Review
CLINICAL TRIALS AND INVESTIGATIONS

Obesity

Registration Status and Methodological Reporting of Randomized Controlled Trials in Obesity Research: A Review

Jillian L.S. Byrne[1], Tamara Yee[1,2], Kathleen O'Connor[1], Michele P. Dyson[1,3], and Geoff D.C. Ball[1]

Objective: To assess registration and reporting details of randomized controlled trials (RCTs) published from 2011 to 2016 across four obesity journals.

Methods: All issues from four leading obesity journals were searched systematically for RCTs from January 2011 to June 2016. Data on registration status were extracted from manuscripts, online trial registries, and a trial database; corresponding authors were contacted for registration details, when necessary. The methodological reporting of RCTs was assessed on specific criteria from the Consolidated Standards of Reporting Trials.

Results: A total of 223 RCTs were reviewed. Three-quarters ($n = 170$) were registered publicly; 94 (55.3%) reported registration details in the manuscript, and 82 (48.2%) were registered prospectively. Newer RCTs were more likely to be registered prospectively than older RCTs (2014-2016: 57.3% vs. 2011-2013: 39.2%; $c^2 = 5.5$, $P = 0.02$). Assessment on the Consolidated Standards of Reporting Trials demonstrated that less than half of all studies reported data collection dates ($n = 108$; 48.4%) or included "randomized trial" in the title ($n = 89$; 39.9%).

Conclusions: The methodological reporting of RCTs published in obesity journals is suboptimal, despite current guidelines and policies. To complement existing standards, editorial boards should incorporate mandatory fields within the online manuscript submission process to enhance the quality, transparency, and comprehensiveness of reporting RCTs in obesity journals.

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Introduction

Since 1978, the International Committee of Medical Journal Editors (ICMJE) has sought to "...help authors, editors, and others involved in peer review and biomedical publishing create and distribute accurate, clear, reproducible, unbiased medical journal articles" (1). This effort has included guidelines that require randomized controlled trials (RCTs) to be registered publicly (2) and prospectively (3) and to adhere to reporting guidelines such as the Consolidated Standards of Reporting Trials (CONSORT) Statement (4,5). When upheld, these guidelines can achieve several aims, including the reduction of selective outcome reporting and publication biases; they also serve to enhance the transparency, validity, and accessibility of their findings (5).

In the field of obesity research, experts have long advocated for increased attention to the conduct and methodological reporting of trials (6). Recently, there have been calls to improve methodological rigor in obesity research (7-10), enhancements that are vital to ensure that the highest-quality evidence possible is generated to inform decision-making for preventing and managing obesity. High-prevalence estimates of obesity in Canadian children (11) and adults (12) underscore the need for rigorously designed trials to determine the efficacy and effectiveness of strategies that are designed to prevent and manage obesity; in turn, this information can form the scientific basis for making policy-related decisions and allocation of resources across multiple jurisdictions (e.g., municipalities, health care and school systems, industry) that can influence our weight and health.

[1] Department of Pediatrics, University of Alberta, Edmonton, Alberta, Canada. Correspondence: Geoff D.C. Ball (gdball@ualberta.ca) [2] Autism Research Centre, Glenrose Rehabilitation Hospital, Alberta Health Services, Edmonton, Alberta, Canada [3] Alberta Research Centre for Health Evidence, University of Alberta, Edmonton, Alberta, Canada.

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Disclosures: Over his career, GB has published manuscripts in all four obesity journals described in this manuscript. He has served as an Associate Editor for *Pediatric Obesity* since 2011. The other authors declared no conflict of interest.

Author contributions: JB and GB designed research; JB, TY, and KO conducted research; JB, TY, MD, and GB analyzed and interpreted data; JB, TY, KO, MD, and GB wrote the paper; JB and GB had the primary responsibility for final content. All authors read and approved the final manuscript.

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In recent years, our team members' anecdotal experiences, which have included serving on a journal's editorial board and peer-reviewing RCTs submitted to obesity journals, suggest that a review of obesity research might help to guide recommendations for improving the methodological quality of conducting and reporting RCTs in this field. To date, studies have reviewed trial registration and reporting quality in clinical psychology (13), oral health (14), and respiratory health research (15); however, to our knowledge, obesity trials have yet to be investigated in this domain. Therefore, the objective of our study was to determine the registration status and proportion of RCTs that adhered to defined CONSORT criteria among studies that were published in four obesity journals over a 5-year period.

Methods

Sample

This review was conducted in May to June 2016 and included articles published in *Clinical Obesity*, *International Journal of Obesity*, *Obesity*, and *Pediatric Obesity*. The selection of these journals was not intended to be exhaustive but was meant to represent periodicals that varied by focus, history, and impact (Table 1). Journals were categorized according to whether their publicly available online authorship guidelines were "explicit" (i.e., required or recommended guidelines) or "not explicit" (i.e., indirectly referred to guidelines or not stated) regarding their requirement for RCT registration and adherence to CONSORT; journals that did not require or recommend trial registration or adherence to CONSORT in their authorship guidelines but in other supplementary editorial documents (e.g., ethical policies document) were considered not explicit.

Independently, two team members (JB, KO) screened manuscript titles and abstracts for published RCTs in the table of contents of all issues of the journals from January 2011 to June 2016. In cases of uncertainty, full-text articles were examined; a third reviewer (GB) was consulted if agreement could not be reached. Papers were eligible for inclusion if they (i) described methodology consistent with RCTs, (ii) documented primary outcomes of the RCT, and (iii) were published between January 2011 and the time of our search (June 2016). Systematic reviews, editorials, study protocols, and secondary analyses of data derived from RCTs were excluded. We defined a RCT as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes" (13,16). An audit of 15% of all issues searched across the four journals was completed by an independent reviewer (TY) to ensure all eligible studies were identified.

Data extraction

One author (JB) examined all full articles of RCTs for (i) the registration status (i.e., prospective, retrospective, not registered), (ii) adherence to a predetermined selection of CONSORT guidelines (5), and (iii) country of data collection. Reporting of RCT registration was examined within the article. If the article did not include registration details, the title of the publication, the name of the trial (if applicable), and the first, last, and corresponding authors' names were searched in the World Health Organization International Clinical Trials Registry Platform Search Portal (http://who.int/trialsearch) as well as ClinicalTrials.gov, the Australian New Zealand Clinical Trials Registry, and the International Standard Randomized Controlled Trial Number, or country-specific registries, if available, as indicated by the corresponding author's country of affiliation. Following this step, if we could not locate trial information in the aforementioned registries or database, corresponding authors, as indicated in the manuscripts, were contacted via email. Corresponding authors were also contacted if the manuscript stated the trial was registered but the identification number was not provided and we could not locate trial information. Authors were followed up once via email if they did not respond within a 1-week time period. Registration status was categorized as "prospective" if the date of registration submission preceded the start date of data collection, "retrospective" if the date of registration submission did not precede the start date of data collection, and "unknown" if the dates of data collection could not be identified in the manuscript or through searching in the trial registries or database. The start and end dates of data collection (if reported) were extracted from the manuscript or from the trial registry; trials that ended data collection prior to July 1, 2005, were flagged given that ICMJE only published requirements for trial registration after this date (2). When dates for data collection reported in the manuscript did not match dates from the trial registry, information reported in the manuscript was prioritized. For example, if the manuscript reported data collection started on July 2010 and the trial registration reported January 2010, then the former date was used to determine prospective or retrospective registration status in relation to the registration submission date. For

TABLE 1 Journals included for review

Journal	Established	5-year impact factor[a]	H Index[b]	Journal ranking[b]
Clinical Obesity	2011	N/A	N/A	N/A
International Journal of Obesity	1977	5.28	173	1st quartile[c]
Obesity	1993	4.38	151	1st quartile[d]
Pediatric Obesity	2006	4.60	44	1st quartile[e]

N/A: not available.
[a]Source: ResearchGate (www.researchgate.net).
[b]Source: Scimago Journal & Country Rank (www.scimagojr.com).
[c]Endocrinology, Diabetes and Metabolism; Medicine (miscellaneous); Nutrition and Dietetics.
[d]Endocrinology; Endocrinology, Diabetes and Metabolism; Medicine (miscellaneous); Nutrition and Dietetics.
[e]Health Policy; Pediatrics, Perinatology and Child Health.

individual RCTs that were conducted in more than one country, the country of the corresponding author was extracted.

Select reporting elements outlined by the CONSORT guidelines were examined, including (i) identification as a "randomized trial" or "RCT" in the title, (ii) dates defining the periods of data collection, and (iii) a participant flow diagram outlining the losses and exclusions, with reasons, for each group after randomization. In lieu of a full review of all elements of the CONSORT checklist, these specific indicators were chosen to derive a general perspective of authors' adherence to the guidelines. RCTs were also examined for explicit documentation of adherence to CONSORT and the degree of adherence, which spanned from reporting (i) a completed CONSORT checklist, (ii) use of CONSORT in the methods section, (iii) an itemized CONSORT flow diagram, or (iv) no explicit mention of the use of CONSORT. An audit of 15% of all reviewed RCTs was completed by an independent reviewer (TY) to ensure extracted data were accurate and complete.

Analyses

Interobserver agreement was calculated to determine the consistency of agreement between two reviewers for (i) RCTs included for review and (ii) data extraction. To determine the overall proportion of RCTs to total original studies published (original studies represented studies that included original data, excluding commentaries, editorials, and reviews), individual original studies were tabulated manually (by JB and TY). For instance, Volume 23 (Issue 5) of *Obesity* included a total of 26 original studies, of which 2 were classified as RCTs. The data we collected were reported as frequencies and proportions. Chi-square statistics were used to determine the relationship between categorical variables. Data were managed in Microsoft Office Excel 2016 and all analyses were performed using SPSS® version 23.0 (SPSS Inc., Chicago, Illinois); $P < 0.05$ was considered statistically significant.

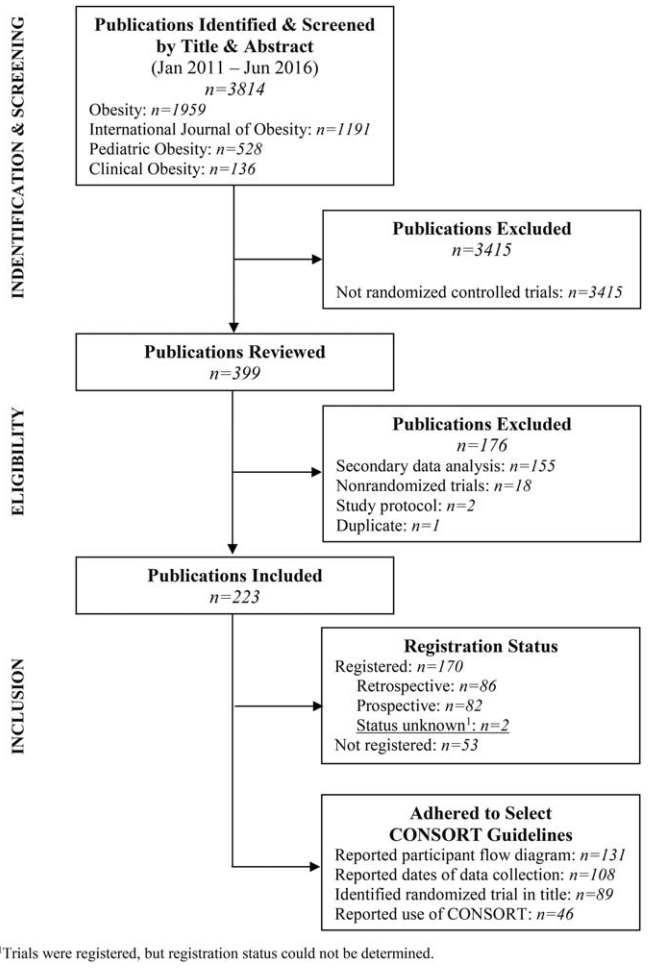

Figure 1 Flowchart of RCTs. [1]Trials were registered, but registration status could not be determined.

Results

A total of 3,814 articles were identified and screened, of which 223 articles reporting RCTs were included for review (Figure 1). A list of all reviewed RCTs is available in Supporting Information Table S1. Interobserver agreement was high among RCTs included for review and data extraction (both kappa > 0.90). There was a 69.3% (52/75) email response rate regarding RCT registration information

TABLE 2 Editorial policies of reviewed journals

		Authorship guidelines		Submission process	
Journals[a]	Guideline category	RCT registration	CONSORT	RCT registration	CONSORT
Clinical Obesity	NE	Recommended[b,d]	N/A	N/A	N/A
International Journal of Obesity	E	Required[c]	Required[c]	Required[f]	N/A
Obesity	NE	Recommended[b,d]	N/A	N/A	N/A
Pediatric Obesity	E	Required[c,e]	Recommended[b]	Required[f]	N/A

E: explicit; NE: not explicit; N/A: not available.
[a]Since the time of our review (May–June 2016), the editorial policies for trial registration and CONSORT requirements have changed for *Obesity*.
[b]Language states "should" (i.e., recommended).
[c]Language states "must" (i.e., required).
[d]Stated under ethical policies, not authorship guidelines.
[e]Trial must be registered prospectively.
[f]Required entry with registration details (i.e., name of trial registry and registration number).

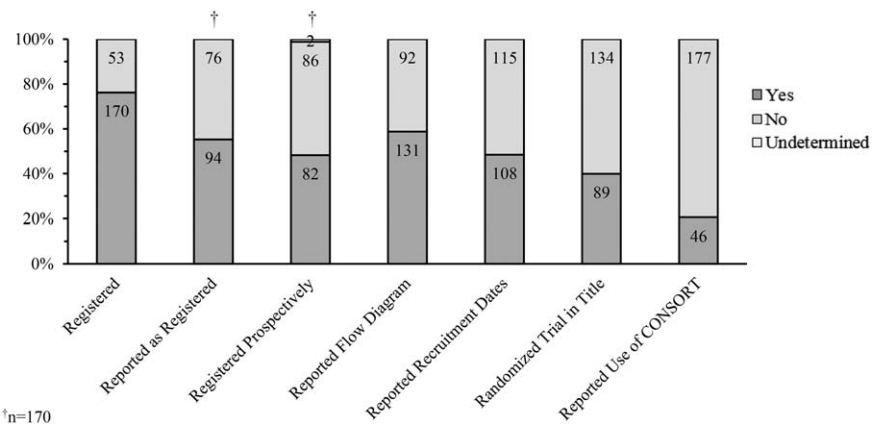

Figure 2 The proportions of RCTs ($n = 223$) categorized by registration and CONSORT reporting elements. †$n = 170$.

among the corresponding authors of manuscripts that (i) did not report RCT registration information in the manuscript and (ii) could not be located through our registry database search. The four journals we surveyed varied in their editorial policies regarding RCT registration and adherence to CONSORT. Specifically, the journals' editorial policies differed based on "explicit" and "not explicit" requirements for RCT registration and adherence to CONSORT (Table 2). The overall proportion of published RCTs to total original studies was 5.8% ($n = 223$/3,814; *Clinical Obesity*: 8.1% [$n = 11$/136]; *International Journal of Obesity*: 3.8% [$n = 45$/1,191]; *Obesity*: 7.4% [$n = 144$/1,959]; and *Pediatric Obesity*: 4.4% [$n = 23$/528]). The publication of RCTs was consistent between 2011 and 2016 (2011 [15.7%]; 2012 [13.0%]; 2013 [20.6%]; 2014 [17.0%]; 2015 [17.0%]; 2016 [16.6%]), with a projected increase in 2016, as our data collection ended part of the way through the year. Based on the location of data collection and corresponding authors, we found that RCTs were conducted in 26 countries, with the majority ($n = 133$; 59.6%) carried out in the United States (Supporting Information Figure S1).

In total, 170 of the 223 RCTs (76.2%) were registered publicly, of which 82 (48.2%) were registered prospectively (Figure 2). Of the registered trials, only 94 (55.3%) reported this information in the manuscript. Of the RCTs that were registered, most were listed with ClinicalTrials.gov ($n = 139$; 81.8%), followed by the Australian New Zealand Clinical Trials Registry ($n = 13$; 7.6%) and International Standard Randomized Controlled Trial Number ($n = 10$; 5.9%). The proportion of RCTs that adhered to specified CONSORT guidelines was low. For example, 46 (20.6%) articles reported that they followed CONSORT, with the majority ($n = 36$) reporting an itemized CONSORT flow diagram. A minority of RCTs explicitly stated their adherence to CONSORT in the methods section ($n = 9$; 4.0%). In addition, only 89 (39.9%) reports included "randomized trial" or "RCT" in their title, and 108 (48.4%) reported dates of data collection. Of those studies for which dates of data collection could be determined (i.e., reported in the manuscript [$n = 108$] or indicated in trial registries or a database, if not reported in the manuscript [$n = 60$]), the majority completed data collection after 2005; only two studies completed data collection prior to July 1, 2005 (i.e., the date on which the ICMJE required trial registration), of which one was registered and one was not registered.

Neither registration status nor quality of methodological reporting of RCTs varied between the journals that did or did not have explicit requirements in their authorship guidelines for trial registration and CONSORT (both $P > 0.05$). However, based on the date of publication, the proportion of RCTs that were registered prospectively was higher among more recently published RCTs (2014 to 2016) compared to RCTs published from 2011 to 2013 (57.3% vs. 39.2%; $\chi^2 = 5.5$, $P = 0.02$). Also, compared to RCTs conducted in the United States, trials completed in non-US countries were more likely to report registration details (51.1% vs. 82.8%; $\chi^2 = 15.2$, $P < 0.001$). Last, a higher proportion of registered studies reported (i) use of CONSORT (registered [25.9%] vs. not registered [3.8%]; $\chi^2 = 12.1$, $P = 0.001$), (ii) a flow diagram (registered [63.5%] vs. not registered [43.4%]; $\chi^2 = 6.8$, $P = 0.009$), and (iii) dates of data collection in the manuscript (registered [56.5%] vs. not registered [22.6%]; $\chi^2 = 18.5$, $P < 0.001$), as well as were identified as a RCT in the title (registered [46.5%] vs. not registered [18.9%]; $\chi^2 = 12.8$, $P < 0.001$).

Discussion

Our review of RCTs that were published in obesity journals over the past 5 years highlighted satisfactory registration status, with three-quarters of RCTs registered, approximately half of which were registered prospectively. However, the transparency of information on RCT registration was lacking, with only half of registered RCTs reporting such information in the manuscript. Additionally, the quality of methodological reporting revealed that the majority of RCTs failed to report other important trial elements, such as dates of data collection and details of participant recruitment, including losses and exclusions, in the form of a flow diagram. Together, these data highlight the need to improve the methodological quality and transparency of reporting RCTs in obesity journals.

Our findings showed that the proportion of registered RCTs in obesity journals slightly exceeds values of RCT registration in major medical journals (17) and far surpasses values reported previously in the fields of clinical psychology (13) and oral health (14). This suggests that the registration status of obesity RCTs is relatively optimal compared to other fields, which may be reflective of recent

calls for improved methodological rigor in the field of obesity research (7-10), an observation that is consistent with our finding regarding increased prospective registration status in more recent years. It is noteworthy that the proportion of registered RCTs did not differ by the degree to which journals' authorship guidelines were explicit, a finding echoed by others (16), indicating that existing authorship guidelines, editorial screening processes, and peer-reviewing procedures may not effectively ensure adherence to registration and reporting requirements. As others have noted (17,18), few journals require trial registration in their authorship guidelines, highlighting room for improvement among guidelines with and without explicit requirements to enhance the methodological transparency of RCTs.

Although three-quarters of RCTs in our review were registered publicly, highlighting that most investigators recognize the importance of completing this step at or near the time of trial onset, similar to other findings (14), approximately half of registered RCTs failed to include this registration information in their report. The inclusion of trial registration details in manuscripts describing the results of RCTs is similar to the inclusion of other items, such as research ethics approvals, description of software programs, and *P* values to denote statistical testing, which authors usually include and peer-reviewers expect to observe in manuscripts, as they are consistent with many journals' authorship guidelines and accepted practices in scientific writing. To ensure that such details are not overlooked at the reporting stage, a mandatory field could be added to the section whereby authors of RCTs are required to enter details regarding their abstract.

The CONSORT statement was first published in 1996 and is essential to improving the quality of reporting among RCTs (19). Yet 20 years on, less than half of the RCTs in our review included details about their RCT in the manuscript title or specified dates of data collection; even fewer published a flow diagram or included a completed CONSORT checklist along with their manuscript to indicate where reporting elements could be located in their article. Similarly, since July 1, 2005, ICMJE has recommended that editors of medical journals require that RCTs should only be considered for publication if they were registered prospectively at or before enrolling the first research participant (1). Since this requirement was first published more than a decade ago, less than half of the RCTs in our study met this standard. These observations are not unique to the field of obesity (20). In response to inconsistent adoption of CONSORT across biomedical journals, experts have made specific recommendations to improve journals' authorship guidelines, such as the inclusion of specific text to endorse reporting guidelines (21). This highlights the importance of continued efforts to improve authors' adherence to and reporting of CONSORT guidelines.

The high prevalence of obesity among children and adults, in conjunction with the economic, political, and public interest to prevent and manage obesity, warrants concerted efforts to enhance the quality and transparency of trials in obesity research. With this ideal in mind, we acknowledge that there are valid, real-world reasons that explain why authors may fail to adhere to, and editors do not consistently apply, CONSORT guidelines. For instance, registering a trial prospectively means that outcome measures cannot be changed post hoc, which can have an impact on study findings and interpretation; in turn, study results, in the form of negative, null, or positive findings, can influence whether or not a trial is published in a prestigious, higher-impact journal. Because publications are a form of academic currency that impacts promotions, merit increments, and professional reputation, it is reasonable to assume that some authors choose to not register trials prospectively in order to give themselves flexibility in data analysis and reporting. Similarly, in a competitive environment in which editors of academic journals seek to enhance the reputational status and impact of their periodicals, strict compliance to CONSORT could restrict their ability to publish trials that are likely to receive a high degree of attention in the popular press and/or be cited often by other researchers in their field. As such, we believe that several factors, from lack of awareness and naiveté regarding CONSORT to deliberately not registering trials (or overlooking the absence of registration details), influenced the findings of our review. Given that more recently published RCTs were more likely to report registration details than older reports, there is evidence that awareness of and adherence to CONSORT have improved over time.

The limitations of this study must be acknowledged. First, our review was limited to RCTs published in four obesity journals, so our findings may not be reflective of obesity-related RCTs published in other journals, including major medical journals. A review of RCTs across a larger and more comprehensive selection of obesity journals as well as RCTs published in nonobesity-specific journals is warranted. Second, although our study demonstrated that a substantial portion of RCTs were registered, we did not compare registered and published outcomes, and therefore the quality of trial registration cannot be inferred from this finding. Third, although two reviewers independently identified RCTs for review and an audit of all journal issues was conducted, it is possible that some eligible studies were not identified and included in our review, especially if articles did not specify "RCT" or "randomized trial" in their titles. Fourth, if RCTs identified through our search did not report details regarding registration, we searched for this information in three different trial registries and one trial database; corresponding authors were then contacted regarding RCT registry information, if required. Although our search protocol was thorough, it is possible that a small number of registered RCTs were not identified as such, and, thus, we may have underestimated the actual number of registered trials. Fifth, our findings demonstrated that approximately one-quarter of RCTs were not registered, but it is noteworthy that the lack of registration for some studies may have been due to some investigators considering their studies to be "experiments" as opposed to RCTs and thus not requiring trial registration. Last, RCTs were only assessed on select criteria from the CONSORT, and other important elements, such as information on allocation concealment, blinding, and sample size calculations, were not included in this study. Given this, our reporting of select CONSORT criteria does not accurately represent RCTs across all 25 reporting elements.

Conclusion

Our review of RCTs published in four obesity journals from 2011 to 2016 suggested satisfactory registration status, with approximately three-quarters of RCTs being registered, a statistic that surpasses reviews of RCT registrations in other fields. However, of the registered RCTs, only 55% indicated registration information in the manuscript, which represents suboptimal transparency. There is a clear need to improve how journals inform authors about

TABLE 3 Proposed required screening criteria for journal editorial boards and administrators

Question	Response
1. Is the submission a randomized controlled trial (RCT)?	☐ Yes (proceed to #2) ☐ No (continue screening for non-RCT related issues) ☐ Unsure (return to authors)
2. Is the RCT registered prospectively and publicly?	☐ Yes (proceed to #3) ☐ No (return to authors) ☐ Unsure (return to authors)
3. Is the RCT registration number reported in the manuscript?	☐ Yes (proceed to #4) ☐ No (return to authors)
4. Is the RCT accompanied by a completed CONSORT (Consolidated Standards of Reporting Trials) checklist?[a]	☐ Yes (screening complete) ☐ No (return to authors)

[a]Cross-checking of the completed CONSORT checklist could be conducted by the journal editor or administrator, depending on availability of resources, or by peer reviewers.

requirements for registering RCTs publicly and reporting important trial elements in their manuscripts. Checklists and online tools have been applied to assist researchers in writing RCT studies (22) as well as for reviewers to assess the overall quality and methodological rigor of studies (23); as such, we recommend that additional mandatory questions (Table 3) should be introduced at the screening level for journal editors and administrators to improve the transparency, reporting, and methodological rigor of RCTs in obesity research. Future research is needed to measure the impact of incorporating mandatory fields in the manuscript submission and review processes to assess the consistency of publishing registration details and reporting components of RCTs. O

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