

# Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial

## 1 Purpose and aims

Trauma is a massive global health issue.<sup>1,2</sup> Many training programmes have been developed to help physicians in the initial management of trauma patients.<sup>3–6</sup> Advanced Trauma Life Support® (ATLS®) is the most popular of these programmes and have been used to train over one million physicians worldwide.<sup>7</sup> Despite its widespread use, there are no controlled trials showing that ATLS® improves patient outcomes.<sup>3,4,6</sup> Multiple systematic reviews emphasise the need for such trials.<sup>3,4,6</sup> Therefore, we will conduct a cluster randomised trial with the aim of comparing the effects of ATLS® training with standard care on outcomes in adult trauma patients.

## 2 State-of-the-Art

Each year, 4.5 million people die from trauma.<sup>1</sup> Among people aged 10-24 and 25-49 years trauma is the largest cause of disability adjusted life years.<sup>2</sup> Most deaths from trauma occur within the first 24-48 hours.<sup>8</sup> Traumatic brain injury and exsanguination are the most common causes of trauma deaths.<sup>9,10</sup> 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.<sup>9,11</sup>

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.<sup>3–6</sup> 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.<sup>7</sup> In the US and many other countries training in ATLS® is virtually mandatory for trauma care physicians.<sup>12</sup> Uptake in low- and middle income countries (LMIC) has been slow, potentially due to high costs.<sup>5</sup>

There are three randomised controlled studies showing that ATLS® improves knowledge and clinical skills,<sup>13–15</sup> but there are no randomised controlled trials or high-quality quasi-experimental trials indicating that ATLS® improves patient outcomes.<sup>3,4,6</sup> We conducted an updated systematic review for this application (Text box 1) and estimated a pooled risk ratio of 0.82 (95% CI 0.60; 1.11) from ten heterogeneous ( $I^2$  0.91) retrospective or small studies on the effect of ATLS on mortality (Figure 1).<sup>16–25</sup> This shows that the evidence that ATLS® has an effect on mortality is weak. No study assessed functional outcomes.

### Text box 1: Systematic Review

We performed a systematic literature search in the Medline, Embase, Cochrane, Web of Science, CINAHL and Google Scholar databases (PROSPERO ID CRD42022373977). The last search was conducted on November 11, 2022. We developed the search strategy in Medline (Ovid) in collaboration with librarians at the Karolinska Institutet University Library. We limited the search to English language articles, searched all databases from inception, and screened a total of 7896 records. We used a random effects model to pool estimates across studies.

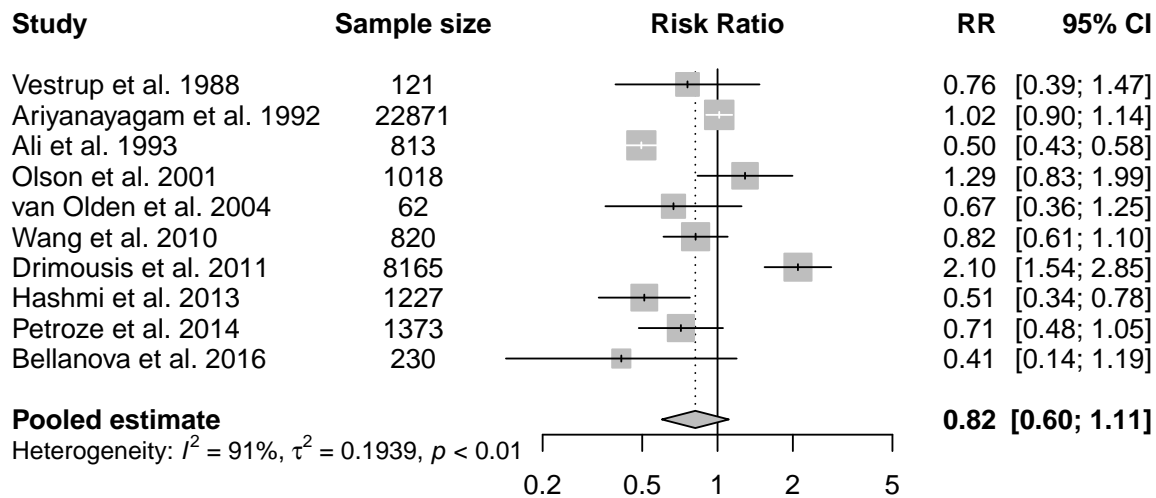


Figure 1: Summary of the systematic review conducted for this application. Abbreviations: CI Confidence Interval, RR Risk Ratio.

### 3 Significance and scientific novelty

We propose an ambitious but high-yield project that will result in the first robust evidence on the effects of ATLS® on patient outcomes since the programme was introduced. We advance the trauma research frontier by conducting large-scale research on a complex system intervention and move beyond the prevailing focus on retrospective research.<sup>16–25</sup> Systematic reviews call for cluster randomised or quasi-experimental trials in settings where ATLS® or similar programmes are not routinely taught.<sup>3,4,6</sup> Our findings will be important regardless of whether they are positive or negative. If ATLS® improves patient outcomes it should be further promoted. If ATLS® does not improve patient outcomes then trauma life support training needs to change.

### 4 Preliminary and previous results

This application was developed jointly by the parties participating in the Trauma life support training Effectiveness Research Network ([www.tern.network](http://www.tern.network)), funded by a Swedish Research Council Network Grant (Dnr. 2020-03779). We have conducted multicentre trauma research in India since 2013 ([www.titco.org](http://www.titco.org)), and identified opportunities for improvement in early trauma care potentially amendable with trauma life support training.<sup>9</sup>

We base this application on 1) data collected in our previous work, including a trial on the effectiveness of trauma audit filters (ClinicalTrials.gov NCT03235388) that ends this year and is funded by the Swedish Research Council (Dnr. 2016-02041) and 2) a pilot cluster randomised controlled trial (ClinicalTrials.gov NCT05417243) that we conducted between April 2022 and February 2023 as part of our network grant to assess the feasibility of a full scale trial. We published the protocol for this pilot study.<sup>26</sup>

We have collected data from 35970 patients across 13 hospitals, out of which eight hospitals and 13979 patients fit the eligibility criteria of this trial. Among those eligible the average in-hospital mortality is 25%. Out of these patients, 81% are males and 19% are females. Our pilot study enrolled 375 patients from seven hospitals across India (unpublished data) and shows that it is feasible to conduct the proposed trial with a high recruitment rate (78%), low loss to follow-up rate (1%), and low missingness in key variables (mean 1%).

To involve patients and the public in the planning of this trial we conducted 19 semi-structured

interviews with trauma patients, caregivers, and community representatives (unpublished data). The aim of these interviews was to understand their views on the trial and important outcomes and the interviews showed high acceptability of our research and emphasised the importance of better recovery before discharge and functional outcomes at and after discharge, including pain, mobility and self-care activities. The interviews also highlighted return to work as an important outcome.

## **5 Project description**

### **5.1 Theory and method**

We report our research plan according to the Consolidated Standards Of Reporting Trials (CONSORT) extension for stepped-wedge cluster randomised controlled trials.<sup>27</sup> The trial will be registered with the Clinical Trials Registry of India and ClinicalTrials.gov.

#### **5.1.1 Trial design**

We will conduct a batched stepped-wedge cluster randomised controlled trial (see Figure 2). The stepped-wedge trial is a uni-directional cross-over trial but the time point when clusters cross-over from standard care to the intervention is randomised.<sup>28</sup> Each cluster will be a tertiary hospital in India. We will conduct this trial in India because of 1) our established collaboration with Indian institutions and experience in conducting multicentre studies in this setting, and 2) physicians in India are not routinely trained in ATLS® or similar programmes.

We will roll out the interventions to 30 clusters over six batches, so there will be 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 transition phase during which the training is delivered, and finally an intervention phase, for a total of 13 months. The implementation sequence determines how long the phases of standard care and intervention are.

#### **5.1.2 Design justification**

We use the cluster randomised design because the intervention cannot be randomised at the individual patient level. We use the stepped-wedge design for two reasons. First, this design is statistically more efficient than the parallel cluster design when the number of clusters is limited.<sup>29</sup> In this trial, the number of clusters is limited due to the constraints of the 1) available budget and time frame of this call and 2) available slots for ATLS® training in India. Second, the stepped-wedge design is likely to enhance participation and engagement because all clusters receive the intervention. The batched stepped-wedge design further improves feasibility as it does not require all clusters to start at the same time, and it is robust to potential delays in cluster recruitment.<sup>30</sup>

#### **5.1.3 Participants**

Because this is a cluster randomised trial, we have eligibility criteria both on the cluster, i.e. hospital, and individual patient levels.

**Clusters** must meet the following criteria:

- tertiary hospitals;
- baseline admission rate of at least 400 patients with trauma per year or 35 patients with trauma per month for at least the last six months;
- provides general surgery, neurosurgery, imaging and blood banking services around the clock; and
- no more than 25% of initial trauma care providers trained in any trauma life support programme.

**Patients participants** must meet the following criteria:

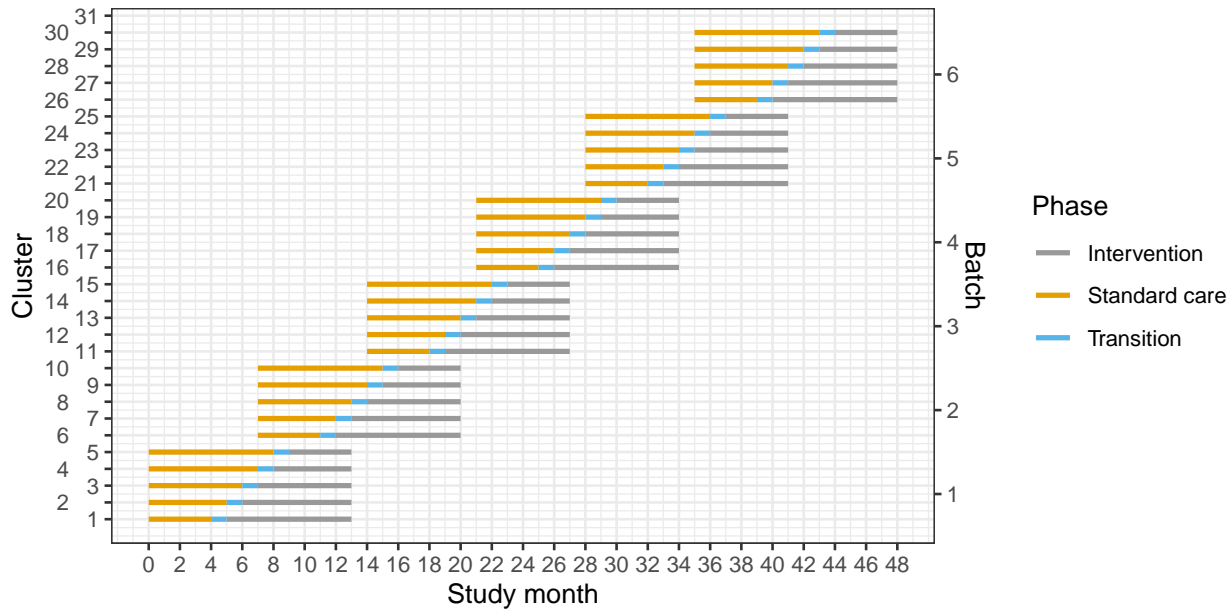


Figure 2: Trial design. Lines represent the duration of patient enrolment across clusters and phases. Clusters will be sequentially allocated to a batch based on when they enter the study. Within each batch clusters will then be randomised to an intervention implementation sequence.

- age of at least 15 years;
- 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;
- transferred from the emergency department of a participating hospital to another hospital for admission; and
- trauma occurred less than 48 hours before arrival at the hospital.

#### 5.1.4 Intervention and control treatment

The intervention will be ATLS® training. The control will be standard care, meaning no formal trauma life support training. 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. The training will occur during the transition phase in each cluster. We will train the number of physicians needed to reach the required patient sample size.

**Advanced Trauma Life Support® (ATLS®)**<sup>7</sup> is 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. Physicians will be trained in an accredited ATLS® training facility in India.

**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. Compared with other settings where a trauma team approach is adopted, nurses and other healthcare professionals are only involved to a limited extent during the initial

management.

### 5.1.5 Outcomes

We chose outcomes that we judged as clinically important and that patients, their caregivers and community representatives perceived as important in our interviews with them.

**Primary outcome** will be in-hospital mortality within 30 days of arrival at the emergency department. Clinical research coordinators will extract information on death from patient hospital records. We chose this outcome as the primary outcome because it is an outcome of clinical and patient importance with very low missing data rates (1%) in our pilot study. We will also be able to compare our findings with previous research.

**Secondary outcomes** will be as follows:

- all cause mortality within 24 hours, 30 days, and three months of arrival at the emergency department;
- 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 EQ5D3L;
- poor functional outcome within seven days of discharge, and at 30 days and three months of arrival at the emergency department, assessed using the EQ5D3L domains of mobility, self-care, usual activities, and pain/discomfort, with poor functional outcome defined as being confined to bed, unable to bath or dress oneself, unable to perform usual activities, or having extreme pain or discomfort;
- return to work at 30 days and three months after arrival at the emergency department; and
- in-hospital pulmonary, septic, or renal complications.

### 5.1.6 Randomisation and blinding

We will assign clusters to batches as they are found to be eligible and receive ethical approval, and will randomise the clusters to intervention implementation sequences within batches. Randomisation will be stratified by geographical region and anticipated cluster size. The Karolinska Trial Alliance will perform the randomisation and conceal the allocation sequence as an independent consultancy. We will not be able to blind patient participants, physicians, or clinical research coordinators conducting the data collection to the intervention; however, we will blind data analysts and the data and security monitoring board during interim analyses.

### 5.1.7 Data collection and management

Clinical research coordinators will collect data, screen patients using emergency department records, and obtain informed consent for post-discharge follow-up. Paper-based CRFs will be securely stored on-site and uploaded to project servers using a VPN with two-factor authentication. Access is granted by the project PI or authorized delegates. Metadata will be publicly accessible via a persistent DOI, and anonymised data will be released upon project completion. The data management plan is published and was reviewed by Karolinska Institutet (<https://doi.org/10.5281/zenodo.7748764>).

### 5.1.8 Quality assurance and monitoring

We will monitor the trial according to a prespecified monitoring plan, with the aim to ensure that participants' rights, safety, and well-being are met, that the trial is carried out according to the protocol and that data are collected, documented, and reported according to the International Conference on Harmonisation - Good Clinical Practice and applicable ethical and regulatory requirements. A data and security monitoring board, comprising four external members, will review trial data for each batch, assessing data quality, completeness, cluster performance in recruitment and loss to follow-up rates, and external factors affecting trial validity, safety, or ethics.

## 5.2 Time plan and implementation

This project will run for five years (see Figure 3). During the first year we will obtain the necessary approvals and start data collection in the first batch. During the following years we will enrol clusters and obtain approvals for each subsequent batch. The final patient follow-up will be in October 2028. The main risks and our corresponding mitigation plans are:

- **delays in obtaining approvals:** be proactive and start necessary processes, for example submissions to ethical review boards, long before the study is planned to start in each centre;
- **delays in cluster recruitment:** approach potential clusters long before the intended study start, leveraging our considerable existing networks to (the hospitals that will participate in the first batch are already finalised);
- **lower than expected enrolment rates:** perform careful on-site evaluations before a cluster is formally enrolled to avoid lower than expected enrolment rates.

There is also the risk of unforeseen global events like the COVID-19 pandemic. While we cannot mitigate this risk we have limited its potential impact on our trial by adopting the batched stepped-wedge design, which makes it feasible to pause and resume the trial between batches without compromising its quality.

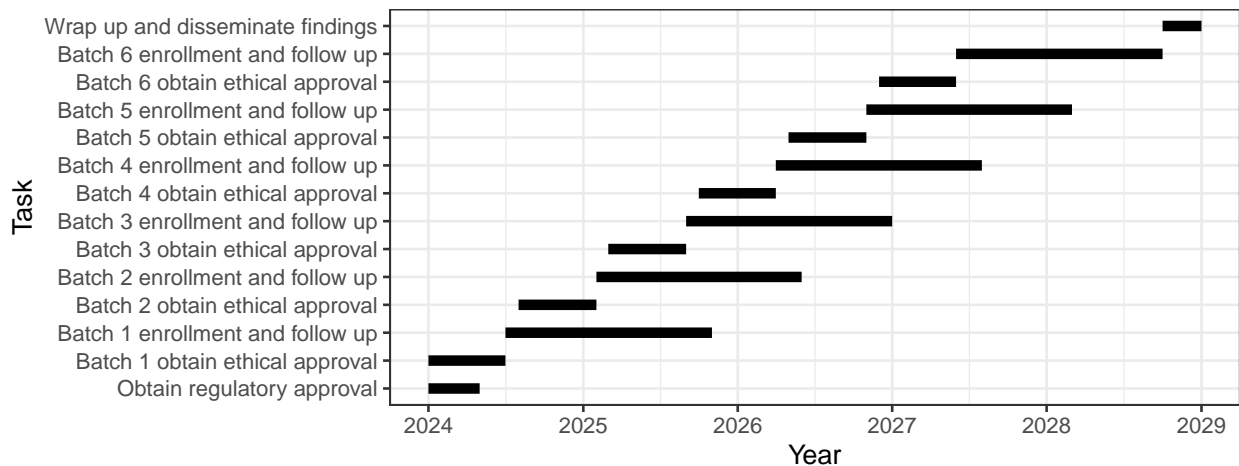


Figure 3: Project time plan with key tasks

## 5.3 Project organisation, international and national collaboration

This is a collaborative project between researchers, clinicians, and institutions in Sweden, India, and the United Kingdom, which will be led by Karolinska Institutet (KI) in Sweden and The George Institute for Global Health (TGI) in India. KI is the university accounting for the largest share of all academic medical research in Sweden. TGI is a leading independent medical research institute with extensive experience in conducting large scale clinical trials across India. KI will be the trial sponsor, maintain the overall responsibility for the trial, store the trial data and conduct the data analyses. TGI will coordinate the project activities in India, including approvals, data collection, ATLS® training, and monitoring, with a full-time team: a project manager, a clinical research associate, and five clinical research coordinators.

### 5.3.1 Principal investigator

**Martin Gerdin Wärnberg** is an Associate Professor of Clinical Epidemiology at KI. Martin has led multicentre observational and interventional trauma research in India for 10 years. He will coordinate the project and oversee data management, analysis and reporting. His activity level will

be 30%. Several of Martin's large projects are coming to an end during 2023, which is why he will be able to dedicate 30% of his research activities to this trial. Except for the pilot study leading up to this application, Martin has no previous experience conducting cluster randomised controlled trials, but this is compensated for by the team of participating researchers.

### 5.3.2 Participating researchers

This team of participating researchers will provide methodological expertise and experience in conducting large scale research, including cluster randomised controlled trials in India and elsewhere, as well as clinical trauma care expertise.

**Vivekanand Jha** is a Professor and the Executive Director of the George Institute for Global Health India. He has led many high-impact clinical trials including cluster randomised trials and contributes with his expertise in managing similar large scale trials in India. **Anita Gadgil** is Professor and Head of Surgery Department at the Bhabha Atomic Research Centre Hospital in Mumbai and headed the WHO Collaboration Centre for Research on Surgical Care Delivery in LMIC. Anita will contribute knowledge on care delivery and patient focused outcome measures research. **Li Felländer-Tsai** is a Professor of Orthopaedic Surgery at KI and Senior Consultant at the Karolinska University Hospital. Li will contribute her experience of delivering and studying training interventions. **Lovisa Strömmer** is a trauma surgeon and Senior Consultant in Surgery at the Karolinska University Hospital, as well as Associate Professor of Surgery at KI. Lovisa will contribute with her substantial clinical trauma expertise and experience in researching trauma outcomes. **Karla Hemming** is a Professor of Biostatistics at the University of Birmingham where she leads a research programme related to stepped-wedge trials. Karla is an international expert in stepped-wedge trials and will provide input on design and analysis.

### 5.4 Project members

In addition to the participating researchers, this trial will be possible because of the extensive networks and key skills of its project members, all of whom all will be directly involved in the research project and developed this application.

**Makhan Lal Saha** is a visiting consultant at M R Bangur Hospital Kolkata and the former Professor and Head of the Department of General Surgery at IPGME&R/SSKM Hospital in Kolkata. He is also the immediate past president of the Association of Surgeons of India West Bengal state chapter. **Girish Bakhshi** is presently working as a professor and is in charge of the trauma services of the Department of Surgery, Grant Government Medical college & Sir J.J.Group of Hospitals, Mumbai, India. **Shamita Chatterjee** is a Professor of General Surgery at IPGME&R/SSKM Hospital in Kolkata with a special interest in trauma management. She teaches and examines General Surgery and Trauma. **Rajdeep Singh** is a Professor of Surgery at Maulana Azad Medical College (MAMC), New Delhi. He practices as a general surgeon and is the principal investigator of several trauma research projects. **Deepa Kizhakke Veetil** is a general surgeon and researcher presently working with Manipal Hospitals in Delhi. She has a Masters in Trauma Sciences and developed the standard treatment guidelines for major trauma for the Government of India. **Monty Khajanchi** is a faculty member in general and trauma surgery at a public university hospital in Mumbai. He worked with the Government of India to develop standard treatment guidelines for trauma care and is a consultant at the WHO for surgical and related services. **Kapil Dev Soni** is a faculty member in Critical and Intensive Care at JPN Apex Trauma Center, All India Institute of Medical Sciences, New Delhi. He has completed a fellowship in designing clinical studies and evidence-based medicine and has contributed to the of standard treatment guidelines for trauma care. **Anurag Mishra** is a surgeon and Associate Professor working at MAMC, New Delhi. **Johanna Berg**, who is an Emergency Medicine physician in Malmo and a PhD candidate at KI, developed the data management

plan. **Siddarth David**, a public health researcher with a PhD from KI, has researched equity in health care access in communities for more than a decade.

## **5.5 Data analysis and statistics**

### **5.5.1 General principles**

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. All secondary outcomes will be interpreted with due consideration for how all are affected by the intervention. We will use a two-sided significance level of 5% and estimate 95% confidence intervals. We will report time-adjusted within-cluster correlations for all outcomes with 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. Additional subgroup analyses will include age, sex, and clinical cohorts with blunt multisystem trauma, penetrating trauma, and severe isolated traumatic brain injury.

### **5.5.2 Analysis models**

All analyses will consider the clustered nature of the design. For the primary and binary secondary outcomes, we will use mixed effects binomial regression with a log-link to estimate the relative risk, and a binomial model with identity link to estimate the risk difference.<sup>31</sup> We will develop non-convergence plans. We will use the Kenward and Roger small sample correction to correct for the potential inflation of the type-I error caused by a small number of clusters. We will adjust for temporal confounding because the design is a stepped-wedge trial. To allow for the randomisation by batches, a different secular trend will be included for each batch. We will use similar model-based approaches for continuous secondary outcomes. In a sensitivity analysis we will explore whether models with more complicated correlation structures are a better fit. 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 that might be plausible.

### **5.5.3 Additional sensitivity analyses**

To additionally explore whether 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 whether the results are sensitive to the assumption of no intervention by cluster interaction. We will also extend models 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. A fully adjusted covariate analysis will additionally adjust for age, sex, mechanism of injury, and trauma severity, which are individual-level covariates of known prognostic importance.

### **5.5.4 Power analysis**

With 30 clusters and a total 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 from 20% under standard care to 15% after ATLS® training. 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,<sup>32,33</sup> and a CAC of 0.9 but considered sensitivity across the range 0.8-1.0, based on our pilot study and current guidance.<sup>34-36</sup> 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.

## **5.6 Equipment (not applicable)**

## **5.7 Need for research infrastructure (not applicable)**

## **5.8 Independent line of research (not applicable)**

## **5.9 Clinical significance**

We will establish the effects of ATLS®, the most widely used trauma life support training programme worldwide, on patient outcomes. The results of our trial are directly applicable to clinical trauma care practice and will influence how trauma life support is trained globally, regardless of its outcome. In the case of a positive trial with ATLS® improving outcomes over standard care this programme should be promoted and ways to increase its uptake should be explored. In the case of a negative trial new ways to perform trauma life support training are needed.

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