Developing a data set to improve recruitment of people to clinical studies of dementia

Piers Kotting, UCL, Assistant Director
National Institute for Health Research (NIHR) Dementias and Neurodegenerative Diseases Research Network (DeNDRoN)
Overview

• Rationale: why it is needed
• Methodology
• Results
• Next steps
Rational 1: innovation needed to increase capacity

**Number of studies**

- Opening and Closing
- Number of recruiting studies

**Number of investigators**

- Number of investigators

**Number of people recruited**

- 08/09 to 13/14

**Study performance**

- 2008/09 to 2013/14
Rationale 2: current practice expensive & inefficient

- Identify
- Pre-screen
- Contact
- Screen
- Consent

21,000 hours

Traditional referral & note screening

£90

17%

59%

5%

45%
WE NEED TO INCREASE THROUGHPUT AND EFFICIENCY

BUT WHAT IF IT'S TIME FOR A WHOLE NEW WAY OF THINKING?

SORRY, CREATIVITY SLOWS DOWN THE LINE

BRAND CAMP
THE IDEA FACTORY

285 DAYS WITHOUT A REMARKABLE IDEA

© 2009 INSPIRED BY SETH GODIN AND TRIBES

TomFishburne.com
Methodology 1: process overview

- Analysis of NIHR Portfolio (n=241)
- Survey of pharmaceutical companies (n=7)
- Review of existing register datasets (n=15)

176 data items

2 x Delphi: feasibility & recruitment

Acceptability testing
Methodology 2: Delphi question

Minimum Data Set (MDS): Items required for register to be more effective than current processes

Extended Data Set (EDS): Those items that if added to the minimum data set would be useful for more than 50% of studies

Complete Data Set (CDS): Those items that would be useful for less than 50% of studies.
Results 1: Delphi outcomes

Criteria 1 - Consensus threshold 75%.
Criteria 2 - Consensus threshold 75% combined EDS / CDS.

Recruitment
- 176 data items
- 33 additional data items suggested by participants
- Consensus Levels:
  - Round 1 = 19 items / 11%
  - Round 2 = 81 items / 39%
  - Round 3 = 159 items / 76%

Feasibility
- 176 data items
- 45 additional data items suggested by participants
- Consensus Levels:
  - Round 1 = 21 items / 10%
  - Round 2 = 43 items / 19%
  - Round 3 = 128 items / 58%
  - Round 3 + EDS / CDS Mergers = 177 items / 80%
Results 2: Minimum Data Set

- Personal demographics: 11
- Health service provider: 7
- Diagnosis and cognitive function: 5
- General health: 4
- Care and support: 19
- Preferences: 5
Results 3: pilot use of consent-for-approach list

- Identify
- Pre-screen
- Contact
- Screen
- Consent

21,000 hours

Traditional referral & note screening

Consent-for-approach register

£90
£28

17%
59%
88%

12 mins per new referral

5% 45% 53% 20%
Next steps: new national system
Summary

• Current system high performing
• Innovation of identification & recruitment required to meet sample size demands
• 51 item data set developed for consent-for-approach system
• Pilot suggests 70% cost saving & 4x as efficient
• National system being launched across England this year
Thank you!

pkotting@ucl.ac.uk

@pkotting

+44(0)20 3206 4960

- Martin Rossor (UCL), NIHR National Director for Dementia Research
- Ian McKeith (Newcastle), Director of NIHR DeNDRoN
- John O’Brien (Cambridge), Associate Director of DeNDRoN
- Adam Smith (UCL), Programme Manager