East Suffolk and North Essex NHS Foundation Trust

Quality improvement initiative: Early mobilisation post stroke

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Acknowledgement to Dr R Sivakumar

Outline

- Early mobilisation
- Implementation of Very early mobilisation at Colchester stroke unit
- AVERT phase III trial publication
- Its impact and protocol change
- Results of prespecified dose response analysis
- Participation in AVERT Dose trial - our experience

What is early mobilisation

- Out of bed activity
  - Active Sitting
  - Standing
  - Walking
- Very early mobilisation within 24 hours
- Early mobilisation within first 48 hours
- Mobility Interventions in the first couple of weeks

Early mobilization: Potential benefits

- Potential benefits of early mobilisation:
- Reduce infections such as Aspiration pneumonia, UTI
- Reduce risk of DVT/PE
- Reduce pressure ulcers
- Reduce deconditioning
- Improve recovery and functional outcomes
- Optimise window of opportunity for brain recovery and neuroplasticity

Early mobilization: The potential risks

- Too much too soon could be harmful
    - Reduced cerebral blood flow
    - Negative impacts on neuroplastic changes
- Optimum timing and dosage remains unclear for clinicians

Very early mobilisation project -2012

- Many clinical discussions and disagreements
- AVERT phase II, RCP guidelines, NICE guidelines
- Very Early mobilisation (within first 24 hours stroke onset) project initiated in 2012

The evidence

- **Most guidelines recommended very early mobilisation**
- **RCP consensus**
- **AVERT phase II – VEM safe and feasible**

(Bernhardt et al. A very early rehabilitation trial for stroke (AVERT): phase II safety and feasibility. Stroke. 2008 Feb;39(2):390-6)

- **Earlier and more intensive mobilization after stroke may fast-track return to unassisted walking and improve functional recovery**

(Cumming et al. Very early mobilization after stroke fast-tracks return to walking: further results from the phase II AVERT randomized controlled trial. Stroke. 2011 Jan;42(1):153-8)

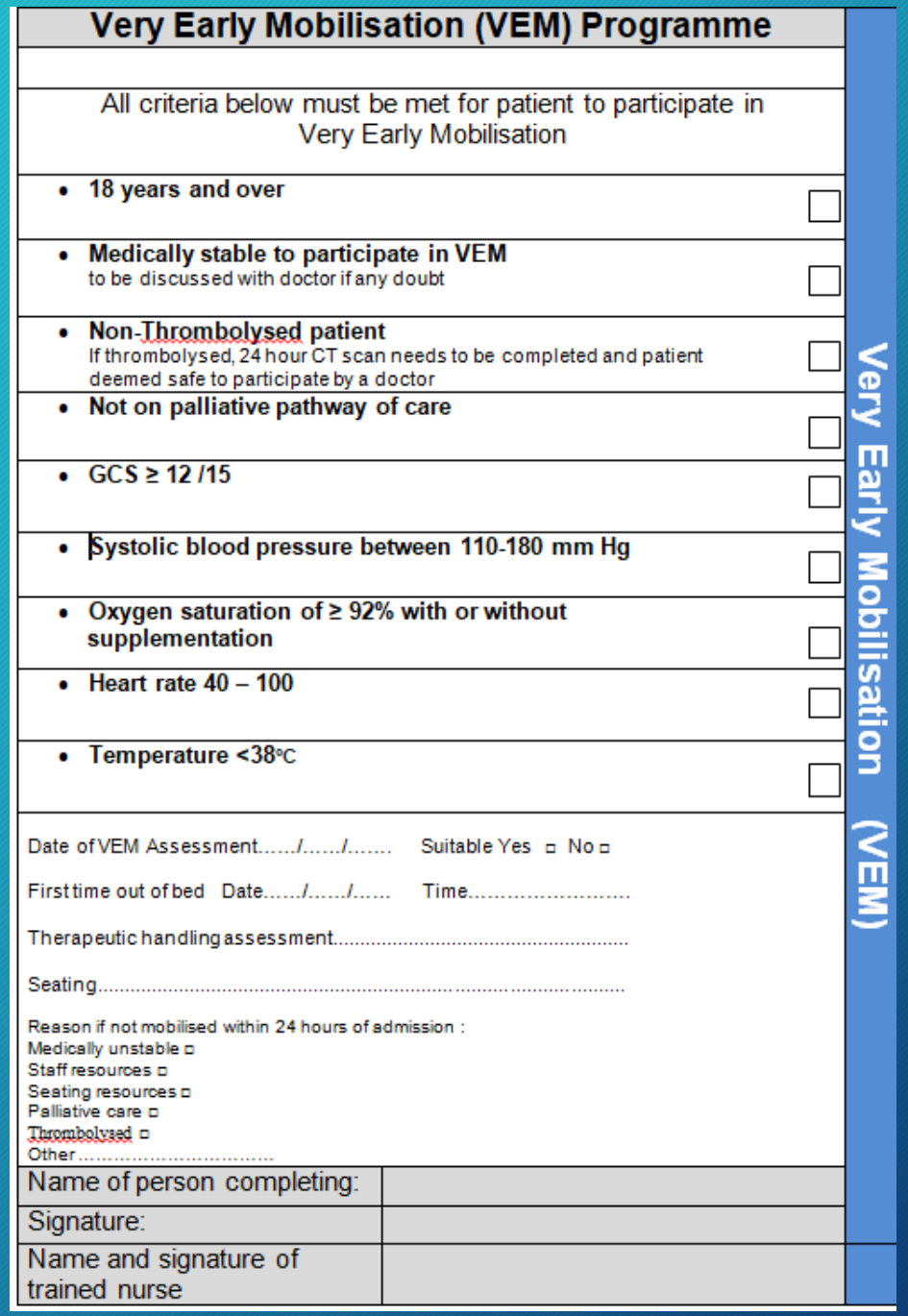
Quality improvement project

Application of evidence to practice

Local eligibility criteria created

Education forums & practical teaching sessions for nursing staff

Early mobility champions



Very Early Mobilisation (VEM) Programme

All criteria below must be met for patient to participate in Very Early Mobilisation

- **18 years and over** ☐
- **Medically stable to participate in VEM**
  to be discussed with doctor if any doubt ☐
- **Non-Thrombolysed patient**
  If thrombolysed, 24 hour CT scan needs to be completed and patient deemed safe to participate by a doctor ☐
- **Not on palliative pathway of care** ☐
- **GCS ≥ 12 /15** ☐
- **Systolic blood pressure between 110-180 mm Hg** ☐
- **Oxygen saturation of ≥ 92% with or without supplementation** ☐
- **Heart rate 40 – 100** ☐
- **Temperature <38°C** ☐

Date of VEM Assessment...../...../..... Suitable Yes ☐ No ☐

First time out of bed Date...../...../..... Time.....

Therapeutic handling assessment.....

Seating.....

Reason if not mobilised within 24 hours of admission :
Medically unstable ☐
Staff resources ☐
Seating resources ☐
Palliative care ☐
Thrombolysed ☐
Other .....

Name of person completing:	
Signature:	
Name and signature of trained nurse	

Very Early Mobilisation (VEM)

Local audit results

- 11 month period in 2013
- 71% met the VEM criteria
- 69% were mobilized within 24 hours
- Protocol facilitated patients admitted outside 8- 4 to be mobilised by the nursing team

AVERT PHASE III Trial, 2015

	Very early mobilisation (n=1054)	Usual care (n=1050)	p value	Median shift (95% CI)
Time to first mobilisation (h)	18·5 (12·8–22·3; n=1042*)	22·4 (16·5–29·3; n=1036*)	<0·0001	4·8 (4·1–5·7)
Frequency per person†	6·5 (4·0–9·5)	3 (2·0–4·5)	<0·0001	3 (3–3·5)
Daily amount per person (min)‡	31 (16·5–50·5)	10 (0–18)	<0·0001	21·0 (20–22·5)
Total amount per person (min)§	201·5 (108–340)	70 (32–130)	<0·0001	117 (107–128)

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)

- *Efficacy and safety of very early mobilisation within 24 h of stroke onset (AVERT): a randomised controlled trial -* ***Lancet 2015; 386: 46–55***

Early mobilisation criteria updated 2016

Early Mobilisation Programme

Date of stroke onset……Time of stroke onset……

<24 hrs post stroke onset	24 - 48 hrs post stroke onset
• **18 years and over** ☐	• **18 years and over** ☐
• **Medically stable to participate in Early Mobilisation** ☐ (Not suitable for patients with thrombolysis early neurological deterioration, planned surgery, suspected PE, and unstable coronary conditions - To be discussed with consultant)	• **Medically stable to participate in Mobilisation** ☐ (Not suitable for patients with suspected fracture or PE or acute coronary syndrome, to be confirmed with medical team if any concerns)
• **Not on palliative pathway of care** ☐	• **Not on palliative pathway of care** ☐
• **GCS 15 or 14 (losing 1 point by confusion)** ☐	• **GCS >12 in right sided strokes and >10(E3, V1, M6) in left sided strokes** ☐
• **Systolic blood pressure between 110-180 mm Hg** ☐	• **Systolic blood pressure between 100-200 mm Hg** ☐
• **Oxygen saturation of ≥ 92% with or without supplementation** ☐	• **Oxygen saturation of ≥ 92% with or without supplementation** ☐
• **Heart rate 40 – 110** ☐	• **Heart rate 40 – 110** ☐
• **Temperature <38°C** ☐	• **Temperature <38°C** ☐
• **Requires little or no assistance to move** ☐	**Patients meeting *all* the above criteria and who have difficulty moving after their stroke should be offered short, frequent mobilisations starting between 24-48 hours post stroke.** **If > 48 hours post stroke and above criteria is not met please discuss with medical team for suitability to mobilise.**
Patients meeting *all* the above criteria may mobilise within 24 hours post stroke. **GTN or infusions are not a contraindication to mobilisation**	

Date of Assessment……/……/……. Suitable Yes ☐ No ☐

First time out of bed Date……/……/…… Time……..

Reason if first time out of bed delayed :

Name of person completing:

Signature:
(and counter signature if required)

Early Mobilisation

Prespecified dose-response analysis for A Very Early Rehabilitation Trial (AVERT)

Neurology® 2016;86:1–8

- **Increased daily frequency of out-of-bed sessions (keeping time to first mobilization and mobilization amount constant) improved the odds of favourable outcome in efficacy and safety outcomes**

  (odds ratio [OR] 1.13,95%confidence interval [CI] 1.09 to 1.18, p,0.001)

- **Increased amount (minutes per day) of mobilization reduced the odds of a good outcome**

  (OR 0.94,95%CI 0.91 to 0.97, p , 0.001)

Rationale for AVERT DOSE Trial

- **Dose analyses showed benefit in those less severely affected (mild and moderate strokes) under certain conditions**

Clinicians still not clear on what is the optimum dose of mobility therapy

Funding for AVERT DOSE obtained

Colchester initiated as a recruiting site for AVERT Dose in September 2022

I became Principal investigator and obtained funding through Greenshoots scheme

Multi-arm, Multi-stage, Covariate-adjusted, response- adaptive randomised trial to Determine Optimal early mobility training after StrokE

AVERT DOSE

- Aim: To define the optimal early mobility intervention regimens for people with mild and moderate stroke

- Hypotheses: The optimal dose intervention regimen(s) will result in:
  1. More patients experiencing no or little disability at 3 months post stroke, (primary outcome)
  2. Patients experiencing fewer and less severe complications
  3. Better quality of life at 6 months

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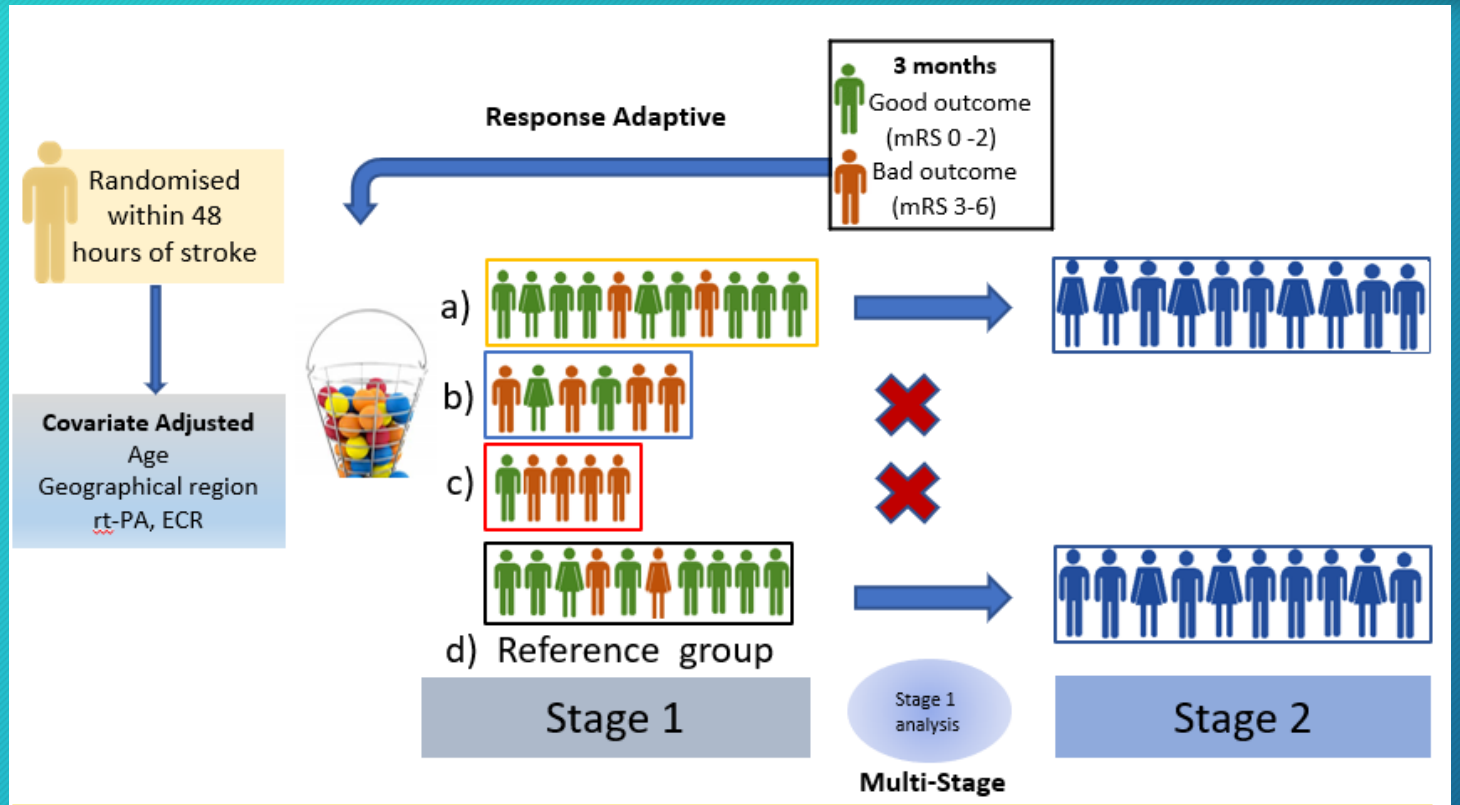
Multi-Arm, Multi-Stage, Covariate-Adjusted Response-Adaptive (CARA) Randomisation Design



6 months
End of trial

DOSE
Varying amount
Varying frequency
Tailored to patient

Number of participants:
n >2,500
approx. 50 hospitals (35)

Where are we now?

- Colchester recruitment - 9 participants
- UK recruitment (8 sites) - 44 participants
- International recruitment - nearly 500 in total
- Recruitment end December 2024, published results to follow

Conclusions: Early mobilisation

- VEM (less than 24 hours) may be associated with clinical harm
- VEM may be appropriate in some cases - patients requiring little or no assistance to mobilise
- Low-quality evidence from an exploratory network meta-analysis indicated that mobilisation at around 24 hours may be associated with the best outcome (Langhorne et al.Cochrane Database Syst Rev. 2018)
- Increased daily frequency of out-of-bed sessions may be beneficial – further evidence is awaited – AVERT Dose

Summary: quality improvement project

- Our experience in implementation of very early mobilisation, subsequent changes to the pathway, therapy-led participation in AVERT Dose trial has galvanised the multidisciplinary team and enabled our MDT to focus on this important area
- It has contributed to improved outcomes as evident in our below national stroke specific mortality
- It has raised the profile of AHPs and improved confidence amongst therapy teams in delivering QI projects and research activities

Thank you for listening

Questions?