Ongoing trial: Determining Optimal early rehabilitation after StrokE (AVERT DOSE)

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@AVERTDOSEtrial

Speaker Disclosure

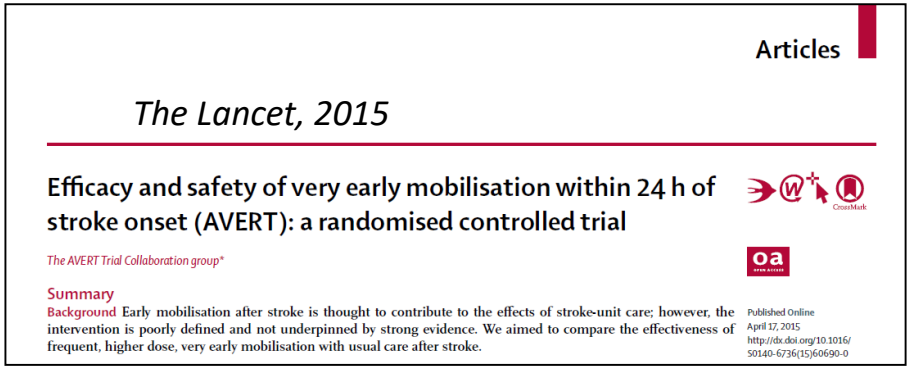
I have no conflicts to disclose.

Trial Funding Acknowledgement

National Health and Medical Research Council Australia project grant (APP1138134)

AVERT

Large, 2 groups, international RCT (n=2104)



Articles

The Lancet, 2015

Efficacy and safety of very early mobilisation within 24 h of stroke onset (AVERT): a randomised controlled trial

*The AVERT Trial Collaboration group**

Summary

Background Early mobilisation after stroke is thought to contribute to the effects of stroke-unit care; however, the intervention is poorly defined and not underpinned by strong evidence. We aimed to compare the effectiveness of frequent, higher dose, very early mobilisation with usual care after stroke.

Published Online April 17, 2015 http://dx.doi.org/10.1016/S0140-6736(15)60690-0

Conclusions

- Too much too soon can be harmful
- Severe stroke patients & ICH showed harm
- Dose analyses showed benefit in those less severely affected patients (mild & moderate stroke)
- Clinicians still don't know what is best. Guidelines to be developed.

Australian Clinical Guidelines

Funding for AVERT DOSE obtained

Aim and Hypotheses

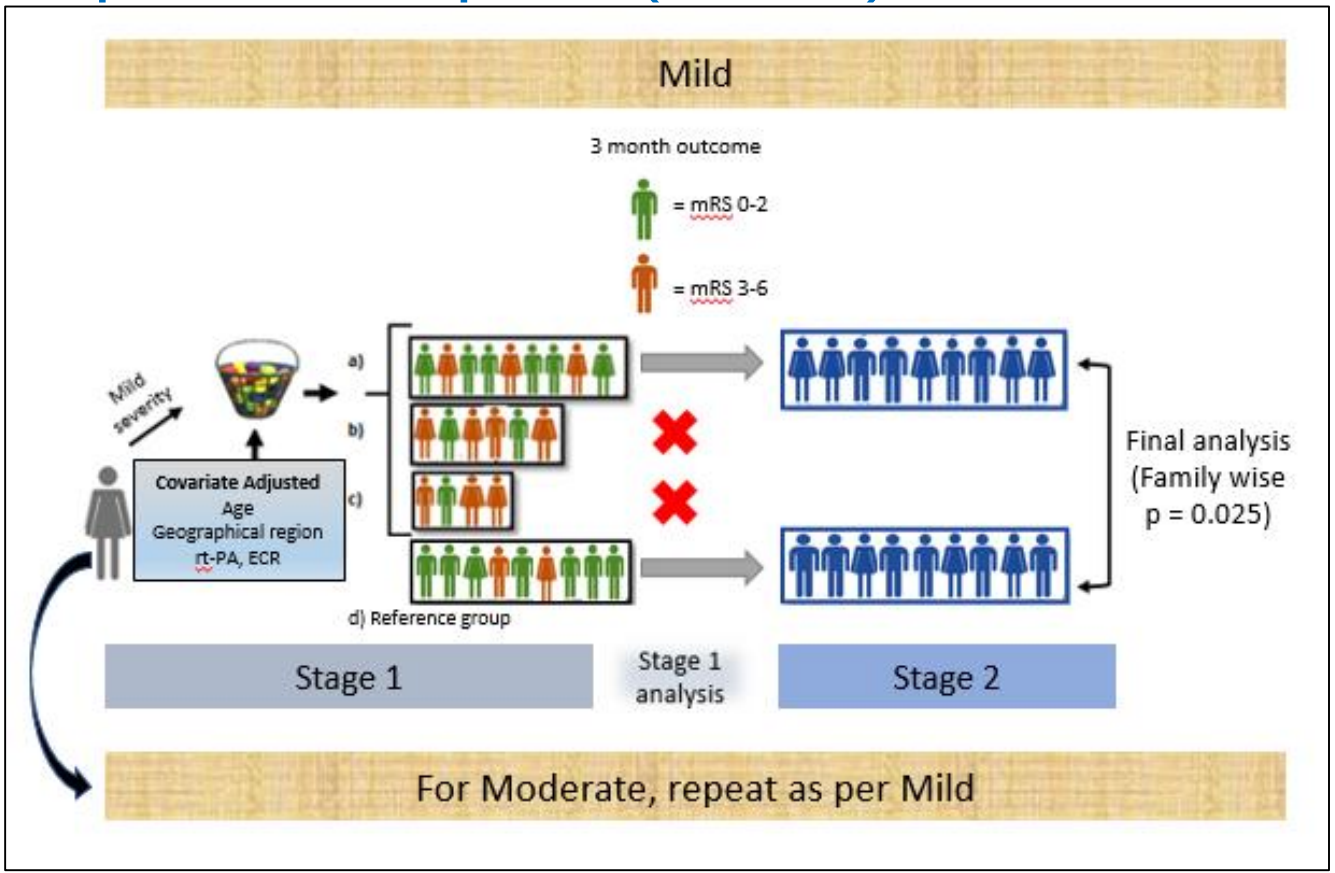
Aim To define optimal early mobility intervention regimens for people with mild and moderate stroke.

Hypotheses Optimal dose intervention regimen(s) will result in:

- More patients with **no or little disability** at 3 months post stroke, (1° outcome)
- Patients with **fewer and less severe complications**
- Better **quality of life** at 6 months

Cost-effectiveness and a range of sub-studies are included to examine recovery processes.

Multi-Arm, Multi-Stage, Covariate-Adjusted Response-Adaptive (CARA) Randomisation Design



DOSE
Varying amount
Varying frequency
Tailored to patient

Number of participants:
n >2,500

Adaptive design differences

Randomised Clinical Trial	AVERT DOSE Adaptive Randomisation
Randomisation to group is remote, computer generated	Randomisation to group is remote, computer generated
Group allocation is concealed	Grou
Randomisation is fixed. For four groups, equal allocation would be 1:1:1:1	• O e gr • Fo ra m • G t to ge • B reference group after stage 1 analysis
Blinded outcomes at 3 and 6 months	Blinded outcomes at 3 and 6 months

Statistician
Leonid Churilov

Coder
Hannah Johns

Inclusion/Exclusion Criteria

Inclusion	Exclusion
Patients ≥ 18 years admitted to a stroke unit within 48 hour of onset of stroke with: Ischaemic stroke • Mild (NIHSS 0-7) or moderate stroke severity (NIHSS 8 ≤ 16) • Pre stroke mRS of 0 – 2 • Medically stable	• Pre-stroke mRS of 3, 4 or 5 • Haemorrhagic stroke or TIA • Severe stroke (NIHSS > 16) • Co-morbid progressive neurological or coronary conditions or other rapidly deteriorating disease • Palliation or immediate surgery • A lower limb fracture/disability • Patients with no evident mobility problems or expected to be discharged within 3 days post enrolment. • Currently in a drug or other intervention trial

Involved Sites

Committed and selected

Interest and under negotiation

Australian and New Zealand sites

Victoria

Austin
Alfred
St Vincent's Hospital Melbourne
Albury Wodonga

Western Australia

Fiona Stanley Hospital
St John of God, Midlands
Joondalup

Queensland

Princess Alexandra Hospital
Sunshine Coast University Hospital

New Zealand

Tauranga

The AVERT DOSE team so far…..


Julie Bernhardt


Leonid Churilov


Peter Langhorne


Jejaraj Pandian


Amanda Thrift


Marj Moodie


Vincent Thijs


Brooke Parsons


Velandri Shrikanth


Helen Dewey


Geoffrey Donnan


Sandy Middleton


Julie Luker


Coralie English


Anna McRae


Katijjahbe Md Ali


Fiona Ellery


Hannah Johns


Oriana Borschmann


Janice Collier

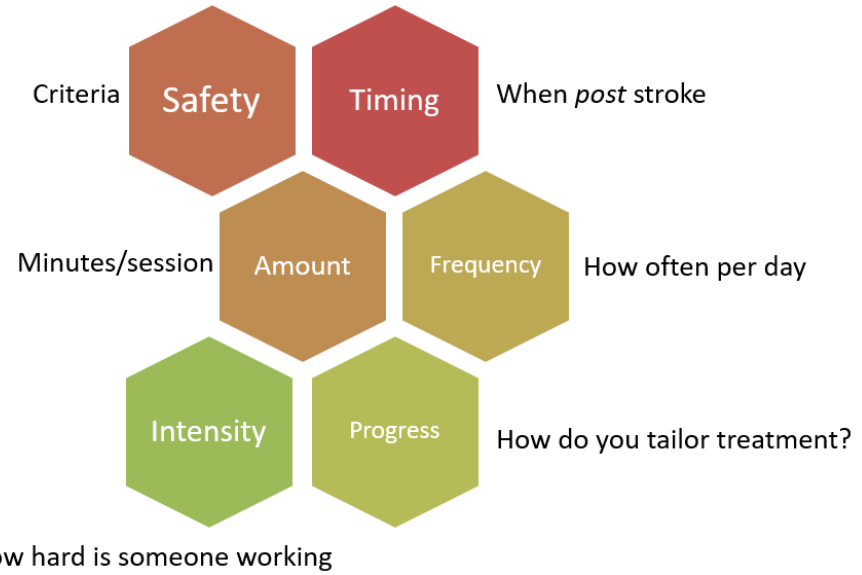

Carol Williams

as well as Prof Richard Lindley, Prof Bent Indredavik, Dawn Tan, Dr Kate Heyward (not pictured) .

Trial Status

AVERT-DOSE will:

1. Commence recruitment in 2019
2. Run for approximately 4 years
3. Include >2,500 patients
4. Be an international collaborative effort
5. Deliver clearer early rehabilitation protocols for clinical practice



Interested in participating?
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