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

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CONSORT 2010 checklist of information to include when reporting a randomised

| | Item | |
|--|------|---|
| Section/Topic | 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 | 2a | Scientific background and explanation of rationale |
| objectives | 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 | 8a | Method used to generate the random allocation sequence |
| generation | 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 | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and |
| diagram is strongly | | were analysed for the primary outcome |
| recommended) | 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 | |
| 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?