Trial Within a Cohort Study method

KATE.MOONEY@YORK.AC.UK

Overview of evaluation of Incredible Years

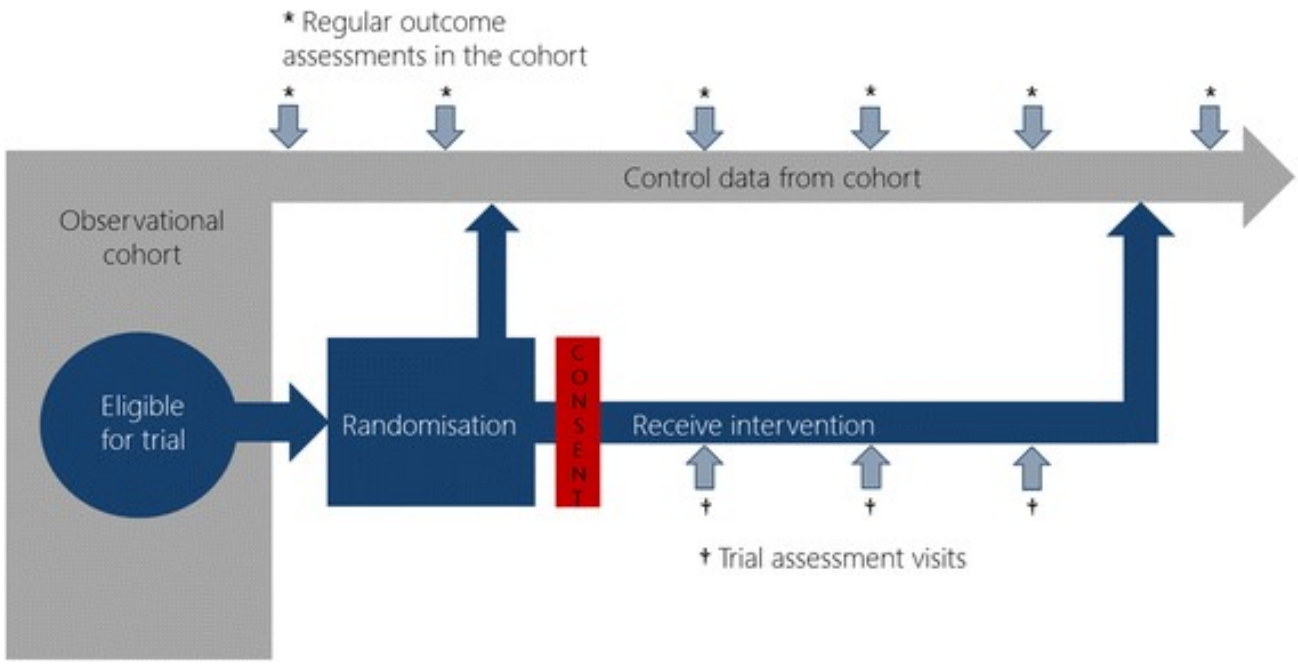
- Quasi-experimental study using propensity score matching to establish intervention effectiveness (and potentially instrumental variable modelling -> triangulation)
- **Feasibility Trial Within a Cohort Study (TWiCS) to test processes and feasibility of conducting a larger scale TWiCS**

What is a TWiCS?

- The TWiCs RCT design was developed to address some of the shortcomings of standard, parallel group approaches to randomised trials and allows multiple trials to take place within a single population (Relton et al., 2010)
  - *poor recruitment rates, unrepresentative trial populations, lack of long term outcomes etc*

1. Uses a large observational cohort with routinely collected data
2. Selects a proportion of eligible population at random to receive the intervention of interest
3. Compares outcomes to those not selected in the remaining eligible population

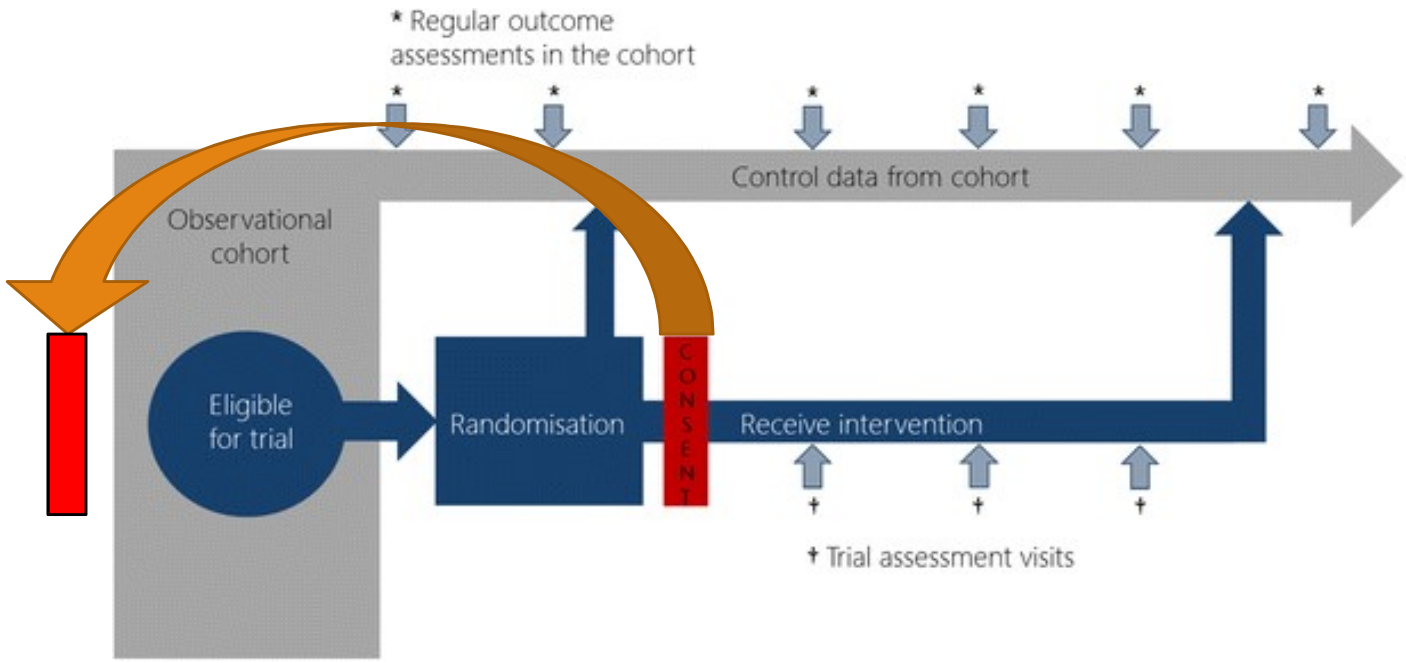
What is a TWiCS?



Staged-informed consent

- ***'patient centred'*** i.e. the process of obtaining patient consent replicates that in real world routine health care, where patients are not told that their treatment will be decided by chance, nor are they told about treatments that they cannot then receive
- However, there is disagreement as to whether control groups should be informed that they have been randomised to not receive an new intervention being trialled/ tested for their condition
- The authors have adapted the cmRCT design where in the first stage, at entry into the cohort, all potential participants are asked for consent to be randomly selected to be approached for experimental interventions or to serve as controls without further notice. This staged-informed consent procedures allows triallists to use the TwiCs approach but avoids pre-randomisation

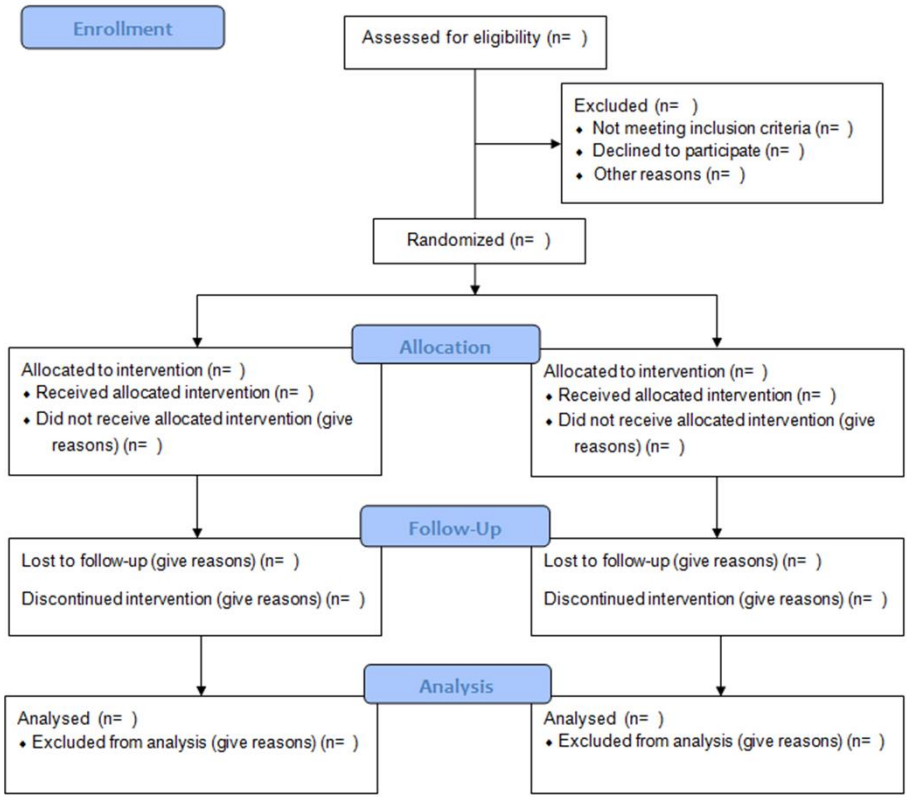
What is a TWiCS?



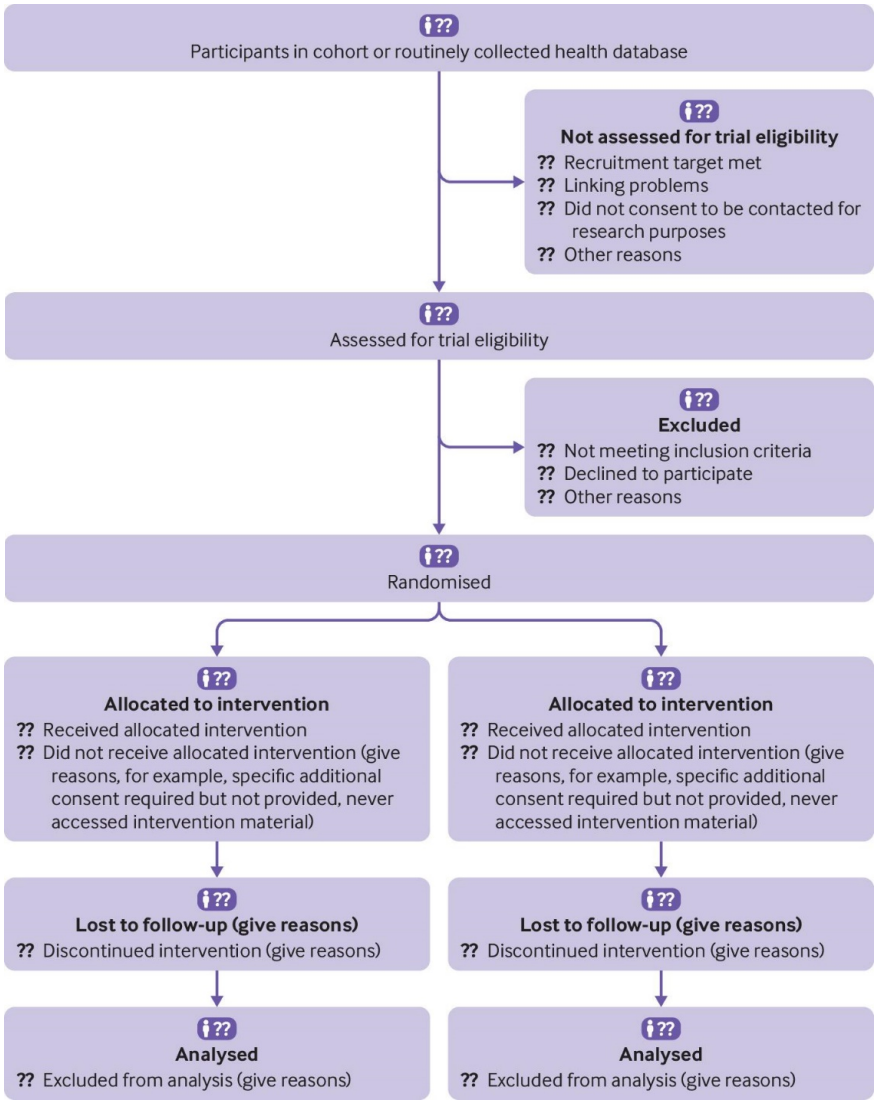
CONSORT diagram for regular RCT

CONSORT
TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram



CONSORT diagram for TWiCS



Feasibility TWiCS objectives (TBC)

1. Establish whether randomisation can be implemented to create a control and intervention group, while documenting any incidences of contamination
2. Establish whether invitation via these routes results in acceptable conversion of randomised participants into intervention participants
3. Establish whether invitation via these routes results in acceptable retention of randomised participants in the intervention
4. Establish whether routinely recorded health visitor (ASQ/ASQ:SE) can be linked, and identify the quality of these data
5. Establish whether routine education data (RBA and EYFSP) can be linked and identify the quality of these data
6. Establish whether routinely linked resource use data can be linked and identify the quality of these data to conduct an economic evaluation

Any questions?