Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes

A Cluster Randomised Trial

Coordinating Institutions

- Karolinska Institutet (KI), an international medical university in Stockholm, Sweden
- The George Institute of Global Health (TGI), an international research organisation in New Delhi, India

Aim

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

Primary Outcome

All-cause mortality within 30 days of arrival at the emergency department

Population

Adult trauma patients presenting to the emergency department of a participating hospital

Intervention

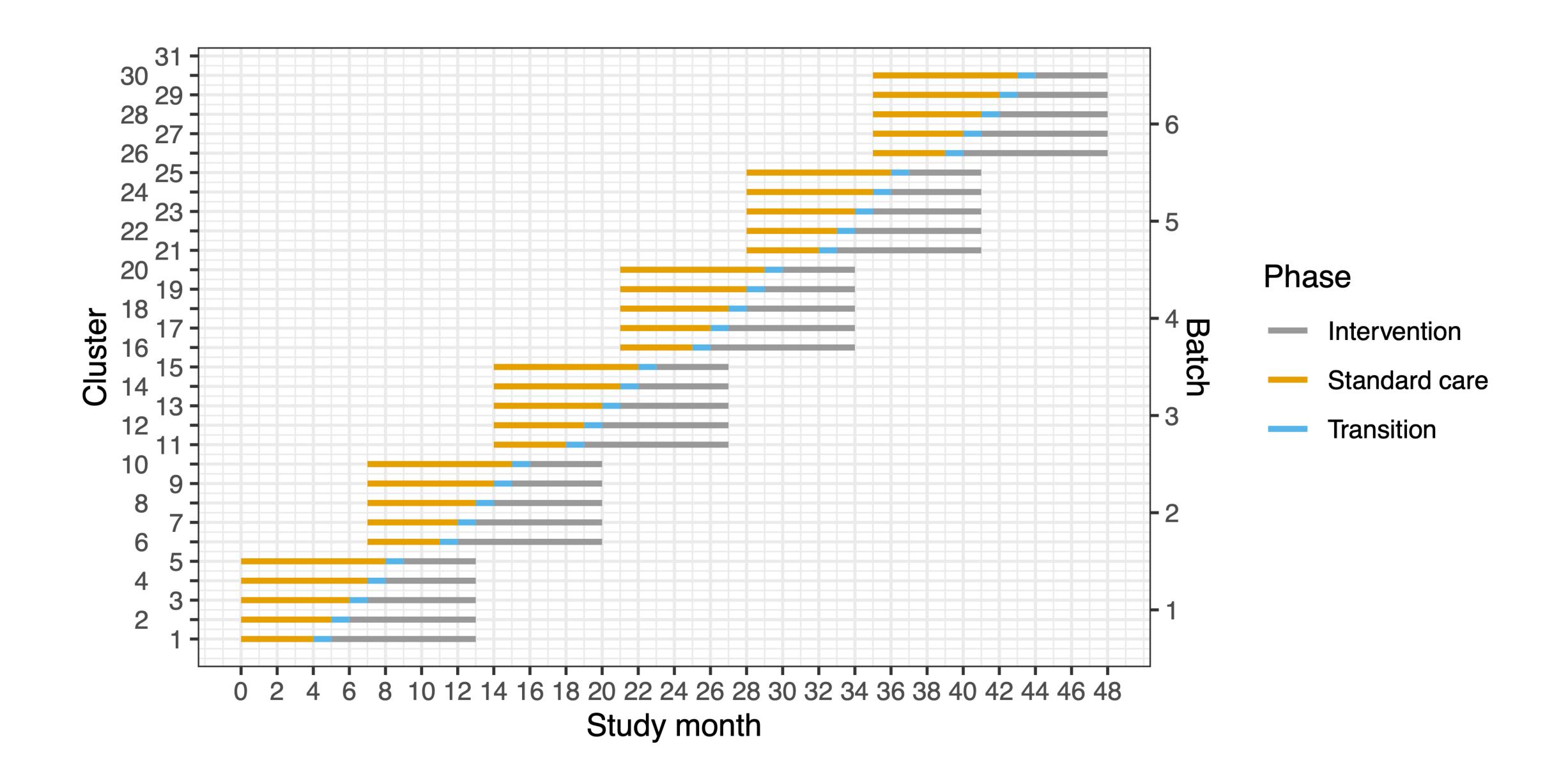
- ATLS® training, a 2.5 day course teaching a standardised approach to trauma patient care
- All hospitals will receive the intervention
- ~10 physicians per hospital will be trained in an accredited ATLS® training facility in India

Design

Batched stepped-wedge cluster randomised controlled trial in 30 hospitals across India

Design

- The time point when the training is implemented will be randomised
- Minimum of 4 months standard care before the training is implemented
- The training is implemented during a 1 month transition phase
- Minimum of 4 months after training
- Each hospital is in the trial for 13 months



Power & Sample Size

- 30 clusters and a total sample size of 4320 patients
- ~90% power to detect a reduction in 30-day inhospital mortality from 20% under standard care to 15% after ATLS® training.

Ethics & Clearances

- We will apply for ethical approvals from:
 - Each participating hospital
 - TGI
- We will apply for HMSC approval

Funding

- Out current funding will cover 10 out of the 30 hospitals planned for
- We are currently applying for additional funding
- If we do not obtain additional funding the trial will be stopped early

Benefits

- 10 physicians at your hospital will be trained in ATLS at no cost to your institution
- We will employ a full time clinical research coordinator stationed at your institution for the duration of the trial
- Multiple opportunities for publications in international scientific journals

Amendments

- If we obtain additional funding, we will add:
 - A cost-effectiveness analysis
 - An assessment of implementation outcomes
- Suggestions for additional sub-studies are very welcome!