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Review article

The reporting quality of abstracts of stepped wedge randomized trials is suboptimal: A systematic survey of the literature

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ABSTRACT

Background: The stepped wedge trial (SWT) design is a type of the randomized clinical trial (RCT) design in which clusters or individuals are randomly and sequentially crossed over from control to intervention over a number of time periods. Trials using SWT design have become increasingly popular in medical, behavioral and social sciences research. Therefore, complete and transparent reporting of these studies is crucial. In particular, the quality of the abstracts of their reports is important because these may be the only accessible sources for their results.

Objective: The aims of this survey were to evaluate the reporting quality of SWT abstracts and to identify factors contributing to better reporting quality.

Methods: We performed literature searches to identify relevant articles in English published from November 1987 to October 2016 in the following electronic databases: Medline, Embase, Web of Science, CINAHL, and PsycINFO. At least two reviewers examined the quality of abstract reporting using the 17-item CONSORT (CONsolidated Standards Of Reporting Trials) Extension for Abstracts tool. Poisson regression models for incidence rate ratio (IRR) were used to identify factors associated with reporting quality (e.g., CONSORT endorsement, the number of authors, abstract format).

Results: A total of 92 eligible articles were identified. Only 6 from the 17 items were reported in more than 80% of the articles (e.g., the statement of conclusions, contact details for the corresponding author). In the multivariable analysis, the year of publication since 2008 (IRR: 1.16; 95% confidence interval (CI): 1.02, 1.33), journal endorsement of the CONSORT Statement (IRR: 1.15; 95% CI: 1.01, 1.31), and multiple authorship (IRR 1.13, 95% CI: 1.01, 1.27) were significantly associated with better reporting quality.

Conclusion: The quality of reporting of SWT abstracts was suboptimal, although there have been some significant improvements since 2008. Endorsement of the CONSORT Statement by journals is an essential element of improvement strategies. Also, multiple authorship is significantly associated with better quality of abstract reporting.

1. Introduction

As a brief summary of a research article, the abstract plays an important role in reporting a clinical study. Readers commonly decide whether or not to read an article based on their impressions of the abstract [1]. An abstract is also the first and fastest way for delivering

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the main study results to busy health care providers [1]. Furthermore, to those who cannot access the full text of a study, the abstract represents the only research resource. Consequently, for quick understanding of the study details, complete, structured and good quality abstract reporting is essential [1,2].

The stepped wedge trial (SWT) design is a type of the randomized clinical trial (RCT) design in which clusters or individuals are randomly and sequentially crossed over from control to intervention over a number of time periods [3]. At the first time point, none of the clusters or individuals receives the intervention of interest, which usually corresponds to a baseline measurement. By the end of SWT, all participants will have been exposed to the intervention. The first application of SWT was in an intervention study by the Gambia Hepatitis Study Group in 1987 [4]. Because of their perceived benefits (e.g. the logical, ethical, and political benefits), trials using SWT design have become increasingly popular in medical, behavioral and social sciences research [5].

Reporting quality has been a subject of concern since the introduction of this unique clinical research design. The first 2006 systematic review by Brown and Lilford [3] identified 12 SWT protocols and articles and concluded that a more consistent approach to reporting is required. Since 2006 reporting quality has been described in several reviews [6,7,8,9,10], but none has systematically examined reporting quality of the SWT abstract. In 1996, the CONSORT (CONsolidated Standards Of Reporting Trials) Statement was developed to standardize and guide researchers on reporting and the conduct of RCTs [11]. To further guide reporting of abstracts, the CONSORT Extension for Abstracts was introduced in 2008 [12,13]. This is a 17-item tool which authors often follow when submitting a study manuscript to a journal so to increase their chances of publication [13]. Although inadequate reporting may not reflect the real quality of studies [14,15], the reporting quality of SWT abstracts remains unclear, and an assessment and recommendations for future studies are required.

The primary aim of this systematic survey was to assess the quality of reporting of SWT abstracts by checking the compliance with 17 items of the CONSORT Extension for Abstracts. The secondary aim was to identify possible factors influencing the reporting quality of SWT abstracts.

2. Materials and methods

The study protocol of this systematic survey was published in Clinical Epidemiology in May 2016 [16].

2.1. Search strategy and eligibility criteria

We performed literature searches to identify relevant articles in English published from November 1987 (the time of the first SWT was published) to October 2016 in the following electronic databases: Medline, Embase, Web of Science, CINAHL, and PsycINFO (Appendix 1). We searched for additional references by cross-checking bibliographies of retrieved studies or relevant reviews. We included studies that carried out SWTs, which crossed over individuals/clusters (roll-out) from no exposure (control) to intervention after a certain length of time (all will be exposed at some point in the study). For eligible studies, outcomes were measured at each time point (at the end of each step), and individuals or groups of individuals (clusters) were randomized at the particular crossover times. Studies were excluded if they were not RCTs or were published in letters, commentaries, protocols or reviews. Other exclusion criteria included the application of the stepped-wedge method post hoc, the secondary publications pertaining to a particular trial, studies which were simple cross-over studies without outcome measurement to each cross-over point, and those using waitlist designs.

2.2. Study selection

One reviewer (OGV) screened the titles and abstracts of retrieved citations for inclusion. A team of reviewers (MW, YJ, ZJH, AT, and OGV) independently screened the full-text articles to determine eligibility. Any disagreement was solved by discussion to reach a consensus.

2.3. Data extraction

At least two reviewers (MW, YJ, ZJH, OGV), with training in methodology, independently extracted the data related to the quality of reporting using a standardized and pilot-tested data collection form based on the CONSORT Extension for Abstracts. The reporting quality of the selected abstracts was assessed by using each of the 17 items. An item was posed as a question with the response options: “Yes,” “No,” and “Unclear.” We treated them in the analysis by summing the scores for each item (1 for “yes”, 0.5 for “unclear” and 0 for “no”) [17].

We also extracted the relevant information from the included full texts, including the first author, year of publication, journal name, number of authors, country where the study was conducted, format of the abstract (structured or not), related setting (healthcare or non-healthcare), type of intervention (behavior change intervention or not), and statistical significance of the main findings (at an alpha level of 0.05). Furthermore, we collected the following information about journals: abstract word limitation, endorsement of the CONSORT Statement, endorsement of the CONSORT Extension for Abstracts.

2.4. Statistical analysis

Descriptive statistics for individual reporting items and study characteristics items are reported as count (percentages).

We estimated the incidence rate ratios (IRRs) for reporting items using generalized estimation equations (GEEs), assuming a Poisson distribution. IRR, their 95% confidence intervals (CI) and p-values were reported. Univariate analysis was performed to determine factors associated with better quality of reporting. For this analysis. We used the number of reported items (i.e. those with YES to whether item is reported) as a count outcome (i.e. dependent variable). The factors include: date of publication (1987–2008 vs. 2009–2016), abstract format (unstructured vs. structured), number of co-authors (≤ 5 vs. > 5), endorsement of the CONSORT (no vs. yes), or the CONSORT Extension for Abstract (no vs. yes), word limitation for abstracts (> 250 or no limitation vs. ≤ 250) and continents in which the studies were conducted. We also checked for multicollinearity (if variance inflation factor (VIF) > 10), but did not find any colinear factors [18].

We also explored internal methodology factors that affect the reporting quality of abstracts. According to PICO (Participants, Intervention, Control and Outcome) format, we included the following variables: setting (healthcare vs. non-healthcare), intervention type (behavior change interventions (BCI) vs. other treatments), and randomization (randomization at individual level vs. randomization at cluster level). The overall level of statistical significance was set at $\alpha = 0.05$. All analyses were performed using Stata 12.1 (Stata Corporation, College Station, Texas, USA).

3. Results

A total of 2189 studies were identified and 92 studies (see reference list in Appendix 2) were included in this analysis (Fig. 1). The frequency of publications on SWT has been increased dramatically in recent years (Fig. 2).

3.1. Study characteristics

The included articles (n = 92) were published in 76 distinct