Workshop on the design and conduct of randomised controlled trials of brief interventions for alcohol and drugs

Jim McCambridge and colleagues

CONSORT 2010 checklist of information to include when reporting a randomised

Section/Topic	Item No	Checklist item
Title and abstract		
	1a	Identification as a randomised trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)
Introduction		
Background and objectives	2a	Scientific background and explanation of rationale
	2b	Specific objectives or hypotheses
Methods		
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
	6b	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines
Randomisation:		
Sequence generation	8a	Method used to generate the random allocation sequence
	8b	Type of randomisation; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those

		assessing outcomes) and how
	11b	If relevant, description of the similarity of interventions
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses
Results		
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
	13b	For each group, losses and exclusions after randomisation, together with reasons
Recruitment	14a	Dates defining the periods of recruitment and follow-up
	14b	Why the trial ended or was stopped
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
Discussion		
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
Generalisability	21	Generalisability (external validity, applicability) of the trial findings
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
Other information		
Registration	23	Registration number and name of trial registry
Protocol	24	Where the full trial protocol can be accessed, if available
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders

What do you want to find out?

Efficacy.....Effectiveness

Can it work? Does it work?

What exactly is the intervention to be evaluated?

Individual-level BI

Training in BI

Implementation of BI

BI programmes

The design of control conditions?

- No treatment
- Assessment only
- Waiting list
- Brief advice
- Usual care
- Bona fide comparison BI
  - Non-inferiority design
- Dismantled contents
- Untrained practitioners

Clients/Participants

- Help-seeking….Opportunistic
- Pristine vs. Nonresponders
- Single problem vs Multiple problem
- Age range
- Severity
- Sociodemographic characteristics
- Motivation?

Practitioners/Interventionists

- Type of interventionist
  - Professional background/education
  - Professional vs. Peer
  - Prescreened for skill (e.g., empathy)
  - Training/experience in specific methods eg MI

- Assignment to conditions
  - Self-selected vs. Random assignment
  - Same practitioners to both?

Training of Interventionists

- Starting skill level
- Training to criterion vs. Training dose
- Skill threshold for efficacy?
  - Basic competence vs. proficiency
  - Set the bar high to get less therapist variability
- Not just initial training
  - Ongoing monitoring, coaching
- Pragmatic (Return on Investment)
  - What effect can I get for X amount of training?
  - Is it cost effective to (re)train providers in MI?

Outcome Assessment

- First: Measure what you want to change!
- Proxy markers
  - Motivation measures (e.g., stage progression)
  - In-session client speech (e.g., CT:ST)
  - Mediational analyses
- *When* to evaluate change
  - Proximal follow-up: Expect MI effect soon
  - Effect size over time. Does it fade? Why?
  - Follow-up: Spacing, sample, retention
- *What* to evaluate
  - Target behaviours only or possible impacts…

Designing your study

What else do you need to give attention to?