



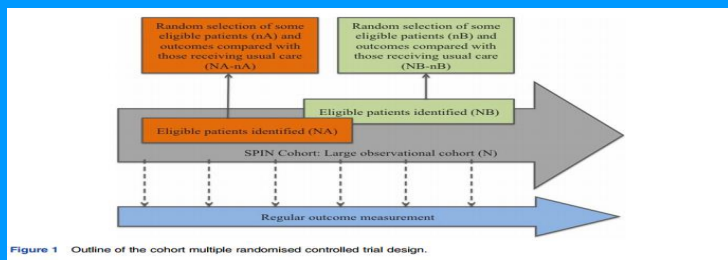
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# Facilitating dementia trials:

Innovative trial design

+

UK research platform



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## Funding

NIHR CLAHRC Yorkshire & Humber

***We have no disclosures***



# 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?*



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# A solution

## 'Cohort multiple RCT' design

BMJ 2010/ BMJ Open 2013

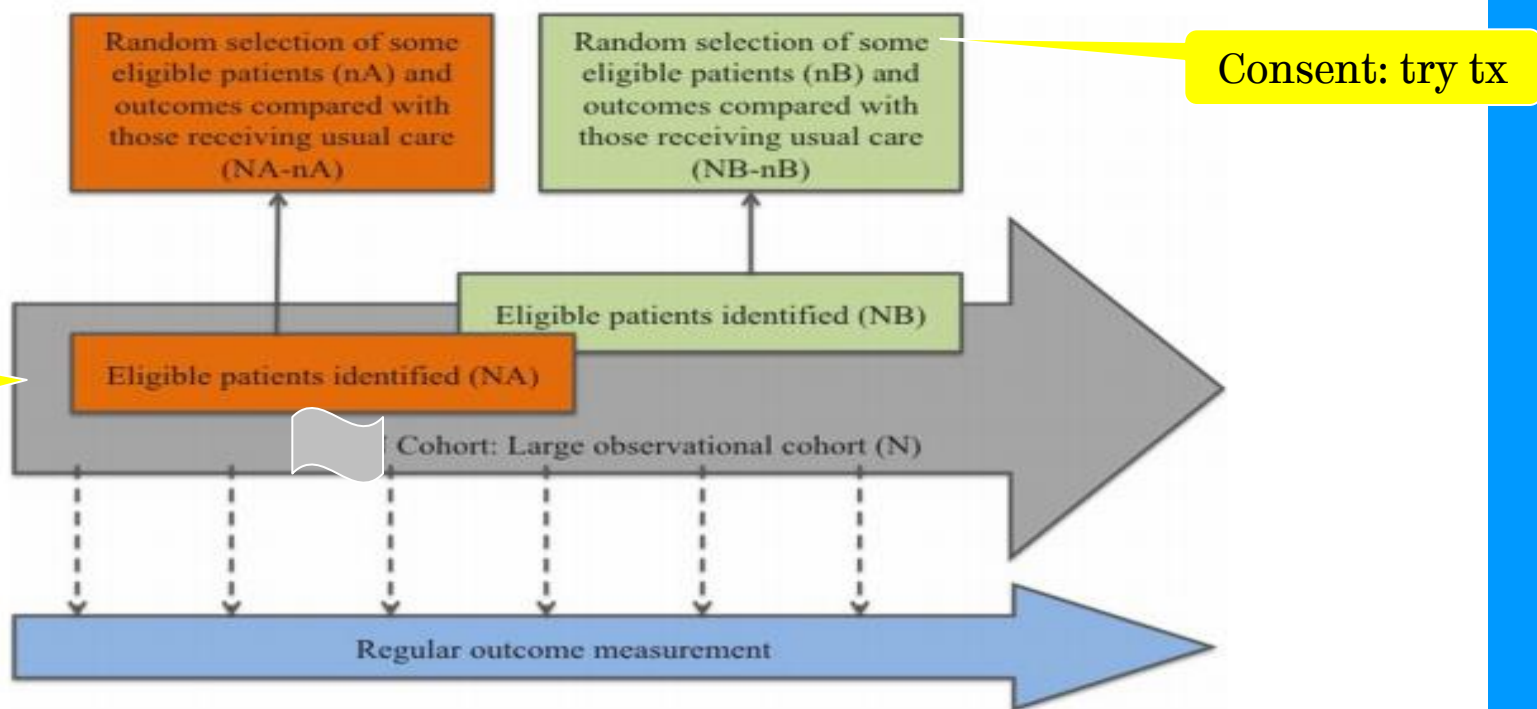
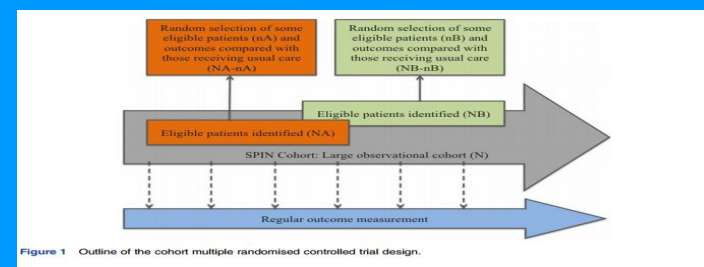


Figure 1 Outline of the cohort multiple randomised controlled trial design.



# 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**



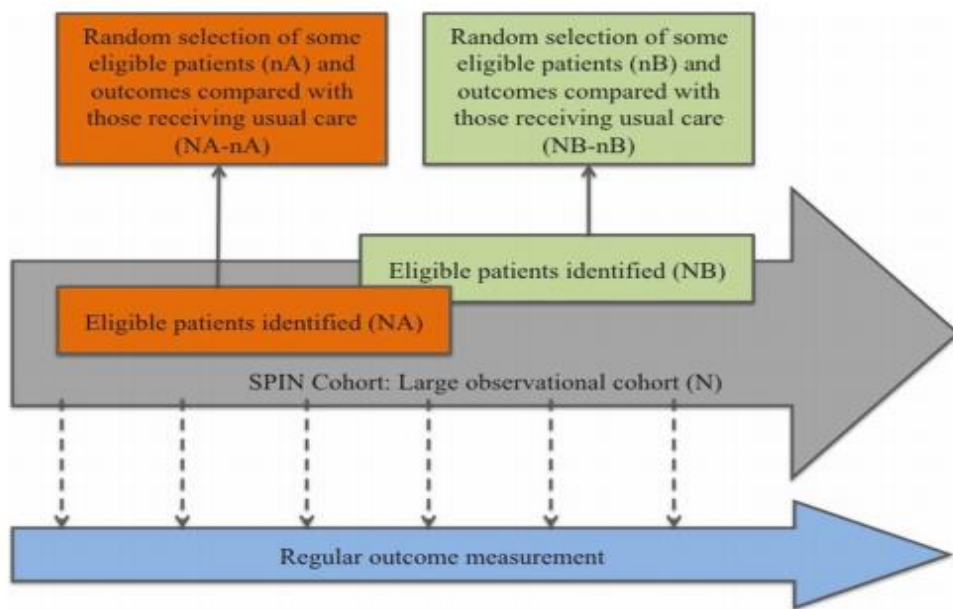
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Your health, your research



- 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
- 1<sup>st</sup> wave 2010- 12

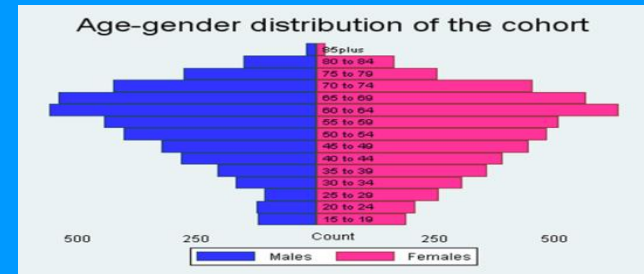


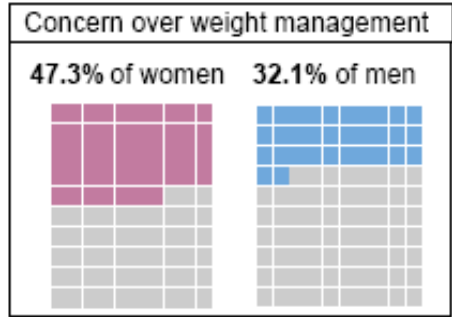
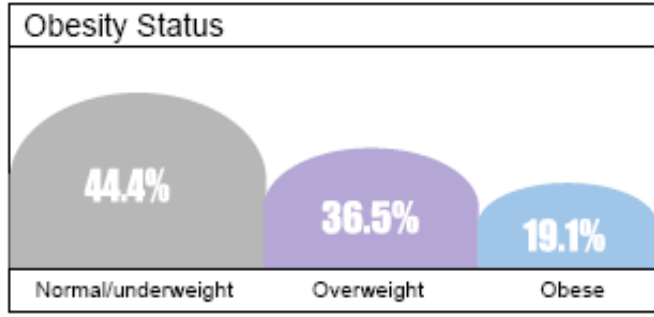
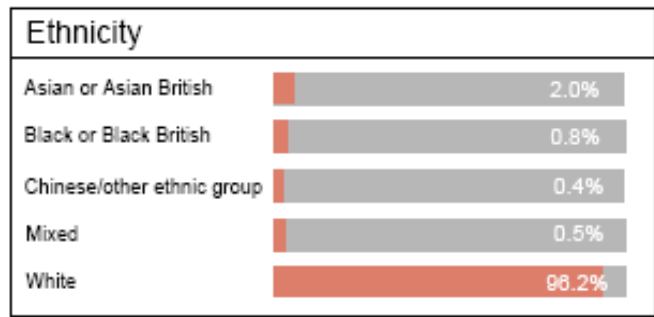
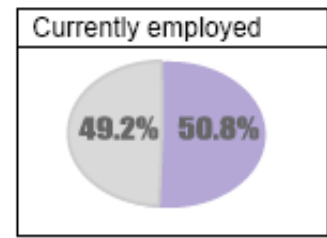
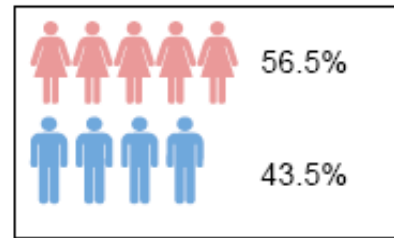
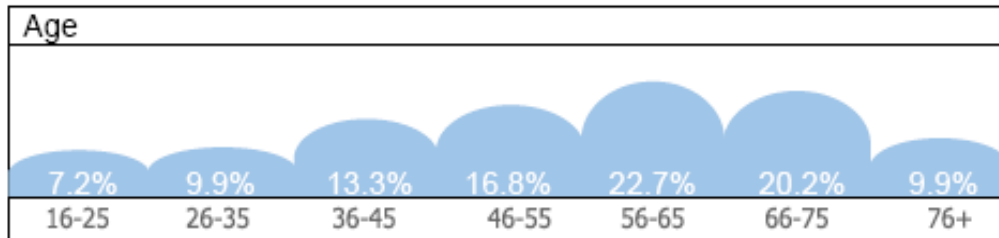


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# Results

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





### Life satisfaction

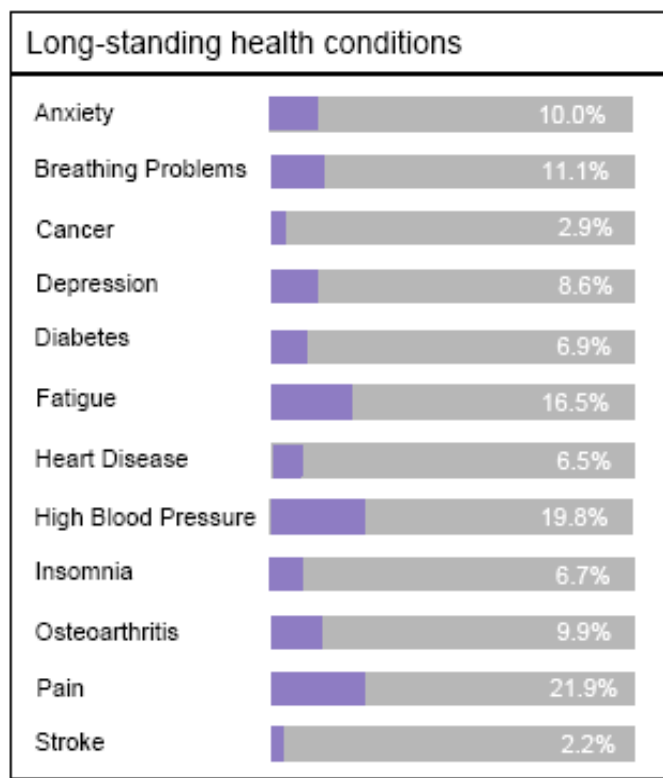
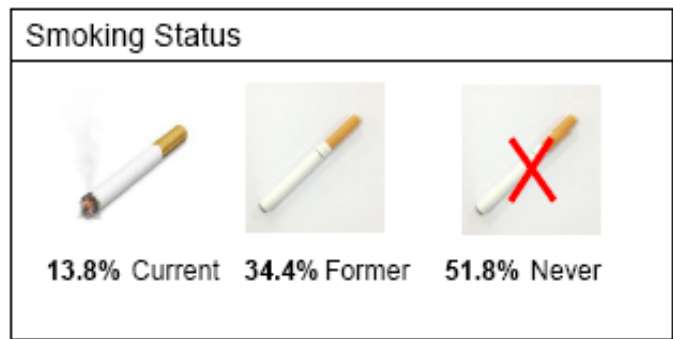
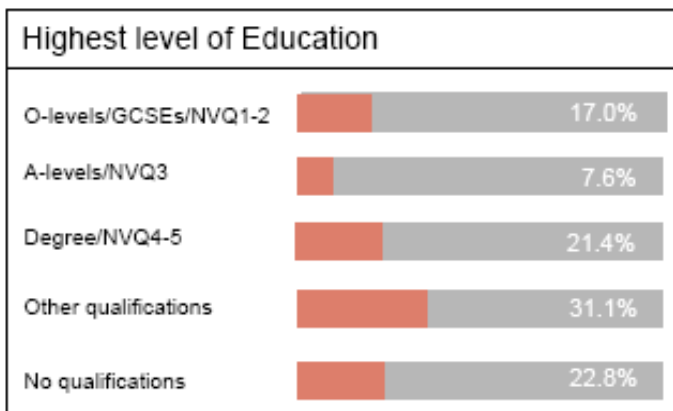
7.5 is the average life satisfaction score based on a scale of 0 to 10

### 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





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# Facilitating dementia research

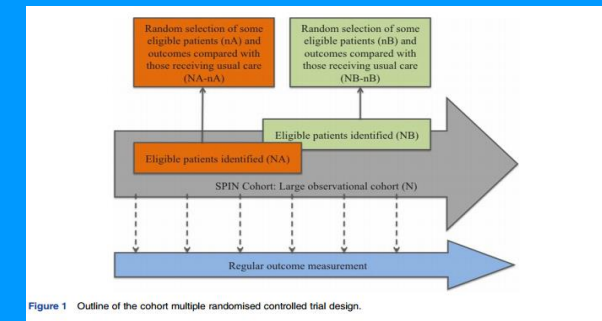
Within 5yrs - 1,700 aged 75 or over

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, 2<sup>nd</sup> wave of data collection, Increase area and size (n=50,000)

- Relton C, Bissell P, et al **South Yorkshire Cohort: a 'cohort trials facility' study of health and weight - Protocol for the recruitment phase.** BMC Public Health 2011
- Green MA, Li J, Relton C, et al, **Cohort Profile: The Yorkshire Health Study,** International Journal of Epidemiology, 2014
- Relton C, Nicholl J et al **'Rethinking pragmatic RCT design: the 'cohort multiple RCT' design.** BMJ 2010
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10-11<sup>th</sup> November 2014  
London School of Hygiene & Tropical  
Medicine, London, UK





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