Challenges for implementation of “new” protocols in acute stroke care

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Disclosures

Fund my salary

Fund my research
Search ‘organisational change’

Can I cope?

At Last something’s going to change

What impact will this have? How will it affect me?

Denial

Change? What Change?

Disillusionment

I’m off!!…this isn’t for me!

I can see myself in the future

Moving Forward

At others

Anxiety

Happiness

At self

Fear

Anger

Did I really do that

Who am I?

Gradual Acceptance

Threat

Guilt

Depression

Hostility

This can work and be good

I’ll make this work if it kills me!!
To determine benefits and risks of lying-flat (supine) vs. sitting-up (≥30 degrees) head positions

- applied early and continued for 24 hours
- broad range of hospitalized stroke patients
Background

- Lying-flat (or head-down) position suggests benefits in small non-randomized studies of acute: 
  - ↑ blood flow, perfusion, and oxygenation

- Concerns over harms - lying-flat may increase risks of pneumonia and cardiorespiratory dysfunction

- Sitting-up (or head-up) may reduce cerebral edema in large strokes – as in patients with head injury

- Variable positioning in practice
  - common in low resource settings
  - influence of transcranial Doppler data and guidelines
Design

Blinded outcome assessment at 90 days

Lying - flat (0°)

Sitting - up (≥30°)

Standard nursing + medical care

Hospital centers

Randomization

Crossover

Cluster

Lying-flat (0°)

Sitting-up (≥30°)

Crossover

Cluster

Sitting-up (≥30°)

Lying-flat (0°)

Blinded outcome assessment at 90 days
11,093 patients recruited from 114 centers between March 2015 and August 2016

- Chile (7 sites, 608 pts)
- China (39 sites; 4479 pts)
- Brazil (4 sites, 264 pts)
- UK (41 sites, 4160 pts)
- Colombia (1 site, 38 pts)
- Taiwan (5 sites; 173 pts)
- India (6 sites; 499 pts)
- Sri Lanka (4 sites; 271 pts)
- Australia (7 sites, 602 pts)
1° Modified Rankin Scale results

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SITTING UP</strong></td>
<td>18.2</td>
<td>33.6</td>
<td>8.6</td>
<td>16.2</td>
<td>8.8</td>
<td>6.4</td>
</tr>
<tr>
<td><strong>LYING FLAT</strong></td>
<td>15.9</td>
<td>36.4</td>
<td>8.8</td>
<td>15.2</td>
<td>9.5</td>
<td>6.1</td>
</tr>
</tbody>
</table>

Percentage of mRS scores

<table>
<thead>
<tr>
<th>Condition</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unadjusted</td>
<td>1.01</td>
<td>0.92 to 1.10</td>
<td>0.84</td>
</tr>
<tr>
<td>Adjusted baseline demographic variables</td>
<td>1.05</td>
<td>0.96 to 1.15</td>
<td>0.30</td>
</tr>
<tr>
<td>Adjusted baseline demographic + risk factors</td>
<td>1.03</td>
<td>0.94 to 1.13</td>
<td>0.55</td>
</tr>
<tr>
<td>Adjusted with imputation</td>
<td>1.03</td>
<td>0.94 to 1.13</td>
<td>0.50</td>
</tr>
</tbody>
</table>

*Not significant for acute ischemic stroke or intracerebral hemorrhage*
Cluster-Randomized, Crossover Trial of Head Positioning in Acute Stroke


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Process evaluation aims

To evaluate intervention fidelity

- How well/if the head positions were understood, implemented and maintained

To evaluate acceptability

- How easy the head positions were to implement (facilitators & barriers)

Identify threats to the generalisability of the trial results

- How compatible are head positions with current stroke care

Determine trial-specific issues not related to intervention
Process evaluation (PE) methods

- PE completed after recruitment at their hospital i.e. after completion of both stroke care positions
- By all staff who provide care for people with stroke (nurses, neurologists, other physicians, physiotherapists, occupational therapists, speech therapists)
- At all participating HeadPoST hospitals
- Online or on paper (English, Spanish, Chinese) questionnaire, closed and open questions
- Combination inductive & deductive thematic coding by 2 or more
Requirements of ‘organisational change’

Motivate Change

- Convey the need for change, ensure realistic approaches for how change might be accomplished
- Leaders must widely communicate the need for the change

Create Vision

- Ideally, all staff have strong input into the creation of the vision/protocol and how it can be achieved
- Important that people believe that the vision/protocol is relevant and realistic
Requirements of organisational change

Develop Political Support

- Network of influential staff who interact and count on each other to support and guide the change effort

Manage Transition

- Implement the protocol. Might require ongoing coaching, training and ‘enforcement’ of new protocol

Sustain Momentum

- The most difficult phase. Can encounter a wide variety of obstacles. Requires strong, visible, ongoing support from trial champion.
More familiar with the post-mortem: an examination of a dead body to determine the cause of death

Pre-mortem
BEFORE you start the trial, with the same people you’d invite to a trial start-up meeting..

- Run through the protocol
- Run through the assessments & CRFs
- Talk about all aspects of the trial processes

STOP
Tell everyone the trial has finished (recruitment, follow-up etc). It was an abject failure. Everyone must provide at least one reason why.
The rest of the day is spent examining all reasons, are they real, can they be mitigated. Change the protocol where needed….now you can start.
Special thanks

Steering Committee

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Patients and families, committees, research monitors and coordinators, hospital staff