# In randomisation we trust?

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# Acknowledgements


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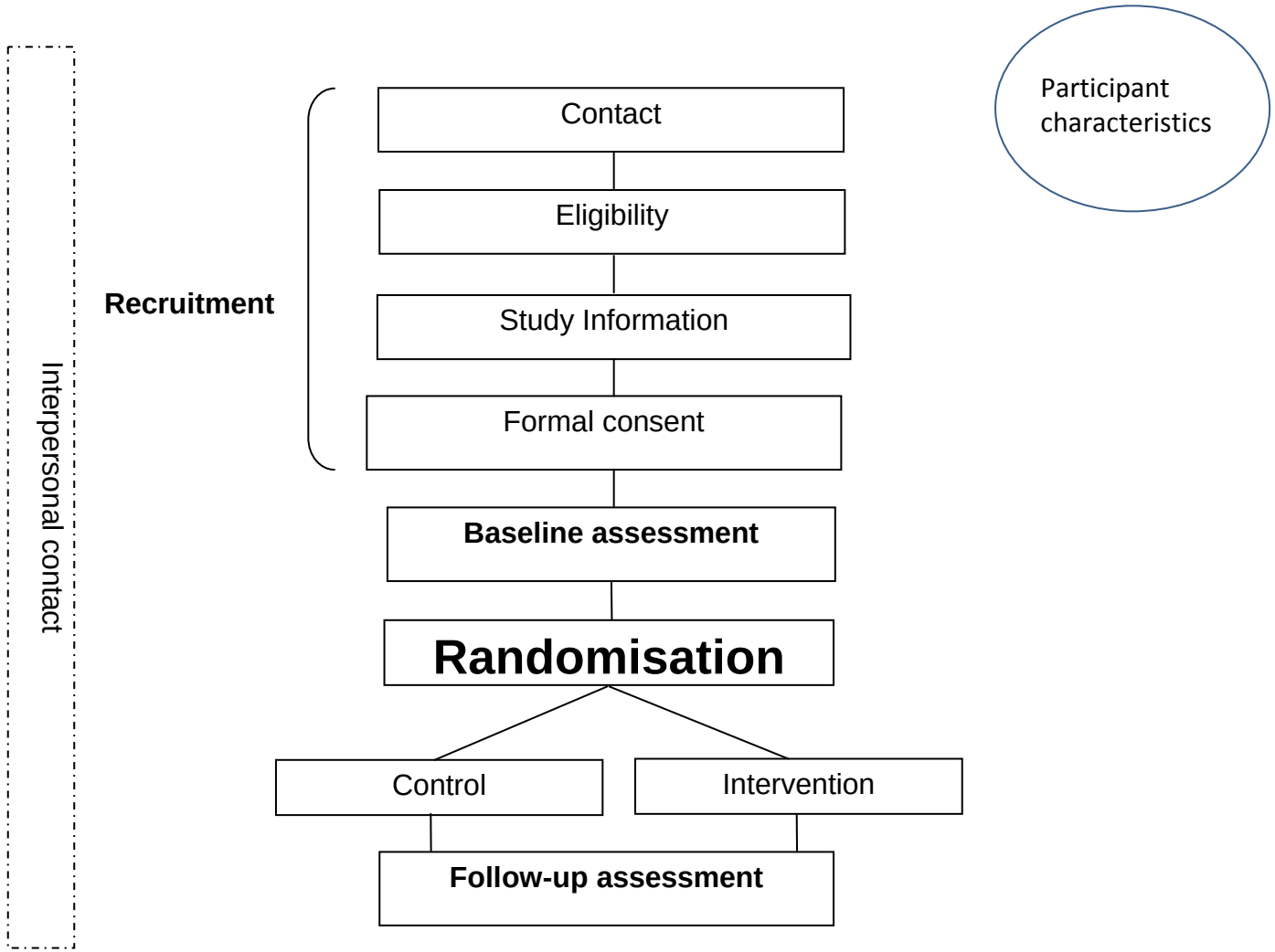
# Typical behaviour change trial process



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# Extending the CONSORT Statement to Randomized Trials of Nonpharmacologic Treatment: Explanation and Elaboration

**Isabelle Boutron, MD, PhD; David Moher, PhD; Douglas G. Altman, DSc; Kenneth F. Schulz, PhD, MBA; and Philippe Ravaud, MD, PhD, for the CONSORT Group***

Adequate reporting of randomized, controlled trials (RCTs) is necessary to allow accurate critical appraisal of the validity and applicability of the results. The CONSORT (Consolidated Standards of Reporting Trials) Statement, a 22-item checklist and flow diagram, is intended to address this problem by improving the reporting of RCTs. However, some specific issues that apply to trials of nonpharmacologic treatments (for example, surgery, technical interventions, devices, rehabilitation, psychotherapy, and behavioral intervention) are not specifically addressed in the CONSORT Statement. Furthermore, considerable evidence suggests that the reporting of nonpharmacologic trials still needs improvement. Therefore, the CONSORT group developed an extension of the CONSORT Statement for trials assessing nonpharmacologic treatments. A consensus meeting of 33 experts was organized in Paris, France, in February 2006, to develop an extension of the CONSORT Statement for trials of nonpharmacologic treatments. The participants extended 11 items from the CONSORT Statement, added 1 item, and developed a modified flow diagram.

To allow adequate understanding and implementation of the CONSORT extension, the CONSORT group developed this elaboration and explanation document from a review of the literature to provide examples of adequate reporting. This extension, in conjunction with the main CONSORT Statement and other CONSORT extensions, should help to improve the reporting of RCTs performed in this field.

*Ann Intern Med.* 2008;148:295-309. www.annals.org

For author affiliations, see end of text.

*For contributors to the CONSORT Extension for Nonpharmacologic Treatment Interventions, see the **Appendix** (available at www.annals.org).

# Does randomisation itself influence behaviour?

- Longstanding concern about unintended effects of randomisation
- Potentially important as source of bias
- Little qual or quant study apart from placebo effects
- Cook & Campbell describe ‘compensatory rivalry’ and ‘resentful demoralization’ possibilities for control groups

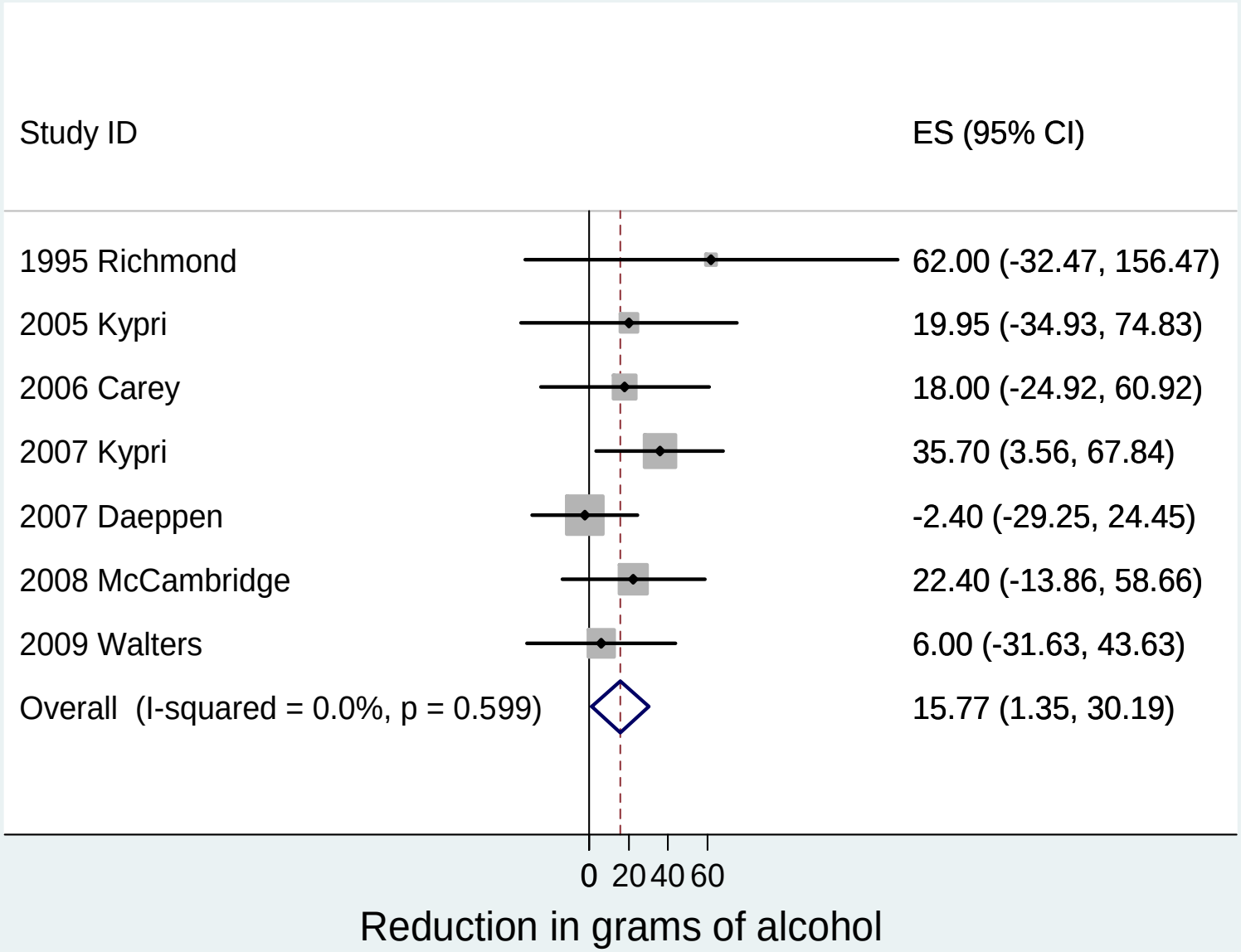
# Why is assessment reactivity important for brief intervention trials?

- Marginal influence of hazardous and harmful drinking at issue in BIs
- Small effects that can be widely disseminated more important than large effects that cannot
- Assessment reactivity bias potential greater with smaller effect sizes
- Intervention application potential greater?

# Brief intervention systematic review data

- 7 published trials providing quant data from randomised comparisons
- 2 other trials did not publish outcome data (Anderson & Scott 1990/92, Gentillelo et al 1999)
- Contacts ascertained data no longer available & non-significant differences between groups
- 18% & 41% power to detect 0.2 SD for Anderson & Gentilello studies respectively

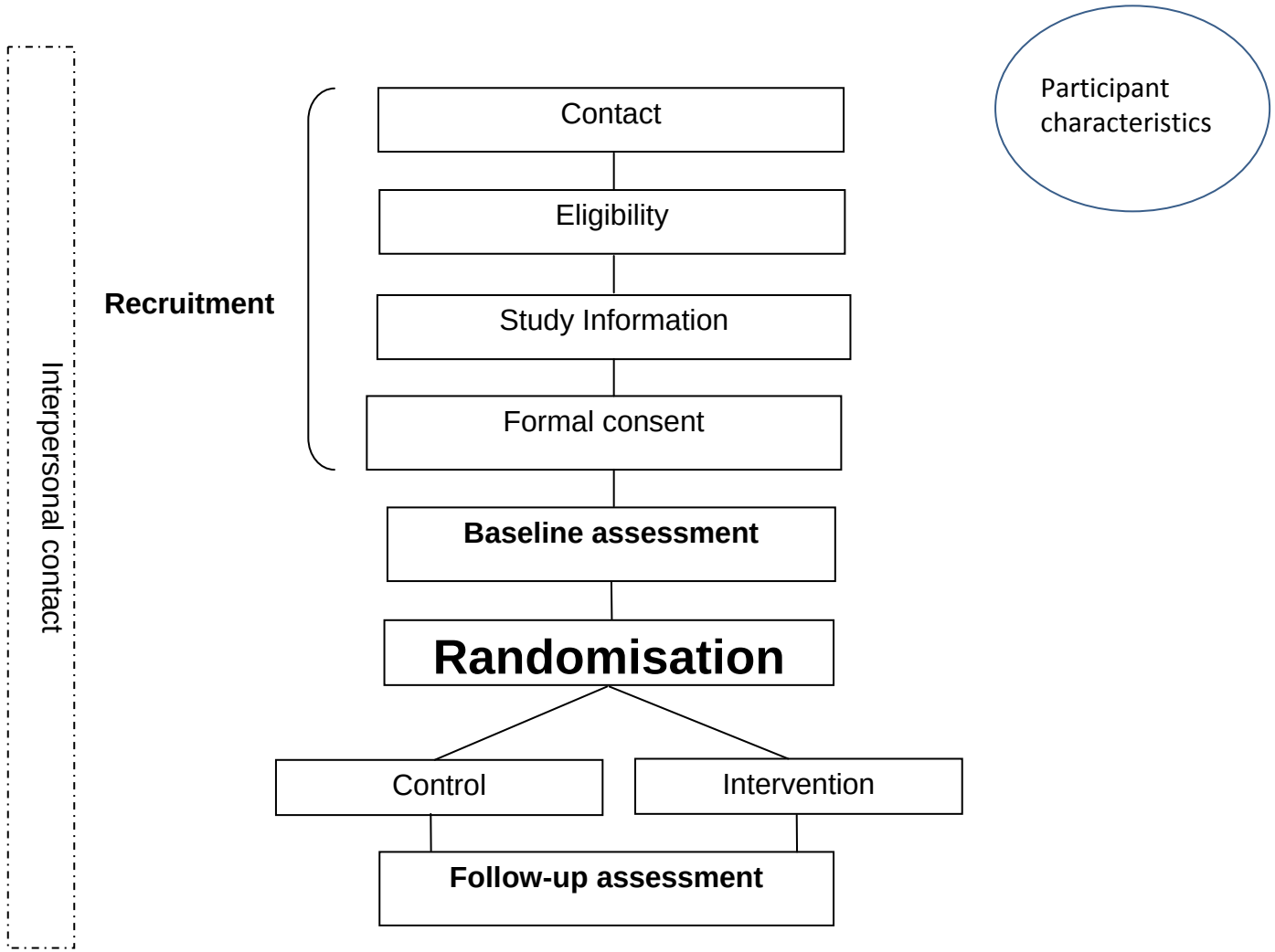
Meta-analysis of effects of assessment procedures on total weekly drinking



# Interpretation

- Small ‘effect’ on past week drinking not apparent in any primary study
- Pattern of effects behaviourally plausible
- Small effects on 2/3 outcomes coherent with other literatures beyond brief alcohol interventions
- Publication bias a clear issue
- Generalisability to non-student populations?

# ADDITIVITY ASSUMPTION



# Contamination
# (additivity assumption preserved)

| | | Assessment | |
|---|---|---|---|
| | | Y | N |
| Brief Intervention | Y | -56g | -40g |
| | N | -16g | 0 |
| | Diff | -40g (Kaner 07) | -40g |

….logic of additivity requires assumption of independence of research reactivity effects and intervention effects

…how plausible is this for brief and other behavioural interventions?

| Component | Intervention Application | Research application | Comments on similarities |
|---|---|---|---|
| Estimating consumption | Included in a wide range of behavioural interventions | Near universal | Form can be identical |
| Answering questions on consequences | To generate individual risk data for simple feedback or more complex tailoring purposes | Near universal | Form can be identical |

# Interaction
# (additivity assumption problematic)

| | | Assessment | |
|---|---|---|---|
| | | Y | N |
| Brief Intervention | Y | -56g | ? eg 30g synergistic<br>eg 50g ceiling effect |
| | N | -16g | 0 |
| | Diff | -40g (Kaner 07) | ? |

# Implications

- Interactions make additivity assumption problematic and trials vulnerable to pre-randomisation sources of bias
- Entails greater uncertainty about the true size of effects
- Synergistic effects more likely for new behaviours, no prior contemplation
- Ceiling effects more likely for existing behaviours, particularly where content of BI and research process are similar

# Ongoing systematic reviews

- Hawthorne effect
- Demand characteristics
- Solomon 4-group studies
- Mere measurement effects in health psychology

# Hypotheses where additivity may be unproblematic (main effects, no interactions)

- Knowing you will be randomised…
- Knowing what the target behaviour is…
- *The process of giving formal consent…
- Baseline assessment doses/content…

# Hypotheses on bias in BI trials
# - where additivity may be problematic

- Assessment-randomisation interactions…
- Recruitment-randomisation interactions…
- *Randomisation direct effects
- Main effects of follow-up assessments (for subsequent assessments)

# Study designs

- Tests of main effects require 2-group experiments
- Tests of interaction effects require 4-group experiments…
  - eg S4G double randomisation to intervention and assessment
- Qualitative research studies to investigate what participants actually think and do in our BI trials...and what researchers know about all this!

# Take home message

There may be problems with the ways we think about the design, conduct and analysis of randomised trials that are potentially very important and are not difficult to study

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