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

A Cluster Randomised Trial

Aim

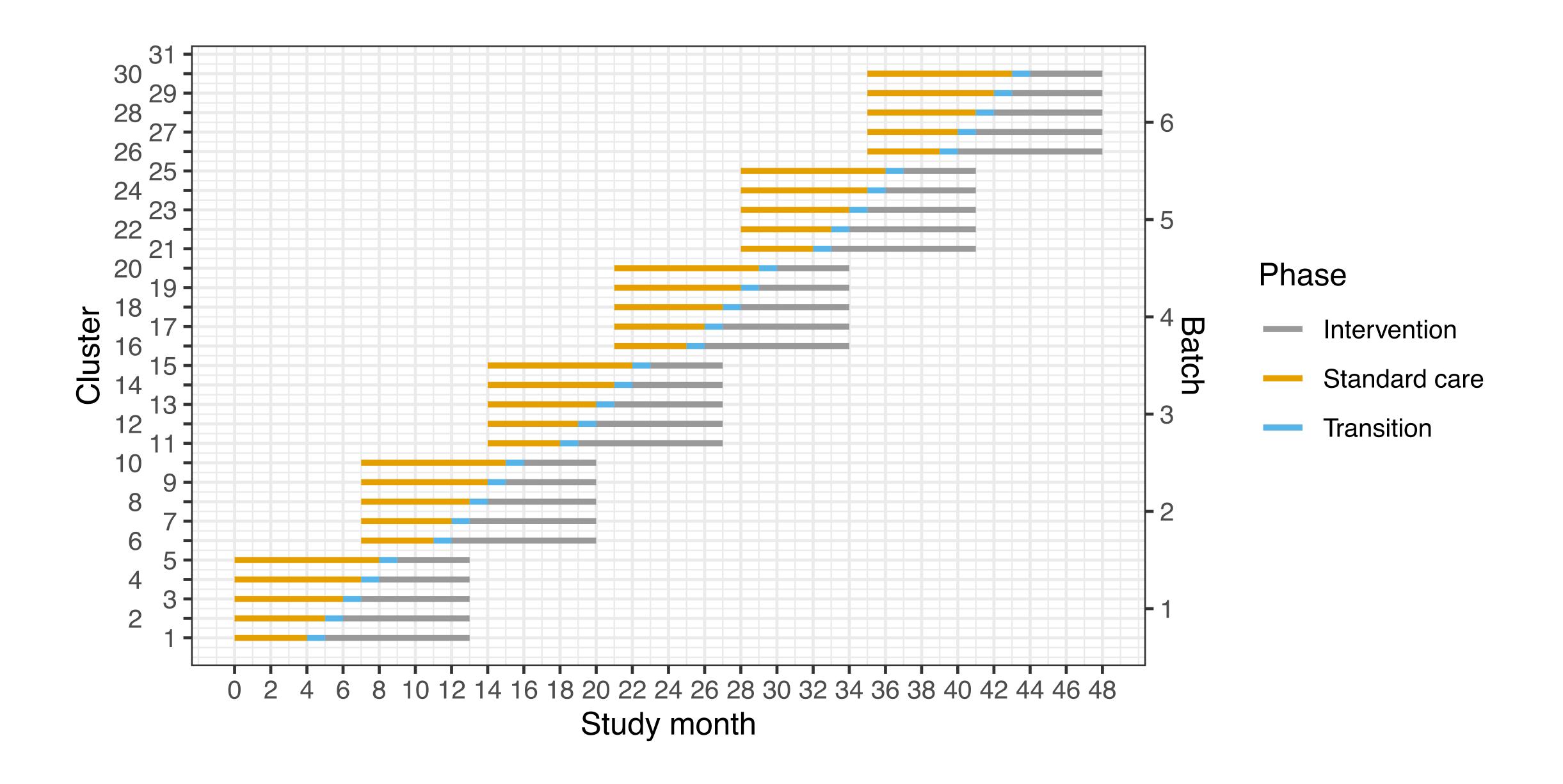
To compare the effects of ATLS® training with standard care on outcomes in adult trauma patients

Design

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

Power & Sample Size

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



Estimated Cost

11.7 million SEK

Granted Amount

5 million SEK

What Does This Mean?

- 42% funded
- 100% coverage year 1
- 33% coverage year 2-3

Our Options

- Adapt study to fit granted amount (fewer hospitals, different design)
- Continue as planned with an optimised design and apply for more funding

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KI Responsibilities

- Trial sponsor, overall responsibility
- Draft Research Collaboration Agreement (money) and Joint Controller Agreement (data)
- Draft trial protocol
- Store trial data
- Conduct analyses

TGI Responsibilities

- Contribute to drafting the trial protocol
- Coordinate trial activities in India
 - HMSC application
 - Help enrol centres
 - Ethical approvals
 - Data collection
 - Coordinate ATLS training
 - Trial monitoring and auditing

Next Steps

- Finalise study protocol (weekly meetings in December)
- Write and sign agreements
- Apply for HMSC approval
- Identify first batch of hospitals
- Apply for ethical approvals
- Identify additional funding opportunities (ICMR?)