

efficacy of LOw dose antihypertensive and lipid lowering pill combinations To improve stroke oUtcomeS (LOTUS)

ACTRN12624001279516

Status	RECRUITING
Phase	Phase 3
Sponsor	The George Institute for Global Health Australia
Enrollment	400 participants

Plain Language Summary

After a stroke or transient ischaemic attack (TIA — sometimes called a mini-stroke), the risk of having another stroke is significantly elevated. Managing blood pressure and cholesterol are two of the most important steps in reducing that risk, but many stroke survivors do not receive optimal treatment. The LOTUS trial is testing whether a low-dose combination pill approach — supported by a nurse-led, telehealth care model — can lower blood pressure more effectively than standard care.

Participants are randomly assigned to either receive the combination treatment plus regular telehealth check-ins with a nurse team, or to continue with their usual GP-based care. The study runs for 26 weeks and also includes an optional arm for cholesterol-lowering treatment. It aims to show that nurse-supported, simplified medication approaches are practical, acceptable, and effective for stroke survivors.

You may be eligible if you are 18 or older, have had a confirmed ischaemic stroke or TIA in the past 12 weeks as diagnosed by a neurologist, and need treatment to lower your blood pressure. People who have had a brain bleed, are pregnant, or have significant kidney problems are not eligible.

Key Eligibility Criteria

Inclusion (6)

- Free & informed consent (paper or electronic)
- Adult aged 18 years or over,
- Recent ischaemic stroke/Transient ischaemic attack in the past 12 weeks, as diagnosed by a neurologist.
- Indicated for pharmacological treatment of high blood pressure.
- Optional factorial arm:

... and 1 more (see full listing online)

Exclusion (13)

- Intracerebral or subarachnoid haemorrhage.
- Contraindication to any of the individual components of the intervention.
- Unable to complete trial procedures.
- Planned overseas travel in the first 30 days of joining the trial and if planning to travel for longer than 1 months during the trial period.
- Pregnant or had a positive pregnancy test or unwilling to undertake a pregnancy test during the screening, or breastfeeding.

... and 8 more (see full listing online)

Locations (14 total)

Riverland General Hospital - Berri, ACT,NSW,NT,QLD,SA,TAS,WA,VIC, Australia

Royal North Shore Hospital - St Leonards, ACT,NSW,NT,QLD,SA,TAS,WA,VIC, Australia

The Canberra Hospital - Garran, ACT,NSW,NT,QLD,SA,TAS,WA,VIC, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12624001279516>

and 11 more locations

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