PRECIS-2: a tool to improve the applicability of randomised controlled trials

Shaun Treweek*
streweek@mac.com

Kirsty Loudon, Frank Sullivan, Merrick Zwarenstein

***Health Services Research Unit**
University of Aberdeen

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PRECIS, something to help trialists think through their decision decisions

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ORIGINAL ARTICLE

A pragmatic–explanatory continuum indicator summary (PRECIS): a tool to help trial designers

Kevin E. Thorpe[a,*], Merrick Zwarenstein[b], Andrew D. Oxman[c], Shaun Treweek[d], Curt D. Furberg[e], Douglas G. Altman[f], Sean Tunis[g], Eduardo Bergel[h], Ian Harvey[i], David J. Magid[j], Kalipso Chalkidou[k]

[a]*Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada M5T 3M7*
[b]*Centre for Health Services Sciences, Sunnybrook Research Institute, Sunnybrook Health Sciences Centre; Institute for Clinical Evaluative Sciences; Department of Health Policy, Management and Evaluation, University of Toronto, Toronto, Ontario, Canada*
[c]*Preventive and International Health Care Unit, Norwegian Knowledge Centre for the Health Services, Oslo, Norway*
[d]*Division of Clinical & Population Sciences and Education, University of Dundee, Dundee, UK; Norwegian Knowledge Centre for the Health Services, Oslo, Norway*
[e]*Division of Public Health Sciences, Wake Forest University School of Medicine, Winston-Salem, NC, USA*
[f]*Centre for Statistics in Medicine, University of Oxford, Oxford, UK*
[g]*Center for Medical Technology Policy, Baltimore, MD, USA*
[h]*UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, Department of Reproductive Health and Research, World Health Organization, Geneva, Switzerland*
[i]*Faculty of Health, University of East Anglia, Norwich, UK*
[j]*Institute for Health Research, Kaiser Permanente Colorado; Departments of Preventive Medicine and Biometrics and Emergency Medicine, University of Colorado Health Sciences Center, Denver, CO, USA*
[k]*National Institute for Health and Clinical Excellence, London, UK*

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Abstract

Objective: To propose a tool to assist trialists in making design decisions that are consistent with their trial's stated purpose.

Study Design and Setting: Randomized trials have been broadly categorized as either having a pragmatic or explanatory attitude. Pragmatic trials seek to answer the question, "Does this intervention work under usual conditions?," whereas explanatory trials are focused on the question, "Can this intervention work under ideal conditions?" Design decisions make a trial more (or less) pragmatic or explanatory, but no tool currently exists to help researchers make the best decisions possible in accordance with their trial's primary goal. During the course of two international meetings, participants with experience in clinical care, research commissioning, health care financing, trial methodology, and reporting defined and refined aspects of trial design that distinguish pragmatic attitudes from explanatory.

Results: We have developed a tool (called PRECIS) with 10 key domains and which identifies criteria to help researchers determine how pragmatic or explanatory their trial is. The assessment is summarized graphically.

Conclusion: We believe that PRECIS is a useful first step toward a tool that can help trialists to ensure that their design decisions are consistent with the stated purpose of the trial.

PRECIS, something to help trialists think through their decision decisions

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A pragmatic–explan
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Kevin E. Thorpe[a,*], Me
Curt D. Furberg[e], Dougl
[a]Dalla Lana School
[b]Centre for Health Services Sciences, Sunnyb
Department of Health Pol
[c]Preventive and International
[d]Division of Clinical & Population Sci
[e]Division of Public Heal
[f]Cent
[g]
[h]UNDP/UNFPA/WHO/World Bank Special
Reproductive
[i]
[j]Institute for Health Research, Kaiser Per
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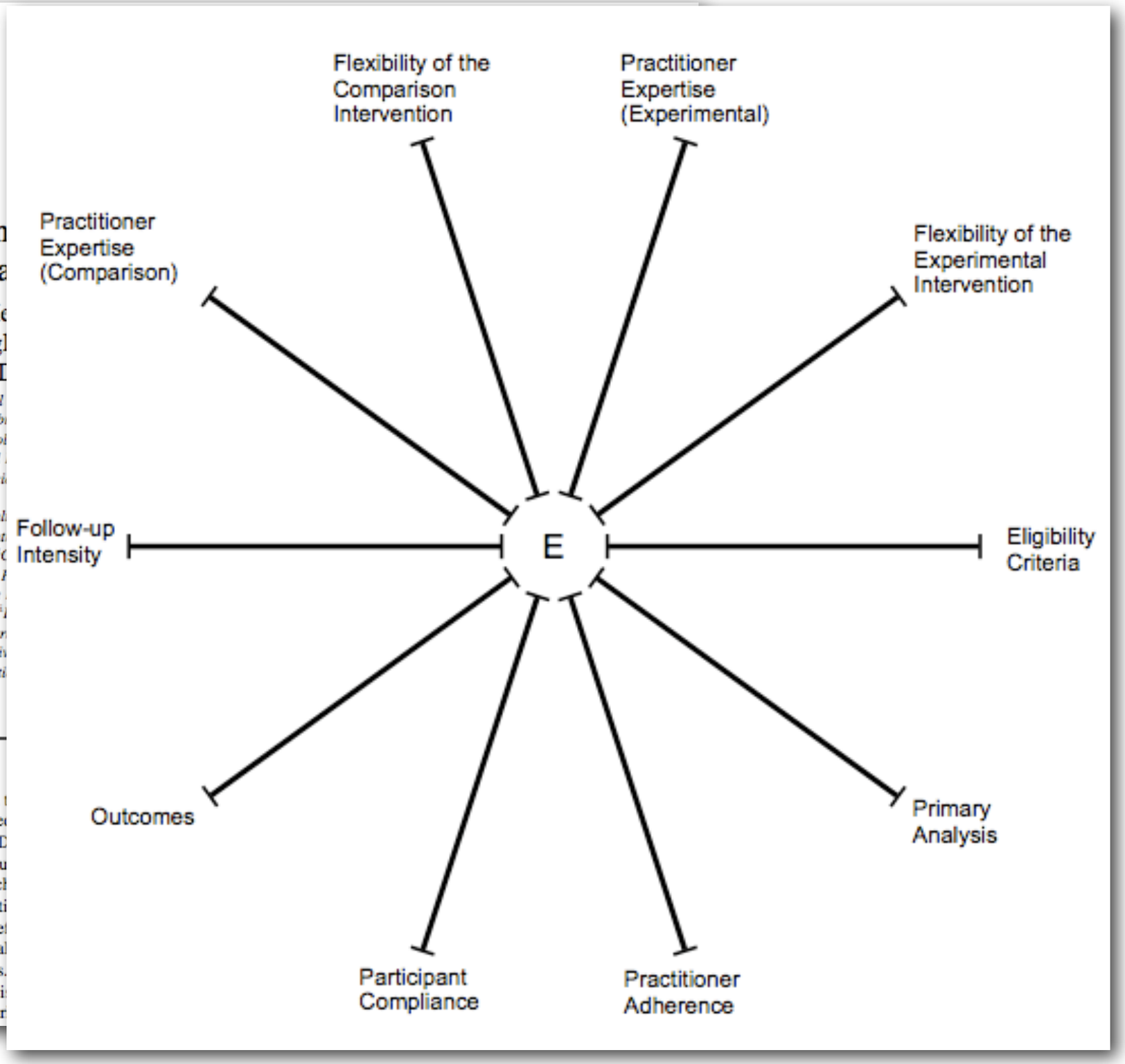


Developing PRECIS-2: three phases

- **Phase 1: brainstorming and a two-round modified Delphi survey of authors who cited PRECIS.**
- **Phase 2: take these results and user test alternative versions of PRECIS-2.**
- **Phase 3: evaluate the validity and reliability of the most promising PRECIS-2 candidate using a sample of 15-20 trials rated by 15 other trialists.**

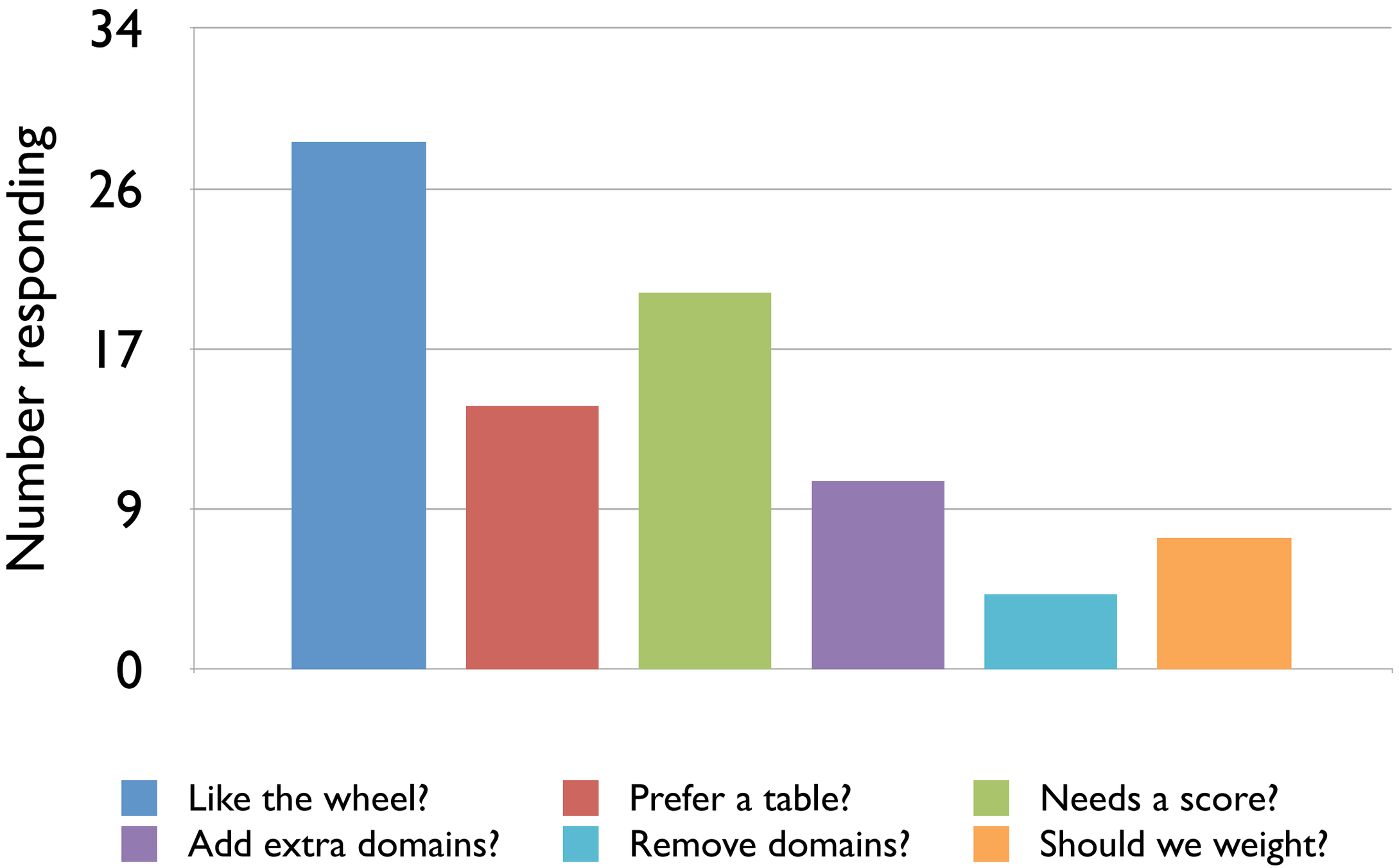
Brainstorming

- Add a scoring system?
- Better guidance
- Drop the analysis domain?
- Do we need to weight domains?
- Inter-rater reliability a problem?
- Is the wheel the best presentation?

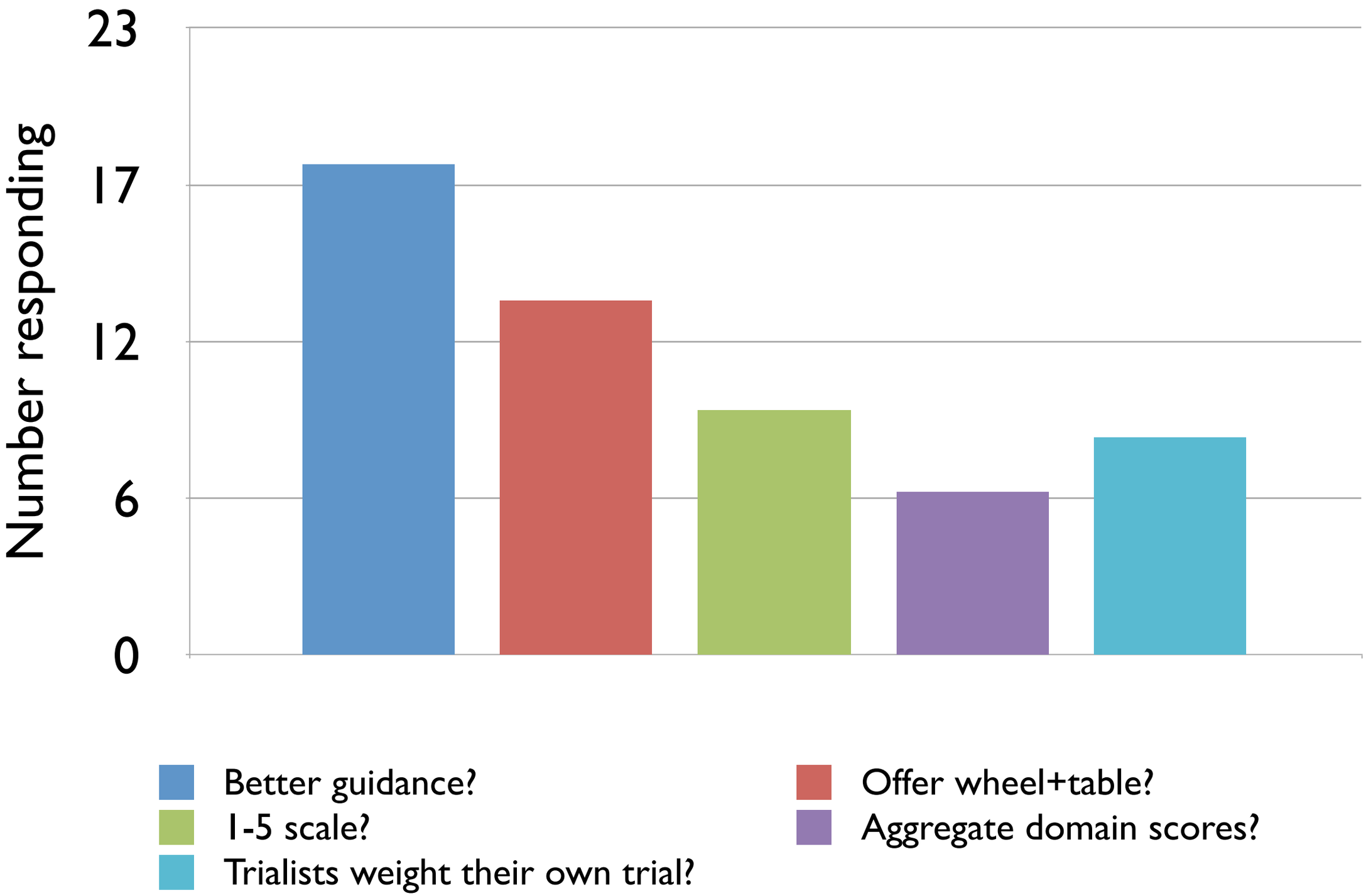
Delphi Round 1

- **Invite authors of papers citing PRECIS to participate (90 - 34 responded).**
- **Ask general questions linked to our brainstorming ideas and questions.**
- **Also asked if people would like to help with Round 2 (23 said Yes)**

Delphi Round 1 (answering 'yes')



Delphi Round 2 (answering 'yes')



Delphi 2: suggestions for extra domains

- Source of patients or setting for recruitment (x12)
- Main objective of trial (x6)
- Budget/costs (x6)
- Integration with the health care system (x5)
- Availability of the drug (x3)
- Feasibility of blinding (x5)
- Risks (x4)
- Appropriateness of methodology/rationale (x3)

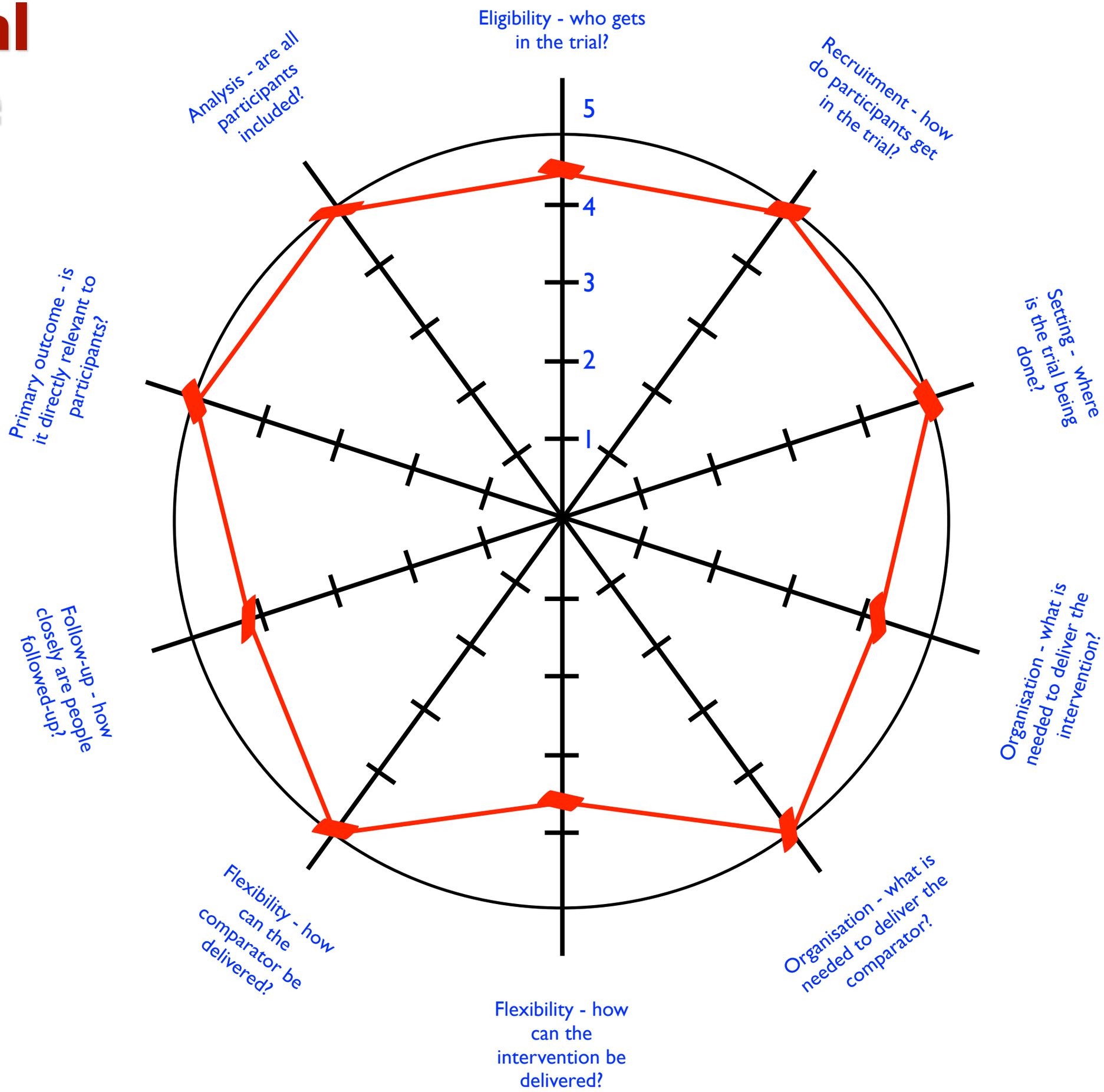
Ten domains to user-test (first 5)

- **Eligibility** - who gets into the trial?
- **Recruitment** - how do participants get into the trial?
- **Setting** - where is the trial being done?
- **Organisation** - what is needed to deliver the intervention?
- **Organisation** - what is needed to deliver the comparator?

Ten domains to user-test (last 5)

- **Flexibility** - how can the intervention be delivered?
- **Flexibility** - how can the comparator be delivered?
- **Follow-up** - how closely are participants followed-up?
- **Primary outcome** - is it directly relevant to participants?
- **Analysis** - are all participants included?

Abdominal massage in MS patients



Conclusions

- **The original PRECIS tool is widely cited and generally liked but some weaknesses have been highlighted.**
- **Our brainstorming and Delphi generated some concrete suggestions for changes.**
- **Our user-testing will tell us whether these changes are improvements or just changes.**
- **If we get the thumbs-up, we'll go to formal validity and reliability testing.**

Thank you!

streweek@mac.com