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Evaluating Completeness of Reporting in Behavioral Interventions Pilot Trials: A Systematic Survey

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Abstract

Purpose: This systematic survey evaluates the completeness of reporting in pilot and feasibility randomized controlled trials investigating behavioral interventions based on the Consolidated Standards of Reporting Trials (CONSORT) extension for pilot trials. **Methods:** The authors searched Medline/Pubmed and randomly selected 100 articles from 2012 through 2016 to determine the proportion of reported CONSORT extension items. They examined study factors related to reporting, including year and country of publication, psychotherapy intervention, multiple centers, industry funding, and journal endorsement of CONSORT. **Results:** The authors found that the mean reporting score on the CONSORT extension was 51.6% ($SD = 15.1$). Studies of psychotherapy interventions had significantly higher reporting scores than other interventions (incidence rate ratio = 1.10, 95% confidence interval: 1.01–1.20). **Conclusions:** Our findings indicate that current reporting quality is suboptimal. Many included trials failed to provide rationale for piloting, assess feasibility objectives, or indicate clear progression to a future large trial. Reporting quality should be reevaluated following uptake of the 2016 CONSORT extension for pilot trials.

Keywords

pilot trials, feasibility trials, behavioral interventions, reporting quality, transparency, guideline adherence

Pilot and feasibility studies are an essential prelude of clinical trials, as they can directly give researchers necessary information about the practicality and acceptability of the design features of a definitive trial (Thabane et al., 2010). This is especially necessary for pilot and feasibility randomized controlled trials (RCTs) of behavioral interventions, as they are crucial in evaluating resource costs, required personnel, recruitment and attrition rates, and acceptability of the intervention and outcome measures (Craig et al., 2008; Van Teijlingen & Hundley, 2010). Researchers have indicated that pilot and feasibility trials receive little attention in methodological literature; however, given the immense quantity of resources required for large RCTs, it is important that pilot trials are conducted with rigorous methodology to adequately inform the definitive trial (Thabane et al., 2010; Van Teijlingen & Hundley, 2010).

Initially published in 1996, the Consolidated Standards of Reporting Trials (CONSORT) statement has improved the transparency and reporting of RCTs and has been widely adopted by journals (Begg et al., 1996). Subsequent revisions of the CONSORT statement, as well as extensions for varying

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trial designs, have been published (Moher, Schulz, Altman, & Consort, 2001). However, it was not until 2016 that the CONSORT statement extension for reporting randomized pilot and feasibility trials was published simultaneously in *Pilot and Feasibility Studies and BMJ* (Eldridge et al., 2016a; Eldridge et al., 2016b). Existing evaluations of pilot trials methodology indicate that reporting is inadequate, largely due to emphasis on hypothesis testing and lack of criteria for evaluating feasibility (Arain, Campbell, Cooper, & Lancaster, 2010; Whitehead, Sully, & Campbell, 2014). The publication of the CONSORT extension to pilot RCTs is expected to enhance the completeness and transparency in the reporting of pilot RCTs. This survey aims to review the completeness of the reporting of pilot trials in behavioral interventional research. A behavioral intervention is defined as one which includes behavioral or social component(s) or targets behavioral or social outcomes (e.g., trials related to education, training, and cognitive-behavioral therapy; National Institutes of Health, 2004). Trials of behavioral interventions are the second most common type registered in clinicaltrials.gov (Bourgeois, Murthy, & Mandl, 2012).

Previous studies have suggested that quality of reporting among RCTs of nonpharmacological interventions is lower in comparison to that in pharmaceutical trials (Mbuagbaw et al., 2014). Therefore, it is important to specifically evaluate studies of behavioral interventions to identify areas for improvement.

Objectives

The current systematic survey aims to evaluate published pilot and feasibility trials of behavioral interventions in terms of quality of reporting using the newly published CONSORT pilot extension as a benchmark. More specifically, we aim to:

1. evaluate the quality of reporting as measured by completeness of reporting based on the 2016 CONSORT extension to pilot and feasibility trials among pilot and feasibility trials investigating behavioral interventions in clinical populations and
2. explore factors that are associated with the completeness of reporting.

Methods

Study Eligibility

We included pilot and feasibility RCTs in this systematic survey such that the study used the words "pilot" or "feasibility" and identified itself as an RCT in the title or abstract. Furthermore, studies were selected if they investigated behavioral interventions in clinical populations, defined as a nonpharmacological approach requiring an active, behavioral change from the receivers during or following the intervention. Such behavioral changes can subsequently aim to improve various medical, psychological, or social outcomes. We utilized a broad definition of clinical populations, including individuals with current or past medical or psychiatric illnesses or symptoms of these conditions. Studies that evaluated group therapies involving persons with illnesses and their caregivers were also included. The articles were limited to English-language publications.

Exclusion criteria were (1) single-arm observational pilot or feasibility studies, (2) quasirandomized trials, and (3) studies among nonclinical populations (i.e., students, community members).

Search Strategy

We searched Medline/Pubmed through Ovid and included studies published from January 1, 2012, to December 31, 2016. The complete search strategy is available as supplementary material (Appendix 1). We randomly selected 20 articles from each year from 2012 through 2016 in order to have equal number of studies from the past 5 years, for a total of 100 included articles. A computerized random number generator was used for study selection. Two authors (MB and LZ) independently screened and conducted a full-text review of randomly selected citations to assess eligibility. Excluded articles were replaced by another random selection until 100 articles were identified that met the eligibility criteria.

Outcome Measures

The primary outcome of this survey was to evaluate the proportion of reported items on the CONSORT statement extension for randomized pilot and feasibility trials. The CONSORT statement extension for randomized pilot and feasibility trials consists of 39 checklist items. Independent pairs of reviewers conducted the scoring for the checklist items. Each of the items on the checklist was scored as either yes or no ($1 = yes$, $0 = no$), indicating whether or not the article reported the appropriate information according to the criteria outlined in the original publication (Eldridge et al., 2016a). Since for the included articles, there were differing numbers of items that were "not applicable" to each study, a final CONSORT score was calculated as a percentage of the number of items reported over the total *applicable* number of items. We also reported the number of studies that reported each individual item on the checklist in order to identify the items with the lowest level of reporting. The secondary outcome was to determine which study characteristics are associated with the level of reporting.

Data Extraction

Three pairs of reviewers performed data extraction in duplicate. Disagreements were resolved by consensus or by consulting an experienced author. An experienced author trained the reviewers through detailed description of each item on the CONSORT statement and the extension for pilot trials. The extraction form was piloted using 5 studies in order to ensure that all reviewers were calibrated. The extracted information included: (1) article characteristics (title, author name, year of publication, journal, and study region); (2) study details

(clinical population, type of behavioral intervention, and number of participants randomized); (3) reporting of individual items on the CONSORT extension for pilot and feasibility studies; and (4) journal journal endorsement of CONSORT statement.

Data Analysis

First, we reported descriptive statistics to provide a summary of the overall level of reporting using the CONSORT statement. Means and standard deviations were used for overall reporting quality scores and counts, and percentages were used to report the general characteristics and number of articles reporting each CONSORT statement item.

Second, to explore factors associated with completeness of reporting, we used Poisson regression with the number of reported items CONSORT items as the dependent variable and the following as explanatory factors—year of publication, study location (North America or other), type of intervention (psychotherapy or other), multisite study (yes or no), industry funding (yes, no, or not reported), and journal endorsement of CONSORT (yes or no). For the purposes of the analysis, we considered "not applicable" items as reported by the corresponding studies. Unadjusted and adjusted incidence rate ratio [IRR], 95% confidence interval [CI], and p value are reported. The level of significance was set at $\alpha = 0.05$. STATA 13 Software (StataCorp. 2013. *Stata Statistical Software: Release 13*, StataCorp LP, College Station, TX) was used to perform all statistical analyses.

Results

Our initial search retrieved 1,770 articles, of which 300 were published in 2012, 396 in 2013, 438 in 2014, 455 in 2015, and 181 in 2016. Of these, we randomly selected 20 articles from each year for a total of 100 included articles. A complete reference list of included studies and details of individual studies are available as supplemental material (Appendices 2 and 3, respectively). During the random selection process, articles were excluded if they were not a pilot or feasibility RCTs and if they were not investigating behavioral interventions.

Table 1 presents the general characteristics of included articles. Overall, the majority of studies were single center (89%) and did not receive industry funding (84%). Additionally, 40% of the studies were published in journals that endorsed the standard CONSORT statement.

Table 1. Distribution of Characteristics of Included Articles by Year of Publication.

Characteristic	Total, $n = 100$ (%)
Year	
2012	20
2013	20
2014	20
2015	20
2016	20
Country	
United States	51
Canada	7
United Kingdom	6
Sweden	5
Other	31
Type of intervention	
Psychotherapy	32
Exercise	18
Mindfulness	5
Yoga	5
Combined	22
Other[a]	18
Multisite study	
Yes	11
No	89
Industry funding	
Yes	5
No	84
Not reported	11
Prelude to future definitive trial	
Yes	13
No	87
Journal endorsement of CONSORT[b]	
Yes	40
No	60

Note. CONSORT = Consolidated Standards of Reporting Trials.
[a]Other interventions included education, art/music/humor therapy, relaxation training, feedback-based interventions, and more specific approaches.
[b]Given the recency of the CONSORT extension for pilot and feasibility trials, we assessed whether the journal endorsed the overarching CONSORT statement.

Evaluation of Reporting Quality Based on CONSORT Extension

The mean CONSORT reporting score across all included articles was 51.6% ($SD = 15.1$). Table 2 shows the level of reporting of individual CONSORT items. Two items were not applicable for any of the included studies: "Changes to pilot trial assessments or measurements" and "Ancillary analyses." Upon evaluating reporting of individual items in the CONSORT statement, we found that the items reported by the largest proportion of articles were "eligibility criteria for participants" (94%) and "analytical methods" (92%). Many poorly reported items were those related to specific pilot study objectives and progression to the future definitive trial including "rationale for the future definitive trial and reasons for the pilot trial" (24%); "prespecified criteria used to judge whether, or how, to proceed with future definitive trial" (3%); "generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies" (32%); and "implications for progression from pilot to future definitive trial, including any proposed amendments" (24%). Also, a number of studies did not appropriately report study methodology such as "rationale for numbers in the pilot trial" (22%), "allocation concealment" (33%), and "implementation of randomization" (30%). Additional items that were poorly reported included "harms or unintended effects in each group" (19%), "where the pilot trial protocol can be accessed" (12%),

Table 2. Reporting of 39 Items on the CONSORT Extension for Pilot and Feasibility Trials.

Item	Criteria	Total, *n*
Title and abstract		
1a	Identification as a pilot or feasibility randomized trial in the title	41
1b	Structured summary of pilot trial design, methods, results, and conclusions	63
Introduction		
Background and objectives		
2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomized pilot trial	24
2b	Specific objectives or research questions for pilot trial	37
Methods		
Trial design		
3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	36
3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	2
Participants		
4a	Eligibility criteria for participants	94
4b	Settings and locations where the data were collected	81
4c	How participants were identified and consented	77
Interventions		
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	79
Outcomes		
6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	49
6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
6c	Prespecified criteria used to judge whether, or how, to proceed with future definitive trial	3
Sample size		
7a	Rationale for numbers in the pilot trial	22
7b	When applicable, explanation of any interim analyses and stopping guidelines	1
Sequence generation		
8a	Method used to generate the random allocation sequence	42
8b	Type of randomization(s); details of any restriction (such as blocking and block size)	40
Allocation concealment		
9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	33
Implementation		
10	Who generated the random allocation sequence, enrolled participants, and assigned participants to interventions	30
Blinding		
11a	If done, who was blinded after assignment to interventions (e.g., participants, care providers, those assessing outcomes) and how	46
11b	If relevant, description of the similarity of interventions	14
Analytical methods		
12a	Methods used to address each pilot trial objective whether qualitative or quantitative	92
Results		
Participant flow		
13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	78
13b	For each group, losses and exclusions after randomization, together with reasons	74
Recruitment		
14a	Dates defining the periods of recruitment and follow-up	33
14b	Why the pilot trial ended or was stopped	NA
Baseline data		
15	A table showing baseline demographic and clinical characteristics for each group	73
Numbers analysed		
16	For each objective, number of participants (denominator) included in each analysis by randomized group	80
Outcomes and estimation		
17a	For each objective, results including expressions of uncertainty (such as 95% CI) for any estimates by randomized group	40

(continued)

Table 2. (continued)

Item	Criteria	Total, *n*
Ancillary analyses		
18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms		
19	All important harms or unintended effects in each group	19
Discussion		
Limitations		
20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	87
Generalizability		
21	Generalizability (applicability) of pilot trial methods and findings to future definitive trial and other studies	32
Interpretation		
22a	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	62
22b	Implications for progression from pilot to future definitive trial, including any proposed amendments	24
Other information		
Registration		
23	Registration number for pilot trial and name of trial registry	29
Protocol		
24	Where the pilot trial protocol can be accessed, if available	12
Funding		
25	Sources of funding and other support (such as supply of drugs), role of funders	90
26	Ethical approval or approval by research review committee, confirmed with reference number	45

Note. NA = not applicable; CONSORT: Consolidated Standards of Reporting Trials. Items 3b, 7b, 11b were not applicable for every study. Items 6b, 14b, 18 were not applicable to any of the included studies.

and "registration number for pilot trial and name of trial registry" (29%). Overall, 19 of the 39 checklist items were reported by less than half of the included studies.

Factors Related to Reporting of CONSORT Extension Items

Table 3 shows the unadjusted and adjusted IRRs for overall CONSORT reporting by study characteristics. In comparing the total number of reported CONSORT items by the prespecified study characteristics, the unadjusted analyses showed that studies investigating psychotherapy rather than other types of interventions had significantly higher CONSORT reporting scores (unadjusted IRR = 1.12, 95% CI [1.02, 1.22], $p = .01$). The remaining study characteristics were not significantly associated with the level of reporting, although results were borderline significant for higher reporting quality among articles published in journals that endorse the CONSORT statement (unadjusted IRR = 1.09, 95% CI [1.00, 1.18], $p = .05$).

In the adjusted analysis, reporting in psychotherapy intervention studies remained significant in comparison to other interventions (adjusted IRR = 1.10, 95% CI 1.01–1.20, $p = .03$). Results reached borderline significance indicating that studies conducted in North America had lower reporting quality compared to those outside North America (adjusted IRR = 0.91, 95% CI [0.84, 1.00], $p = .05$). The remaining study characteristics, including year of publication, multisite study, industry funding, and journal endorsement of CONSORT, were not significantly related to the level of reporting in the adjusted analysis. Studies that did not report funding had lower reporting than those that did not receive industry funding (adjusted IRR = 0.83, 95% CI [0.72, 0.96], $p = .01$).

Discussion

In this systematic survey, we found that the reporting quality based on CONSORT guidelines for pilot and feasibility RCTs is currently suboptimal, with mean overall reporting score at 51.6%. First, only 41% of the included articles identified themselves as pilot and feasibility RCTs in the title. The actual deficiency in reporting may be even higher, as our eligibility criteria for the review required an indication of study design in the title or abstract. Other areas of poor reporting included methodological areas related to randomization, such as "sequence generation," "allocation concealment," "implementation," and "blinding," all of which were reported by less than half of the studies. Multiple systematic reviews have also shown deficiencies in reporting of these areas across main/definitive RCTs (Cairo, Sanz, Matesanz, Nieri, & Pagliaro, 2012; Liu, Morris, & Pengel, 2013). It is especially important for authors to provide information on these methodological areas, since it informs the risk of bias assessment and helps to assess the methodological quality of the study (Higgins et al., 2011).

Overall, we found that participant and intervention details, analytical methods, estimation of outcomes, and study limitations were reported adequately across included pilot studies (>80% adherence). Researchers should still aim to improve reporting quality of behavioral interventions and predefined outcome measures because it allows for replication of the intervention and assessment in various settings. Additionally, we did not find significant differences in reporting to the CONSORT extension for pilot and feasibility RCTs by year of publication from 2012 through 2016. Considering reporting of the original CONSORT statement improved over time following revisions and publication of extensions, we expect that reassessment in the following 5 years will show an improvement by year of publication. Type of intervention was the only study

Table 3. Incidence Rate Ratios for the Total Number of CONSORT Pilot Trial Extension Items Reported.

Characteristic	Unadjusted analysis		Adjusted analysis	
	Incidence rate ratio (95% CI)	*p*-Value	Incidence rate ratio (95% CI)	*p*-Value
Year of publication				
2012	Ref		Ref	
2013	0.97 (0.85–1.11)	0.66	1.00 (0.87–1.14)	0.99
2014	0.97 (0.85–1.11)	0.69	0.96 (0.84–1.10)	0.60
2015	1.02 (0.90–1.17)	0.71	1.01 (0.88–1.15)	0.91
2016	1.00 (0.87–1.14)	0.95	1.03 (0.90–1.18)	0.67
Study location				
Other	Ref		Ref	
North America	0.95 (0.88–1.04)	0.26	0.91 (0.84–1.00)	0.05
Type of intervention				
Other	Ref		Ref	
Psychotherapy	1.12 (1.02–1.22)	0.01	1.10 (1.01–1.20)	0.03
Multisite study				
No	Ref		Ref	
Yes	1.08 (0.95–1.23)	0.25	1.08 (0.94–1.25)	0.25
Industry funding				
No	Ref		Ref	
Yes	0.93 (0.77–1.14)	0.50	0.93 (0.76–1.15)	0.51
Not reported	0.83 (0.72–0.96)	0.01	0.83 (0.71–0.96)	0.01
Journal endorsement of CONSORT[a]				
No	Ref		Ref	
Yes	1.09 (1.00–1.18)	0.05	1.08 (0.99–1.17)	0.10

Note. Ref = reference category; CI = confidence interval; CONSORT = Consolidated Standards of Reporting Trials.
The dependent variable was the total number of reported CONSORT items for each study. Items that were 'not applicable' were considered as reported for the purposes of this analysis.
[a]Given the recency of the CONSORT extension for pilot and feasibility trials, we assessed whether the journal endorsed the standard CONSORT statement.

characteristic that was significantly related to improved reporting in the adjusted analysis, with studies of psychotherapy interventions having a higher level of reporting. Notably, only 40% of the journals in this survey endorsed the CONSORT statement. Although we did not find journal endorsement to be related to significantly higher reporting in the adjusted analyses, improvement in reporting will likely be enhanced if journals that publish pilot and feasibility trials endorse the CONSORT extension, as seen with other reporting guidelines (Samaan et al., 2013).

To our knowledge, reporting quality of pilot and feasibility RCTs has not been previously investigated, and this serves as a baseline assessment of reporting. We recognize that suboptimal reporting may be due to the fact that the CONSORT extension for pilot and feasibility RCTs was only recently published in 2016. However, authors of pilot trials could have made use of the original CONSORT statement to improve reporting standards of pilot trials. As seen with other reporting guidelines (Moher, Jones, Lepage, & Consort, 2001), the uptake of the CONSORT pilot trials extension is expected to improve over time, and the adherence to reporting should be reevaluated to measure the level of improvement. However, the CONSORT pilot extension has many similarities to the standard CONSORT statement. Despite the underlying RCT design, only 8% of included articles stated that their study was reported in accordance with the CONSORT statement. Given that pilot studies of behavioral interventions are a specific area requiring attention, there may be a need to combine aspects of the TREND (Transparent Reporting of Evaluations with Nonrandomized Designs) statement for reporting behavioral interventions with the CONSORT extension for pilot and feasibility RCTs to increase overall level of reporting (Des Jarlais, Lyles, & Crepaz, 2004).

Importantly, our survey of pilot RCTs found that reporting of items related to the rationale for the pilot study, specific pilot study objectives, and progression to future definitive trials was severely lacking. This was because many of the included pilot studies were not conducted for appropriate pilot and feasibility reasons as outlined in our previous tutorial for pilot studies (Thabane et al., 2010). The majority of the included studies did not assess feasibility of the process, issues with time and resources, or study management issues and rather focused on finding significant effects of the intervention. Furthermore, only 13% of the included studies were conducted as a prelude to a future definitive trial, while most did not directly make amendments or recommendations for future definitive trials, which serves as the primary purpose of pilot and feasibility RCTs. It is important that future pilot and feasibility RCTs assess feasibility criteria and indicate specific improvements or amendments for larger definitive trials (Thabane et al.,

2010). This is crucial among behavioral intervention trials, as they may require amendments and participants' feedback to improve recruitment and implementation. These findings indicate that many pilot trials are not conducted for appropriate reasons, even in the years following the publication of a detailed tutorial in the leading journal for pilot studies. Given these findings, it is important for journals to not only endorse the pilot trial extension to the CONSORT reporting statement but also to ensure that authors are addressing appropriate objectives in their pilot trials.

Limitations

Our study was limited in that we only included English-language studies. This approach was used for resource and feasibility purposes; however, it is also important to assess the level of reporting in the broader literature. We also searched the Medline/Pubmed database alone to identify trials for inclusion. As we aimed to conduct a systematic survey of pilot trials in clinical areas, we deemed that one large database of biomedical research would be sufficient in order to randomly sample 100 pilot trials. Additionally, these findings can only be generalized to pilot trials of behavioral interventions, since RCTs investigating pharmaceutical interventions have been shown to have higher reporting quality (Mbuagbaw et al., 2014; Samaan et al., 2013). However, we determined that it was important to conduct a distinct evaluation for behavioral interventions due to the suggested differences in reporting between pharmacological and nonpharmacological trials.

Conclusions

Pilot studies are an essential aspect of medical literature, as they prevent the loss of resources and increase feasibility for future definitive trials. Pilot and feasibility trials of behavioral interventions can inform amendments to intervention designs and provide useful participant feedback for study design improvement. As it stands, reporting quality based on the CONSORT statement extension for pilot and feasibility studies is suboptimal. Publication of the CONSORT extension specific to pilot and feasibility trials is expected to improve overall reporting. However, this baseline assessment highlights areas with low quality of reporting to guide researchers conducting pilot trials of behavioral interventions. Journal editors can utilize this research to adopt endorsement of the CONSORT statement as a way to improve the overall quality of reporting of pilot trials or trials in general.

Declaration of Conflicting Interests

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Supplemental Material

Supplementary material for this article is available online.

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