Journal of Clinical Epidemiology 111 (2019) 41−48

Journal of Clinical Epidemiology

ORIGINAL ARTICLE

Following Cochrane review protocols to completion 10 years later: a retrospective cohort study and author survey

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Accepted 1 March 2019; Published online 27 March 2019

Abstract

Objective: We analyzed patterns of publication of Cochrane review protocols (CRPs).

Study Design and Setting: We analyzed CRPs published in 2010, extracted their characteristics, and analyzed whether they were published by February 2018. We surveyed corresponding authors and Cochrane review groups to analyze reasons for nonpublication of protocols and analyzed factors predicting the time to publication.

Results: Of 576 CRPs, 446 (77.4%) were published as a full review and 130 (22.6%) were still unpublished in February 2018; among unpublished, 37 (28.5%) were withdrawn and 93 (71.5%) were still active. The most common authors' reason for abandoning a protocol was a lack of time to work on the review. The median time to publication was 2.78 years (range 0.96 to 8.05). Multivariate analysis showed that factors with the strongest association with shorter time to publication were review being an update and new authors added. Analysis only on methodological variables indicated that the strongest association for a shorter time until publication was found for including only published data.

Conclusions: Almost a quarter of CRPs remains unpublished after 8 years. This figure is slightly higher than in a previous analysis 10 years ago. Strategies for enhancing completion of Cochrane reviews should be considered.

Keywords: Systematic review; Cochrane; Review protocol; Methodology; Publication; Review process

1. Introduction

Cochrane reviews are considered the gold standard of evidence in knowledge synthesis [1]. Multiple studies have shown that Cochrane reviews have higher methodological and reporting quality compared with non-Cochrane reviews [2−5]. Tricco et al. reported in 2008 that 20% of Cochrane review protocols (CRPs) are not published as full reviews after 8 years of follow-up [6]. The study followed 411 CRPs published in 2000 and 2001, and their subsequent publication status up to Issue 1, 2008 in the Cochrane Database of Systematic Reviews (CDSR). Survival analysis indicated that although the median time from CRP publication to full review publication was 2.4 years, some reviews took much longer, up to 8.96 years [6].

The aim of the study was to assess the frequency of publication of Cochrane protocols 10 years later (using similar

Conflict of interest: A.C.T. is an associate editor for the Journal of Clinical Epidemiology; all other authors do not have any conflicts of interest to declare.

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https://doi.org/10.1016/j.jclinepi.2019.03.006
0895-4356/

What is new?

Key findings

- Almost a quarter of Cochrane review protocols do not get published as a review 8 years after protocol publication.
- Median time from Cochrane protocol to review publication was 2.78 years and one of the strongest factors for shorter time to publication was addition of new authors.

What this adds to what was known?

- The percentage of nonpublished protocols after 8 years is higher, and median time to publication is longer compared with the previous such analysis which was conducted 10 years ago.

What is the implication and what should change now?

- Strategies for enhancing completion of Cochrane reviews should be considered.
- Cochrane protocols which did not result in a published review in 8 years should be withdrawn.
- Original protocol authors may benefit from involving additional authors.

methodology as Tricco et al. [6]), survey corresponding authors of nonpublished reviews about reasons for nonpublication, and analyze factors that may be associated with publication of Cochrane reviews in a new cohort of protocols that were published in 2010.

2. Methods

2.1. Study design

This study consists of two parts; first, a retrospective cohort study, which analyzes published CRPs and their full publication trajectory and second, a survey of corresponding authors of those protocols. The study protocol is available on Open Science Framework (OSF) (https://osf.io/6rn3j/); the study was conducted once the protocol was deposited in the OSF.

2.2. Protocol inclusion criteria

We tried using the advanced search feature of The Cochrane Library [7] to retrieve all CRPs published in 2010. However, we could only access protocols for unpublished reviews. Therefore, we obtained a list of 665 protocols published in 2010 from the support team of Wiley, publisher of The Cochrane Library. All protocols, regardless of the review type, were eligible for inclusion. If another updated version of the protocol was published in 2010, we analyzed only the first version, and the second version was excluded. Protocols that were published before 2010 and whose updated version was published in 2010 were also excluded. Protocols that were published in 2010 and later taken over by another author team were excluded. Protocols which were split into more than one review were also excluded.

2.3. Assessing the publication status of Cochrane protocols

Each Cochrane title has a unique identification number, which is assigned to a protocol, the corresponding review, and all the updated versions of that same review. To determine whether included protocols were published, we entered the CRP identification number in the search box of The Cochrane Library and chose the ''Search all text'' function. The search for published reviews was conducted in February 2018. Based on the search results, we categorized CRPs as ''full review published,'' ''full review not yet published,'' and ''withdrawn.''

Sometimes, the identification number is revised for updated versions of the review and as such we also searched The Cochrane Library based on the key words of the title to see whether several versions of the full review may have been published with different identification numbers. We also determined whether any of the included CRPs was subsequently split into multiple reviews and whether any CRP was later taken over by another Cochrane review group (CRG).

2.4. Data extraction

One author (E.R.) extracted data using a 54-item data extraction form based on the data extraction form developed by Tricco et al. [6] and updated for the purpose of this study. The data extraction form is available on the OSF (https://osf.io/6rn3j/). Another author (D.B.) conducted a random check of 10 percent of the extracted data to ensure data accuracy and only two corrections were made. Disagreements were reviewed and resolved by consensus via a face-to-face meeting. One investigator extracted descriptive characteristics of the CRPs and completed Cochrane reviews, as described in Appendix A.

2.5. Author survey

For CRPs that were not published, we contacted the corresponding author by using the e-mail address provided in their protocol. In ten cases, the corresponding author e-mail address was no longer correct, so we used the e-mail address of the last author, which we found through searching the internet.

Authors were asked about the status of their Cochrane review and responses were categorized as screening stage,

data extraction stage, analysis stage, article drafting stage, submitted and waiting for peer review, completed but published elsewhere, and those where information about the protocol status could not be obtained (example of an e-mail for an author of an unpublished/withdrawn protocol is in Appendix B). Corresponding authors received a reminder after 2 weeks if they did not respond to the initial e-mail. If they did not respond within another week, an e-mail was sent to the CRG to ask about the CRP status (example of an e-mail for CRG related to an unpublished/withdrawn protocol is in Appendix C). In cases where multiple protocols with unclear publication statuses belonged to the same CRG, we contacted the CRG with a summary e-mail inquiring about all protocols at the same time.

2.6. Ethical issues

The first part of this study only involved an analysis of publicly available data published in the CDSR. As such, it was exempt from requiring approval of a research ethics committee. The survey was approved by the Ethics Committee of the University of Split School of Medicine.

2.7. Data analysis

We described the sample using absolute numbers and percentages for nominal data and medians and ranges for ordinal and interval scaled data. We used multivariate Cox proportional hazard regression to determine the time to publication and the predictive factors for time to publication (details on survival analyses in Appendix A). We conducted the descriptive analyses using MedCalc (MedCalc Corp., Mariakerke, Belgium) and all survival analyses with SPSS 24 (SPSS, Inc.; Chicago, IL, USA).

3. Results

Among 665 CRPs that were published in 2010, we were unable to find 50 of them in the CDSR. We excluded 39 CRPs from the analysis: four published in 2010 as an updated version; 27 published before 2010; six that were taken over by another author team and two that were split into more than one review. We analyzed the remaining 576 CRPs (86.6%) in detail, of which 446 (of 576; 77.4%) were published as a full review and 130 (22.6%) were still unpublished in February 2018.

3.1. Characteristics of Cochrane protocols

Most CRPs (95.8%, 552/576) were reviews of interventions. Fourteen (2.4%) CRPs had more than one published protocol. The median number of authors in the 576 analyzed protocols was 4. About half of the authors were affiliated with four countries: UK, Australia, China, and USA. In only 4 (0.7%) CRPs, authors had affiliations in multiple countries (Table 1).

In 41.5% of the CRPs, the authors planned to include all studies without age restrictions and 29.7% planned to include studies only including adult and elderly populations. Most of the protocols included only randomized studies; they mostly included both published and unpublished studies (70.8%, 408/576), and most of them did not have language restrictions in terms of inclusion criteria (81.3%, 468/576).

Primary outcomes were specified in most protocols (95.5%), with a median number of two primary outcomes per protocol. The median number of searched databases per protocol was 5; most CRPs planned to search trial registries and gray literature. Almost all protocols planned to assess for heterogeneity (98.4%) and publication bias (87.2%).

Funding or other sources of support was reported in most of the CRPs (64.2%). Half of them reported funding or support from not-for-profit organizations, a fifth reported government organization support and 28.4% both not-for-profit and government organizations (Table 1).

3.2. Survival analysis

In the observation period, 446 (77.4%) Cochrane reviews were published and 130 (22.6%) were withdrawn or still not published at the cutoff date (February 2018). The median time from protocol publication to publication of the completed review was 2.78 years (range 0.96 to 8.05; 95% confidence interval [CI] 2.55 to 3.04). Figure 1 shows the cumulative publication rate; after approximately 2000 days, it is unlikely that additional publications will occur.

We performed a univariate analysis on 17 factors (for univariate analysis see Appendix D). Of these, 14 factors were included in the preliminary model for the multivariate analysis. Table 2 shows the results of the final multivariate analysis. The review being an update (hazards ratio [HR] 0.251: 95% CI 0.201 to 0.315) and new authors added (HR 0.705: 95% CI 0.581 to 0.855) showed the strongest association with a shorter time to publication.

In the analysis of methodological variables (Appendix E), three characteristics remained in the final model (publication status, study types included, and searching trial registries). The strongest association for a shorter time to publication was found for including only published data (HR 0.595: 95% CI 0.378 to 0.936). By checking the proportional HR assumptions visually with the (Log-Log) survival plot, we were unable to find any indication for deviation from the proportional HR assumptions.

3.3. Survey of authors and review groups regarding unpublished protocols

From the 130 unpublished CRPs, 37 (28.5%) were withdrawn from the CDSR and 93 (71.5%) were still active. We received responses for 107 (82.3%) protocols. We first contacted protocol authors and received a

Table 1. Characteristics of Cochrane protocols ($N = 576$) published in 2010

Item	Result
Review type, *n* (%)	
Intervention	552 (95.8)
Diagnostic test accuracy	16 (2.8)
Overview	6 (1)
Methodology	2 (0.4)
More than one published protocol, *n* (%)	
No	562 (97.6)
Yes	14 (2.4)
Number of authors, median (range)	4 (2, 15)
Country/countries of authors, *n* (%)	***N* = 859**
UK	229 (26.7)
Australia	92 (10.7)
China	77 (9)
USA	61 (7.1)
Canada	56 (6.5)
Netherlands	37 (4.3)
Italy	22 (2.6)
India	21 (2.4)
Germany	19 (2.2)
Brazil	17 (2)
Other	228 (26.5)
Authors with multiple countries in affiliation, *n* (%)	
No	572 (99.3)
Yes	4 (0.7)
Population included, *n* (%)	
All	239 (41.5)
Adult and elderly	171 (29.7)
Women	65 (11.3)
Adolescent and adult	24 (4.1)
Neonate	18 (3.1)
Children and adolescent	14 (2.4)
Just children	9 (1.6)
Neonate and children	8 (1.4)
Children, adolescent, and adult	7 (1.2)
Neonate, children, and adolescent	5 (0.9)
Just adult	5 (0.9)
Men	4 (0.7)
Neonate and women	3 (0.5)
Just elderly	1 (0.2)
Did not include people	3 (0.5)
Type of studies eligible, *n* (%)	
Randomized	319 (55.4)
Randomized and quasirandomized	145 (25.2)
Both randomized and nonrandomized	90 (15.6)
Nonrandomized	16 (2.8)
Reviews	6 (1)
Publication status of eligible studies, *n* (%)	
Both published and unpublished	408 (70.8)
Authors did not specify	144 (25)
Published	23 (4)
Unpublished	1 (0.2)
Language inclusion, *n* (%)	
No restrictions	468 (81.3)
Not stated	102 (17.7)
English only	6 (1)
Primary outcome reported, *n* (%)	
Yes	550 (95.5)
No	10 (1.7)
Studies that do not have primary outcomes (diagnostic test accuracy)	16 (2.8)
Number of primary outcomes, median (range)	2 (1, 10)
Number of searched databases, median (range)	5 (1, 33)
Trial registries searched, *n* (%)	
Yes	338 (58.7)
No	238 (41.3)
Gray literature searched, *n* (%)	
Yes	393 (68.2)
No	183 (31.8)
Heterogeneity assessment planned in the methods, *n* (%)	
Yes	567 (98.4)
No	9 (1.6)
Publication bias planned in methods, *n* (%)	
Yes	502 (87.2)
No	74 (12.8)
Funding or sources of support reported, *n* (%)	
Yes	370 (64.2)
No	206 (35.8)
Type of reported funding/source of support, *n* (%)	***N* = 370**
Not-for-profit organization	188 (50.8)
Government and not-for-profit organization	105 (28.4)
Government organization	77 (20.8)

response from authors of 51/130 protocols (39.2% response rates from protocol authors). For the remaining 79 protocols, we contacted CRGs and received 56 responses (70.9% response rate from CRGs). The overall response rate from authors and CRGs for protocols that were still active was 75.3% (70/93). The status of those protocols is shown in Table 3.

About half (41.4%) of the active protocols were at different stages of review production, with the most

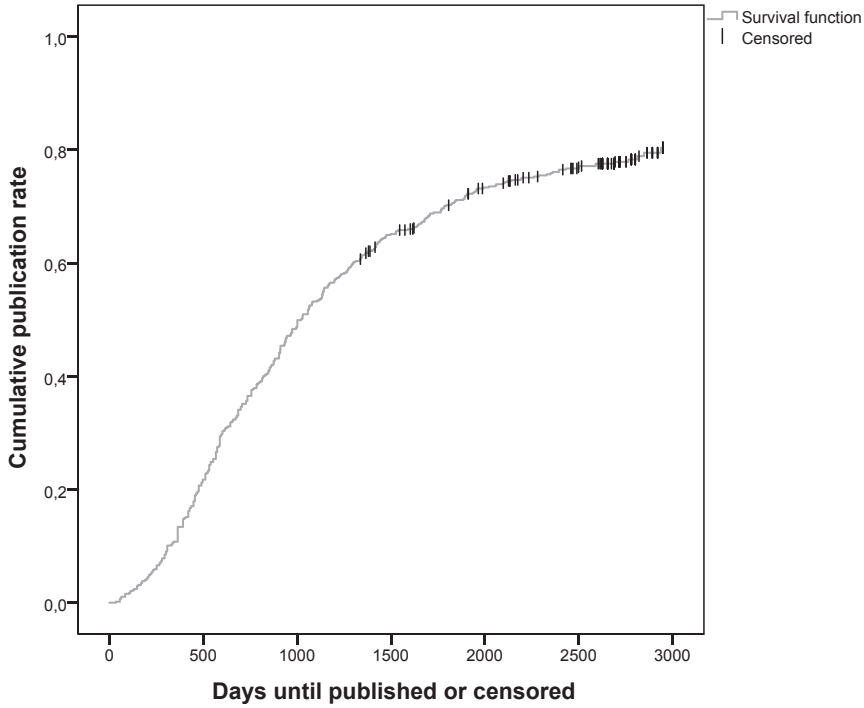

Fig. 1. Kaplan-Meier curve for the cumulative publication rate.

common stage being review completed and submitted to Cochrane for peer review. However, for 4.3% of the CRPs, the CRG responded that they are not aware of the current review status (Table 3).

For 40% of unpublished CRPs, authors or CRGs reported that protocols, although they were still active in CDSR, were abandoned by authors for various reasons, with the most common reason being lack of time to work on the review (Table 3). For several cases, the review topic went out of date because of the long Cochrane production process or the CRG rejected the completed reviews and the authors published them elsewhere (Table 3).

For all 37 withdrawn protocols, we received a response about the reason for withdrawing, either from the protocol authors or CRGs. The most common reasons for withdrawing the protocol were a lack of progress by review authors (27%), the protocol being out of date and not meeting the current methodological standards of Cochrane (24%) and authors' lack of time to finish review (24%) (Table 3).

4. Discussion

We found that 22.6% ($n = 130$) Cochrane protocols published in 2010 still had not published their completed review 8 years later. Among the unpublished protocols, the majority were still active and not abandoned. The most common reasons for abandoning a protocol was the

Table 2. Multivariate analysis of predictors for time to publication

Predictor[a]	HR	HR lower 95% CI	HR upper 95% CI	*P*-value
Publication status (published only vs. published and unpublished)	0.753	0.474	1.195	0.229
Language restrictions (English only vs. other)	0.627	0.249	1.578	0.321
Two protocols (yes vs. no)	1.437	0.764	2.703	0.260
More than four authors (yes vs. no)	1.094	0.907	1.319	0.350
Authors from multiple countries (yes vs. no)	5.059	0.710	36.036	0.106
Population specific (yes vs. no)	0.894	0.719	1.111	0.310
Review type diagnostic (yes vs. no)	1.817	0.934	3.535	0.079
Update (yes vs. no)	0.251	0.201	0.315	0.000
Authors added (yes vs. no)	0.705	0.581	0.855	0.000

Abbreviations: CI, confidence interval; HR, hazards ratio.
[a] Reference category is always the second mentioned in the brackets.

Table 3. Status of the active (N = 70) and withdrawn (N = 37) Cochrane protocols that were published in 2010 and for which we received information about their status from protocol authors or Cochrane review groups

Status	*n*/*N* (%)
Active protocols	
Review is in progress, in various current stages:	29/70 (41.4)
Literature search	4/29 (13.8)
Data abstraction	1/29 (3.4)
Analysis of study quality	1/29 (3.4)
Synthesis of results	4/29 (13.8)
Writing the first draft of review	5/29 (17.3)
Review completed and submitted to Cochrane	10/29 (34.5)
Review in the process of publication	4/29 (13.8)
Protocols were abandoned by authors for various reasons:	29/70 (41.4)
Lack of time to work on review	6/29 (20.7)
Review topic went out of date because of protraction during production	4/29 (13.8)
Problems due to authors' change of workplace	2/29 (6.9)
Lack of funding	1/29 (3.4)
Unspecified "operational problems"	1/29 (3.4)
Authors or review groups did not provide explanation	15/29 (51.8)
Authors did not make progress with a review and are preparing new update of the protocol	7/70 (10)
Review group is not aware of the review status	3/70 (4.3)
Review completed, but rejected by the Cochrane, and published elsewhere	2/70 (2.9)
Withdrawn protocols	
Reasons for withdrawal provided by authors and Cochrane groups:	37/37 (100)
Absence of progress by review authors	10/37 (27.1)
Protocol being out of date and not meeting the current methodological standards of Cochrane	9/37 (24.3)
Lack of time to finish review	9/37 (24.3)
Lack of interest to continue review after it was rejected by Cochrane	3/37 (8.1)
Operational difficulties	2/37 (5.4)
Methodological difficulties impossible to overcome	1/37 (2.7)
Multiple reasons	3/37 (8.1)

authors' lack of time to work on review. Although the median time from protocol publication to publication of a completed Cochrane review was 2.78 years, some reviews took 8 years to be published. That is contradictory to the Cochrane Handbook that states that protocols that have not been published as full reviews within 2 years should generally be withdrawn from the CDSR [8]. Multivariate analysis showed that factors with the strongest association for a shorter time to publication were the review being an update and new authors added to the review. Analysis of methodological variables indicated that the strongest association for a shorter time until publication was found for including only published data.

The result that updates of Cochrane reviews are completed within a shorter time frame is not surprising. The workload for performing an update is much lower compared with preparing a new Cochrane review. The finding that adding new authors to the review can decrease completion time is interesting and may be indicative of the fact that conducting Cochrane reviews is an extensive and long-term commitment. It might be difficult to find appropriate coauthors with a sufficient level of knowledge, experience, and time. Platforms such as TaskExchange offered by Cochrane might be able to connect people and facilitate finding new collaborators. The successful composition of the team is essential in the production of systematic reviews [9].

When focusing on the methodological aspects of systematic reviews, it is seen that omitting time-consuming tasks results in faster production. This might come at a price in terms of bias. The strongest association was found for searching unpublished data. Unpublished data can be very important in evidence syntheses [10]. However, the impact of unpublished data on effect measures remains controversial based on the current evidence [11–14]. Authors have to decide whether it is worth searching for and including unpublished data in their reviews.

In the study of Tricco et al. [6], published 10 years ago, the percentage of unpublished protocols after 8 years of follow-up was 19.1%, indicating that there was a slight increase in the proportion of nonpublished reviews over the past 10 years. Surveying the authors provided multiple reasons for abandoning a review, including lack of time, the review topic going out of date, and various operational

issues. Similar reasons for not publishing a review were observed in the earlier study as well [6]. Cochrane reviews are regarded as difficult to produce, and in turn, they produce trusted, high-quality evidence [15]. Therefore, it is unfortunate that certain topics are abandoned or neglected by authors after the protocol publication.

Among protocols that are still active, the most common phase was ''review completed and submitted to Cochrane,'' which is encouraging because publication might be in sight. However, half of the other authors with reviews in progress responded that they are in various much earlier methodological stages of Cochrane review production, indicating that it may take a while to complete those reviews.

For withdrawn protocols, a third of respondents indicated that a protocol was withdrawn because of a lack of author progress. It is reasonable for a CRG to withdraw a protocol from this team if no progress is being made. In such cases, a CRG should advertise that a review is available that another team could take over.

For several protocols, it was indicated that the review that was produced was rejected by a CRG. Cochrane indeed has a policy for rejecting Cochrane reviews [16]. According to the policy, a CRG can reject a Cochrane review at any stage, including unpublished protocols and reviews. With this policy, Cochrane aimed to emphasize that registration of a new title of a review or drafting the CRP by a specific author team does not guarantee publication of that team. Under this policy, the author team whose Cochrane review was rejected is free to submit their article elsewhere but without reference that it was a Cochrane review. The following reasons for rejection were cited by Cochrane: ''poor quality; agreed timelines not met; evidence that the author team lacks the core competencies to complete the review; concerns about conflicts of interest or other aspects of publication ethics'' [16].

However, only a minority of nonpublished Cochrane protocols for which we received responses from authors were described as abandoned, and therefore, it is worrying that a major portion of CRPs were not published 8 years later. Cochrane could consider introducing measure that would reverse increasing the number of nonpublished reviews. Such measures could be providing more methodological support or funding to review teams. For example, centralized methodological support by experienced authors and the publication of frequently asked questions could be very helpful to enable timely completion of Cochrane reviews.

The median time to publication in our study was slightly longer, 2.78 years, compared to the study of Tricco et al. [6], when it took median 2.4 years to publish a Cochrane review from the time of protocol publication. Both ours and the previous study [6] showed that it can take more than 8 years from protocol publication for a Cochrane review to be published; information from our multivariate analysis can be useful for shortening time to review publication. One of the strongest factors for shorter time to publication was the addition of new authors on the published Cochrane review compared with the Cochrane protocol. This indicates that the original protocol authors may benefit from involving additional authors if their review is not advancing as anticipated.

Furthermore, the asymptotic nature of the figure with our results about the ''survival'' of Cochrane protocols indicates that after a certain time point, it is unlikely that a Cochrane protocol will be published and that perhaps it makes little sense in maintaining these reviews. Our data also indicate that CRGs could invest more effort into recognizing teams that cannot finish their review on time.

Although our analysis also showed that a review update has a shorter time to publication, this relates only to some reviews that have reached the update stage and may not be relevant for many new Cochrane reviews. From the methodological point of view, only including published data was another strong factor predicting shorter time to Cochrane review publication. This is a pragmatic choice that Cochrane authors should consider because efforts to obtain unpublished or missing data can be very time consuming.

A limitation of this study is the short duration of follow-up of published CRPs. In our survival analysis, the maximum time to publication of a Cochrane review is 8 years because we analyzed their publication within an 8-year period. As our results indicated, some of the unpublished protocols were still in the production stage and certainly some of them will be published, which means that some Cochrane protocols may take much more than 8 years to be published.

In conclusion, almost a quarter of Cochrane protocols were still unpublished after 8 years of follow-up, but most nonpublished protocols were still active, not abandoned. The percentage of nonpublished protocols after 8 years is higher than that in a previous study conducted 10 years ago [6]. Strategies for enhancing the completion of Cochrane reviews should be considered.

Acknowledgments

The authors are very grateful to Mr. Gavin Stewart of the Wiley's support team for providing the detailed information about Cochrane protocols analyzed in this study. A.C.T. is funded by a Tier 2 Canada Research Chair in Knowledge Synthesis. D.M. is supported by a University Research Chair.

Authors' contributions: D.M., A.C.T., and L.P. conceived and designed the experiments; E.R. and D.B. performed the experiments; E.R., D.B., D.P., T.M., A.C.T., D.M., and L.P. analyzed and interpreted the data; E.R., D.B., D.P., T.M., A.C.T., D.M., and L.P. contributed reagents, materials, and analysis tools or data; E.R., D.B., D.P., T.M., A.C.T., D.M., and L.P. wrote the article; E.R., D.B., D.P., T.M., A.C.T., D.M., and L.P. agree to be accountable for the article.

Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jclinepi.2019.03.006.

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