Facilitating dementia trials:
Innovative trial design + UK research platform

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Outline

• Challenges
• A solution – ‘cohort multiple RCT’ design
• An example - Yorkshire Health Study
  • Research platform for testing interventions to prevent/ manage obesity, dementia and other long term conditions
Challenges

• Multiple questions
• Trials – expensive, answer one or two questions each
• Recruitment – difficult & unrepresentative
• Results – generalisable to routine healthcare?
• Standard approach to Informed Consent? (ethical?)
• Routine healthcare: are patients told
  • Treatments they will *not then be given*?
  • Treatment will *decided by chance*?
A solution

‘Cohort multiple RCT’ design

BMJ 2010/ BMJ Open 2013

Figure 1 Outline of the cohort multiple randomised controlled trial design.
Advantages

• Quick recruitment of large sample
• Information on health, health behaviours & healthcare resource use
• Longitudinal design – long term outcomes routine
• Research platform for multiple trials
  A vs usual care, B vs usual care…..
• Multiple treatment comparisons: A vs B
• Real world approach to informed consent
• Design is REC/IRB approved, funded (NIHR & CIHR), depression, cancers, depression, surgery (SPIN, YHS, REFORM, FORBOW, DEPSY, PICNIC, UMBRELLA, PRESENT, DiRECT, CLASSIC, York Older People)
An example

Multiple health challenges

- Obesity
- Diabetes
- COPD/Heart disease/Hypertension
  - Depression/Anxiety
  - Stroke
- Fatigue/Insomnia
- Chronic pain
- Dementia
Longitudinal observational study

Track health & health behaviours

Research platform

Identify & recruit participants quickly for research esp. Phase III - V pragmatic RCTs

Multiple trials

Long term follow up

Data linkage

Multiple treatment comparisons
Methods

- 2010-2012 - recruited 43 GP practices in Yorkshire
- Invited all patients aged 16-85 yrs
- Self reported information:
  - Personal characteristics
  - Health & health related behaviours
  - Health care usage
    - Gender, DOB, Height, Weight, Waist, Ethnicity, Life Satisfaction;
    - Health related quality of life (EQ-5D), Long standing conditions
    - Alcohol, smoking, medication, Exercise (GPPAQ), food, slimming clubs, Healthcare resource use, Education, Socio-economic status

- 1st wave 2010-12
Results

- N = 27,806 returned
- N = 22,716 consent to contact
- 17% response rate
- Broadly representative
- Facilitated 12 studies to date
**Age**

- 16-25: 7.2%
- 26-35: 9.9%
- 36-45: 13.3%
- 46-55: 16.8%
- 56-65: 22.7%
- 66-75: 20.2%
- 76+: 9.9%

**Currently employed**

- Employed: 56.5%
- Not employed: 43.5%

**Ethnicity**

- Asian or Asian British: 2.0%
- Black or Black British: 0.8%
- Chinese/other ethnic group: 0.4%
- Mixed: 0.5%
- White: 96.2%

**Obesity Status**

- Normal/underweight: 44.4%
- Overweight: 36.5%
- Obese: 19.1%

**Concern over weight management**

- 47.3% of women
- 32.1% of men

**Life satisfaction**

- 7.5 is the average life satisfaction score based on a scale of 0 to 10.

**Medication usage**

- 2.75 is the average number of medications being taken by SYC participants.

**Alcohol consumption**

- 7.8 units is the average reported number of units drank in the last week.

**Highest level of Education**

- O-levels/GCSEs/NVQ1-2: 17.0%
- A-levels/NVQ3: 7.6%
- Degree/NVQ4-5: 21.4%
- Other qualifications: 31.1%
- No qualifications: 22.8%

**Long-standing health conditions**

- Anxiety: 10.0%
- Breathing Problems: 11.1%
- Cancer: 2.9%
- Depression: 8.6%
- Diabetes: 6.9%
- Fatigue: 16.5%
- Heart Disease: 6.5%
- High Blood Pressure: 19.8%
- Insomnia: 6.7%
- Osteoarthritis: 9.9%
- Pain: 21.9%
- Stroke: 2.2%

**Smoking Status**

- 13.8% Current
- 34.4% Former
- 51.8% Never

[http://ciahr-c-sy.nihr.ac.uk/south-yorkshire-cohort.html](http://ciahr-c-sy.nihr.ac.uk/south-yorkshire-cohort.html)
Facilitating dementia research

Within 5yrs - 1,700 aged 75 or over
Within 10 yrs - 2-3000 will have dementia

Opportunities……..

- Analyse data - understand health-related behaviours
- Trial interventions to prevent/predict/treat/manage dementia (individual/public health level)

- Memory question added, 2nd wave of data collection, Increase area and size (n=50,000)


• Relton C, Nicholl J et al ‘*Rethinking pragmatic RCT design: the ‘cohort multiple RCT’ design*. BMJ 2010

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