In defence of clinical trials *(up to a point!)*

Sonia Johnson
Division of Psychiatry
UCL

@soniajohnson
Before there were trials...

“Evidence” before RCTs – expert opinion, clinical judgement, case series, hierarchy and power

Unfettered commercial claims
The point of RCTs

- A radical move towards trying to achieve objectivity, moving away from power of interest groups
- A fair comparison, not affected by initial differences between groups
- Everything possible to achieve objectivity – replicable measures, independent observers and analysts who do not know what group participants are in
RCTs do...

- Allow objective claims to be made that a treatment works and should be available
  - Eg psychological treatment in psychosis
- Allow objective claims to be made that an intervention doesn’t work/does harm and should not be used
  - Eg Community Treatment Orders
- Allow limited resources to be focused on whatever’s most likely to help
- Form part of a research process also involving theory, modelling of potential mechanisms in interventions, studies of implementation barriers and facilitators
- Allow results from several studies to be combined
RCTs don’t

 Exclude other methods
  – MRC framework on development of interventions suggests a range of other methods in process of developing/testing interventions

 Exclude qualitative perspectives
  - Most NIHR trials also now have a qualitative component

 Exclude use of user-led or co-produced interventions
  - Trials of WRAP, Open dialogue, other recovery-focused interventions

 Require clinical diagnosis
  - Participants can be recruited based on what service they use/any other characteristic. Randomisation ensures comparable groups

 Preclude user input to measures and design
  - Recovery, client satisfaction etc. frequently outcomes.
  - PPI is a requirement
In summary

- RCTs are at centre of evidence based healthcare – not likely to go away. NICE relies on them.
- RCTs vs. professional hierarchies, big pharma etc. A radical force.
- RCTs are powerful persuasive tools – worth using to try to improve quality/eliminate harms
- RCTs can be designed so as to allow considerable PPI
- RCTs are at their most powerful when linked with other methods that allow us to understand how things work and for whom
- Novel research designs likely e.g. realist RCT