ADVANCE TRAUMA

Effects of ATLS® Training on Adult Trauma Patient Outcomes: A Cluster Randomised Trial

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Aim

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

Importance

Despite widespread use, there is no high-quality evidence showing that ATLS® improves patient outcomes. This trial will be the first to address this gap.

Primary outcome

30-day in-hospital mortality

- Collected through medical records for patients admitted or discharged home
- Collected through telephonic follow-up for patients transferred to another hospital

Secondary outcomes

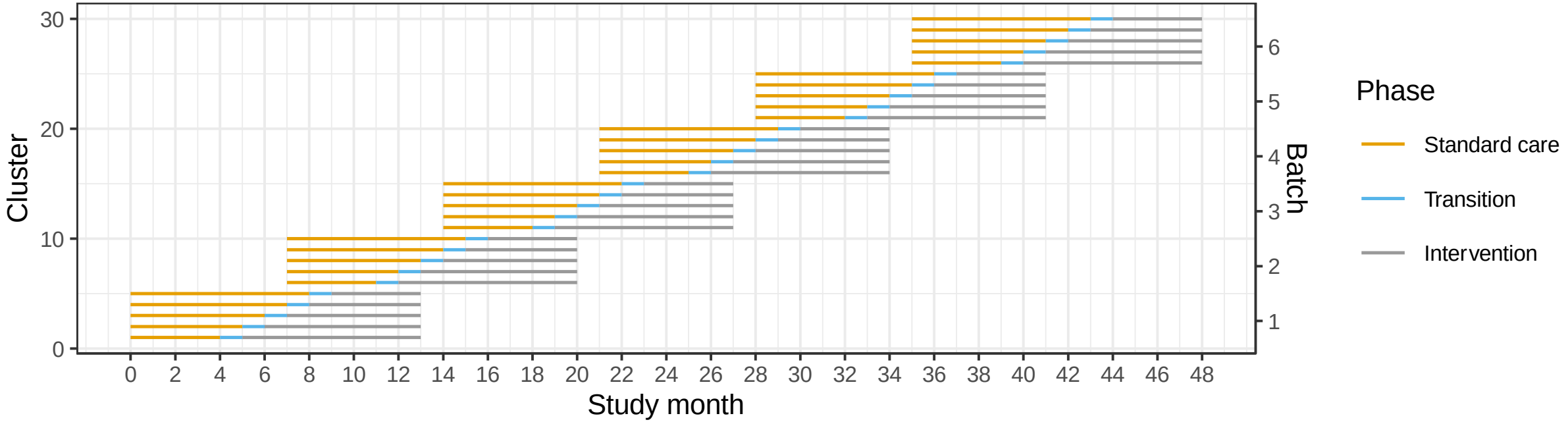
- **All cause and in-hospital mortality** at 24 hours, 30 days and 90 days
- **Quality of life**, measured using EQ5D5L at 30 days and 90 days
- **Disability**, measured using WHODAS 2.0 at 30 days and 90 days
- **Return to work**, measured at 30 days and 90 days
- **Length of stay**, in the ED, ICU and hospital
- **Adherence to ATLS principles**, collected through observations

Design

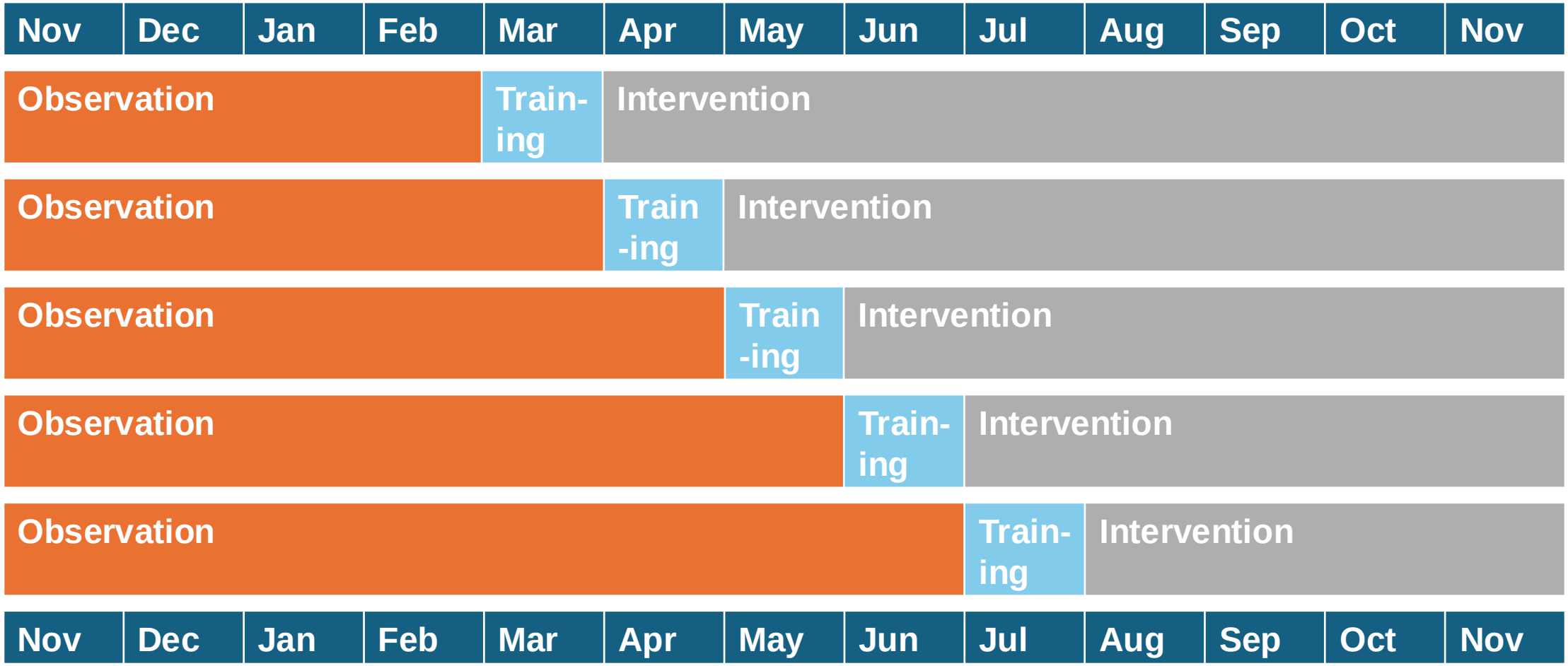
Batched stepped-wedge cluster randomised trial:

- 30 hospitals
- 6 batches
- 5 sequences
- 13 months in trial

Design


Cluster
30
20
10
0
0 2 4 6 8 10 12 14 16 18 20 22 24 26 28 30 32 34 36 38 40 42 44 46 48
Study month
Batch
6
5
4
3
2
1
Phase
Standard care
Transition
Intervention

Design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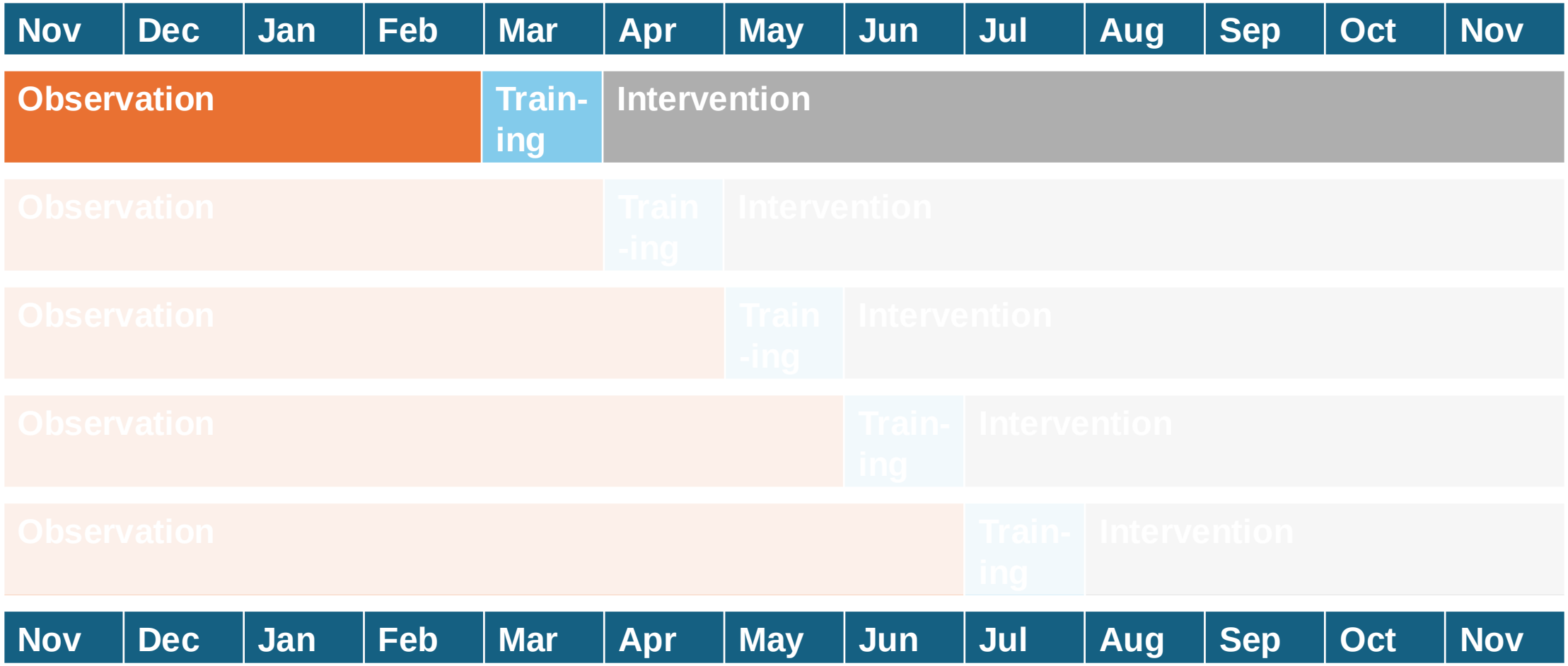
Design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Eligibility criteria

Hospital
Secondary or tertiary hospitals in India that admit or refer/transfer for admission at least 400 patients with trauma per year

Cluster
One or more units of physicians providing initial trauma care in the participating hospitals

Patient
Adult trauma patients presenting to the emergency department of participating hospitals and who are admitted

Intervention and control

Intervention

- 2.5 day ATLS training course
- Accredited ATLS training facility in India
- 1-2 units per hospital

Control

- Standard care, meaning care as usual
- No modifications

Intervention implementation

- We can train an average of 10 physicians per hospital
- Important
  - Train those who initially resuscitates trauma patients
  - Maximise the number of trained physicians in the emergency department on a given day
  - Train as many as possible in the same unit
- The timing of the training will be randomised
  - The first hospital will undergo training four months after the trial starts
  - Hospitals will be informed about their sequence one month in advance

Intervention implementation

	Unit 1/Monday & Thursday	Unit 2/Tuesday & Friday	Unit 3/Wednesday & Saturday
Resident 1			
Resident 2			
Resident 3			
Resident 4			

	Unit 1/Monday & Thursday	Unit 2/Tuesday & Friday	Unit 3/Wednesday & Saturday
Resident 1			
Resident 2			
Resident 3			
Resident 4			

Intervention implementation

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Resident 4			

Sample size

- We count on each cluster (often 1 cluster = 1 unit) to enrol at least 12 patients per month
- We need at least 4320 patients to be able to detect a reduction in mortality from 20 to 15%

Consent

Opt-out

- Majority, including primary outcome
- All variables considered routinely collected and adherence data

Opt-in

- Less common
- Variables that are not routinely collected, including follow-up

Waiver

For patients who are unconscious and are without a legally authorized representative

Data collection

- One Clinical Research Coordinator (CRC) per participating hospital
- Enrols patients admitted under the participating unit(s)
- Most data are extracted from medical records
- Some outcomes will be collected through observation or telephone follow-up
  - Not all patients, but from a random sample of patients

Data collection

- Adherence to ATLS principles will be collected through observation
- 14 step checklist covering assessments and interventions that are part of the primary survey
- Will require training of CRCs to recognize these assessments and interventions
  - Brief introduction today
  - Observe ATLS course or training by the trial team
  - Collection of adherence data from 10 patients under supervision of ATLS-trained senior clinician at each study site

Study timeline 2024

19/10

Site initiation meeting

21/10-4/11

Pilot data collection including supervised adherence observation

24/10

ATLS-observation or online training session by the trial team

11/11

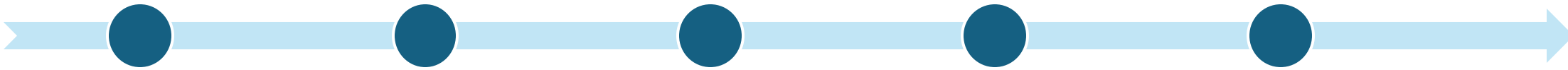
Trial start

- CTAs are signed

- First SDMC meeting held

November

Site visit by TGI team once 10 patients have been enrolled



Study timeline 2025

March

1st site undergoes ATLS training

April

2nd site undergoes ATLS training

May

3rd site undergoes ATLS training

June

4th site undergoes ATLS training

July

5th site undergoes ATLS training

11/12

End of study batch 1

Safety reporting

We collect safety events indicative of pulmonary, renal, septic or bleeding complications:

- 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
- Any other event resulting in prolonged hospitalisation, death, or other meaningful harm as determined by the investigator

Safety reporting

- Safety events will be captured by Clinical Research Coordinators
- Require review by investigator to assess if the event is potentially related to the intervention
- This assessment is recorded in the CRF
- Events assessed to be potentially related to the intervention are reported to the Trial Management Group
- Decision by the Trial Steering and Data Monitoring Committee

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