

Submitting the original participant information letter as supplementary material of a trial report is useful and can be easily implemented

Citation for published version (APA):

Kotz, D., Viechtbauer, W., Spigt, M., & Crutzen, R. (2020). Submitting the original participant information letter as supplementary material of a trial report is useful and can be easily implemented. *Journal of Clinical Epidemiology*, 117, 151-153. <https://doi.org/10.1016/j.jclinepi.2019.09.013>

Document status and date:

Published: 01/01/2020

DOI:

[10.1016/j.jclinepi.2019.09.013](https://doi.org/10.1016/j.jclinepi.2019.09.013)

Document Version:

Publisher's PDF, also known as Version of record

Document license:

Taverne

Please check the document version of this publication:

- A submitted manuscript is the version of the article upon submission and before peer-review. There can be important differences between the submitted version and the official published version of record. People interested in the research are advised to contact the author for the final version of the publication, or visit the DOI to the publisher's website.
- The final author version and the galley proof are versions of the publication after peer review.
- The final published version features the final layout of the paper including the volume, issue and page numbers.

[Link to publication](#)

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal.

If the publication is distributed under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license above, please follow below link for the End User Agreement:

www.umlib.nl/taverne-license

Take down policy

If you believe that this document breaches copyright please contact us at:

repository@maastrichtuniversity.nl

providing details and we will investigate your claim.

<https://doi.org/10.1016/j.jclinepi.2019.09.014>

Submitting the original participant information letter as supplementary material of a trial report is useful and can be easily implemented



We thank Dal-Ré et al. for their response [1] to our commentary [2] and for participating in the discussion about

DOI of original article: <https://doi.org/10.1016/j.jclinepi.2019.09.014>.

Conflict of interest statement: The authors declare to have no conflict of interest.

reporting of informed consent procedures in the context of clinical trials.

The proposal we made was two fold: (a) essential features of how potential participants were informed about a trial should be briefly summarized in the methods section of the trial report and (b) the full, original participant information letter should be published alongside the report as supplementary material [2].

We agree with Dal-Ré et al. that seeking informed consent is a process; that the participants' information letter is only part of that process; and that more information about the actual implementation of the informed consent process would be valuable. However, we disagree with the following points.

First, Dal-Ré et al. seem to suggest that we are concerned with participants being “insufficiently informed” about the nature of a trial. We made no such claim in our letter. We agree that the responsibility of a formal judgment of the informed consent procedure lies with the ethical review committee, who should take into account the applicable laws and guidelines. They should judge whether the informed consent procedure was according to these standards. However, our main concern was not the legal aspect of the informed consent procedure. We are concerned that the little information about the informed consent procedure typically provided in trial reports is insufficient to allow readers of the trial to assess whether the procedure might have introduced bias or the degree to which the procedures might have affected participant behavior.

More precisely, the rationale behind our proposal was that the information given to potential participants may affect (a) their decision to take part in a trial and (b) their behavior during the trial. Dal-Ré et al. seem to miss this aspect when they say “... since any deficiency on the quality of a [participant information letter] would have affected all trial participants—regardless the treatment received”. We kindly disagree. If at all, this statement would only apply to double-blind placebo-controlled trials. In trials where such blinding is not possible, bias can be introduced when participants know which intervention they are going to receive or not going to receive (through low uptake of, or adherence to, an intervention; contamination; attrition etc.). For example, somebody might be interested in an intervention aimed at weight reduction, but not be motivated to exercise daily [3]. If the information letter informs participants about the focus of the intervention in one of the study arms being on exercise, then this might increase the chances that participants in this study arm are more likely to (a) stop taking part in the trial after they have been randomized. This differential attrition is a common problem in, for example, health behavior change trials [4]. In a previous study, we also found that information received beforehand affected (b) the way in which participants in a trial behaved on a patient information website about hepatitis A, B, and C virus infections [5].

Second, we also disagree with the argument that the implementation of our proposal would be too costly. Publishing the original participant information letter as supplementary material comes at no cost at all. Researchers from non-English speaking countries could, in addition, decide to translate their letter into English. The cost for this would be marginal in relation to the cost of the trial. Regardless, we only suggested that it would be ideal if a translation was provided. If doing so is deemed too costly or demanding, the original letter can always be provided. Interested readers could then use the original letter and translate it at their own cost. The same applies to any other regulations or guidelines relevant for the informed consent procedure.

To conclude, we still believe that our aforementioned proposal is useful because having access to the original participant information letter from a trial gives readers more information about the manner in which participants were informed about a trial than having no access to it. The letter serves as a basis for the discussion between potential participants and investigators, and as there is no verbatim record of the actual discussions, it serves as a proxy for the information that potential participants received. Our proposal is therefore a good step into the right direction, and a step which could be easily implemented.

Acknowledgments

The authors have not received any funding for the current report.

Daniel Kotz*

*Institute of General Practice
Addiction Research and Clinical Epidemiology Unit
Medical Faculty of the Heinrich-Heine-University
Düsseldorf, Germany
Department of Family Medicine
CAPHRI School for Public Health and Primary Care
Maastricht University
The Netherlands*

Wolfgang Viechtbauer

*Department of Psychiatry and Neuropsychology
School for Mental Health and Neuroscience
Maastricht University*

Mark Spigt

*Department of Family Medicine
CAPHRI School for Public Health and Primary Care
Maastricht University
The Netherlands*

Rik Crutzen

*Department of Health Promotion
CAPHRI School for Public Health and Primary Care
Maastricht University
The Netherlands*

*Corresponding author. Institute of General Practice, Addiction Research and Clinical Epidemiology Unit,

Medical Faculty of the Heinrich-Heine-University
Düsseldorf, P.O. Box 101007, 40001 Düsseldorf, Germany.

Tel.: +49-211-81-16327; fax: +49-211-81-08622.

E-mail address: Daniel.Kotz@med.uni-duesseldorf.de (D. Kotz)

URL: <https://www.daniel-kotz.de>

Twitter: @daniel_kotz (D. Kotz)

References

- [1] Dal-Re R, Solberg B, Fuhr U, Eriksson S. Reporting the details of consent procedures in clinical trials. *J Clin Epidemiol* 2019.
- [2] Kotz D, Viechtbauer W, Spigt M, Crutzen R. Details about informed consent procedures of randomized controlled trials should be reported transparently. *J Clin Epidemiol* 2019;109:133–5.
- [3] Crutzen R, Rutter R. Interest in behaviour change interventions: a conceptual model. *Eur Health Psychol* 2015;17(1):6–11.
- [4] Crutzen R, Viechtbauer W, Spigt M, Kotz D. Differential attrition in health behaviour change trials: a systematic review and meta-analysis. *Psychol Health* 2014;30(1):122–34.
- [5] Crutzen R, Rutter RA, de Vries NK. Can interest and enjoyment help to increase use of Internet-delivered interventions? *Psychol Health* 2014;29(11):1227–44.

<https://doi.org/10.1016/j.jclinepi.2019.09.013>

Letter in response to: Cooper et al. Established search filters may miss studies when identifying randomized controlled trials [J Clin Epidemiol. 2019 Apr 13;112:12-19. doi: 10.1016/j.jclinepi.2019.04.002]. Language for trial phase necessary when searching for RCT



We read “Established search filters may miss studies when identifying randomized controlled trials” [1] with interest. The authors highlight an important shortcoming in the two search filters used in their case study; however, we question whether the study would have benefited from considering additional search filters which are more frequently utilized in systematic reviews.

The authors identified their chosen search filters from the “ISSG Search Filters Resource” [2] which provides an extensive list published filters. The authors also provide their rationale for choosing the search filters used in the case study; however, we question why, if the authors had noticed phase 3 trials not identifying themselves as randomized in the title or abstract, they did not assess the effectiveness of search filters that have made some attempt to capture studies with limitations in their reporting.

Two examples of such filters which are available for both Medline and Embase, and which are regularly maintained by recognized groups, are those produced by the Scottish Intercollegiate Guidelines Network (SIGN) [3]

and the Canadian Agency for Drugs and Technology in Health (CADTH) [4]. It was noted for instance that the CADTH filter was updated at the end of April 2019 to include the very terms that Cooper et al. suggest to capture phase 3 trials. Even before this update, we believe that the breadth of terms used by both SIGN and CADTH would capture studies even if the term “random” was not utilized in the title or abstract.

For example, the SIGN filter includes the following:

- clinical trial, phase I.pt [pt = publication type];
- clinical trial, phase II.pt;
- clinical trial, phase III.pt;
- clinical trial, phase IV.pt.

And the CADTH filter includes the following:

- (random* or sham or placebo*).ti,ab,hw,kf,kw.
- ((singl* or doubl*) adj (blind* or dumm* or mask*).ti,ab,hw,kf,kw.
- ((tripl* or trebl*) adj (blind* or dumm* or mask*).ti,ab,hw,kf,kw.
- (control* adj3 (study or studies or trial* or group*).ti,ab,hw,kf,kw.
- ((open label or open-label) adj5 (study or studies or trial*).ti,ab,hw,kf,kw.

It is important reviewers understand the limitations which are undoubtedly present in any search filter. The authors’ findings highlight the importance of selecting the most appropriate “established” search filter when starting a new systematic review and the need for constant search filter development.

Juliette C. Thompson
Visible Analytics Ltd, Oxford, UK

David A. Scott
*Visible Analytics Ltd
Oxford, UK
Diabetes Research Centre
University of Leicester
Leicester, UK*

*Corresponding author. Tel.: +44 (0)1865 606333.
E-mail address: juliette.thompson@visibleanalytics.co.uk (J.C. Thompson)

References

- [1] Cooper C, Varley-Campbell J, Carter P. Established search filters may miss studies when identifying randomized controlled trials. *J Clin Epidemiol* 2019;112:12–9.
- [2] ISSG Search Filters Resource. Available at <https://sites.google.com/a/york.ac.uk/issg-search-filters-resource/home>. Accessed June 25, 2019.
- [3] Search filters. Available at <https://www.sign.ac.uk/search-filters.html>. Accessed June 25, 2019.