Very Early Rehabilitation

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Director, AVERT Very Early Rehabilitation Research Program, National Stroke Research Institute (part of Florey Neuroscience Institutes), Melbourne, Australia
“Rehabilitation is both a philosophy and a set of tasks aimed at maximising functional outcome and minimising handicap” (National Stroke Strategy p.37)

Key questions in rehabilitation:
Who needs it most? When should it begin?
What should it consist of? Where should it be delivered?
How long should it last? Who should deliver it?
After stroke rehabilitation should begin as early as possible
Rehabilitation Models

Traditional model

Acute → Post acute → Longer term

1 - 3 wks → 4 - 12 wks
Rehabilitation Audit 1989

- Time from stroke onset to rehab admission
  - 22.0 days (SD 17.2) *

- Stroke rehabilitation average LOS
  - 84.9 days (SD 66.0)

- Outcome: 75% home, 7.5% Hostel, 16% NH

Mount Royal Hospital, Melb (1989)
• Time from stroke onset to rehab admission
  - 17.6 days ↓ 2.4 days

• Stroke rehabilitation *average* LOS
  - 54.9 days (SD 32.5) ↓ 30 days

• Outcome: 77.2% home, 9.6% Hostel, 13.3% NH

*North West Hospital, Melb (1995)*
Rehabilitation Models

Traditional model

- **Acute**: 1 - 3 wks
- **Post acute**: 4 - 12 wks
- **Longer term**

New model

- **Acute+rehab**: 1 - 3 wks
- **Post acute**: 3 - 4 wks
- **Longer term**
After Stroke…

“Rehabilitation should begin as early as possible”

......after stabilisation
......after all acute tests/procedures are completed
......after there is no risk to the penumbra with activity
......when we know they can cope with 30 mins of training
......when we’ve decided they are suitable for rehabilitation
......once they’ve been transferred to a rehabilitation unit

“..early seems to mean shortly after a stroke occurs, which could span a variable number of days” (VA/DoD CPG, 2002)

Definitions are important!
Controversy: Can We Start TOO Early?

Instead of waiting for this

Can we start here?

Or even here?
Early Rehabilitation in ICU

Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomised controlled trial *Lancet* 2009; 373: 1874

William D Schweickert *et al.*, Department of Medicine, Division of Pulmonary, Allergy and Critical Care Medicine, University of Pennsylvania, Philadelphia, PA, USA

**Design:** Multi-site RCT, blinded assessors

**Target population:** ICU patients, mixed pathology, requiring ventilation

**Intervention:** Sedation interruption & early OT and PT daily

**Primary outcome:** Functional independence at discharge
# Shorter Time to Achieve Milestones

*Schweickert et al. Lancet 2009*

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=49)</th>
<th>Control (n=55)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time from intubation to first PT/OT session (days)</td>
<td>1.5 (1.0–2.1)</td>
<td>7.4 (6.0–10.9)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Independent ADLs total at ICU discharge</td>
<td>3 (0–5)</td>
<td>0 (0–5)</td>
<td>0.15</td>
</tr>
<tr>
<td>Independent ADLs total at hospital discharge</td>
<td>6 (0–6)</td>
<td>4 (0–6)</td>
<td>0.06</td>
</tr>
<tr>
<td>MRC examination score at hospital discharge</td>
<td>52 (25–58)</td>
<td>48 (0–58)</td>
<td>0.38</td>
</tr>
<tr>
<td>Hand-grip strength at hospital discharge (kg-force)</td>
<td>39 (10–58)</td>
<td>35 (0–57)</td>
<td>0.67</td>
</tr>
<tr>
<td>Greatest walking distance at hospital discharge (m)</td>
<td>33.4 (0–91.4)</td>
<td>0 (0–30.4)</td>
<td>0.004</td>
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</table>

<table>
<thead>
<tr>
<th>Time from intubation to milestones achieved (days)</th>
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<tbody>
<tr>
<td>Out of bed</td>
</tr>
<tr>
<td>Standing</td>
</tr>
<tr>
<td>Marching in place</td>
</tr>
<tr>
<td>Transferring to a chair</td>
</tr>
<tr>
<td>Walking</td>
</tr>
</tbody>
</table>

Data are median (IQR). ADLs=activities of daily living. ICU=intensive care unit. MRC=Medical Research Council. PT/OT=physical therapy and occupational therapy. MRC examination scale 0–60.

*Table 4: Function and muscle strength outcomes according to study group*
Better Functional Outcomes

Schweickert et al. Lancet 2009

Figure 2: Probability of return to independent functional status in intervention and control groups
Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomised controlled trial *Lancet* 2009; 373: 1874

William D Schweickert et al, Department of Medicine, Division of Pulmonary, Allergy and Critical Care Medicine, University of Pennsylvania, Philadelphia, PA, USA

**Conclusion:** “A strategy for whole-body rehabilitation—consisting of interruption of sedation and physical and occupational therapy in the earliest days of critical illness—was safe and well tolerated, and resulted in better functional outcomes at hospital discharge, a shorter duration of delirium, and more ventilator-free days compared with standard care.”
Rapid loss of muscle strength 1.5-5.5% / day
40% decline first week
Selective atrophy of anti-gravity muscles
Rapid loss of cardiovascular fitness

These 2o changes slow recovery

Increased orthostatic intolerance

Reduced O2 saturation

Increased risk of 2o complications

Topp et al, AACN Clinical Issues, 2002
What does rehabilitation do to the injured brain?

Stroke models may help our understanding

Very early forced use may be harmful
Jones & Schallert (1994)

Early & higher intensity voluntary exercise improves brain reorganisation & function
Teasell et al, Top Stroke Rehab (2005)

Translation research pipeline

VECTORS trial Neurology, 2009
Man versus Mouse

Physical & physiological effects only part of the picture
Mood
Motivation
Self-efficacy
Hope
No Clear Guidelines in Stroke

Acute Stroke Clinical Practice Guidelines

- Patients should be mobilised as early and frequently as possible

- People with acute stroke should be mobilised as soon as possible (when condition permits)

- Rehabilitation should start as early as possible once medical stability is reached

Indirect evidence
Very Early Rehabilitation

Getting patients out of bed within 24 hours of stroke onset

Simple intervention

“We do it already”
Indredavik, Norway

“It’s not safe”
Evidence Needed

Important steps in trial development:

• Preliminary work/ proof of concept (Phase I) *(Stroke, 2004)*
• Develop a trial protocol and test for safety & feasibility (Phase II) *(Bernhardt et al, Stroke, 2008)*
• Cochrane Systematic Review *(Bernhardt et al, 2009)*
• Test for efficacy (Phase III)
• Test if it works in the real world (Phase IV)
<table>
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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>LuSST</td>
<td>Ludwigshafen Stroke Study</td>
</tr>
<tr>
<td>INVADE</td>
<td>Intervention project on cerebrovascular diseases and dementia in the community of Ebersberg - Bavaria</td>
</tr>
<tr>
<td>AVERT</td>
<td>A Very Early Rehabilitation Trial</td>
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The Collaboration

Current Funding
NHMRC & NHF, Australia
CH&S Scotland, UK
Northern Ireland CH&S, UK
SingHealth, Singapore

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Dr T Ahmad/Dawn Tan, Singapore
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A Very Early Rehabilitation Trial

Design

Large, multicentre, randomised controlled trial of very early rehabilitation (< 24 hrs) versus standard care post stroke.
Hypotheses

Early rehab delivered by a PT/nurse team will:

1. Results in fewer deaths & less disability at 3 months
2. Lead to fewer complications at 3 months post stroke
3. Results in better quality of life at 12 months
4. Be cost effective
# Inclusion Criteria

<table>
<thead>
<tr>
<th>Included</th>
<th>Excluded</th>
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<tr>
<td>Confirmed stroke (first / recurrent)</td>
<td>TIA</td>
</tr>
<tr>
<td>Admitted &lt; 24 hrs symptom onset</td>
<td>Mod – severe premorbid disability</td>
</tr>
<tr>
<td>Age &gt; 18 years, no upper limit</td>
<td>Admitted directly to ICU</td>
</tr>
<tr>
<td>Physiological parameters within set limits:</td>
<td>Unstable cardiac conditions, severe heart failure</td>
</tr>
<tr>
<td>tPA OK if physician allows</td>
<td>Progressive neurological conditions</td>
</tr>
<tr>
<td></td>
<td>For palliative care</td>
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</tbody>
</table>
Arrive hospital, screened, recruited < 24 hrs

Stratified stroke severity & site

First intervention, < 24 hrs Nurse / PT team, 6 days/wk

Very Early Rehabilitation + Standard Care  n=1052

Day 14 Treatment ceases

Usual care until discharge

Standard Care  n=1052

3 month 1° outcome

Blinded outcome assessor
Progress

2104

14 hospitals

July 06  Dec 06  July 07  Dec 07
Barriers?

626 patients!

97 treated with tPA

Only 1 drop out at 3 months!!
Babies Born

Year

2006
2007
2008
2009

Number of Babies Born

0
5
10
15
20
25
December 2009
37 hospitals approved
21 hospitals recruiting
Encouraging Early Findings

- Fewer ER patients experienced depression
  (Cumming et al, JRM, 2008)
- Significantly lower care costs in ER group (~$9,000)
  (Tay-Teo et al, Cerebrovasc Dis 2008)
- Trend for long term reduction in death/disability
  (Bernhardt et al, Stroke, 2008)
- ER protocols ensure patients with neglect start rehabilitation early
  (Cumming et al, APMR, 2009)
Other Early Rehabilitation Trials

Communication

**SAE-IT** (Study of Aphasia Early Intensive Therapy)
Single site Phase II RCT, 60 patients, ST > 3 days
Erin Godecke, Curtin University, Perth WA, Australia
E.Godecke@curtin.edu.au

**ACT NoW** (Assessing Communication Therapy in the North West). Multi-site RCT (12), 170 patients.
Audrey Bowen, Uni of Manchester, Manchester, UK
Consensus

After stroke rehabilitation should begin as early as possible
Melbourne, Australia

Stroke 2010
1-3 September 2010

Stroke Society of Australasia
ANNUAL SCIENTIFIC MEETING
Sofitel Melbourne
SAE-IT (Study of Aphasia Early Intensive Therapy)
Erin Godecke*, Curtin University, Perth WA

- Design: Single blind RCT
- Target group: Patients with mod-severe aphasia
- Interventions: Early: daily therapy vs Control: 1 x wk therapy
- Primary outcome: Aphasia Quotient and Functional Communication Profile

- Results: 59 patients at 3.2 days post stroke. Early: 2hrs/week vs Control: 11 mins/week. Sig better outcomes for intensive group

*E.Godecke@curtin.edu.au
ACT NoW (Assessing Communication Therapy in the North West) Audrey Bowen, University of Manchester

- **Design**: Single blind, multi-centre RCT, >170 patients with aphasia, randomised to receive up to 3 x week therapy or ‘attentional control’. Primary outcome functional communication.
- Cost effectiveness and qualitative studies embedded
- **Progress**: 12 sites, 161 patients recruited