

Extending follow up of randomised clinical trials by linkage to routinely collected data – results of a scoping review of the published literature

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Introduction

Although RCTs remain the gold standard for generating clinical evidence, follow up of participants to study long-term effects is limited by cost and other logistical considerations. Linkage of participant information to routinely collected data potentially offers a cost-effective solution to achieving long-term follow-up of treatment effects

Conclusion/Implications

Although we uncovered over 100 RCTs that were extended by record linkage this is tiny compared with the number of trials that have been undertaken. Linkage to routinely collected data seems to be a feasible but under-used approach to extending the follow-up of clinical trial participants for very long periods.

Objectives and Approach

This scoping review aimed to identify RCTs that had been extended by record linkage, and characterize these in terms of nationality, numbers of trials, disease areas and outcomes, types of data, linkage modes and duration of follow-up. We followed published guidelines for the conduct of scoping reviews, with a registered protocol and comprehensive literature search. Criterion-based selection of studies and extraction of data were performed in duplicate. Descriptive statistics were used to summarise the characteristics of eligible studies.

Results

One hundred thirteen RCTs had been extended by record linkage. Fifty-six were conducted in Nordic countries, 26 in the USA and 24 in the UK. Types of linkage data used were: vital statistics 36, administrative data 31, cancer registry 28, special registries 13 and others 11. The literature spanned 45 years, but 66 (58%) were published between 2010 and 2016. Linkage methods were reported as: deterministic 33, probabilistic 16 and unspecified 64. In 44 studies researchers reported ethics approval for linkage; this was not obtained in 39 cases and was absent in 30 reports. The overall follow up times achieved by record linkage were: 1-4 y (6 studies), 5-9y (34), 10-19y (48), 20-29y (21), 30-39y(4) and over 50y (1).

