

Strategies to improve recruitment to randomised controlled trials

Shaun Treweek

streweek@mac.com

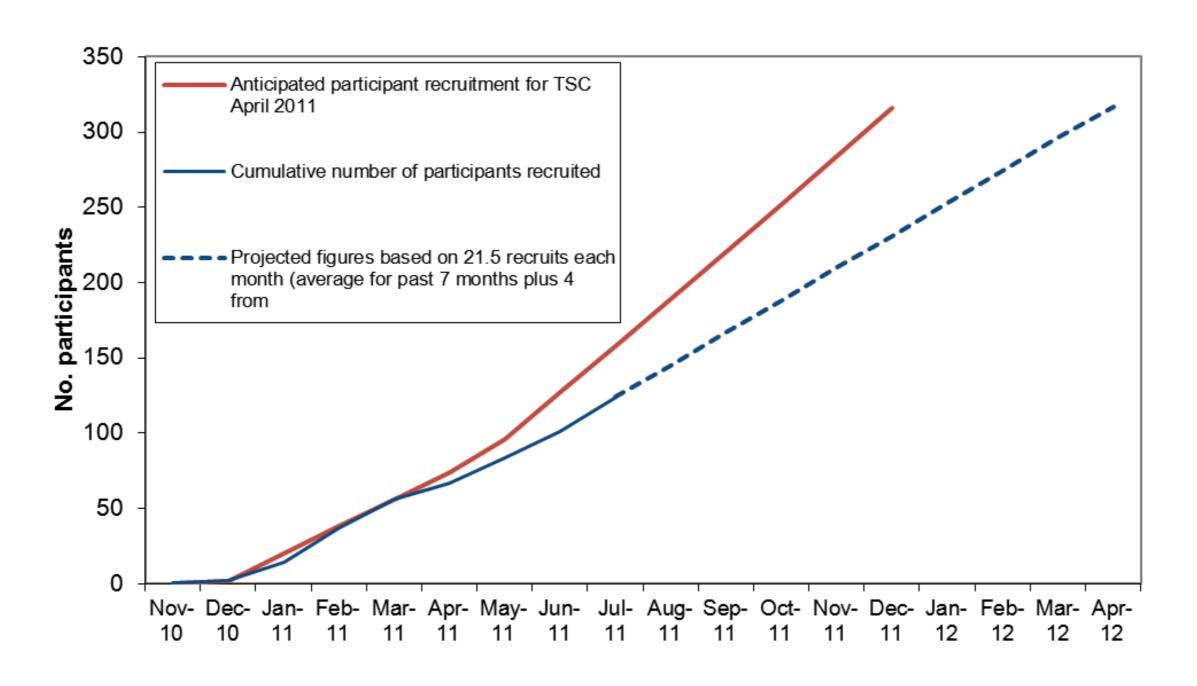
Health Services Research Unit University of Aberdeen

HSRU is funded by the Chief Scientist Office of the Scottish Government Health Directorates. The author accepts full responsibility for this talk.

Recruitment can be quite frustrating..



A common graph..



Recruitment interventions

Strategies to improve recruitment to randomised controlled trials (Review)

Treweek S, Mitchell E, Pitkethly M, Cook J, Kjeldstrøm M, Johansen M, Taskila TK, Sullivan F, Wilson S, Jackson C, Jones R, Lockhart P



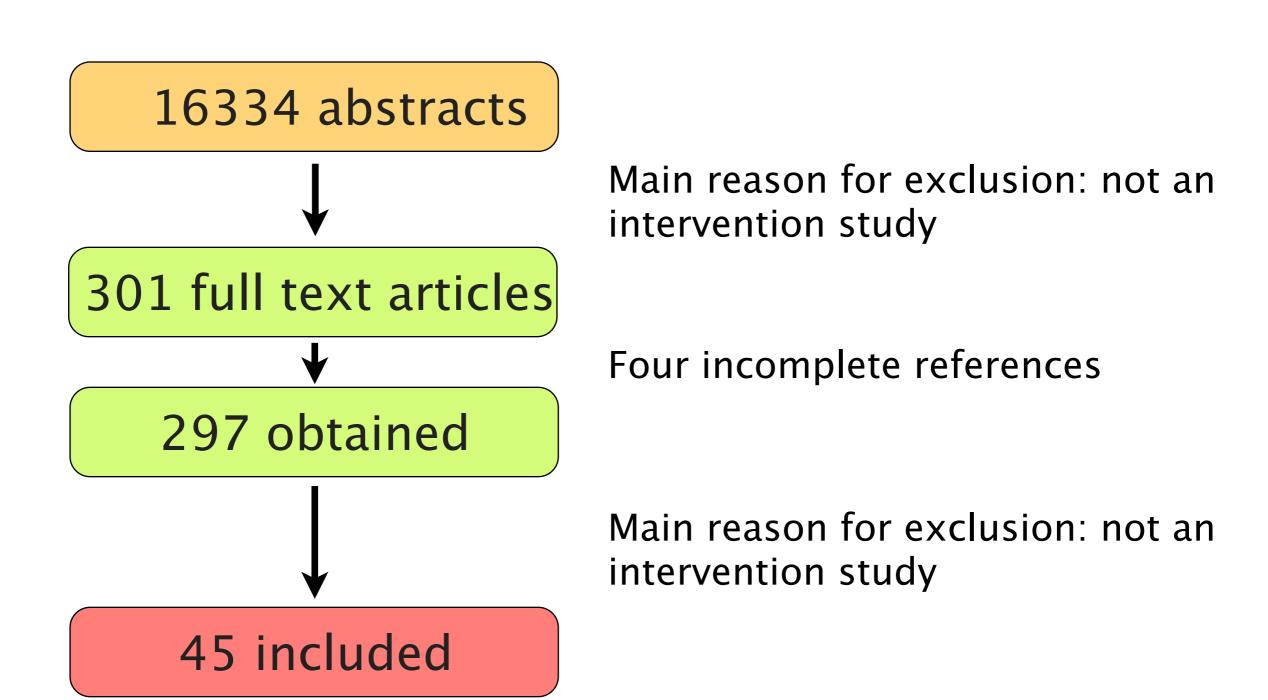
Where did we look?

- The Cochrane Methodology Review Group Specialised Register (CMR)
- MEDLINE
- EMBASE
- ERIC
- Science Citation Index Expanded
- Social Sciences Citation Index
- National Research Register
- C2-SPECTR
- PubMed to retrieve Related Articles to the 27 studies included in our previous version of the review.

What did we do?

- Each abstract checked by at least two reviewers for relevance
- Full text obtained for anything that did look relevant
- Text checked by at least two reviewers
- If a study was included its data were extracted using a data extraction form by two reviewers
- Data were put into RevMan 5 and checked and analysed by two reviewers (one of whom was a statistician)

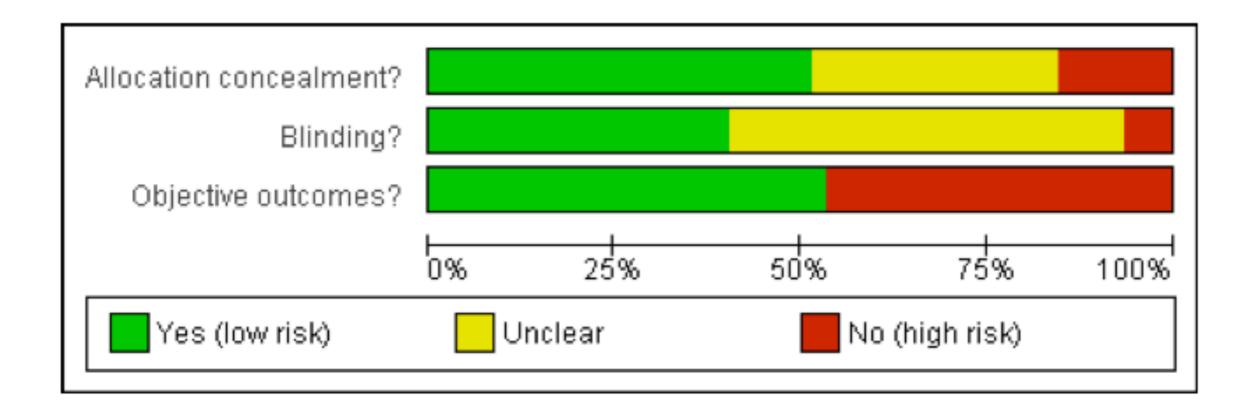
Trial recruitment interventions



Categories of interventions

- Design changes
- Modification to the consent form or process
- Modification to the approach made to potential participants
- Financial incentives for participants
- Modification to the training given to recruiters
- Greater contact between trial coordinator and trial site

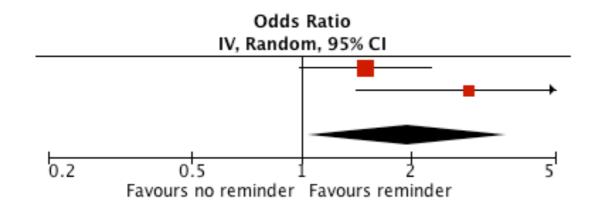
Risk of bias



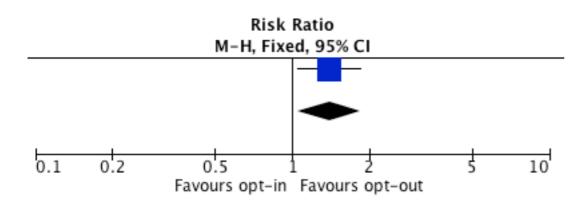
Cut to the chase...

What works?

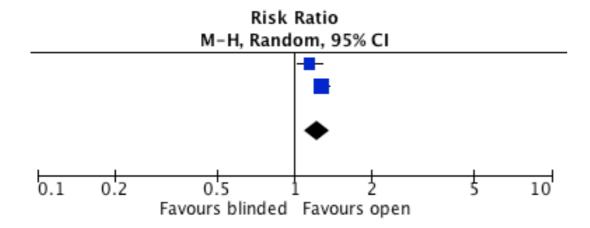
Interventions: what looks effective



Telephone reminders

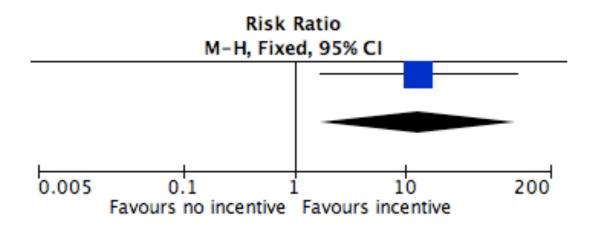


Opt-out

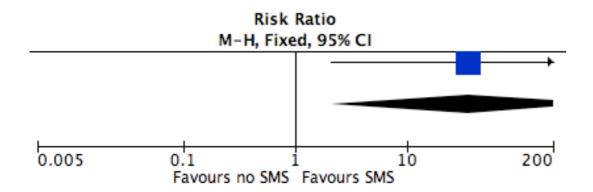


Open design

Interventions: what looks promising



Financial incentives



SMS messages to participants

GRADE Summary of Findings table

| Telephone reminder versus no telephone reminder | | | | | | | | |
|--|--|------------------------------|-----------------------------|---------------------------------|------------------------------------|--|--|--|
| Patient or population: Settings: Any Intervention: Telephon Comparison: No teleph | | | | | | | | |
| Outcomes | Illustrative comparative risks* (95% CI) | | Relative effect (95% CI) | No of participants (studies) | Quality of the evidence (GRADE) | | | |
| | Assumed risk | Corresponding risk | | | | | | |
| | No telephone reminder | Telephone reminder | | | | | | |
| Number recruited | Low ¹ | | OR 1.95 | 778 | ⊕⊕⊕⊝ | | | |
| | 30 per 100 | 46 per 100 (31 to 61) | (1.04 to 3.66) | (2 studies) | moderate ² | | | |
| | Moderate ¹ | | | | | | | |
| | 50 per 100 | 66 per 100 (51 to 79) | | | | | | |
| | High ¹ | | | | | | | |
| | 70 per 100 | 82 per 100 | | | | | | |

(71 to 90)

The effect of many interventions remains unclear

- Financial incentives
- Changes to consent
- Changes to information provision
- Newspaper and radio advertising
- More/better training of recruiters



Something from the BMJ Open version (in press)

| Recruitment intervention Reference ID | Increases | Decreases | Little impact | Inconclusive |
|--|-----------|-----------|---------------|--------------|
| Trial design | | | | |
| Open design ^{16, 32} | • | | | |
| Placebo* 59 | | • | | |
| Patient preference design ¹⁸ | | | ⊙ | |
| Zelen design† ²⁵ | | 0 | | |
| Internet-based data capture† 42 | | o | | |
| Obtaining consent | | | | |
| Process – opt-out approach ⁵⁵ | • | | | |
| Process – consent to experimental treatment* 48,50 | | | • | |
| Process – consent to standard treatment* 48,50 | | | • | |
| Process – refuser chooses treatment option* 50 | | | ⊙ | |
| Process – physician modified chance of experimental* 48 | | | © | |
| Process – participant modified chance of experimental* 48 | | | ⊙ | |
| Form – researcher read aloud ⁵⁶ | | | © | |
| Form – altered readability level ^{† 19} | | | © | |
| Approach to participants | | | | |
| Delivery – video presentation*† 28, 35 | | | • | |
| Delivery – video presentation plus written information 60 | • | | | |
| Delivery – audiovisual overview of trials ^{21-22, 33} | | | • | |
| Delivery – interactive computer presentation* 36, 44 | | | | • |
| Delivery – verbal education session ⁴⁵ | • | | | |
| Supplementing info – booklet on clinical trials* 23, 34 | | | • | |
| Supplementing info – study-relevant questionnaire 31, 37 | | | • | |
| Supplementing info – newspaper article ⁵¹ | | | ⊙ | |
| Framing – treatment as faster* 52 | • | | | |
| Framing – treatment as new* 38 | | 0 | | |

Conclusions

- Some interventions are effective at increasing recruitment
- The effect of far more is unclear
- It's hard to know what to do with studies of hypothetical trials
- Trialists should aim to embed methodological studies of their recruitment strategies into their trials (Peter Bower will talk about this later today)

A coalition of the willing...

- Jonathan Cook: University of Aberdeen
- Taina Taskila, Sue Wilson: University of Birmingham
- Ritu Jones, Elizabeth Mitchell, Marie Pitkethly, Frank Sullivan: University of Dundee (Ritu Jones is now doing something else)
- Monica Kjeldstrøm: Ex-Nordic Cochrane Centre, now doing something else
- Marit Johansen: Norwegian Knowledge Centre for the Health Services
- Cathy Jackson: University of St Andrews