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# BMJ Open

## Reporting of methodological studies in health research: a protocol for the development of the METHodological study ReportIng Checklist (METRIC)

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3 **1 Reporting of methodological studies in health research: a protocol for the development of**  
4 **2 the METHodological study ReportIng Checklist (METRIC)**

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51 **Word count:** 3798  
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3 46 **ABSTRACT**  
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5 47 **Introduction:** Methodological studies (i.e. studies that evaluate the design, conduct, analysis or  
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8 48 reporting of other studies in health research) address various facets of health research including,  
9  
10 49 for instance, data collection techniques, differences in approaches to analyses, reporting quality,  
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12 50 adherence to guidelines, or publication bias. As a result, methodological studies can help to  
13  
14 51 identify knowledge gaps in the methodology of health research, and suggest strategies for  
15  
16 52 improvement in research practices. Differences in methodological study names and a lack of  
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18 53 reporting guidance contribute to lack of comparability across studies, and difficulties in  
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20 54 identifying relevant previous methodological studies. This paper outlines the methods we will  
21  
22 55 use to develop an evidence-based tool—the METHodological study ReportIng Checklist  
23  
24 56 (METRIC)—to harmonize naming conventions and improve the reporting of methodological  
25  
26 57 studies.  
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30 58 **Methods and analysis:** We will search for methodological studies in the Cumulative Index to  
31  
32 59 Nursing and Allied Health Literature, Cochrane Library, Embase, MEDLINE, Web of Science,  
33  
34 60 check reference lists, and contact experts in the field. We will extract and summarize data on the  
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36 61 study names, design, and reporting features of the included methodological studies. Consensus  
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38 62 on study terms and recommended reporting items will be achieved via video conference  
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40 63 meetings with a panel of experts including researchers who have published methodological  
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42 64 studies.  
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46 65 **Ethics and dissemination:** The consensus study has been exempt from ethics review by the  
47  
48 66 Hamilton Integrated Research Ethics Board. The results of the review and the reporting guideline  
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50 67 will be disseminated in stakeholder meetings, conferences, peer-reviewed publications, in  
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3 68 requests to journal editors (to endorse or make the guideline a requirement for authors), and on  
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5 69 the EQUATOR Network and METRIC websites.  
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8 70 **Registration:** We have registered the development of METRIC with the EQUATOR Network,  
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10 71 and publicly posted this project on the Open Science Framework ([www.osf.io/9hgbq](http://www.osf.io/9hgbq)).  
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For peer review only



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3 72 **STRENGTHS AND LIMITATIONS OF THIS STUDY**  
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- 5 73 • To the best of our knowledge, this is the first study to design an evidence-based tool to  
6  
7 support the complete and transparent reporting of methodological studies in health research.  
8 74  
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10 75 • This project will help to highlight the current reporting practices of authors of  
11  
12 methodological studies to outline a list of key reporting items.  
13 76  
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15 77 • The stakeholders recruited for the consensus study will represent a diverse group of expert  
16  
17 health research methodologists including biostatisticians, clinical researchers, journal  
18 78  
19 editors, healthcare providers, and reporting guideline developers.  
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22 80 • Our study does not incorporate a blinded consensus process and this may impact the flow of  
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24 discussions during the conference meetings.  
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## 82 INTRODUCTION

83 Concerns with the quality and quantity of research have sparked interest in the rapidly evolving  
84 field which has been called meta-epidemiology, meta-research, or research-on-research [1-3].  
85 This field of research addresses the entire research process, from question development to  
86 design, conduct and reporting issues, and most often uses research-related reports (e.g. protocols,  
87 published manuscripts, registry entries, conference abstracts) as the unit of analysis. These  
88 studies have also been previously described as systematic reviews that “(1) describe the  
89 distribution of research evidence for a specific question; (2) examine heterogeneity and  
90 associated risk factors; and (3) control bias across studies and summarize research evidence as  
91 appropriate” [4]. For the purpose of this project, we will refer to these research outputs as  
92 “methodological studies”, i.e. studies that evaluate the design, conduct, analysis (including bias),  
93 or reporting of other studies in health research. This definition does not include statistical  
94 methodological studies (e.g. studies testing new algorithms or analytical methods, simulation  
95 studies, and experimental studies in which the unit of analysis is not a research report).  
96 Methodological studies are important because they can identify gaps, biases, and inefficiencies in  
97 research practices, and propose improvements and solutions. A PubMed search performed in  
98 April 2020 for terms often used to describe methodological studies suggests that the rate of  
99 publication of methodological studies has increased over time, illustrated in Figure 1.

100 — Figure 1. Trends in methodological studies indexed in PubMed from 2009 to 2019. —

101 In the past 20 years, methodological studies have influenced the conduct of health  
102 research by informing many popular practices such as double data extraction in systematic  
103 reviews [5]; optimal approaches to conducting subgroup analyses [6]; and reporting of  
104 randomized trials, observational studies, pilot studies, and systematic reviews [7-10] to name a

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3 105 few. Methodological studies have played an important role in ensuring that health research is  
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5 106 reliable, valid, transparent and replicable. These types of studies may investigate: bias in research  
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7 107 [11, 12], quality or completeness of reporting [13, 14], consistency of reporting [15], methods  
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9 108 used [16], factors associated with reporting practices [17]; and may provide summaries of other  
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11 109 methodological studies [18], and other issues. Methodological studies may also be used to  
12  
13 110 evaluate the uptake of methods over time to investigate whether (and where) practices are  
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15 111 improving and allow researchers to make comparisons across different medical areas [19, 20].  
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17 112 These studies can also highlight methodological strengths and shortcomings such as sample size  
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19 113 calculations in randomized controlled trials [21, 22], quality of clinical prediction models [23],  
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21 114 and spin and over-interpretation of study findings [24-26]. As such, methodological studies  
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23 115 promote robust, evidence-based science and help to discard inefficient research practices [27]. A  
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25 116 draft conceptual framework of the various categories of methodological studies that we have  
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27 117 observed is outlined in Figure 2. Broadly, some categories of methodological studies include  
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29 118 those investigating: bias and spin, methodological approaches to study design, or reporting  
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31 119 issues.

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38 120 — Figure 2. Draft conceptual framework of categories of methodological studies. —  
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40 121 Despite the importance of methodological studies, there is no guidance for their  
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42 122 reporting. Murad and Wang have suggested a modification to the Preferred Reporting Items for  
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44 123 Systematic Reviews and Meta-Analyses (PRISMA), a widely used reporting tool that is  
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46 124 sometimes used for methodological studies because these studies often use methods that are also  
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48 125 used in systematic reviews [28]. Although useful for reporting some aspects of methodological  
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50 126 studies, the modified PRISMA approach does not fully address the many types of questions that  
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52 127 methodological studies attempt to answer, and the specific methods and results of these studies.  
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3 128 Studies that include a random sample of research reports [29], or those structured as before-after  
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5 129 investigations [19] are examples of methodological studies that would be a poor fit for the  
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8 130 modified PRISMA tool, which is best suited for studies designed in the style of systematic  
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10 131 reviews. Likewise, studies in which the unit of analysis is not the “study” require more specific  
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12 132 guidance (e.g. when investigating multiple subgroup analyses or multiple outcomes within the  
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15 133 same study) [30]. Thus, guidelines for transparent reporting of methodological studies are  
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17 134 needed, and this need is widely acknowledged in the scientific community [31, 32]

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19 135 Our work will address two main concerns:

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21 136 1. There are no globally accepted names for methodological studies, making them difficult to  
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23 137 identify. Methodological studies have been called ‘methodological review’, ‘systematic  
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25 138 review’, ‘systematic survey’, ‘literature review’, ‘meta-epidemiological study’ and many  
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27 139 other names. The diversity in names compromises training and educational activities [33], and  
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29 140 it makes it difficult for end-users (e.g. clinical researchers, guideline developers) to search for,  
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31 141 identify and use these studies [34, 35].
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33 142 2. The reporting of methodological studies is inconsistent, which may relate to differences in  
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35 143 objectives, and to differences in transparency and completeness. That is, some studies may be  
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37 144 better reported than others. While the most appropriate approach to reporting will depend on  
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39 145 the research question, explicit, user-friendly, and consensus-based guidance is needed to  
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41 146 ensure that methodological studies are reported transparently and comprehensively [36].

#### 42 43 44 45 46 147 ***Aims***

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49 148 The aims of this study protocol are to outline the procedures to define and harmonize the names  
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51 149 describing methodological studies, and to develop reporting guidelines for methodological  
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53 150 studies in human health research.  
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## 151 **METHODS AND ANALYSIS**

### 152 *Study design*

153 We have adopted the strategy for the development of reporting guidelines proposed by Moher et  
154 al. [37]. A visual overview of this approach, highlighting key components of the process, is  
155 presented in Figure 3. The three parts of the project which will be addressed using the above  
156 strategy are outlined in detail below (see Supplementary File for an outline of the data flow  
157 informing subsequent parts of the project).

158 — Figure 3. Project overview for the development of reporting guidelines for methodological  
159 studies in health research. —

### 160 **Part 1: Methodological Review**

161 The objectives of this part are to: a) identify names used to describe methodological studies, b)  
162 identify the various designs, analysis and reporting features of methodological studies, c) find  
163 any previous reporting guidance, and d) identify methodological study experts.

### 164 *Search strategy*

165 We developed a search strategy informed by our pilot work [38] targeting health-related sciences  
166 and biomedicine databases: Cumulative Index to Nursing and Allied Health Literature  
167 (CINAHL), Cochrane Library, Excerpta Medica (Embase), MEDLINE, and Web of Science. We  
168 will limit our search to the last complete ten years (2009-2019). There will be no limits by  
169 publication type or language. We will perform searches for authors known to publish in this  
170 field, check reference lists of relevant studies, check existing methodological study repositories  
171 (Studies Within a Trial [SWATs] and Studies Within a Review [SWARs]), preprints (bioRxiv  
172 and medRxiv), setup Google Alerts for key words (e.g. meta-epidemiology, research-on-  
173 research), and contact experts (e.g. via email, meetings, following relevant journals, subscribing

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3 174 to methods email newsletters including the Methods in Research on Research [MiRoR] and the  
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5 175 National Institute for Health and Care Excellence [NICE] groups, and following researchers on  
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7 176 social media platforms such as ResearchGate and Twitter) to identify additional methodological  
8  
9 177 studies. We will also check the EQUATOR library to identify any published or under  
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11 178 development reporting guidance. These approaches are informed by previous work and  
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13 179 published literature [35, 38]. Two health sciences librarians at the Health Sciences Library  
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15 180 (McMaster University) were consulted and reviewed the final search strategy (see  
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17 181 Supplementary File) in line with the Peer Review of Electronic Search Strategies (PRESS)  
18  
19 182 framework [39].  
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### 24 183 ***Eligible studies***

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26 184 Studies that investigate methods—design, conduct, analysis, or reporting—in other studies of  
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28 185 health research in humans will be eligible. The ‘other studies’ (or research reports) refers to the  
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30 186 unit of analysis of the methodological studies (e.g. abstracts, cohort studies, randomized trials,  
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32 187 registry records, study protocols, systematic reviews). Only published protocols and final reports  
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34 188 of studies that investigate methods will be eligible. Statistical methodological studies will not be  
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36 189 eligible (e.g. studies testing new algorithms/analytical methods and simulation studies in which  
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38 190 the unit of analysis is not another research report).  
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### 42 191 ***Screening***

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44 192 A team of reviewers led by DOL will screen titles and abstracts independently, in duplicate in  
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46 193 *Rayyan* [40], and full-texts in standardized forms in *DistillerSR* [41]. Both are online  
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48 194 collaborative platforms for screening and reviewing literature. We will measure agreement on  
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50 195 screening and study inclusion using Cohen’s Kappa statistic [42, 43]. Any discrepancies between  
51  
52 196 reviewers will be resolved through discussion.  
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197 **Data extraction**

198 In order to document the current reporting practices we will extract data from included studies  
 199 independently, in duplicate based on a standardized data collection form. Key data extraction  
 200 fields for documenting methodological study features and reporting practices (e.g. study design  
 201 name, databases search, any guideline use) are outlined in Table 1. All data will be compiled in  
 202 *DistillerSR*. Any discrepancies between reviewers will be resolved through discussion.

203 **Table 1.** Overview of data extraction fields for the review.

Section	Data to be collected
Bibliometrics	<ul style="list-style-type: none"> <li>• Corresponding or last author (first and last name) and contact information (email address). We will first verify whether the corresponding author has academic faculty status, and if not, we will contact the last author</li> <li>• Country of author</li> <li>• Publication year</li> <li>• Study design name in title (verbatim quotation/descriptor)</li> <li>• Type of article (protocol or final publication, and letter/brief report or full publication)</li> <li>• Journal</li> </ul>
Methods	<ul style="list-style-type: none"> <li>• Study design name in methods section (verbatim quotation/descriptor)</li> <li>• Objectives (verbatim quotation)</li> <li>• Outcomes (verbatim quotation)</li> <li>• Search strategy reported (yes/no)</li> <li>• Search time limits and justifications (yes/no and verbatim quotation)</li> <li>• Databases searched</li> </ul>

	<ul style="list-style-type: none"> <li>• Included research report types (e.g. randomized trials, systematic reviews, cohort studies)</li> <li>• Sampling method (where applicable)</li> <li>• Analysis type (e.g. correlation, descriptive, regression, time-series)</li> <li>• Reporting guidance used and justification (yes/no, name and verbatim quotation)</li> <li>• Prospective registration and existence of a published protocol (yes/no, where applicable)</li> </ul>
Results	<ul style="list-style-type: none"> <li>• Presence of flow diagrams (yes/no)</li> <li>• Total records screened and included</li> <li>• Type of final synthesis performed (qualitative, quantitative, both)</li> </ul>
Discussion	<ul style="list-style-type: none"> <li>• Intended use of findings (verbatim quotation)</li> <li>• Limitations (verbatim quotation)</li> </ul>
Other	<ul style="list-style-type: none"> <li>• Conflicts of interest (yes/no)</li> <li>• Funding type (e.g. industry, institutional, non-profit)</li> <li>• Provide access to data (yes/no)</li> </ul>

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205 All reviewers will undergo calibration exercises and pilot the screening and data  
 206 collection forms (25 studies per reviewer). We will incorporate an emergent design in the data  
 207 collection stage of the review, which is characterized by a flexibility in the methodology,  
 208 allowing researchers to remain open to modifications [44]. Should any new information that is of  
 209 interest arise during the full-text screen or data extraction, we will update the data collection  
 210 form and collect this information for all studies retrospectively and going forward. Any  
 211 modifications to the present protocol will be reported in the final published review. This iterative  
 212 approach will allow for the capture of information as new methodological study design features



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3 213 come to light during the full-text screening and data extraction phases. Based on this approach,  
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5 214 data extraction will be updated accordingly for previously reviewed studies as needed. For  
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8 215 example, we expect to see overlaps in methodological study names, some of which might be  
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10 216 attributed to collaborating research groups. There also appear to be similarities in methodological  
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12 217 study reporting styles that are borrowed from systematic review [4] or survey study designs,  
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14 218 which have both been extensively developed and are omnipresent in health research literature.  
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17 219 However, if the current data collection fields, listed in Table 1, are insufficient to capture the  
18  
19 220 nuances of the varieties of methodological studies, we will revise our data collection forms  
20  
21 221 accordingly and collect the data for all studies.

### 22 223 ***Generation of a list of candidate items***

23  
24 223 The generation of a list of candidate items will be informed by two sources. First, a list of  
25  
26 224 reporting items will be compiled based on what has been reported by authors of the included  
27  
28 225 studies in the methodological review (e.g. flow diagram, search strategy). We will also note the  
29  
30 226 use of any reporting guidance as mentioned by authors (e.g. PRISMA, STrengthening the  
31  
32 227 Reporting of OBservational studies in Epidemiology [STROBE]). Each item will be ranked from  
33  
34 228 most frequently reported to those less frequently reported. Second, this list will be presented to  
35  
36 229 expert user stakeholders alongside the proportion of methodological studies that report on each  
37  
38 230 item. Stakeholders will be asked to propose additional relevant items to finalize the list of  
39  
40 231 candidate reporting items for Part 2.

### 41 232 ***Data analysis***

42 233 We will present the flow of articles retrieved and screened in a study flow diagram, and  
43  
44 234 summarize data in tables with explanatory text. We will provide descriptive statistics, i.e. counts  
45  
46 235 (percentage) for categorical data, and means (standard deviation [SD]) or medians (interquartile  
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3 236 range [IQR]) for continuous data. In addition to study names, we will synthesize and tabulate  
4  
5 237 verbatim quotations for the study objectives, outcomes, and intended use of findings to provide  
6  
7  
8 238 context and clarification for methodological study rationales [48]. We will qualitatively group  
9  
10 239 studies into categories based on similarities in reporting features. All statistical analyses will be  
11  
12 240 done in *STATA version 15.1* [46]. We will identify additional potential stakeholders from the list  
13  
14  
15 241 of authors of included studies.  
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17 242

## 19 243 **Part 2: Consensus Study**

21 244 This part of the project will consist of consultation with expert user stakeholders in a consensus  
22  
23 245 study. The objectives are to define methodological studies, and outline the recommended study  
24  
25 246 name(s) and best reporting practices. The project steering group (DOL, GG, LM, LT), which  
26  
27 247 includes members with expertise in health research methods, will oversee the consensus study  
28  
29 248 and development of the reporting guideline.  
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### 33 249 ***Identification of stakeholders***

35 250 The steering group will be responsible for identifying expert user stakeholders based on expertise  
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37 251 with methodological studies and expertise with reporting guideline development [49]. Additional  
38  
39 252 stakeholders will be identified from the list of authors (either corresponding or senior, with  
40  
41 253 academic faculty-status) of methodological studies from the review. In our selection of  
42  
43 254 stakeholders, we will seek individuals who will be committed to participating and providing  
44  
45 255 feedback for the reporting guideline. We define expert user stakeholders as researchers involved  
46  
47 256 in the design, conduct, analysis, interpretation, or dissemination of methodological studies.  
48  
49 257 Approximately 20-30 stakeholders will be selected (including the protocol authors) as  
50  
51 258 participants in the consensus exercises. We will track response rates to invitations to participate  
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259 in the consensus study. We will collect participant demographics (e.g. country, primary job title,  
260 academic rank, and methodological study publication history) to provide insight into the  
261 representation in this field of research based on sociocultural factors.

### 262 ***Measuring agreement and achieving consensus***

263 The above definition of methodological studies (i.e. studies that evaluate the design, conduct,  
264 analysis, or reporting of other studies in health research) will be used during the online consensus  
265 exercises and video conference meetings. Participants will discuss the following: a) names for  
266 methodological studies, b) categories of methodological studies, and c) reporting requirements.  
267 These three components, outlined in Table 2, will be completed electronically through a  
268 McMaster Ethics Compliant service, *LimeSurvey* (<https://reo.mcmaster.ca/limesurvey>) for online  
269 surveys [50].

270 **Table 2.** Overview of consensus study activities and expected outputs.

Stage	Description of activities to be completed	Expected outputs
Online consensus exercise: categories of methodological studies*	<ul style="list-style-type: none"> <li>We will present the <b>proposed categories of methodological studies</b> (i.e. based on the aim, design, sampling strategy and unit of analysis) with rationale for each. For each category (e.g. methodological studies that evaluate study design; methodological studies that evaluate reporting practices) an example of studies that belong in each category will also be presented. An example of potential categories are outlined in Figure 2.</li> </ul>	<ul style="list-style-type: none"> <li>List of ‘appropriate’ categories for methodological studies</li> </ul>

	<ul style="list-style-type: none"><li>• Participants will be asked to rate and comment on the appropriateness of each category on a 3-point ordinal scale: 3- appropriate; 2- somewhat appropriate; 1- inappropriate</li><li>• A validity ratio (VR) will be computed as follows: <math display="block">VR = \frac{(Ne - N/2)}{(N/2)}</math> where <math>Ne</math> is the number of participants who indicated that the category was appropriate (i.e., a rating of “3”) and <math>N</math> is the total number of participants. This ratio will indicate the category that at least half of the participants consider appropriate. The VR will be interpreted based on a table of critical values [51]. For example, for 30 participants (<math>N = 30</math>), the critical value is 0.33 (i.e., at least 20 participants must deem the category appropriate). Only items based on a critical value greater than the set threshold will be considered further [52]. This approach allows consensus to be achieved remotely, and makes decision-making objective.</li></ul>	
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<p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p>Online consensus exercise: name(s) for methodological studies*</p>	<ul style="list-style-type: none"> <li>• We will present the <b>names of methodological studies</b> and for each name (i.e. meta-epidemiological study, systematic survey etc.), an example of a study using that name will be provided.</li> <li>• Participants will be asked to rate the appropriateness of each potential name on a 3-point ordinal scale, and VR will be computed: 3- appropriate; 2- somewhat appropriate; 1- inappropriate</li> </ul>	<ul style="list-style-type: none"> <li>• List of ‘appropriate’ names for methodological studies</li> </ul>
<p>26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47</p> <p>Online consensus exercise: reporting items*</p>	<ul style="list-style-type: none"> <li>• We will present the <b>proposed reporting items</b> and participants will be asked to rate the usefulness of each item on a 3-point ordinal scale, and VR will be computed: 3- essential; 2- maybe essential; 1- not essential</li> <li>• Participants will be asked to indicate if each reporting item applies to each different methodological study category.</li> </ul>	<ul style="list-style-type: none"> <li>• List of ‘essential’ reporting items for methodological studies</li> </ul>
<p>48 49 50 51 52 53 54 55 56 57 58 59 60</p> <p>First video conference meeting (two</p>	<ul style="list-style-type: none"> <li>• Participants will confirm the appropriate name(s) and categories for methodological studies, and agree on reporting items that should be included or excluded, and</li> </ul>	<ul style="list-style-type: none"> <li>• First drafts of the: <ul style="list-style-type: none"> <li>a) reporting checklist</li> <li>b) user guide</li> </ul> </li> </ul>

<p>calls<sup>†</sup>, 2 hours each)</p>	<p>discuss the rationales behind their selections. All participants will be required to come to a consensus to include an item.</p> <ul style="list-style-type: none"> <li>• Meeting minutes and summary of the discussion and decisions will be shared with participants to provide additional feedback after the meeting.</li> <li>• Based on these discussions and decisions, the steering group will develop a <b>first draft of the reporting checklist</b> (e.g. with a checkbox to indicate Yes/Reported, No/Not Reported, and a space to indicate on what page the information is reported).</li> <li>• The checklist will be divided into different reporting sections in a methodological study (e.g. Introduction, Methods, Results, Discussion).</li> <li>• Examples of how to report information for each item will be provided alongside the checklist as part of the <b>draft user guide</b>. This will be shared with participants for comment prior to the next meeting.</li> </ul>	<p>c) recommended methodological study name(s) and categories</p>
<p>Second video conference meeting (two</p>	<ul style="list-style-type: none"> <li>• Participants will agree on a structure and format for the checklist (e.g. general layout, decision tree to delineate the</li> </ul>	<ul style="list-style-type: none"> <li>• Revised drafts of the: <ul style="list-style-type: none"> <li>a) reporting checklist</li> <li>b) user guide</li> </ul> </li> </ul>

<p>calls<sup>†</sup>, 2 hours each)</p>	<p>category of the methodological study, core items for each category of methodological study, optional items). The group will also review the examples of reporting to be included in the user guide for each reporting item.</p> <ul style="list-style-type: none"> <li>• Meeting minutes and summary of the discussion and decisions will be shared with participants to provide additional feedback after the meeting.</li> <li>• Based on these discussions and decisions, the steering group will develop a <b>revised draft of the reporting checklist</b> and an <b>elaborated user guide</b>.</li> </ul>	<p>c) recommended methodological study name(s) and categories</p>
<p>Final video conference meeting (4 hours)</p>	<ul style="list-style-type: none"> <li>• Discussion with participants will focus on confirming rationales for the final selected items, and providing examples for each reporting item to be outlined in the consensus statement and elaboration.</li> </ul>	<ul style="list-style-type: none"> <li>• Final documents for the: <ul style="list-style-type: none"> <li>a) reporting checklist</li> <li>b) user guide</li> <li>c) recommended methodological study name(s) and categories</li> </ul> </li> <li>• Consensus statement and elaboration</li> </ul>
<p>* During the online exercises, participants can suggest additional categories, names, or items that they wish to discuss during the video conferences.  <sup>†</sup> Two calls will be scheduled to accommodate stakeholders in Eastern and Western time zones.</p>		

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3 272 All video conferences will be facilitated by two investigators (DOL and LM).  
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5 273 Stakeholders will be consulted for the development of drafts, elaborations and explanations for  
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7 274 specific items. All steering committee members and stakeholders will be required to participate  
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9 275 and vote during the consensus meetings. Disagreements will be resolved through discussion, and  
10  
11 276 if no consensus can be reached, the steering committee will convey the recommendations for the  
12  
13 277 stakeholder group to approve. *Zoom*, or comparable video conferencing software, will be used to  
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15 278 allow for the collection of recordings [53].  
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### 19 279 ***Data analysis***

20  
21 280 Findings from the consensus exercise will be summarized descriptively in tables that include  
22  
23 281 counts (percentage) for categorical data, and means (SD) or medians (IQR) for continuous data.  
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25 282 We will measure the levels of agreement (i.e. percentage increase in agreement for successive  
26  
27 283 rounds, number of comments made for each successive round, and rounds with emergence of  
28  
29 284 new themes) and instability (i.e. spread and SD of ranked responses for each item) for each  
30  
31 285 round [54]. After the online exercises, one investigator (DOL) will qualitatively synthesize and  
32  
33 286 code the suggestions for the methodological study names, categories and reporting items into  
34  
35 287 common themes in *Dedoose*, a qualitative research software [55]. The steering committee will  
36  
37 288 synthesize data from the participant discussions to revise each subsequent draft.  
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### 44 290 **Part 3: Reporting Guideline**

45  
46 291 The objectives of this part are to develop, refine, publish, and disseminate the reporting guideline  
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48 292 for methodological studies. We have registered the development of the reporting guideline—  
49  
50 293 METHodological study ReportIng Checklist (METRIC)—with the EQUATOR Network [56].  
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52 294 This record may see updates to its name and acronym after deliberations during the consensus  
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3 295 study. We will also consider which reporting items are appropriate for different categories of  
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5 296 methodological studies. This will include discussions about whether a decision tree may be  
6  
7 297 useful to direct users to other existing reporting guidelines should they be more appropriate for  
8  
9 298 specific categories of methodological studies (e.g. STROBE for methodological studies designed  
10  
11 299 as cohort studies). Quantitative and qualitative findings from the consensus study will be  
12  
13 300 incorporated into the final guideline document to include the: a) recommended methodological  
14  
15 301 study name(s) and categories, b) recommended checklist with agreed upon reporting items, c)  
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17 302 user guide and elaboration (e.g. an explanation of why it is important, rationales and an example  
18  
19 303 of how it can be presented in a methodological study), and d) consensus statement. The draft  
20  
21 304 document will be returned to the steering group and stakeholders to collect additional feedback.  
22  
23 305 The checklist will be tested with end-users for face validity and clarity, and for additional fine-  
24  
25 306 tuning as needed prior to publication. We will distribute the finalized checklist to a group of  
26  
27 307 authors of methodological studies identified from the review (Part 1) to assess its usefulness and  
28  
29 308 whether the checklist appropriately captures items relevant to the reporting of methodological  
30  
31 309 studies [57].

### 310 *Patient and public involvement*

311 Although patients and the general public are not directly involved in this project, the findings of  
312 this research will be relevant to a broad range of knowledge users including methodological  
313 study authors, health researchers, methodologists, statisticians, and journal editors. We will seek  
314 recommendations from investigators for general public members and patients that could be  
315 recruited for this project.

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## 317 **ETHICS AND DISSEMINATION**

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3 318 This research has received an exemption (October 2019) from the Hamilton Integrated Research  
4  
5 319 Ethics Board (HiREB) for the consensus study. Ethics committee approval and consent to  
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7  
8 320 participate is not required for any other component of this project since only previously  
9  
10 321 published data will be used.

### 11 12 322 ***Data deposition and curation***

13  
14 323 All participant records and data will be stored in MacDrive, a secure cloud storage drive that is  
15  
16 324 privately hosted and based in-house at McMaster University [58]. Only two researchers (DOL  
17  
18 325 and LM) will have direct access to study related documents and source data. Qualitative data will  
19  
20 326 be promptly coded and transcribed, and all audio files will be encrypted. As part of our  
21  
22 327 knowledge translation (KT) strategy and a consequence of the difficulties we faced in retrieving  
23  
24 328 methodological studies from literature databases during our pilot work, we have developed an  
25  
26 329 open-access database of methodological studies ([www.methodsresearch.ca](http://www.methodsresearch.ca)). We will catalogue  
27  
28 330 all included studies from the pilot and full reviews on this website such that end-users can easily  
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30 331 retrieve these studies. We have also setup a submission portal for researchers to submit their  
31  
32 332 studies to be catalogued in this database. Parallel research by our colleagues will use this  
33  
34 333 database as well as explore the automation of retrieving and indexing methodological studies in a  
35  
36 334 dedicated space [59]. Lastly, we will setup a complementary website to serve as the primary  
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38 335 repository for the published reporting guideline document.

### 39 40 336 ***Dissemination***

41  
42 337 We will publish all manuscripts arising from this research and present the findings at  
43  
44 338 conferences. We will setup a complementary website to serve as the primary repository for the  
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46 339 published reporting guideline document. The inclusion of knowledge users and representatives  
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48 340 from methodology journals and guideline groups on our core study team will aid the wide  
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3 341 dissemination of the reporting guideline. We continue to contact journal editors for their  
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5 342 endorsement, and encourage researchers to reach out to us about this work, as we have done  
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8 343 previously [34]. We will also encourage user feedback to inform future updates of the guideline  
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10 344 as needed. These approaches are informed by our collective experience in developing and  
11  
12 345 disseminating health research guidelines [7, 60-64].  
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## 16 17 347 **DISCUSSION**

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19 348 Our work is contributing to reducing research waste by: 1) making methodological studies  
20  
21 349 transparent through streamlining their reporting; 2) permitting researchers to appraise  
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23 350 methodological studies based on adherence to proposed guidelines; 3) allowing end-users of  
24  
25 351 methodological studies to be able to locate inaccessible research in a dedicated database and  
26  
27 352 promoting its continued development; and in doing so 4) allowing end-users of methodological  
28  
29 353 studies to better evaluate and identify issues with study design and reporting that influence  
30  
31 354 patient health, enabling them to apply methodological study evidence to their own research  
32  
33 355 practices. Many methodological studies are done to improve the design, conduct, analysis and  
34  
35 356 reporting of primary and secondary research. We anticipate that, in reviewing this body of  
36  
37 357 evidence on research methods, we will further highlight the importance of studies that aim to  
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39 358 improve the design of health research [65].  
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### 44 359 ***Strengths and limitations***

45  
46 360 We acknowledge that there are inherent challenges in the search and retrieval of studies that lack  
47  
48 361 consistent names, or dedicated indexing in common health research databases. As such, it is  
49  
50 362 plausible that certain methodological studies that use terms not previously identified in the pilot  
51  
52 363 or from our systematic database searches may be missed. To mitigate this limitation, we will  
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3 364 (and have already) contact(ed) experts in the field to identify additional studies, and screen  
4  
5 365 references and citing articles of relevant studies. We have consulted extensively with librarians at  
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7 366 the McMaster Health Sciences Library on optimal approaches to capture the maximum number  
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10 367 of studies.

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12 368 The uncertainty in the number of methodological studies that are currently available and  
13  
14 369 published in the literature can present additional logistic and timing constraints to the review  
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17 370 component and overall progress of this work. However, given the landscape of methodological  
18  
19 371 studies, we believe it is essential to apply a comprehensive search. To help with the organization  
20  
21 372 of screening and data extraction, we will use robust systematic review management software  
22  
23 373 (*DistillerSR*) [41]. Further, we have designed all screening and data extraction prompts to ensure  
24  
25 374 consistency and replicability of our work.

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28 375 Lastly, our study does not incorporate a blinded consensus process and this may impact  
29  
30 376 the flow of discussions during the video conference meetings. We will aim to regulate  
31  
32 377 discussions such that dominant speakers do not steer the discussion and ensuring that all  
33  
34 378 participants have a chance to speak. Additionally, we will share summaries of the discussion and  
35  
36 379 decisions after the meetings. This will allow for participants to privately provide any additional  
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38 380 written feedback to the steering group that may not have been addressed.

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42 381 A key strength of this research is the diversity of our study team. We have brought  
43  
44 382 together an international, multidisciplinary team with expertise in consensus activities and  
45  
46 383 guideline development, and research methodology and synthesis. This gives us an advantage in  
47  
48 384 the breadth of feedback and fruitful discussions to be had with a wide array of users of the  
49  
50 385 forthcoming guideline. Given the rise in the conduct of methodological studies, a general call for  
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52 386 guidelines in the scientific community, and the number of teams that have reached out to us with  
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3 387 interest in participating in this work, we are confident that the guideline will be used. However,  
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5 388 we fully acknowledge the factors associated with implementation and use of guidelines, notably  
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7 389 journal endorsement of the guidelines, the passage of time and other study level characteristics  
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10 390 [20, 66-70]. Therefore, our stakeholders include editors from key journals that publish  
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12 391 methodological studies such as the *Journal of Clinical Epidemiology*, *BMC Medical Research*  
13  
14 392 *Methodology*, *BMC Systematic Reviews*, *The Campbell Collaboration*, and *Cochrane*.  
15  
16 393 Stakeholders also include representatives from academic programs building capacity, at the  
17  
18 394 master's and doctoral level, in conducting methodological research. To encourage better uptake,  
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20 395 it has been suggested that researchers should work collaboratively with journals in the  
21  
22 396 prospective design, knowledge translation, and evaluation of reporting guidelines [71], as well as  
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24 397 following up on user feedback and incorporating a system to revise the reporting guidelines  
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26 398 when necessary [72]. These strategies have been incorporated in our KT plan.  
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## 32 33 400 **CONCLUSIONS**

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35 401 This research will improve the transparency of reporting of methodological studies, and help  
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37 402 streamline their indexing and easier retrieval in literature databases. This work stands to make a  
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39 403 substantial impact by informing research reporting standards for studies that investigate the  
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41 404 design, conduct, analysis, or reporting of other health studies, and thereby improving the  
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43 405 transparency, reliability and replicability of health research, and ultimately benefitting patients  
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45 406 and decision makers. Future efforts will focus on field-testing the published checklist with  
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47 407 authors of methodological studies, gathering feedback from end-users, and optimizing and  
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49 408 adapting the checklist for different typologies of methodological studies as needed.  
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4

5 607 DOL and LM conceived the idea. DOL, GG, LM and LT contributed to the design of the study.  
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7 608 DOL wrote the first draft of the manuscript. AKN, AWC, BDT, DBA, DM, DP, EMW, GG,  
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40 **622 COMPETING INTERESTS**  
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42 623 All study authors have published methodological studies.  
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44 624

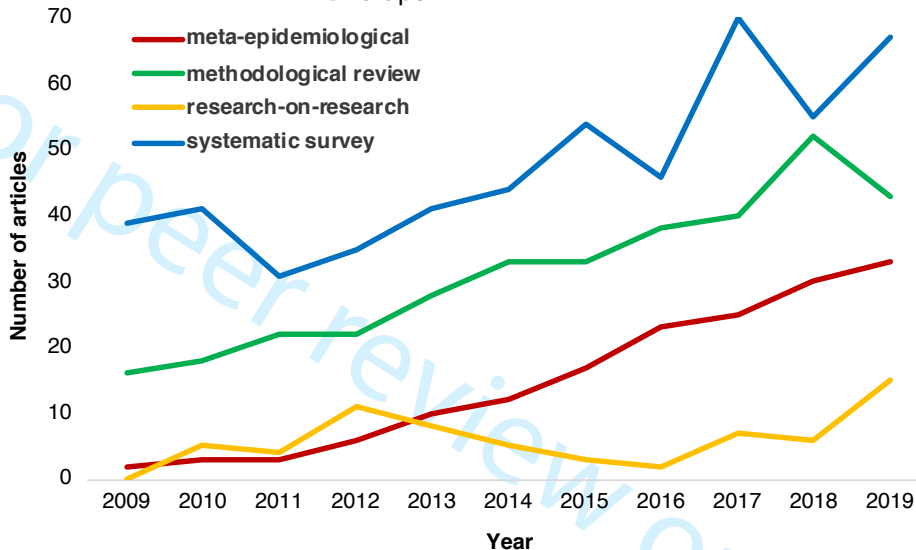
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For peer review only





For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
<b>meta-epidemiological</b>	2	3	3	6	10	12	17	23	25	30	33
<b>methodological review</b>	16	18	22	22	28	33	33	38	40	52	43
<b>research-on-research</b>	0	5	4	11	8	5	3	2	7	6	15
<b>systematic survey</b>	39	41	31	35	41	44	54	46	70	55	67

# Methodological Studies

## Features of methodological studies

### Study Aim

*(purpose is to investigate...)*

### Study Design

*(cross-sectional or over time)*

### Sampling Strategy

*(from a target population)*

### Unit of Analysis

## Categories of the feature

1. Bias
2. Methods
3. Reporting
4. Summarize

1. Descriptive
2. Analytical

1. Obtain all
2. Obtain sample

1. Design or analysis type
2. Research record type

## Examples of categories or the factors investigated

1. in **primary studies**, e.g. trial registry vs. final manuscript; in **secondary studies**, e.g. meta-bias
2. **describe** or **test** new methods; **compare** methods
3. **quality**, e.g. adherence to guidelines (CONSORT); **consistency**, e.g. abstract vs. full-text
4. **summarize data** from other methodological studies

1. **outline characteristics**, e.g. survey of randomized trials at predefined timepoint(s)
2. **evaluate groups or change over time**, e.g. different databases, timepoint; **pool data**, e.g. evaluate outcomes via synthesis

1. **systematic search and screen**, e.g. all eligible cohort studies on topic
2. **consecutive sampling**, e.g. first 150 trials on topic; **purposeful sample**, e.g. all eligible abstracts from designated journal(s); **random sample**, e.g. randomized selection from all eligible records

1. **design type**, e.g. randomized trial; **analysis type**, e.g. dose-response meta-analysis
2. **record type**, e.g. abstract, published manuscript, protocol document, registry entry

1. **Identifying the need for a guideline, review of the literature and obtain funding** for the guideline initiative

- Identify previous relevant guidance
- Establish feasibility for full review of methodological studies
- Complete full review of methodological studies
- Funding sought



2. Pre-meeting activities including **identification of stakeholders, a consensus exercise, and generation of a list of items** for consideration at the face-to-face meeting

- Establish working group, identification of stakeholders
- Share full review findings
- Ethics, online consensus exercise, and generation of a list of candidate items



3. **Face-to-face consensus meeting and discussion of a knowledge translation strategy**

- Conduct video conference meetings and final consensus meeting
- Share guideline (draft)
- Collect feedback



4. Post-meeting activities including development and **publication of the guidance** statement

- Disseminate guideline (final)

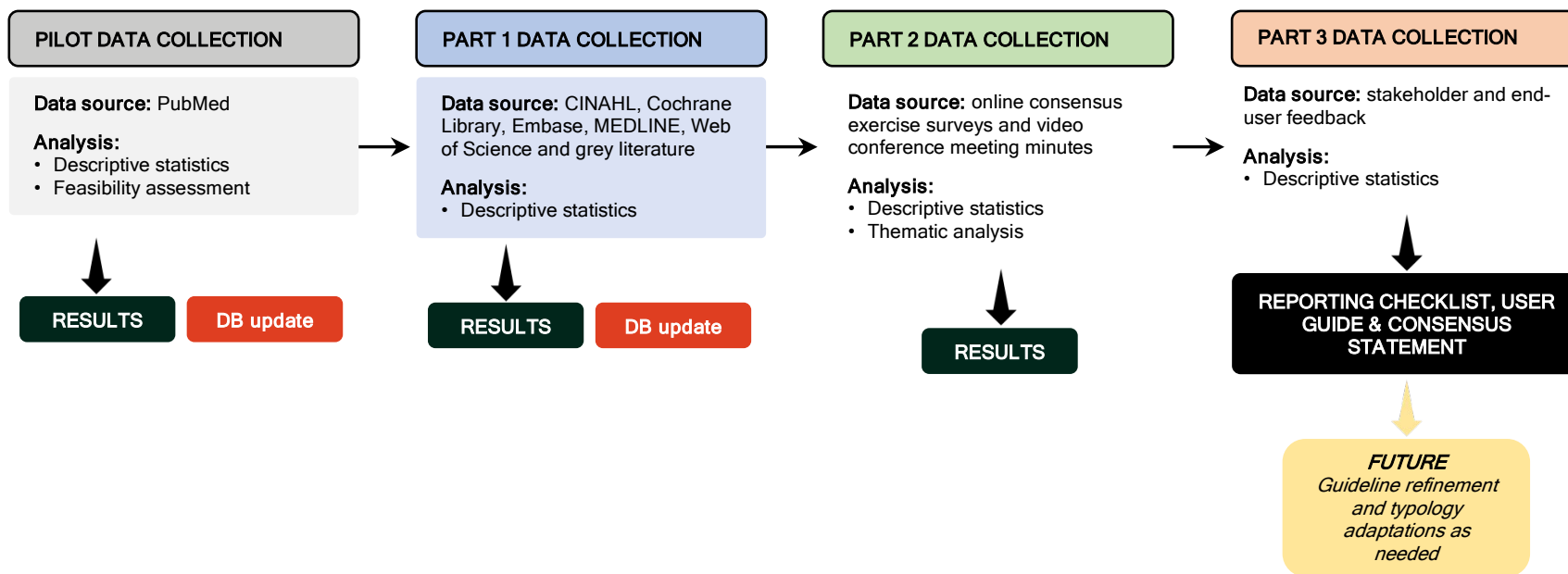


5. Post-publication activities including **encouragement of endorsement, adherence, web site development and translation of the guideline**

- Build and populate database of methodological studies
- Knowledge translation strategies for guideline, website and database

**SUPPLEMENTARY FILE**

**Flow of data for informing subsequent stages of the project:**



CINAHL: Cumulative Index for Nursing and Allied Health Literature, DB: database ([www.methodsresearch.ca](http://www.methodsresearch.ca))

### Sample search strategy for MEDLINE:

#### *Concept: names of methodological studies*

- 1 (meta-epidemiolog\* OR metaepidemiolog\* OR meta-research OR methodolog\* analysis OR methodolog\* evidence OR methodolog\* investigation OR methodolog\* literature OR methodolog\* overview OR methodolog\* report\* OR methodolog\* review OR methodolog\* survey OR methodolog\* synthesis OR method\* overview OR systematic database review OR systematic literature survey OR systematic survey).mp.
- 2 (methodolog\* study OR method\* review OR method\* survey)

#### *Concept: topics in methodological research (i.e. analysis, design and reporting)*

- 3 exp Data Collection/
- 4 exp Data Interpretation, Statistical/
- 5 exp Epidemiologic Research Design/
- 6 exp Nursing Methodology Research/
- 7 exp Reproducibility of Results/
- 8 exp Research Design/
- 9 3 OR 4 OR 5 OR 6 OR 7 OR 8
- 10 2 AND 9

#### *Concept: methodological studies that are called 'systematic reviews'*

- 11 systematic review.mp.
- 12 Cochrane Database of Systematic Reviews.jn
- 13 11 NOT 12
- 14 \*Data Collection/
- 15 \*Data Interpretation, Statistical/
- 16 \*Epidemiologic Research Design/
- 17 \*Nursing Methodology Research/
- 18 \*Reproducibility of Results/
- 19 \*Research Design/
- 20 14 OR 15 OR 16 OR 17 OR 18 OR 19
- 21 13 AND 20
- 22 1 OR 10 OR 21

# BMJ Open

## Reporting of methodological studies in health research: a protocol for the development of the Methodological Study reporting Checklist (MISTIC)

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<b>Primary Subject Heading</b> :	Research methods
Secondary Subject Heading:	Epidemiology, Evidence based practice, Medical publishing and peer review
Keywords:	STATISTICS & RESEARCH METHODS, EPIDEMIOLOGY, EDUCATION & TRAINING (see Medical Education & Training)

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3 **1 Reporting of methodological studies in health research: a protocol for the development of**  
4 **the Methodological Study reporTIng Checklist (MISTIC)**  
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51 **Word count:** 3823  
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3 46 **ABSTRACT**  
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5 47 **Introduction:** Methodological studies (i.e. studies that evaluate the design, conduct, analysis or  
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7 48 reporting of other studies in health research) address various facets of health research including,  
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9  
10 49 for instance, data collection techniques, differences in approaches to analyses, reporting quality,  
11  
12 50 adherence to guidelines, or publication bias. As a result, methodological studies can help to  
13  
14 51 identify knowledge gaps in the methodology of health research, and strategies for improvement  
15  
16 52 in research practices. Differences in methodological study names and a lack of reporting  
17  
18 53 guidance contribute to lack of comparability across studies, and difficulties in identifying  
19  
20 54 relevant previous methodological studies. This paper outlines the methods we will use to develop  
21  
22 55 an evidence-based tool—the Methodological Study reporting Checklist (MISTIC)—to  
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24 56 harmonize naming conventions and improve the reporting of methodological studies.  
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28 57 **Methods and analysis:** We will search for methodological studies in the Cumulative Index to  
29  
30 58 Nursing and Allied Health Literature, Cochrane Library, Embase, MEDLINE, Web of Science,  
31  
32 59 check reference lists, and contact experts in the field. We will extract and summarize data on the  
33  
34 60 study names, design, and reporting features of the included methodological studies. Consensus  
35  
36 61 on study terms and recommended reporting items will be achieved via video conference  
37  
38 62 meetings with a panel of experts including researchers who have published methodological  
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40 63 studies.  
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44 64 **Ethics and dissemination:** The consensus study has been exempt from ethics review by the  
45  
46 65 Hamilton Integrated Research Ethics Board. The results of the review and the reporting guideline  
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48 66 will be disseminated in stakeholder meetings, conferences, peer-reviewed publications, in  
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50 67 requests to journal editors (to endorse or make the guideline a requirement for authors), and on  
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52 68 the EQUATOR Network and reporting guideline websites.  
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3 69 **Registration:** We have registered the development of the reporting guideline with the  
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5 70 EQUATOR Network, and publicly posted this project on the Open Science Framework  
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8 71 ([www.osf.io/9hgbq](http://www.osf.io/9hgbq)).  
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For peer review only

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3 72 **STRENGTHS AND LIMITATIONS OF THIS STUDY**  
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- 5 73 • To the best of our knowledge, this is the first study to design an evidence-based tool to  
6  
7 support the complete and transparent reporting of methodological studies in health research.  
8 74  
9  
10 75 • This project will help to highlight the current reporting practices of authors of  
11  
12 methodological studies to outline a list of key reporting items.  
13 76  
14  
15 77 • The stakeholders recruited for the consensus study will represent a diverse group of expert  
16  
17 health research methodologists including biostatisticians, clinical researchers, journal  
18 78  
19 editors, healthcare providers, and reporting guideline developers.  
20 79  
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22 80 • Our study does not incorporate a blinded consensus process and this may impact the flow of  
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24 discussions during the conference meetings.  
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## 82 INTRODUCTION

83 Concerns with the quality and quantity of research have sparked interest in the rapidly  
84 evolving field which has been called meta-epidemiology, meta-research, or research-on-research  
85 [1-3]. This field of research addresses the entire research process, from question development to  
86 design, conduct and reporting issues, and most often uses research-related reports (e.g. protocols,  
87 published manuscripts, registry entries, conference abstracts) as the unit of analysis. These  
88 studies may seek to “(1) describe the distribution of research evidence for a specific question; (2)  
89 examine heterogeneity and associated risk factors; and (3) control bias across studies and  
90 summarize research evidence as appropriate” [4]. For the purpose of this project, we will refer to  
91 these research outputs as “methodological studies”, i.e. studies that evaluate the design, conduct,  
92 analysis (e.g. including bias, statistical plan and methods), or reporting of other studies in health  
93 research. This definition does not include statistical methodological studies (e.g. studies testing  
94 new algorithms or analytical methods, simulation studies), and experimental studies in which the  
95 unit of analysis is not a research report. Methodological studies are important because they can  
96 identify gaps, biases, and inefficiencies in research practices, and propose improvements and  
97 solutions.

98 A PubMed search performed in April 2020 for terms often used to describe  
99 methodological studies suggests that the rate of publication of methodological studies has  
100 increased over time, illustrated in Figure 1.

101 — Figure 1. Trends in methodological studies indexed in PubMed from 2009 to 2019. —

102 In the past 20 years, methodological studies have influenced the conduct of health research by  
103 informing many popular practices such as double data extraction in systematic reviews [5];  
104 optimal approaches to conducting subgroup analyses [6]; and reporting of randomized trials,

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3 105 observational studies, pilot studies, and systematic reviews [7-10] to name a few.  
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5 106 Methodological studies have played an important role in ensuring that health research is reliable,  
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7 107 valid, transparent and replicable. These types of studies may investigate: bias in research [11,  
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9 108 12], quality or completeness of reporting [13, 14], consistency of reporting [15], methods used  
10  
11 109 [16], factors associated with reporting practices [17]; and may provide summaries of other  
12  
13 110 methodological studies [18], and other issues. Methodological studies may also be used to  
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15 111 evaluate the uptake of methods over time to investigate whether (and where) practices are  
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17 112 improving and allow researchers to make comparisons across different medical areas [19, 20].  
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19 113 These studies can also highlight methodological strengths and shortcomings such as sample size  
20  
21 114 calculations in randomized controlled trials [21, 22], quality of clinical prediction models [23],  
22  
23 115 and spin and over-interpretation of study findings [24-26]. As such, methodological studies  
24  
25 116 promote robust, evidence-based science and help to discard inefficient research practices [27]. A  
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27 117 draft conceptual framework of the various categories of methodological studies that we have  
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29 118 observed is outlined in Figure 2. Broadly, some categories of methodological studies include  
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31 119 those investigating: bias and spin, methodological approaches to study design, or reporting  
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33 120 issues.

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40 121 — Figure 2. Draft conceptual framework of categories of methodological studies. —

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42 122 Despite the importance of methodological studies, there is no guidance for their  
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44 123 reporting. Murad and Wang have suggested a modification to the Preferred Reporting Items for  
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46 124 Systematic Reviews and Meta-Analyses (PRISMA), a widely used reporting tool that is  
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48 125 sometimes used for methodological studies because these studies often use methods that are also  
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50 126 used in systematic reviews [28]. Although a modification of PRISMA may work well for the  
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52 127 data collection components of some methodological studies, it would fail to appropriately  
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3 128 address the many different types of research questions that methodological studies attempt to  
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5 129 answer. For example, if researchers were interested in changes in reporting quality of trials since  
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8 130 the publication of the CONSORT guidelines, they could use an interrupted time-series design.  
9  
10 131 Also, methodological studies that include a random sample of research reports [29], or those  
11  
12 132 structured as before-after designs [19] would be a poor fit for the modified PRISMA tool, which  
13  
14 133 is best suited for studies designed in the style of systematic reviews. Likewise, studies in which  
15  
16 134 the unit of analysis is not the “study” require more specific guidance (e.g. when investigating  
17  
18 135 multiple subgroup analyses or multiple outcomes within the same study) [30]. Thus, guidelines  
19  
20 136 for transparent reporting of methodological studies are needed, and this need is widely  
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23 137 acknowledged in the scientific community [31, 32]

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26 138 Our work will address two main concerns:

- 27  
28 139 1. There are no globally accepted names for methodological studies, making them difficult to  
29  
30 140 identify. Methodological studies have been called ‘methodological review’, ‘systematic  
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32 141 review’, ‘systematic survey’, ‘literature review’, ‘meta-epidemiological study’ and many  
33  
34 142 other names. The diversity in names compromises training and educational activities [33], and  
35  
36 143 it makes it difficult for end-users (e.g. clinical researchers, guideline developers) to search for,  
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38 144 identify and use these studies [34, 35].  
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41 145 2. The reporting of methodological studies is inconsistent, which may relate to differences in  
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43 146 objectives, and to differences in transparency and completeness. That is, some studies may be  
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45 147 better reported than others. While the most appropriate approach to reporting will depend on  
46  
47 148 the research question, explicit, user-friendly, and consensus-based guidance is needed to  
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49 149 ensure that methodological studies are reported transparently and comprehensively [36].  
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54 150 ***Aims***  
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3 151 The aims of this study protocol are to outline the procedures to define and harmonize the names  
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5 152 describing methodological studies, and to develop reporting guidelines for methodological  
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8 153 studies in human health research.  
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## 11 12 155 **METHODS AND ANALYSIS**

### 13 14 15 156 *Study design*

16  
17 157 We have adopted the strategy for the development of reporting guidelines proposed by Moher et  
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19 158 al. [37]. A visual overview of this approach, highlighting key components of the process, is  
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21 159 presented in Figure 3. The three parts of the project which will be addressed using the above  
22  
23  
24 160 strategy are outlined in detail below (see Supplementary File for an outline of the data flow  
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26 161 informing subsequent parts of the project).

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28 162 — Figure 3. Project overview for the development of reporting guidelines for methodological  
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31 163 studies in health research. —

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### 34 35 165 **Part 1: Methodological Review**

36  
37 166 The objectives of this part are to: a) identify names used to describe methodological studies, b)  
38  
39 167 identify the various designs, analysis and reporting features of methodological studies, c) find  
40  
41  
42 168 any previous reporting guidance, and d) identify methodological study experts.

### 43 44 45 169 *Search strategy*

46  
47 170 We developed a search strategy informed by our pilot work [38] targeting health-related sciences  
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49 171 and biomedicine databases: Cumulative Index to Nursing and Allied Health Literature  
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51 172 (CINAHL), Cochrane Library, Excerpta Medica (Embase), MEDLINE, and Web of Science.  
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54 173 There will be no limits by publication year, type or language. We will perform searches for  
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3 174 authors known to publish in this field, check reference lists of relevant studies, check existing  
4  
5 175 methodological study repositories (Studies Within a Trial [SWATs] and Studies Within a  
6  
7 176 Review [SWARs]), preprints (bioRxiv and medRxiv), setup Google Alerts for key words (e.g.  
8  
9 177 meta-epidemiology, research-on-research), and contact experts (e.g. via email, meetings,  
10  
11 178 following relevant journals, subscribing to methods email newsletters including the Methods in  
12  
13 179 Research on Research [MiRoR] and the National Institute for Health and Care Excellence  
14  
15 180 [NICE] groups, and following researchers on social media platforms such as ResearchGate and  
16  
17 181 Twitter) to identify additional methodological studies. We will also check the EQUATOR library  
18  
19 182 to identify any published or under development reporting guidance. These approaches are  
20  
21 183 informed by previous work and published literature [35, 38]. Two health sciences librarians at  
22  
23 184 the Health Sciences Library (McMaster University) were consulted and reviewed the final search  
24  
25 185 strategy (see Supplementary File) in line with the Peer Review of Electronic Search Strategies  
26  
27 186 (PRESS) framework [39].  
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### 33 187 *Eligible studies*

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35 188 Studies that investigate methods—design, conduct, analysis, or reporting—in other studies of  
36  
37 189 health research in humans will be eligible. The ‘other studies’ (or research reports) refers to the  
38  
39 190 unit of analysis of the methodological studies (e.g. abstracts, cohort studies, randomized trials,  
40  
41 191 registry records, study protocols, systematic reviews). Only published protocols and final reports  
42  
43 192 of studies that investigate methods will be eligible. We will exclude simulation studies, studies  
44  
45 193 testing new statistical methods (i.e. there is no specific unit of analysis) and experimental studies  
46  
47 194 of methods (i.e. the unit of analysis is not a research report). These sorts of studies either already  
48  
49 195 have reporting guidelines or can be reported in a commentary-style format.  
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### 54 196 *Screening*

197 A team of reviewers led by DOL will screen titles and abstracts independently, in duplicate in  
 198 *Rayyan* [40], and full-texts in standardized forms in *DistillerSR* [41]. Both are online  
 199 collaborative platforms for screening and reviewing literature. We will measure agreement on  
 200 screening and study inclusion using Cohen's Kappa statistic [42, 43]. Any discrepancies between  
 201 reviewers will be resolved through discussion.

### 202 **Data extraction**

203 In order to document the current reporting practices we will extract data from included studies  
 204 independently, in duplicate based on a standardized data collection form. Key data extraction  
 205 fields for documenting methodological study features and reporting practices (e.g. study design  
 206 name, databases search, any guideline use) are outlined in Table 1. All data will be compiled in  
 207 *DistillerSR*. Any discrepancies between reviewers will be resolved through discussion.

208 **Table 1.** Overview of data extraction fields for the review.

Section	Data to be collected
Bibliometrics	<ul style="list-style-type: none"> <li>• Corresponding or last author (first and last name) and contact information (email address). We will first verify whether the corresponding author has academic faculty status, and if not, we will contact the last author</li> <li>• Country of author</li> <li>• Publication year</li> <li>• Study design name in title (verbatim quotation/descriptor)</li> <li>• Type of article (protocol or final publication, and letter/brief report or full publication)</li> <li>• Journal</li> </ul>
Methods	<ul style="list-style-type: none"> <li>• Study design name in methods section (verbatim quotation/descriptor)</li> <li>• Objectives (verbatim quotation)</li> </ul>

	<ul style="list-style-type: none"> <li>• Outcomes (verbatim quotation)</li> <li>• Search strategy reported (yes/no)</li> <li>• Search time limits and justifications (yes/no and verbatim quotation)</li> <li>• Databases searched</li> <li>• Included research report types (e.g. randomized trials, systematic reviews, cohort studies)</li> <li>• Sampling method (where applicable)</li> <li>• Analysis type (e.g. correlation, descriptive, regression, time-series)</li> <li>• Reporting guidance used and justification (yes/no, name and verbatim quotation)</li> <li>• Prospective registration and existence of a published protocol (yes/no, where applicable)</li> </ul>
Results	<ul style="list-style-type: none"> <li>• Presence of flow diagrams (yes/no)</li> <li>• Total records screened and included</li> <li>• Type of final synthesis performed (qualitative, quantitative, both)</li> </ul>
Discussion	<ul style="list-style-type: none"> <li>• Intended use of findings (verbatim quotation)</li> <li>• Limitations (verbatim quotation)</li> </ul>
Other	<ul style="list-style-type: none"> <li>• Conflicts of interest (yes/no)</li> <li>• Funding type (e.g. industry, institutional, non-profit)</li> <li>• Provide access to data (yes/no)</li> </ul>

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210 All reviewers will undergo calibration exercises and pilot the screening and data  
 211 collection forms (25 studies per reviewer). We will incorporate an emergent design in the data  
 212 collection stage of the review, which is characterized by a flexibility in the methodology,  
 213 allowing researchers to remain open to modifications [44]. Should any new information that is of

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3 214 interest arise during the full-text screen or data extraction, we will update the data collection  
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5 215 form and collect this information for all studies retrospectively and going forward. Any  
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7 216 modifications to the present protocol will be reported in the final published review. This iterative  
8  
9 217 approach will allow for the capture of information as new methodological study design features  
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11 218 come to light during the full-text screening and data extraction phases. Based on this approach,  
12  
13 219 data extraction will be updated accordingly for previously reviewed studies as needed. For  
14  
15 220 example, we expect to see overlaps in methodological study names, some of which might be  
16  
17 221 attributed to collaborating research groups. There also appear to be similarities in methodological  
18  
19 222 study reporting styles that are borrowed from systematic review [4] or survey study designs,  
20  
21 223 which have both been extensively developed and are omnipresent in health research literature.  
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23 224 However, if the current data collection fields, listed in Table 1, are insufficient to capture the  
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25 225 nuances of the varieties of methodological studies, we will revise our data collection forms  
26  
27 226 accordingly and collect the data for all studies.  
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### 33 227 ***Generation of a list of candidate items***

34  
35 228 The generation of a list of candidate items will be informed by two sources. First, a list of  
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37 229 reporting items will be compiled based on what has been reported by authors of the included  
38  
39 230 studies in the methodological review (e.g. flow diagram, search strategy). We will also note the  
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41 231 use of any reporting guidance as mentioned by authors (e.g. PRISMA, STrengthening the  
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43 232 Reporting of OBServational studies in Epidemiology [STROBE]). Each item will be ranked from  
44  
45 233 most frequently reported to those less frequently reported. Second, this list will be presented to  
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47 234 expert user stakeholders alongside the proportion of methodological studies that report on each  
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49 235 item. Stakeholders will be asked to propose additional relevant items to finalize the list of  
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51 236 candidate reporting items for Part 2.  
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### 237 ***Data analysis***

238 We will present the flow of articles retrieved and screened in a study flow diagram, and  
239 summarize data in tables with explanatory text. We will provide descriptive statistics, i.e. counts  
240 (percentage) for categorical data, and means (standard deviation [SD]) or medians (interquartile  
241 range [IQR]) for continuous data. In addition to study names, we will synthesize and tabulate  
242 verbatim quotations for the study objectives, outcomes, and intended use of findings to provide  
243 context and clarification for methodological study rationales [45]. We will qualitatively group  
244 studies into categories based on similarities in reporting features. All statistical analyses will be  
245 done in *STATA version 15.1* [46]. We will identify additional potential stakeholders from the list  
246 of authors of included studies.

### 248 **Part 2: Consensus Study**

249 This part of the project will consist of consultation with expert user stakeholders in a consensus  
250 study. The objectives are to define methodological studies, and outline the recommended study  
251 name(s) and best reporting practices. The project steering group (DOL, GG, LM, LT), which  
252 includes members with expertise in health research methods, will oversee the consensus study  
253 and development of the reporting guideline.

### 254 ***Identification of stakeholders***

255 The steering group will be responsible for identifying expert user stakeholders based on expertise  
256 with methodological studies and expertise with reporting guideline development [47]. Additional  
257 stakeholders will be identified from the list of authors (either corresponding or senior, with  
258 academic faculty-status) of methodological studies from the review. In our selection of  
259 stakeholders, we will seek individuals who will be committed to participating and providing

260 feedback for the reporting guideline. We define expert user stakeholders as researchers involved  
 261 in the design, conduct, analysis, interpretation, or dissemination of methodological studies.  
 262 Approximately 20-30 stakeholders will be selected (including the protocol authors) as  
 263 participants in the consensus exercises. We will track response rates to invitations to participate  
 264 in the consensus study. We will collect participant demographics (e.g. country, primary job title,  
 265 academic rank, and methodological study publication history) to provide insight into the  
 266 representation in this field of research based on sociocultural factors.

### 267 ***Measuring agreement and achieving consensus***

268 The above definition of methodological studies (i.e. studies that evaluate the design, conduct,  
 269 analysis, or reporting of other studies in health research) will be used during the online consensus  
 270 exercises and video conference meetings. Participants will discuss the following: a) names for  
 271 methodological studies, b) categories of methodological studies, and c) reporting requirements.  
 272 These three components, outlined in Table 2, will be completed electronically through a  
 273 McMaster Ethics Compliant service, *LimeSurvey* (<https://reo.mcmaster.ca/limesurvey>) for online  
 274 surveys [48].

275 **Table 2.** Overview of consensus study activities and expected outputs.

Stage	Description of activities to be completed	Expected outputs
Online consensus exercise: categories of methodological studies*	<ul style="list-style-type: none"> <li>We will present the <b>proposed categories of methodological studies</b> (i.e. based on the aim, design, sampling strategy and unit of analysis) with rationale for each. For each category (e.g. methodological studies that evaluate study design; methodological studies that evaluate</li> </ul>	<ul style="list-style-type: none"> <li>List of ‘appropriate’ categories for methodological studies</li> </ul>

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3 reporting practices) an example of studies  
4 that belong in each category will also be  
5 presented. An example of potential  
6 categories are outlined in Figure 2.

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11  
12 • Participants will be asked to rate and  
13 comment on the appropriateness of each  
14 category on a 3-point ordinal scale: 3-  
15 appropriate; 2- somewhat appropriate; 1-  
16 inappropriate
- 17  
18 • A validity ratio (VR) will be computed as  
19 follows:

$$20 \quad VR = \frac{(Ne - N/2)}{(N/2)} \quad \text{where } Ne \text{ is the number}$$

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of participants who indicated that the  
category was appropriate (i.e., a rating of  
“3”) and  $N$  is the total number of  
participants. This ratio will indicate the  
category that at least half of the  
participants consider appropriate. The VR  
will be interpreted based on a table of  
critical values [49]. For example, for 30  
participants ( $N = 30$ ), the critical value is  
0.33 (i.e., at least 20 participants must  
deem the category appropriate). Only  
items based on a critical value greater  
than the set threshold will be considered



	<p>further [50]. This approach allows consensus to be achieved remotely, and makes decision-making objective.</p>	
<p>Online consensus exercise: name(s) for methodological studies*</p>	<ul style="list-style-type: none"> <li>• We will present the <b>names of methodological studies</b> and for each name (i.e. meta-epidemiological study, systematic survey etc.), an example of a study using that name will be provided.</li> <li>• Participants will be asked to rate the appropriateness of each potential name on a 3-point ordinal scale, and VR will be computed: 3- appropriate; 2- somewhat appropriate; 1- inappropriate</li> </ul>	<ul style="list-style-type: none"> <li>• List of ‘appropriate’ names for methodological studies</li> </ul>
<p>Online consensus exercise: reporting items*</p>	<ul style="list-style-type: none"> <li>• We will present the <b>proposed reporting items</b> and participants will be asked to rate the usefulness of each item on a 3-point ordinal scale, and VR will be computed: 3- essential; 2- maybe essential; 1- not essential</li> <li>• Participants will be asked to indicate if each reporting item applies to each different methodological study category.</li> </ul>	<ul style="list-style-type: none"> <li>• List of ‘essential’ reporting items for methodological studies</li> </ul>

<p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60</p> <p>First video conference meeting (two calls<sup>†</sup>, 2 hours each)</p>	<ul style="list-style-type: none"> <li>• Participants will confirm the appropriate name(s) and categories for methodological studies, and agree on reporting items that should be included or excluded, and discuss the rationales behind their selections. All participants will be required to come to a consensus to include an item.</li> <li>• Meeting minutes and summary of the discussion and decisions will be shared with participants to provide additional feedback after the meeting.</li> <li>• Based on these discussions and decisions, the steering group will develop a <b>first draft of the reporting checklist</b> (e.g. with a checkbox to indicate Yes/Reported, No/Not Reported, and a space to indicate on what page the information is reported).</li> <li>• The checklist will be divided into different reporting sections in a methodological study (e.g. Introduction, Methods, Results, Discussion).</li> <li>• Examples of how to report information for each item will be provided alongside the checklist as part of the <b>draft user guide</b>.</li> </ul>	<ul style="list-style-type: none"> <li>• First drafts of the:             <ol style="list-style-type: none"> <li>a) reporting checklist</li> <li>b) user guide</li> <li>c) recommended methodological study name(s) and categories</li> </ol> </li> </ul>
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	This will be shared with participants for comment prior to the next meeting.	
Second video conference meeting (two calls <sup>†</sup> , 2 hours each)	<ul style="list-style-type: none"> <li>• Participants will agree on a structure and format for the checklist (e.g. general layout including appropriate sectioning such as ‘Title’, ‘Abstract’ and ‘Body’ of reports; a decision tree to delineate the category of the methodological study, core items for each category of methodological study, optional items). The group will also review the examples of reporting to be included in the user guide for each reporting item.</li> <li>• Meeting minutes and summary of the discussion and decisions will be shared with participants to provide additional feedback after the meeting.</li> <li>• Based on these discussions and decisions, the steering group will develop a <b>revised draft of the reporting checklist</b> and an <b>elaborated user guide</b>.</li> </ul>	<ul style="list-style-type: none"> <li>• Revised drafts of the: <ul style="list-style-type: none"> <li>a) reporting checklist</li> <li>b) user guide</li> <li>c) recommended methodological study name(s) and categories</li> </ul> </li> </ul>
Final video conference meeting (4 hours)	<ul style="list-style-type: none"> <li>• Discussion with participants will focus on confirming rationales for the final selected items, and providing examples for each reporting item to be outlined in the consensus statement and elaboration.</li> </ul>	<ul style="list-style-type: none"> <li>• Final documents for the: <ul style="list-style-type: none"> <li>a) reporting checklist</li> <li>b) user guide</li> </ul> </li> </ul>

		c) recommended methodological study name(s) and categories <ul style="list-style-type: none"> <li>• Consensus statement and  elaboration</li> </ul>
* During the online exercises, participants can suggest additional categories, names, or items that they wish to discuss during the video conferences. † Two calls will be scheduled to accommodate stakeholders in Eastern and Western time zones.		

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277 All video conferences will be facilitated by two investigators (DOL and LM).

278 Stakeholders will be consulted for the development of drafts, elaborations and explanations for  
279 specific items. All steering committee members and stakeholders will be required to participate  
280 and vote during the consensus meetings. Disagreements will be resolved through discussion, and  
281 if no consensus can be reached, the steering committee will convey the recommendations for the  
282 stakeholder group to approve. *Zoom*, or comparable video conferencing software, will be used to  
283 allow for the collection of recordings [51].

#### 284 ***Data analysis***

285 Findings from the consensus exercise will be summarized descriptively in tables that include  
286 counts (percentage) for categorical data, and means (SD) or medians (IQR) for continuous data.  
287 We will measure the levels of agreement (i.e. percentage increase in agreement for successive  
288 rounds, number of comments made for each successive round, and rounds with emergence of  
289 new themes) and instability (i.e. spread and SD of ranked responses for each item) for each  
290 round [52]. After the online exercises, one investigator (DOL) will qualitatively synthesize and  
291 code the suggestions for the methodological study names, categories and reporting items into  
292 common themes in *Dedoose*, a qualitative research software [53]. The steering committee will  
293 synthesize data from the participant discussions to revise each subsequent draft.

### 294 **Part 3: Reporting Guideline**

295 The objectives of this part are to develop, refine, publish, and disseminate the reporting guideline  
296 for methodological studies. We have registered the development of the reporting guideline—  
297 Methodological Study reporTIng Checklist (MISTIC)—with the EQUATOR Network [54]. This  
298 record may see updates to its name and acronym after deliberations during the consensus study.  
299 We will also consider which reporting items are appropriate for different categories of  
300 methodological studies. This will include discussions about whether a decision tree may be  
301 useful to direct users to other existing reporting guidelines should they be more appropriate for  
302 specific categories of methodological studies (e.g. STROBE for methodological studies designed  
303 as cohort studies). Quantitative and qualitative findings from the consensus study will be  
304 incorporated into the final guideline document to include the: a) recommended methodological  
305 study name(s) and categories, b) recommended checklist with agreed upon reporting items, c)  
306 user guide and elaboration (e.g. an explanation of why it is important, rationales and an example  
307 of how it can be presented in a methodological study), and d) consensus statement. The draft  
308 document will be returned to the steering group and stakeholders to collect additional feedback.  
309 The checklist will be tested with end-users for face validity and clarity, and for additional fine-  
310 tuning as needed prior to publication. We will distribute the finalized checklist to a group of  
311 authors of methodological studies identified from the review (Part 1) to assess its usefulness and  
312 whether the checklist appropriately captures items relevant to the reporting of methodological  
313 studies [55].

### 314 ***Patient and public involvement***

315 Although patients and the general public are not directly involved in this project, the findings of  
316 this research will be relevant to a broad range of knowledge users including methodological

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3 317 study authors, health researchers, methodologists, statisticians, and journal editors. We will seek  
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5 318 recommendations from investigators for general public members and patients that could be  
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7 319 recruited for this project.  
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## 11 321 **ETHICS AND DISSEMINATION**

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14 322 This research has received an exemption (October 2019) from the Hamilton Integrated Research  
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16 323 Ethics Board (HiREB) for the consensus study. Ethics committee approval and consent to  
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18 324 participate is not required for any other component of this project since only previously  
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20 325 published data will be used.  
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### 23 326 *Data deposition and curation*

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26 327 All participant records and data will be stored in MacDrive, a secure cloud storage drive that is  
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28 328 privately hosted and based in-house at McMaster University [56]. Only two researchers (DOL  
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30 329 and LM) will have direct access to study related documents and source data. Qualitative data will  
31  
32 330 be promptly coded and transcribed, and all audio files will be encrypted. As part of our  
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34 331 knowledge translation (KT) strategy and a consequence of the difficulties we faced in retrieving  
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36 332 methodological studies from literature databases during our pilot work, we have developed an  
37  
38 333 open-access database of methodological studies ([www.methodsresearch.ca](http://www.methodsresearch.ca)). We will catalogue  
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40 334 all included studies from the pilot and full reviews on this website such that end-users can easily  
41  
42 335 retrieve these studies. We have also setup a submission portal for researchers to submit their  
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44 336 studies to be catalogued in this database. Parallel research by our colleagues will use this  
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46 337 database as well as explore the automation of retrieving and indexing methodological studies in a  
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48 338 dedicated space [57]. Lastly, we will setup a complementary website to serve as the primary  
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50 339 repository for the published reporting guideline document.  
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3 340 ***Dissemination***  
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5 341 We will publish all manuscripts arising from this research and present the findings at  
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7 342 conferences. We will setup a complementary website to serve as the primary repository for the  
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9 343 published reporting guideline document. The inclusion of knowledge users and representatives  
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11 344 from methodology journals and guideline groups on our core study team will aid the wide  
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13 345 dissemination of the reporting guideline. We continue to contact journal editors for their  
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15 346 endorsement, and encourage researchers to reach out to us about this work, as we have done  
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17 347 previously [34]. We will also encourage user feedback to inform future updates of the guideline  
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19 348 as needed. These approaches are informed by our collective experience in developing and  
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21 349 disseminating health research guidelines [7, 58-62].  
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28 351 **DISCUSSION**  
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30 352 Our work is contributing to reducing research waste by: 1) making methodological studies  
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32 353 transparent through streamlining their reporting; 2) permitting researchers to appraise  
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34 354 methodological studies based on adherence to proposed guidelines; 3) allowing end-users of  
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36 355 methodological studies to be able to locate inaccessible research in a dedicated database and  
37  
38 356 promoting its continued development; and in doing so 4) allowing end-users of methodological  
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40 357 studies to better evaluate and identify issues with study design and reporting that influence  
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42 358 patient health, enabling them to apply methodological study evidence to their own research  
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44 359 practices. Many methodological studies are done to improve the design, conduct, analysis and  
45  
46 360 reporting of primary and secondary research. We anticipate that, in reviewing this body of  
47  
48 361 evidence on research methods, we will further highlight the importance of studies that aim to  
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50 362 improve the design of health research [63].  
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3 363 ***Strengths and limitations***  
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5 364 We acknowledge that there are inherent challenges in the search and retrieval of studies that lack  
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7 365 consistent names, or dedicated indexing in common health research databases. As such, it is  
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10 366 plausible that certain methodological studies that use terms not previously identified in the pilot  
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12 367 or from our systematic database searches may be missed. To mitigate this limitation, we will  
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14 368 (and have already) contact(ed) experts in the field to identify additional studies, and screen  
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16 369 references and citing articles of relevant studies. We have consulted extensively with librarians at  
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18 370 the McMaster Health Sciences Library on optimal approaches to capture the maximum number  
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21 371 of studies.  
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24 372 The uncertainty in the number of methodological studies that are currently available and  
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26 373 published in the literature can present additional logistic and timing constraints to the review  
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28 374 component and overall progress of this work. However, given the landscape of methodological  
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30 375 studies, we believe it is essential to apply a comprehensive search. To help with the organization  
31  
32 376 of screening and data extraction, we will use robust systematic review management software  
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34 377 (*DistillerSR*) [41]. Further, we have designed all screening and data extraction prompts to ensure  
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36 378 consistency and replicability of our work.  
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39 379 Lastly, our study does not incorporate a blinded consensus process and this may impact  
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41 380 the flow of discussions during the video conference meetings. We will aim to regulate  
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43 381 discussions such that dominant speakers do not steer the discussion and ensuring that all  
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45 382 participants have a chance to speak. Additionally, we will share summaries of the discussion and  
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47 383 decisions after the meetings. This will allow for participants to privately provide any additional  
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49 384 written feedback to the steering group that may not have been addressed.  
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3 385 A key strength of this research is the diversity of our study team. We have brought  
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5 386 together an international, multidisciplinary team with expertise in consensus activities and  
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7 387 guideline development, and research methodology and synthesis. This gives us an advantage in  
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10 388 the breadth of feedback and fruitful discussions to be had with a wide array of users of the  
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12 389 forthcoming guideline. Given the rise in the conduct of methodological studies, a general call for  
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14 390 guidelines in the scientific community, and the number of teams that have reached out to us with  
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16 391 interest in participating in this work, we are confident that the guideline will be used. However,  
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18 392 we fully acknowledge the factors associated with implementation and use of guidelines, notably  
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20 393 journal endorsement of the guidelines, the passage of time and other study level characteristics  
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22 394 [20, 64-68]. Therefore, our stakeholders include editors from key journals that publish  
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24 395 methodological studies such as the *Journal of Clinical Epidemiology*, *BMC Medical Research*  
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26 396 *Methodology*, *BMC Systematic Reviews*, *The Campbell Collaboration*, and *Cochrane*.  
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28 397 Stakeholders also include representatives from academic programs building capacity, at the  
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30 398 master's and doctoral level, in conducting methodological research. To encourage better uptake,  
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32 399 it has been suggested that researchers should work collaboratively with journals in the  
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34 400 prospective design, knowledge translation, and evaluation of reporting guidelines [69], as well as  
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36 401 following up on user feedback and incorporating a system to revise the reporting guidelines  
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38 402 when necessary [70]. These strategies have been incorporated in our KT plan.  
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## 47 404 **CONCLUSIONS**

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49 405 This research will improve the transparency of reporting of methodological studies, and help  
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51 406 streamline their indexing and easier retrieval in literature databases. This work stands to make a  
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53 407 substantial impact by informing research reporting standards for studies that investigate the  
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3 408 design, conduct, analysis, or reporting of other health studies, and thereby improving the  
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5 409 transparency, reliability and replicability of health research, and ultimately benefitting patients  
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7 410 and decision makers. Future efforts will focus on field-testing the published checklist with  
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9 411 authors of methodological studies, gathering feedback from end-users, and optimizing and  
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11 412 adapting the checklist for different typologies of methodological studies as needed.  
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3 **606 AUTHORS' CONTRIBUTIONS**  
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5 607 DOL and LM conceived the idea. DOL, GG, LM and LT contributed to the design of the study.  
6  
7 608 DOL wrote the first draft of the manuscript. AKN, AWC, BDT, DBA, DM, DP, EMW, GG,  
8  
9 609 GSC, JCJ, LM, LP, LT, MB, PT, RBP, SS, TY, VW and ZS contributed to the refinement of the  
10  
11 610 study methods and critical revision of the manuscript. All authors read and approved the final  
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13 611 version of the manuscript.  
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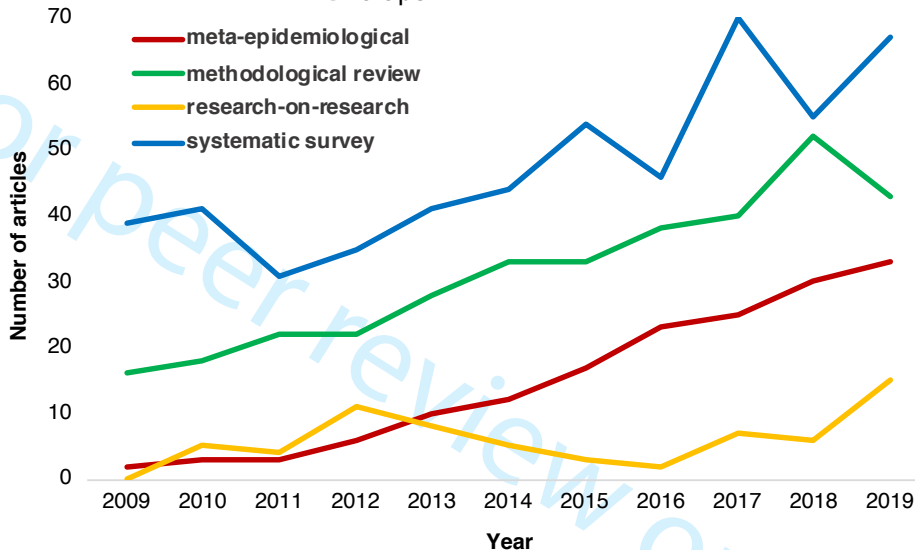
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31 619 interpretation, preparation of or decision to publish the manuscript.  
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38 **621 COMPETING INTERESTS**  
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40 622 All study authors have published methodological studies.  
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	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
<b>meta-epidemiological</b>	2	3	3	6	10	12	17	23	25	30	33
<b>methodological review</b>	16	18	22	22	28	33	33	38	40	52	43
<b>research-on-research</b>	0	5	4	11	8	5	3	2	7	6	15
<b>systematic survey</b>	39	41	31	35	41	44	54	46	70	55	67

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# Methodological Studies

## Features of methodological studies

### Study Aim

*(purpose is to investigate...)*

### Study Design

*(cross-sectional or over time)*

### Sampling Strategy

*(from a target population)*

### Unit of Analysis

## Categories of the feature

1. Bias
2. Methods
3. Reporting
4. Summarize

1. Descriptive
2. Analytical

1. Obtain all
2. Obtain sample

1. Design or analysis type
2. Research record type

## Examples of categories or the factors investigated

1. in **primary studies**, e.g. trial registry vs. final manuscript; in **secondary studies**, e.g. meta-bias
2. **describe** or **test** new methods; **compare** methods
3. **quality**, e.g. adherence to guidelines (CONSORT); **consistency**, e.g. abstract vs. full-text
4. **summarize data** from other methodological studies

1. **outline characteristics**, e.g. survey of randomized trials at predefined timepoint(s)
2. **evaluate groups or change over time**, e.g. different databases, timepoint; **pool data**, e.g. evaluate outcomes via synthesis

1. **systematic search and screen**, e.g. all eligible cohort studies on topic
2. **consecutive sampling**, e.g. first 150 trials on topic; **purposeful sample**, e.g. all eligible abstracts from designated journal(s); **random sample**, e.g. randomized selection from all eligible records

1. **design type**, e.g. randomized trial; **analysis type**, e.g. dose-response meta-analysis
2. **record type**, e.g. abstract, published manuscript, protocol document, registry entry

1 **1. Identifying the need for a guideline, review**  
2 **of the literature and obtain funding** for the  
3 guideline initiative

- ✓ Identify previous relevant guidance
- ✓ Establish feasibility for full review of methodological studies
- ✓ Funding sought
- Complete full review of methodological studies

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6 **2. Pre-meeting activities including identification**  
7 **of stakeholders, a consensus exercise,**  
8 **and generation of a list of items** for  
9 consideration at the consensus meeting

- ✓ Establish working group, identification of stakeholders
- Share full review findings
- Ethics, online consensus exercise, and generation of a list of candidate items

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13 **3. Consensus meeting and discussion of a**  
14 **knowledge translation strategy**

- Conduct video conference meetings and final consensus meeting
- Share guideline (draft)
- Collect feedback

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19 **4. Post-meeting activities including development**  
20 **and publication of the guidance** statement

- Disseminate guideline (final)

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23 **5. Post-publication activities including**  
24 **encouragement of endorsement,**  
25 **adherence, web site development and**  
26 **translation of the guideline**

- ✓ Build and populate database of methodological studies
- Knowledge translation strategies for guideline, website and database

Completed In progress Not started

## SUPPLEMENTARY FILE

## Timeline of the development of reporting guidelines:

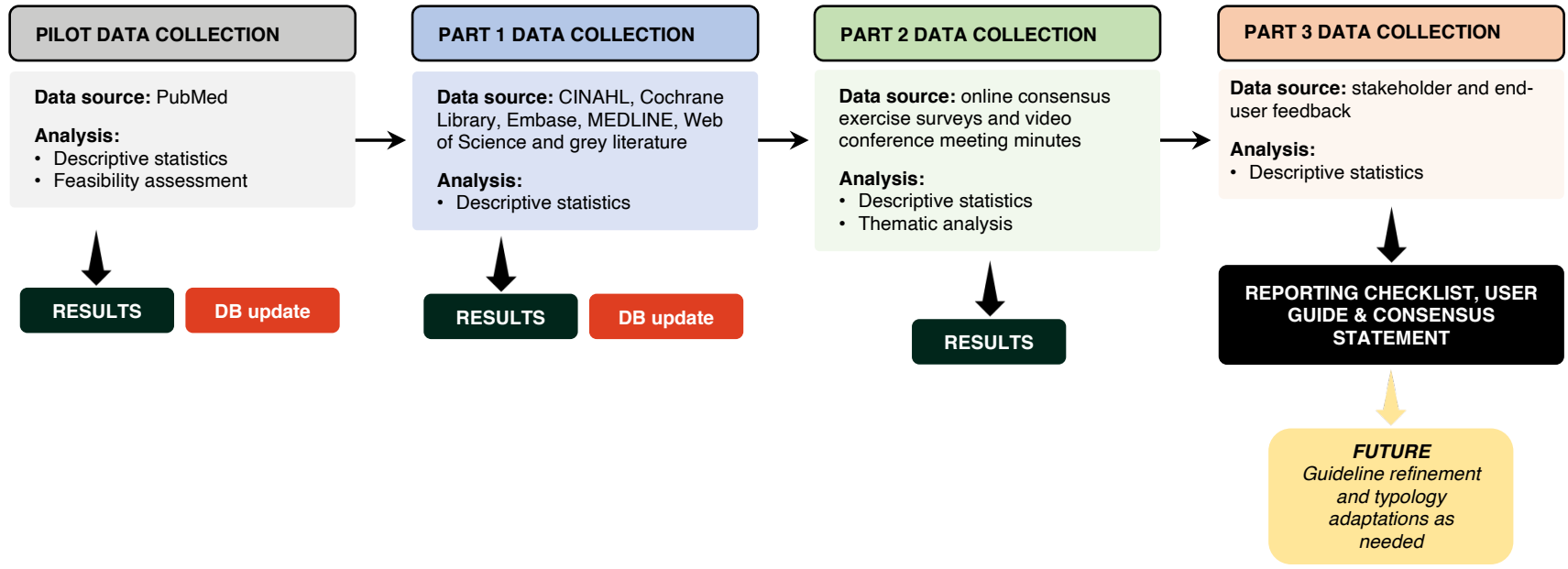
OBJECTIVES & STEPS		DURATION (MONTHS)	YEAR 1 (2021)				YEAR 2 (2022)			
			Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
1	<b>Methodological review</b> of the literature	8	●	●						
2	Development of an <b>electronic database</b> for methodological studies	8		●	●					
3	<b>Consensus study</b> and development of a <b>reporting guideline</b>	6			●	●	●	●		
4	Knowledge translation activities	—	●	●	●	●	●	●	●	●

Q: quarter.



SUPPLEMENTARY FILE

Flow of data for informing subsequent stages of the project:



CINAHL: Cumulative Index for Nursing and Allied Health Literature, DB: database ([www.methodsresearch.ca](http://www.methodsresearch.ca))

For peer review only

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## SUPPLEMENTARY FILE

### Sample search strategy for MEDLINE:

*Concept: names of methodological studies*

- 1 (meta-epidemiolog\* OR metaepidemiolog\* OR meta-research OR methodolog\* analysis OR
- 2 methodolog\* evidence OR methodolog\* investigation OR methodolog\* literature OR
- 3 methodolog\* overview OR methodolog\* report\* OR methodolog\* review OR methodolog\*
- 4 survey OR methodolog\* synthesis OR method\* overview OR systematic database review OR
- 5 systematic literature survey OR systematic survey).mp.
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- 14 2 (methodolog\* study OR method\* review OR method\* survey)

*Concept: topics in methodological research (i.e. analysis, design and reporting)*

- 3 exp Data Collection/
- 4 exp Data Interpretation, Statistical/
- 5 exp Epidemiologic Research Design/
- 6 exp Nursing Methodology Research/
- 7 exp Reproducibility of Results/
- 8 exp Research Design/
- 9 3 OR 4 OR 5 OR 6 OR 7 OR 8
- 10 2 AND 9

*Concept: methodological studies that are called 'systematic reviews'*

- 11 systematic review.mp.
- 12 Cochrane Database of Systematic Reviews.jn
- 13 11 NOT 12
- 14 \*Data Collection/
- 15 \*Data Interpretation, Statistical/
- 16 \*Epidemiologic Research Design/
- 17 \*Nursing Methodology Research/
- 18 \*Reproducibility of Results/
- 19 \*Research Design/
- 20 14 OR 15 OR 16 OR 17 OR 18 OR 19
- 21 13 AND 20
- 22 1 OR 10 OR 21