Is dedication all you need to deliver to time and target in a multicentre study?

Lessons learned from the Prevention of Delirium (POD) study

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on behalf of the POD trial team

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Overview

- Brief overview of study
- What were the targets?
- What were the challenges?
- What did we achieve?
- Is dedication all you need?

Trial design

Aim:

- To improve delirium prevention for older people admitted to NHS acute hospitals through a programme of linked projects

Population:

- Inclusion: aged ≥65 years
- Exclusion: prevalent delirium

Intervention:

- Prevention of delirium (POD) System of Care vs Usual Care

Main Outcome:

- Incidence of new onset delirium within ten days of hospital admission

Study Design:

- pragmatic, multi-centre, cluster randomised, controlled, feasibility study
- Target sample size = 720

Timelines

- Programme start in Dec 2009

- Feasibility study - 01 October 2013 – 30 September 2015
  - 5 month set-up
  - 6 month implementation
  - 6 month recruitment
  - 3 month follow-up
  - 4 month analysis & write-up

Site Identification & set-up

Challenge:

- 8 hospitals / 16 wards
- Hospitals to meet ‘ward readiness’
- All sites randomised at same time

Strategy:

- ✓ Early engagement
- ✓ Define ‘research readiness’
- ✓ Site visit
- ✓ CTU complete local governance forms

Recruitment

Challenge:

- Target
- Vulnerable population
- Delirium status required on day of admission

Strategy:

- ✓ Appoint trial Research Assistants (RAs)
- ✓ Involve a patient group
- ✓ Seek approval for consultee agreement
- ✓ 3 stage recruitment process
  - ✓ Screen →within 24 hrs
  - ✓ Test for delirium → within 24 hrs / pre-operatively
  - ✓ Obtain consent / agreement → within 48hrs

Outcome assessment

Problem:

- Daily assessments for 10 days and at 30 days
- Delirium tool widely used in clinical research, not in practice
- Missing data due to loss of capacity

Solution:

- ✓ Appoint trial RAs
- ✓ Pre-recruitment training
- ✓ Ethical approval for continuation of delirium assessment, but data not transferred without personal / consultee agreement

WHAT DID WE ACHIEVE?

Identification of sites

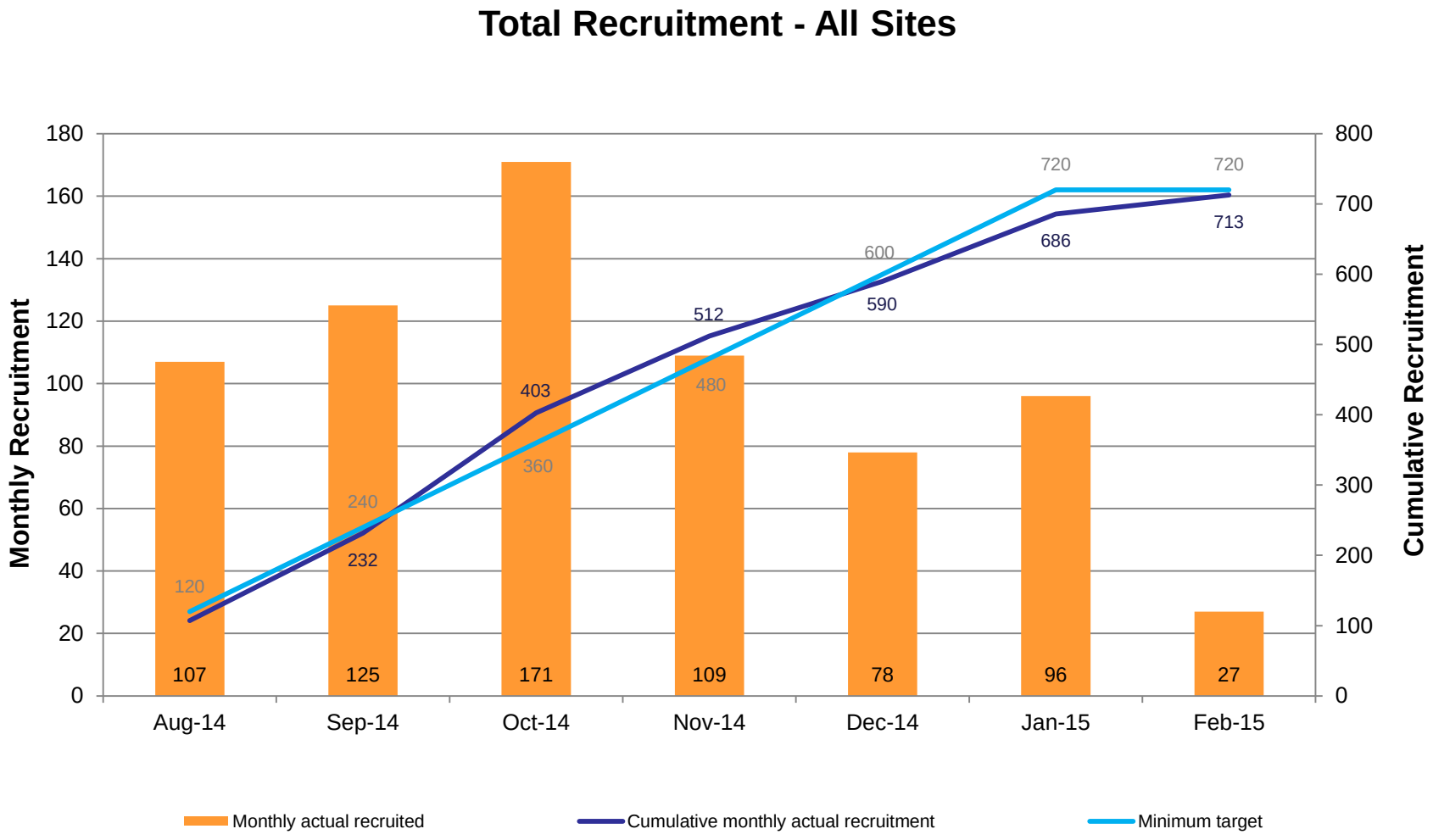
Site Identification:

- ✓ 20 potential sites → 13 Site visits → 8 NHS permissions
- ✓ 4 weeks from ethical approval → all NHS permissions
- ✓ 4 weeks from ethical approval → randomisation

POD Implementation:

- ✓ 7 wards → fully implementation
- X 1 ward → partial implementation

Recruitment



Outcome assessment

- ✓ High compliance with Confusion Assessment Method:
  - ✓ 70.3% → assessed on consecutive days
  - ✓ 24% → 1 day missed
  - ✓ 71.9% → assessed on Day 30
- ✓ Trained 35 research assistants
  - ✓ High Inter-rater reliability
- ✓ No data missing due to loss of capacity

Is dedication all you need…..??

Select sites with ability to **dedicate** time and resource

- ✓ Ward readiness
- ✓ Research readiness
- ✓ Visit sites

Employ **dedicated** staff

- ✓ Research assistants: recruitment, outcome assessment, data collection
- ✓ Trial researchers: implementation, training, recruitment
- ✓ CTU: trial oversight & support, ethics, data management

Develop a **dedicated** team

- ✓ Important research question
- ✓ Training and support
- ✓ Keep it logical & simple

Anything else…..?

- Detailed Project Plan
  - ✓ Identify the challenges
  - ✓ Devise the strategies
  - ✓ Monitor
- Cluster vs individual randomisation
- Short duration
  - ✓ Work on a trial from beginning to end
  - ✓ Exposure to a broad range of activities
- Luck

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Trial Management Group

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Questions?

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