at the identification of CRCTs in clinicaltrials.gov and other registries. We sought to determine whether adherence to CONSORT guidelines has improved and whether CRCTs could be identified in trial registries.

Methods

We focused our review on CRCTs designed to improve the care of patients with diabetes through interventions aimed at either patients or health care providers. We searched pubmed in September 2016 using the terms Diabetes AND ((cluster randomized) OR (cluster randomised) OR (group-randomized) OR (group-randomised)). Reviews, bibliographies, and registries were searched for additional publications. Publications were classified as: diabetes treatment, diabetes prevention, or not diabetes and as CRCT or not. We extracted data on the adherence to CONSORT guidelines and determined the trial registration status for each publication (included in the publication, registered but not included, or not registered). This information was used to group publications by trial and we selected the primary results publication, if any, for each trial.

Results

Our search identified 557 English language publications between 2000 and 2015, 349 of which included patients with diabetes. 262 (75%) were reports of CRCT. Excluded publications used terms like "parallel group randomized", "cluster of risk factors", "cluster sampling", and "Cluster analysis" or were reviews. A few excluded publications called themselves CRCT but were trials where individuals were randomized to receive treatment in groups. An additional 54 publications were found for a total of 316 publications from 186 trials: 143 primary results, 81 design, and 92 secondary. We grouped the 143 results publications by year published: 44 in 2000–2007, 39 in 2008–2011, and 60 in 2012–2015. The percent with CRCT in the title (18%, 51%, 63%) and the percent registered (11%, 79%, 83%) increased over time. 86% had the number of clusters in the abstract, 78% discussed clusters in the statistical analysis plan, and 49% included the sample size intracluster correlation. Only 39/86 registered trials included the word cluster in the registration (clinicaltrials.gov 17/47, ISRCT 14/26, ACTRN 4/6, others (4/7).

Conclusions

The quality of CRCT publications has increased, but there continue to be publications that are underpowered and do not account for the effect of clustering in the analysis. Trial registries do not currently include a code for CRCT or a structured means of recording the number of clusters in results. The description of CRCTs in registries needs to be improved so these trials can be included in systematic reviews.

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Building on the past: systematic identification, data extraction and synthesis of pre-existing individual stroke patient datasets to inform the development and design of future clinical trials

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Background

The number of stroke rehabilitation trials reported is rapidly increasing. Efficient trial design contributing to advances in rehabilitation should be informed by completed trials in the field. More than 50,000 people in the UK each year acquire aphasia: a stroke related language impairment affecting the ability to speak, understand speech, read and write with significant consequences for quality of life. Existing Cochrane systematic review evidence indicates that speech and language therapy (SLT) benefits language recovery in people with aphasia, however, the specific patient and intervention factors which predict optimal recovery and rehabilitation are unclear. By using a wider dataset with individual patient data (IPD) analysis we are enhancing the evidence synthesis process with the aim of addressing these evidence gaps. RELEASE (rehabilitation and recovery of people with Aphasia after stroke) is an international collaboration of aphasia researchers which seeks to achieve this goal.

Objectives

Funded by the National Institute for Health Research (Health Services and Delivery Research - 14/04/22) we have systematically gathered IPD from pre-existing aphasia research datasets to examine the natural history of recovery from aphasia, the predictors of recovery and optimal interventions (by rehabilitation regimen, delivery model and the aims and content of treatment).

Methods

We invited contributions of primary datasets from members of the Collaboration of Aphasia Trialists (cats). We also conducted a systematic search of existing published research to identify a comprehensive set of potentially existing aphasia research datasets which met our inclusion criteria. Research datasets were required to include a minimum of 10 people, a measure of aphasia severity as a consequence of stroke and information on time since stroke. We invited researchers from these studies to contribute data and to create a unique multilingual, international, interdisciplinary resource in this clinical field.

Results

Following a systematic search of the literature, we screened 5276 titles (including 2346 abstracts and 1152 full texts), from which we identified 874 eligible studies. We have received 76 study datasets contributing IPD from 4597 people with aphasia (56 through the systematic search and 20 via cats). These data have been contributed from 23 countries and we have identified a further 2400 IPD in the public domain. The substantive challenge is our planned IPD meta-analysis to examine recovery, predictors of recovery and effectiveness of intervention approaches. Our statistical analysis plan states that a one-stage approach will be conducted for the primary analyses, although a two-stage approach will also be explored. Network meta-analyses and meta-regression (some of which includes subgroup analyses) are also planned. We will discuss the methodological challenges, particularly which arise when there are non-standardized data, some non-randomized data, a large number of outcome measurements and some degree of sparse data.

Conclusions

RELEASE is the largest systematically developed, evidence synthesis study in the field of aphasia, and is more complex than most IPD trial meta-analyses. Our research will not only provide important evidence relating to the recovery of people with aphasia, but will also be an exemplar to researchers who plan to create databases to analyse complex individual patient data.

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A literature review of the use of adaptive design methods in oncology trials

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Background

The implementation of adaptive design methods in phase II, phase III or phase II/III has increased over the years [1]. There is a need for a set of guidelines to report adaptive design methodology used in clinical trials in addition to the CONSORT guidelines [2] to ensure full transparency of trials implementing predetermined or concurrent adaptations. The aim of this literature review is to understand the current application of adaptive design methodology in oncology trials, and to ascertain how this methodology is reported.

Methods

A literature search of PubMed, Embase and Ovid databases for full text publications of phase II, phase III or phase II/III cancer trials using adaptive design methodology during 2015 was conducted. The key words used for the literature search are as follows: adaptive design, flexible design, group sequential, sample size re-estimation, MAMS, adaptive randomisation, interim analyses, adaptive seamless, biomarker adaptive, two-stage adaptive, dose escalation, 'Drop the loser', 'Pick the winner', multiple adaptive, adaptive enrichment.