलना में अन्य सवालों के जवाब देने की मांग कर सकते हैं।

अध्ययन से वापसी

इस अध्ययन में भागीदारी पूरी तरह से स्वैच्छिक है। यहां तक कि अगर आप अब भाग लेने के लिए सहमत हैं तो आप ऐसा करने के लिए कोई कारण दिए बिना किसी भी समय वापस लेने के लिए स्वतंत्र हैं। वापस लेने से आपके साधारण उपचार या आपको दी गई देखभाल प्रभावित नहीं होगी। प्रदान की गई संपर्क जानकारी का उपयोग करके किसी भी संपर्क व्यक्ति से संपर्क वापस लेना। ध्यान दें कि हम केवल इस अस्पताल में एकत्र किए गए डेटा से डेटा हटा सकते हैं। एक बार डाटा को डी-आइडेंटिफाई करने के बाद हम डेटा डिलीट नहीं कर सकते क्योंकि हम यह नहीं बता पाएंगे कि कौन सा डेटा किससे आया था।

संभावित जोखिम, बेचैनी और असुविधायें

हम इस अध्ययन में भाग लेने के साथ जुड़े किसी भी प्रमुख जोखिम की पहचान करने में सक्षम नहीं किया है। यहां तक कि अगर आप अब भाग लेने के लिए सहमत हैं तो आप ऐसा करने के लिए कोई कारण दिए बिना किसी भी समय वापस लेने के लिए स्वतंत्र हैं। आप उस बिंदु पर, या नीचे दी गई संपर्क जानकारी का उपयोग करके किसी भी समय वापस लेने के लिए स्वतंत्र हैं।

संभावित लाभ

इस शोध से घायल मरीजों की देखभाल में सुधार हो सकता है। हालांकि इस अध्ययन से आपको इस समय इस अस्पताल में दिया जाने वाला देखभाल प्रभावित नहीं होगा, आपकी भागीदारी चिकित्सा ज्ञान के लिए योगदान देगा, और आप के लिए देखभाल में सुधार हो सकता है अगर आप फिर से दुबारा घायल होते है या दूसरों के लिए भविष्य में घायल होने पर सुधार मिल सकता हैं।

वषिय के अधकिार

इस अध्ययन में आपकी भागीदारी पूरी तरह से स्वैच्छकि है । आपके सवालो के जवाब स्पष्ट रूप से और आपकी संतुष्टि के लिए दिए जाएंगे। किसी भी नई जानकारी के उपलब्ध होने की स्थिति में जो इस अध्ययन में जारी रखने की आपकी इच्छा के लिए प्रासंगकि हो सकती है, आपको प्रधान अन्वेषक या उसके प्रतिनिधि द्वारा समय पर सूचति कयिा जाएगा।

अध्ययन और मेडकिल रकिॉर्ड की गोपनीयता

इस शोध के परणिाम एक वैज्ञानकि लेख के रूप में प्रकाशति कए जा सकते हैं; हालांकि, इस काम से परणिाम देने वाले किसी भी लेख को पढ़कर आपकी पहचान करना संभव नही होगा। इसके अलावा, इस परयिोजना से डेटा को अन्य अस्पतालो के डेटा के साथ जोड़ा जाएगा जो एक ही प्रणाली का उपयोग करते हैं और उपयोग करने के लिए अन्य शोधकर्ताओं और व्यक्तियों के लिए साझा करते हैं, लेकनि उस डेटा का उपयोग करके आपकी पहचान करना संभव नहीं होगा।

इसके अलावा, नयिामक एजेंसयिों, संस्थागत समीक्षा बोर्ड और स्वास्थ्य मंत्रालय को आपकी किसी भी जानकारी को सार्वजनकि कए बनिा अध्ययन प्रक्रयिाओं और डेटा की जांच करने के लिए आपके मूल मेडकिल रकिॉर्ड तक सीधी पहुंच प्रदान की जाएगी। संलग्न सूचति सहमति फॉर्म पर हस्ताक्षर करके, आप अपने अध्ययन और मेडकिल रकिॉर्ड तक ऐसी पहुंच को अधकिृत कर रहे हैं।

भागीदारी की लागत

यदि आप इस अध्ययन में भाग लेते हैं तो आप की भागीदारी पर कोई शुल्क नहीं लगाया जाएगा। इस अध्ययन में भाग लेने के लिए आपको कोई मुआवजा नहीं मलिेगा।

अनुसंधान से संबंधति चोट और मुआवजा

इस परयिोजना की अवलोकन प्रकृति के कारण, यह किसी भी अनुसंधान से संबंधति चोट का कारण होने की संभावना नहीं है। इस अध्ययन के दौरान उत्पन्न होने वाली किसी भी समस्या के लिए अस्पताल चकित्सिा देखभाल प्रदान करेगा।

यदि आपके पास प्रश्न हैं, तो संपर्क करें-

यदि आपके पास इस अध्ययन और आपके अधकिारों, या किसी चोट के मामले में प्रश्न हैं इस परयिोजना के दौरान नरितर, आप प्रधान अन्वेषक से संपर्क कर सकते हैं।

3.3 Patient Information Sheet - Marathi | भागीदार माहिती पत्रक

आपल्याला एका संशोधन अभ्यासामध्ये भाग घेण्यासाठी आमंत्रित केले जात आहे. आपला डेटा समाविष्ट करण्यापूर्वी हा डेटा बँक मध्ये डेटा संकलनाचा हेतू आपल्याला समजावून सांगला जाणे आवश्यक आहे आणि प्रश्न विचारण्याची संधी दिली पाहिजे. कृपया येथे प्रदान केलेली माहिती काळजीपूर्वक वाचा. आपण सहभागी होण्यास सहमत असल्यास, कृपया माहिती संमती फॉर्म स्वाक्षरी करा. आपल्याला आपल्याकडे ठेवण्यासाठी आपल्याला या दस्तऐवजाची एक प्रत दिली जाईल.

प्रोटोकॉल शीर्षक

प्रधान अन्वेषक

संशोधन अभ्यासाचा हेतू

आम्ही या रुग्णालयात जखम झालेल्या रूग्णांची काळजी आणि परिणाम यावर आघात जीवन समर्थन प्रशिक्षण कार्यक्रमांचा परिणाम याची तपासणी करण्याच्या व्यवहार्यतेचा अभ्यास करण्यासाठी सध्या संशोधन करीत आहोत. आम्ही आपणास या अभ्यासामध्ये सहभागी होण्यास सांगू कारण आपणास या रुग्णालयात दुखापत झाल्यानंतर सादर केल आहे.

अभ्यास प्रक्रिया आणि भेट वेळापत्रक

आपण सहभागी होण्यास सहमत असल्यास, आम्ही असे करू:

- आपल्या रुग्णालयातील नोंदीमध्ये नोंदवलिले आरोग्य डेटा आणि त्यामधील महत्त्वपूर्ण चिन्हे रेकॉर्डगि आपत्कालीन वभिाग मधून जमा करु. - आपल्याबद्दल माहिती मळिवण्यिासाठी आपल्यास पाठपुरावासाठी व्यक्तगितपणे कविा टेलफिोनद्वारे खालील वेळी आरोग्याची स्थिती साठी संपर्क साधू.

- आपत्कालीन वभिाग आणि प्रभागात आगमना वर डस्चिार्ज होईपर्यंत. - रुग्णालयातील डस्चिार्ज होईपर्यंत. - रुग्णालयात दाखल झाल्यानंतर 24 तासानंतर. - रुग्णालयात दाखल झाल्यानंतर 30 दविसानंतर.

जेव्हा आपण रुग्णालयात पोहोचलो आम्ही आपले वय, लगि आणि आपण कसे जखमी झाले यासारखी काही मूलभूत मापदंड नोंदवलिी. आम्ही आरोग्य डेटा देखील नोंदवलिा, जसे की रक्तदाब, हृदय गती, ऑक्सजिन पातळी, श्वसन दर, शस्त्रक्रयिा काळजी आणि उपचार प्रदान. आपल्या रुग्णालयात थांब दरम्यान, आम्ही ठरावकि काळाने आरोग्याचा डेटा, आपल्याकडे असलेली तपासणी आणि उपचारांची नोंद ठेवू. पाठपुरावा कॉल दरम्यान आम्ही आपणास आपल्या आरोग्यावषियी आणि सामान्यबद्दल तपशील विचारू शकतो, आपल्या सामान्य आयुष्याकडे परत येण्याबद्दल माहिती आणि आपल्या आयुष्यातील दुखापतीचा अनुभव. आपल्याला रेकॉर्ड केलेल्या सर्व पॅरामीटर्सशी संबंधति संपूर्ण माहिती हवी आहे, तर अजबिात संकोच न करता कृपया करुन विचारा आणि आम्ही आपल्याला कळवण्यिात आनंदी होऊ.

आपला डेटा अभ्यासामधून हटवलिा पाहिजे अशी आपली इच्छा असल्यास आपण कृपया आम्हाला आत्ता सांगा कविा खाली दलिेली संपर्क माहिती वापरुन आमच्याशी संपर्क साधा. अभ्यासाचे नकिाल संशोधनासाठी वापरले जाऊ शकतात जे वैज्ञानकि लेख म्हणून प्रकाशति केले जाऊ शकतात;तथापि, या डेटा बँक मधून उद्भवू शकणारा कोणताही लेख वाचून आपणास ओळखणे शक्य होणार नाही. पुढे या प्रकल्पातील डेटा अन्य रुग्णालयांमधील डेटासह एकत्र केला जाईल, जी समान प्रणाली वापरते आणि इतर संशोधक आणि व्यक्तच्यि वापरण्यासाठी सामायकि करते, परंतु तो डेटा वापरुन आपल्याला ओळखणे शक्य नाही. अभज्ञिापकांशविाय डेटावर संशोधन करून वरील प्रश्नांव्यतरिक्ति इतर प्रश्नांची उत्तरे देण्याचा प्रयत्न करु शकेल.

अभ्यासातून माघार घेणे

या अभ्यासाचा सहभाग पूर्णपणे ऐच्छकि आहे. जरी आपण आता सहभागी होण्यासाठी सहमत आहात तरीही असे करण्यास कोणतेही कारण न देता कधीही माघार घेण्यास मोकळे आहेत. माघार घेतल्याने आपल्या सामान्य उपचारांवर कविा आपल्याला दलिेल्या काळजीवर परणिाम होणार नाही. तुम्हाला अभ्यासातून माघार घेण्यासाठी. खाली सूचीबद्ध केलेल्या कोणत्याही व्यक्तीशी नंबरवर कविा ईमेलवर संपर्क साधा. लक्षात ठेवा आम्ही केवळ या रुग्णालयात गोळा केलेल्या डेटा मधुन डेटा हटवू शकतो. एकदा तो डेटा अभज्ञिापकांशविाय केलय्या नंतर आम्ही हटवू शकत नाही कारण डेटा कोणाकडून आला हे सांगू शकणार नाही.

संभाव्य जोखीम, वसिंगती आणि गुंतवणूक

या अभ्यासामध्ये भाग घेण्याशी संबंधति कोणतेही मोठे धोके आम्ही ओळखू शकलो नाही. जरी आपण आता सहभागी होण्यास सहमत असाल तरीही आपण कधीही कारण न देता माघार घेण्यास मोकळे आहात. आपण या वेळी कविा इतर कोणत्याही वेळी, यात सहभागी होण्यास माघार घेण्यास मोकळे आहात.

संभाव्य फायदे

या संशोधन मधून जखमी रूग्णांची काळजी सुधारण्यासाठी मदत होवु शकते.

यावेळी या अभ्यासाचा आपल्याला या रुग्णालयात देण्यात आलेल्या काळजीवर परणिाम करणार नाही, आपला सहभाग वैद्यकीय ज्ञान यामध्ये योगदान देईल आणि भवष्यिात आपण कविा इतर पुन्हा जखमी झाल्यास आपली काळजी सुधारू शकेल.

रुग्णाचे हक्क

या अभ्यासामधील आपला पूर्णपणे ऐच्छकि आहे. तुमच्या प्रश्नांची स्पष्ट आणि समाधानकारक उत्तरे दलिी जातील. या अभ्यासामध्ये कोणतीही नवीन माहतिी उपलब्ध झाल्यास आणि ती आपल्या सहभाग सुरू ठेवण्याच्या संबंधति असेल, मग प्रधान अन्वेषक कवि प्रतनिधिीद्वारे आपल्याला वेळेवर तचिी माहतिी दलिी जाईल.

अभ्यास आणि वैद्यकीय अभलिेखांची गोपनीयता

या संशोधनाचे नकिाल वैज्ञानकि लेख म्हणून प्रकाशति केले जाऊ शकतात; तथापि,या कार्यामुळे उद्भवू शकणारा कोणताही लेख वाचून आपल्याला

ओळखणे शक्य होणार नाही आहे. पुढे या प्रकल्पातील डेटा अन्य रुग्णालयांमधील डेटासह एकत्र केला जाईल, जी समान प्रणाली वापरते आणि इतर संशोधक आणि व्यक्तच्यि वापरण्यासाठी सामायकि करते, परंतु तो डेटा वापरुन आपल्याला ओळखणे शक्य नाही. तसेच नयिामक एजन्सी, संस्थात्मक पुनरावलोकन मंडळ आणि आरोग्य मंत्रालय यांना कोणताही डेटा सार्वजनकि न करता या अभ्यासाचा भाग म्हणून एकत्रति केलेल्या डेटाचा थेट वापर यास मंजुरी दलिी जाईल. संलग्न माहतिी दलिेल्या संमती फॉर्मवर स्वाक्षरी करून, आपण अशा प्रवेशास अधकिृत करणे.

परचि्छेदन शुल्क

आपण या अभ्यासामध्ये भाग घेतल्यास आपल्यावर कोणतेही शुल्क आकारले जाणार नाही. या अभ्यासात भाग घेतल्याबद्दल आपल्याला काहीही भरपाई प्राप्त होणार नाही.

संशोधन आणि नुकसान भरपाई संबंधति

हा नरिक्षिण स्वरुपाचा अभ्यास असल्यास, त्यासंदर्भात कोणत्याही इजा असण्याची शक्यता नाही. या अभ्यासाच्या दरम्यान उद्भवणाऱ्या कोणत्याही समस्यांसाठी रुग्णालय वैद्यकीय सेवा पुरवेल.

आपल्याकडे प्रश्न असल्यास कोणाशी संपर्क साधावा

आपल्याकडे या अभ्यासाबद्दल आणि आपल्या अधकिारांबद्दल कवि या प्रकल्पात काही जखम झाल्यास, प्रश्न असल्यास

आपण प्रधान अन्वेषकांशी संपर्क साधू शकता.

3.4 Patient Information Sheet - Bengali | অংশগ্রহণকারীর তথ্য নথীপত্র

আপনাকে একটি গবেষণায় অংশ নিতে আমন্ত্রণ জানানো হচ্ছে। আপনার তথ্য এই তথ্য সংগ্রহালয়ে অন্তর্ভুক্ত করার আগে তথ্য সংগ্রহের উদ্দেশ্যটি আপনার কাছে অবশ্যই ব্যাখ্যা করতে হবে এবং আপনাকে অবশ্যই প্রশ্ন জিজ্ঞাসা করার সুযোগ দেওয়া হবে। এখানে প্রদত্ত তথ্যগুলি মনোযোগ সহকারে পড়ুন। আপনি যদি অংশ নিতে রাজি হন তবে দয়া করে অবহিতি সম্মতি ফর্মটিতে স্বাক্ষর করুন। আপনাকে বাড়িতে নিয়ে যাওয়ার জন্য এই দস্তাবেজের একটি অনুলিপি দেওয়া হবে।

প্রোটোকল শিরোনাম

প্রধান অবেক্ষক

গবেষণার উদ্দেশ্যের কারণ

আহত রোগীদের যত্ন এবং ফলাফলের উপর ট্রমা লাইফ সাপোর্ট প্রশিক্ষণ কর্মসূচির প্রভাব মূল্যায়নের সম্ভাব্যতা অধ্যয়নের জন্য আমরা বর্তমানে এই হাসপাতালে গবেষণা চালাচ্ছি। আমরা আপনাকে এই গবেষণায় অংশ নিতে বলছি কারণ আপনি এই হাসপাতালে আঘাতপ্রাপ্ত হয়ে এসেছেন।

অধ্যয়ন পদ্ধতি এবং পরিদর্শনের সময় সূচি

আপনি যদি অংশ নিতে সম্মত হন তবে আমরা:

- জরুরি বিভাগ থেকে আপনার স্বাস্থ্য সম্পর্কিত হাসপাতালের রেকর্ডে নিবন্ধিত গুরুত্বপূর্ণ শারীরবৃত্তীয় তথ্য সংরক্ষণ করব। - আপনার শারীরিক অবস্থা সম্পর্কে জানতে ব্যক্তিগতভাবে বা টেলিফোনে আপনার সাথে নিম্নোক্ত সময়ে যোগাযোগ করা হবে

- জরুরি বিভাগে এবং ওয়ার্ডে পৌঁছানোর সময় থেকে ছুটি হওয়া পর্যন্ত - হাসপাতাল থেকে ছুটি হওয়ার সময় - হাসপাতালে আসার ২৪ ঘন্টা পরে - হাসপাতালে আসার ৩০ দিন পরে

আপনি যখন হাসপাতালে পৌঁছেছিলেন তখন আমরা আপনার সম্পর্কে কিছু বুনিয়াদি তথ্য নথিভুক্ত করেছি, যেমন আপনার বয়স, লিঙ্গ এবং আপনি কীভাবে আহত হয়েছেন। আমরা স্বাস্থ্য সম্পর্কিত কিছু তথ্য যেমন রক্তচাপ, হার্টরেট হার, অক্সিজেনের মাত্রা, শ্বাস প্রশ্বাসের হার, অস্ত্রোপচারের ধরণ এবং প্রদত্ত চিকিৎসার তথ্য নথিভুক্ত করেছি। আপনার থাকার সময়, আমরা পর্যায়ক্রমে স্বাস্থ্য তথ্য, আপনার যে চিকিৎসাপ্রণালী চলছে তা নথিভুক্ত করব। পরবর্তী ফোন কল চলাকালীন, আমরা আপনাকে আপনার স্বাস্থ্য এবং আপনার সাধারণ জীবনে ফিরে আসার সাধারণ তথ্য এবং আপনার জীবনে আঘাতের অভিজ্ঞতা সম্পর্কে বেশি জিজ্ঞাসা করতে পারি। আপনি যদি রেকর্ডকৃত সমস্ত নথির সম্পূর্ণ তথ্য চান, দয়া করে জিজ্ঞাসা করতে দ্বিধা করবেন না, এবং আমরা আপনাকে অবশ্যই তা অবহিত করব।

আপনি যদি চান যে আপনার তথ্য অধ্যয়ন থেকে মুছে ফেলা হয়, আপনি দয়া করে এখনই আমাদের জানান বা নীচে সরবরাহ করা যোগাযোগের তথ্য ব্যবহার করে আমাদের সাথে যোগাযোগ করতে পারেন। গবেষণার ফলাফলগুলি গবেষণার জন্য ব্যবহার করা যেতে পারে যা বৈজ্ঞানিক নিবন্ধ হিসাবে প্রকাশিত হতে পারে; যদিও, এই তথ্য সংগ্রহালয়ে থেকে ফলাফল হতে পারে এমন কোনও নিবন্ধ পড়ে আপনাকে সনাক্ত করা সম্ভব হবে না। তদতিরিক্ত, এই প্রকল্পের তথ্য অন্যান্য হাসপাতালের তথ্যগুলির সাথে মিলিত হবে যা একই পদ্ধতিতে অন্যান্য গবেষক এবং ব্যক্তিদের ব্যবহারের জন্য ভাগ করে নেওয়া হয়, তবে সেই তথ্য ব্যবহার করে আপনাকে সনাক্ত করা সম্ভব হবে না।

অধ্যয়ন থেকে প্রত্যাহার

এই গবেষণায় অংশগ্রহণ সম্পূর্ণ স্বেচ্ছাকৃত। এমনকি যদি আপনি এখন অংশ নিতে রাজি হন তবুও কোনও কারণ না দিয়ে আপনি যে কোনও সময় প্রত্যাহার করতে পারেন। প্রত্যাহার করা আপনার সাধারণ চিকিৎসা বা আপনাকে দেওয়া যত্নকে প্রভাবিত করবে না। প্রদত্ত যোগাযোগের তথ্য ব্যবহার করে কোনও ব্যক্তির সাথে যোগাযোগ করে আসন্ন নাম প্রত্যাহার করতে পারেন। দ্রষ্টব্য যে আমরা কেবল এই হাসপাতাল থেকে সংগৃহীত তথ্য থেকে তথ্য মুছতে পারি। তথ্য শনাক্ত করার পরে আমরা তা মুছতে পারি না কারণ তথ্য কার কাছ থেকে এসেছে তা আমরা জানাতে পারব না।

সম্ভাব্য ঝুঁকিগুলি, অস্বস্তি ও অসুবিধাগুলি

আমরা এই গবেষণায় অংশগ্রহণের সাথে জড়িত কোনও বড় ঝুঁকি সনাক্ত করতে সক্ষম হইনি। এমনকি যদি আপনি এখন অংশ নিতে রাজি হন তবুও কোনও কারণ না দিয়ে আপনি যে কোনও সময় নাম প্রত্যাহার করতে পারেন। আপনি সেই সময়ে, বা যে কোনও সময় নীচে প্রদত্ত যোগাযোগের তথ্য ব্যবহার করে প্রত্যাহার করতে পারেন।

সম্ভাব্য সুবিধাগুলি

এই গবেষণা আহত রোগীদের যত্ন বাড়াতে সহায়তা করতে পারে। যদিও এই অধ্যয়ন এই মুহূর্তে হাসপাতালে আপনাকে দেওয়া যত্নের উপর প্রভাব ফেলবে না, তবে আপনার অংশগ্রহণ চিকিৎসা জ্ঞানের ক্ষেত্রে অবদান রাখবে, এবং যদি আপনি ভবিষ্যতে আহত হয়ে থাকেন তবে ভবিষ্যতে আপনাকে ও অন্যান্যদের যত্নের উন্নতি করতে পারে।

রোগীর অধিকার

এই গবষেণায় আপনার অংশগ্রহণ সম্পূর্ণ স্বচ্ছোকৃত। আপনার প্রশ্নরে স্পষ্ট ও সন্তুষ্টমিূলক উত্তর দওেয়া হবে।এই গবষেণায় আপনার চকিৎিসা প্রাসঙ্গকি কোনও নতুন তথ্য উপলভ্য হলে ঘটনায় অধ্যক্ষ অবক্ষেক বা তার প্রতনিধিি আপনাকে সময়মতো অবহতি করবনে।

অধ্যয়নরে গোপনীয়তা এবং চকিৎিসা নথী

এই গবষেণার ফলাফলগুলি একটি বজ্ঞৈানকি নবিন্ধ হসিাবে প্রকাশতি হতে পার; তবে এমন কোনও নবিন্ধ পড়ে আপনাকে সনাক্ত করা সম্ভব হবে না। তদতরিক্তি, এই প্রকল্পরে তথ্য অন্যান্য হাসপাতালরে তথ্যগুলরি সাথে মলিতি হবে যা একই পদ্ধতি ব্যবহার করে অন্যান্য গবষেক এবং ব্যক্তদিরে ব্যবহাররে জন্য ভাগ করে নওেয়া হব, তবে সইে তথ্য ব্যবহার করে আপনাকে সনাক্ত করা সম্ভব হবে না।

এছাড়াও, নয়িন্ত্রক সংস্থাগুলি, ইনস্টটিউিশনাল রভিউি বোর্ড এবং স্বাস্থ্য মন্ত্রনালয়কে আপনার কোনও তথ্য জনসমক্ষে না এনে অধ্যয়ন পদ্ধতি এবং তথ্য পরীক্ষা করার জন্য আপনার মূল মডেকিলে নথীগুলতিে সরাসরি অধগিত করতে দওেয়া হব। সংযুক্ত অবগত অনুমতি ফর্মটতিে স্বাক্ষর কর, আপনি আপনার অধ্যয়ন এবং চকিৎিসা নথীতে এ জাতীয় অধগিত করার অনুমোদন দচ্ছিনে।

অংশগ্রহণরে মূল্য

এই গবষেণায় অংশ নতিে আপনার থকেে কোনও মূল্য নওেয়া হবে না। এই গবষেণায় অংশ নওেয়ার জন্য কোনও ক্ষতপিূরণ ও পাবনে না।

গবষেণা সংক্রান্ত আঘাত এবং ক্ষতপিূরণ

এই প্রকল্পরে পর্যবক্ষেণরে প্রকৃতরি কারণ,কোনও আঘাতরে সম্ভাবনা কম। এই সময় হওয়া যে কোন সমস্যায় হাসপাতাল চকিৎিসা সবো সরবরাহ করব।

আপনার কাছে যদি প্রশ্ন থাকে তবে কার সাথে যোগাযোগ করবনে

আপনার যদি এই অধ্যয়ন এবং আপনার অধকিার সম্পর্কতি প্রশ্ন থাকে বা এই প্রকল্পরে সময় কোনও আঘাতরে শকিার হওয়ার ক্ষত্রেে আপনি অধ্যক্ষ অবক্ষেক কে যোগাযোগ করতে পারনে।

3.5 Patient Consent Form - English

Protocol Title Trauma Training Effectiveness Pilot Study

Principal Investigator [ADD NAME OF PRINCIPAL INVESTIGATOR HERE]

Participant details

Name:

NRIC/PNR/SSN No.:

Address:

Date of birth (dd/mm/yyyy):

Phone No:

Phone number(s) of your relatives or friends that you agree we may contact, in case you do not answer your phone:

Part I – to be filled by the Participant

I, _____ (Pt ID No._____) **agree / do not agree** to participate in the project as described and, on the terms detailed in the Patient Information Sheet. The nature of my participation in the proposed project has been explained to me in _____ by Dr/Mr/Ms _____. I have fully discussed and understood the purpose and procedures of this project. I have been given the Patient Information Sheet and the opportunity to ask questions about this project and have received satisfactory answers and information. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected. I also give permission for information in my medical records to be used for this project. In any event of publication and sharing of the data with other researchers and individuals, I understand that this information will not bear my name or other identifiers and that due care will be taken to preserve the confidentiality of this information.

_____ _____

(Signature/Thumbprint (Right / Left) of Subject) (Date of signing)

Part II – to be filled by parent / legal guardian, where applicable

I, _____ hereby give consent for the above patient to participate in the proposed project. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

_____ _____

(Signature/Thumbprint (Right / Left) (Date of signing)

of parent /legal guardian]

Part III – to be filled by witness, where applicable

An impartial witness should be present during the entire informed consent discussion if a subject or the subject's legally acceptable representative is unable to read. After the written informed consent form and any written information to be provided to subjects, is read and explained to the subject or the subject's legally acceptable representative, and after the subject or the subject's legally representative has orally consented to the subject's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form.

_____

(Name of witness)(Designation of witness)

_____ _____

(Signature of witness) (Date of signing)

3.6 Patient Consent Form - Hindi | सहमतपित्र

प्रोटोकॉल शीर्षक:

वषिय ववरण

नाम:

NRIC / PNR / SSN NO:

पता:

जन्म की तारीख _____

फोन नंबर

(dd/mm/yyyy):

भाग 1 - वषिय द्वारा भरा जाना है

मैं _____ (पीआईडी संख्या._____) (रोगी का नाम) रोगी सूचना पत्र में वर्णति और नर्धिारति शर्तों पर अनुसंधान अध्ययन में भाग लेने के लिए सहमत हूं /सहमत नहीं हूं । प्रस्तावति अनुसंधान अध्ययन में मेरी भागीदारी की प्रकृतमिुझे डॉ/ श्री / सुश्री _____ द्वारा _____(भाषा) में समझाई गई है। मुझे रोगी सूचना पत्र और इस अध्ययन के बारे में प्रश्न पूछने का अवसर दयिा गया है और संतोषजनक उत्तर और जानकारी प्राप्त हुई है । मैं समझता हूं कमिेरी भागीदारी स्वैच्छकि है और मैं कसिी भी समय वापस लेने के लिए स्वतंत्र हूं, बनिा कोई कारण दिए और बनिा मेरी चकित्सिा देखभाल प्रभावति हो रही है ।मैं अपने मेडकिल रकॉर्ड में जानकारी के लिए अनुमतभिी देता हूं ताकइिस परयिोजना के लिए उपयोग कयिा जा सके । मैं समझता हूं कि प्रकाशन की कसिी भी स्थतिमिें, मेरा नाम या अन्य जानकारी पहचानकर्ताओं को साझा नहीं करेगी और इस जानकारी की गोपनीयता को बनाए रखने के लिए उचति सावधानी बरती जाएगी ।

_____ _____

(वषिय के हस्ताक्षर/ हस्तचहि (बायां / दायाँ) (हस्ताक्षर करने की तथि)

भाग-2- माता पति /कानूनी अभभिावक, द्वारा भरा जाएगा जहां लागू हो

मैं _____ इस प्रस्तावति परयिोजना में भाग लेने के लिए उपरोक्त रोगी के लिए सहमतदि ।अध्ययन की प्रकृति, जोखमि और लाभों को मुझे स्पष्ट रूप से समझाया गया है और मैं उन्हें पूरी तरह से समझता हूं ।

_____ _____

(वषिय के हस्ताक्षर/ हस्तचहि (बायां / दायाँ)) (हस्ताक्षर करने की तथि)

माता पति /कानूनी अभभिावक)

भाग-3 - गवाह द्वारा भरा जाएगा, जहां लागू हो

यदकिोई वषिय या वषिय का कानूनी रूप से स्वीकार्य प्रतनिधि पढ़ने में असमर्थ है तो पूरी सूचति सहमतचिर्चा के दौरान एक नष्पिक्ष गवाह उपस्थति होना चाहए ।लखिति सूचति सहमतफिार्म और वषियों को प्रदान की जाने वाली कसिी भी लखिति जानकारी के बाद, वषिय या वषिय के कानूनी रूप से स्वीकार्य प्रतनिधिको पढ़ा और समझाया जाता है, और वषिय या वषिय के कानूनी रूप से प्रतनिधिके बाद मौखकि रूप से अध्ययन में वषिय की भागीदारी के लिए सहमतदि ी है और, यदऐिसा करने में सक्षम है, पर हस्ताक्षर कए है और व्यक्तगित रूप से सहमतफिार्म दनिांकति , गवाह को हस्ताक्षर करना चाहए और व्यक्तगित रूप से सहमतफिार्म की तारीख चाहए ।

_____

(गवाह का नाम) (गवाह का पदनाम)

_____ _____

(गवाह के हस्ताक्षर) (हस्ताक्षर करने की तथि)

3.7 Patient Consent Form - Marathi | संमती पत्र

प्रोटोकॉल शीर्षक

रुग्ण तपशील

नाव:

एनआरआयसी / पीएनआर / एसएसएन क्रमांक:

पत्ता:

जन्म तारीख _____

फोन नंबर: (दि / मिमी / ये)

आपल्या नातेवाईकांचे कवि मित्रांचे फोन नंबर जे आपण सहमत आहात की आपण फोन नंबर वर उत्तर दिले नाही तर आम्ही संपर्क साधू शकतो

भाग पहिला - रुग्ण द्वारेभरले जाणे

मी, _____ (पं. आयडी क्रमांक. _____) सहमत / सहमत नाही

प्रकल्पामध्ये वर्णन केल्याप्रमाणे आणि रुग्ण माहिती पत्रकात तपशीलवार अटींवर सहभागी होण्यासाठी. प्रस्तावित प्रकल्पात माझ्या सहभागाचे स्वरूप मला _____ द्वारे डॉ / श्री / सुश्री _____ स्पष्ट केले आहे. या प्रकल्पातील हेतू आणि कार्यपद्धती मी पूर्णपणे चर्चा केल्या आहेत आणि मला समजल्या आहेत. या प्रकल्पातील मला रुग्णांची माहिती पत्रक आणि त्याबद्दल प्रश्न विचारण्याची संधी दिली गेली आहे व या प्रकल्पाला समाधानकारक उत्तरे आणि माहिती मिळाली आहे. मला समजले की माझा सहभाग ऐच्छिक आहे आणि मी कोणत्याही कारणास्तव आणि वैद्यकीय काळजीत परिणाम न करता कधीही कधीही माघार घेण्यास मोकळे आहे. या प्रकल्पासाठी वापरल्या जाणाऱ्या माझ्या वैद्यकीय नोंदीमधील माहितीसही मी परवानगी देतो. मला समजले की इतर संशोधक आणि व्यक्तींसह डेटा प्रकाशन आणि सामायिक केल्याच्या कोणत्याही घटनेत ही माहिती माझे नाव कवि इतर अभिज्ञापक बाळगणार नाही आणि त्या जतन करण्यासाठी काळजीपूर्वक काळजी घेत जाईल या माहितीची गोपनीयता ठेवली जाईल.

_____ _____

(रुग्ण याची सही / अंगठा (उजवीकडे / डावे)) (स्वाक्षरीची तारीख)

भाग 2 - पालक / कायदेशीर पालकांनी भरावे, जेथे लागू असेल

मी, _____ याद्वारे उपरोक्त रुग्णाला प्रस्तावित प्रकल्प मध्ये सहभागी होण्यासाठी संमती देतो. अभ्यासाचे स्वरूप, जोखीम आणि फायदे मला स्पष्टपणे स्पष्ट केले आहेत आणि मला ते पूर्णपणे समजले आहे.

_____ _____

(स्वाक्षरी / अंगठा (उजवीकडे / डावे) (स्वाक्षरीची तारीख)

पालक / कायदेशीर पालक

भाग 3 - साक्षीदारांनी भरावे, जेथे लागू असेल

जर रुग्ण कवि रुग्णाची कायदेशीर प्रतिनिधी वाचण्यात अक्षम असल्यास संपूर्ण माहिती संमती चर्चे दरम्यान एक निष्पक्ष साक्षीदारची उपस्थिती असावी. लेखी संमती फॉर्म आणि कोणत्याही लेखी माहिती रुग्ण यांना दिल्या नंतर, त्यांचे वाचन व स्पष्टीकरण रुग्ण कवि रुग्णाचे कायदेशीर प्रतिनिधी यांना दिले जाते, आणि रुग्ण कवि रुग्णाचे कायदेशीर प्रतिनिधीचे सहभागास तोंडी मान्यता संमती दिल्या नंतर आणि, जर असे करण्यास सक्षम असल्यास, स्वाक्षरी आणि वैयक्तिकरित्या संमती फॉर्मवर तारीख दिल्यास, साक्षीदाराने स्वाक्षरी करुन स्वत: च्या संमती फॉर्मवर तारीख करावी.

_____ _____

(साक्षीदाराचे नाव) (साक्षीदाराचा पदभार)

_____ _____

(साक्षीची सही) (स्वाक्षरीची तारीख)

3.8 Patient Consent Form - Bengali | অনুমতি ফরম

প্রোটোকল শিরোনাম

অংশগ্রহণকারীর ববিরণ

নাম:

NRIC/PNR/SSN No.

ঠিকানা:

জন্ম তারিখ: _____

ফোন নম্বর (দিন/মাস/বছর):

আপনার ফোন থকেে উত্তর না পলে,ে আপনার যে আত্মীয়স্বজন বা বন্ধুদরে সঙ্গে যোগাযোগ করা যাবে তাদরে ফোন নম্বর:

পর্ব ১- অংশগ্রহণকারী দ্বারা পূরণ করতে হবে

আমি,_____

(Pt ID No._____)

অংশীদারী তথ্য পত্রকিায় বর্ণতি শর্তাদি এবং রোগীর তথ্য পত্রকিায় বর্ণতি শর্তাদি অনুযায়ী এই প্রকল্পে অংশ নতিে সম্মত/সম্মত না।প্রস্তাবতি প্রকল্পে আমার ভূমকিা আমাকে ব্যাখ্যা করছেনে ডা./মি./মসি

_____ , _____ ভাষায়। আমি এই প্রকল্পরে উদ্দশ্যে এবং পদ্ধতগিুলি সম্পর্কে সম্পূর্ণ আলোচনা করছেি এবং বুঝতে পরেছে।িআমাকে রোগী সম্পর্কতি তথ্য পত্র দয়ো হয়ছেএবং এই প্রকল্প সম্পর্কে প্রশ্ন করার সুযোগ দওেয়া হয়ছে এবং আমি সন্তোষজনক উত্তর এবং তথ্য পয়েছে।ি আমি বুঝছে যিে আমার অংশগ্রহণ স্বচ্ছোকৃত এবং আমি কোনও কারণ ছাড়াই যে কোনো সময় এর থকেে বড়েয়িে আসতে পারি এবং তার জন্য আমার চকিৎিসা,যত্ন ক্ষতগি্রস্থ হবে না। আমি এই প্রকল্পরে জন্য আমার মডেকিলে তথ্যগুলি ব্যবহাররে জন্য অনুমতওি দয়িছে।ি আমি বুঝতে পারছি যিে, অন্যান্য গবষেক এবং ব্যক্তদিরে সাথে এই তথ্য প্রকাশ ও ভাগ করে নবোর সময় তাতে আমার নাম বা অন্যান্য শনাক্তকারী চহ্নি থাকবে না এবং এই তথ্যরে গোপনীয়তা রক্ষার জন্য যথাযথ যত্ন নওেয়া হবে।

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(অংশগ্রহণকারীর স্বাক্ষর / থাম্বপ্রন্টি (ডান / বাম))(স্বাক্ষর করার তারখি)

পর্ব ২-পতিামাতার/আইনী অভভিাবক দ্বারা পূরণ করা হবে (যখোনে প্রযোজ্য)

আমি,_____এই প্রকল্পে উপরোক্ত রোগীর অংশ নওেয়ায় সম্মতি দচ্ছি।ি এই প্রকল্প অধ্যয়নরে প্রকৃতি, ঝুঁকি এবং সুবধিাগুলি আমার কাছে পরষ্কিারভাবে ব্যাখ্যা করা হয়ছেে এবং আমি পুরোপুরি বুঝতে পরেছে।ি

_____

(স্বাক্ষর / থাম্বপ্রন্টি (ডান / বাম)পতিামাতার / আইনী অভভিাবকরে)(স্বাক্ষর করার তারখি)

পর্ব ৩-সাক্ষীর দ্বারা পূরণযোগ্য (যখোনে প্রযোজ্য)

সম্পূর্ণ সম্মতি আলোচনার সময় একজন নরিপক্ষে সাক্ষী উপস্থতি থাকতে হবে যদি অংশগ্রহণকারী বা তার অভভিাবক/আইনত অভভিাবক পড়তে অক্ষম হন।সম্মতি ফর্মে লখিতি তথ্য সরবরাহ করার পরে অংশগ্রহণকারী বা অংশগ্রহণকারীর আইনত গ্রহণযোগ্য প্রতনিধিকি পড়া এবং ব্যাখ্যা করার পরে এবং অংশগ্রহণকারীর বা অংশগ্রহণকারীর আইনীভাবে প্রতনিধিি মৌখকিভাবে গবষেণায় অংশ নওেয়ার বষিয়ে সম্মতি জানায় তবে সাক্ষীকে ব্যক্তগিতভাবে সম্মতি ফর্মে তারখি দয়িে স্বাক্ষর করতে হবে।

_____

(সাক্ষীর নাম)(সাক্ষীর পদ)

_____

(সাক্ষীর স্বাক্ষর)(স্বাক্ষর করার তারখি)

3.9 Resident Information Sheet - English

You are being invited to participate in a research study being conducted at your hospital. Please read carefully the information provided here. If you agree to participate, please sign the informed consent form. You will be given a copy of this document to keep with you.

Protocol Title

Principal Investigator

Purpose of the research study

We are currently conducting research in this hospital to study the feasibility of assessing the effect of trauma life support training programs on care and outcome of patients with injury. Life support training, which involves skills in how to take care of injured patients when they come to hospital, may improve how well patients recover from their injuries and we are studying if, and to what extent, that is true. To better measure the outcomes of the training program at your hospital on surgical residents undergoing, we would want to measure your knowledge and confidence during the course of the study. We ask you to participate in this study because you trained at this hospital as part of the study.

Study procedures

If you agree to participate, we will collect information related to your demography, academic background and training, as well as measure your perception of improvement in knowledge, skills, and confidence at specific points before, during, and after the training. The data collected will be confidential and anonymous.

The results of the study may be used for research that can be published as scientific articles; however, it will not be possible to identify you by reading any article that may result from this data bank. Further, data from this project will be combined with data from other hospitals that use the same system and shared for other researchers and individuals to use, but it will not be possible to identify you using that data. Research on the data without identifiers may seek to answer other questions than those stated above.

Withdrawal from study

Participation in this study is completely voluntary. Even if you agree to participate now you are free to withdraw at any time without giving any reason for doing so. To withdraw you contact any of the study contact persons on the numbers or emails listed below.

Possible risks, discomforts and inconveniences

We have not been able to identify any major risks associated with participating in this study. If you would at that point, or any other point of time, wish to withdraw from participating in the study, you are free to do so.

Potential benefits

This research may help to improve the implementation of trauma life support training as well as improve the care of injured patients. Although you will not directly benefit from this study, your participation will contribute to medical knowledge about the effect of training surgical residents in trauma life support training programs to improve trauma care management in India.

Confidentiality of study and medical records

The results of this research may be published as a scientific article; however, it will not be possible to identify you by reading any article that may result from this work. Further, data from this project will be combined with data from other hospitals that use the same system and shared for other researchers and individuals to use, but it will not be possible to identify you using that data.

Also, Regulatory Agencies, Institutional Review Board and Ministry of Health will be granted direct access to the data collected as part of this study to check study procedures, without making any of the data public. By signing the Informed Consent Form attached, you are authorizing such access.

Costs of participation

No charge will be levied on you if you take part in this study. You will not receive any compensation for participating in this study.

Research related injury and compensation

Due to the observational nature of this study, it is unlikely to cause any research related injury.

Whom to contact if you have questions

If you have questions about this research study and your rights during the course of this study, you may contact:

3.10 Resident Information Sheet - Hindi | प्रतभिागी सूचना पत्र

आपको अपने अस्पताल में कएि जा रहे एक शोध अध्ययन में भाग लेने के लएि आमंत्रति कयिा जा रहा है।कृपया यहां दी गई जानकारी को ध्यान से पढ़ें । यदआिप भाग लेने के लएि सहमत हैं, तो कृपया सूचति सहमतफिॉर्म पर हस्ताक्षर करें ।आपको अपने साथ रखने के लएि इस दस्तावेज़ की एक प्रतदिी जाएगी।

प्रोटोकॉल शीर्षक

प्रमुख अन्वेषक

अनुसंधान अध्ययन का उद्देश्य

वर्तमान में हम इस अस्पताल में अनुसंधान का आयोजन कर रहे है देखभाल और चोट के साथ रोगयिों के जीवन पर आघात परणिाम समर्थन प्रशक्षिण कार्यक्रमों के प्रभाव का आकलन करने की व्यवहार्यता का अध्ययन है। जीवन सहायता प्रशक्षिण की कैसे घायल रोगयिों की देखभाल करने के लएि जब वे अस्पताल में आने में कौशल शामलि है, कैसे अच्छी तरह से रोगयिों को अपनी चोटों से उबरने में सुधार हो सकता है और हम अध्ययन कर रहे है अगर, और कसि हद तक, यह सच है ।बेहतर शल्य चकित्सिा के दौर से गुजर नविासयिों पर अपने अस्पताल में प्रशक्षिण कार्यक्रम के परणिामों को मापने के लएि, हम अध्ययन के दौरान अपने ज्ञान और वशि्वास को मापने के लएि करना चाहते हैं ।हम आपको इस अध्ययन में भाग लेने के लएि कहते हैं क्योंकआिपने अध्ययन के हस्सि के रूप में इस अस्पताल में आपको प्रशक्षिति कयिा था।

अध्ययन प्रक्रयिाएं

यदआिप भाग लेने के लएि सहमत हैं, तो हम आपकी जनसांख्यकिी, अकादमकि पृष्ठभूमऔिर प्रशक्षिण से संबंधति जानकारी एकत्र करेंगे, साथ ही प्रशक्षिण से पहले, दौरान और बाद में वशिष्टि बदिुओं पर ज्ञान, कौशल और आत्मवशि्वास में सुधार की आपकी धारणा को मापेंगे। एकत्र कएि गए आंकड़े गोपनीय और गुमनाम होंगे।

अध्ययन के परणिामों का उपयोग अनुसंधान के लएि कयिा जा सकता है जसिे वैज्ञानकि लेखों के रूप में प्रकाशति कयिा जा सकता है; हालांकि, इस डेटा बैंक से परणिाम देने वाले कसिी भी लेख को पढ़कर आपकी पहचान करना संभव नहीं होगा।इसके अलावा, इस परयिोजना से डेटा को अन्य अस्पतालों के डेटा के साथ जोड़ा जाएगा जो एक ही प्रणाली का उपयोग करते हैं और उपयोग करने के लएि अन्य शोधकर्ताओं और व्यक्तयिों के लएि साझा करते हैं, लेकनि उस डेटा का उपयोग करके आपकी पहचान करना संभव नहीं होगा।पहचानकर्ताओं के बनिा डेटा पर अनुसंधान ऊपर बताए गए लोगों की तुलना में अन्य सवालों के जवाब देने की मांग कर सकते हैं।

अध्ययन से वापसी

इस अध्ययन में भागीदारी पूरी तरह से स्वैच्छकि है ।यहां तक कअिगर आप अब भाग लेने के लएि सहमत हैं तो आप ऐसा करने के लएि कोई कारण दएि बनिा कसिी भी समय वापस लेने के लएि स्वतंत्र हैं ।वापस लेने के लएि आप नीचे सूचीबद्ध नंबर या ईमेल पर अध्ययन संपर्क व्यक्तयिों में से कसिी से संपर्क करें ।

संभावति जोखमि, बेचैनी और असुवधिाएं

हम इस अध्ययन में भाग लेने के साथ जुड़े कसिी भी प्रमुख जोखमि की पहचान करने में सक्षम नहीं है। यदआिप उस समय, या कसिी अन्य समय, अध्ययन में भाग लेने से हटना चाहते हैं, तो आप ऐसा करने के लएि स्वतंत्र हैं ।

संभावति लाभ

इस शोध से ट्रॉमा लाइफ सपोर्ट ट्रेनगि के क्रयिान्वयन में सुधार के साथ-साथ घायल मरीजों की देखभाल में सुधार करने में मदद मलि सकती है। हालांकआिपको इस अध्ययन से सीधे लाभ नहीं होगा, लेकनि आपकी भागीदारी भारत में ट्रामा केयर प्रबंधन में सुधार के लएि ट्रामा लाईफ सपोर्ट ट्रेनगि प्रोग्राम में सर्जकिल रेसडिेंट्स के प्रशक्षिण के प्रभाव के बारे में चकित्सिा ज्ञान में योगदान देगी।

अध्ययन और मेडकिल रकिॉर्ड की गोपनीयता

इस शोध के परणिाम एक वैज्ञानकि लेख के रूप में प्रकाशति कएि जा सकते हैं; हालांकि, इस काम से परणिाम देने वाले कसिी भी लेख को पढ़कर आपकी पहचान करना संभव नहीं होगा। इसके अलावा, इस परयिोजना से डेटा को अन्य अस्पतालों के डेटा के साथ जोड़ा जाएगा जो एक ही प्रणाली का उपयोग करते हैं और उपयोग करने के लएि अन्य शोधकर्ताओं और व्यक्तयिों के लएि साझा करते हैं, लेकनि उस डेटा का उपयोग करके आपकी पहचान करना संभव नहीं होगा साथ ही, नयिामक एजेंसयिों, संस्थागत समीक्षा बोर्ड और स्वास्थ्य मंत्रालय को कसिी भी डेटा को सार्वजनकि कएि बनिा अध्ययन प्रक्रयिाओं की जांच करने के लएि इस अध्ययन के हस्सि के रूप में एकत्र कएि गए आंकड़ों तक सीधी पहुंच प्रदान की जाएगी। संलग्न सूचति सहमतफिॉर्म पर हस्ताक्षर करके, आप ऐसी पहुंच को अधकिृत कर रहे हैं।

भागीदारी की लागत

यदआिप इस अध्ययन में भाग लेते हैं तो आप पर कोई शुल्क नहीं लगाया जाएगा। आप को इस अध्ययन में भाग लेने के लएि कोई मुआवजा प्राप्त नहीं होगा ।

अनुसंधान से संबंधति चोट और मुआवजा

इस अध्ययन की अवलोकन प्रकृति के कारण, अनुसंधान से संबंधति किसी भी चोट का कारण होने की संभावना नहीं है ।

किससे संपर्क करें अगर आपके पास सवाल हैं

अगर आपके पास इस शोध अध्ययन और इस अध्ययन के दौरान आपके अधिकारों के बारे में सवाल हैं, तो आप संपर्क कर सकते हैं:

3.11 Resident Information Sheet - Marathi | भागीदार माहिती पत्रक

आपल्याला आपल्या हॉस्पटिलमध्ये आयोजति केलय्या या संशोधन अभ्यासामध्ये भाग घेण्यासाठी आमंत्रति केले जात आहे.

कृपया येथे प्रदान केलेली माहिती काळजीपूर्वक वाचा. आपण सहभागी होण्यास सहमत असल्यास, कृपया माहिती संमती फॉर्म स्वाक्षरी करा. आपल्याला आपल्याकडे ठेवण्यासाठी आपल्याला या दस्तऐवजाची एक प्रत दिली जाईल.

प्रोटोकॉल शीर्षक

प्रधान अन्वेषक

संशोधन अभ्यासाचा हेतू

आम्ही या रुग्णालयात जखम झालेल्या रूग्णांची काळजी आणि परिणाम यावर आघात जीवन समर्थन प्रशक्षिण कार्यक्रमांचा परिणाम याची तपासणी करण्याच्या व्यवहार्यतेचा अभ्यास करण्यासाठी सध्या संशोधन करीत आहोत.

लाइफ सपोर्ट प्रशक्षिण, ज्यामध्ये जखमी झालेल्या रुग्णांची काळजी रूग्णालयात कशी घ्यावी याबद्दल कौशल्य समावष्टि आहे, जखमी रूग्ण बरे होन्या मधे सुधारणा होऊ शकते

आणि आम्ही अभ्यास करत आहोत, जर आणि कोणत्या प्रमाणात ते सत्य आहे. आपल्या हॉस्पटिलमधील प्रशक्षिण कार्यक्रमाचे नकिाल चांगले मोजण्यासाठी शस्त्रक्रयिेच्या रहविाशांवर, आम्ही अभ्यासादरम्यान आपले ज्ञान आणि आत्मवश्विास याची मोजमाप करू इच्छतिो. आम्ही तुम्हाला अभ्यासाचा भाग म्हणून यामध्ये सहभागी होण्यासाठी सांगतो कारण आपण या रुग्णालयात प्रशक्षिण घेतले आहे.

अभ्यास प्रक्रयिा

आपण यास भाग घेण्यास सहमती दर्शवल्यास, आम्ही आपल्या लोकसंख्याशास्त्रवषियक, शैक्षणकि संबंधति पार्श्वभूमी आणि प्रशक्षिण तसेच ज्ञानातील सुधारणांची आपली धारणा मोजा,कौशल्य आणि प्रशक्षिणापूर्वी, दरम्यान आणि नंतर वशिष्टि मुद्यांवर आत्मवश्विास माहिती संकलति करू.

गोळा केलेली माहिती गोपनीय आणि निनिावी असेल

अभ्यासाचे नकिाल संशोधनासाठी वापरले जाऊ शकतात जे वैज्ञानकि लेख म्हणून प्रकाशति केले जाऊ शकतात;तथापि, या डेटा बँक मधून उद्भवू शकणारा कोणताही लेख वाचून आपणास ओळखणे शक्य होणार नाही. पुढे या प्रकल्पातील डेटा अन्य रुग्णालयांमधील डेटासह एकत्र केला जाईल, जी समान प्रणाली वापरते आणि इतर संशोधक आणि व्यक्तच्यि वापरण्यासाठी सामायकि करते, परंतु तो डेटा वापरुन आपल्याला ओळखणे शक्य नाही. अभज्ञिापकांशवािय डेटावर संशोधन करून वरील प्रश्नांव्यतरिक्ति इतर प्रश्नांची उत्तरे देण्याचा प्रयत्न प्रयत्न करु शकेल.

अभ्यासातून माघार घेणे

या अभ्यासाचा सहभाग पूर्णपणे ऐच्छकि आहे. जरी आपण आता सहभागी होण्यासाठी सहमत आहात तरीही असे करण्यास कोणतेही कारण न देता कधीही माघार घेण्यास मोकळे आहेत. तुम्हाला अभ्यासातून माघार घेण्यासाठी

खाली सूचीबद्ध केलेल्या कोणत्याही व्यक्तीशी नंबरवर कवि ईमेलवर संपर्क साधा.

संभाव्य जोखीम, वसिंगती आणि गुंतवणूक

या अभ्यासामध्ये भाग घेण्याशी संबंधति कोणतेही मोठे धोके आम्ही ओळखू शकलो नाही. आपण या वेळी कवि इतर कोणत्याही वेळी, यात सहभागी होण्यास माघार घेण्यास मोकळे आहात.

संभाव्य फायदे

या संशोधन मधून ट्रॉमा लाइफ सपोर्ट प्रशक्षिण अंमलात आणण्यास तसेच

जखमी रूग्णांची काळजी सुधारण्यासाठी मदत होवु शकते. जरी आपल्याला या अभ्यासाचा थेट फायदा नसला तरी या संशोधन मधून आपला सहभाग रहविासी शस्त्रक्रयिेच्या प्रशक्षिण ट्रॉमा केअर मॅनेजमेंट परणिामाबद्दल वैद्यकीय ज्ञानात योगदान व ट्रॉमा लाइफ समर्थन प्रशक्षिण कार्यक्रम, भारत सुधारण्यासाठी होईल.

अभ्यास आणि वैद्यकीय अभलिेखांची गोपनीयता

या संशोधनाचे नकिाल वैज्ञानकि लेख म्हणून प्रकाशति केले जाऊ शकतात; तथापि,या कार्यामुळे उद्भवू शकणारा कोणताही लेख वाचून आपल्याला

ओळखणे शक्य होणार नाही आहे. पुढे या प्रकल्पातील डेटा अन्य रुग्णालयांमधील डेटासह एकत्र केला जाईल, जी समान प्रणाली वापरते आणि इतर संशोधक आणि व्यक्तच्यि वापरण्यासाठी सामायकि करते, परंतु तो डेटा वापरुन आपल्याला ओळखणे शक्य नाही.

तसेच नियामक एजन्सी, संस्थात्मक पुनरावलोकन मंडळ आणि आरोग्य मंत्रालय यांना कोणताही डेटा सार्वजनिक न करता या अभ्यासाचा भाग म्हणून एकत्रित केलेल्या डेटाचा थेट वापर यास मंजुरी दिली जाईल. संलग्न माहिती दिलेल्या संमती फॉर्मवर स्वाक्षरी करून, आपण अशा प्रवेशास अधिकृत करणे.

परिच्छेदन शुल्क

आपण या अभ्यासामध्ये भाग घेतल्यास आपल्यावर कोणतेही शुल्क आकारले जाणार नाही. या अभ्यासात भाग घेतल्याबद्दल आपल्याला काहीही भरपाई प्राप्त होणार नाही.

संशोधन आणि नुकसान भरपाई संबंधित

हा निरिक्षण स्वरुपाचा अभ्यास असल्यास, त्यासंदर्भात कोणत्याही इजा असण्याची शक्यता नाही.

आपल्याकडे प्रश्न असल्यास कोणाशी संपर्क साधावा

या अभ्यासाच्या दरम्यान आपल्याकडे या संशोधन अभ्यासाबद्दल आणि आपल्या हक्कांबद्दल प्रश्न असल्यास, आपण संपर्क साधू शकता:

3.12 Resident Information Sheet - Bengali | অংশগ্রহণকারীর তথ্য নথীপত্র

আপনি যদি এতে অংশ নিতে রাজি হন তবে আমরা আপনাকে অধ্যয়ন নিয়ে সম্পর্কে অবহিত করব এবং আপনার এবং আপনার হাসপাতালের অন্যান্য অংশগ্রহণকারীদের যারা এই অধ্যয়নের অংশ, তাদের জন্য সুবিধাজনক সময় নির্ধারণ করব। ফোকাস গ্রুপ ডিসকাশন বিষয়টি আপনার হাসপাতালে অনুষ্ঠিত হবে যেখানে অধ্যয়ন নিয়ে আলোচনা করা হবে এবং আপনার হাসপাতালে ট্রমা জীবন রক্ষাকারী প্রশিক্ষণ নিয়ে আপনার যে কোনও প্রতিক্রিয়া বা পরামর্শ থাকলে তা আপনি নির্দ্বিধায় জানাতে পারেন। এফজিডির কার্যবিধির বিষয়টি নথীভুক্ত করা হবে এবং এফজিডি-র একটি অডিও রেকর্ডিং প্রতিলিপি নেওয়া হতে পারে।

অধ্যয়ন থেকে প্রত্যাহার

এই এফজিডিতে অংশ নেওয়া সম্পূর্ণ স্বেচ্ছাকৃত।যদি আপনি এখন অংশ নিতে রাজি হন তবুও কোনও কারণ না দিয়ে আপনি যে কোনও সময় নিজের নাম প্রত্যাহার করতে পারেন। প্রত্যাহার করতে নীচে তালিকাভুক্ত নম্বর বা ইমেলগুলিতে যোগাযোগ করতে পারেন।

সম্ভাব্য ঝুঁকিগুলি, অস্বস্তি ও অসুবিধাসমূহ

আমরা এই এফজিডিতে অংশ নেওয়ার সাথে জড়িত কোনও বড় ঝুঁকি সনাক্ত করতে পারিনি। আপনি যদি সেই সময়ে, বা অন্য কোনও সময়ে, এফজিডিতে অংশ নেওয়া থেকে সরে আসতে চান, আপনি তা নির্দ্বিধায় করতে পারেন।

সম্ভাব্য সুবিধাগুলি

এই এফজিডি আপনার হাসপাতালে অধ্যয়নটি আরও ভালভাবে প্রয়োগ করতে সহায়তা করতে পারে। আপনি সরাসরি এই গবেষণা থেকে উপকৃত হবেন না। তবে আপনার অংশগ্রহণ ভারতের ট্রমা জীবন রক্ষাকারী প্রশিক্ষণ কার্যক্রমগুলির উন্নত ব্যবহার সম্পর্কে চিকিৎসা বিজ্ঞানে অবদান রাখতে পারে।

অধ্যয়নের গোপনীয়তা এবং চিকিৎসা নথী

এই □□□ এর অনুলিপিগুলি সনাক্ত করা হবে এবং প্রতিলিপিগুলি পড়ে আপনাকে সনাক্ত করা সম্ভব হবে না। এফজিডির অনুসন্ধানগুলি একটি বৈজ্ঞানিক নিবন্ধ হিসাবে প্রকাশিত হতে পারে; তবে এমন কোনও নিবন্ধ পড়ে আপনাকে সনাক্ত করা সম্ভব হবে না। আরও, এই এফজিডি থেকে প্রাপ্ত তথ্য ভারত এবং বিদেশের অন্যান্য গবেষকদের সাথে ভাগ করা যেতে পারে, তবে সেই তথ্য ব্যবহার করে আপনাকে সনাক্ত করা সম্ভব হবে না।

অংশগ্রহণের মূল্য

আপনি যদি এই এফজিডিতে অংশ নেন তবে আপনার থেকে কোনো শুল্ক নেওয়া হবে না। আপনি এই এফজিডিতে অংশ নেওয়ার জন্য কোনও ক্ষতিপূরণ পাবেন না।

গবেষণা সংক্রান্ত আঘাত এবং ক্ষতিপূরণ

এফজিডি পর্যবেক্ষণমূলক হওয়ার কারণে গবেষণা সংক্রান্ত কোনও আঘাতের সম্ভাবনা নেই।

আপনার কাছে যদি প্রশ্ন থাকে তবে কার সাথে যোগাযোগ করবেন

এই গবেষণা সমীক্ষা চলাকালীন আপনার যদি এই গবেষণা অধ্যয়ন এবং আপনার অধিকার সম্পর্কে প্রশ্ন থাকে তবে আপনি যোগাযোগ করতে পারেন:

3.13 Resident Consent Form - English

Protocol Title

Subject Details

Name:

NRIC/PNR/SSN No.:

Address:

Date of birth (dd/mm/yyyy) _____

Phone No:

I, _____ **agree / do not agree** to participate in the project as described and, on the terms detailed in the Participant Information Sheet. The nature of my participation in the proposed project has been explained to me in _____ by Dr/Mr/Ms _____. I have fully discussed and understood the purpose and procedures of this project. I have been given the Participant Information Sheet and the opportunity to ask questions about this project and have received satisfactory answers and information. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons. I also give permission to the data collected form me to be used for this project. In any event of publication and sharing of the data with other researchers and individuals, I understand that this information will not bear my name or other identifiers and that due care will be taken to preserve the confidentiality of this information.

_____ _____

(Signature/Thumbprint (Right / Left) of Subject) (Date of signing)

3.14 Resident Consent Form - Hindi | सहमतिपत्र

प्रोटोकॉल शीर्षक

वषिय ववरिण

नाम:

NRIC / PNR / SSN NO:

पता:

जन्म की तारीख

(dd/mm/yyyy) _____

फोन नंबर:

मैं_____ सूचना पत्र में वर्णति और नरि्धारति शर्तों पर अनुसंधान अध्ययन में भाग लेने के लिए सहमत हूं /सहमत नहीं हूं। प्रस्तावति अनुसंधान अध्ययन में मेरी भागीदारी की प्रकृति मुझे डॉ/ श्री */ *सुश्री _____द्वारा_____(भाषा) समझाई गई है। मुझे रोगी सूचना पत्र और इस अध्ययन के बारे में प्रश्न पूछने का अवसर दिया गया है और संतोषजनक उत्तर और जानकारी प्राप्त हुई है । मैं समझता हूं कि मेरी भागीदारी स्वैच्छिक है और मैं बिना कोई कारण बताए किसी भी समय हटने के लिए स्वतंत्र हूं । मैं इस परियोजना के लिए उपयोग किए जाने वाले डेटा को एकत्र करने की अनुमति भी देता हूं। मैं समझता हूं कि, प्रकाशन की किसी भी स्थिति में, मेरा नाम या अन्य जानकारी पहचानकर्ताओं को साझा नहीं करेगी और इस जानकारी की गोपनीयता को बनाए रखने के लिए उचित सावधानी बरती जाएगी ।

_____ _____

(वषिय हस्ताक्षर/हस्तचिह्न (बाए / दाए) (हस्ताक्षर करने की तिथि)

3.15 Resident Consent Form - Marathi | संमती पत्र

प्रोटोकॉल शीर्षक

रुग्ण तपशील

नाव:

एनआरआयसी / पीएनआर / एसएसएन क्रमांक:

पत्ता:

जन्म तारीख (दि / ममी / ये) _____

फोन नंबर:

मी, _____ (सहमत / सहमत नाही)

प्रकल्पामध्ये वर्णन केल्याप्रमाणे आणि माहिती पत्रकात तपशीलवार अटींवर सहभागी होण्यासाठी. प्रस्तावित प्रकल्पात माझ्या सहभागाचे स्वरूप मला _____ द्वारे डॉ / श्री / सुश्री _____ स्पष्ट केले आहे. या प्रकल्पातील हेतू आणि कार्यपद्धती मी पूर्णपणे चर्चा केल्या आहेत आणि मला समजल्या आहेत. या प्रकल्पातील मला रुग्णांची माहिती पत्रक आणि त्याबद्दल प्रश्न विचारण्याची संधी दिली गेली आहे व या प्रकल्पाला समाधानकारक उत्तरे आणि माहिती मिळाली आहे. मला समजले की माझा सहभाग ऐच्छिक आहे आणि मी कोणत्याही कारणास्तव आणि वैद्यकीय काळजीत परिणाम न करता कधीही कधीही माघार घेण्यास मोकळे आहे. या प्रकल्पासाठी वापरल्या जाणाऱ्या माझ्या वैद्यकीय नोंदीमधील माहितीसही मी परवानगी देतो. मला समजले की इतर संशोधक आणि व्यक्तींसह डेटा प्रकाशन आणि सामायिक केल्याच्या कोणत्याही घटनेत ही माहिती माझे नाव किंवा इतर अभिज्ञापक बाळगणार नाही आणि त्या जतन करण्यासाठी काळजीपूर्वक काळजी घेत जाईल या माहितीची गोपनीयता ठेवली जाईल.

_____ _____

(रुग्ण याची सही / अंगठा (उजवीकडे / डावे)) (स्वाक्षरीची तारीख)

3.16 Resident Consent Form - Bengali | অনুমতি ফরম

প্রোটোকল শিরোনাম

অংশগ্রহণকারীর বিবরণ

নাম:

NRIC/PNR/SSN No.:

ঠিকানা:

জন্ম তারিখ (দিন/মাস/বছর): _____

ফোন নম্বর:_____

আমি,_____অংশীদারী তথ্য পত্রিকায় বর্ণিত শর্তাদি অনুযায়ী প্রকল্পে অংশ নিতে সম্মত / সম্মত নই।প্রস্তাবিত প্রকল্পে আমার ভূমিকা, এই প্রকল্পের উদ্দেশ্য এবং পদ্ধতিগুলি সম্পূর্ণ আলোচনা দ্বারা বুঝতে সাহায্য করেছেন ডা./মি./মিসি_____। এই প্রকল্পের উদ্দেশ্য এবং কার্যপ্রণালী আমি সম্পুর্ণ আলোচনা করেছি এবং বুঝেছি। আমাকে অংশগ্রহণকারী তথ্য শীট দেওয়া হয়েছে এবং এই প্রকল্প সম্পর্কে প্রশ্ন করার সুযোগ দেওয়া হয়েছে এবং তার সন্তোষজনক উত্তর এবং তথ্য পেয়েছি। আমি বুঝতে পারছি যে আমার অংশগ্রহণ স্বেচ্ছাকৃত এবং আমি কোন কারণ ছাড়াই যে কোনও সময় এর থেকে বেড়িয়ে আসতে পারি। আমার দ্বারা সংগৃহীত তথ্য আমি এই প্রকল্পে ব্যবহারের অনুমতি দিচ্ছি। আমি বুঝতে পেরেছি যে, অন্যান্য গবেষক এবং ব্যক্তিদের সাথে এই তথ্য ভাগ করে নেবার সময় তথ্যগুলিতে আমার বা অন্যান্য শনাক্তকারীর নাম থাকবে না,এই তথ্যের যথাযথ গোপনীয়তা রক্ষার জন্য।

_____

স্বাক্ষর / থাম্বপ্রিন্ট (ডান / বাম) (স্বাক্ষর করার তারিখ)

4 References

1. GBD 2016 Causes of Death Collaborators. Global, regional, and national age-sex specific mortality for 264 causes of death, 1980 – 2016: a systematic analysis for the Global Burden of Disease Study 2016. *Lancet* **390**, 1151–210 (2017).

2. Mohammad, A. *et al.* Educational and Clinical Impact of Advanced Trauma Life Support (ATLS) Courses: A Systematic Review. *World J Surg* **38**, 322–329 (2014).

3. Jayaraman, S. *et al.* Advanced trauma life support training for hospital staff. *Cochrane Db Syst Rev* **8**, CD004173 (2014).

4. Kadhum, M. *et al.* Are Primary Trauma Care (PTC) courses beneficial in low- and middle-income countries - A systematic review. *Injury* **51**, 136–141 (2020).

5. American College of Surgeons. *ATLS Advanced Trauma Life Support 10th Edition Student Course Manual*. (American College of Surgeons, 2018).

6. Primary Trauma Care Foundation. *Primary Trauma Care Course Manual: For Trauma Care in Locations with Limited Resources*. (The Primary Trauma Care Foundation, 2015).

7. World Health Organization. *Surgical care at the district hospital*. (World Health Organization, 2003).

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Supplement
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	5 and 9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Supplement
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	8
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	8

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9-10, Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	9-10
Recruitment	14a	Dates defining the periods of recruitment and follow-up	9
	14b	Why the trial ended or was stopped	9-10
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 3
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9-10, Table 3, Supplement
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Supplement
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Supplement
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	Supplement
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	12

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.