1   Title page

1.1   Title {1}
Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial Protocol (ADVANCE TRAUMA)

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2   Abstract

Background: Advanced Trauma Life Support® (ATLS®) is the most widely adopted trauma life support training worldwide, but there is no high quality evidence showing that it improves patient outcomes. This trial aims to compare the effects of ATLS® training with standard care on outcomes in adult trauma patients.

Methods: ADVANCE TRAUMA is a batched stepped-wedge cluster randomised controlled trial in India, where ATLS® is currently not routinely taught. The trial will be conducted in 30 clusters over six batches in the secondary or tertiary hospitals. There will be five clusters in each batch. These clusters in each batch will be randomised to one of five implementation sequences, with one hospital randomised to each implementation sequence. All clusters will transition through three phases, first a standard care phase, then a one-month transition phase during which the training is delivered, and finally an intervention phase, for a total of 13 months. The implementation sequence will determine the duration of the standard care and intervention phases. Participants will be adult trauma patients above 15 years of age who presents to the emergency department of participating hospitals and are admitted or transferred for admission to another hospital. At least 4320 participants will be included into this trial.

Discussion: This will be the first large scale trial to provide robust evidence of the effectiveness of ATLS® since the programme was first started in 1978. Regardless of its findings, it will have important implications for trauma life support training globally. If ATLS® training improves patient outcomes, then ways to promote its use and optimise its implementation, especially in low- and middle income countries such as India, should be explored. If patient outcomes do not improve, then trauma life support training needs to change.
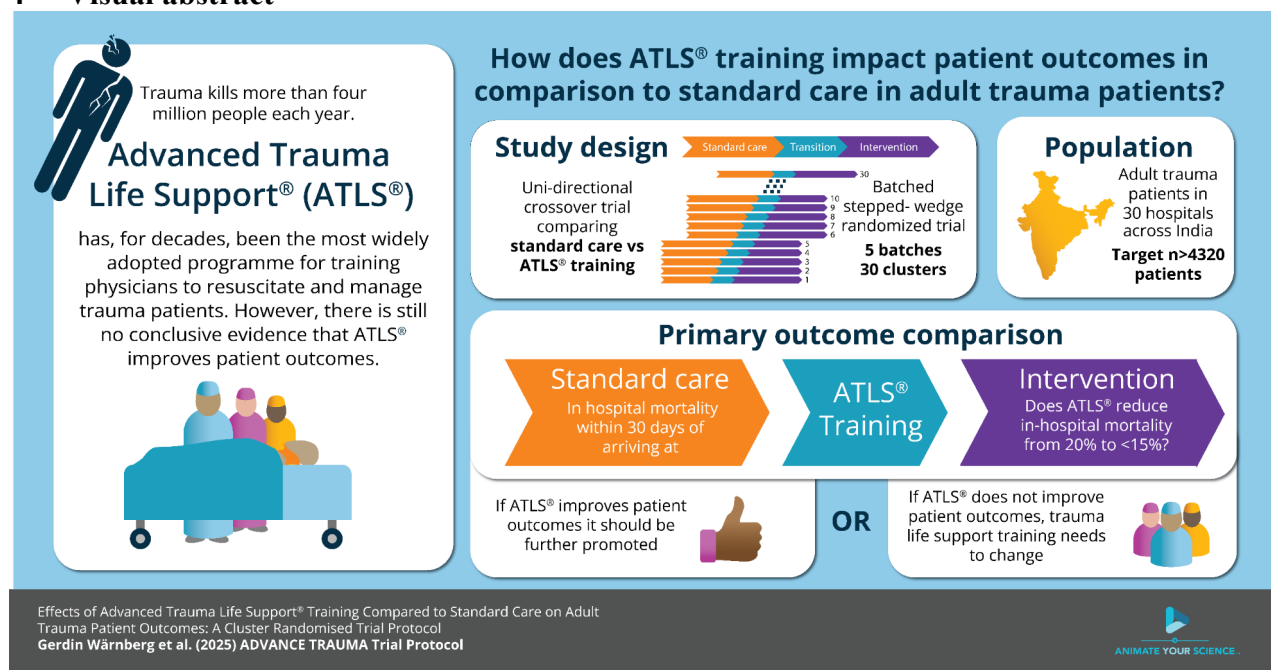
2.1   Trial registration

{2a} Clinical Trials Registry - India identifier: CTRI/2024/07/071336
{2b} ClinicalTrials.gov identifier: NCT06321419

3   Keywords

Advanced Trauma Life Support, Traumatology, Life Support Care

4   Visual abstract

How does ATLS® training impact patient outcomes in comparison to standard care in adult trauma patients?

Trauma kills more than four million people each year.

Advanced Trauma Life Support® (ATLS®)

has, for decades, been the most widely adopted programme for training physicians to resuscitate and manage trauma patients. However, there is still no conclusive evidence that ATLS® improves patient outcomes.

Study design
Standard care | Transition | Intervention
Uni-directional crossover trial comparing **standard care vs ATLS® training**
Batched stepped- wedge randomized trial
5 batches 30 clusters

Population
Adult trauma patients in 30 hospitals across India
Target n>4320 patients

Primary outcome comparison
Standard care — In hospital mortality within 30 days of arriving at
ATLS® Training
Intervention — Does ATLS® reduce in-hospital mortality from 20% to <15%?

If ATLS® improves patient outcomes it should be further promoted

OR

If ATLS® does not improve patient outcomes, trauma life support training needs to change

Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial Protocol
Gerdin Wärnberg et al. (2025) ADVANCE TRAUMA Trial Protocol

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5   Introduction

5.1   Background and rationale {6a}

Each year, 4.3 million people die from trauma (1). Among people aged 10-24- and 25-49-years trauma is the largest cause of disability adjusted life years (2). Most deaths from trauma occur within the first 24-48 hours (3). Traumatic brain injury and exsanguination are the most common causes of trauma deaths (4, 5). Most preventable trauma deaths are caused by clinical judgement errors during initial resuscitation or early care including airway management and haemorrhage control, even though the deaths occur later during the hospital stay (4,6).

Several trauma life support training programmes have been developed to improve the early management of patients in the hospital by providing a structured framework for assessment and treatment (7-11). The proprietary Advanced Trauma Life Support® (ATLS®) is the most established trauma life support training programme and more than one million physicians in over 80 countries have been trained in the programme since the first course in 1978 (12). In the US and many other countries training in ATLS® is virtually mandatory for trauma care physicians (13). Uptake in low- and middle-income countries (LMIC) has been slow, potentially due to high costs (9).

There are three randomised studies showing that ATLS® improves knowledge and clinical skills (14-16), but there are no randomised controlled trials or high-quality quasi- experimental trials indicating that ATLS® improves patient outcomes (7,8,10,11,17). We conducted an updated systematic review (unpublished) and estimated a pooled risk ratio of 0.82 (95% CI 0.60; 1.11) from ten heterogeneous (I2 0.91) observational studies on the effect of ATLS on mortality (18- 27). We also conducted a pilot cluster randomised controlled trial showing that a full scale trial should be feasible (28), as well as semi- structured interviews showing high acceptability of our research and helped identify important outcomes (29)

5.2   Objectives {7}

To compare the effects of ATLS® training with standard care on outcomes in adult trauma patients.

5.3   Trial design {8}

This is a batched stepped-wedge cluster randomised controlled trial (**see Figure 1**). The stepped-wedge trial is a unidirectional cross-over trial, with the time point when clusters cross-over from standard care to the intervention being randomised (30). In this trial, each cluster is at least one unit of physicians performing initial resuscitation of trauma patients in the emergency department of tertiary hospitals in India. The number of units that will be trained in each hospital will depend on the sizes of these units and the volumes of patients the physicians attend. If more than one unit is trained in the same hospital these units will be considered as one unit for the purpose of randomisation.

We will have a total of 30 clusters in six batches, having five clusters in each batch. The clusters in each batch will be randomised to one of five implementation sequences, with one hospital randomised to each implementation sequence. All clusters will transition through three phases, first a standard care phase, then a month of transition phase during which the ATLS® training is to be delivered to the physicians and lastly, the intervention phase. The overall period of participant recruitment will last for a total of 13 months. The duration of standard care and intervention phase will be determined by the implementation sequence.

Within the main stepped-wedge design, we will nest a staircase design to measure a range of secondary outcomes (see Figure 2). The staircase design will include a random subset of patients presenting during the three months preceding the transition phase, and the three months following the transition phase.
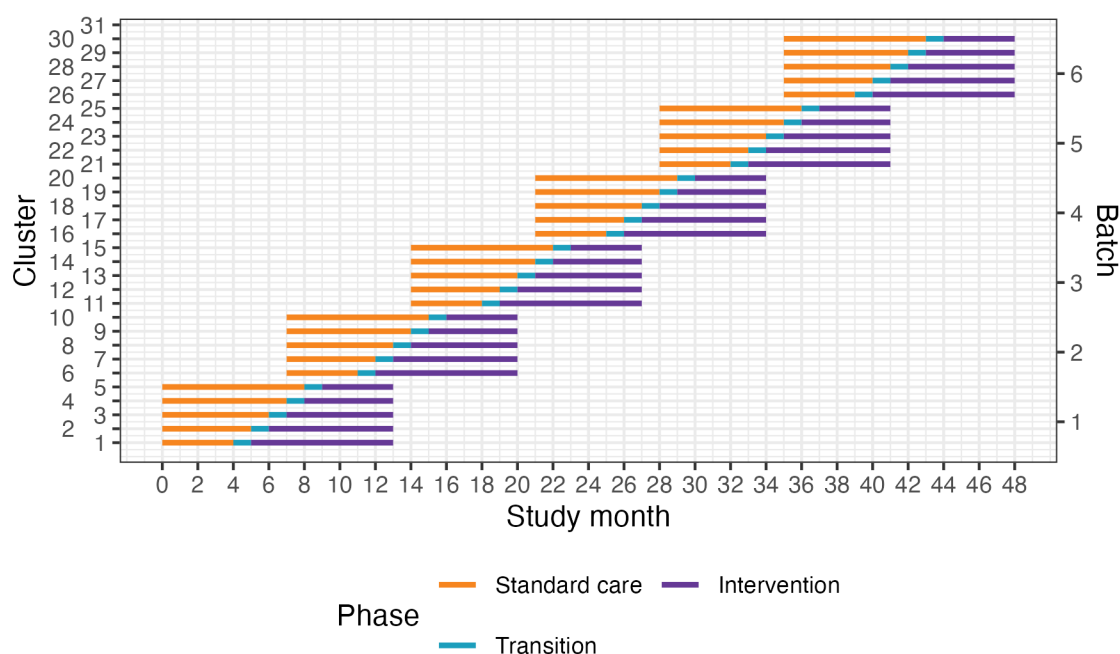
Figure 1: Trial design. Lines represent the duration of patient enrolment across clusters and phases. Clusters will be sequentially allocated to a batch based on when they enter the study. Within each batch clusters will then be randomised to an intervention implementation sequence.
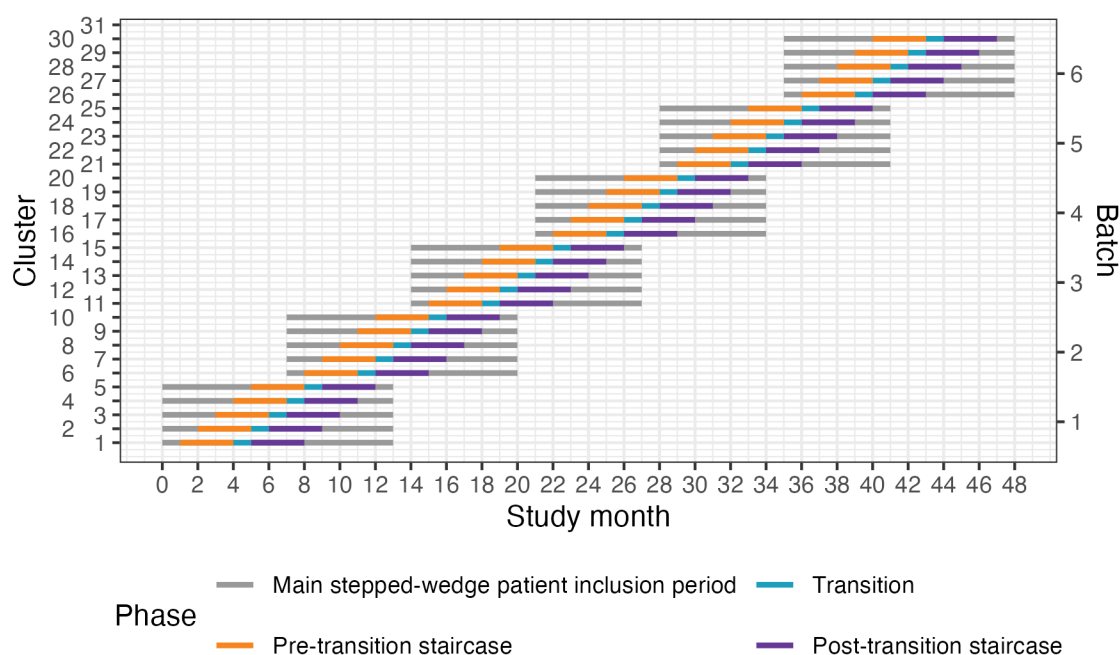

Figure 2: Nested staircase design. The design includes a random subset of patients presenting during the three months preceding the transition phase, and the three months following the transition phase.

6   Methods: participants, interventions, and outcomes

6.1   Study setting {9}

Study setting includes 30 secondary or tertiary hospitals distributed across India. These hospitals will be clubbed into six batches and each batch will constitute five hospitals. Each hospital will be having a cluster of one or more units of physicians providing initial trauma care in the emergency department of tertiary hospitals in India. Included hospitals will be enrolling participants for 13 months.

6.2   Eligibility criteria {10}

In this study eligibility criteria are on three levels: hospitals, clusters and participants.

6.2.1 Hospitals

Eligibility for the hospitals will be conducted through the screening process. This will include compiling a list of potentially eligible cluster and complete an initial hospital screening instrument. This will be followed by an in-depth interview with the selected hospitals. Ony those hospitals will be included for the in-depth interview which conducts primary resuscitation of trauma patients to a large extent, rather than hospitals that primarily receives transferred patients from other hospitals.

Participating hospital in the study to be selected based upon the following eligibility criteria:
- Hospital with an admission or refer/transfer for admission at least 400 patients with trauma per year or 35 patients with trauma per month for at least the last six months;
- Participating hospital to provide surgical and orthopaedic emergency services around the clock;
- Hospitals to have at most 25% of physicians providing initial trauma care trained in a formalised trauma life support training programme, like ATLS® or Primary Trauma Care (PTC).

Exclusion criteria for the participating hospitals to be excluded if they meet the following criteria:
- If the hospital of the cluster implements a formalised trauma life support training programme during the trial period.
- The hospital of the cluster plan to implement or implements other major interventions that affects trauma care during the trial period.

6.2.2 Clusters

Custer selection will be done with one or more units of physicians providing initial trauma care in the emergency department of secondary or tertiary hospitals in India. These units already exist in the hospitals and rotate through the emergency department on specific days of the week. Each of the cluster must meet the following criteria:
- Admits or refers/transfers for admission at least 12 patients with trauma per month for at least the last six months;
- No more than 25% of physicians providing initial trauma care trained in a formalised trauma life support training programme.

6.2.3 Patient participants

Inclusion criteria for the participant to include following criteria:
- Age of at least 15 years;
- Trauma occurred less than 48 hours before arrival at the hospital;
- Present to the emergency department of participating hospitals, with a history of trauma defined as having any of the reasons listed in the International Classification of Diseases chapter XX as the reason for presenting;
- Admitted, or died between arrival at the hospital and admission, or referred/ transferred from the emergency department of a participating hospital to another hospital for admission; and
- Managed by a participating cluster in the emergency department.

Participants are excluded if they:
- Present with isolated limb injuries;
- Participants directly admitted to a ward without being seen by a physician in the emergency department.

6.3 Who will take informed consent or assent? {26a, 26b}

ATLS ® intervention will be given to the training physicians which are at the cluster level. It is unreasonable to expect these physicians to temporarily disregard their training. Therefore, for this study, consent will refer to consent for data collection, as participants cannot opt out of the

intervention.

Participants will be included in this trial under the following modes of consent:

- Opt out consent for routinely recorded data and measurement of adherence to ATLS® principles. Consent for the collection of routinely recorded data, either through interviews or by extracting information from medical records, as well as for the measurement of adherence to ATLS® principles, will be presumed unless explicitly declined. This approach is justified because the trial is considered to pose minimal risk and because data collection will be non-invasive. Additionally, obtaining consent specifically for the measurement of adherence to ATLS® principles could interfere with the provision of care and cause undue stress for the patient and their representatives. Participants, or their legally authorized representatives, will be provided with written information about the study upon their arrival at the hospital.
- Opt in consent and assent for non-routinely recorded data. Informed consent for non-routinely recorded data will be actively sought from participants or their legally authorized representative. For participants who are between 15 and 18 years of age we will obtain both the assent of the participant as well as the consent of their guardian or legally authorized representative. Participants and their representatives will be approached after admission. The consent and assent will be written for participants who are admitted to the hospital and verbal for participants who are transferred or discharged before the clinical research coordinators have had an opportunity to approach them. The verbal consent will be audio recorded.
- Waiver of informed consent for participants who are unconscious or otherwise unable to provide consent and do not have a legally authorized representative. This group represents the most severely injured participants, and they have to be included to make the trial representative of the entire population of trauma participants. Participants who regain consciousness will be informed about the study and asked for consent for collection of non-routinely recorded data.

7 Intervention
7.1 Explanation for the choice of comparators {6b}
The control will be standard care, meaning no formal trauma life support training. Standard care varies across hospitals in India, but trauma patients are initially managed by casualty medical officers, surgical residents, or emergency medicine residents. They are mainly first- or second-year residents who resuscitate patients, perform interventions and refer patients for imaging or other investigations.

7.2 Intervention description {11a}
The intervention in this study is the ATLS® training, (12) a proprietary 2.5-day course teaching a standardised approach to trauma patient care using the concepts of a primary and secondary survey. The programme was developed by the Committee of Trauma of the American College of Surgeons. The course includes initial treatment and resuscitation, triage and interfacility transfers. Learning is based on practical scenario-driven skill stations, lectures and includes a final performance proficiency evaluation.

We will train the physicians that initially resuscitate and provide trauma care during the first hour after patient arrival at the emergency department. These physicians can be casualty medical officers, surgical residents, or emergency medicine residents, depending on the setup at each participating centre. Physicians will be trained in an accredited ATLS® training facility in India. The training will occur during the transition phase in each cluster. Our experience from the pilot study is that study sites adhere to the training slot allotted to them through the trial, so we judge the risk of clusters implementing ATLS ® before their randomised implementation sequence as very low.

We will train the number units of physicians needed to reach the required patient sample size but estimate that this will require training an average of ten physicians per hospital, which on average should be mean that we can train one to two units per hospital. This is possible because many hospitals in India organise physicians staffing their emergency departments in units, and the physicians in the same unit work together in the emergency department on the same days of the week. Often, these physicians' duties may change into another department as per the residency program. Therefore, we will collect data only on the days when these units work. The units selected to constitute a cluster from each hospital will be a convenience sample out of all eligible units in those hospitals. We will also assess adherence to ATLS principles before and after implementing ATLS training.

7.3 Procedures to monitor adherence to intervention {11c}
Adherence to ATLS is one of the secondary outcomes and will be monitored by using a checklist covering the key steps of the ATLS® (see **Table 1**).
7.4
7.5 Concomitant care and interventions {11d}
Other than implementing another formalised trauma life support training programme or other major interventions to change the care of trauma patients as specified in the exclusion criteria, concomitant use of other medications and treatments may be provided at the discretion of the investigators and will not be considered an exclusion criterion.

7.6 Provisions for post-trial care {30}
Not relevant in this study as the intervention is given on the trauma physicians.

8 Outcomes {12}
The primary outcome will be in-hospital mortality within 30 days of arrival at the emergency department. There are a number of secondary outcomes (**see Table 1.**)

Table 1. Primary and secondary outcomes.

Outcome	Source of data	Mode of collection
Primary outcome		
In-hospital mortality within 30 days of arrival at the emergency department.	Patient hospital records. If the patient has been transferred to another hospital, the clinical research coordinators will collect data on this outcome by calling the patient or a patient representative, or by contacting the hospital to which the patient was transferred. Data on this outcome will be collected continuously during the trial.	Main stepped-wedge design. Collected for all patients.
Secondary outcome		
All-cause mortality within 24 hours, 30 days and 3 months after arrival at the emergency department.	Patient hospital records. If the patient has been transferred to another hospital, the clinical research coordinators will collect data on this outcome by calling the patient or a patient representative, or by contacting the hospital to which the patient was transferred. Data on this outcome will be	Main stepped-wedge design. Collected for all patients.

	collected continuously during the trial.	
Length of emergency department stay	Data on this outcome will be collected from patient hospital records.	Main stepped-wedge design. Collected for all patients.
Length of hospital stay.	Data on this outcome will be collected from patient hospital records.	Main stepped-wedge design. Collected for all patients.
Intensive care unit admission.	Data on this outcome will be collected from patient hospital records.	Main stepped-wedge design. Collected for all patients.
Length of intensive care unit stay.	Data on this outcome will be collected from patient hospital records.	Main stepped-wedge design. Collected for all patients.
Return to work at 30 days and three months after arrival at the emergency department.	Data on this outcome will be collected in person if the patient is still in hospital, or by phone if the patient has been discharged. This data will be collected using a nested staircase design.	Main stepped-wedge design. Collected for all patients.
Adherence to ATLS® principles during initial patient resuscitation, up to one hour after the physician has first seen the patient.	This assessment will be done using a 14 item checklist covering the key steps of the ATLS® primary survey, which was modelled based on previous work on ATLS® adherence (31) . We will consider completion of all 14 steps as 100% adherence. The clinical research coordinators collecting the data will be trained by the trial team to do this, prior to the start of the trial. We will collect this data by observing the care of a random sample of patients. The sampling will be designed as a nested staircase design.	Nested staircase design. Collected for a random subset of patients.
Quality of life within seven days of discharge, and at 30 days and three months of arrival at the emergency department, measured by the official and validated translations of the	Data on this outcome will be collected in person if the patient is still in hospital, or by phone if the patient has been discharged. We will collect this data using a nested staircase design.	Nested staircase design. Collected for a random subset of patients.

EQ5D3L.		
Disability within seven days of discharge, and at 30 days and three months of arrival at the emergency department, assessed using the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0).	Data on this outcome will be collected in person if the patient is still in hospital, or by phone if the patient has been discharged. This data will also be collected using a nested staircase design.	Nested staircase design. Collected for a random subset of patients.

9   Participant timeline {13}

Participants are adult trauma patients who present to the emergency department of participating hospitals and are admitted or transferred for admission. All participants who meet the eligibility criteria will be included in the study. Participant baseline and other subsequent data will be collected as per Table 2.

Table 2: Schedule of assessment

Procedures	Screening	Consenting	Initial assessment	In-hospital care
Eligibility criteria	√			
Study information [1]		√		
Informed consent [1]		√		
Baseline data collection			√	
Prehospital data collection			√	
ATLS adherence [2]			√	
ED data collection [3]			√	
Hospital data collection				√
Surgery data collection				√
Imaging data collection				√
Transfusion data collection				√
Injury data collection				√
Mortality data collection				√
Assessment of safety events				√

[1]Clinical research coordinators will inform patient participants about the study, including that they are free to withdraw their data from the study at any time, and approach them for informed consent for collection of non-routinely recorded data in person or telephonically.

[2]ATLS adherence will be assessed by observing the care provided to a random sample of patient participants.

[3]Emergency Department

10   Sample size {14}

10.1   Main stepped wedge design and primary outcome

With 30 clusters across 6 batches and a total participant sample size of 4320 our study has ~90% power across different combinations of cluster autocorrelations (CAC) and intra-cluster correlations (ICC) to detect a reduction in the primary outcome of in-hospital mortality within 30 days from 20% under standard care to 15% after ATLS® training (see Figure 3). This effect is a conservative estimate, and the reduction equals a risk ratio of 0.75, which would be clinically important while also being consistent with our pilot study and updated systematic review. We allowed for the clustered design and assumed an ICC of 0.02, but considered sensitivity across the range 0.01-0.05 (32,33) and a CAC of 0.9 but considered sensitivity across the range 0.8-1.0, based on our pilot study and current guidance (34,35). We included the CAC to allow for variation in clustering over time. We assume that each cluster will contribute approximately 12 observations per month to the analysis, based on our previous work.
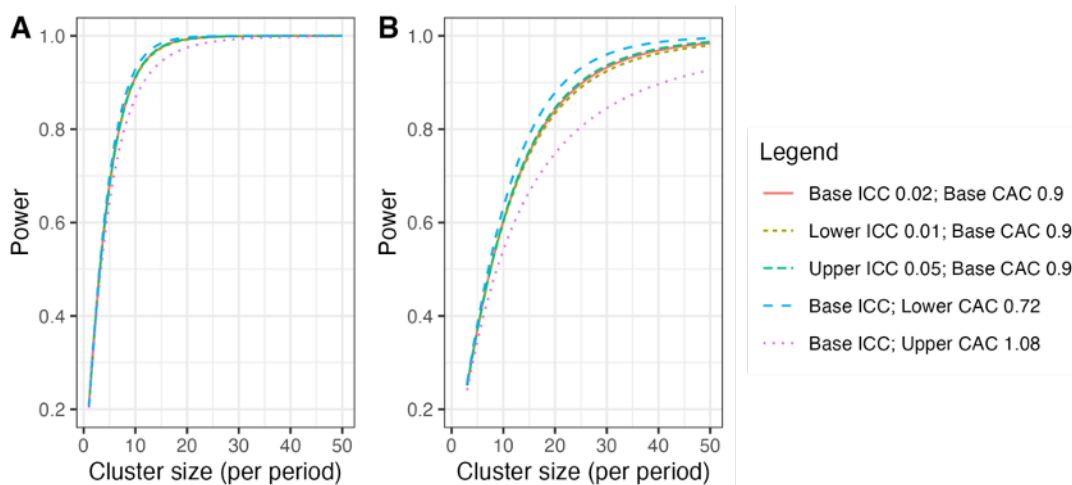
Figure 3: Power curves for different combinations of cluster autocorrelations (CAC) and intra-cluster correlations (ICC). A) Shows power curves assuming a reduction in the primary outcome of in-hospital mortality within 30 days from 20% under standard care to 15% after ATLS® training. B) Shows power curves assuming a reduction in the primary outcome from 10% under standard care to 7.5% after ATLS® training. Under this scenario, we would need to increase the sample size per month to around 30 observations to achieve 90% power under most combinations of CAC and ICC.

10.2   Nested staircase design and secondary outcomes

The secondary outcomes that will be measured using the nested staircase design are adherence to ATLS^®^ principles during initial patient resuscitation, quality of life, and disability. The expected effect of the intervention on each of these outcomes are an improvement in adherence from 50% during standard care to 70% after training [@lashoher_implementation_2017], an increase in EQ5D5L health status from 70 during care to 75 after training [@kapitan_effect_2024], and finally a decrease in disability from a baseline value of 25 during standard care to 22.5 after training [@higgins_psychometric_2021]. For quality of life and disability, these effects correspond to standardised effect sizes, expressed as Cohen's d, of 0.5. With 30 clusters in total, six per sequence, for a discrete time decay correlation structure, with ICCs of 0.01 to 0.15 and a CAC of 0.8, there is >80% power to detect an these effects by including four patients in each cluster in each period. Accounting for loss to follow-up, we will include at least six patients per cluster per month. These patients will be a random subset of patients included during the staircase months. The random subset will be selected using simple random sampling on the shift level, meaning that the timing of the clinical research coordinator's shift will be randomised to cover approximately eight hours during the morning, afternoon, or night shift. Adherence to ATLS^®^ principles, quality of life, and disability will be measured in all patients included during these shifts. In each hospital, the number of shifts that will be randomised will be determined by the volume of patients included during the months preceding the staircase months.

11 Recruitment {15}

Participant data collection will include all the participants who meets the eligibility criteria. These will be adult trauma patients presenting to the emergency department of a participating hospital.

Participants cannot opt out of the intervention as the intervention is implemented at the cluster level, involving training physicians in ATLS ®, it is unreasonable to expect these physicians to temporarily disregard their training. However, Patient participants can choose to withdraw their consent for collection of non-routinely recorded data at any time before the final analysis. If they withdraw their consent for the data collection no further data collection will be done which will include follow-up data. Participant can also choose to remove the already collected data in the trial at any time before final analysis of the data. Withdrawal of consent or removal of data from the trial will not affect their care in any way. If the participant withdraws consent, follow-up of this participant will be performed according to the participating hospitals routine.

12 Assignment of interventions: allocation
12.1 Sequence generation {16a}

Clusters will be assigned to batches as they are found to be eligible and receive ethical approval. Batches will include clusters from hospitals in different regions to optimize trial logistics. We will randomise the clusters allotted to each batch to the different intervention implementation sequences within that batch (36). The randomisation will be balanced within each batch on cluster size, defined as monthly volume of eligible patient participants, using covariate constrained randomisation. Cluster sizes are expected to vary between 12 and 20 patients per month, based on our previous experiences.

12.2 Allocation concealment mechanism {16b}

The randomisation will be concealed for as long as it is logistically possible, considering that arrangements for sending physicians to ATLS® training need to be made in advance.

13 Assignment of interventions: blinding
13.1 Blinding (masking) {17a}

It is not possible to blind a stepped-wedge trial, because all clusters receive the intervention.

13.2 Procedure for unblinding if needed {17b}

This is an open label trial hence, unblinding procedures are not required.

14 Data collection and management
14.1 Data collection methods {18a, 18b}

Data collection will be done using a paper based case record form (CRF), which will be then transferred to an electronic CRF (eCRF) on REDCap. Site investigators will keep source documents for each patient participant in the trial. A document describing what has been classified as source data in the trial (source data reference document) will be included in the Investigator Site File (ISF). Data will be registered, managed, and stored in a manner that enables correct reporting, interpretation, and verification. All documentation will be stored securely and retained according to regulatory requirements. The complete Trial Master File, as well as source documents, will be archived for at least 10 years after the trial is completed. Source data in the medical records system are stored and archived in accordance with Indian national regulations. Metadata will be publicly accessible via a persistent DOI, and anonymized data will be released upon project completion.

14.2 Data management {19}

Data entry will be done in an electronic data collection platform (REDCap). The George Institute India will be regional coordinating center. It will be the responsibility of George Institute to train site investigators, site staff, before the trial about the documentation requirements and data collection procedures in the study. Data management will be done through ongoing quality metrics assessment,

review of missing data and outliers, documentation in the investigator site file. Study related documents will be stored securely and retained according to regulatory requirements. Data management will strictly follow ICH GCP principles and Indian regulations. Access to trial-related documentation, such as patient participants' medical records, CRFs, other source data and other trial documentation will be provided for monitoring and auditing purposes. Access will also be granted in the context of regulatory inspections.

14.3 Confidentiality {27}

All data will be handled according to the Indian Council of Medical Research's guidelines and standard operating procedures of the George Institute for Global Health India on data security and protection. Trial data will be stored and shared via the trial electronic CRF (eCRF) throughout the trial. The eCRF will be accessible via VPN with a two-factor authentication and the data will be held on a secure server. All investigators and trial site staff involved in this trial must comply with the requirements of the ICMR Guidelines on data security and protection.

15 Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

No biological specimens are collected in this trial.

16 Statistical methods
16.1 Statistical methods for primary and secondary outcomes {20a}

In this study we will conduct all analysis by modified intention to treat. Clusters and observations within clusters will be considered exposed to the intervention after the date at which the cluster was scheduled to transition. All data will be included with the exception of the transition phases. We will not adjust for multiplicity of analyses because none of the secondary outcomes will be singularly more important. However, all secondary outcomes will be interpreted with due consideration for how all are affected by the intervention without putting any undue emphasis on a single outcome that might be statistically significant but where all others appear to have remained unchanged.

For the analysis model we have several requirements. Firstly, all analysis will consider the clustered nature of the design. Secondly, as the trial has only 30 clusters, it will be essential that the model allows for a correction due to the small number of clusters. Thirdly, as the design is a stepped-wedge study, we will adjust for temporal confounding using categorical effects for period of the study (month). (37).

In case of binary outcomes, a mixed effects binomial regression with a logit link will be used to estimate the odds ratio; and a binomial model with identity link used to estimate the risk difference. These models will be fitted using residual pseudo-likelihood estimation based on linearization with subject-specific expansion (RSPL). If the binomial model with the identity link does not converge then only a odds ratio will be reported.

We will include fixed effects for period and a fixed effect for intervention exposure. The primary analysis will allow for clustering by as a random cluster and random cluster by period effect. To correct the potential inflation of the type I error rate due to small number of clusters, a correction for a small number of clusters will be applied, but the correction that will be selected will be based on the best available evidence available closer to the time, and it may differ for the outcomes collected via the complete and incomplete designs. In a sensitivity analysis we will explore if models with more complicated correlation structures are a better fit to the data. These models are not being used as our primary analysis models as there is limited understanding as to when such models will converge and how to choose between the various different correlation structures which might be plausible.

To this end we will additionally fit generalised linear mixed models (with same link functions and fixed effects as described above) to include a discrete time decay correlation structure including a random

cluster effect with auto-regressive structure (AR (1)). To allow for the randomisation by batches, a different secular trend will be included for each batch (interaction between batch and period). For continuous, count and prevalence outcomes similar model-based approaches will be used but with appropriate links and distribution functions, using transformations where appropriate.

We will use a two-sided significance level of 5% and estimate 95% confidence intervals. The primary subgroup analyses will be based on geographical region because demonstrating the consistency of any effect across multiple regions will enhance the generalisability of the results (batches will not be based on regions because it will be logistically more feasible to include clusters from different regions in each batch) (4). Additional subgroup analyses will include age across the groups such as older adolescents (15-19 years), young adults (20-24 years), adults (25-59 years), and older adults (60 years and older) (38); sex; and the among the clinical cohorts grouped as blunt multisystem trauma, penetrating trauma, and severe isolated traumatic brain injury.

16.2 Interim analyses {21b}
No interim analyses will be conducted in this trial.

16.3 Method for additional analyses (eg, subgroup and adjusted analyses) {20b}
To additionally explore if the fixed period effect is both parsimonious and adequate to represent the extent of any underlying secular trend, we will model the time effect using a spline function. Models will also be extended to include random cluster by intervention effects (with a non-zero covariance term) to examine if results are sensitive to the assumption of no intervention by cluster interaction. Models will also be extended to include an interaction between treatment and number of periods since first treated, to examine if there is any indication of a relationship between duration of exposure to the intervention and outcomes.

This will allow us to different lag effects (whereby it takes time for the intervention to become embedded within the culture before its impact can properly start to be realised); as well as weaning effects (whereby the effect of the intervention starts to decrease – or fade). This type of analysis attempts to disentangle how some clusters end up having a long exposure to the intervention and others have a much shorter exposure time. A fully adjusted covariate analysis will additionally adjust for a set of pre-specified individual- level covariates of known prognostic importance.

16.4 Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

16.5 Plans to give access to the full protocol, participant-level data, and statistical code {31c}
The full protocol and statistical code will be publicly available. A de-identified anonymous dataset will also be publicly available.

17 Oversight and monitoring
17.1 Composition of the coordinating center and trial steering committee {5d}
The trial management and oversight is governed by three trial committees and groups: the Trial Team (TT), the Trial Management Group (TMG), the joint Trial Steering and Data Monitoring Committee (SDMC). The Trial Team is responsible to run the trial operations on a day-to-day basis, maintain trial databases, randomise clusters, ensuring complete and correct data, preparing reports for meetings (including those of the TMG, and the SDMC). The trial team will also be dealing with research governance and regulatory matters wherever required. The trial management group will be responsible to manage the trial, including its clinical and practical aspects. These will also include the technical aspects, any safety issues related with trial participant. Besides this, the TMG will be also responsible to provide inputs to the SDMC meeting.

17.2 Composition of the data monitoring committee, its role, and reporting structure {21a}

In this trial a joint Trial Steering and Data Monitoring Committee (SDMC) is developed. The SDMC's responsibility is to oversee and safeguard the trial and the trial participants, monitor the main outcome measures including safety and efficacy, and monitor the overall conduct of the trial. The SDMC also should receive and review information on the progress and accruing data of this trial and provide advice on the conduct of the trial to the TMG. The relationship between the groups is briefly described in **Figure 3.** Details of the composition, roles, and meeting frequency of TT, TMG and SDMC are tabulated in the T**able 3.**
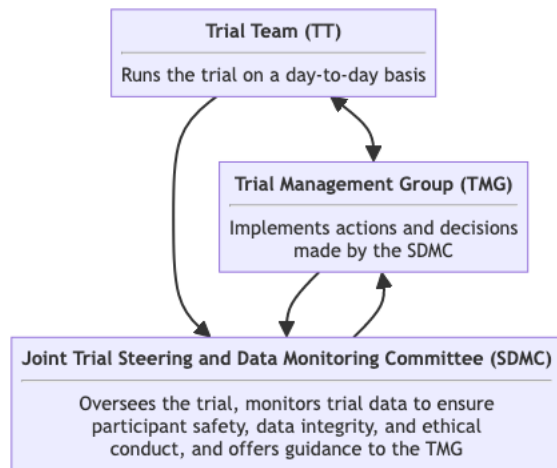
Figure 3: Trial organisation overview.

17.3 Adverse event reporting and harms {22}

In line with other current trials including critically ill patients, we will not collect adverse events or serious adverse events, because many of these events are expected in this patient population and we already collect many of these events, for example mortality, as part of our outcomes. We will only report safety events if they are life-threatening, prolong hospitalisation or result in meaningful harm to the participant. It is difficult to pre-define a comprehensive list of events that can be considered safety events, but will actively assess the presence of the following safety events:

- Prolonged mechanical ventilation (> 7 days)
- Initiation of renal replacement therapy
- Prolonged (> 2 days) or renewed (restart after at least 2 days without) use of vasopressors such as norepinephrine or vasopressin

These are considered as safety events because they may suggest pulmonary, renal, septic or bleeding complications and an increase in their occurrence following ATLS® training could be an indication that the intervention is harmful. These events therefore need to be tracked during the standard care phase as well as the intervention phase but will only be considered indicative of harm related to the intervention if occurred more often during the intervention phase than during the standard care phase. Besides this, safety reports will also be collected other than the list mentioned above. These events will be identified during the trial, and the reporting of these safety events will be based on the clinical judgement of site investigators. Examples of such safety events could include missed injuries or missed investigations, which could be suspected if certain injuries or investigations were identified or conducted more often during the standard care phase than during the intervention phase.

All safety events will be recorded in the Case Record Form (CRF) and reported to the trial management team within 24 hours of its occurrence. The trial management team will then assess if the event can be considered related to the trial or the intervention within 24 hours of it being reported. Events that are considered probably related will be reported immediately to the joint Trial Steering and Data Monitoring Committee. All safety events to be followed up by the local investigator until they are fully evaluated. Besides this, site investigators will also report safety events based upon the local ethics

committee as per the Indian guidelines.

17.4 Frequency and plans for auditing trial conduct {23}

Authorized representatives for the sponsor and Competent Authorities (CA) may carry out audits or inspections at the trial site, including source data verification. The investigator must ensure that all source documents are available for audits and inspections. The audit or inspection will ensure that all study related activities were performed, registered, analysed and reported correctly and according to protocol, ICH- GCP and national regulations. These audits will be done to systematically and independently review all trial-related activities and documents.

17.5 Plans for communicating important protocol amendments to relevant parties (e.g., trial participants, ethical committees) {25}

Substantial amendments to the signed clinical trial protocol are only possible through approved protocol amendments and by agreement between the sponsor and the principal investigator.

17.6 Dissemination plans {31a}

The trial will be reported to the Funders within a year of completion. The results of the trial will also be prepared as manuscripts for publication. Authorship on trial manuscripts will be based on the International Committee of Medical Journal Editors (ICMJE) criteria:
- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or reviewing it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors. The most recent version of the ICMJE criteria will be adhered to. We will also use the ICMJE criteria for non-author Contributorship. Before work on a trial manuscript is initiated, a writing group will be formed and first and last authors will be designated. This writing group will be formed by discussion in the Trial Management Group.

18 Discussion

Several trauma life support training programmes have been developed to improve the early management of patients in the hospital by providing a structured framework for assessment and treatment (40-44). The proprietary Advanced Trauma Life Support® (ATLS®) is the most established trauma life support training programme and more than one million physicians in over 80 countries have been trained in the programme since the first course in 1978 (12). In the US and Europe training in ATLS® is virtually mandatory for trauma care physicians (13). Being widely used training programmes there is lack of evidence on how ATLS ® training can influence patient outcomes. There are practically no randomised controlled trials or high-quality quasi- experimental trials indicating the efficiency of ATLS ® training on patient outcomes to date (45-49). Few randomised control trials were done which showed that ATLS® can improve knowledge and clinical skills (50-52). Countries like India, often lack formal trauma-specific training, such as ATLS® due to high training cost of ATLS® coupled with absence of robust evidence on the impact of ATLS® training on patient outcomes. The findings from this trial could provide crucial insights to improve trauma care practices, standardize trauma protocols, and ultimately enhance patient outcomes.

19 Trial status

The most updated protocol version is Version 1.4.0, 2025-04-30.

Necessary approvals have been undertaken. The trial and the first batch of five hospitals started to include patient participants in February 2025. The second batch of five hospitals will start in September 2025.

Table 4: The composition, roles and responsibilities and the meeting frequencies of the Advance Trauma Study.

	Composition	Roles & Responsibilities	Meeting Frequency
The George Institute of Global Health	□ Prof Vivekanand Jha □ Nobhojit Roy □ Abhinav Bassi □ Samriddhi Ranjan □ Prashant Kharat □	As a regional coordinating center, The George Institute, India will ensure proper conduct of the trial through quality control measures including on-site training of personnel, standard operating procedures, ongoing quality metrics assessment, review of missing data and outliers. This will also include maintenance of the Trial Master File (TMF) and Investigator Site File (ISF) at the site level. The institute will be responsible for data security and protection. The institute will also be responsible for the ensuring an appropriate insurance for the duration of the study to cover against claims for compensation by participants arising out of their participation in the trial in India.	
Trial Team (TT)	□ Martin Gerdin Wärnberg □ Monty Khajanchi □ Abhinav Bassi □ Prashant Kharat □ Samriddhi Ranjan □ Bijini Bahuleyan □ Manoj Soni	To run the trial on a day-to-day basis, maintain trial databases, randomise clusters, ensuring complete and correct data, preparing reports for meetings (including those of the TMG, SDMC) and dealing with research governance and, if appropriate, regulatory matters.	
Trial Management Goup (TMG)	□ Anurag Alok □ Li Felländer-Tsai □ Debojit Basak □ Shamita Chatterjee □ G D Bakhshi □ Karla Hemming □ K D Soni □ Nobhojit Roy □ Vivekanand Jha □ Rajdeep Singh □ Martin Gerdin Wärnberg □ Johanna Berg □ Monty Khajanchi □ Abhinav Bassi □ Prashant Kharat □ Samriddhi Ranjan	To manage the trial, including its clinical and practical aspects. Includes members with broad expertise appropriate to the trial. The TMG will be chaired by the Principal Investigator.	Monthly to every six months.

Trial Steering and Data Monitoring Committee (SDMC)	- Ganesan Karthikeyan: Chair, Independent Member - Richard Hooper: Independent Member, Statistician Kathryn Chu (Independent Member, Clinical expert) - Elamurugan TP: Independent Member, Clinical expert - Sai Kulkarni: Independent Member, Lay-person representative)	The SDMC's responsibility is to oversee and safeguard the trial and the trial participants, monitor the main outcome measures including safety and efficacy, and monitor the overall conduct of the trial. The SDMC also should receive and review information on the progress and accruing data of this trial and provide advice on the conduct of the trial to the Trial Management Group (TMG). The specific roles of the SDMC are detailed below: **Expert supervision and monitoring** • Providing expert supervision of the trial. • Monitoring recruitment figures, follow-up rates, and losses to follow-up. • Monitoring compliance with the protocol by investigators. • Assessing data quality, including completeness, and encouraging the collection of high-quality data. • Overseeing the completion of CRFs and advising on TMG's future strategies for satisfactory completion. • Reviewing interim analyses including main outcomes and safety data. • Assessing the impact and relevance of external evidence. • Monitoring planned sample size assumptions, preferably with regards to: – a priori assumptions about the control arm outcome; and/or – emerging differences in clinically relevant subgroups. **Advising and approving changes** • Sanctioning any changes to the protocol proposed by the TMG (e.g., to design, inclusion criteria, trial endpoints, or sample size). • Approving TMG's proposals for new sub studies. • Suggesting additional data analyses if necessary. **Decision making on trial**	

| | | **continuation**
• Deciding whether to recommend that the trial continues to recruit participants or
whether recruitment should be terminated either for everyone or for some treatment
groups and/or some participant subgroups.
• Deciding whether trial follow-up should be stopped earlier.

Oversight of trial completion and findings

• Supervising the prompt disclosure of trial findings.
• Providing input on the policy for publication.
• Approving and giving feedback on the main trial manuscript.

Confidentiality and appropriateness

• Maintaining confidentiality of all trial information that is not in the public domain.
• Monitoring the continuing appropriateness of patient information. | |

20 List of abbreviations

ATLS: Advance Trauma Life Support
CRF: Case Record Form
ISF: Investigator Site File
SAE: Serious adverse event
TMF: Trial Master File
TMG: Trial management group
TT: Trial team
SDMC: Trial Steering and Data Monitoring Committee

20.1 Acknowledgements
Authors' contributions

20.2 Authors' information (optional)

20.3 Funding {4}

no. 2023-0297). However, the funding for this study is partial, and additional funding will be secured during the course of study. In case the funding is not secured, the study will be stopped, which will likely to result in an underpowered study. But as the intervention in this case is standard of care in many countries and data collection is considered with minimal risk. Therefore, risk of harm among participants is minimal and there is potentially direct benefit to the participants who receive the intervention. Therefore, benefit-risk ratio is considered favourable, even if the study is underpowered.

20.4 Availability of data and materials {29}

21   Declarations
21.1 Ethics approval and consent to participate {24}
Ethics approval has been taken from The George Institute Ethics committee (ECR/272/Indt/DL/2017).

21.2 Consent for publication {32}
This manuscript does not contain individual personal data from patients.

21.3 Competing interests {28}
Several of the contributors are active instructors of ATLS® and/or other trauma life support training programmes.

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