Development of a Tool To Assist in the Identification of Study Designs for the Purposes of HTA

Lavinia Ferrante Di Ruffano[1], Katie Reddish[1], Emma Bishop[1], Deborah Watkins[1], Mary Edwards[1], Rachael McCool[1]

[1] York Health Economics Consortium, University of York, York, YO10 5NQ

INTRODUCTION

As the most internally rigorous designs, randomised controlled trials (RCTs) are the gold standard for assessing the efficacy and safety profile of interventions. Increasingly, health technology assessment (HTA) considers evidence from non-randomised studies. Guidance recommends synthesising different study designs separately due to their different inherent biases/limitations. However, when authors or reviewers misclassify studies, this can affect which studies are included in a review and, therefore, the review results.

METHODS

This methods study aimed to:

1. Identify a clear study design classification system for studies evaluating pharmaceutical treatments.
2. Explore whether the use of such a system produces consistent study design categorisations amongst reviewers.
3. Iteratively improve the classification system.

A pragmatic web-based search for study design categorisation tools was conducted. The resulting schemas were used to develop a clear algorithm for use by reviewers of all levels of experience. We tested tool consistency and user experience by web-based survey of a small internal sample of reviewers, each independently using the system to categorise 18 published studies.

RESULTS

A median of 7 reviewers (range 4 to 8) categorised each study. 3 studies (17%) had a rater agreement of 100% (2 RCTs and 1 case series). 6 studies (33%) had a rater agreement of between 75% and 86%. Agreement was most commonly reached on RCTs and non-randomised controlled trials.

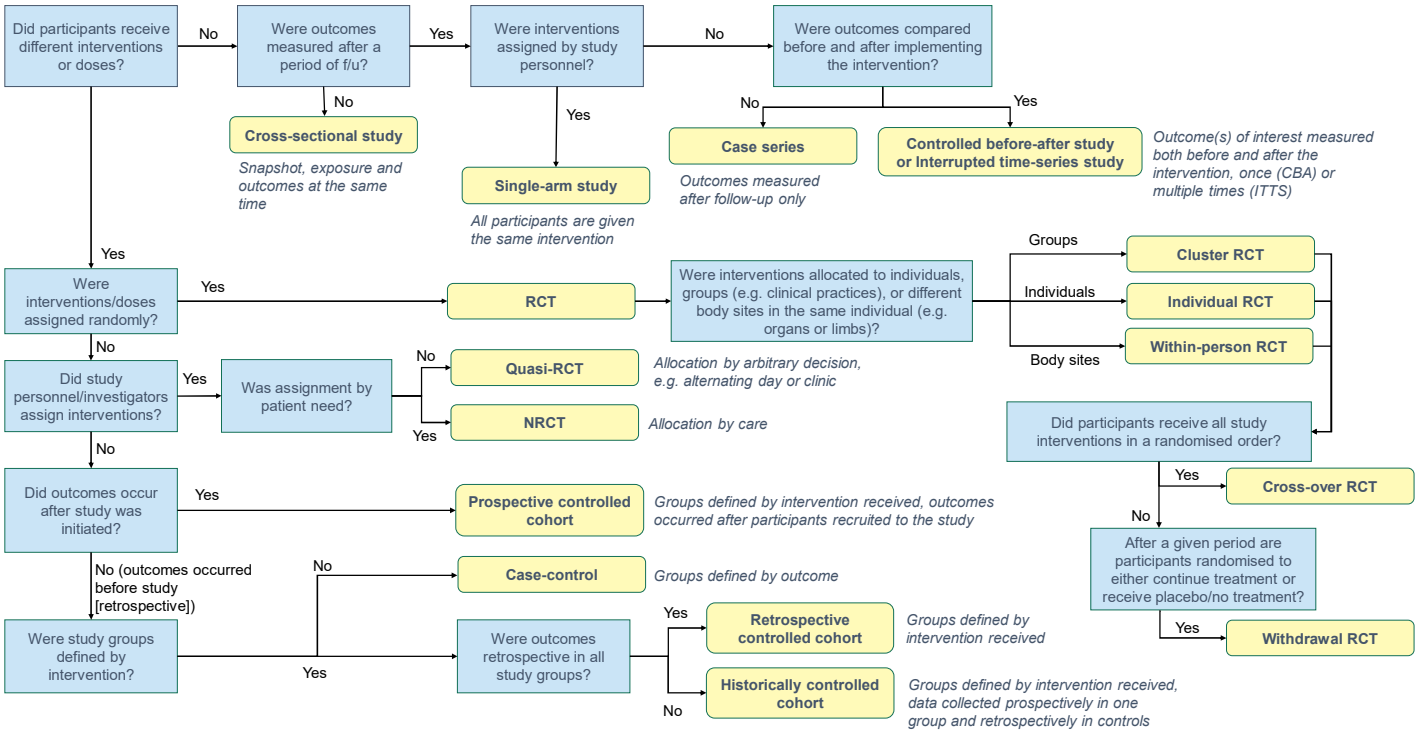
The most common sources of disagreement were between different types of cohort studies, and between case series and controlled cohort studies, largely due to inconsistent reporting by study authors. Disagreement was very heterogeneous, with a single paper being classified as 3 or 4 different study designs across the sample of 8 reviewers.

We identified several improvements to be made to the flowchart: the wording of prompt questions, the ordering of designs and the addition of new elements. New elements added to the latest iteration of the flow chart include single-arm trials, interrupted time series studies, and different types of RCT.

CONCLUSIONS

Increased consistency in defining study designs would increase the transparency of clinical studies and the consistency of reviews. However, a definitive consensus on each study design is hard to reach. The classification system as initially designed led to too much variation in study design categorisation to be useful. Consequently, we present a revised version that we now aim to evaluate in a larger sample of reviewers. Further research will **1) test this new version** (scan the QR code below) and 2) investigate whether using the tool could change the results of systematic reviews, using a small sample of published reviews.

Figure 1: Revised study designs identification diagram



CONTACT US

lavinia.ferrante@york.ac.uk

+44 1904 326475

www.yhec.co.uk

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