



Review article

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



Mei Wang^{a,k}, Yanling Jin^a, Zheng Jing Hu^b, Alex Thabane^{c,d}, Brittany Dennis^{a,e},
Olga Gajic-Veljanoski^{a,f,g}, James Paul^{a,d}, Lehana Thabane^{a,h,i,j,k,*}

^a Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, ON, Canada

^b Biostatistics Program, University of Toronto Dalla Lana School of Public Health, Toronto, ON, Canada

^c Life Sciences Program, Queen's University, Kingston, ON, Canada

^d Department of Anesthesia, McMaster University, Hamilton, ON, Canada

^e St. George's University of London, London, England, UK

^f Department of Medicine, McMaster University, Hamilton, ON, Canada

^g Hamilton Health Sciences, St. Peter's Hospital, Hamilton, ON, Canada

^h Department of Pediatrics and Anesthesia, McMaster University, Hamilton, Canada

ⁱ Centre for Evaluation of Medicine, St Joseph's Healthcare Hamilton, ON, Canada

^j Population Health Research Institute, Hamilton Health Sciences, Hamilton, Canada

^k Father Sean O'Sullivan Research Institute, St Joseph's Healthcare, Hamilton, ON, Canada

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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 multi-variable 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

* Corresponding author. Department of Clinical Epidemiology and Biostatistics. Biostatistics Unit, Father Sean O'Sullivan Research Centre, St. Joseph's Healthcare Hamilton, 3rd floor Martha Wing, 50 Charlton Avenue East. Hamilton, ON, L8N 4A6, Canada.

E-mail address: thabanl@mcmaster.ca (L. Thabane).

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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

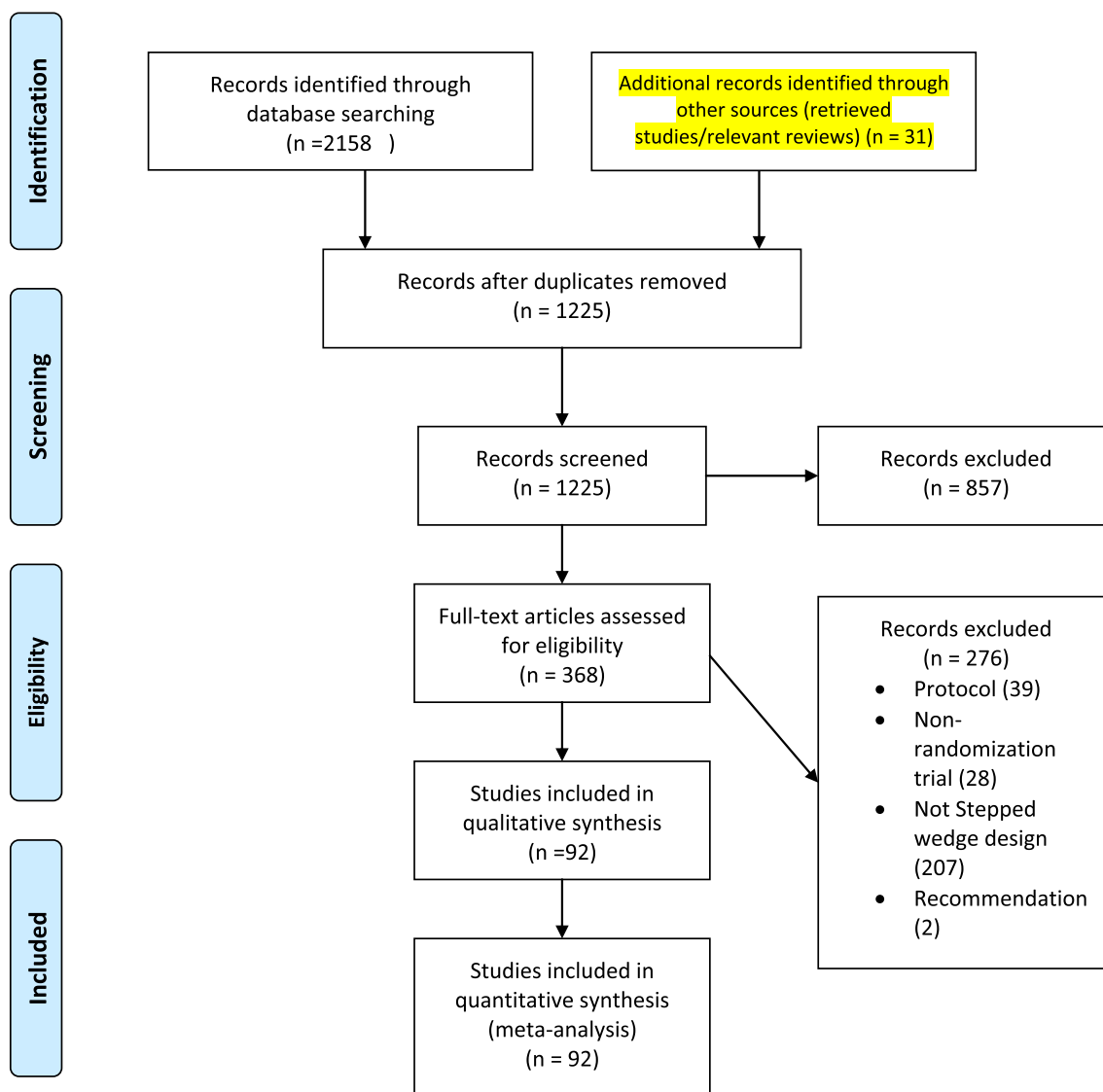


Fig. 1. PRISMA flow diagram.

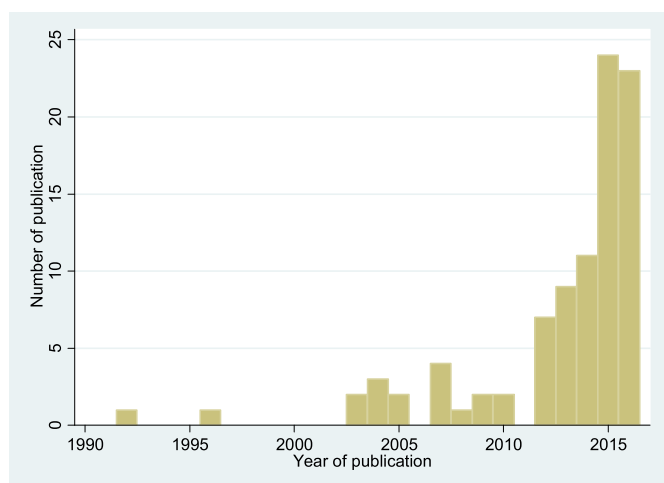


Fig. 2. Histogram of frequency of publications on stepped wedge design trial.

journals. The majority of SWTs were conducted in Europe (34.8%) or North and South America (33.7%), following with Africa (13.0%), Australia – Oceania (13.0%), and lastly with Asia - Middle-East (5.4%)

(Table 1). Ninety-two reports included 72 structured and 20 un-structured abstracts. More than half of the journals (63.0%) endorsed the CONSORT statement, while only 30.4% endorsed the CONSORT Extension for Abstracts. Although SWTs are commonly carried out with cluster randomization, we found 18.5% of the included studies to have randomization at the individual level. As SWTs were often used in behavioral and social sciences research, the majority of the studies (90.2%) applied BCI [19]. Statistical significance at alpha-level 0.05 was reported in 70.7% of the studies. More than 60% of SWTs were conducted in the healthcare setting.

The mean number (SD) of the reporting quality items is 9.08 (2.56). This means that on average, 53.4% (9.08/17) of the items were reported in the SWT abstracts. The best-reported item was the statement of conclusions (98.9%). Particular shortcomings in reporting were found regarding randomization (13.0%), blinding (masking) (2.2%), and harms (3.3%). Only six of 17 items were reported by more than 80% of abstracts, and ten items were reported in less than 60% of abstracts (Table 2).

3.2. External factors influencing the reporting of 17 items of abstracts

In the univariate analyses, the year of publication since 2008 (IRR 1.25; 95% confidence interval (CI) 1.07, 1.47; p = 0.005), structured

Table 1
Characteristics of the included 92 studies.

Characteristic	Category	Number (%)
Year of publication	1987–2008	14 (15.2)
	2009–2016	78 (84.8)
Continents	Africa	12 (13.0)
	Americas	31(33.7)
	Australia - Oceania	12(13.0)
	Asia - Middle-East	5 (5.4)
	Europe	32 (34.8)
Abstract format	Structured	72 (78.3)
	Unstructured	20 (21.7)
Number of authors	≤ 5	27 (29.4)
	> 5	65 (70.6)
Journal endorses CONSORT	Yes	58 (63.0)
	No	34 (37.0)
Journal endorses CONSORT extension for abstract	Yes	28 (30.4)
	No	64 (69.6)
Word limitation for abstracts	≤ 250	39 (42.4)
	> 250	53(57.6)
Type of setting	Healthcare	60 (65.2)
	Non-healthcare	32 (34.8)
Intervention type	BCI	83 (90.2)
	Other treatments	9 (9.8)
Randomization	Cluster randomization	75 (81.5)
	Individual randomization	17 (18.5)
Statistical significance of main finding	Yes	65 (70.7)
	No	27 (29.3)

Abbreviation: CONSORT, Consolidated Standards of Reporting Trials. BCI, behavior change intervention (e.g. education, training, or service et al.).

abstracts (IRR 1.26; 95% CI 1.11, 1.42; $P < 0.001$), the number of authors more than 5 (IRR 1.23; 95% CI 1.09, 1.39; $p = 0.001$), journal endorsing CONSORT (IRR 1.25; 95% CI 1.11, 1.40; $p < 0.001$), and journal endorsing CONSORT extension for abstract (IRR 1.24; 95% CI 1.11, 1.38; $p < 0.001$) were associated with statistically significant better reporting quality (Table 3).

In the multivariable analysis, we found that the year of publication (adjusted IRR 1.16; 95% CI 1.02, 1.33; $p = 0.027$), endorsement of the CONSORT (adjusted IRR 1.15; 95% CI 1.01, 1.31; $P = 0.029$) and

Table 2

The 17-item reporting status for all 92 included stepped wedge randomized trials (SWTs) according to the Consolidated Standards of Reporting Trial (CONSORT) extension for Abstracts.

Items	Required Information to Meet Criteria	Number and percentage of trials reporting each item in the abstract (total n = 92)		
		Count#	%	95% CI*
Title	Identification of the study as stepped wedge trial	39	42.4	(32.2, 53.1)
Authors	Contact details for the corresponding author	87	94.6	(87.8, 98.2)
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority, stepped wedge)	77	83.7	(74.5, 90.6)
Methods				
-Participants	Eligibility criteria for participants/clusters and the settings where the data were collected	86	93.5	(86.3, 97.6)
-Interventions	Interventions intended for each group (cluster)	89	96.7	(90.8, 99.3)
-Objective	Specific objective or hypothesis	87	94.6	(87.8, 98.2)
-Outcome	Clearly defined primary outcome for this report	54	58.7	(48.0, 68.9)
-Randomization	How participants/clusters were allocated to interventions	12	13.0	(6.9, 21.7)
-Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	2	2.2	(0.3, 7.6)
Results				
-Numbers randomized	Number of clusters (number of participants) randomized to each group;	33	35.9	(26.1, 46.5)
-Recruitment	Trial status	38	41.3	(31.1, 52.1)
-Numbers analyzed	Number of participants analyzed in each group (cluster)	26	28.3	(19.4, 38.6)
-Outcome	For the primary outcome, a result for each group (cluster) and the estimated effect size and its precision	62.5	67.9	(58.7, 77.2)
-Harms	Important adverse events or side effects	3.5	3.3	(0.0, 7.6)
-Conclusions	General interpretation of the results	91	98.9	(94.1, 100)
Trial registration	Registration number and name of trial register	27	29.4	(20.3, 39.8)
Funding	Source of funding	21	22.8	(14.7, 32.8)

Abbreviation: CI, confidence interval. # the score of Count is calculated as yes = 1, unclear = 0.5 & no = 0. *95% CI for the percentage of trials reporting the item.

number of authors (adjusted IRR 1.13; 95% CI 1.01, 1.27; $p = 0.031$) were associated with statistically significant better reporting quality (Table 3).

3.3. Internal methodology factors influencing the reporting of 17 items of abstracts

Randomization at a cluster level was significantly ($p < 0.05$) with better reporting quality of abstracts in the univariate analyses (IRR: 1.25, 95% CI 1.09, 1.44; $p = 0.002$) but not in the multivariable analysis (adjusted IRR: 1.09, 95% CI 0.96, 1.24; $p = 0.182$). The other three factors including the trial setting, intervention type and statistical significance of the main findings were not significantly associated with the number of reporting items (Table 3).

4. Discussion

4.1. Summary and implication of the results

In this study, we evaluated the reporting quality of abstracts in SWT articles using the CONSORT extension for abstracts. Only six items from the CONSORT for Abstracts were reported in at least 80% of the articles. Particular shortcomings were found about information on randomization (13.0%), blinding (masking) (2.2%), and harms (3.3%). A low level of reporting of harms may be understandable as the majority of SWTs are related to behavior change intervention that may at rare circumstances be associated with adverse effects (e.g. education, training, or service et al.). Randomization and blinding are necessary and important components of RCTs, and better reporting quality of these items in abstracts is urgent. Overall, our findings are similar to previous studies that focused on the reporting quality of abstracts of RCTs [17,20–23]. As abstract reporting quality plays an important role in clinical decision-making [13], abstracts should contain sufficient information for readers. However, in this survey, most abstracts did not provide enough details to allow readers to appraise the quality of the research and to evaluate study relevance to clinical practice.

It has been shown that journal endorsement of the CONSORT Statement significantly improves reporting of abstracts of RCT [24].

Table 3

Poisson regression results with robust error variance for the total number of CONSORT extension for abstract items reported in 92 included articles.

Characteristic	Category	Mean Reporting Quality Score (95% CI)	Poisson regression	
			Univariate analysis IRR (95%CI); p-value	Multivariable analysis IRR (95%CI); p-value
Year of publication	1987–2008	14.9 (12.4, 17.4)	1	1.16 (1.02, 1.33); 0.027
	2009–2016	18.7 (17.6, 19.9)	1.25 (1.07, 1.47); 0.005	
Abstract format	Unstructured	15.2 (13.6, 16.9)	1	1.08 (0.96, 1.21); 0.206
	Structured	19.0 (17.8, 20.2)	1.26 (1.11, 1.42); < 0.001	
Number of authors	≤ 5	15.2 (13.5, 16.9)	1.23 (1.09, 1.39); 0.001	1.13 (1.01, 1.27); 0.031
	> 5	19.4 (18.1, 20.6)		
Continents	Africa	17.1 (13.3, 21.5)	1	0.98 (0.83, 1.15); 0.768
	Americas	17.7 (15.4, 19.9)	1.01 (0.80, 1.28); 0.901	
	Australia - Oceania	18.8 (16.4, 21.3)	1.08 (0.86, 1.36); 0.504	
	Asia - Middle-East	20.0 (13.7, 26.3)	1.15 (0.86, 1.53); 0.340	
	Europe	18.3 (16.9, 19.8)	1.05 (0.85, 1.30); 0.635	
Journal endorses CONSORT	No	15.7 (14.0, 17.4)	1	1.15 (1.01, 1.31); 0.029
	Yes	19.6 (18.3, 20.8)	1.25 (1.11, 1.40); < 0.001	
Journal endorses CONSORT extension for abstract	No	16.9 (15.7, 18.1)	1	1.11 (0.95, 1.30); 0.203
	Yes	21.0 (19.1, 22.8)	1.24 (1.11, 1.38); < 0.001	
Word limitation for abstracts	≤ 250	17.2 (15.9, 18.4)	1	0.96 (0.83, 1.11); 0.588
	> 250 or No limitation	18.9 (17.3, 20.5)	1.10 (0.99, 1.23); 0.083	
Type of setting	Non-healthcare	16.9 (15.0, 18.6)	1	0.99 (0.89, 1.11); 0.883
	Healthcare	18.9 (17.6, 20.2)	1.12 (0.99, 1.27); 0.064	
Intervention type	BCI	19.4 (15.1, 23.8)	1	0.99 (0.87, 1.33); 0.905
	All other treatments	18.0 (16.9, 19.1)	0.92 (0.78, 1.10); 0.359	
Randomization	IR	15.1 (12.9, 17.2)	1	1.09 (0.96, 1.24); 0.182
	CR	18.9 (17.7, 20.0)	1.25 (1.09, 1.44); 0.002	
	No	19.0 (17.2, 20.9)	1	
Statistical significance of main finding	No	19.0 (17.2, 20.9)	1	0.97 (0.88, 1.08); 0.585
	Yes ($\alpha < 0.05$)	17.8 (16.5, 19.1)	0.93 (0.83, 1.05); 0.250	

Abbreviation IRR, incidence rate ratio. CI, confidence interval. CONSORT, Consolidated Standards of Reporting Trials. BCI, behavior change intervention (e.g. education, training, or service et al.). CR, cluster randomization. IR, individual randomization.

According to Can et al. [25] even three years since the CONSORT for Abstract was published (i.e., 2011), the overall quality of RCT abstracts remained unchanged. However, our multivariable analysis showed significant improvements in reporting quality in the SWT abstracts after 2008. Our data analysis also showed that journal endorsement of the CONSORT statement was significantly associated with higher reporting quality (adjusted IRR 1.15, 95% CI 1.01, 1.31). Hence, our study findings endorse previous recommendations that both authors and journal editors should use the CONSORT guidelines to prepare and evaluate SWT abstracts [24,25].

Another important factor associated with the reporting quality of SWT abstracts is the number of authors (adjusted IRR 1.13, 95% CI 1.01, 1.27). Guo et al. [21] and Kiriakou et al. [22] reported that multiple-authorship was associated with better reporting quality of abstracts than single-authorship. Pandis et al. [26] also found that the number of co-authors was significantly associated with overall study reporting quality. This is a sensible finding since multiple authors make contributions by applying their diverse expertise; moreover, different authors reviewing the abstract through multiple lenses may catch some omissions leading to better reporting.

The structured format for abstracts is recommended by the CONSORT for abstracts [12], but research is inconsistent regarding its usefulness for the quality of reporting. There are several advantages of a structured abstract including simplifying text mining, facilitating computerized searches and readability [27,28]. Similar to some of the previous studies [29–31], our study found that the abstracts with structured formatting were associated with better reporting quality in the univariate analysis (IRR: 1.26; 95% CI 1.11, 1.42), but not in the multivariable analysis (IRR: 1.08, 95% CI 0.96, 1.21). Scherer et al. [32] reported that there was no difference in the reporting quality of abstracts of the format. Therefore, the structured formatting of abstracts may represent a high-quality abstract, but may not be the most influential predictor of better reporting quality.

The word limit for abstract reporting is always a challenge to authors [21]. In the multivariable analysis, we found that the reporting

quality of abstracts was not significantly better if word limitation was not tight (≤ 250 words) (adjusted IRR 0.96; 95% CI 0.83, 1.11; $p = 0.588$). Therefore, increasing the number of words in an abstract may not result in better quality reporting.

We tried to explore whether some of the internal methodological factors can affect the reporting quality of SWT abstracts. We did not find any significant differences in the type of setting, intervention type, and statistical significance of main findings. However, randomization at cluster level was found to be significantly associated with better reporting quality than randomization at the individual level in the univariate analysis (IRR 1.25; 95% CI 1.09, 1.44; $P = 0.002$), although it is not significant in the adjusted multivariable analysis (IRR 1.09; 95% CI 0.96, 1.24; $P = 0.182$). As the randomization itself should not lead to differences in the quality of reporting, this result suggests that more attention should be put on complete reporting in SWTs using individual-level randomization.

4.2. Strengths and limitations

Our study has several strengths. We performed systematic searches of the literature, examined the trends in abstract reporting for SWTs and did not limit our study to specific journals or diseases. We carried out full-text screening results, eligibility decisions, and data extraction in duplicate. Using multiple reviewers for data abstraction enhanced the accuracy data extraction and quality assessment processes.

One of the potential limitations of our study is that the reviewers were not blinded to abstracts' authors although a controversy remains whether this procedure influence the assessments of study reporting [33–36]. Another possible limitation is the inclusion of the English language only studies, which may introduce selection bias.

We made some implicit adaptations to the statement items – especial for the first item “title”. We modified it from “identification of the study as randomized” to “identification of the study as stepped wedge trial”, as the CONSORT statement for abstracts are not specific to SWTs. The CONSORT extension for SWTs is being currently under development

[37].

5. Conclusion

This survey provides a systematic assessment of the quality of reporting of SWT abstracts based on the CONSORT extension for Abstracts. We found that the quality of reporting of SWT abstracts is suboptimal. The results also showed that research collaboration as measured by multiple co-authorship is associated with better reporting of SWT abstracts. All stakeholders including authors, journal reviewers, and editors have collective responsibility to enhance transparent and complete of reporting of all studies including the abstracts of the reports. This essential is not only essential to guide evidence-based decision-making, but for the reproducibility and advancement of science.

Appendix 1. Search Strategy of Electronic Databases

Database	Search Terms
MEDLINE Search Details = _____	1. "stepped wedge design"[All Fields] OR "stepped wedge"[All Fields] OR "wedge design"[All Fields] OR (stepped[All Fields] AND wedge[All Fields] AND design[All Fields] AND protocol[All Fields]) OR (stepped[All Fields] AND wedge [All Fields] AND protocol[All Fields]) OR (stepped[All Fields] AND wedge[All Fields] AND design[All Fields] AND ("clinical trials as topic"[MeSH Terms] OR ("clinical"[All Fields] AND "trials"[All Fields] AND "topic"[All Fields]) OR "clinical trials as topic"[All Fields] OR "trial"[All Fields])) OR (wedge[All Fields] AND design[All Fields] AND ("clinical trials as topic"[MeSH Terms] OR ("clinical"[All Fields] AND "trials"[All Fields] AND "topic"[All Fields]) OR "clinical trials as topic"[All Fields] OR "trial"[All Fields])) OR "stepped wedge trial"[All Fields] OR (stepped[All Fields] AND wedge[All Fields] AND design[All Fields] AND abstract[All Fields]) OR (stepped[All Fields] AND wedge[All Fields] AND ("clinical trials as topic"[MeSH Terms] OR ("clinical"[All Fields] AND "trials"[All Fields] AND "topic"[All Fields]) OR "clinical trials as topic"[All Fields] OR "trial"[All Fields]) AND abstract[All Fields]) AND ("1987/01/01"[PDAT]: "3000/12/31"[PDAT])
Web of Science Search = _____	TOPIC: ("stepped wedge design" OR TOPIC: ("stepped wedge") OR TOPIC: ("stepped wedge design trial") OR TOPIC: ("stepped wedge design protocol") OR TOPIC: ("stepped wedge trial") OR TOPIC: ("stepped wedge protocol") OR TOPIC: ("stepped wedge design abstract") OR TOPIC: ("wedge design") OR TOPIC: ("wedge design trial") OR TOPIC: ("wedge design protocol")) 2. Timespan: 1987–2015. 3. Indexes: SCI-EXPANDED, SSCI, A & HCI, CPCI-S, CPCI-SSH.
CINAHL Search = _____	1. Suggest Subject Terms: ""stepped wedge design OR stepped wedge OR stepped wedge trial OR stepped wedge proctor OR stepped wedge design trial OR stepped wedge design protocol OR wedge design OR wedge design trial OR wedge design protocol OR stepped wedge design abstract OR wedge design abstract OR stepped wedge abstract""
EMBASE (Ovid Interface) Search = _____	1. "stepped wedge design" or "stepped wedge" or "stepped wedge design trial" or "stepped wedge design protocol" or "stepped wedge design abstract" or "stepped wedge trial" or "stepped wedge protocol" or "stepped wedge abstract" or "wedge design" or "wedge design trial" or "wedge design protocol" or "wedge design abstract" 2. Limit to Human 3. Limit to Publishing Year = 1987
PsycINFO (Ovid Interface) Search = _____	1. "stepped wedge design" or "stepped wedge" or "stepped wedge design trial" or "stepped wedge design protocol" or "stepped wedge design abstract" or "stepped wedge trial" or "stepped wedge protocol" or "stepped wedge abstract" or "wedge design" or "wedge design trial" or "wedge design protocol" or "wedge design abstract" 2. Limit to Human 3. Limit to Publishing Year = 1987

Appendix 2. Reference list of included 92 studies

- 1 Schnelle JF, Newman DR, White M, et al. Reducing and managing restraints in long-term-care facilities. *J Am Geriatr Soc.* 1992 Apr; 40(4):381–5.
- 2 Cook RF, Back A, Trudeau J. Substance abuse prevention in the workplace: Recent findings and an expanded conceptual model. *Journal of Primary Prevention.* 1996; 16:319–39.
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