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.

Methods We did this parallel-group, single-blind, randomised controlled trial at 56 acute stroke units in five countries. Patients (aged ≥18 years) with ischaemic or haemorrhagic stroke, first or recurrent, who met physiological criteria were randomly assigned (1:1), via a web-based computer generated block randomisation procedure (block size of six), to receive usual stroke-unit care alone or very early mobilisation in addition to usual care. Treatment with recombinant tissue plasminogen activator was allowed. Randomisation was stratified by study site and stroke severity. Patients, outcome assessors, and investigators involved in trial and data management were masked to treatment allocation. The primary outcome was a favourable outcome 3 months after stroke, defined as a modified Rankin Scale score of 0–2. We did analysis on an intention-to-treat basis. The trial is registered with the Australian New Zealand Clinical Trials Registry, number ACTRN12606000185561.

Findings Between July 18, 2006, and Oct 16, 2014, we randomly assigned 2104 patients to receive either very early mobilisation (n=1054) or usual care (n=1050); 2083 (99%) patients were included in the 3 month follow-up assessment. 965 (92%) patients were mobilised within 24 h in the very early mobilisation group compared with 623 (59%) patients in the usual care group. Fewer patients in the very early mobilisation group had a favourable outcome than those in the usual care group (n=480 [46%] vs n=525 [50%]; adjusted odds ratio [OR] 0·73, 95% CI 0·59–0·90; p=0·004). 88 (8%) patients died in the very early mobilisation group compared with 72 (7%) patients in the usual care group (OR 1·34, 95% CI 0·93–1·93, p=0·113). 201 (19%) patients in the very early mobilisation group and 208 (20%) of those in the usual care group had a non-fatal serious adverse event, with no reduction in immobility-related complications with very early mobilisation.

Interpretation First mobilisation took place within 24 h for most patients in this trial. The higher dose, very early mobilisation protocol was associated with a reduction in the odds of a favourable outcome at 3 months. Early mobilisation after stroke is recommended in many clinical practice guidelines worldwide, and our findings should affect clinical practice by refining present guidelines; however, clinical recommendations should be informed by future analyses of dose–response associations.

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See Online for appendix

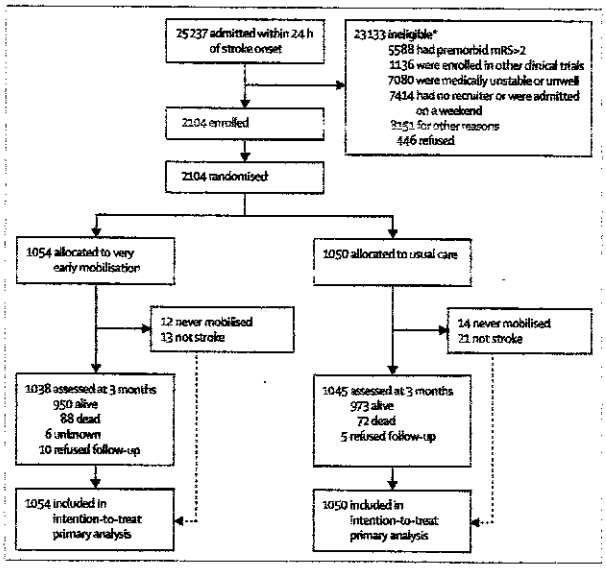

Figure 1: Trial profile
mRS=modified Rankin Scale. *More than one reason possible per patient.

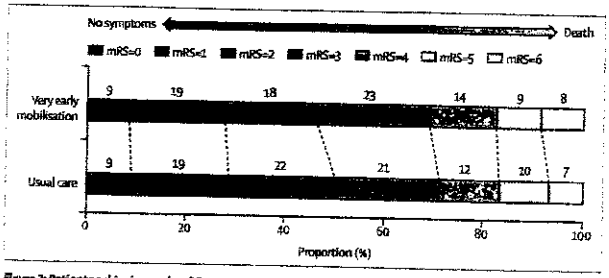

Figure 2: Patients achieving each mRS score at 3 months
mRS=modified Rankin Scale.

	Very early mobilisation (n=1054)	Usual care (n=1050)
Recruitment region		
Australia and New Zealand	617 (59%)	626 (60%)
Asia	126 (12%)	125 (12%)
UK	311 (29%)	299 (28%)
Age (years)	72·3 (62·3–80·3)	72·7 (63·4–80·4)
<65	331 (31%)	298 (28%)
65–80	448 (43%)	481 (46%)
>80	275 (26%)	271 (26%)
Sex		
Female	411 (39%)	407 (39%)
Male	643 (61%)	643 (61%)
Risk factors		
Hypertension	707 (67%)	717 (68%)
Ischaemic heart disease	235 (22%)	251 (24%)
Hypercholesterolaemia	419 (40%)	423 (40%)
Diabetes mellitus	239 (23%)	228 (21%)
Smoking		
Never smoked	454 (43%)	491 (47%)
Smoker*	227 (22%)	204 (19%)
Ex-smoker*	352 (33%)	341 (33%)
Unknown	21 (2%)	14 (1%)
Atrial fibrillation	229 (22%)	237 (23%)
Premorbid history		
Premorbid modified Rankin Scale		
0	799 (75%)	786 (75%)
1	145 (14%)	158 (15%)
2	110 (10%)	106 (10%)
Living arrangement at time of admission		
Home alone	257 (25%)	275 (26%)
Home with someone	781 (74%)	761 (73%)
Supported accommodation	16 (1%)	14 (1%)
Independent walking		
Without aid	908 (86%)	925 (88%)
With aid	146 (14%)	125 (12%)
Time to randomisation (h)	18·2 (12·1–21·8)	18·2 (12·5–21·8)
Stroke history		
First stroke	878 (83%)	843 (80%)
NIHSS score	7 (4–12)	7 (4–12)
Mild (1–7)	592 (56%)	578 (55%)
Moderate (8–16)	315 (30%)	328 (31%)
Severe (>16)	147 (14%)	144 (14%)
Stroke type (Oxfordshire Stroke Classification)		
Total anterior circulation infarct	224 (21%)	232 (22%)
Partial anterior circulation infarct	340 (32%)	328 (31%)
Posterior circulation infarct	93 (9%)	106 (10%)

(Table 1 continues in next column)