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ORIGINAL ARTICLE

Established search filters may miss studies when identifying randomized controlled trials

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Abstract

Objectives: The authors were becoming increasingly aware of studies reporting randomized controlled trial (RCT), which reported trial phase but did not mention study design or randomization in the title or abstract. The objective of this study was to determine if established RCT literature search filters should include terms for trial phase.

Study Design and Setting: This study is a case study. A search filter for trial phase (the P3 filter) was developed, and its sensitivity, efficiency, and value were determined when compared with two established RCT literature search filters (The Cochrane Highly Sensitive Search Strategies [HSSS] and the Royle and Waugh Brief RCT Search Strategy [BRSS]) in the year 2015—improved sensitivity was determined where the P3 filter identified studies missed by either of the established filters; efficiency was determined by the number needed to read; and the Cochrane risk of bias tool was used to determine study quality as a proxy for value.

Results: Both established filters missed studies. The HSSS missed one RCT and four follow-up RCT studies. The BRSS missed one RCT and five follow-up RCT studies. Study quality was unclear.

Conclusion: Established RCT literature search filters may miss studies where trial phase is reported instead of terms for study design or randomization. The P3 filter can be incorporated to improve sensitivity.

Keywords: Literature searching; Randomised controlled trials; RCT; Search filters; Literature search effectiveness; Systematic reviews

1. Introduction

Although undertaking systematic reviews of intervention effectiveness and reviewing industry submissions as part of the Single Technology Appraisal process in the United Kingdom, the authors were becoming increasingly aware of a tendency for study authors to report randomized controlled trials (RCTs), not by study design or process of randomization, but by trial phase. This meant that an RCT was referred to as a phase III (or phase 3) study, with no mention of study design (i.e., controlled trial) or the method of randomization used. We informally observed this in original reports of studies and for follow-up or pooled analysis of RCT.

Specific reporting guidance has been developed to aid study authors when reporting RCT. Consolidated Standards of Reporting Trials (CONSORT) guidance recommends identifying the report of a trial using the term ''trial'' in the title of the study (CONSORT guidance 1a) and using a structured summary in the abstract to report aspects of trial design and study methodology (CONSORT guidance 1b) [1]. The use of CONSORT has been linked to improving the effectiveness and efficiency of literature searching for RCT [1−4]. CONSORT reporting guidance works hand-in-hand with corresponding advances in biomedical databases (namely, the introduction of indexing terms for studies reporting RCT into MEDLINE and EMBASE [5], the creation of Cochrane's CENTRAL register

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The initial draft of this study and preliminary findings based on title or abstract screening were presented at HTAi (2016) in Tokyo by C.C. based on work by C.C., Simon Briscoe, and Louise Crathorne. C.C. attended HTAi with funding from the PenTAG HTA (Project Number 16/54/11). The principal investigator of the grant at the time was Prof. Chris Hyde.

This paper extends the work presented there. The screening was entirely redone in 2018 and 100% double-screened at title or abstract and full text. Study quality was also determined. The literature searching, screening, and quality appraisal were undertaken by C.C. and J.V.-C. P.C. acted as third reviewer.

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What is new?

Key findings

- Established study design literature search filters for RCT miss studies where authors report study phase (i.e., ''this was a phase 3 trial'') as opposed to study design or methodological terminology.

What this adds to what is known?

- We developed, tested, and report the P3 search filter. The P3 search filter can be incorporated into established study design literature search filters for RCT to identify studies that report RCT but do not follow CONSORT reporting guidance.

What is the implication and what should change now?

- In systematic reviews of intervention effectiveness it is imperative to identify all relevant studies to produce a reliable estimate of intervention effectiveness. Our findings suggest that researchers undertaking intervention effectiveness reviews should incorporate the P3 filter in their literature searching to ensure a comprehensive identification of studies.

of controlled clinical trials [6,7], and the retrospective ''retagging'' of relevant study records in MEDLINE and EMBASE [8−10]), which has developed the process of literature searching in intervention effectiveness systematic reviews and it has paved the way for the use of study design literature search filters to identify studies reporting RCTs [11−15].

A study design literature search filter is a predetermined (and preferably validated) list of study design or methodological search terms likely to appear in the title or abstract of relevant studies [16−21]. Search filters used to identify RCT and studies reporting RCT focus on key methodological aspects commonly found in trials, such as ''random'' to indicate randomization, ''trial'' to indicate that a trial has taken place, or ''placebo'' to indicate a comparator or nonactive treatment. The presence of these terms in a study design literature search filter then ''mesh'' with the report of the study in the title, abstract, and bibliographic indexing terms to ensure that relevant studies are identified for screening.

Where study authors do not adhere to CONSORT reporting guidance, for example, by labeling a study by trial phase not study design, it may affect the operating characteristics of study design literature search filters for RCTs. This is potentially problematic for study identification in health technology assessment (HTA), and other reviews of intervention effectiveness, such as Cochrane systematic reviews, which prioritize RCT as their primary unit of analysis [22]. It could mean that potentially relevant studies are missed in literature searching where study design literature search filters are used, and that studies and study data are omitted in systematic reviews, leading to incomplete estimates of intervention effectiveness.

2. Study aim and objectives

The aim of this study was to test the hypothesis that including search terms for study phase in addition to study design or methodological search terms improves the sensitivity of RCT study design literature search filters.

The objectives of this study were as follows:

(1) To develop a set of search terms to identify studies reporting by trial phase. These search terms will be represented as a search filter called the P3 filter, where P represents study phase, and 3 indicates the trial phase;
(2) To determine if the use of the P3 filter improves the sensitivity of two established RCT literature search filers (i.e., does the inclusion of the P3 filter identify relevant studies missed by two RCT literature search filters); and
(3) To determine the efficiency of study identification and value of any studies identified by the P3 filter missed by the two established RCT literature search filters.

3. Methods

The methods set out below relate to the three objectives enumerated above.

3.1. Objective 1: developing the P3 filter

A search filter to identify studies reporting by trial phase (but not identifying by study design) was developed for the database MEDLINE (Ovid interface).

This search filter is set out in Figure 1 in the form of a search narrative [23,24]. Search narratives aim to define the conceptual and contextual purpose of literature searches [23]. In this instance, it explains the decision-making behind the development of the P3 search filter.

The search filter was checked using the PRESS checklist by the study coauthors [25,26]. No issues or amendments were identified.

3.2. Objective 2: to determine if the use of the P3 filter improves the sensitivity of two well-known RCT literature search filers

Two established RCT literature search filters were selected by the study authors from the ISSG Search Filters resource [27]. The search filters chosen were as follows:

(1) The Cochrane Highly Sensitive Search Strategies (HSSS). The HSSS were written and developed by

Conceptual purpose: The purpose of this search filter is to identify studies that report RCT by trial phase (i.e. Phase 3) but which do not report study design terminology (i.e. trial or controlled or randomisation). We aim that this filter be combined with established literature search filters for RCTs to increase sensitivity in study identification.

Database: MEDLINE
Host: Ovid
Data Parameters: 1946 to October 23, 2018
Date Searched: Friday October 26th 2018
Searched: CC PRESS Checked by: JVC

Search strategy	Search Narrative
1 clinical trial, phase iii/ (14273)	Line one represents MeSH (controlled indexing language for the database MEDLINE) for phase III clinical trials. The number reported in parentheses (14273) is the number of studies identified by this specific search line.
2 ("Phase 3" or "phase3" or "phase III" or P3 or "PIII").ti,ab,kw. (59575)	Line two represents free-text terminology for trial phase. Free-text terminology means that the words identified in parenthesis in line two will be searched in the title (ti), abstract (ab), or author generated keywords (kw). Any incidence of any of these terms will be identified in the fields specified.
3 1 or 2 (64807)	The MeSH and free-text terminology are combined at line 3 using the Boolean connector OR. This means that either or both items will be identified.

Fig. 1. The P3 filter.

Carol Lefebvre and were first published in 1994 [8,22] (Fig. 2). The HSSS filters were selected based on their widespread use for Cochrane systematic reviews and in other types of systematic reviews. The sensitivity and precision-maximizing version of the HSSS were selected following the guidance of the Cochrane Handbook since the sensitivity-maximizing version of the HSSS produced an unmanageable number of studies to process [22];

The Cochrane HSSS RCT literature search filter
1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. clinical trials as topic.sh.
6. randomly.ab.
7. trial.ti.
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. exp animals/ not humans.sh.
10. 8 not 9

Ovid search syntax
.pt. denotes a Publication Type term
.ab. denotes search in abstract
.ti. detonates search in title
.shj. denotes subject heading
.sh. denotes a Medical Subject Heading (MeSH) term
.ti. denotes a word in the title

Roy le and Waugh BRSS RCT literature search filter
1. Random$.af.

Ovid search syntax
.af. denotes all fields
$ denotes truncation

Fig. 2. The Cochrane HSSS and Royle and Waugh BRSS search filter.

(2) The Royle and Waugh search filter (Brief RCT Search Strategy [BRSS]) [4]. The BRSS was developed by Royle and Waugh and published in 2005 [4] (Fig. 2). Royle and Waugh argued that the Cochrane collaboration had undertaken the exhaustive work to identify and report trials in CENTRAL, and CONSORT reporting guidance has since improved the visibility of trials generally that a simple search of MEDLINE and EMBASE using the filter Random$.af., and a search of CENTRAL, is now sufficient to identify RCT for systematic reviews in most cases [4]. This filter was selected based on its ease of use (one search line compared with 10 in the HSSS) and the strength of its operating characteristics as reported in the validation study by the authors [4].

To determine any improvement in sensitivity, a systematic search and double-screening of studies identified were undertaken in MEDLINE (Ovid interface).

3.2.1. Study identification

Rather than select a population, intervention, or topic area to focus on, which would limit the scope for evaluation to a specific context, a year was selected at random from the last 20 completed years (1997–2017). This provides a broader scope, across a range of clinical areas, to test the study objectives. Each of the last completed years (i.e., 1997–2017) were entered into Microsoft Excel sequentially and then randomized. The year 2015 was reported in the top cell after randomization.

The database used for testing was MEDLINE (Ovid interface). The following search logic was used to complete the search:

(1) HSSS search filter
(2) The P3 search filter
(3) 2 NOT 1
(4) Limit 3 to 2015

This process was repeated for the BRSS filter. The results of both searches were kept separate for screening.

3.2.2. Screening

All studies were independently screened by two reviewers using the following criteria:

3.2.3. Title or abstract screening

- Include (1) study reported a phase 3 RCT or a follow-up report of an RCT or a posthoc analysis of an RCT;
- Include (2) if uncertainty around inclusion criteria 1 exists.
- Exclude: study reported was a cohort study, case series, study conducted on animals, or the study reported pooled analysis of two or more RCTs.

At full-text screening, the screening decision was binary: include if the study was a phase 3 RCT and exclude if not. The following definition of an RCT was used:

"A published or unpublished report of a study in which a number of individuals (or other units) are prospectively randomised and allocated to 1 or 2 (or more) groups to test a specific technology, treatment or device" [22,28].

3.3. Objective 3: to determine the value of any studies identified by the P3 filter and missed by the RCT literature search filters

An increase in sensitivity would be represented by the identification of any study meeting inclusion at full text, which was missed by either of the established RCT study design literature search filters. To contextualize sensitivity, the efficiency of the P3 filter and the potential value of any relevant studies identified was determined.

3.3.1. Efficiency

The Number Needed to Read (NNR) was used to contextualize any improvement in sensitivity relative to any additional workload required to identify additional relevant studies. The NNR indicates the number of studies a researcher would need to read to identify a relevant study. It is calculated as 1/precision [21].

3.3.2. Value

The value of any missed studies was also measured. The Cochrane Risk of Bias tool was used to determine study quality as a proxy for study value [29]. All studies meeting inclusion at full text were independently appraised by the lead reviewer and checked for accuracy by a second reviewer.

4. Results

Literature searching was undertaken on April 7, 2018, and there were no reported problems with the bibliographic database MEDLINE (Ovid interface) on this day. PRISMA flowcharts are reported in supplementary material for each search filter.

4.1. The HSSS: objective 2

The P3 search filter identified 2,023 studies not identified by the HSSS. Of these, 1,983 were discarded at title or abstract as not meeting the inclusion criteria (interrater reliability for screening was 98%), and 40 studies were taken to full-text screening. Five studies met inclusion at full-text: one RCT [30] and four follow-up studies [31–34]. Table 1 reports study characteristics and the reason why studies were missed by the HSSS.

4.2. The BRSS: objective 2

The P3 search filter identified 2,256 studies not identified by the BRSS. Of these, 2,219 were discarded at title

Table 1. Studies identified by the P3 filter

	Study identified by filters					
Study	**BRSS**	**BRSS + P3**	**HSSS**	**HSSS + P3**	**Characteristics**	**Reason why missed**
Attard et al. 2015 [31]	X	√	X	√	Follow-up or new analysis of previously reported trial	No mention of randomization or study design in title or abstract. Not indexed as an RCT.
He et al. 2015 [32]	√	√	X	√	Follow-up or new analysis of previously reported trial	Indexed as "Randomized controlled Trials as Topic" and not as Randomized Controlled Trial.mp. (line 1 of the HSSS). No reference to placebo or randomization in the abstract (lines 4 and 6) and no reference to trial in the title (line 7).
Kim et al. 2015 [33]	X	√	X	√	Follow-up or new analysis of previously reported trial	No study indexing. No mention of randomization or study design in the title or abstract.
Kuhle et al. 2015 [35]	X	√	√	√	Follow-up or new analysis of previously reported trial[a]	No mentioned of randomization in the title or abstract.
Nasr et al. 2015 [30]	X	√	X	√	Randomized trial	No mention of randomization or study design in the title or abstract. Not indexed as an RCT.
Tarhini et al. 2015 [34]	X	√	X	√	Follow-up or new analysis of previously reported trial[a]	No mentioned of randomization or study design in the title or abstract.
Zhang et al. 2015 [36]	X	√	√	√	Follow-up or new analysis of previously reported trial	No mentioned of randomization or study design in the title or abstract.

Abbreviations: BRSS, The Royle and Waugh Brief RCT search strategy; HSSS, The Cochrane Highly Sensitive Search Strategies; RCT, randomized controlled trial.

[a] Study included at FT, no evidence of randomization in the paper but trial registry identified the study was an RCT.

or abstract as not meeting the inclusion criteria (interrater reliability for screening was 98.6%), and 37 studies were taken to full-text screening. Six studies met inclusion at full text: one RCT [30] and five follow-up studies [31,33–36]. Table 1 reports study characteristics and the reason why studies were missed by the BRSS.

4.3. Sensitivity, efficiency, and value: and objective 3

One study reporting an RCT was missed by both the HSSS and BRSS filter [30]. Naser et al. [30] were missed as it did not report either study design terms or terms for randomization in the title or abstract, and the study was not indexed as an RCT. We therefore find that the P3 search filter did improve the sensitivity of both the HSSS and BRSS RCT search filters. As reported previously, in terms of effectiveness, the NNR for HSSS was 1/2,023 and 1/2,256 for the BRSS filter.

Study quality was used as a proxy to interpret what value a missed study might add to a systematic review. The findings of the assessment of Risk of Bias are reported in Figure 3 for all studies. There is an unclear risk of bias for the majority of the domains assessed. Overall, it is unclear what the likely value would be of the RCT and follow-up studies should they have been missed in a systematic review.

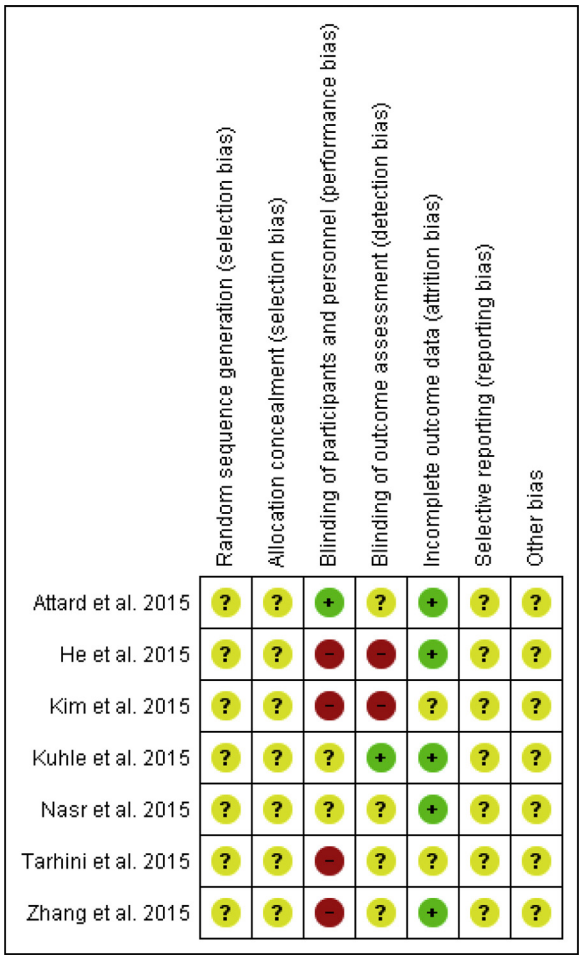

Fig. 3. Cochrane risk of bias for included studies.

5. Discussion

This study demonstrated that two established study design literature search filters for RCT missed one RCT and six follow-up RCT studies where study authors reported the phase of the trial (i.e., phase iii or phase 3) and not study design terminology (i.e., RCT).

5.1. What does our finding mean?

The results of this study demonstrate that the HSSS and BRSS RCT filters may not identify all potentially relevant studies where study authors neglect to use study design terminology or identify the process of randomization, following CONSORT reporting guidance. It would seem likely that this finding applies to other study design literature search filters for RCT, which also do not include search terms for study phase.

5.2. Is this an important finding?

In intervention effectiveness systematic reviews, yes. To generate a reliable estimate of intervention effect, it is important to identify all relevant studies in the literature search and include them in a systematic review [37]. Researchers have explored and demonstrated this by including and excluding studies from statistical meta-analysis, finding a change in the point estimate where relevant studies were omitted from meta-analysis [37]. This finding has generally been used to argue for the importance of comprehensive literature searches for systematic reviews of intervention effectiveness [38]. Understood in this specific context, missing any relevant, yet potentially accessible study, would be considered a limitation of study identification in the review process.

Six of the studies identified uniquely by the P3 filter were follow-up studies. The purpose of literature searching in intervention effectiveness reviews is to identify all relevant studies and study data; therefore, this finding reflects a potentially important finding in addition to the identification of an original study report. Follow-up studies often provide further or additional outcome data, which aid interpretation of the effectiveness of the intervention. This can be of particular importance in certain clinical situations in determining the long-term safety or effectiveness of new treatments, for example. In the currently controversial area of mesh surgery, 1-year effectiveness data [39] are not nearly as crucial as long-term complication data, which would only be reported in follow-up publications (e.g., a study by Milani et al. [40]).

Bibliographic database searching is indicated as the primary method of study identification in leading systematic

guidance documents [38]. Identifying these follow-up studies in the bibliographic database searches—as opposed to later in the process of a systematic review, through citation chasing included studies, for instance—allows for a more complete assessment of study data at an earlier stage of review. This may be more important than perceived, as citation chasing included studies is a step in the review process often not conducted, particularly when rapid reviews are undertaken.

5.3. What are the implications of this finding?

The findings that are presented are based on one case study and an example based on 1 year. Although these limitations are acknowledged, the principle implication of our findings is that the two established RCT literature search filters examined in this case study, missed studies because study authors did not follow CONSORT reporting guidance. To the best of our knowledge, other RCT search filters do not typically include terms that would cover the phase of the trial either.

The implication of our findings suggests that the P3 search filter should be incorporated alongside the study design literature search filters examined in this case study if a comprehensive or exhaustive identification of studies is the aim of literature searching. It is important to state, clearly, that the P3 filter should be used in addition to, and not in place of, any established RCT literature search filters.

Including the P3 filter will increase the number of studies to screen. It is not, however, anticipated to make a substantial difference because literature searches for intervention effectiveness systematic reviews commonly use the PICO mnemonic to structure their literature searches [38]. The NNR reported in this study overstates the likely number of studies to screen because we have not used population or intervention search terms in this experimental case study.

This study aimed to test a hypothesis of increased sensitivity in literature searching for RCT and infer if high- or low-quality studies were identified by the P3 but missed by the HSSS/BRSS. Incorporating an evaluation of study quality was an attempt to contextualize our findings, moving the interpretation of our results beyond purely quantitative outcomes (i.e., the P3 filter identified a greater number of relevant studies than the HSSS/BRSS) to explain why they matter and what they mean. It is likely that researchers may be asked to screen additional studies if the P3 filter is used, and this increase in resources (which we anticipate to be minor) needs to be suitably justified.

The quality of the studies uniquely identified is unclear, which does not help interpret the value of missing them through the HSSS/BRSS or identifying them via the P3. Six of the seven studies were follow-up studies, which referred to previously published papers where more details could be found on the methods. It is therefore likely that greater clarity on the risk of bias from each study could have been gathered through combining the assessment with these papers too. It was decided that, given the purpose of the risk of bias was to understand the value of the missed papers, that the risk of bias should only be conducted on the paper identified rather than all linked published papers as we would have done in a full systematic review.

This is a potential limitation because it only demonstrates the quality of the specific studies identified and not the effect of the study in the context of synthesis or meta-analysis. We are unable to determine the ‘‘true value’’ of the studies as a contribution to synthesis as has been done elsewhere [37,41] but extending the analysis of literature search evaluation beyond ‘‘more studies were identified’’ to explain ‘‘why this matters’’ is an important if yet imperfect area of development [42].

The findings of this study would suggest that study authors, particularly those reporting trials, may benefit from a reminder of CONSORT guidance. This may take the form of greater diligence from editors and peer reviewers to comment on and ensure that CONSORT reporting guidance is followed by study authors. The findings identified in this study are not a criticism of the RCT literature search filters but rather an identification of issues in study reporting to which a solution is required in intervention effectiveness systematic reviews.

The implications identified are not limited to literature searching using RCT literature search filters. Study authors who have sought to test text mining or machine learning for trials identify similar issues with studies that do not follow CONSORT guidance (c.f. [43]). Moreover, clear reporting of methodological terms in the title and abstract may improve the effectiveness and efficiency of study identification in other areas of research, such as identifying studies reporting diagnostic or prognostic test evaluation.

5.4. Study limitations

We have conducted a robust and novel study; however, some limitations should be acknowledged.

Royle and Waugh suggest that the BRSS should be used in EMBASE in addition to searches of MEDLINE and CENTRAL [4]. The Cochrane Handbook suggests that EMBASE be searched where resources permit for the HSSS [22]. The work reported in this study was undertaken without any specific funding to support it; accordingly, our attention was focused on study identification in MEDLINE. The findings of this study appear to suggest that studies which report by trial phase and not methodological terms for study design may be missed by study design literature search filters. Because the focus is on the free-text terminology reported by study authors, it would seem unlikely that repeating this analysis in EMBASE would alter the findings of this study, but we acknowledge this limitation.

It is possible that the studies missed by RCT literature search filters may have been identified by other

nondatabase search methods in a systematic review. It is important to acknowledge that literature searching is a holistic approach to study identification, drawing on a variety of search methods, to identify relevant studies and study data for review. It is, however, also acknowledged that many systematic reviews, particularly when conducted under tight resource and time constraints, rely entirely on the database search and do not conduct further levels of searching. There is also some potential advantage in identifying studies and study data in the early stages of review as opposed to later and by nondatabase search methods.

6. Conclusions

Researchers who aim to identify studies reporting RCT should be aware that established RCT literature search filters may miss studies where the terminology of study design or process of randomization is not reported in the study.

Researchers may, accordingly, be advised to incorporate search terms for trial phase in addition to using RCT literature search filters to ensure the comprehensiveness of their literature searches. An initial suggestion for a search filter to identify Phase III trials is presented in this study, which can easily be adapted to include or exclude other phases and incorporated for use alongside existing RCT search filters.

Authors of studies reporting RCT would be reminded of the importance of following CONSORT reporting guidance when reporting RCT because this relates to the effective and efficient identification of their studies.

CRediT authorship contribution statement

Chris Cooper: Conceptualization, Writing - original draft, Data curation, Formal analysis, Investigation, Methodology, Writing - review & editing. **Jo Varley-Campbell:** Data curation, Formal analysis, Investigation, Methodology, Writing - review & editing. **Patrice Carter:** Formal analysis, Writing - review & editing.

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Supplementary data

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