FAce validity of Back pain Outcome reporting methods (FABO)

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Background

- How outcomes of clinical trials are reported alters the way clinicians interpret the effectiveness of the interventions under investigation
- Interventions are interpreted as more effective when results have been reported in relative terms as opposed to absolute terms
- It is not clear which reporting methods have the highest face validity from clinicians' perspectives – which reporting methods best describe outcomes?

Aims

- To explore the face validity of different reporting methods of LBP trial outcomes, through series of qualitative interviews with clinicians who see patients with LBP
- To explore how these clinicians would prefer to see LBP trial outcomes reported, which methods they feel offer the most relevant information to decision making, which of the presented methods are preferred, and why they are preferred

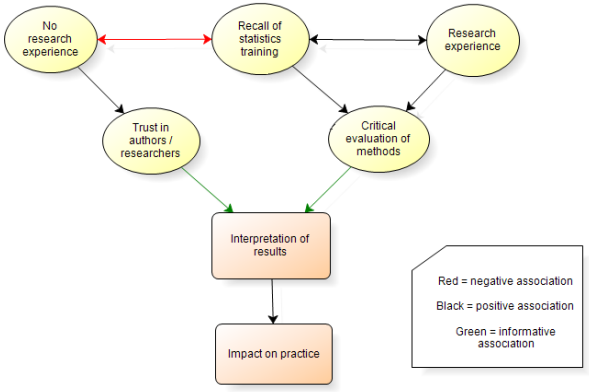
Materials and methods

- In-depth interviews
- Purposive sample of clinicians who see patients with LBP, by experience, sector, sex, and specialty
- Participants presented with five summary cards reporting a fictional RCT of a fictional intervention: 'physical behavioural praxis'
- Primary outcome was a hypothetical measure of pain and disability: the iBAQ scale
- Comparisons of iBAO results between intervention and control groups reported in scenarios were a transformation of results ofthe manual therapy arm of the UK Back Pain Exercise And Manipulation (BEAM) trial
- Outcomes reported using:
  1. Between group mean difference (with and without advice on minimally important change *for an individual*) and including the standardised mean difference (SMD)
  2. Proportion of individual responders to treatment – *i.e., with a score decrease greater than the minimally important change*
  3. Relative risk
  4. Odds ratio
  5. Number needed to treat (NNT) for improvement, and for 'benefit'- *the number needed to treat on average for one patient to improve or to prevent one deterioration*
- Participants perceptions and preferences for each method were explored
- Interviews recorded and transcribed
- Analysed using the Framework method
- QSR NVIVO 7 for data management
- Ethics and research governance approval from local REC and four health trusts

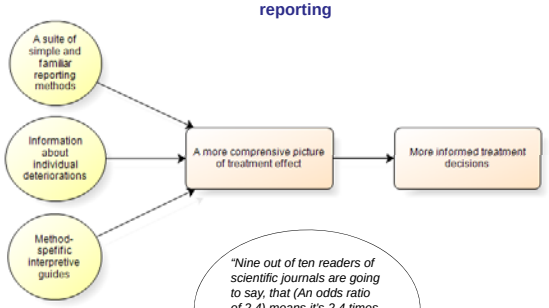
Results

- Data saturation after 14 interviews
- Sample included: 1 chiropractor, 2 GPs, 1 Neurosurgeon, 1 Orthopaedic surgeon, 3 osteopaths, 2 pain psychologists, 3 physiotherapists, and 1 rheumatologist
- 6 clinicians practised in the NHS only, 5 in the private sector only, and 3 practiced in both sectors

Model one: associations between participant attributes and interpreting results



Model two: preferences for future reporting



"I'd need to know what is a clinically meaningful change on the iBAQ. It (between-group difference) could be completely irrelevant ,or it could be highly relevant."

"I find that this (Proportion of responders) is understandable. And it can't be spun."

"Nine out of ten readers of scientific journals are going to say, that (An odds ratio of 2.4) means it's 2.4 times more likely (as opposed to 2.4 times the odds)."

""…it's just fascinating how it (NNT) can totally alter how effective you think something is! (slight laugh) Because I'm kind of … I think if I were to see that… oh, god… you know to get three people well, I'm going to have to see eighteen people…"

"I would probably have to go and google relative risk!"

"…they all tell different bits of the story. You're giving me drip, drip…"

"I think it's quite nice to have kind of a rough pointer as to whether it's a small, medium or large thing (SMD)"

Discussion

Results suggest that those clinicians who were interviewed:

1. Were not confident about interpreting results of RCTs
   - ➢ Primarily due to poor recall of statistics and unfamiliarity with contemporary reporting methods. They felt trial reports were not written with them in mind.
2. Were familiar with mean differences, proportion improved, and NNT; unfamiliar with SMD, odds ratios and relative risk
3. Found the proportion improved, relative risk and NNT the most intuitively understandable; were concerned that mean difference (when reported with minimally important change), relative risk and odds ratios, may mislead
4. Felt each method uniquely contributed to their understanding of the treatment effect and reporting using a variety of methods would prevent erroneous portrayal of treatment effect
5. Felt guidance on how to interpret unusual reporting methods would be useful; their preference would be for simpler methods that do not require explanation

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