National Collaborating Centre for Methods and Tools

Centre de collaboration nationale des méthodes et outils

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Methods for the synthesis of studies without control groups

Why is it important to consider evidence from studies without control groups?

Randomized controlled trials (RCTs) provide rigorous results for effectiveness questions, yet may not be the best or even possible study design for all questions. It is therefore important to consider the best available evidence.

Currently, there is no standardized method for synthesizing results of studies that do not have control groups.

What are the potential benefits of including data from non-controlled quantitative and qualitative studies?

- Include a wider body of literature in search strategies.
- Broaden scope of review to include long-term effectiveness, adverse events and rare events.
- Provide insight into intervention/program success or failure.

Who are the primary target audiences for studies that synthesize non-controlled studies?

Researchers, government policy-makers, decision-makers, health professionals

How was this resource created?

A systematic search and integration of the literature was conducted to examine methods to synthesize and tools to critically evaluate evidence from quantitative studies without control groups.

What did we find?

- Primary studies should undergo quality assessment.
- Critical appraisal tools help assess methodological quality.
- Critical appraisal tools should include issues such as the management of confounders, potential biases, and adequacy of data analysis.
- Some methods for synthesizing data from both quantitative and qualitative studies are available.

What impact does the inclusion of quantitative non-controlled studies have on systematic review results?

Studies that combine RCTs with well designed non-controlled studies can produce similar results, regardless of study type. Systematic reviews can benefit from the inclusion of primary studies that clearly identify potential for bias and probable impact on effect.

Challenges related to quantitative primary study quality include:

- poor reporting of methodology;
- poor management of confounders;
- lack of consistent terminology in primary studies that limits data comparison and analysis.

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What impact does the inclusion of qualitative data within mixed methods studies have on systematic review results?

Incorporating data from both qualitative and quantitative data in one report can more fully explain the success or failure of interventions.

Challenges related to systematic reviews in assessing the quality of these studies include:

- Traditional criteria for systematic reviews and meta-analyses are not useful for assessing the quality of non-controlled and qualitative studies.
- Results of quality assessment should not be used as exclusion criteria, but rather incorporated into the discussion.
- Thematic and aggregate reporting may be an appropriate and alternative approach to meta-analysis.

Future recommendations:

1. Studies without control groups can usefully be incorporated into systematic reviews.
2. Integrative review methods are an effective way to include results of non-RCTs.
3. Results of non-controlled trials can be synthesized when non-controlled primary studies have been well designed. Effect sizes are similar for well-designed quantitative studies.

For methods of systematic review, including studies without control groups:

- Use a critical appraisal tool that has been tested for internal consistency, test-retest and inter-rater reliability, and at least face and criterion validity.
- Do not meta-analyze results from observational studies.

For authors of primary studies:

- Use strong and transparent study design in all non-RCTs so readers have sufficient information to determine what research methods have been utilized.
- Allow study design to determine research question.
- Use consistent terminology and descriptions across studies to facilitate comparisons.

For future research:

- Test critical appraisal tools to assess the quality of non-controlled studies for reliability and validity.
- Conduct further studies to explain the different results obtained by randomized versus non-randomized trials.

How can I find out more about this study?

Visit the National Collaborating Centre for Methods and Tools Registry website at http://www.nccmt.ca/registry/index-eng.html.

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