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Reporting quality for abstracts of randomised trials on child and adolescent depression prevention: A meta-epidemiological study on adherence to CONSORT for abstracts

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5 2 depression prevention: A meta-epidemiological study on adherence to CONSORT for abstracts
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8 3 Corresponding author: Jascha Wiehn; jascha.wiehn@charite.de, Charitéplatz 1, 10117 Berlin
9

10
11 4 First author: Jascha Wiehn, Institute of Public Health, Charité – Universitätsmedizin Berlin, Berlin,
12
13 5 Germany
14

15
16 6 Second author: Johanna Nonte, Department of Population Medicine and Health Services
17
18 7 Research, Bielefeld School of Public Health, Bielefeld University, Bielefeld, Germany
19

20
21 8 Third author: Christof Prugger, Institute of Public Health, Charité – Universitätsmedizin Berlin,
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23 9 Berlin, Germany
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12 **ABSTRACT**

13 **Objectives**

14 This meta-epidemiological study aimed to investigate adherence to CONSORT for abstracts in
15 reports of randomised trials on child and adolescent depression prevention. Secondary objective
16 was to examine factors associated with overall reporting quality.

18 **Participants**

19 Trials were eligible if the sample consisted of children and adolescents under 18 years with or
20 without an increased risk for depression or subthreshold depression.

22 **Interventions**

23 We included reports on RCTs and CRTs assessing universal, selective, and indicated
24 interventions aiming to prevent the onset of depression or reducing depressive symptoms.

26 **Primary and secondary outcome measures**

27 As the primary outcome measure, we assessed for each trial abstract whether information
28 recommended by CONSORT was adequately reported, inadequately reported, or not reported.

29 Moreover, we calculated a summative score of overall reporting quality and analysed associations
30 with trial and journal characteristics.

32 **Results**

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3 33 We identified 169 eligible studies, 103 (61%) RCTs and 66 (39%) CRTs. Adequate reporting
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5 34 varied considerably across CONSORT items: while 9 out of 10 abstracts adequately reported the
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7 35 study objective, no abstract adequately provided information on blinding. Important adverse
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9 36 events or side effects were only adequately reported in one out of 169 abstracts. Summative
10
11 37 scores for the abstracts' overall reporting quality ranged from 17% to 83%, with a median of 40%.
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13 38 Scores were associated with the number of authors, abstract word count, journal impact factor,
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15 39 year of publication and abstract structure.
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21 **Conclusions**

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24 42 Reporting quality for abstracts of trials on child and adolescent depression prevention is
25
26 43 suboptimal. To help health professionals make informed judgments, efforts for improving
27
28 44 adherence to reporting guidelines for abstracts are needed.
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31 **Strengths and limitations of this study**

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36 47
- 37 • This study is the first to systematically assess the reporting quality for abstracts of
38 randomized trials on paediatric depression prevention.
 - 39 • Our extensive, reproducible search strategy identified 169 eligible journal articles reflecting
40 the available evidence from such trials published 2003 to 2020.
 - 41 • Two reviewers independently screened abstracts and extracted data using standardised
42 methods, but the reviewers were not blinded to meta-data such as study authors, journal
43 name or year of publication.
 - 44 • Since no method has so far been established for determining overall reporting quality of
45 abstracts, we approximated overall reporting quality by calculating a summative score
46 based on CONSORT items.
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- 57 • Because we applied a topic-based approach without restricting the information source to
58 specific journals, our study findings offer insights into general reporting quality in trials on
59 childhood depression prevention.

For peer review only

1 INTRODUCTION

Reports of trials should provide all necessary information allowing readers to evaluate the reproducibility, validity and utility of studies and findings. [1, 2] Poor reporting of health research leads, at the very least, to avoidable waste of resources [3] and can ultimately jeopardize patient care. [4] The same applies to abstracts of trials. Due to time, access and language constraints, health professionals often use abstracts as the primary source of information to learn about a trial, [5, 6] and the way abstracts report study details can influence their decisions in patient management. [7] Researchers conducting systematic reviews and meta-analyses may incorrectly exclude eligible studies in title and abstract screening due to poor reporting which can distort evidence synthesis. [8] Moreover, indexers of literature databases rely on adequate title and abstract reporting to correctly determine search terms such as medical subject headings, otherwise relevant journal articles cannot be found, read and quoted to affect medical practice.

For these reasons, authors of randomized trial reports are encouraged to follow the Consolidated Standards of Reporting Trials (CONSORT) guidelines [5–8] and its extension for abstracts (CONSORT-A). [9, 10] CONSORT-A was published in 2008 to provide guidance to authors on information to be reported in abstracts of randomized controlled trials (RCTs). In 2012, the guidelines were further complemented by a module for cluster randomized trial (CRT) abstracts (CONSORT-C). [11] Although some improvement in reporting quality of trials has been observed over recent years, [12] general adherence to CONSORT guidelines remains suboptimal in articles published both in general medicine [13–17] and psychiatry/psychology journals. [18–20] Similar results have been reported from studies on adherence to CONSORT-A for abstract reporting in various health disciplines including one previous study on abstracts of psychiatric RCTs.[21] However, no prior study has investigated the abstract reporting quality of depression prevention trials in young people. We therefore aimed to evaluate to what extent CONSORT-A and CONSORT-C criteria are met by abstracts of reports on child and adolescent depression

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3 85 prevention trials. Secondary objective of our study was to explore trial and journal characteristics
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5 86 associated with the abstracts' overall reporting quality.
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8 87 **2 METHODS**

9 88 **2.1 Eligibility criteria**

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14 89 We included reports on RCTs and CRTs assessing universal, selective and indicated interventions
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16 90 aiming to prevent the onset of depression or reducing depressive symptoms in children and
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18 91 adolescents under 18 years with or without an increased risk for depression or subthreshold
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20 92 depression. A detailed list of the eligibility criteria is provided in Supplementary S1. We only
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22 93 included research articles published in peer-reviewed journals, the primary source of information
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24 94 for paediatric health specialists,[22] and we considered the period between January 1, 2003 and
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26 95 August 5, 2020 to assess reporting quality before and after the publication of CONSORT-A and -
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28 96 C guidelines.
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31 97 **2.2 Information sources**

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34 98 We searched the electronic literature databases MEDLINE (via PubMed and Ovid®), EMBASE
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36 99 (via Ovid®), PsychINFO (via EBSCOhost®), PsycArticles (via EBSCOhost®), and CENTRAL (via
37
38 100 Cochrane Library) on March 9, 2019 and updated the search on August 8, 2019. Search strings
39
40 101 were developed in collaboration with a trained librarian. The electronic search strategy for
41
42 102 MEDLINE via PubMed is shown in Supplementary S2. Electronic search strategies for the other
43
44 103 databases are provided in an online repository
45
46 104 (https://osf.io/ahzwn/?view_only=e2f08c5c0d2d4936ba88d38968aba5d9). Additional articles
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48 105 were retrieved by hand-searching four specialty journals and the reference lists of systematic
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50 106 reviews (Supplementary S3).
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2.3 Study selection

After merging records from literature databases and removing duplicates, records of 4,279 articles entered title and abstract screening, and 520 articles were subsequently evaluated in full text screening by three pairs of independent reviewers (Figure 1). In consensus, 162 articles were judged to be eligible and 276 articles were judged to be not eligible. The reviewers disagreed in 82 cases and reached a consensus through discussions to include 5 and exclude 67 articles. Ten discussions did not result in consensus, so a third reviewer decided to discard eight and include two articles. Interrater reliability as assessed by Cohen's kappa (unweighted) for the agreement between the three reviewer pairs (article eligible vs. non-eligible) was moderate in the title and abstract screening with $\kappa = 0.39$, $\kappa = 0.47$ and $\kappa = 0.55$ and higher in the full-text screening with $\kappa = 0.59$, $\kappa = 0.73$ and $\kappa = 0.67$.

2.4 Data collection

Two independent reviewers extracted information from the 169 identified articles into piloted spreadsheets with drop-down menus. The reviewers first determined whether randomization was performed on an individual (RCT) or cluster level (CRT) and subsequently assessed all abstracts according to CONSORT-A and CRTs additionally according to CONSORT-C. [10, 11] For each item, the reviewers judged whether the abstract reported information adequately, inadequately or not at all. For interrater reliability on CONSORT items, please refer to Supplementary S4.

For items with multiple dimensions, we operationalized each dimension separately and then created item variables for analysis based on the extracted information. For example, CONSORT-A item 03 *Participants* requires reporting the eligibility criteria for participants and settings where the data were collected. Thus, if both dimensions were reported adequately (or not at all), then the item was judged as adequately reported (or as not reported). However, if either the eligibility criteria for participants or for settings was reported inadequately, the item was judged as

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3 131 inadequately reported. Additional variables for which data were extracted are listed in
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5 132 Supplementary S5.
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8 133 **2.5 Statistical analysis**

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10 134 We used descriptive statistics to summarize the extent to which RCT and CRT abstracts adhered
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12 135 to the 15 CONSORT-A items and CRT abstracts adhered to the additional eight CONSORT-C
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14 136 items. For each CONSORT item we thus present the proportion of trial abstracts adequately,
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16 137 inadequately, or not reporting the item information as required by the appropriate guideline.
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19 138 We calculated summative scores of overall reporting quality grading CONSORT items as follows:
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21 139 (i) adequately reported (2 points), (ii) inadequately reported (1 point), and (iii) not reported (0
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23 140 points). Depending on the study design, these overall reporting quality scores (RQS) could thus
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25 141 theoretically range from 0 to 30 for RCTs (15 CONSORT-A items) and from 0 to 46 for CRTs (eight
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27 142 additional CONSORT-C items). We transformed RQS to standardized percentages with possible
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29 143 ranges from 0 (lowest reporting quality) to 100 (highest reporting quality).
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33 144 We compared unstructured (1 section), structured (2-4 sections) and highly structured (>4
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35 145 sections) abstracts [23] in relation to RQS using the Kruskal-Wallis test. We fitted separate linear
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37 146 regression models to quantify associations between overall reporting quality and (i) number of
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39 147 authors, (ii) sample size, (iii) number of sampling points, (iv) abstract word count, (v) journal impact
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41 148 factor and (vi) year of publication. Because of heavily skewed distributions (Supplementary S6)
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43 149 we log-transformed (log 10) the first five abovementioned variables for analysis. It should be noted
44
45 150 that this is descriptive modelling not aiming at prediction or causal inference. [24] We used RStudio
46
47 151 (R version 4.1.1) for data analysis.
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50 152 **2.6 Patient and public involvement**

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52 153 Instead of patient data we used information of previously published trial reports. Thus, no patients
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54 154 or public were involved in this study. Yet, our results can inform authors, editors, reviewers, and
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56 155 readers of the scientific literature.
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156 **3 RESULTS**

157 **3.1 Characteristics of included abstracts**

158 We identified 169 articles, of which 61% were reports on RCTs (n=103) and 39% reports on CRTs
159 (n=66). More than half of these articles were published between 2015 and 2020 (Supplementary
160 S7). Median number of authors was five (range: 1 – 24, Q1: 4, Q3: 8). Sample size ranged from
161 23 to 12,391 participants, with a median of 271 (Q1: 120, Q3: 670). Twenty-one of the reported
162 studies were performed at a single site, while 117 were reports of multicenter studies. Median
163 abstract word count was 225 words, with range from 68 to 623 (Q1: 175, Q3: 253). The median
164 journal impact factor was 3.2 (Q1: 2.1, Q3: 4.3). Fifty-seven percent of the included abstracts were
165 unstructured (n=97), one-third of the abstracts were structured with two to four sections (n=56),
166 and the remaining 10% were highly structured (n=16), i.e., with more than four sections.

167 **3.2 Adherence to CONSORT for abstracts**

168 Figure 2 summarizes the results on adherence to CONSORT for abstracts items, i.e. the
169 proportion of trial abstracts reporting item information adequately, inadequately and not at all
170 (please see also Supplementary S4 for exact figures). The percentage of adequate reporting
171 among general items ranged from 58.0% (item *01 Title*) to 30.2% (item *02 Trial design*). With
172 regards to trial methodology, the highest percentage of adequate reporting was in item *05*
173 *Objective*. Nine out of ten trial abstracts adequately reported the specific study objective or
174 hypothesis. On the contrary, not a single trial abstract adequately reported whether participants,
175 care givers and those assessing the outcomes were blinded to group assignment (item *08*
176 *Blinding*). Regarding trial results, item *13 Conclusions* had the highest percentage of adequate
177 reporting (36.7%) and item *12 Harms* the lowest (0.6%).

178 **3.3 Overall reporting quality and associated factors**

179 The distribution of the RQS among all abstracts and stratified by study design is depicted in Figure
180 3. In all abstracts, the median RQS was 40% (range 17 – 47) with 25th and 75th percentile of 33%

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3 181 and 47%, respectively. The RQS was slightly higher in RCT abstracts than in CRT abstracts
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5 182 (median 43% vs. 37%). The graphs in Figure 4 visualize the relationship of trial and journal
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7 183 characteristics with RQS. Number of authors, abstract word count and journal impact factor were
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9 184 positively associated with RQS. For example, for every 10% increase in the journal impact factor,
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11 185 the RQS increased by about 1.9 percentage points (calculation: coefficient $5.6 \times \log(1.10) \approx 1.9$).
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13 186 Moreover, RQS increased with each year after publication of CONSORT-A in 2008. Structured (2-
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15 187 4 sections) and in particular highly structured abstracts (>4 sections) had a higher RQS than
16
17 188 unstructured abstracts (1 section). Sample size and number of sampling points were not related
18
19 189 to RQS.
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23 190 **4 DISCUSSION**

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26 191 In the present study, we assessed reporting quality for abstracts of child and adolescent
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28 192 depression prevention trial reports. Overall, we found that adherence with CONSORT-A and
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30 193 -C for abstracts is suboptimal in journal articles reporting on such studies between 2003 and
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32 194 2020. Reporting quality plays a crucial role generating and translating scientific evidence as
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34 195 it increases transparency and accuracy and thereby enables health professionals to identify,
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36 196 evaluate, replicate and implement trial results. Thus, the scientific interest in assessing and
37
38 197 improving reporting quality of trials has steadily increased over time.[25]
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42 198 **4.1 Comparison with previous studies**

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44 199 Meta-epidemiological studies of reporting quality follow two distinct methodological approaches.
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46 200 In the journal-based approach, one or more journals are selected, usually top journals in a specific
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48 201 field with a high-impact factor, and the published articles are assessed. Examples comprise
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50 202 studies on the abstract reporting quality in general [15, 16, 26–28] and internal medicine, [29–
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52 203 31] anesthesiology, [32–34] surgery, [35, 36] nursing [37] and critical care.[38] The only prior
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54 204 study on abstracts of psychiatric trials followed this approach as well. [21] However, the
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3 205 restriction to top journals could affect generalizability, as a higher impact factor may be associated
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5 206 with better reporting quality. [21, 29, 37, 39–43] Thus, journal-based meta-epidemiological studies
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7 207 might overestimate the quality of abstract reporting. On the contrary, in the topic-based approach,
8
9 208 no constraints are made regarding the journals. Instead, literature databases are systematically
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11 209 searched for articles on a specific disease, therapy or other topic.[39, 40, 43–49] This increases
12
13 210 the variety of journals, making it difficult to draw conclusions about reporting quality of specific
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15 211 journals. However, the topic-based approach increases generalizability by also including journals
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17 212 with a lower impact factor and thus provide a more complete picture of reporting quality.
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20
21 213 Another methodological aspect that differs between studies is the selected time frame for eligible
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23 214 studies. While some studies cover one [15, 16, 37, 46] or two years, [27, 32, 40, 47, 50, 51] others
24
25 215 look at several decades.[39] Moreover, studies differ regarding the temporal relation to the release
26
27 216 of CONSORT-A in 2008. For example, Chen et al. cover a period prior to the guideline release
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29 217 (1998 to 2007),[26] the work by Menne et al. concerns a post-release period (2016 to 2021),[52]
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31 218 and some but not all studies including the year 2008 compare periods up to and after the
32
33 219 publication of CONSORT-A.[21, 27, 29, 30, 33, 35, 37, 39, 41, 42, 44]
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36 220 In setting our study within the available evidence, special mention deserves the study by Song et
37
38 221 al. that applied a journal-based approach investigating reporting quality in RCT abstracts
39
40 222 published in high-impact psychiatry journals both prior (2005-2007) and after (2012-2014) the
41
42 223 release of CONSORT-A. [21] In this systematic review of RCT abstracts in psychiatry,[21] about
43
44 224 one out of five included trials addressed depression, and few studies among children or
45
46 225 adolescents with clinical depression were evaluated. [53, 54] However, in contrast to our study,
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48 226 with the exception of one single RCT, Song et al. left trials on non-pharmacological interventions
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50 227 in childhood prevention unconsidered.
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228 4.1.1 General items

229 In our study, the general items *01 Title* and *02 Trial design* were adequately reported in about
230 60% and 30% of trial abstracts, respectively. Similarly, Song et al. reported in their study that
231 66% of trials stated "randomized" in the title but only 14% of trials described the study design
232 in the abstract.[21] It is noticeable that studies which have chosen a time frame closer to the
233 present tend to have higher reporting quality on these items. For example, Menne et al.
234 including trial abstracts published in the period from 2016 to 2021 found all studies adequately
235 reported the title and a quarter of trial abstracts had adequate information on trial design.[52]
236 On the other hand, Cui et al. evaluating trial abstracts published between 1999 and 2012
237 found only 5.5% and 3% of abstracts adequately reported the title and trial design,
238 respectively.[39]

239 CONSORT-C requires that abstracts are denoted as cluster randomized in the title (item *01*
240 *Title (cluster extension)*). In our study, however, only one third of all CRT abstracts adequately
241 reported this item. To our knowledge, the present study is the first to examine adherence to
242 CONSORT-C guidelines in CRT abstracts. Yet, some meta-epidemiological studies examined
243 adherence to CONSORT-C for full texts, which includes the same item. For example, Chan
244 et al. showed that about two thirds of pilot or feasibility CRT reports published between 2011
245 and 2014 adequately met this CONSORT item. [55] Similarly, Ivers et al., Diaz-Ordaz et al.,
246 and Walleser et al. found that 48%, 60%, and 98% of CRTs, respectively, state in the title or
247 abstract that the study is a CRT. [56–58]

248 4.1.2 Trial methodology

249 Among all 169 included abstracts, 36% adequately reported both eligibility criteria for participants
250 and setting. In line with many previous studies,[16, 21, 29, 34, 38, 59] we extracted the originally
251 combined information for CONSORT item *03 Participants* using separate dimensions: (i) eligibility

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3 252 criteria for participants and (ii) eligibility criteria for settings. Some differences to Song et al. can
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5 253 be observed for these sub-dimensions (participants: 81% in this study vs. 95% in Song et al.;
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7 254 setting: 36% in this study vs. 32% in Song et al.). In contrast, other studies assessed reporting
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9 255 of eligibility criteria for participants only.[27, 44, 50, 60] It is not surprising that these studies show
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11 256 the highest proportions of adequate reporting for this item.

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13
14 257 We found that 98% of abstracts failed to adequately include information on how participants were
15
16 258 assigned to interventions and that 96% of abstracts lacked complete information on whether
17
18 259 participants, program deliverer and data collectors/analysts were blinded. Generally, this issue of
19
20 260 inadequate abstract reporting of CONSORT items *07 Randomization* and *08 Blinding* can be
21
22 261 observed both in studies using journal- and topic-based approaches; with a few exceptions,[16,
23
24 262 37, 43–45, 49] most previous studies reported adherence to these items of well below 10%. [15,
25
26 263 21, 26, 27, 29–36, 38–42, 46, 47, 50, 51, 61–64]

264 4.1.3 Trial results

265 We found that the number of participants randomized to each group was adequately reported in
266 approximately a third of all abstracts. The proportion of adequately reporting abstracts drops to
267 four percent when it comes to the number of participants analyzed in each group. This gap
268 between adequate reporting of numbers randomized versus numbers analyzed has also been
269 observed in previous meta-epidemiological studies. As an example, Fleming et al. reported
270 that 96% of abstracts published in leading orthodontic journals between 2006 and 2011
271 provided adequate information on the number of participants randomized, but only one in four
272 of the included abstracts adequately reported the number of participants analyzed.[61]

273 Only one article in our sample elaborated on adverse or unintended effects in the abstract,
274 whereas all other 168 abstracts failed to mention important adverse events or side effects (item
275 *12 Harms*). Other meta-epidemiological studies found considerably higher proportions of

276 adequate reporting for this item, particularly trials that also included pharmacologic interventions.
277 [27, 35, 45]

278 Finally, our study showed that about 12% of abstracts adequately reported the item *15 Funding*.
279 Many meta-epidemiological studies even found the proportion of abstracts that adequately report
280 funding is in the single digits [21, 31, 34, 38, 41, 47, 52, 63] or even zero percent. [30, 32, 33, 35,
281 36, 39, 42, 46, 50, 51, 61, 64] However, it may be rather the journal regulations than CONSORT
282 to influence whether funding information appears in the abstract or in another place, for example
283 at the end of the manuscript.

284 4.1.4 Associations with overall reporting quality

285 We found that most of the trial and journal characteristics investigated in our study were
286 associated with overall abstract reporting quality.

287 In line with previous findings,[29, 40–42, 47, 63] we observed that overall reporting quality
288 increases with the number of authors. In contrast, some studies found no such relationship.[21,
289 37, 47, 51, 61, 62] Other studies suggest, although not consistently[65], that the involvement of
290 methodologists is associated with higher reporting quality.[57, 66, 67] However, number of authors
291 may reflect at least to some extent whether author groups include methodologists.

292 Our data suggests that a higher journal impact factor correlates with increased overall reporting
293 quality. If the impact factor is an indicator for journal quality,[68] journals with a higher impact factor
294 may apply more rigorous quality control to reporting. This result would thus underline that
295 restricting studies to top journals may hamper generalizability.

296 We observed that structured abstracts showed higher overall reporting quality compared to
297 unstructured abstracts. With some exceptions,[16, 41, 47, 49, 61] many meta-epidemiological
298 studies have shown similar results both since [21, 29, 37, 40, 42, 43, 51, 52] and before the

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3 299 publication of CONSORT-A.[69–75] However, few studies also suggest that structured abstracts
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5 300 are not superior [76–78] and that abstract structure was unrelated to reporting quality.[79]
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8 301 It may take time for guidelines to spread and be applied by authors, reviewers and editors. Our
9
10 302 data provide some indication that overall reporting quality is improving over time: although the
11
12 303 RQS remained basically unchanged between 2003 and 2007, a clear increase was observed in
13
14 304 the period between 2008 and 2020. Guo et al. reported a significant increase of reporting quality
15
16 305 per year between 1984 and 2010. [43] Chhapola et al. similarly found positive temporal trends
17
18 306 when comparing the slopes of reporting quality of 2003 to 2007 vs. 2010 to 2014.[80] Menne et
19
20 307 al. analysed reporting quality between 2016 and 2021 and observed no increase of reporting
21
22 308 quality over these years. [52] However, most studies observed that abstract reporting quality was
23
24 309 higher in the period after publication compared to the period prior to CONSORT-A publication. [21,
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26 310 27, 30, 35, 39, 41, 42]
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29 311 **4.2 Strengths and limitations**

31
32 312 This study is the first on reporting quality of trial abstracts in childhood depression prevention. Key
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34 313 strength of our study is the topic-based approach we have chosen; compared to journal-based
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36 314 studies, our results provide a more complete picture of abstract reporting in the field. We carried
37
38 315 out an extensive, reproducible methodology to screen the literature for eligible studies and retrieve
39
40 316 study information. We analysed abstracts published over a broad timespan allowing for
41
42 317 comparison of reporting quality before and after publication of CONSORT guidelines. We assess
43
44 318 adherence not only to CONSORT-A for RCT abstracts but also to CONSORT-C for CRT abstracts,
45
46 319 which was not evaluated by any prior study.
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49 320 We applied CONSORT to measure reporting quality, although it was not designed for this purpose.
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51 321 However, in the current absence of standardized tools for assessment, validated guidelines such
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53 322 as CONSORT are the best available choice to evaluate reporting quality. Moreover, CONSORT
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55 323 for social and psychological interventions were not checked for adherence. [81, 82] However,
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3 324 these guidelines were only published in 2017 and 2018, respectively, and thus few studies could
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5 325 have considered these standards. We assess the reporting quality of trial abstracts and cannot
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7 326 draw conclusions about the quality of reporting in the main text. Reviewers were not blinded to
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9 327 trial and journal characteristics such as authors, publication date and impact factor, during the
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11 328 study selection and the data extraction. We can therefore not exclude the possibility of bias in the
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13 329 evaluation due to metadata insight of the judging reviewers.
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16 330 When we calculated overall reporting quality scores, we treated each CONSORT item equally,
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18 331 although some items could be more or less relevant than others.[31, 38, 44] These scores are
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20 332 simplified proxies to represent reporting quality with a single measure. The assessment of
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22 333 reporting quality should however primarily be based on the individual items. [32]
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25 334 We used descriptive modelling to explore factors associated of reporting quality; neither predictive
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27 335 nor causal conclusions can be derived from this. Unmeasured factors such as journal
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29 336 endorsement of CONSORT [83] may also be associated with reporting quality. Findings from our
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31 337 secondary research aim may thus be incomplete and should be interpreted with caution.
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34 338 **4.3 Conclusions**

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37 339 CONSORT extensions are valuable tools for authors, reviewers and editors to formulate trial
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39 340 abstracts in a transparent and comprehensible way. Although these tools have been openly
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41 341 available for years, the reporting quality of RCT and CRT abstracts on the prevention of
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43 342 depression in children and adolescents remains suboptimal. Of particular concern is inadequate
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45 343 reporting of methodological CONSORT-A items such as *07 Randomization* and *08 Blinding*, which
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47 344 are critical for readers seeking to evaluate reproducibility, validity and utility, since lack of
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49 345 information on allocation concealment or blinding hamper to assess the risks of potential bias.
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51 346 Another issue of particular concern is poor reporting of CONSORT-A item *12 Harms*. Side effects
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53 347 are reported more commonly in pharmacological studies than in social or psychological studies,
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3 348 [84] however, unintended adverse effects may also occur in social or psychological studies and
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5 349 should therefore also be reported in the corresponding abstracts.[82]
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8 350 Some CONSORT-A and -C items such as *05 Objective* are adequately reported in most
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10 351 depression prevention trial abstracts, and this should be the benchmark for all items. Interventions
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12 352 aimed at strengthening abstract reporting quality are thus needed. According to Blanco et al., such
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14 353 interventions should aim to train authors, reviewers and editors on the practical use of CONSORT
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16 354 and its extensions.[85] Moreover, academic institutions could promote CONSORT and other
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18 355 reporting guidelines. Further interventions proposed by Blanco and colleagues would aim to
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20 356 improve understanding, encourage and check adherence, as performed by our study, provide
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22 357 critical feedback and involve methodology experts in the publication process.[85] These efforts
23
24 358 will very likely not only benefit the scientific community and practitioners in the field, but may
25
26 359 ultimately improve mental health care for children and adolescents worldwide.
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31
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33
34 362 public, commercial or not-for-profit sectors.
35
36

37 363 **Authors' contributions.** JW is the guarantor. JW conceived the idea for the project. JW and CP
38
39 364 developed the concept and methods. JW and JN performed the data selection and extraction. CP
40
41 365 gave final instructions when consensus could not be reached. JW performed the statistical
42
43 366 analysis and interpreted the study findings. JW drafted the first version of the manuscript. CP
44
45 367 contributed to data interpretation, writing, and editing. All authors reviewed and approved the final
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47 368 manuscript before submission.
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51 369 **Ethics.** We analysed information from published abstracts and not from human subjects or
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53 370 animals. Therefore, ethics committee approval is not required for this study.
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371 **Registration.** Even though reporting quality may indirectly affect patient care in the long-term, we
372 did not assess outcomes of direct patient or clinical relevance. As this is a pre-requisite for
373 registration, we could not register this study in the international prospective register of systematic
374 reviews database (PROSPERO).

375 **Competing interests' statement.** All authors declare that they have no competing interests
376 regarding the publication of this article.

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378 Universitätsmedizin Berlin, who with his expertise provided support for the research project in the
379 development and evaluation of the literature search strategy.

380 **Reporting guidelines.** Strictly speaking, meta-epidemiological studies are not systematic
381 reviews. [86] Nevertheless, we used an adapted version of the Preferred Reporting Items for
382 Systematic Reviews and Meta-Analyses (PRISMA) checklist to report our research (see PRISMA
383 checklist available from the OSF repository). [87]

384 **Data sharing statement.** Statistical code and dataset available from the OSF repository, DOI:
385 https://osf.io/ahzwn/?view_only=e2f08c5c0d2d4936ba88d38968aba5d9

386 **Keywords.** Meta-research, methodology research, quality of reporting, mental health, paediatrics,
387 psychiatry, psychology

388 Additional MeSH: Depression, Research Report, Reproducibility of Results, Checklist, Reference
389 Standards, Quality Control, Child, Adolescent

390 **FIGURES AND ILLUSTRATIONS**

391 Figure 1: PRISMA flowchart depicting the study selection process.

392 Figure 2: Percentage of abstracts adhering to CONSORT items in 169 trial reports on the
393 prevention of depression in children and adolescents.

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3 394 Figure 3: Distribution of overall reporting quality by study design.
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6 395 Figure 4: Associations of overall reporting quality with abstract and journal characteristics.
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For peer review only

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Identification
Screening
Eligibility
Included

Records identified through database search between 01.01.2003 and 09.04.2019 (n= 8,043)

Records identified through database search between 01.01.2003 and 05.08.2020 (n= 9,581)

Additional records identified through hand search (n= 75) and reference lists of previous reviews (n= 328)

Records after duplicates removed (n= 4,279)

Title-Abstract-Screening (n= 4,279)

Records excluded if both reviewers vote 'non-eligible' (n= 3,759)

Full-Text-Screening (n= 520)

Records excluded if both reviewers vote 'non-eligible' (n= 276)

Discussion and consensus (n= 82)

Both reviewers agree to discard the record (n= 67)

No consensus leads to third reviewer decision (n= 10)

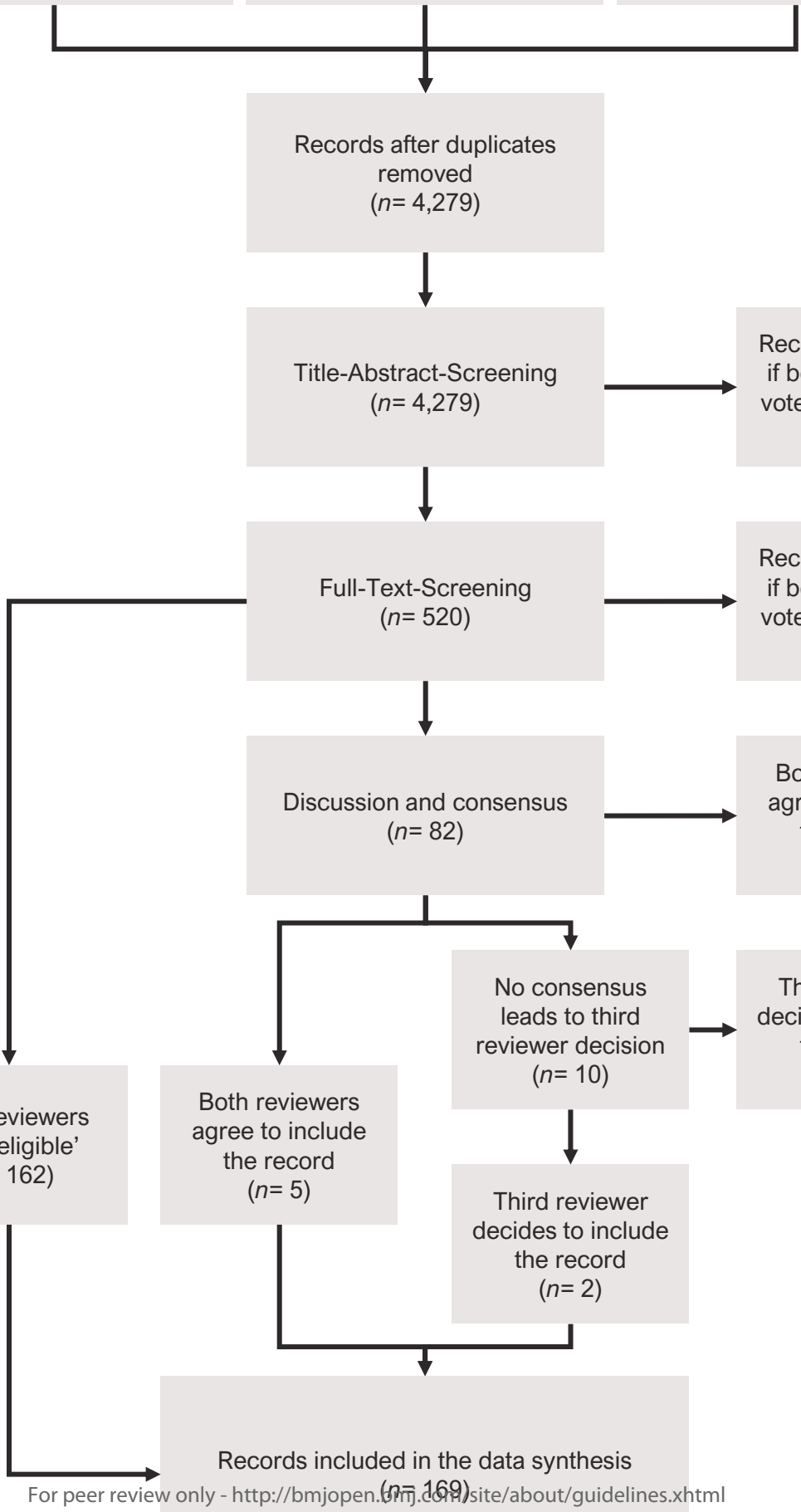
Third reviewer decides to discard the record (n= 8)

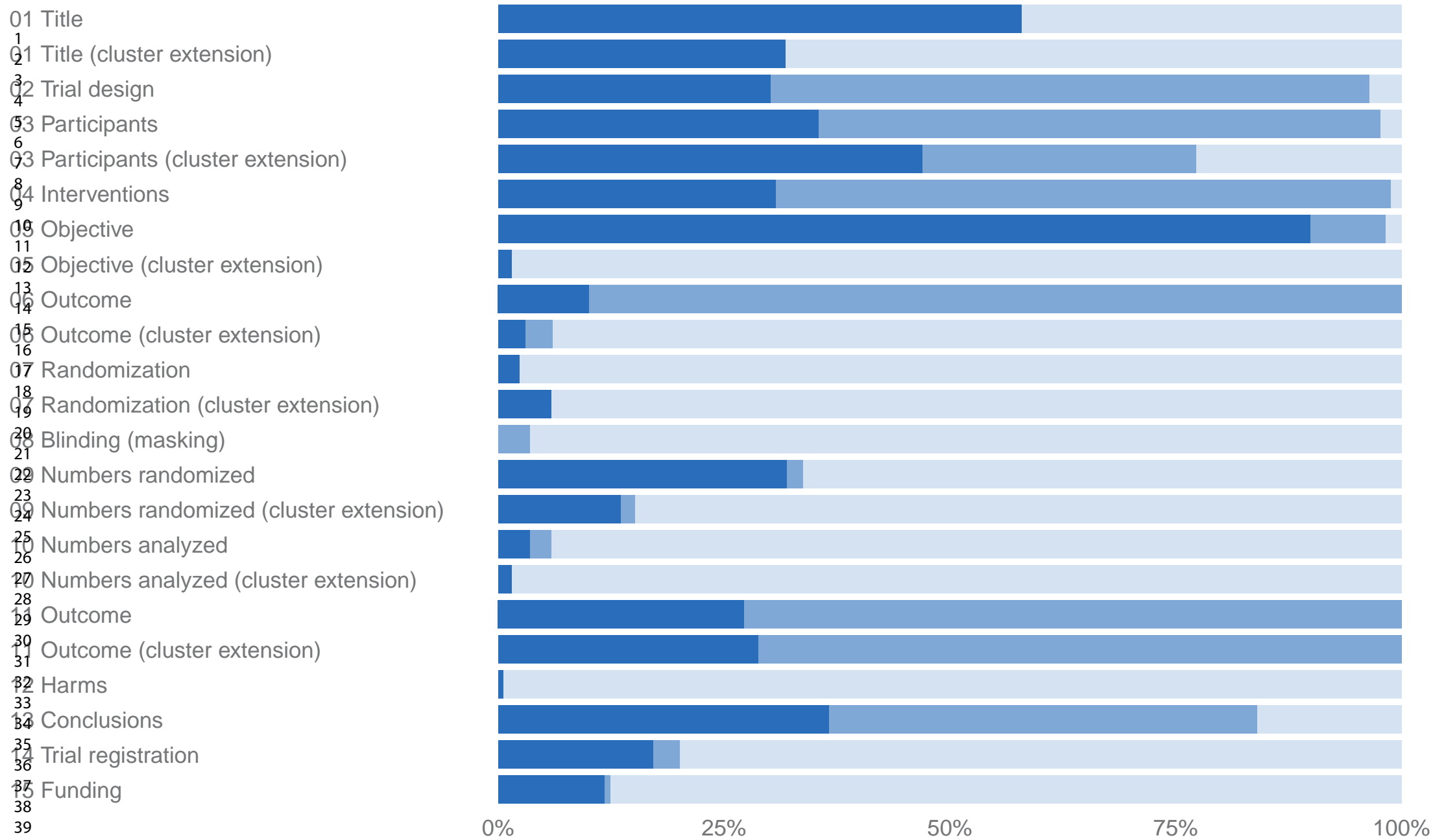
Third reviewer decides to include the record (n= 2)

Both reviewers vote 'eligible' (n= 162)

Both reviewers agree to include the record (n= 5)

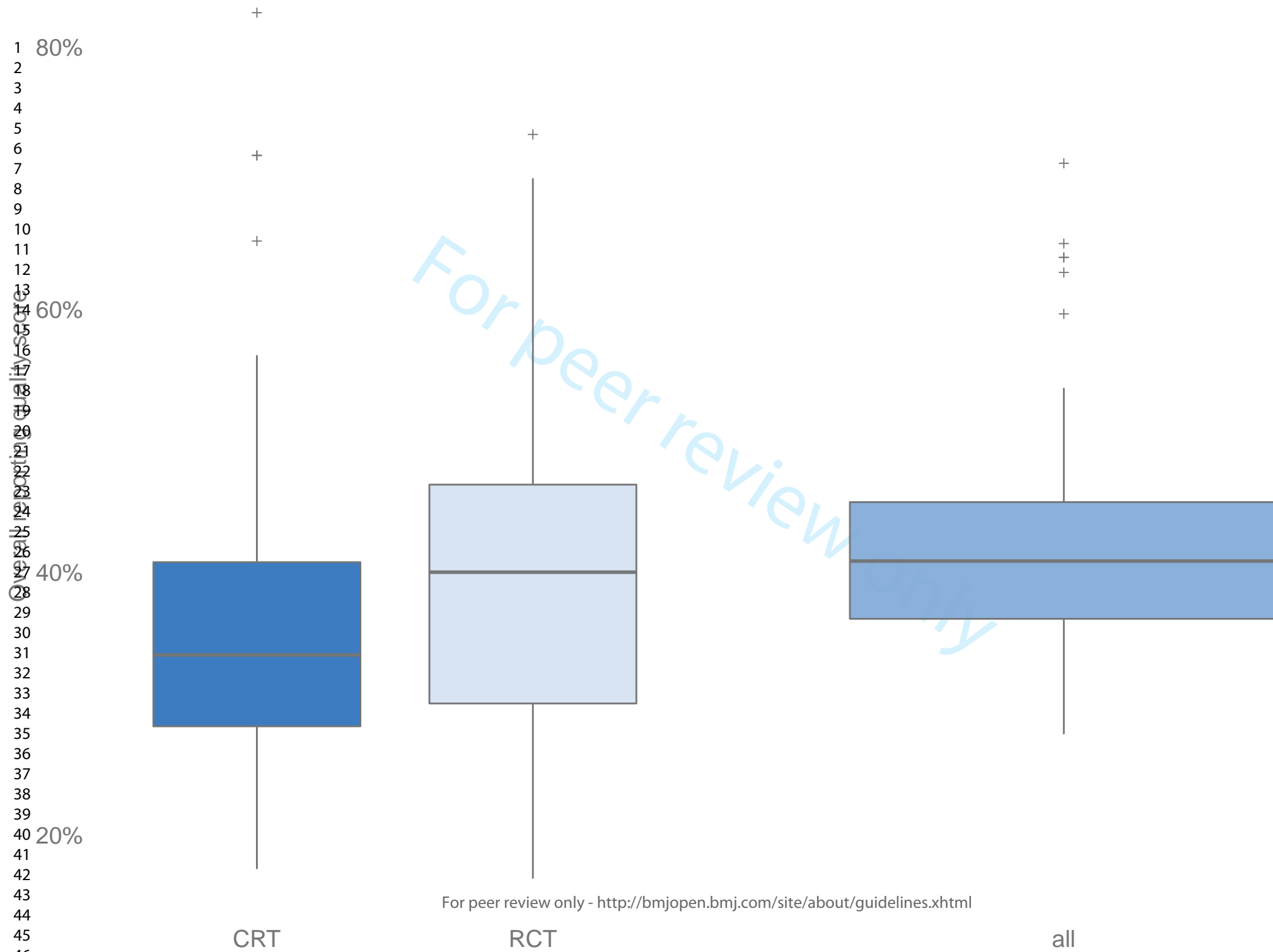
Records included in the data synthesis (n= 169)
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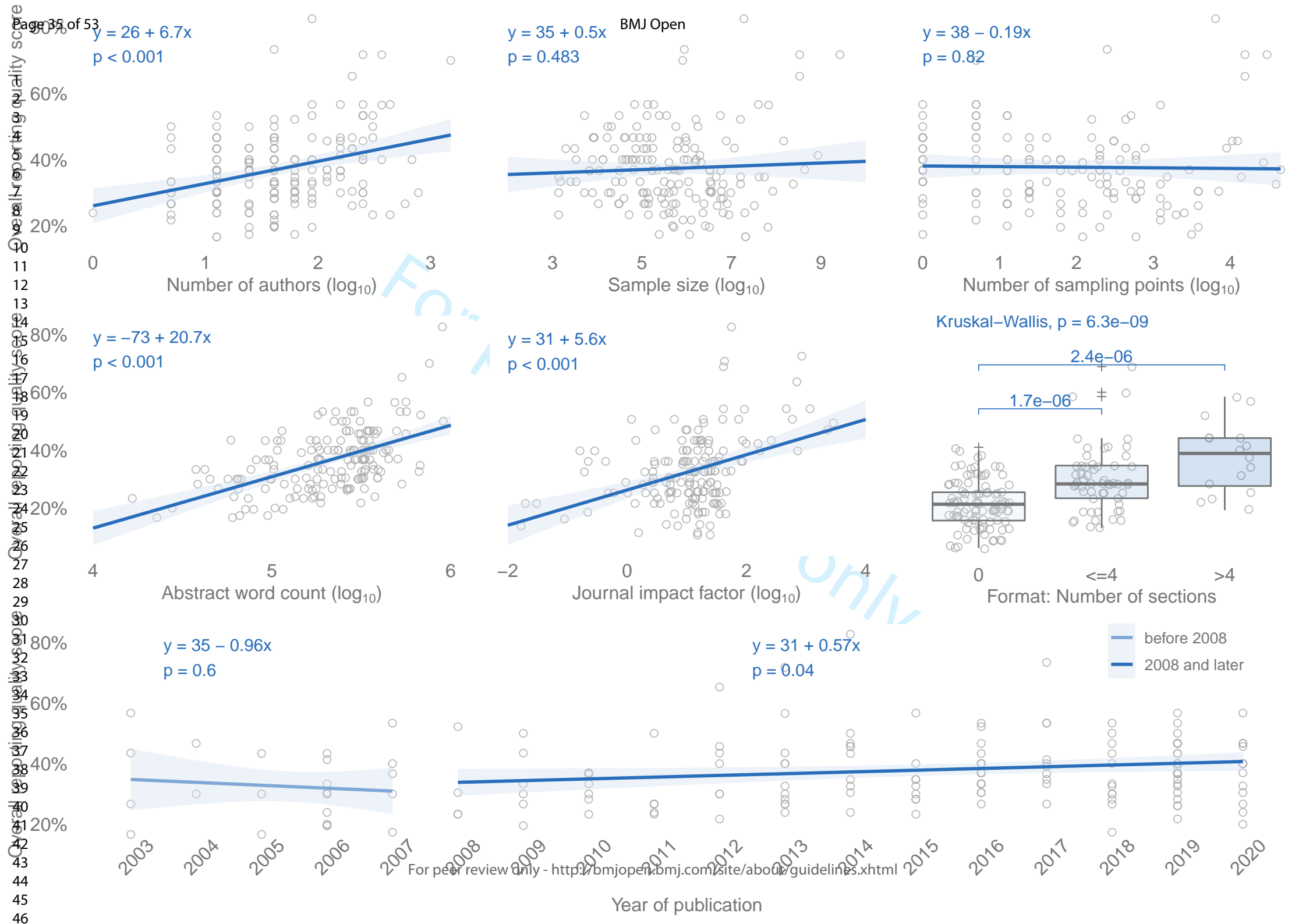


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Supplementary Material

S 1 Eligibility criteria for the study selection procedure

	Inclusion criteria	Exclusion criteria
Population	<ul style="list-style-type: none"> • subjects are children or adolescents ≤ 18 years before treatment initiation (if age range is not available, then use mean age: ≤ 18.0 years) • clinical or community samples as well as samples drawn from the general population • participants with or without increased risk for depression • participants with or without subthreshold depression 	<ul style="list-style-type: none"> • adult samples (>18 years) • clinically depressed samples ($\geq 50\%$ of participants currently meet or formerly met criteria for clinical diagnosis of depression before treatment initiation)
Intervention	<ul style="list-style-type: none"> • interventions aiming at preventing the onset of depression or reducing depressive symptoms (universal, selective, and indicated prevention) • social, psychological, or educational interventions targeting children and adolescents 	<ul style="list-style-type: none"> • interventions aiming at treating depression or preventing its reoccurrence (secondary or tertiary prevention) • interventions only targeting caregiver including any pharmacological and hormonal components or solely relying on music-based or physical activity components
Control	<ul style="list-style-type: none"> • treatment as usual • wait-list control • attention placebo control • control arm with no treatment 	<ul style="list-style-type: none"> • no control group • drug placebo

S1 Continued

	Inclusion criteria	Exclusion criteria
Outcome	<ul style="list-style-type: none"> outcome assessment before and after treatment initiation meeting diagnostic criteria for unipolar depressive disorder by administering fully structured or semi-structured diagnostic interviews or applying cut-off values on self- or proxy-report screening scales depressive symptom severity by administering fully structured or semi-structured diagnostic interviews or applying self- or proxy-report screening scales 	<ul style="list-style-type: none"> bipolar depression, no depression, or depression only as secondary outcome only cost-effectiveness, process evaluation, surrogate outcome measures or multifactorial outcome index scores
Study design	<ul style="list-style-type: none"> randomised controlled trials cluster randomised controlled trials 	<ul style="list-style-type: none"> meta-analysis systematic reviews narrative reviews/ overview articles observational studies qualitative studies non-controlled trials non-randomised trials quasi-randomised trials cross-over randomised controlled trials

S 2 Electronic search strategy for MEDLINE via PubMed.

Component	ID	Search term
Search filter for the "children" component [1]	#1	child*[tiab]
	#2	adolescent[tiab]
	#3	infan*[tiab]
	#4	#1 OR #2 OR #3
MeSH terms for "prevention" component	#5	"Mental Health Services"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#6	"Preventive Health Services"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#7	"Child Health Services"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#8	"Adolescent Health Services"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#9	"Community Mental Health Services"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#10	"Preventive Medicine"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#11	"Early Intervention (Education)"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#12	"Health Education"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#13	"Health Promotion"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#14	"Family Therapy"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#15	"Psychotherapy, Group"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#16	"School Health Services"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#17	#5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16

S 2 Continued.

Component	ID	Search term
Keywords for "prevention" component	#18	primary[tiab]
	#19	targeted[tiab]
	#20	universal[tiab]
	#21	selective[tiab]
	#22	selected[tiab]
	#23	indicated[tiab]
	#24	psycho*[tiab]
	#25	educat*[tiab]
	#26	social[tiab]
	#27	#18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26
	#28	prevent*[tiab]
	#29	intervention*[tiab]
	#30	program*[tiab]
#31	promot*[tiab]	
#32	#28 OR #29 OR #30 OR #31	
#33	#27 AND #32	
Keywords and MeSH terms for "prevention" component	#34	#17 OR #33
MeSH terms for "depression" component	#35	"Depression"[mesh:noexp] AND (Epidemiology[sh:noexp] OR Psychology[sh:noexp])
	#36	"Depressive Disorder"[mesh:noexp] AND (Epidemiology[sh:noexp] OR Psychology[sh:noexp])
	#37	"Depressive Disorder, Major"[mesh:noexp] AND (Epidemiology[sh:noexp] OR Psychology[sh:noexp])
	#38	"Dysthymic Disorder"[mesh:noexp] AND (Epidemiology[sh:noexp] OR Psychology[sh:noexp])
	#39	"Depression, Postpartum"[mesh:noexp] AND (Epidemiology[sh:noexp] OR Psychology[sh:noexp])
	#40	#35 OR #36 OR #37 OR #38 OR #39
Keyword for "depression" component	#41	depress*[tiab]
MeSH terms and keywords for "depression" component	#42	#40 OR #41

S 2 Continued.

Component	ID	Search term
MeSH terms for "study design" component	#43	"Controlled Clinical Trials as Topic"[mesh:noexp] AND (Methods[sh:noexp] OR Epidemiology[sh:noexp])
	#44	exp "Randomized Controlled Trial"[Publication Type]
	#45	#43 OR #44
Keywords for "study design" component	#46	random*[tiab]
	#47	trial[tiab]
	#48	#46 OR #47
MeSH terms and keywords for "study design" component	#49	#45 OR #48
Exclude animal-related research	#50	exp "Animals"[mesh]
	#51	exp "Humans"[mesh]
	#52	#50 NOT #51
	#53	#49 NOT #52
Exclude reviews, meta-analyses and research protocols	#54	Review [Publication Type]
	#55	"Review Literature as Topic"[mesh:noexp]
	#56	#54 OR #55
	#57	meta analysis[ti]
	#58	review[ti]
	#59	protocol[ti]
	#60	#57 OR #58 OR #59
Components: "child" + "prevention"	#61	#56 OR #60
	#62	#53 NOT #61
Components: "child" + "prevention" + "depression"	#63	#4 AND #34
Components: "child" + "prevention" + "depression"	#64	#63 AND #42
Components: "child" + "prevention" + "depression" + "study design"	#65	#64 AND #62
Restrict to records published between 2003 and 2019	#66	#65 AND 2003:2019[dp]

S3 Hand-searched journals and systematic reviews as additional sources of information

Journals hand-searched for eligible primary studies

Journal of the American Academy of Child & Adolescent Psychiatry

Journal of Abnormal Child Psychology

Journal of Paediatric Psychology

Behaviour Research and Therapy

Systematic reviews for which the reference lists were searched for eligible primary studies

Ahlen, J., Lenhard, F., & Ghaderi, A. (2015). Universal prevention for anxiety and depressive symptoms in children: a meta-analysis of randomized and cluster-randomized trials. *The journal of primary prevention*, 36(6), 387-403.

Barry, M. M., Clarke, A. M., Jenkins, R., & Patel, V. (2013). A systematic review of the effectiveness of mental health promotion interventions for young people in low- and middle-income countries. *BMC public health*, 13(1), 835.

Bastounis, A., Callaghan, P., Banerjee, A., & Michail, M. (2016). The effectiveness of the Penn Resiliency Programme (PRP) and its adapted versions in reducing depression and anxiety and improving explanatory style: A systematic review and meta-analysis. *Journal of adolescence*, 52, 37-48.

Brunwasser, S. M., & Garber, J. (2016). Programs for the prevention of youth depression: Evaluation of efficacy, effectiveness, and readiness for dissemination. *Journal of Clinical Child & Adolescent Psychology*, 45(6), 763-783.

Brunwasser, S. M., Gillham, J. E., & Kim, E. S. (2009). A meta-analytic review of the Penn Resiliency Program's effect on depressive symptoms. *Journal of consulting and clinical psychology*, 77(6), 1042-1054.

Calear, A. L., & Christensen, H. (2010). Review of internet-based prevention and treatment programs for anxiety and depression in children and adolescents. *Medical Journal of Australia*, 192(11), S12.

Calear, A. L., & Christensen, H. (2010). Systematic review of school-based prevention and early intervention programs for depression. *Journal of adolescence*, 33(3), 429-438.

Cary, C. E., & McMillen, J. C. (2012). The data behind the dissemination: A systematic review of trauma-focused cognitive behavioral therapy for use with children and youth. *Children and Youth Services Review*, 34(4), 748-757.

Christensen, H., Pallister, E., Smale, S., Hickie, I. B. & Calear, A. L. (2010). Community-based prevention programs for anxiety and depression in youth: A systematic review. *Journal of Primary Prevention*, 31, 139-170.

Corrieri, S., Heider, D., Conrad, I., Blume, A., König, H. H., & Riedel-Heller, S. G. (2013). School-based prevention programs for depression and anxiety in adolescence: A systematic review. *Health promotion international*, 29(3), 427-441.

Cuijpers, P., van Straten, A., Smit, F., Mihalopoulos, C., & Beekman, A. (2008). Preventing the onset of depressive disorders: a meta-analytic review of psychological interventions. *American Journal of Psychiatry*, 165(10), 1272-1280.

Dardas, L. A., van de Water, B., & Simmons, L. A. (2017). Parental involvement in adolescent depression interventions: A systematic review of randomized clinical trials. *International journal of mental health nursing*, 27(2), 555-570.

Dray, J., Bowman, J., Campbell, E., Freund, M., Wolfenden, L., Hodder, R. K., ... & Small, T. (2017). Systematic review of universal resilience-focused interventions targeting child and adolescent mental health in the school setting. *Journal of the American Academy of Child & Adolescent Psychiatry*, 56(10), 813-824.

Ebert, D. D., Zarski, A. C., Christensen, H., Stikkelbroek, Y., Cuijpers, P., Berking, M., & Riper, H. (2015). Internet and computer-based cognitive behavioral therapy for anxiety and depression in youth: a meta-analysis of randomized controlled outcome trials. *PLOS ONE*, 10(3), e0119895.

Erford, B. T., Erford, B. M., Lattanzi, G., Weller, J., Schein, H., Wolf, E., ... & Peacock, E. (2011). Counseling outcomes from 1990 to 2008 for school-age youth with depression: A meta-analysis. *Journal of Counseling & Development*, 89(4), 439-457.

S3 Continued

Systematic reviews for which the reference lists were searched for eligible primary studies

- Garber, J., Brunwasser, S. M., Zerr, A. A., Schwartz, K. T., Sova, K., & Weersing, V. R. (2016). Treatment and Prevention of Depression and Anxiety in Youth: Test of Cross-Over Effects. *Depression and anxiety, 33*(10), 939-959.
- Grist, R., Porter, J., & Stallard, P. (2017). Mental health mobile apps for preadolescents and adolescents: a systematic review. *Journal of medical internet research, 19*(5), e176.
- Grist, R., Croker, A., Denne, M., & Stallard, P. (2018). Technology Delivered Interventions for Depression and Anxiety in Children and Adolescents: A Systematic Review and Meta-analysis. *Clinical Child and Family Psychology Review, 22*(2), 147-171.
- Hetrick, S., Cox, G., & Merry, S. (2015). Where to go from here? An exploratory meta-analysis of the most promising approaches to depression prevention programs for children and adolescents. *International journal of environmental research and public health, 12*(5), 4758-4795.
- Hetrick, S. E., Cox, G. R., Witt, K. G., Bir, J. J., & Merry, S. N. (2016). Cognitive behavioural therapy (CBT), third-wave CBT and interpersonal therapy (IPT) based interventions for preventing depression in children and adolescents. *Cochrane Database of Systematic Reviews, 8*.
- Merry, S. N., Hetrick, S. E., Cox, G. R., Brudevold-Iversen, T., Bir, J. J., & McDowell, H. (2012). Psychological and educational interventions for preventing depression in children and adolescents. Evidence-Based Child Health: *A Cochrane Review Journal, 7*(5), 1409-1685.
- Merry, S. N. & Spence, S. H. (2007). Attempting to prevent depression in youth: A systematic review of the evidence. *Early Intervention in Psychiatry, 1*, 128-137.
- Neil, A. L., & Christensen, H. (2007). Australian school-based prevention and early intervention programs for anxiety and depression: a systematic review. *Medical Journal of Australia, 186*(6), 305.
- Richardson, T., Stallard, P., & Velleman, S. (2010). Computerised cognitive behavioural therapy for the prevention and treatment of depression and anxiety in children and adolescents: a systematic review. *Clinical child and family psychology review, 13*(3), 275-290.
- Stice, E., Shaw, H., Bohon, C., Marti, C. N., & Rohde, P. (2009). A meta-analytic review of depression prevention programs for children and adolescents: factors that predict magnitude of intervention effects. *Journal of consulting and clinical psychology, 77*(3), 486.
- Stockings, E. A., Degenhardt, L., Dobbins, T., Lee, Y. Y., Erskine, H. E., Whiteford, H. A., & Patton, G. (2016). Preventing depression and anxiety in young people: a review of the joint efficacy of universal, selective, and indicated prevention. *Psychological medicine, 46*(1), 11-26.
- Werner-Seidler, A., Perry, Y., Calcar, A. L., Newby, J. M., & Christensen, H. (2017). School-based depression and anxiety prevention programs for young people: A systematic review and meta-analysis. *Clinical psychology review, 51*, 30-47.

S4 Interrater-reliability (Cohen's Kappa) and adequate reporting (proportion of trial abstracts) in 169 abstracts assessed according to CONSORT-A and CONSORT-C checklist items.

Item	Extension for cluster trials *	Description	Cohen's kappa			Proportion of trial abstract that reported...		
			unweighted	equal weights	squared weights	adequately	inadequately	not at all
General items								
01 Title	No	a) Identification of the study as randomized	.96	.96	.96	58.0	-	42.0
	Yes	b) Identification of study as cluster randomized	1		1	31.8	-	68.2
02 Trial design	No	Description of the trial design (e.g. parallel, cluster, non-inferiority)	.38	.45	.53	30.2	66.3	3.6
Trial Methodology								
03 Participants	No	a) Eligibility criteria for participants <u>and</u> the settings where the data were collected **				35.5	62.1	2.4
		(i) The authors report eligibility criteria for participants	.77	.78	.80	80.5	17.2	2.4
		(ii) The authors report eligibility criteria for setting	.81	.85	.89	35.5	30.2	34.3
	Yes	b) Eligibility criteria for clusters	.80		.79	47.0	30.3	22.7
04 Interventions	No	Interventions intended for each group **				30.8	68.0	1.2
		(i) Authors report essential features of the experimental intervention	.80	.81	.82	52.7	45.6	1.8
		(ii) Authors report essential features of the comparison intervention	.76	.82	.86	47.9	21.3	30.8
05 Objective	No	(a) Specific objective <u>or</u> hypothesis	.73	.74	.76	89.9	8.3	1.8

	Yes	(b) Whether objective <u>or</u> hypothesis pertains to the cluster level, the individual participant level, <u>or</u> both	.66		.89	1.5	-	98.5
06 Outcome	No	(a) Clearly defined primary outcome for this report **				10.1	89.9	-
		(i) Authors explicitly state the primary outcome	.91	.91	.91	14.8	84.6	0.6
		(ii) Authors explicitly state when the primary outcome was assessed	.69	.78	.84	51.5	23.1	25.4
	Yes	(b) Whether the primary outcome pertains to the cluster level, the individual participant level <u>or</u> both	.56		.61	3.0	3.0	93.9
07 Randomization	No	(a) How participants were allocated to interventions	.49	.59	.66	2.4	-	97.6
	Yes	(b) How clusters were allocated to interventions	.88		.88	6.1	-	93.9
08 Blinding (masking)	No	Whether or not participants, care givers, <u>and</u> those assessing the outcomes were blinded to group assignment **				-	3.6	96.4
		(i) Authors describe if participants were blinded	.77	.85	.92	1.2	1.8	97.0
		(ii) Authors describe if program deliverer were blinded	.77	.85	.92	1.2	1.8	97.0
		(iii) Authors describe if data collectors/analysts were blinded	.66	.66	.66	0.6	1.8	97.6
Trial results								
09 Numbers randomized	No	(a) Number of participants randomized to each group	.95	.97	.98	32.0	1.8	66.3
	Yes	(b) Number of clusters randomized to each group	.76		.78	13.6	1.5	84.8

10 Numbers analyzed	No	(a) Number of participants analyzed in each group	.88	.93	.96	3.6	2.4	94.1
	Yes	(b) Number of clusters analyzed in each group	1		1	1.5	-	98.5
11 Outcome	No	(a) For the primary outcome, a result for each group and the estimated effect size and its precision	.94	.94	.94	27.2	72.8	-
	Yes	(b) Results at the cluster <u>or</u> individual level as applicable for each primary outcome	.96		.96	28.8	71.2	-
12 Harms	No	Important adverse events <u>or</u> side effects	0***	0***	0***	0.6	-	99.4
13 Conclusions	No	General interpretation of the results **				36.7	47.3	16.0
		(i) Authors state the conclusions of the trial	.75	.79	.82	71.0	1.8	27.2
		(ii) Authors state implications for further research or clinical practice	.74	.78	.81	46.2	8.3	45.6
14 Trial registration	No	Registration number <u>and</u> name of trial register **				17.2	3.0	79.9
		(i) Authors provide details on the trial registration number	1	1	1	20.1	-	79.9
		(ii) Authors provide details on the name of the trial register	.98	.98	.98	17.2	0.6	82.2
15 Funding	No	Source of funding	.88	.89	.95	11.8	0.6	87.6

Comments: Items corresponding to author contact information and trial status were not assessed because these items are specific to conference abstracts that were excluded from this study. Because journals often have their own standards for positioning funding information, we rated funding as adequately reported if it was reported in the abstract or in a section other than the abstract (e.g., at the end of the article). Due to rounding errors, the percentages may not add up.

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3 * Studies that randomized their intervention on the cluster level were assessed for adherence to CONSORT-A and CONSORT-C (N = 66). Studies that randomized on
4 the individual level were evaluated for adherence to CONSORT-A, only (N = 103). As a result, all 169 reports were assessed for CONSORT-A, but only 66 cluster
5 randomized trial reports were additionally checked for CONSORT-C.
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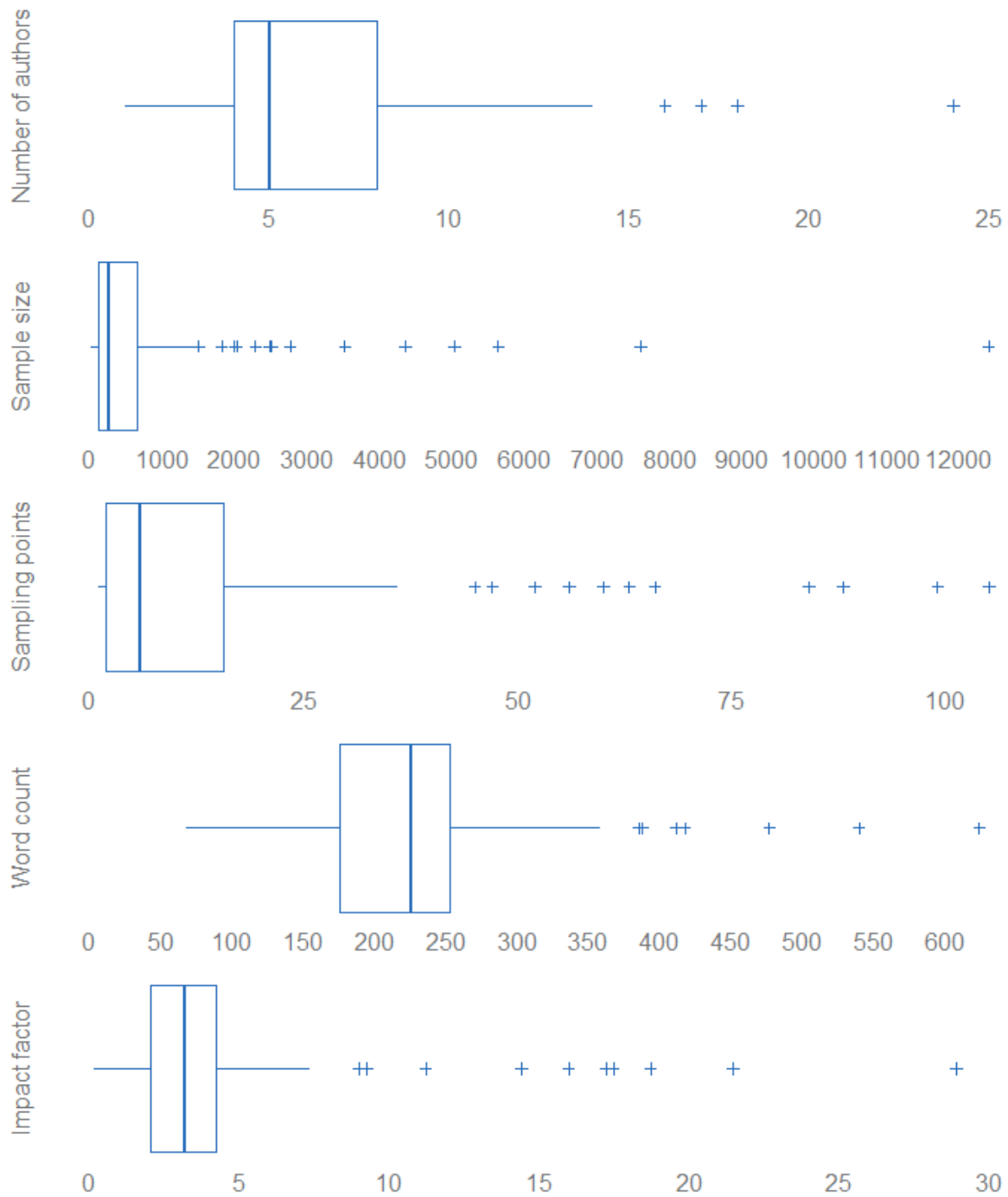
8 ** For those items where multiple dimensions are required, we operationalized each dimension separately. Subsequently we merged these dimensions into summary
9 variables. If all dimensions were reported adequately, the summary variable was reported adequately. If at least one dimension was reported inadequately, the summary
10 variable was reported inadequately. If all dimensions were not reported, the summary variable was not reported.
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13 *** The agreement of the CONSORT items Harms was almost identical. Kappa is nevertheless equal to zero. The correction factor of the kappa formula is responsible
14 for this paradox. The factor corrects for random agreement between raters. If the proportion of observed agreement is high, it can lower the kappa values toward zero.
15 For further explanation and examples, see Feinstein and Cicchetti. [2]
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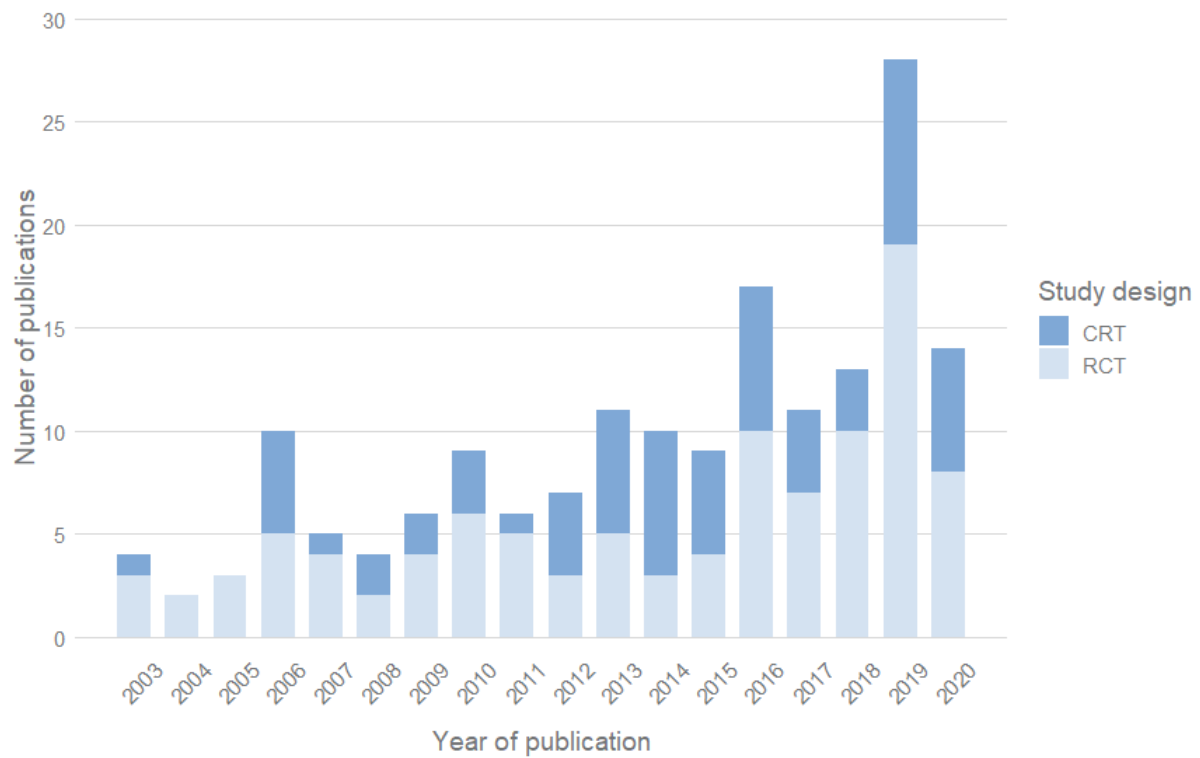
S5 Additional variables extracted during the data collection process.

Variable	Definition	Source
Number of authors	The number of authors who have published the trial report.	First page of the trial report
Sample size	The number of subjects in all study arms.	Methods of the manuscript
Number of sampling points	The number of sampling points in all study arms.	Methods of the manuscript
Abstract word count	The number of words used only for the abstract, excluding keywords, author information and such.	Abstract of the trial report
Journal impact factor	The journal impact factor calculated from data indexed in the Web of Science Core Collection. If data was missing for a certain year, the journal impact factor from the latest year available was used.	Journal Citation Reports as provided by Clarivate
Abstract format	The number of sections used to structure the abstract. Following Hua et al., abstracts were categorized as unstructured (1 section), structured (2-4 sections) or highly structured (>4 sections).[3]	Abstract of the trial report
Year of publication	The year in which the trial report was first published.	First page of the trial report

S6 Boxplots visualizing the distribution of continuous variables possibly related to overall reporting quality.



S7 Annual number of included trial reports by study design between January 2003 and August 2020 (N= 169).



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<http://www.sciencedirect.com/science/article/pii/089543569090158L>.
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Proposed items to be used for reporting methodology research, adapted from the PRISMA Checklist (Murad & Wang, 2017)

Section and Topic	Checklist item	Location where item is reported
TITLE		
Title	Identify the report as a meta-epidemiologic study	p. 1, l. 2
ABSTRACT		
Structured summary	Provide a structured summary that includes the background of the topic, goal of the study, data sources, method of data selection, appraisal and synthesis methods, results, limitations, conclusions and implications of key findings	p. 2, l. 11 -p. 3, l. 36
INTRODUCTION		
Rationale	Describe the rationale for the meta-epidemiological study in the context of what is already known	p. 4, l. 53 - 75
Objective	Provide an explicit statement of the goal of the meta-epidemiological study and the hypothesis being empirically tested	p. 4, l. 75 - p. 5, l. 78
METHODS		
Protocol	Indicate if a protocol exists, if and where it can be accessed (eg, Web address). Registration of a protocol is not mandatory	p. 16, l. 358 - p. 17, l. 361
Eligibility criteria	Specify study characteristics used as criteria for eligibility with a rationale	p. 5, l. 81-88
Information sources	Describe all information sources (eg, databases with dates of coverage, contact with experts to identify additional studies, Internet searches) and search date	p. 5, l. 90-98
Search	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. Search is commonly not driven by a clinical question	Supplementary S2 (Tables longer than 2 pages are published as online only supplementary)

1			
2			
3	Study selection	Describe the process for selecting studies	p. 6, l. 100-109
4		for inclusion (ie, how many reviewers	
5		selected studies, reviewing in duplicate or	
6		by single individuals)	
7			
8			
9	Data collection process	Describe method of data extraction from	p. 6, l. 111-116
10		reports (eg, piloted forms, independently, in	
11		duplicate) and any processes used for	
12		manipulating data or obtaining and	
13		confirming data from investigators	
14			
15			
16			
17	Data items	List and define all variables for which data	Supplementary S4
18		were sought and any assumptions and	and S 5
19		imputations made	
20			
21			
22	Risk of bias in individual studies	If risk of bias assessment of individual	Not relevant
23		studies was relevant to the analysis,	
24		describe the items used and how this	
25		information is to be used during data	
26		synthesis	
27			
28			
29			
30	Summary measures	State the principal summary measures (eg,	p. 7, l. 126-135
31		ratio of risk ratios, difference in means) and	
32		explain its meaning and direction to readers	
33			
34	Synthesis of results	Describe the statistical or descriptive	Not relevant
35		methods of synthesis including measures	
36		of consistency if relevant. If applicable,	
37		describe the development of statistical or	
38		simulation modelling based on theoretical	
39		background. Describe and justify	
40		assumptions and computational	
41		approximations. Describe methods of	
42		additional analyses (eg, sensitivity or	
43		subgroup analyses, meta-regression), if	
44		done, indicating which were prespecified	
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RESULTS

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54	Study selection	Give numbers of studies assessed for	p. 6, l. 100-106
55		eligibility and included in the study, with	
56		reasons for exclusions at each stage,	
57		ideally with a flow diagram. Present a	
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		measure of inter-reviewer agreement (eg, kappa statistic)	
Study characteristics	For each study, present characteristics for which data were extracted and provide the citations. Clinical characteristics may not always be relevant		p. 8, l. 146 - 154
Risk of bias within studies	If risk of bias assessment of individual studies was used in the meta-epidemiological analysis, report risk of bias indicators of each study to allow replication of findings		Not relevant
Results of individual studies	Present data elements used in the meta-epidemiological analysis from each study (results of clinical outcomes may not be relevant)		Data of individual studies can be retrieved from an online repository (https://bit.ly/3tl7kvz)
Synthesis of results	Present results of statistical analysis done, including measures of precision and measures of consistency. Present validity of assumptions and fit of statistical or simulation modelling, if applicable		p. 8, l.156 – p. 9, l. 177
Additional analysis	Give results of additional analyses, if done (eg, sensitivity or subgroup analyses, metaregression)		Not relevant
DISCUSSION			
Summary of evidence	Summarise the main findings and compare them with existing knowledge about the topic. The quality of evidence may not be relevant; however, investigators should describe their certainty in the results to readers		p. 9, l. 179 – p. 14, l. 298
Limitations	Discuss limitations at research methodology level (eg, likelihood of reporting or publication bias)		p. 14, l. 308 – p. 15, l. 326
Conclusions	Provide general interpretation of the results and implications for future research.		p. 15, l. 327 - p. 16, l. 348

1
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3 Provide any plausible impact on clinical
4 practice
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6 FUNDING

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8 Funding

9 Describe sources of funding for the
10 methodology research and role of funders

11 p. 16, l. 350-351
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For peer review only

BMJ Open

Reporting quality for abstracts of randomised trials on child and adolescent depression prevention: A meta-epidemiological study on adherence to CONSORT for abstracts

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Primary Subject Heading:	Mental health
Secondary Subject Heading:	Paediatrics, Mental health, Research methods
Keywords:	STATISTICS & RESEARCH METHODS, MENTAL HEALTH, PAEDIATRICS, Child & adolescent psychiatry < PSYCHIATRY, Depression & mood disorders < PSYCHIATRY

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1 Title of the article: Reporting quality for abstracts of randomised trials on child and adolescent
2 depression prevention: A meta-epidemiological study on adherence to CONSORT for abstracts

3 Corresponding author: Jascha Wiehn; jascha.wiehn@charite.de, Charitéplatz 1, 10117 Berlin

4 First author: Jascha Wiehn, Institute of Public Health, Charité – Universitätsmedizin Berlin, Berlin,
5 Germany

6 Second author: Johanna Nonte, Department of Population Medicine and Health Services
7 Research, Bielefeld School of Public Health, Bielefeld University, Bielefeld, Germany

8 Third author: Christof Prugger, Institute of Public Health, Charité – Universitätsmedizin Berlin,
9 Berlin, Germany

10 Word count: 3,850

11

12 **ABSTRACT**

13 **Objectives**

14 This study aimed to investigate adherence to CONSORT for abstracts in reports of randomised
15 trials on child and adolescent depression prevention. Secondary objective was to examine factors
16 associated with overall reporting quality.

18 **Design**

19 Meta-epidemiological study.

21 **Data Sources**

22 We searched MEDLINE, EMBASE, PsychINFO, PsycArticles, and CENTRAL.

24 **Eligibility Criteria**

25 Trials were eligible if the sample consisted of children and adolescents under 18 years with or
26 without an increased risk for depression or subthreshold depression. We included reports
27 published from January 1, 2003 to August 8, 2020 on RCTs and CRTs assessing universal,
28 selective, and indicated interventions aiming to prevent the onset of depression or reducing
29 depressive symptoms.

31 **Data extraction and synthesis**

32 As the primary outcome measure, we assessed for each trial abstract whether information
33 recommended by CONSORT was adequately reported, inadequately reported, or not reported.

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3 34 Moreover, we calculated a summative score of overall reporting quality and analysed associations
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5 35 with trial and journal characteristics.
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10 37 **Results**
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13 38 We identified 169 eligible studies, 103 (61%) RCTs and 66 (39%) CRTs. Adequate reporting
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15 39 varied considerably across CONSORT items: while 9 out of 10 abstracts adequately reported the
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17 40 study objective, no abstract adequately provided information on blinding. Important adverse
18
19 41 events or side effects were only adequately reported in one out of 169 abstracts. Summative
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21 42 scores for the abstracts' overall reporting quality ranged from 17% to 83%, with a median of 40%.
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23 43 Scores were associated with the number of authors, abstract word count, journal impact factor,
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25 44 year of publication and abstract structure.
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31 46 **Conclusions**
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34 47 Reporting quality for abstracts of trials on child and adolescent depression prevention is
35
36 48 suboptimal. To help health professionals make informed judgments, efforts for improving
37
38 49 adherence to reporting guidelines for abstracts are needed.
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41 50 42 43 44 51 **Strengths and limitations of this study**

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47 52 • This study is the first to systematically assess the reporting quality for abstracts of
48
49 53 randomized trials on paediatric depression prevention.
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51 54 • Our extensive, reproducible search strategy identified 169 eligible journal articles reflecting
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53 55 the available evidence from such trials published 2003 to 2020.
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3 56 • Two reviewers independently screened abstracts and extracted data using standardised
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5 57 methods, but the reviewers were not blinded to meta-data such as study authors, journal
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7 58 name or year of publication.
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9 59 • Since no method has so far been established for determining overall reporting quality of
10
11 60 abstracts, we approximated overall reporting quality by calculating a summative score
12
13 61 based on CONSORT items.
14
15 62 • Because we applied a topic-based approach without restricting the information source to
16
17 63 specific journals, our study findings offer insights into general reporting quality in trials on
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19 64 childhood depression prevention.
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1 INTRODUCTION

Reports of trials should provide all necessary information allowing readers to evaluate the reproducibility, validity and utility of studies and findings. [1, 2] Poor reporting of health research leads, at the very least, to avoidable waste of resources [3] and can ultimately jeopardize patient care. [4] The same applies to abstracts of trials. Due to time, access and language constraints, health professionals often use abstracts as the primary source of information to learn about a trial, [5, 6] and the way abstracts report study details can influence their decisions in patient management. [7] Researchers conducting systematic reviews and meta-analyses may incorrectly exclude eligible studies in title and abstract screening due to poor reporting which can distort evidence synthesis. [8] Moreover, indexers of literature databases rely on adequate title and abstract reporting to correctly determine search terms such as medical subject headings, otherwise relevant journal articles cannot be found, read and quoted to affect medical practice.

For these reasons, authors of randomized trial reports are encouraged to follow the Consolidated Standards of Reporting Trials (CONSORT) guidelines [5–8] and its extension for abstracts (CONSORT-A). [9, 10] CONSORT-A was published in 2008 to provide guidance to authors on information to be reported in abstracts of randomized controlled trials (RCTs). In 2012, the guidelines were further complemented by a module for cluster randomized trial (CRT) abstracts (CONSORT-C). [11] Although some improvement in reporting quality of trials has been observed over recent years, [12] general adherence to CONSORT guidelines remains suboptimal in articles published both in general medicine [13–17] and psychiatry/psychology journals. [18–20] Similar results have been reported from studies on adherence to CONSORT-A for abstract reporting in various health disciplines including one previous study on abstracts of psychiatric RCTs.[21] However, no prior study has investigated the abstract reporting quality of depression prevention trials in young people. We therefore aimed to evaluate to what extent CONSORT-A and CONSORT-C criteria are met by abstracts of reports on child and adolescent depression

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3 90 prevention trials. Secondary objective of our study was to explore trial and journal characteristics
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5 91 associated with the abstracts' overall reporting quality.
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10 93 **2 METHODS**

11 94 **2.1 Eligibility criteria**

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15 95 We included reports on RCTs and CRTs assessing universal, selective and indicated interventions
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17 96 aiming to prevent the onset of depression or reducing depressive symptoms in children and
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19 97 adolescents under 18 years with or without an increased risk for depression or subthreshold
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21 98 depression. A detailed list of the eligibility criteria is provided in Supplementary S1. We only
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23 99 included research articles published in peer-reviewed journals, the primary source of information
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25 100 for paediatric health specialists,[22] and we considered the period between January 1, 2003 and
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27 101 August 5, 2020 to assess reporting quality before and after the publication of CONSORT-A and -
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29 102 C guidelines.
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33 103 **2.2 Information sources**

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35 104 We searched the electronic literature databases MEDLINE (via PubMed and Ovid®), EMBASE
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37 105 (via Ovid®), PsychINFO (via EBSCOhost®), PsycArticles (via EBSCOhost®), and CENTRAL (via
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39 106 Cochrane Library) on March 9, 2019 and updated the search on August 8, 2020. Search strings
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41 107 were developed in collaboration with a trained librarian. The electronic search strategy for
42
43 108 MEDLINE via PubMed is shown in Supplementary S2. Electronic search strategies for the other
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45 109 databases are provided in an online repository. [23] Additional articles were retrieved by hand-
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47 110 searching four specialty journals and the reference lists of systematic reviews (Supplementary
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49 111 S3).
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2.3 Study selection and data collection

The study selection process consisted of a title and abstract screening, a full text screening and a discussion and consensus phase (Figure 1). Two independent reviewers extracted information from articles into piloted spreadsheets with drop-down menus. The reviewers first determined whether randomization was performed on an individual (RCT) or cluster level (CRT) and subsequently assessed all abstracts according to CONSORT-A and CRTs additionally according to CONSORT-C. [10, 11] For each item, the reviewers judged whether the abstract reported information adequately, inadequately or not at all.

For items with multiple dimensions, we operationalized each dimension separately and then created item variables for analysis based on the extracted information. For example, CONSORT-A item *03 Participants* requires reporting the eligibility criteria for participants and settings where the data were collected. Thus, if both dimensions were reported adequately (or not at all), then the item was judged as adequately reported (or as not reported). However, if either the eligibility criteria for participants or for settings was reported inadequately, the item was judged as inadequately reported.

Based on previous studies, we pre-specified seven study characteristics previously associated with overall reporting quality (Supplementary S4). We operationalized these study characteristics using the variable definitions in Supplementary S5.

2.4 Statistical analysis

We used descriptive statistics to summarize the extent to which RCT and CRT abstracts adhered to the 15 CONSORT-A items and CRT abstracts adhered to the additional eight CONSORT-C items. For each CONSORT item we thus present the proportion of trial abstracts adequately, inadequately, or not reporting the item information as required by the appropriate guideline.

We calculated summative scores of overall reporting quality grading CONSORT items as follows:

(i) adequately reported (2 points), (ii) inadequately reported (1 point), and (iii) not reported (0

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3 137 points). Depending on the study design, these overall reporting quality scores (RQS) could thus
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5 138 theoretically range from 0 to 30 for RCTs (15 CONSORT-A items) and from 0 to 46 for CRTs (eight
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7 139 additional CONSORT-C items). We transformed RQS to standardized percentages with possible
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9 140 ranges from 0 (lowest reporting quality) to 100 (highest reporting quality). We compared
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11 141 unstructured (1 section), structured (2-4 sections) and highly structured (>4 sections) abstracts
12
13 142 [24] in relation to RQS using the Kruskal-Wallis test. We fitted separate linear regression models
14
15 143 to quantify associations between overall reporting quality and (i) number of authors, (ii) sample
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17 144 size, (iii) number of sampling points, (iv) abstract word count, (v) journal impact factor and (vi) year
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19 145 of publication. Because of heavily skewed distributions (Supplementary S6) we log-transformed
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21 146 (log 10) the first five abovementioned variables for analysis. We used RStudio (R version 4.1.1)
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23 147 for data analysis.
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27 148 **2.5 Patient and public involvement**

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29 149 Instead of patient data we used information of previously published trial reports. Thus, no patients
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31 150 or public were involved in this study. Yet, our results can inform authors, editors, reviewers, and
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33 151 readers of the scientific literature.
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39 153 **3 RESULTS**

42 154 **3.1 Included abstracts**

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44 155 We screened the title and abstract of 4279 articles and the full text of 520 articles, and we
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46 156 ultimately included 169 articles in the data synthesis (Figure 1). Interrater reliability as assessed
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48 157 by Cohen's kappa (unweighted) for the agreement between the three reviewer pairs (article
49
50 158 eligible vs. non-eligible) was moderate in the title and abstract screening with $\kappa=0.39$, $\kappa=0.47$ and
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52 159 $\kappa=0.55$ and higher in the full text screening with $\kappa=0.59$, $\kappa=0.73$ and $\kappa=0.67$. For interrater
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54 160 reliability on CONSORT items, please refer to Supplementary S7.
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3 161 Of all 169 articles, 61% were reports on RCTs (n=103) and 39% reports on CRTs (n=66). More
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5 162 than half of these articles were published between 2015 and 2020 (Supplementary S8). Median
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7 163 number of authors was five (range: 1 – 24, Q1: 4, Q3: 8). Sample size ranged from 23 to 12,391
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9 164 participants, with a median of 271 (Q1: 120, Q3: 670). Twenty-one of the reported studies were
10
11 165 performed at a single site, while 117 were reports of multicenter studies. Median abstract word
12
13 166 count was 225 words, with range from 68 to 623 (Q1: 175, Q3: 253). The median journal impact
14
15 167 factor was 3.2 (Q1: 2.1, Q3: 4.3). Fifty-seven percent of the included abstracts were unstructured
16
17 168 (n=97), one-third of the abstracts were structured with two to four sections (n=56), and the
18
19 169 remaining 10% were highly structured (n=16), i.e., with more than four sections.
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22 170 **3.2 Adherence to CONSORT for abstracts**

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25 171 Figure 2 summarizes the results on adherence to CONSORT for abstracts items, i.e. the
26
27 172 proportion of trial abstracts reporting item information adequately, inadequately and not at all
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29 173 (please see also Supplementary S7 for exact figures). The percentage of adequate reporting
30
31 174 among general items ranged from 58.0% (item *01 Title*) to 30.2% (item *02 Trial design*). With
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33 175 regards to trial methodology, the highest percentage of adequate reporting was in item *05*
34
35 176 *Objective* and the lowest in item *08 Blinding*. Regarding trial results, item *13 Conclusions* had the
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37 177 highest percentage of adequate reporting (36.7%) and item *12 Harms* the lowest (0.6%).
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40 178 **3.3 Overall reporting quality and associated factors**

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43 179 The distribution of the RQS among all abstracts and stratified by study design is depicted in Figure
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45 180 3.

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48 181 The graphs in Figure 4 visualize the relationship of trial and journal characteristics with RQS.
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50 182 Number of authors, abstract word count and journal impact factor were positively associated with
51
52 183 RQS. For example, for every 10% increase in the journal impact factor, the RQS increased by
53
54 184 about 1.9 percentage points (calculation: coefficient $5.6 \times \log(1.10) \approx 1.9$). Structured (2-4
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56 185 sections) and in particular highly structured abstracts (>4 sections) had a higher RQS than
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3 186 unstructured abstracts (1 section). Sample size and number of sampling points were not related
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5 187 to RQS. Finally, after publication of CONSORT-A in 2008, RQS annually increased by 0.57 units.
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8 188 An additional before-and-after comparison illustrates that the RQS was higher in the period from
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10 189 2008 to 2020 (median: 36.7, Q1: 30.0, Q3: 43.5) than in the period from 2003 to 2007 (median:
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12 190 32.0, Q1: 22.9, Q3: 41.8).

15 16 191 **4 DISCUSSION**

17
18 192 In the present study, we assessed reporting quality for abstracts of child and adolescent
19
20 193 depression prevention trial reports. Overall, we found that adherence with CONSORT-A and
21
22 194 -C for abstracts is suboptimal in journal articles reporting on such studies between 2003 and
23
24 195 2020.

25 26 27 28 196 **4.1 Comparison with previous studies**

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30 197 Meta-epidemiological studies of reporting quality follow two distinct methodological approaches.
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32 198 In the journal-based approach, one or more journals are selected, usually top journals in a specific
33
34 199 field with a high-impact factor, and the published articles are assessed. Examples comprise
35
36 200 studies on the abstract reporting quality in general [15, 16, 25–27] and internal medicine, [28–
37
38 201 30] anesthesiology, [31–33] surgery, [34, 35] nursing [36] and critical care.[37] The only prior
39
40 202 study on abstracts of psychiatric trials followed this approach as well. [21] However, the
41
42 203 restriction to top journals could affect generalizability, as a higher impact factor may be associated
43
44 204 with better reporting quality. [21, 28, 36, 38–42] Thus, journal-based meta-epidemiological studies
45
46 205 might overestimate the quality of abstract reporting. On the contrary, in the topic-based approach,
47
48 206 no constraints are made regarding the journals. Instead, literature databases are systematically
49
50 207 searched for articles on a specific disease, therapy or other topic.[38, 39, 42–48] This increases
51
52 208 the variety of journals, making it difficult to draw conclusions about reporting quality of specific
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209 journals. However, the topic-based approach increases generalizability by also including journals
210 with a lower impact factor and thus provide a more complete picture of reporting quality.

211

212 4.1.1 General items

213 In our study, the general items *01 Title* and *02 Trial design* were adequately reported in about
214 60% and 30% of trial abstracts, respectively. Similarly, Song et al. reported in their study that
215 66% of trials stated “randomized” in the title but only 14% of trials described the study design
216 in the abstract.[21]

217 CONSORT-C requires that abstracts are denoted as cluster randomized in the title (item *01*
218 *Title (cluster extension)*). In our study, however, only one third of all CRT abstracts adequately
219 reported this item. To our knowledge, the present study is the first to examine adherence to
220 CONSORT-C guidelines in CRT abstracts. Yet, some meta-epidemiological studies examined
221 adherence to CONSORT-C for full texts, which includes the same item. For example, Chan
222 et al. showed that about two thirds of pilot or feasibility CRT reports published between 2011
223 and 2014 adequately met this CONSORT item. [49] Similarly, Ivers et al., Diaz-Ordaz et al.,
224 and Walleser et al. found that 48%, 60%, and 98% of CRTs, respectively, state in the title or
225 abstract that the study is a CRT. [50–52]

226 4.1.2 Trial methodology

227 Among all 169 included abstracts, 36% adequately reported both eligibility criteria for participants
228 and setting. In line with many previous studies,[16, 21, 28, 33, 37, 53] we extracted the originally
229 combined information for CONSORT item *03 Participants* using separate dimensions: (i) eligibility
230 criteria for participants and (ii) eligibility criteria for settings. In contrast, other studies assessed
231 reporting of eligibility criteria for participants only.[26, 43, 54, 55] It is not surprising that these
232 studies show the highest proportions of adequate reporting for this item.

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3 233 We found that 98% of abstracts failed to adequately include information on how participants were
4
5 234 assigned to interventions and that 96% of abstracts lacked complete information on whether
6
7 235 participants, program deliverer and data collectors/analysts were blinded. With a few
8
9 236 exceptions,[16, 36, 42–44, 48] most previous studies reported adherence to these items of well
10
11 237 below 10%. [15, 21, 25, 26, 28–35, 37–41, 45, 46, 55–60]

14 238 4.1.3 Trial results

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17 239 The number of participants randomized to each group was adequately reported in approximately
18
19 240 a third of all abstracts and only four percent of the included trial abstracts adequately reported the
20
21 241 number of participants analyzed in each group. This gap between item 09 *Numbers randomized*
22
23 242 and item 10 *Numbers analyzed* has also been observed in previous studies. [57]

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25
26 243 Only one article in our sample elaborated on adverse or unintended effects in the abstract,
27
28 244 whereas all other 168 abstracts failed to mention important adverse events or side effects (item
29
30 245 12 *Harms*). Other meta-epidemiological studies found considerably higher proportions of
31
32 246 adequate reporting for this item, particularly trials that also included pharmacologic interventions.
33
34 247 [26, 34, 44]

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36
37 248 Finally, our study showed that about 12% of abstracts adequately reported the item 15 *Funding*.
38
39 249 Many meta-epidemiological studies even found the proportion of abstracts that adequately report
40
41 250 funding is in the single digits [21, 30, 33, 37, 40, 46, 59, 61] or even zero percent. [29, 31, 32, 34,
42
43 251 35, 38, 41, 45, 55–57, 60] However, it may be rather the journal regulations than CONSORT to
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45 252 influence whether funding information appears in the abstract or in another place, for example at
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47 253 the end of the manuscript.

50 254 4.1.4 Associations with overall reporting quality

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52
53 255 In line with previous findings,[28, 39–41, 46, 59] we observed that overall reporting quality
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55 256 increases with the number of authors. In contrast, some studies found no such relationship.[21,

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3 257 36, 46, 56–58] Other studies suggest, although not consistently[62], that the involvement of
4
5 258 methodologists is associated with higher reporting quality.[51, 63, 64] However, number of authors
6
7 259 may reflect at least to some extent whether author groups include methodologists.

8
9
10 260 Furthermore, overall reporting quality seems to be positively related with the abstract word count.
11
12 261 This observation is consistent with the results of previous meta-epidemiological studies. [39–43,
13
14 262 46, 48, 56, 61] It seems that the more words authors have at their disposal, the more information
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16 263 they can provide.

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18
19 264 Our data suggests that a higher journal impact factor correlates with increased overall reporting
20
21 265 quality. If the impact factor is an indicator for journal quality,[65] journals with a higher impact factor
22
23 266 may apply more rigorous quality control to reporting. This result would thus underline that
24
25 267 restricting studies to top journals may hamper generalizability.

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27
28 268 We observed that structured abstracts showed higher overall reporting quality compared to
29
30 269 unstructured abstracts. With some exceptions,[16, 40, 46, 48, 57] many meta-epidemiological
31
32 270 studies have shown similar results both since [21, 28, 36, 39, 41, 42, 56, 61] and before the
33
34 271 publication of CONSORT-A.[66–72] However, few studies also suggest that structured abstracts
35
36 272 are not superior [73–75] and that abstract structure was unrelated to reporting quality.[76]

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38
39 273 In line with previous studies, we found that abstract reporting quality was higher in the period since
40
41 274 the publication of CONSORT-A as compared to the period before. [21, 26, 29, 34, 38, 40, 41]
42
43 275 However, our data do not allow causal conclusions. Our data indicate that overall reporting quality
44
45 276 is improving since 2008: in contrast to the period from 2003 to 2007, the RQS increased between
46
47 277 2008 and 2020. Chhapola et al. observed a similar trend comparing the reporting quality of trial
48
49 278 abstracts published in high-impact paediatric journals in 2003 to 2007 and 2010 to 2014. [77]

52 53 279 **4.2 Strengths and limitations**

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55 280 This study is the first on reporting quality of trial abstracts in childhood depression prevention. Key
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57 281 strength of our study is the topic-based approach we have chosen; compared to journal-based

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3 282 studies, our results provide a more complete picture of abstract reporting in the field. We carried
4
5 283 out an extensive, reproducible methodology to screen the literature for eligible studies and retrieve
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7 284 study information. We analysed abstracts published over a broad timespan allowing for
8
9 285 comparison of reporting quality before and after publication of CONSORT guidelines. We assess
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11 286 adherence not only to CONSORT-A for RCT abstracts but also to CONSORT-C for CRT abstracts,
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13 287 which was not evaluated by any prior study.

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16 288 We applied CONSORT to measure reporting quality, although it was not designed for this purpose.
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18 289 However, in the current absence of standardized tools for assessment, validated guidelines such
19
20 290 as CONSORT are the best available choice to evaluate reporting quality. Moreover, CONSORT
21
22 291 for social and psychological interventions were not checked for adherence. [78, 79] However,
23
24 292 these guidelines were only published in 2017 and 2018, respectively, and thus few studies could
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26 293 have considered these standards. We assess the reporting quality of trial abstracts and cannot
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28 294 draw conclusions about the quality of reporting in the main text. Reviewers were not blinded to
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30 295 trial and journal characteristics such as authors, publication date and impact factor, during the
31
32 296 study selection and the data extraction. We can therefore not exclude the possibility of bias in the
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34 297 evaluation due to metadata insight of the judging reviewers.

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38 298 When we calculated overall reporting quality scores, we treated each CONSORT item equally,
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40 299 although some items could be more or less relevant than others.[30, 37, 43] These scores are
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42 300 simplified proxies to represent reporting quality with a single measure. The assessment of
43
44 301 reporting quality should however primarily be based on the individual items. [31]

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46
47 302 We did not assess associations between overall reporting quality and journal requirements, such
48
49 303 as word count limits and format structure. However, the word count and structure of the included
50
51 304 abstracts may largely reflect these journal requirements.

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54 305 We used descriptive modelling to explore factors associated of reporting quality; neither predictive
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56 306 nor causal conclusions can be derived from this. Unmeasured factors such as journal

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3 307 endorsement of CONSORT [80] may also be associated with reporting quality. Findings from our
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5 308 secondary research aim may thus be incomplete and should be interpreted with caution.
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8 309 **4.3 Conclusions**

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10 310 Reporting quality plays a crucial role in generating and translating scientific evidence as it
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12 311 increases transparency and accuracy and thereby enables health professionals to identify,
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14 312 evaluate and replicate trial results. CONSORT extensions are valuable tools for authors,
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16 313 reviewers and editors to formulate trial abstracts in a transparent and comprehensible way.
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18 314 Although these tools have been openly available for years, the reporting quality of RCT and CRT
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20 315 abstracts on the prevention of depression in children and adolescents is suboptimal. According to
21
22 316 our results, some CONSORT-A and -C items are adequately reported in most depression
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24 317 prevention trial abstracts, and this should be the benchmark for all items. Interventions aimed at
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26 318 strengthening abstract reporting quality are thus needed. [81] These efforts will very likely not only
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28 319 benefit the scientific community and practitioners in the field, but may ultimately improve mental
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30 320 health care for children and adolescents worldwide.
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40 323 **Funding statement.** This research received no specific grant from any funding agency in the
41
42 324 public, commercial or not-for-profit sectors.
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44
45 325 **Authors' contributions.** JW is the guarantor. JW conceived the idea for the project. JW and CP
46
47 326 developed the concept and methods. JW and JN performed the data selection and extraction. CP
48
49 327 gave final instructions when consensus could not be reached. JW performed the statistical
50
51 328 analysis and interpreted the study findings. JW drafted the first version of the manuscript. CP
52
53 329 contributed to data interpretation, writing, and editing. All authors reviewed and approved the final
54
55 330 manuscript before submission.
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331 **Ethics.** We analysed information from published abstracts and not from human subjects or
332 animals. Therefore, ethics committee approval is not required for this study.

333 **Registration.** Even though reporting quality may indirectly affect patient care in the long-term, we
334 did not assess outcomes of direct patient or clinical relevance. As this is a pre-requisite for
335 registration, we could not register this study in the international prospective register of systematic
336 reviews database (PROSPERO).

337 **Competing interests' statement.** All authors declare that they have no competing interests
338 regarding the publication of this article.

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340 Universitätsmedizin Berlin, who with his expertise provided support for the research project in the
341 development and evaluation of the literature search strategy.

342 **Reporting guidelines.** Strictly speaking, meta-epidemiological studies are not systematic
343 reviews. Nevertheless, we used an adapted version of the Preferred Reporting Items for
344 Systematic Reviews and Meta-Analyses (PRISMA) checklist to report our research (see PRISMA
345 checklist available from the OSF repository).

346 **Data sharing statement.** Statistical code and dataset available from the OSF repository, [23]

347 **Keywords.** Meta-research, methodology research, quality of reporting, mental health, paediatrics,
348 psychiatry, psychology

349 Additional MeSH: Depression, Research Report, Reproducibility of Results, Checklist, Reference
350 Standards, Quality Control, Child, Adolescent

351 **FIGURES AND ILLUSTRATIONS**

352 Figure 1: PRISMA flowchart depicting the study selection process.

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3 353 Figure 2: Percentage of abstracts adhering to CONSORT items in 169 trial reports on the
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5 354 prevention of depression in children and adolescents.
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8 355 Figure 3: Distribution of overall reporting quality by study design.
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11 356 Figure 4: Associations of overall reporting quality with abstract and journal characteristics.
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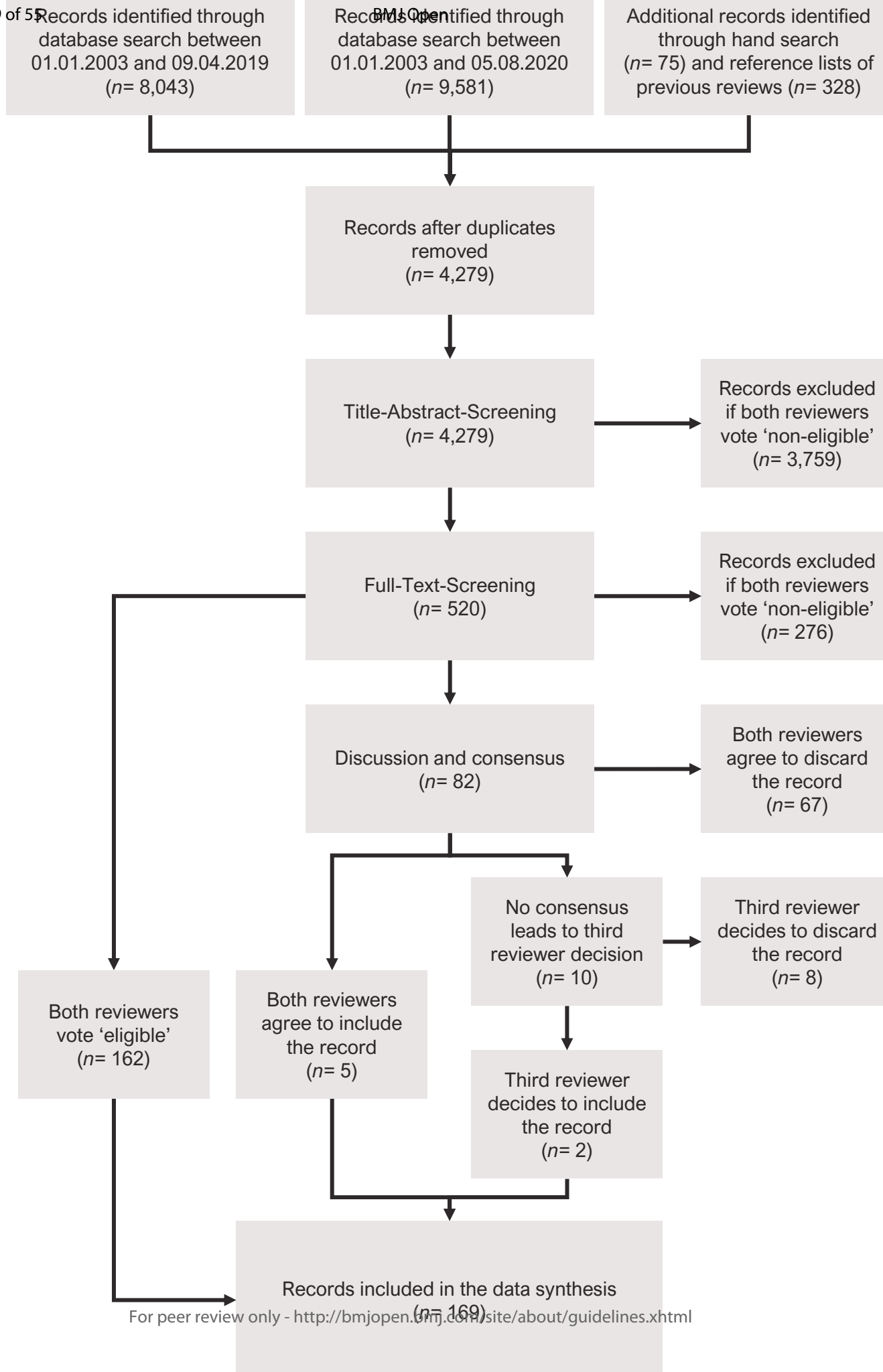
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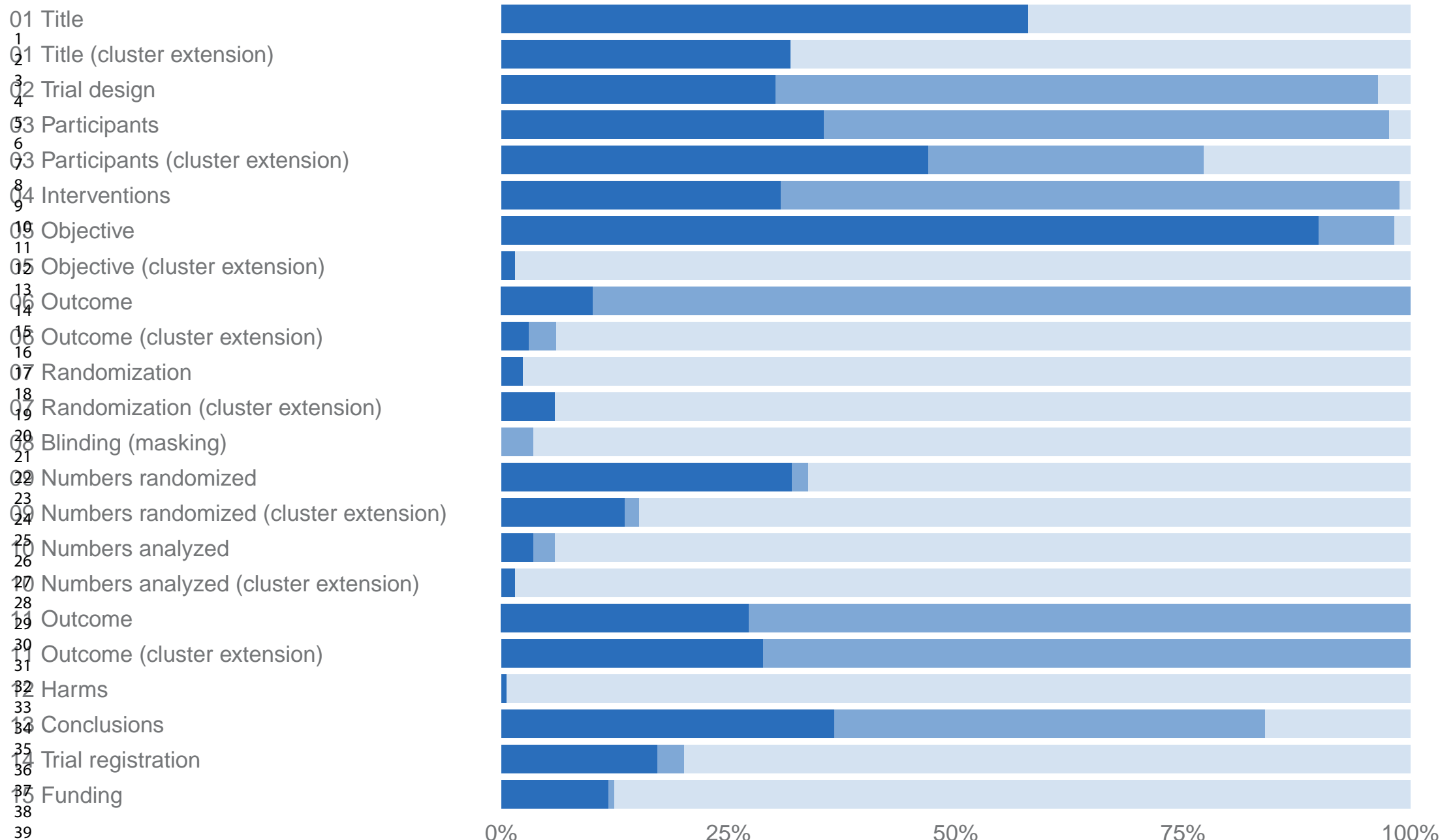
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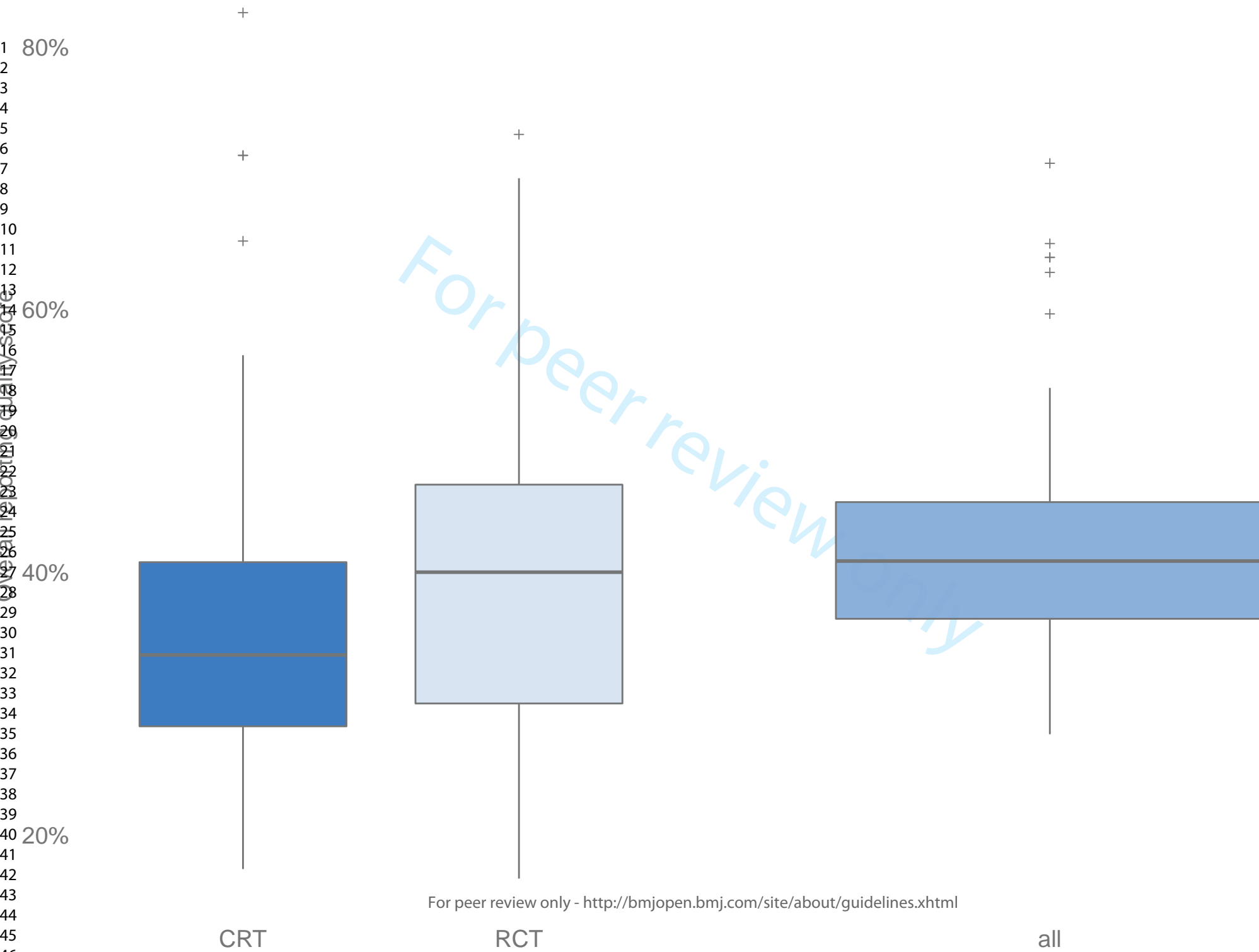
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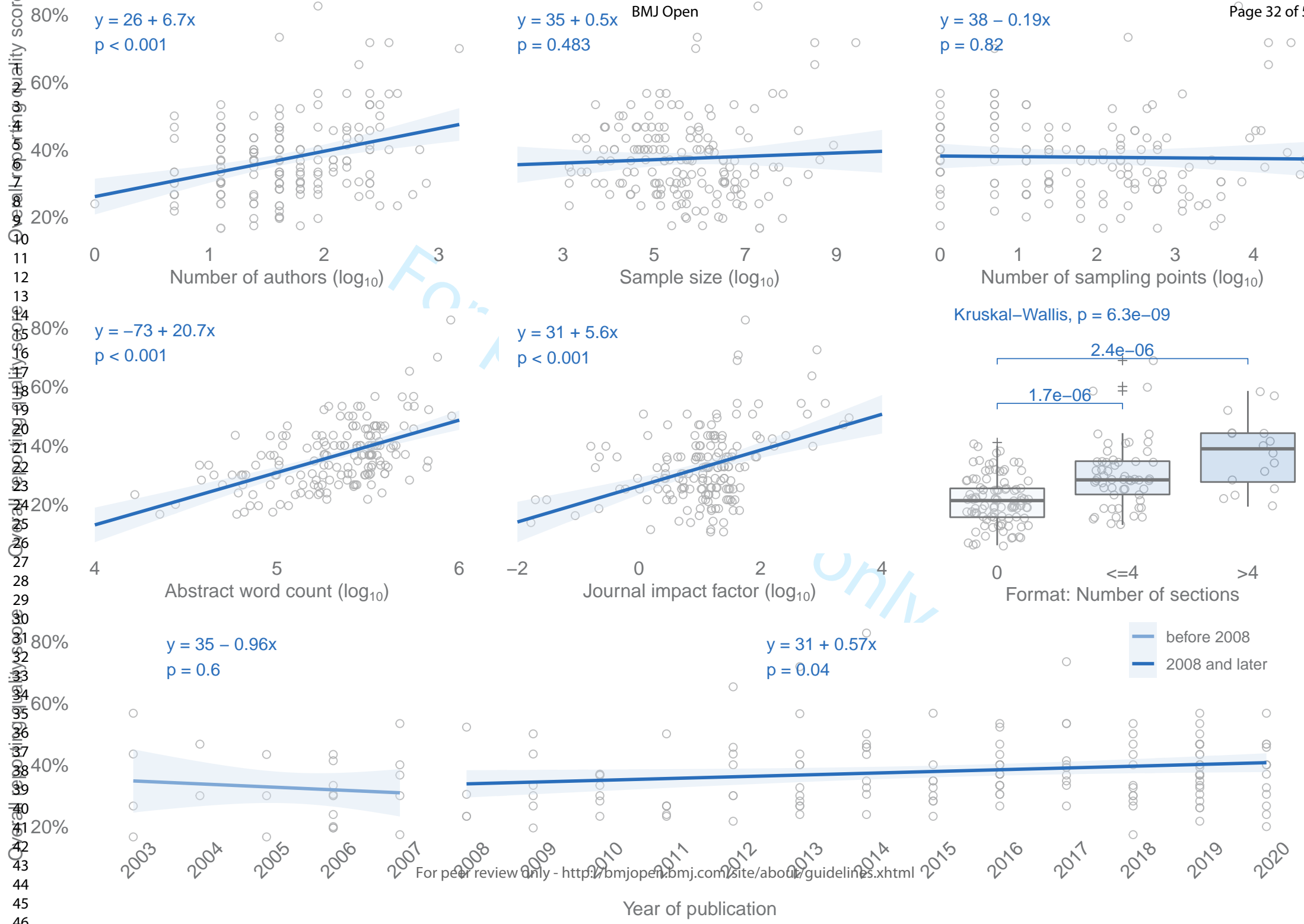
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Supplementary material

S 1 Eligibility criteria for the study selection procedure.

	Inclusion criteria	Exclusion criteria
Population	<ul style="list-style-type: none"> • subjects are children or adolescents ≤ 18 years before treatment initiation (if age range is not available, then use mean age: ≤ 18.0 years) • clinical or community samples as well as samples drawn from the general population • participants with or without increased risk for depression • participants with or without subthreshold depression 	<ul style="list-style-type: none"> • adult samples (> 18 years) • clinically depressed samples ($\geq 50\%$ of participants currently meet or formerly met criteria for clinical diagnosis of depression before treatment initiation)
Intervention	<ul style="list-style-type: none"> • interventions aiming at preventing the onset of depression or reducing depressive symptoms (universal, selective, and indicated prevention) • social, psychological, or educational interventions targeting children and adolescents 	<ul style="list-style-type: none"> • interventions aiming at treating depression or preventing its reoccurrence (secondary or tertiary prevention) • interventions only targeting caregiver including any pharmacological and hormonal components or solely relying on music-based or physical activity components
Control	<ul style="list-style-type: none"> • treatment as usual • wait-list control • attention placebo control • control arm with no treatment 	<ul style="list-style-type: none"> • no control group • drug placebo

S1 Continued.

	Inclusion criteria	Exclusion criteria
Outcome	<ul style="list-style-type: none"> outcome assessment before and after treatment initiation meeting diagnostic criteria for unipolar depressive disorder by administering fully structured or semi-structured diagnostic interviews or applying cut-off values on self- or proxy-report screening scales depressive symptom severity by administering fully structured or semi-structured diagnostic interviews or applying self- or proxy-report screening scales 	<ul style="list-style-type: none"> bipolar depression, no depression, or depression only as secondary outcome only cost-effectiveness, process evaluation, surrogate outcome measures or multifactorial outcome index scores
Study design	<ul style="list-style-type: none"> randomised controlled trials cluster randomised controlled trials 	<ul style="list-style-type: none"> meta-analysis systematic reviews narrative reviews/ overview articles observational studies qualitative studies non-controlled trials non-randomised trials quasi-randomised trials cross-over randomised controlled trials

S 2 Electronic search strategy for MEDLINE via PubMed.

Component	ID	Search term
Search filter for the "children" component [1]	#1	child*[tiab]
	#2	adolescent[tiab]
	#3	infan*[tiab]
	#4	#1 OR #2 OR #3
MeSH terms for "prevention" component	#5	"Mental Health Services"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#6	"Preventive Health Services"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#7	"Child Health Services"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#8	"Adolescent Health Services"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#9	"Community Mental Health Services"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#10	"Preventive Medicine"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#11	"Early Intervention (Education)"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#12	"Health Education"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#13	"Health Promotion"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#14	"Family Therapy"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#15	"Psychotherapy, Group"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#16	"School Health Services"[mesh:noexp] AND Prevention and Control[sh:noexp]
	#17	#5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16

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S 2 Continued.

Component	ID	Search term
Keywords for "prevention" component	#18	primary[tiab]
	#19	targeted[tiab]
	#20	universal[tiab]
	#21	selective[tiab]
	#22	selected[tiab]
	#23	indicated[tiab]
	#24	psycho*[tiab]
	#25	educat*[tiab]
	#26	social[tiab]
	#27	#18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26
	#28	prevent*[tiab]
	#29	intervention*[tiab]
	#30	program*[tiab]
#31	promot*[tiab]	
#32	#28 OR #29 OR #30 OR #31	
#33	#27 AND #32	
Keywords and MeSH terms for "prevention" component	#34	#17 OR #33
MeSH terms for "depression" component	#35	"Depression"[mesh:noexp] AND (Epidemiology[sh:noexp] OR Psychology[sh:noexp])
	#36	"Depressive Disorder"[mesh:noexp] AND (Epidemiology[sh:noexp] OR Psychology[sh:noexp])
	#37	"Depressive Disorder, Major"[mesh:noexp] AND (Epidemiology[sh:noexp] OR Psychology[sh:noexp])
	#38	"Dysthymic Disorder"[mesh:noexp] AND (Epidemiology[sh:noexp] OR Psychology[sh:noexp])
	#39	"Depression, Postpartum"[mesh:noexp] AND (Epidemiology[sh:noexp] OR Psychology[sh:noexp])
	#40	#35 OR #36 OR #37 OR #38 OR #39
Keyword for "depression" component	#41	depress*[tiab]
MeSH terms and keywords for "depression" component	#42	#40 OR #41

S 2 Continued.

Component	ID	Search term
MeSH terms for "study design" component	#43	"Controlled Clinical Trials as Topic"[mesh:noexp] AND (Methods[sh:noexp] OR Epidemiology[sh:noexp])
	#44	exp "Randomized Controlled Trial"[Publication Type]
	#45	#43 OR #44
Keywords for "study design" component	#46	random*[tiab]
	#47	trial[tiab]
	#48	#46 OR #47
MeSH terms and keywords for "study design" component	#49	#45 OR #48
Exclude animal-related research	#50	exp "Animals"[mesh]
	#51	exp "Humans"[mesh]
	#52	#50 NOT #51
	#53	#49 NOT #52
Exclude reviews, meta-analyses and research protocols	#54	Review [Publication Type]
	#55	"Review Literature as Topic"[mesh:noexp]
	#56	#54 OR #55
	#57	meta analysis[ti]
	#58	review[ti]
	#59	protocol[ti]
	#60	#57 OR #58 OR #59
Components: "child" + "prevention"	#61	#56 OR #60
	#62	#53 NOT #61
Components: "child" + "prevention" + "depression"	#63	#4 AND #34
Components: "child" + "prevention" + "depression"	#64	#63 AND #42
Components: "child" + "prevention" + "depression" + "study design"	#65	#64 AND #62
Restrict to records published between 2003 and 2019	#66	#65 AND 2003:2019[dp]

S3 Hand-searched journals and systematic reviews as additional sources of information.

Journals hand-searched for eligible primary studies

Journal of the American Academy of Child & Adolescent Psychiatry

Journal of Abnormal Child Psychology

Journal of Paediatric Psychology

Behaviour Research and Therapy

Systematic reviews for which the reference lists were searched for eligible primary studies

Ahlen, J., Lenhard, F., & Ghaderi, A. (2015). Universal prevention for anxiety and depressive symptoms in children: a meta-analysis of randomized and cluster-randomized trials. *The journal of primary prevention*, 36(6), 387-403.

Barry, M. M., Clarke, A. M., Jenkins, R., & Patel, V. (2013). A systematic review of the effectiveness of mental health promotion interventions for young people in low- and middle-income countries. *BMC public health*, 13(1), 835.

Bastounis, A., Callaghan, P., Banerjee, A., & Michail, M. (2016). The effectiveness of the Penn Resiliency Programme (PRP) and its adapted versions in reducing depression and anxiety and improving explanatory style: A systematic review and meta-analysis. *Journal of adolescence*, 52, 37-48.

Brunwasser, S. M., & Garber, J. (2016). Programs for the prevention of youth depression: Evaluation of efficacy, effectiveness, and readiness for dissemination. *Journal of Clinical Child & Adolescent Psychology*, 45(6), 763-783.

Brunwasser, S. M., Gillham, J. E., & Kim, E. S. (2009). A meta-analytic review of the Penn Resiliency Program's effect on depressive symptoms. *Journal of consulting and clinical psychology*, 77(6), 1042-1054.

Calear, A. L., & Christensen, H. (2010). Review of internet-based prevention and treatment programs for anxiety and depression in children and adolescents. *Medical Journal of Australia*, 192(11), S12.

Calear, A. L., & Christensen, H. (2010). Systematic review of school-based prevention and early intervention programs for depression. *Journal of adolescence*, 33(3), 429-438.

Cary, C. E., & McMillen, J. C. (2012). The data behind the dissemination: A systematic review of trauma-focused cognitive behavioral therapy for use with children and youth. *Children and Youth Services Review*, 34(4), 748-757.

Christensen, H., Pallister, E., Smale, S., Hickie, I. B. & Calear, A. L. (2010). Community-based prevention programs for anxiety and depression in youth: A systematic review. *Journal of Primary Prevention*, 31, 139-170.

Corrieri, S., Heider, D., Conrad, I., Blume, A., König, H. H., & Riedel-Heller, S. G. (2013). School-based prevention programs for depression and anxiety in adolescence: A systematic review. *Health promotion international*, 29(3), 427-441.

Cuijpers, P., van Straten, A., Smit, F., Mihalopoulos, C., & Beekman, A. (2008). Preventing the onset of depressive disorders: a meta-analytic review of psychological interventions. *American Journal of Psychiatry*, 165(10), 1272-1280.

Dardas, L. A., van de Water, B., & Simmons, L. A. (2017). Parental involvement in adolescent depression interventions: A systematic review of randomized clinical trials. *International journal of mental health nursing*, 27(2), 555-570.

Dray, J., Bowman, J., Campbell, E., Freund, M., Wolfenden, L., Hodder, R. K., ... & Small, T. (2017). Systematic review of universal resilience-focused interventions targeting child and adolescent mental health in the school setting. *Journal of the American Academy of Child & Adolescent Psychiatry*, 56(10), 813-824.

Ebert, D. D., Zarski, A. C., Christensen, H., Stikkelbroek, Y., Cuijpers, P., Berking, M., & Riper, H. (2015). Internet and computer-based cognitive behavioral therapy for anxiety and depression in youth: a meta-analysis of randomized controlled outcome trials. *PLOS ONE*, 10(3), e0119895.

Erford, B. T., Erford, B. M., Lattanzi, G., Weller, J., Schein, H., Wolf, E., ... & Peacock, E. (2011). Counseling outcomes from 1990 to 2008 for school-age youth with depression: A meta-analysis. *Journal of Counseling & Development*, 89(4), 439-457.

S3 Continued.

Systematic reviews for which the reference lists were searched for eligible primary studies

- Garber, J., Brunwasser, S. M., Zerr, A. A., Schwartz, K. T., Sova, K., & Weersing, V. R. (2016). Treatment and Prevention of Depression and Anxiety in Youth: Test of Cross-Over Effects. *Depression and anxiety*, 33(10), 939-959.
- Grist, R., Porter, J., & Stallard, P. (2017). Mental health mobile apps for preadolescents and adolescents: a systematic review. *Journal of medical internet research*, 19(5), e176.
- Grist, R., Croker, A., Denne, M., & Stallard, P. (2018). Technology Delivered Interventions for Depression and Anxiety in Children and Adolescents: A Systematic Review and Meta-analysis. *Clinical Child and Family Psychology Review*, 22(2), 147-171.
- Hetrick, S., Cox, G., & Merry, S. (2015). Where to go from here? An exploratory meta-analysis of the most promising approaches to depression prevention programs for children and adolescents. *International journal of environmental research and public health*, 12(5), 4758-4795.
- Hetrick, S. E., Cox, G. R., Witt, K. G., Bir, J. J., & Merry, S. N. (2016). Cognitive behavioural therapy (CBT), third-wave CBT and interpersonal therapy (IPT) based interventions for preventing depression in children and adolescents. *Cochrane Database of Systematic Reviews*, (8).
- Merry, S. N., Hetrick, S. E., Cox, G. R., Brudevold-Iversen, T., Bir, J. J., & McDowell, H. (2012). Psychological and educational interventions for preventing depression in children and adolescents. Evidence-Based Child Health: *A Cochrane Review Journal*, 7(5), 1409-1685.
- Merry, S. N. & Spence, S. H. (2007). Attempting to prevent depression in youth: A systematic review of the evidence. *Early Intervention in Psychiatry*, 1, 128-137.
- Neil, A. L., & Christensen, H. (2007). Australian school-based prevention and early intervention programs for anxiety and depression: a systematic review. *Medical Journal of Australia*, 186(6), 305.
- Richardson, T., Stallard, P., & Velleman, S. (2010). Computerised cognitive behavioural therapy for the prevention and treatment of depression and anxiety in children and adolescents: a systematic review. *Clinical child and family psychology review*, 13(3), 275-290.
- Stice, E., Shaw, H., Bohon, C., Marti, C. N., & Rohde, P. (2009). A meta-analytic review of depression prevention programs for children and adolescents: factors that predict magnitude of intervention effects. *Journal of consulting and clinical psychology*, 77(3), 486.
- Stockings, E. A., Degenhardt, L., Dobbins, T., Lee, Y. Y., Erskine, H. E., Whiteford, H. A., & Patton, G. (2016). Preventing depression and anxiety in young people: a review of the joint efficacy of universal, selective, and indicated prevention. *Psychological medicine*, 46(1), 11-26.
- Werner-Seidler, A., Perry, Y., Calcar, A. L., Newby, J. M., & Christensen, H. (2017). School-based depression and anxiety prevention programs for young people: A systematic review and meta-analysis. *Clinical psychology review*, 51, 30-47.

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S4 Pre-specified characteristics for the analysis based on previous studies on associations with reporting quality.

Characteristic	Previous studies reporting on associations with reporting quality
Number of authors	Bigna (2016) [2] Chen (2018) [3] Fang (2020) [9] Fleming (2012) [10] Guo (2014) [4] Hua (2015) [5] Jin (2016) [11] Kiriakou (2014) [6] Menne (2021) [7] Seehra (2013) [12] Song (2017) [13] Wang (2021) [8] Zhang (2021) [14]
Sample size	Baulig (2018) [15] Chen (2018) [3] Fang et al. (2020) Jin (2016) [11] Mbuagbaw (2014) [16] Song (2017) [13] Sriganesh (2017) [17] Wang (2021) [8]
Number of sampling points	Chen (2018) [3] Fang (2020) [9] Fleming (2012) [10] Guo (2014) [4] Hua (2015) [5] Jin (2016) [11] Kiriakou (2014) [6] Mbuagbaw (2014) [16] Menne (2021) [7] Seehra (2013) [12] Song (2017) [13] Sriganesh (2017) [17] Wang (2021) [8] Zhang (2021) [14]
Abstract word count	Baulig (2018) [15] Chen (2018) [3] Fang et al. (2020) Guo (2014) [4] Hua (2015) [5] Jin (2016) [11] Knippschild (2021) [18] Menne (2021) [7] Wang (2021) [8]

S4 Continued.

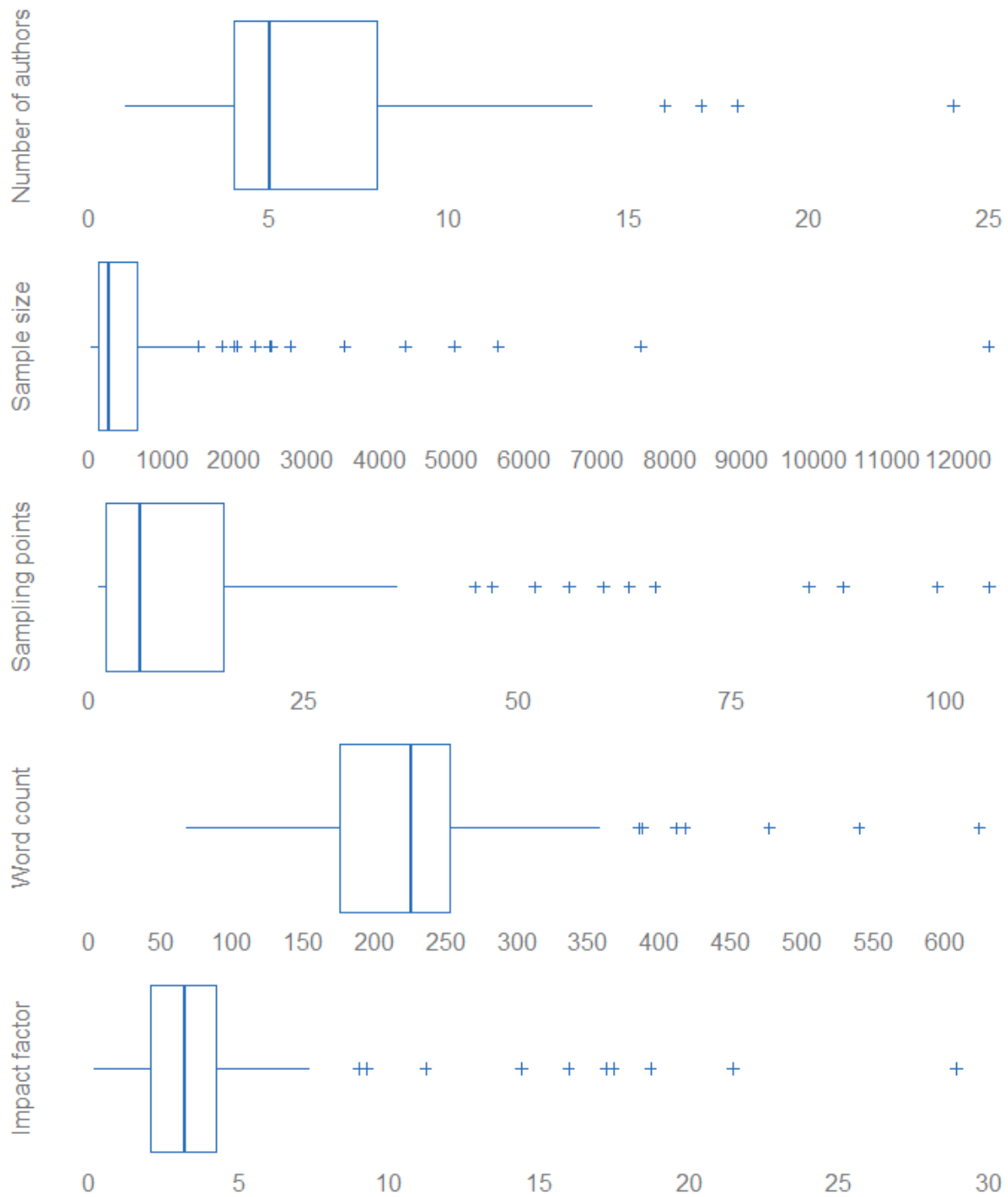
Characteristic	Previous studies reporting on associations with reporting quality
Journal impact factor	Baulig (2018) [15] Bigna (2016) [2] Chen (2018) [3] Cui (2014) [19] Guo (2014) [4] Hua (2015) [5] Knippschild (2021) [18] Menne (2021) [7] Song (2017) [13] Wang (2021) [8] Zhang (2021) [14]
Abstract format	Bigna (2016) [2] Chen (2018) [3] Fang (2020) [9] Fleming (2012) [10] Guo (2014) [4] Hua (2015) [5] Jin (2016) [11] Knippschild (2021) [18] Menne (2021) [7] Song (2017) [13] Wang (2021) [8] Zhang (2021) [14]
Year of publication	Baulig (2018) [15] Bigna (2016) [2] Can (2011) [20] Chen (2018) [3] Chow (2018) [21] Cui (2014) [19] Guo (2014) [4] Hua (2015) [5] Jin (2016) [11] Knippschild (2021) [18] Mbuagbaw (2014) [16] Menne (2021) [7] Sivendran (2015) [22] Song (2017) [13] Speich (2019) [23] Sriganesh (2017) [17] Zhang (2021) [14]

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S5 Variables extracted during the data collection process according to S4.

Variable	Definition	Source
Number of authors	The number of authors who have published the trial report.	First page of the trial report
Sample size	The number of subjects in all study arms.	Methods of the manuscript
Number of sampling points	The number of sampling points in all study arms.	Methods of the manuscript
Abstract word count	The number of words used only for the abstract, excluding keywords, author information and such.	Abstract of the trial report
Journal impact factor	The journal impact factor calculated from data indexed in the Web of Science Core Collection. If data was missing for a certain year, the journal impact factor from the latest year available was used.	Journal Citation Reports as provided by Clarivate
Abstract format	The number of sections used to structure the abstract. Following Hua et al., abstracts were categorized as unstructured (1 section), structured (2-4 sections) or highly structured (>4 sections).[24]	Abstract of the trial report
Year of publication	The year in which the trial report was first published.	First page of the trial report

S6 Boxplots visualizing the distribution of continuous variables possibly related to overall reporting quality.



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S7 Interrater-reliability (Cohen's Kappa) and adequate reporting (proportion of trial abstracts) in 169 abstracts assessed according to CONSORT-A and CONSORT-C checklist items.

Item	Extension for cluster trials *	Description	Cohen's kappa			Proportion of trial abstract that reported...		
			unweighted	equal weights	squared weights	adequately	inadequately	not at all
General items								
01 Title	No	a) Identification of the study as randomized	.96	.96	.96	58.0	-	42.0
	Yes	b) Identification of study as cluster randomized	1		1	31.8	-	68.2
02 Trial design	No	Description of the trial design (e.g. parallel, cluster, non-inferiority)	.38	.45	.53	30.2	66.3	3.6
Trial Methodology								
03 Participants	No	a) Eligibility criteria for participants <u>and</u> the settings where the data were collected **				35.5	62.1	2.4
		(i) The authors report eligibility criteria for participants	.77	.78	.80	80.5	17.2	2.4
		(ii) The authors report eligibility criteria for setting	.81	.85	.89	35.5	30.2	34.3
	Yes	b) Eligibility criteria for clusters	.80		.79	47.0	30.3	22.7
04 Interventions	No	Interventions intended for each group **				30.8	68.0	1.2
		(i) Authors report essential features of the experimental intervention	.80	.81	.82	52.7	45.6	1.8
		(ii) Authors report essential features of the comparison intervention	.76	.82	.86	47.9	21.3	30.8

S7 Continued.

Item	Extension for cluster trials *	Description	Cohen's kappa			Proportion of trial abstract that reported...		
			unweighted	equal weights	squared weights	adequately	inadequately	not at all
Trial Methodology								
05 Objective	No	(a) Specific objective <u>or</u> hypothesis	.73	.74	.76	89.9	8.3	1.8
	Yes	(b) Whether objective <u>or</u> hypothesis pertains to the cluster level, the individual participant level, <u>or</u> both	.66		.89	1.5	-	98.5
06 Outcome	No	(a) Clearly defined primary outcome for this report **				10.1	89.9	-
		(i) Authors explicitly state the primary outcome	.91	.91	.91	14.8	84.6	0.6
		(ii) Authors explicitly state when the primary outcome was assessed	.69	.78	.84	51.5	23.1	25.4
	Yes	(b) Whether the primary outcome pertains to the cluster level, the individual participant level <u>or</u> both	.56		.61	3.0	3.0	93.9
07 Randomization	No	(a) How participants were allocated to interventions	.49	.59	.66	2.4	-	97.6
	Yes	(b) How clusters were allocated to interventions	.88		.88	6.1	-	93.9

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S7 Continued.

Item	Extension for cluster trials *	Description	Cohen's kappa			Proportion of trial abstract that reported...		
			unweighted	equal weights	squared weights	adequately	inadequately	not at all
Trial Methodology								
08 Blinding (masking)	No	Whether or not participants, care givers, <u>and</u> those assessing the outcomes were blinded to group assignment **				-	3.6	96.4
		(i) Authors describe if participants were blinded	.77	.85	.92	1.2	1.8	97.0
		(ii) Authors describe if program deliverer were blinded	.77	.85	.92	1.2	1.8	97.0
		(iii) Authors describe if data collectors/analysts were blinded	.66	.66	.66	0.6	1.8	97.6
Trial results								
09 Numbers randomized	No	(a) Number of participants randomized to each group	.95	.97	.98	32.0	1.8	66.3
	Yes	(b) Number of clusters randomized to each group	.76		.78	13.6	1.5	84.8
10 Numbers analyzed	No	(a) Number of participants analyzed in each group	.88	.93	.96	3.6	2.4	94.1
	Yes	(b) Number of clusters analyzed in each group	1		1	1.5	-	98.5

S7 Continued.

Item	Extension for cluster trials *	Description	Cohen's kappa			Proportion of trial abstract that reported...		
			unweighted	equal weights	squared weights	adequately	inadequately	not at all
Trial results								
11 Outcome	No	(a) For the primary outcome, a result for each group and the estimated effect size and its precision	.94	.94	.94	27.2	72.8	-
	Yes	(b) Results at the cluster or individual level as applicable for each primary outcome	.96		.96	28.8	71.2	-
12 Harms	No	Important adverse events or side effects	0***	0***	0***	0.6	-	99.4
13 Conclusions	No	General interpretation of the results **				36.7	47.3	16.0
		(i) Authors state the conclusions of the trial	.75	.79	.82	71.0	1.8	27.2
		(ii) Authors state implications for further research or clinical practice	.74	.78	.81	46.2	8.3	45.6
14 Trial registration	No	Registration number and name of trial register **				17.2	3.0	79.9
		(i) Authors provide details on the trial registration number	1	1	1	20.1	-	79.9
		(ii) Authors provide details on the name of the trial register	.98	.98	.98	17.2	0.6	82.2
15 Funding	No	Source of funding	.88	.89	.95	11.8	0.6	87.6

Comments: Items corresponding to author contact information and trial status were not assessed because these items are specific to conference abstracts that were excluded from this study. Because journals often have their own standards for positioning funding information, we rated funding as adequately reported if it was reported in the abstract or in a section other than the abstract (e.g., at the end of the article). Due to rounding errors, the percentages may not add up.

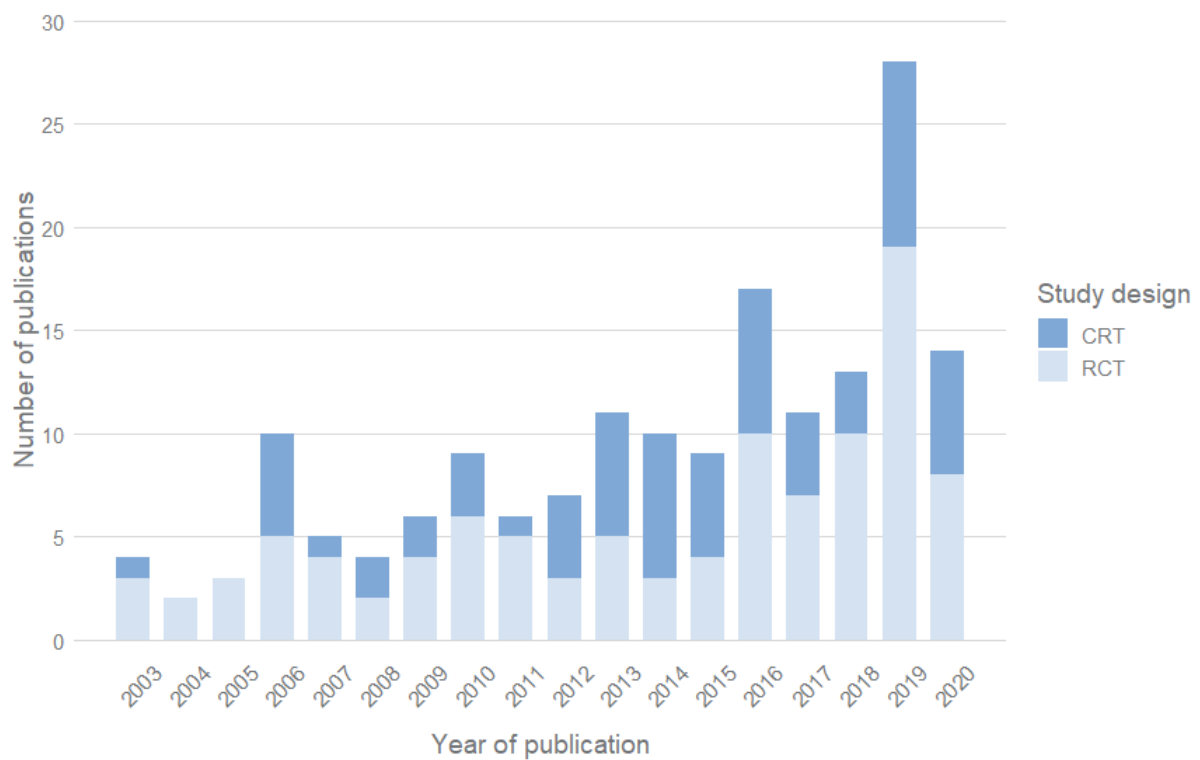
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3 * Studies that randomized their intervention on the cluster level were assessed for adherence to CONSORT-A and CONSORT-C (N = 66). Studies that randomized on the individual level were evaluated
4 for adherence to CONSORT-A, only (N = 103). As a result, all 169 reports were assessed for CONSORT-A, but only 66 cluster randomized trial reports were additionally checked for CONSORT-C.
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6 ** For those items where multiple dimensions are required, we operationalized each dimension separately. Subsequently we merged these dimensions into summary variables. If all dimensions were reported
7 adequately, the summary variable was reported adequately. If at least one dimension was reported inadequately, the summary variable was reported inadequately. If all dimensions were not reported, the
8 summary variable was not reported.
9

10 *** The agreement of the CONSORT items Harms was almost identical. Kappa is nevertheless equal to zero. The correction factor of the kappa formula is responsible for this paradox. The factor corrects
11 for random agreement between raters. If the proportion of observed agreement is high, it can lower the kappa values toward zero. For further explanation and examples, see Feinstein and Cicchetti. [25]
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S8 Annual number of included trial reports by study design between January 2003 and August 2020 (N= 169).



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Proposed items to be used for reporting methodology research, adapted from the PRISMA Checklist (Murad & Wang, 2017)

Section and Topic	Checklist item	Location where item is reported
TITLE		
Title	Identify the report as a meta-epidemiologic study	p. 1, l. 2
ABSTRACT		
Structured summary	Provide a structured summary that includes the background of the topic, goal of the study, data sources, method of data selection, appraisal and synthesis methods, results, limitations, conclusions and implications of key findings	p. 2, l. 13 -p. 3, l. 49
INTRODUCTION		
Rationale	Describe the rationale for the meta-epidemiological study in the context of what is already known	p. 5, l. 66 - 88
Objective	Provide an explicit statement of the goal of the meta-epidemiological study and the hypothesis being empirically tested	p. 5, l. 88 - p. 6, l. 91
METHODS		
Protocol	Indicate if a protocol exists, if and where it can be accessed (eg, Web address). Registration of a protocol is not mandatory	p. 16, l. 334-337
Eligibility criteria	Specify study characteristics used as criteria for eligibility with a rationale	p. 6, l. 95-102 Supplementary S1
Information sources	Describe all information sources (eg, databases with dates of coverage, contact with experts to identify additional studies, Internet searches) and search date	p. 6, l. 104-112 Supplementary S3
Search	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. Search is commonly not driven by a clinical question	Supplementary S2 (tables longer than two pages are published as online only supplementary)

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3	Study selection	Describe the process for selecting studies	p. 7, l. 114-115
4		for inclusion (ie, how many reviewers	Figure 1
5		selected studies, reviewing in duplicate or	
6		by single individuals)	
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9	Data collection process	Describe method of data extraction from	p. 7, l. 115-130
10		reports (eg, piloted forms, independently, in	
11		duplicate) and any processes used for	
12		manipulating data or obtaining and	
13		confirming data from investigators	
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17	Data items	List and define all variables for which data	Supplementary S5
18		were sought and any assumptions and	Supplementary S7
19		imputations made	
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22	Risk of bias in individual studies	If risk of bias assessment of individual	Not relevant
23		studies was relevant to the analysis,	
24		describe the items used and how this	
25		information is to be used during data	
26		synthesis	
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30	Summary measures	State the principal summary measures (eg,	p. 7, l. 136 –
31		ratio of risk ratios, difference in means) and	p. 8, l. 141
32		explain its meaning and direction to readers	
33			
34	Synthesis of results	Describe the statistical or descriptive	Not relevant
35		methods of synthesis including measures	
36		of consistency if relevant. If applicable,	
37		describe the development of statistical or	
38		simulation modelling based on theoretical	
39		background. Describe and justify	
40		assumptions and computational	
41		approximations. Describe methods of	
42		additional analyses (eg, sensitivity or	
43		subgroup analyses, meta-regression), if	
44		done, indicating which were prespecified	
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RESULTS

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53	Study selection	Give numbers of studies assessed for	p. 8, l. 156-161
54		eligibility and included in the study, with	Figure 1
55		reasons for exclusions at each stage,	Supplementary S7
56		ideally with a flow diagram. Present a	
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		measure of inter-reviewer agreement (eg, kappa statistic)	
Study characteristics	For each study, present characteristics for which data were extracted and provide the citations. Clinical characteristics may not always be relevant		p. 9, l. 162 - 170
Risk of bias within studies	If risk of bias assessment of individual studies was used in the meta-epidemiological analysis, report risk of bias indicators of each study to allow replication of findings		Not relevant
Results of individual studies	Present data elements used in the meta-epidemiological analysis from each study (results of clinical outcomes may not be relevant)		Data of individual studies can be retrieved from an online repository (https://bit.ly/3tl7kvz)
Synthesis of results	Present results of statistical analysis done, including measures of precision and measures of consistency. Present validity of assumptions and fit of statistical or simulation modelling, if applicable		p. 8, l. 155 – p. 9, l. 178
Additional analysis	Give results of additional analyses, if done (eg, sensitivity or subgroup analyses, metaregression)		p. 9, l. 180 – - 191
DISCUSSION			
Summary of evidence	Summarise the main findings and compare them with existing knowledge about the topic. The quality of evidence may not be relevant; however, investigators should describe their certainty in the results to readers		p. 10, l. 198 – p. 13, l. 279
Limitations	Discuss limitations at research methodology level (eg, likelihood of reporting or publication bias)		p. 13, l. 280 – p. 15, l. 309
Conclusions	Provide general interpretation of the results and implications for future research.		p. 15, l. 310 – p. 15, l. 321

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3 Provide any plausible impact on clinical
4 practice
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6 FUNDING

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8 Funding

9 Describe sources of funding for the
10 methodology research and role of funders

11 p. 15, l. 324-325
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For peer review only