



Quality of randomised controlled trials in medical education reported between 2012 and 2013: A systematic review protocol.

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2014-005155
Article Type:	Protocol
Date Submitted by the Author:	28-Feb-2014
Complete List of Authors:	Tolsgaard, Martin; Copenhagen University Hospital Rigshospitalet, Capital Region of Denmark, Centre for Clinical Education and the Juliane Marie Centre Ku, Cheryl; University of Toronto and University Health Network, The Wilson Centre Woods, Nicole; University of Toronto and University Health Network, Department of Surgery and The Wilson Centre Kulasegaram, Kulamakan; University of Toronto and University Health Network, Department of Family and Community Medicine and The Wilson Centre Brydges, Ryan; University of Toronto and University Health Network, Department of Medicine and The Wilson Centre Ringsted, Charlotte; University Health Network, The Wilson Centre
Primary Subject Heading:	Medical education and training
Secondary Subject Heading:	Medical publishing and peer review
Keywords:	EDUCATION & TRAINING (see Medical Education & Training), EPIDEMIOLOGY, Health informatics < BIOTECHNOLOGY & BIOINFORMATICS

SCHOLARONE™
Manuscripts

1
2
3
4
5 **1 Quality of randomised controlled trials in medical**
6 **2 education reported between 2012 and 2013: A**
7 **3 systematic review protocol.**
8
9
10
11
12
13

14 Martin G. Tolsgaard, MD, PhD¹, Cheryl Ku, MSci², Nicole N. Woods, PhD³,
15 Kulamakan Mahan Kulasegaram, PhD⁴, Ryan Brydges, PhD⁵, Charlotte Ringsted,
16 MD, PhD, MHPE⁶.
17

18 ¹ Centre for Clinical Education and the Juliane Marie Centre, Copenhagen
19 University Hospital Rigshospitalet, Denmark.
20

21 ² The Wilson Centre, University of Toronto and University Health Network,
22 Canada.
23

24 ³ Department of Surgery and The Wilson Centre, University of Toronto and
25 University Health Network, Canada
26

27 ⁴ Department of Family and Community Medicine and The Wilson Centre,
28 University of Toronto and University Health Network, Canada
29

30 ⁵ Department of Medicine and The Wilson Centre, University of Toronto and
31 University Health Network, Canada
32

33 ⁶ Department of Anesthesia and The Wilson Centre, University of Toronto and
34 University Health Network, Canada
35

36 Running head: Quality of randomised controlled trials in medical education.
37
38
39

40
41
42
43
44 Corresponding author:

45 Martin G. Tolsgaard, MD, PhD

46 Postdoctoral research fellow, Centre for Clinical Education and the Juliane Marie
47 Center, Copenhagen University Hospital Rigshospitalet

48 9 Blegdamsvej, 2100 Copenhagen-O

49 Denmark

50 Tel: +456103072

51 martintolsgaard@gmail.com
52
53

54
55 Word count: XXX
56

57
58 Keywords: Randomised controlled trials, medical education
59
60

Abstract

Introduction: Research in medical education has increased in volume over the last decades but concerns have been raised regarding the quality of trials conducted within this field. Randomised controlled trials (RCTs) involving educational interventions that are reported in biomedical journals have been criticised for insufficient conceptual, theoretical framework. RCTs published in journals dedicated to medical education, on the other hand, have been questioned regarding their methodological rigor.

The aim of this study is therefore to assess the quality of RCTs of educational interventions reported in 2012 and 2013 in journals dedicated to medical education compared to biomedical journals with respect to objective quality criteria.

Methods and analysis: RCTs published between 1 January 2012 and 31 December 2013 in English are included. The search strategy is developed by the help of experienced librarians to search online databases for key terms. All of the identified RCTs are screened based on their titles and abstracts individually by the authors and then compared in pairs to assess agreement. Data is extracted from the included RCTs by independently scoring each RCT using a data collection form. The data collection form consists of four steps. Step 1 includes confirmation of RCT eligibility; Step 2 consists of the CONSORT checklist; Step 3 consists of the MERSQI framework; Step 4 consists of a Medical Education Extension (MEdEx) to the CONSORT checklist. The MEdEx includes the following elements: Description of scientific background, explanation of rationale, quality of research questions and hypotheses, clarity in the description of the use of the intervention and control as well as interpretation of results.

Ethics and Dissemination: This review is the first to systematically examine the quality of RCTs conducted in medical education. We plan to disseminate the results through publications and presentation at relevant conferences. Ethical approval is not sought for this review.

Article summary

Strengths and Limitations of this study

Strengths:

- The first systematic review of the quality of randomised controlled trials in medical education.
- The use of duplicate, independent, and reproducible data coding of quality measures pertaining to research methodology and reporting.

Limitations:

- To provide a current state of evidence on trial quality, only studies reported from 2012 to 2013 are included in this review.
- Only articles in English are included in this systematic review.

93 Introduction

94 Medical education as a field has grown during the past twenty years. It has
95 become a billion dollar industry accounting for about US\$100 billion per year
96 worldwide¹ and increasing awareness of linking education to patient outcomes
97 has brought focus on evidence-based medical education.² The growing interest is
98 reflected in the rise in number of publications within this area over the past
99 several decades.³ However, this is not unproblematic, as several scholars have
100 warned that the medical education research lacks methodological rigor.³ In a
101 study of randomised controlled trials (RCTs) published between 2000 and 2003,
102 a large proportion fell short of the criteria developed by the International
103 Committee of Medical Journal Editors for reporting RCTs.⁴ Meanwhile, some
104 argue that judging the quality of research being performed in medical education
105 by any 'objective' checklist is insufficient.⁵ Instead, quality of medical education
106 research should be based on how well the theoretical understanding of a
107 problem becomes, rather than on how well a particular research methodology
108 has been adopted. ⁵ Other viewpoints state that whatever method is used should
109 comply with the highest standards of practice for that design.⁶ Thus, two
110 discourses of evaluating quality have been promoted. One is assessing quality
111 against 'gold-standards' such as the checklists and guidelines, and another is
112 judging the advancement of theory.

113 In clinical epidemiological research, RCTs take on a central role when evaluating
114 health care interventions. Since 2000, the CONSORT group has provided
115 guidelines to improve the transparency and rigor when reporting randomised
116 trials within biomedicine (ref). Although the CONSORT statement does not

1
2
3 117 include recommendations for designing, conducting, and analysing trials, it
4
5 118 indirectly affects design and conduct as transparent reporting may expose
6
7 119 deficiencies in research if they exist⁷ Furthermore, CONSORT is informed by
8
9
10 120 methodological theorists and practitioners in clinical epidemiology as well as
11
12 121 biostatistics. Assessing quality of RCTs in medical education using the CONSORT
13
14 122 statement may, however, not capture advancement of theory. Insufficient use of
15
16 123 a conceptual theoretical framework may lead to failure to identify the active
17
18 124 component of training interventions and poor description of context of the study
19
20
21 125 as well as trainee characteristics limit the external validity in terms of
22
23 126 generalizability to other settings and populations. Reporting should therefore
24
25 127 also relate the study to a relevant theoretical context to justify how it uses and
26
27 128 advances existing theory⁵ including thorough descriptions of context,
28
29 129 educational intervention and control circumstances, and trainee characteristics.⁸
30
31
32 130 However, these aspects are not assessed using the CONSORT statement and
33
34 131 other measures to evaluate study quality within medical education research may
35
36 132 be warranted. To further evolve our understanding of quality of RCTs conducted
37
38 133 in medical education, we aim to explore the adherence to standardised quality
39
40 134 criteria as well as the use of theory in recent literature. The research question of
41
42 135 this review is:
43
44
45
46 136

47
48 137 In randomised controlled trials in medical education reported between 2012 and
49
50 138 2013, what characterises the quality of papers published in journals dedicated to
51
52 139 medical education compared to papers published in biomedical journals with
53
54 140 respect to objective quality criteria?
55
56
57 141

142 Methods

143 This systematic review is designed according to the seven-step approach
144 recommended for conducting systematic reviews in medical education² and
145 reported according to the PRISMA statement.⁹

147 Study eligibility

148 Broad inclusion criteria are used to obtain a broad range of randomised trials in
149 medical education. Studies published between 1 January 2012 and 31 December
150 2013 in English are included. This period is chosen as new guidelines for
151 reporting randomised trials were published in June 2010 and previous studies
152 argued that the evaluation of reporting guidelines should first be evaluated 18-
153 24 months following publication.¹⁰⁻¹¹ All research papers in medical education
154 using randomised designs are included. Medical education research is defined as
155 “any original research study pertaining to medical students, residents, fellows,
156 faculty development, or continuing medical education for physicians.”¹² Using
157 this definition, studies on veterinary-, nursing-, pharmacist-, physiotherapist-
158 and dentistry education research are not eligible. Parallel group studies, cross-
159 over studies, non-inferiority and equivalence studies are all included whereas
160 pseudo-randomised studies are not.

162 Search

163 The search strategy is developed by the help of experienced librarians to search
164 MEDLINE, EMBASE, CINAHL, PsychINFO, ERIC, Web of Science, and Scopus for
165 key terms. These terms include truncated search on random* and MeSH terms

1
2
3 166 relating to medical education (e.g. "Education, Professional"). Related domains
4
5 167 are also included in the search to account for research not categorised under
6
7 168 medical education (e.g. health professions education, simulation, undergraduate
8
9 169 medical education, technology-enhanced education, clinical reasoning, skills
10
11 170 assessment, education professional, student health occupation, internship and
12
13 171 residency, curriculum planning, instructional method, self-directed learning etc.).
14
15 172 The search is supplemented by adding the reference-lists of recent reviews in
16
17 173 simulation-based medical education and with authors' records of studies
18
19 174 published in the period of interest. The authors' records are used to refine the
20
21 175 search strategy in an iterative way so that as many relevant randomised studies
22
23 176 as possible are included in the online search.
24
25
26
27
28
29

30 31 178 **Study selection**

32
33 179 All of the identified studies are screened based on their titles and abstracts
34
35 180 individually and compared in pairs to assess agreement so that all studies have
36
37 181 been screened by two authors. Potential disagreement is solved by discussion
38
39 182 until consensus is reached. If the title or abstract is insufficient for determining
40
41 183 eligibility, the full text is reviewed. The agreement between the raters is
42
43 184 determined using intra-class correlation coefficients (ICCs).
44
45
46
47
48
49

50 186 **Data collection process**

51
52 187 Data is extracted from included studies by duplicate and independent scoring of
53
54 188 each study using a data collection form. The data collection form consists of four
55
56 189 steps. Step 1 includes confirmation of study eligibility; Step 2 consists of the
57
58
59
60

1
2
3 190 CONSORT checklist; Step 3 consists of the Medical Education Research Study
4
5 191 Quality Instrument (MERSQI) framework; Step 4 consists of a Medical Education
6
7 192 Extension to the CONSORT statement developed by the review group.
8

9
10 193

11
12 194 *Step 1.* The first step includes confirmation of study eligibility, extraction of
13
14 195 Study ID (created by review author) as well as name and focus of journal
15
16 196 (medical education/biomedical).

17
18
19 197 *Step 2.* The dichotomous CONSORT checklist is completed by ticking off each
20
21 198 item when either present (=1), absent (=0), or not applicable (N/A). The
22
23 199 CONSORT statement recommends that researchers provide a scientific
24
25 200 background for the study as well as present specific objectives and hypothesis,
26
27 201 thoroughly describe the intervention and control conditions, randomisation
28
29 202 procedure, data analysis and interpretation of results.

30
31
32 203 *Step 3.* The Medical Education Research Study Quality Instrument (MERSQI)¹² is
33
34 204 used to provide an established measure of study quality and scores are
35
36 205 compared in pairs and discussed until consensus. Evidence of validity of the
37
38 206 MERSQI framework has been established in a previous study.¹² The MERSQI
39
40 207 framework provides a measure of trial size (single- or multiple institutions),
41
42 208 validity of assessment instruments used, and the Kirkpatrick level of outcome
43
44 209 measures used (a taxonomy for classifying training programmes). Hence, studies
45
46 210 of a certain size and focusing on patient outcomes would receive higher scores
47
48 211 than single-institution studies that assess the impact of interventions on health
49
50 212 care professionals' knowledge or behaviour in a simulated setting.

51
52
53 213 *Step 4.* The Medical Education Extension (MEdEx) is developed by the study
54
55 214 group through a literature review of relevant quality research in medical
56
57
58
59
60

1
2
3 215 education. To further advance our understanding of the use of theory in the
4
5 216 scientific background of the RCTs, the reporting of specific hypotheses, clarity of
6
7 217 description of interventions¹³ and controls, and the use of theory in the
8
9 218 interpretation of the observed results, we chose to include these factors in a
10
11 219 medical education extension (MEdEx) to the CONSORT checklist. In step 4, the
12
13 220 following items are therefore included: 1) Scientific background, 2) Explanation
14
15 221 of rationale, 3) Objectives or research question, 4) Hypotheses, 5) Description of
16
17 222 the intervention and control circumstances, 6) Interpretation of results (see
18
19 223 Appendix).
20
21
22
23
24

25 26 27 225 **Statistical analysis**

28
29 226 Inter-rater reliability is calculated using Intra-Class Correlation Coefficients. In
30
31 227 the event of disagreement, the assessments will be solved by consensus. The
32
33 228 CONSORT-scores, MERSQI-scores, and MEdEx-scores are correlated to each
34
35 229 other, to journal impact factor, and compared across papers published in
36
37 230 journals dedicated to medical education and biomedical journals using
38
39 231 parametric statistics if the conditions are met.
40
41
42
43
44

45 233 **Discussion and dissemination**

46
47 234 In parallel with the rise in publications in medical education over the last
48
49 235 decades, increasing interest is being paid to systematically evaluate the quality of
50
51 236 research conducted within this field. We chose to include three different quality
52
53 237 measures in the data collection form for this systematic review. To evaluate the
54
55 238 quality of reporting, the CONSORT checklist is included as a measure of the
56
57
58
59
60

1
2
3 239 degree to which current medical education research adhere to the guidelines
4
5 240 endorsed by the *World Association of Medical Editors, the International*
6
7 241 *Committee of Medical Journal Editors (ICMJE), and the Council of Science Editors.*¹⁴
8
9
10 242 The second quality measure includes the MERSQI framework, which has been
11
12 243 used extensively in several recent reviews.¹⁵⁻¹⁷ Although MERSQI-scores have
13
14 244 been shown to correlate with journal impact factor,¹² it provides limited
15
16 245 information on the use of theory or clarity in the description of interventions.
17
18
19 246 Hence, to account for the use of conceptual theoretical frameworks in medical
20
21 247 education RCTs, we include a third quality measure, the MEdEx,
22
23 248
24
25 249 We hypothesise that this review may demonstrate differences between different
26
27
28 250 quality measures in RCTs reported in biomedical journals compared to those
29
30 251 published in journals dedicated to medical education. We expect that RCTs
31
32 252 reported in biomedical journals adhere more strictly to the CONSORT statement
33
34 253 and use outcome measures that relate to the upper Kirkpatrick levels than RCTs
35
36 254 reported in medical education journals. Finally, we hypothesise that RCTs
37
38 255 published in medical education journals use theory in the rationale for their
39
40 256 research question, methods, and in their interpretation of the results, whereas
41
42 257 this may be missing in research published in biomedical or clinical journals.
43
44
45 258 The review results will be submitted for publication in a peer-reviewed general
46
47 259 medical journal and will be disseminated through relevant international
48
49 260 conferences.
50
51
52 261 The results of this review will help clarify the state of quality of education
53
54 262 research by using common quality standards. The comparative analysis with
55
56 263 clinical epidemiology will provide feedback for the medical education
57
58
59
60

1
2
3 264 community and contribute to raising the quality of research and improve the
4
5 265 reporting of studies within this field.
6

7 266
8

9
10 267 *Funding statement:* This review has been supported by the Laerdal Foundation.
11

12 268

13
14 269 *Competing interest statement:* None disclosed.
15

16 270
17

18
19 271 *Contributors:* All authors contributed to the design of the review and all authors
20

21 272 contributed and approved the final manuscript.
22

23 273
24

25 274
26

27
28 275
29

30
31 276
32

33 277
34

35 278
36

37
38 279
39

40
41 280
42

43
44 281
45

46 282
47

48
49 283
50

51 284
52

53
54 285
55

56
57 286
58
59
60

287 References

288

289 1) Frenk J, Chen L, Bhutta ZA, Cohen J, Crisp N, Evans T, Fineberg H, Garcia P, Ke
290 Y, Kelley P, Kistnasamy B, Meleis A, Naylor D, Pablos-Mendez A, Reddy S,
291 Scrimshaw S, Sepulveda J, Serwadda D, Zurayk H. Health professionals for a new
292 century: transforming education to strengthen health systems in an
293 interdependent world. *Lancet*. 2010 Dec 4;376(9756):1923-58.

294

295 2) Cook DA, West CP. Conducting systematic reviews in medical education: a
296 stepwise approach. *Med Educ*. 2012 Oct;46(10):943-52. doi: 10.1111/j.1365-
297 2923.2012.04328.x.

298

299 3) Lee K, Whelan JS, Tannery NH, Kanter SL, Peters AS. 50 years of publication in
300 the field of medical education. *Med Teach*. 2013 Apr 22

301

302 4) Todres M, Stephenson A, Jones R. Medical education research remains the
303 poor relation. *BMJ* 2007;335:335-5.

304

305 5) Eva KW. *Med Educ*. Broadening the debate about quality in medical education
306 research. 2009 Apr;43(4):294-6. doi: 10.1111/j.1365-2923.2009.03342.x.

307

308 6) Stephenson A, Todres M, Jones R. Reply to Dornan et al.'s 'On evidence'. *Med*
309 *Educ*. 2009 Apr;43(4):390-1. doi: 10.1111/j.1365-2923.2009.03306.x.

310

1
2
3 311 7) Schulz KF, Altman DG, Moher D; CONSORT Group .CONSORT 2010 statement:
4
5 312 updated guidelines for reporting parallel group randomized trials. Ann Intern
6
7 313 Med. 2010 Jun 1;152(11):726-32. doi: 10.1059/0003-4819-152-11-201006010-
8
9 314 00232. Epub 2010 Mar 24.

11
12 315

13
14 316 8) Frambach JM, van der Vleuten CP, Durning SJ. AM last page. Quality criteria in
15
16 317 qualitative and quantitative research. Acad Med. 2013 Apr;88(4):552. doi:
17
18 318 10.1097/ACM.0b013e31828abf7f.

19
20
21 319

22
23 320 9) Prisma statement, available at www.prisma-statement.org. Accessed 5
24
25 321 January 2014.

26
27
28 322

29
30 323 10) Prady SL, Richmond SJ, Morton VM, et al. A Systematic evaluation of the
31
32 324 impact of STRICTA and CONSORT recommendations on quality of reporting for
33
34 325 acupuncture trials. PLoS One 2008;3:e1577.

35
36
37 326

38
39 327 11) Fuller T, Pearson M, Peters JL, Anderson R. Evaluating the impact and use of
40
41 328 Transparent Reporting of Evaluations with Non-randomised Designs (TREND)
42
43 329 reporting guidelines. BMJ Open. 2012 Dec 19;2(6). pii: e002073. doi:
44
45 330 10.1136/bmjopen-2012-002073. Print 2012.

46
47
48 331

49
50 332 12) Reed DA, Cook DA, Beckman TJ, Levine RB, Kern DE, Wright SM. Association
51
52 333 between funding and quality of published medical education research. JAMA.
53
54 334 2007 Sep 5;298(9):1002-9.

55
56
57 335
58
59
60

- 1
2
3 336 13) Hoffmann TC, Eructi C, Glasziou PP. Poor description of non-pharmacological
4
5 337 interventions: analysis of consecutive sample of randomised trials. BMJ. 2013
6
7 338 Sep 10;347:f3755. doi: 10.1136/bmj.f3755
8
9 339
10
11 340 14) Altman DG. Endorsement of the CONSORT statement by high impact medical
12
13 341 journals: survey of instructions for authors. BMJ. 2005 May 7;330(7499):1056-7.
14
15 342
16
17 343 15) Cook DA, Hatala R, Brydges R, Zendejas B, Szostek JH, Wang AT, Erwin PJ,
18
19 344 Hamstra SJ. Technology-enhanced simulation for health professions education: a
20
21 345 systematic review and meta-analysis. JAMA. 2011 Sep 7;306(9):978-88. doi:
22
23 346 10.1001/jama.2011.1234. Review.
24
25 347
26
27 348 16) Cook DA, Brydges R, Zendejas B, Hamstra SJ, Hatala R. Mastery learning for
28
29 349 health professionals using technology-enhanced simulation: a systematic review
30
31 350 and meta-analysis. Acad Med. 2013 Aug;88(8):1178-86. doi:
32
33 351 10.1097/ACM.0b013e31829a365d. Review.
34
35 352
36
37 353 17) Cook DA, Levinson AJ, Garside S. Method and reporting quality in health
38
39 354 professions education research: a systematic review. Med Educ. 2011
40
41 355 Mar;45(3):227-38. doi: 10.1111/j.1365-2923.2010.03890.x.
42
43 356
44
45 357
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60



PRISMA 2009 Checklist

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A – not subject for registration with PROSPERO as this is a methodological review.
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	6
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	8



PRISMA 2009 Checklist

Page 1 of 2

4	Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	8
7	Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	8
8	Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	N/A

Page 1 of 2

Section/topic	#	Checklist item	Reported on page #	
15	Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	8
18	Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS				
22	Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	N/A
24	Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	N/A
27	Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A
28	Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
31	Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
32	Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
34	Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION				
37	Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	N/A
40	Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	N/A
42	Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	N/A
FUNDING				



PRISMA 2009 Checklist

4	Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	10
---	---------	----	--------------------------------------------------------------------------------------------------------------------------------------------	----

8 *From:* Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097.
doi:10.1371/journal.pmed1000097

9 For more information, visit: www.prisma-statement.org.

11 Page 2 of 2

For peer review only

BMJ Open

Quality of randomised controlled trials in medical education reported between 2012 and 2013: A systematic review protocol.

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2014-005155.R1
Article Type:	Protocol
Date Submitted by the Author:	14-Jul-2014
Complete List of Authors:	Tolsgaard, Martin; Copenhagen University Hospital Rigshospitalet, Capital Region of Denmark, Centre for Clinical Education and the Juliane Marie Centre Ku, Cheryl; University of Toronto and University Health Network, The Wilson Centre Woods, Nicole; University of Toronto and University Health Network, Department of Surgery and The Wilson Centre Kulasegaram, Kulamakan; University of Toronto and University Health Network, Department of Family and Community Medicine and The Wilson Centre Brydges, Ryan; University of Toronto and University Health Network, Department of Medicine and The Wilson Centre Ringsted, Charlotte; University Health Network, The Wilson Centre
Primary Subject Heading:	Medical education and training
Secondary Subject Heading:	Medical publishing and peer review
Keywords:	EDUCATION & TRAINING (see Medical Education & Training), EPIDEMIOLOGY, Health informatics < BIOTECHNOLOGY & BIOINFORMATICS

SCHOLARONE™
Manuscripts

1
2
3
4
5 **1 Quality of randomised controlled trials in medical**
6 **2 education reported between 2012 and 2013: A**
7 **3 systematic review protocol.**
8
9
10
11
12

13 7 Martin G. Tolsgaard, MD, PhD¹, Cheryl Ku, MSci², Nicole N. Woods, PhD³,
14 8 Kulamakan Mahan Kulasegaram, PhD⁴, Ryan Brydges, PhD⁵, Charlotte Ringsted,
15 9 MD, PhD, MHPE⁷.

16
17
18 1 Centre for Clinical Education and the Juliane Marie Centre, Copenhagen
19 12 University Hospital Rigshospitalet, Denmark.

20
21 2 The Wilson Centre, University of Toronto and University Health Network,
22 15 Canada.

23
24 3 Department of Surgery and The Wilson Centre, University of Toronto and
25 18 University Health Network, Canada

26
27
28 4 Department of Family and Community Medicine and The Wilson Centre,
29 21 University of Toronto and University Health Network, Canada

30
31 5 Department of Medicine and The Wilson Centre, University of Toronto and
32 24 University Health Network, Canada

33
34 6 Surgical Divisions, Neuroscience, & Medical Education, Health Sciences Library,
35 27 University Health Network, Toronto General Hospital, Canada.

36
37
38 7 Department of Anesthesia and The Wilson Centre, University of Toronto and
39 30 University Health Network, Canada

40
41 32 Running head: Quality of randomised controlled trials in medical education.
42 33

43 34 Conflicts of interest: None of the authors report any conflicts of interest.
44 35

45
46 36 Corresponding author:

47 37 Martin G. Tolsgaard, MD, PhD

48 38 Postdoctoral research fellow, Centre for Clinical Education and the Juliane Marie
49 39 Center, Copenhagen University Hospital Rigshospitalet

50 40 9 Blegdamsvej, 2100 Copenhagen-O

51 41 Denmark

52 42 Tel: +456103072

53 43 martintolsgaard@gmail.com
54 44

55
56
57 46 Word count: XXX

58 47 Keywords: Randomised controlled trials, medical education
59
60

Abstract

Introduction: Research in medical education has increased in volume over the last decades but concerns have been raised regarding the quality of trials conducted within this field. Randomised controlled trials (RCTs) involving educational interventions that are reported in biomedical journals have been criticised for insufficient conceptual, theoretical framework. RCTs published in journals dedicated to medical education, on the other hand, have been questioned regarding their methodological rigor.

The aim of this study is therefore to assess the quality of RCTs of educational interventions reported in 2012 and 2013 in journals dedicated to medical education compared to biomedical journals with respect to objective quality criteria.

Methods and analysis: RCTs published between 1 January 2012 and 31 December 2013 in English are included. The search strategy is developed by the help of experienced librarians to search online databases for key terms. All of the identified RCTs are screened based on their titles and abstracts individually by the authors and then compared in pairs to assess agreement. Data is extracted from the included RCTs by independently scoring each RCT using a data collection form. The data collection form consists of four steps. Step 1 includes confirmation of RCT eligibility; Step 2 consists of the CONSORT checklist; Step 3 consists of the MERSQI framework; Step 4 consists of a Medical Education Extension (MEdEx) to the CONSORT checklist. The MEdEx includes the following elements: Description of scientific background, explanation of rationale, quality of research questions and hypotheses, clarity in the description of the use of the intervention and control as well as interpretation of results.

Ethics and Dissemination: This review is the first to systematically examine the quality of RCTs conducted in medical education. We plan to disseminate the results through publications and presentation at relevant conferences. Ethical approval is not sought for this review.

Article summary

Strengths and Limitations of this study

Strengths:

- The first systematic review of the quality of randomised controlled trials in medical education.
- The use of duplicate, independent, and reproducible data coding of quality measures pertaining to research methodology and reporting.

Limitations:

- To provide a current state of evidence on trial quality, only studies reported from 2012 to 2013 are included in this review.
- Only articles in English are included in this systematic review.

93 Introduction

94 Medical education as a field has grown during the past twenty years. It has
95 become a billion dollar industry accounting for about US\$100 billion per year
96 worldwide¹ and increasing awareness of linking education to patient outcomes
97 has brought focus on evidence-based medical education.² The growing interest is
98 reflected in the rise in number of publications within this area over the past
99 several decades.³ However, this is not unproblematic, as several scholars have
100 warned that the medical education research lacks methodological rigor.³ In a
101 study of randomised controlled trials (RCTs) published between 2000 and 2003,
102 a large proportion fell short of the criteria developed by the International
103 Committee of Medical Journal Editors for reporting RCTs.⁴ Meanwhile, some
104 argue that judging the quality of research being performed in medical education
105 by any 'objective' checklist is insufficient.⁵ Instead, quality of medical education
106 research should be based on the advancement of our theoretical understanding,
107 rather than on how well a particular research methodology has been adopted.⁵
108 Other viewpoints state that whatever method is used should comply with the
109 highest standards of practice for that design.⁶ Thus, two discourses of evaluating
110 quality have been promoted. One is assessing quality against 'gold-standards'
111 such as the checklists and guidelines, and another is judging the advancement of
112 theory.

113 In clinical epidemiological research, RCTs take on a central role when evaluating
114 health care interventions. Since 2000, the CONSORT group has provided
115 guidelines to improve the transparency and rigor when reporting randomised
116 trials within biomedicine.⁷ Although the CONSORT statement does not include

1
2
3 117 recommendations for designing, conducting, and analysing trials, it indirectly
4
5 118 affects design and conduct as transparent reporting may expose deficiencies in
6
7 119 research if they exist⁷ Furthermore, CONSORT is informed by methodological
8
9
10 120 theorists and practitioners in clinical epidemiology as well as biostatistics.
11
12 121 Assessing quality of RCTs in medical education using the CONSORT statement
13
14 122 may, however, not capture advancement of theory. Insufficient use of a
15
16 123 conceptual theoretical framework may lead to failure to identify the active
17
18 124 component of training interventions. Furthermore, poor description of context of
19
20 125 the study as well as trainee characteristics limit the external validity in terms of
21
22 126 generalizability to other settings and populations. Reporting should therefore
23
24 127 also relate the study to a relevant theoretical context to justify how it uses and
25
26 128 advances existing theory⁵ including thorough descriptions of context,
27
28 129 educational intervention and control circumstances, and trainee characteristics.⁸
29
30
31 130 However, these aspects are not assessed using the CONSORT statement and
32
33 131 other measures to evaluate study quality within medical education research may
34
35 132 be warranted. To further evolve our understanding of quality of RCTs conducted
36
37 133 in medical education, we aim to explore the adherence to standardised quality
38
39 134 criteria as well as the use of theory in recent literature. The research question of
40
41 135 this review is:
42
43
44
45
46 136

47
48 137 In randomised controlled trials in medical education reported between 2012 and
49
50 138 2013, what characterises the quality of papers published in journals dedicated to
51
52 139 medical education compared to papers published in biomedical journals with
53
54 140 respect to objective quality criteria?
55
56
57
58 141

142 Methods

143 This systematic review is designed according to the seven-step approach
144 recommended for conducting systematic reviews in medical education² and
145 reported according to the PRISMA statement.⁹

147 Study eligibility

148 Broad inclusion criteria are used to obtain a broad range of randomised trials in
149 medical education. Studies published between 1 January 2012 and 31 December
150 2013 in English are included. This period is chosen as new guidelines for
151 reporting randomised trials were published in June 2010 and previous studies
152 argued that the evaluation of reporting guidelines should first be evaluated 18-
153 24 months following publication.¹⁰⁻¹¹ All research papers in medical education
154 using randomised designs are included. Medical education research is defined as
155 “any original research study pertaining to medical students, residents, fellows,
156 faculty development, or continuing medical education for physicians.”¹² Using
157 this definition, studies on veterinary-, nursing-, pharmacist-, physiotherapist-
158 and dentistry education research are not eligible. Parallel group studies, cross-
159 over studies, non-inferiority and equivalence studies are all included whereas
160 pseudo-randomised studies are not.

162 Search

163 The search strategy is developed by the help of experienced librarians to search
164 MEDLINE, EMBASE, CINAHL, PsychINFO, ERIC, Web of Science, and Scopus for
165 key terms. These terms include truncated search on random* and MeSH terms

1
2
3 166 relating to medical education (e.g. "Education, Professional"). Related domains
4
5 167 are also included in the search to account for research not categorised under
6
7 168 medical education (e.g. health professions education, simulation, undergraduate
8
9 169 medical education, technology-enhanced education, clinical reasoning, skills
10
11 170 assessment, education professional, student health occupation, internship and
12
13 171 residency, curriculum planning, instructional method, self-directed learning etc.).
14
15 172 The search is supplemented by adding the reference-lists of recent reviews in
16
17 173 simulation-based medical education and with authors' records of studies
18
19 174 published in the period of interest. The authors' records are used to refine the
20
21 175 search strategy in an iterative way so that as many relevant randomised studies
22
23 176 as possible are included in the online search.
24
25
26
27
28
29

30 31 178 **Study selection**

32
33 179 All of the identified studies are screened based on their titles and abstracts
34
35 180 individually and compared in pairs to assess agreement so that all studies have
36
37 181 been screened by two authors. Potential disagreement is solved by discussion
38
39 182 until consensus is reached. If the title or abstract is insufficient for determining
40
41 183 eligibility, the full text is reviewed. If consensus cannot be reached by two of the
42
43 184 co-authors, the whole author team will decide whether to include the paper or
44
45 185 not. The agreement between the raters is determined using intra-class
46
47 186 correlation coefficients (ICCs).
48
49
50

51 187
52
53
54
55
56
57
58
59
60

1
2
3 188 **Data collection process**
4

5 189 Data is extracted from included studies by duplicate and independent scoring of
6
7 190 each study using a data collection form. The data collection form consists of four
8
9
10 191 steps. Step 1 includes confirmation of study eligibility; Step 2 consists of the
11
12 192 CONSORT checklist; Step 3 consists of the Medical Education Research Study
13
14 193 Quality Instrument (MERSQI) framework; Step 4 consists of a Medical Education
15
16 194 Extension to the CONSORT statement developed by the review group.
17
18

19 195

20
21 196 *Step 1.* The first step includes confirmation of study eligibility, extraction of
22
23 197 Study ID (created by review author) as well as name and focus of journal
24
25 198 (medical education/biomedical).
26

27
28 199 *Step 2.* The dichotomous CONSORT checklist is completed by ticking off each
29
30 200 item when either present (=1), absent (=0), or not applicable (N/A). The
31
32 201 CONSORT statement recommends that researchers provide a scientific
33
34 202 background for the study as well as present specific objectives and hypothesis,
35
36 203 thoroughly describe the intervention and control conditions, randomisation
37
38 204 procedure, data analysis and interpretation of results.
39

40
41 205 *Step 3.* The Jadad Scale for reporting randomised trials¹³ is used to assess the
42
43 206 methodological rigor of the included studies. The Jadad scale consists of three
44
45 207 items pertaining to randomisation procedure, blinding, and participant
46
47 208 withdrawal or dropouts.
48

49
50 209 *Step 4.* The Medical Education Research Study Quality Instrument (MERSQI)¹² is
51
52 210 used to provide an established measure of study quality and scores are
53
54 211 compared in pairs and discussed until consensus. Evidence of validity of the
55
56 212 MERSQI framework has been established in a previous study.¹² The MERSQI
57
58
59
60

1
2
3 213 framework provides a measure of trial size (single- or multiple institutions),
4
5 214 validity of assessment instruments used, and the Kirkpatrick level of outcome
6
7 215 measures used (a taxonomy for classifying training programmes). Hence, studies
8
9 216 of a certain size and focusing on patient outcomes would receive higher scores
10
11 217 than single-institution studies that assess the impact of interventions on health
12
13 218 care professionals' knowledge or behaviour in a simulated setting.

14
15
16 219 *Step 5.* The Medical Education Extension (MEdEx) is developed by the study
17
18 220 group through a literature review of relevant quality research in medical
19
20 221 education. To further advance our understanding of the use of theory in the
21
22 222 scientific background of the RCTs, the reporting of specific hypotheses, clarity of
23
24 223 description of interventions¹⁴ and controls, and the use of theory in the
25
26 224 interpretation of the observed results, we chose to include these factors in a
27
28 225 medical education extension (MEdEx) to the CONSORT checklist. In step 4, the
29
30 226 following items are therefore included: 1) Scientific background,⁵ 2) Explanation
31
32 227 of rationale,⁵ 3) Objectives or research question,^{4, 6} 4) Hypotheses,^{4, 6} 5)
33
34 228 Description of the intervention and control circumstances,^{6, 8, 14} 6)
35
36 229 Interpretation^{4, 5, 12} of results (see Appendix).

37
38
39
40
41 230

42 43 44 231 **Statistical analysis**

45
46 232 Inter-rater reliability is calculated using Intra-Class Correlation Coefficients. In
47
48 233 the event of disagreement, the assessments will be solved by consensus.
49
50 234 Descriptive statistics for each of the three different quality measures will be
51
52 235 performed. Logistic regression will be performed using journal type as
53
54 236 dependent and CONSORT-scores, MERSQI-scores, and MEdEx-scores as

1
2
3 237 predictor variables. Multiple regression using the same predictor variables and
4
5 238 journal impact factor will also be performed to assess the relation between
6
7 239 quality measures and journal impact factor.
8

9
10 240

11 241 Discussion and dissemination

12
13
14
15 242 In parallel with the rise in publications in medical education over the last
16
17 243 decades, increasing interest is being paid to systematically evaluate the quality of
18
19 244 research conducted within this field. We chose to include three different quality
20
21 245 measures in the data collection form for this systematic review. To evaluate the
22
23 246 quality of reporting, the CONSORT checklist is included as a measure of the
24
25 247 degree to which current medical education research adhere to the guidelines
26
27 248 endorsed by the *World Association of Medical Editors*, the *International*
28
29 249 *Committee of Medical Journal Editors (ICMJE)*, and the *Council of Science Editors*.¹⁵
30
31

32
33 250 The second quality measure includes the MERSQI framework, which has been
34
35 251 used extensively in several recent reviews.¹⁶⁻¹⁸ Although MERSQI-scores have
36
37 252 been shown to correlate with journal impact factor,¹² it provides limited
38
39 253 information on the use of theory or clarity in the description of interventions.
40
41 254 Hence, to account for the use of conceptual theoretical frameworks in medical
42
43 255 education RCTs, we plan to include a third quality measure in terms of the
44
45 256 MEdEx framework.
46
47

48
49 257

50
51 258 We hypothesise that this review may demonstrate differences between different
52
53 259 quality measures in RCTs reported in biomedical journals compared to those
54
55 260 published in journals dedicated to medical education. We expect that RCTs
56
57
58
59
60

1
2
3 261 reported in biomedical journals adhere more strictly to the CONSORT statement
4
5 262 and use outcome measures that relate to the upper Kirkpatrick levels than RCTs
6
7 263 reported in medical education journals. Finally, we hypothesise that RCTs
8
9 264 published in medical education journals use theory in the rationale for their
10
11 265 research question, methods, and in their interpretation of the results, whereas
12
13 266 this may be missing in research published in biomedical or clinical journals.
14
15

16 267 The review results will be submitted for publication in a peer-reviewed general
17
18 268 medical journal and will be disseminated through relevant international
19
20 269 conferences.
21
22

23 270 The results of this review will help clarify the state of quality of education
24
25 271 research by using common quality standards. The comparative analysis with
26
27 272 clinical epidemiology will provide feedback for medical education researchers
28
29 273 and contribute to raising the quality of research and improve the reporting of
30
31 274 studies within this field.
32
33

34 275

35 276

36 277

37 278

38 279

39 280

40 281

41 282

42 283

43 284

44 285

1
2
3 286
4

5 287 **Funding statement:** This review has been supported by the Laerdal Foundation.
6
7

8 288
9

10 289 **Competing interest statement:** None disclosed.
11
12

13 290

14 291 **Contribution statement:** All authors contributed to the design of the review and
15
16

17 292 all authors contributed and approved the final manuscript. Everyone listed as an
18

19 293 author fulfils all three of the ICMJE guidelines for authorship. MGT and CR were
20

21 294 responsible for conception of the review. CK, KMK, RB, NW, MGT, and CR were
22

23 295 responsible for designing the review and the MEdEx. MGT drafted the first
24

25 296 version of the protocol and CK, RB, NW, KMK, and CR were critically revised the
26

27 297 paper.
28
29

30 298
31

32 299
33
34

35 300
36
37

38 301
39

40 302
41
42

43 303
44
45

46 304
47
48

49 305
50

51 306
52
53

54 307
55

56 308
57
58
59
60

309 References

- 1
2
3
4
5
6 310 1) Frenk J, Chen L, Bhutta ZA, et al. Health professionals for a new century:
7
8 311 transforming education to strengthen health systems in an interdependent
9
10 312 world. *Lancet*. 2010 Dec 4;376(9756):1923-58.
- 11 313 2) Cook DA, West CP. Conducting systematic reviews in medical education: a
12
13 314 stepwise approach. *Med Educ*. 2012 Oct;46(10):943-52. doi: 10.1111/j.1365-
14
15 315 2923.2012.04328.x.
- 16 316 3) Lee K, Whelan JS, Tannery NH, et al. 50 years of publication in the field of
17
18 317 medical education. *Med Teach*. 2013 Apr 22
- 19 318 4) Todres M, Stephenson A, Jones R. Medical education research remains the
20
21 319 poor relation. *BMJ* 2007;335:335-5.
- 22 320 5) Eva KW. *Med Educ*. Broadening the debate about quality in medical education
23
24 321 research. 2009 Apr;43(4):294-6. doi: 10.1111/j.1365-2923.2009.03342.x.
- 25 322 6) Stephenson A, Todres M, Jones R. Reply to Dornan et al.'s 'On evidence'. *Med*
26
27 323 *Educ*. 2009 Apr;43(4):390-1. doi: 10.1111/j.1365-2923.2009.03306.x.
- 28 324 7) Schulz KF, Altman DG, Moher D; CONSORT Group .CONSORT 2010 statement:
29
30 325 updated guidelines for reporting parallel group randomized trials. *Ann Intern*
31
32 326 *Med*. 2010 Jun 1;152(11):726-32. doi: 10.1059/0003-4819-152-11-201006010-
33
34 327 00232. Epub 2010 Mar 24.
- 35 328 8) Frambach JM, van der Vleuten CP, et al. AM last page. Quality criteria in
36
37 329 qualitative and quantitative research. *Acad Med*. 2013 Apr;88(4):552. doi:
38
39 330 10.1097/ACM.0b013e31828abf7f.
- 40 331
- 41 332 9) Prisma statement, available at www.prisma-statement.org. Accessed 5
42
43 333 January 2014.
- 44 334 10) Prady SL, Richmond SJ, Morton VM, et al. A Systematic evaluation of the
45
46 335 impact of STRICTA and CONSORT recommendations on quality of reporting for
47
48 336 acupuncture trials. *PLoS One* 2008;3:e1577.
- 49 337 11) Fuller T, Pearson M, Peters JL, et al. Evaluating the impact and use of
50
51 338 Transparent Reporting of Evaluations with Non-randomised Designs (TREND)
52
53 339 reporting guidelines. *BMJ Open*. 2012 Dec 19;2(6). pii: e002073. doi:
54
55 340 10.1136/bmjopen-2012-002073. Print 2012.
- 56
57
58
59
60

- 1
2
3 341 12) Reed DA, Cook DA, Beckman TJ, et al. SM. Association between funding and
4 342 quality of published medical education research. JAMA. 2007 Sep 5;298(9):1002-
5 343 9.
6
7 344
8
9 345 13) Jadad AR1, Moore RA, Carroll D, et al. Assessing the quality of reports of
10 346 randomized clinical trials: is blinding necessary? Control Clin Trials.
11 347 1996;17(1):1-12.
12
13 348
14
15 349 14) Hoffmann TC, Eructi C, Glasziou PP. Poor description of non-pharmacological
16 350 interventions: analysis of consecutive sample of randomised trials. BMJ. 2013
17 351 Sep 10;347:f3755. doi: 10.1136/bmj.f3755
18 352
19
20 353 15) Altman DG. Endorsement of the CONSORT statement by high impact medical
21 354 journals: survey of instructions for authors. BMJ. 2005 May 7;330(7499):1056-7.
22 355
23
24 356 16) Cook DA, Hatala R, Brydges R, et al. Technology-enhanced simulation for
25 357 health professions education: a systematic review and meta-analysis. JAMA.
26 358 2011 Sep 7;306(9):978-88. doi: 10.1001/jama.2011.1234.
27 359
28
29 360 17) Cook DA, Brydges R, Zendejas B, et al. Mastery learning for health
30 361 professionals using technology-enhanced simulation: a systematic review and
31 362 meta-analysis. Acad Med. 2013 Aug;88(8):1178-86. doi:
32 363 10.1097/ACM.0b013e31829a365d.
33 364
34
35 365 18) Cook DA, Levinson AJ, Garside S. Method and reporting quality in health
36 366 professions education research: a systematic review. Med Educ. 2011
37 367 Mar;45(3):227-38. doi: 10.1111/j.1365-2923.2010.03890.
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8 1 **Quality of randomised controlled trials in medical**
9 2 **education reported between 2012 and 2013: A**
10 3 **systematic review protocol.**
11 4
12 5
13 6

14 7 Martin G. Tolsgaard, MD, PhD¹, Cheryl Ku, MSci², Nicole N. Woods, PhD³,
15 8 Kulamakan Mahan Kulasegaram, PhD⁴, Ryan Brydges, PhD⁵, Charlotte Ringsted,
16 9 MD, PhD, MHPE⁷.

17 10
18 11 ¹ Centre for Clinical Education and the Juliane Marie Centre, Copenhagen
19 12 University Hospital Rigshospitalet, Denmark.

20 13
21 14 ² The Wilson Centre, University of Toronto and University Health Network,
22 15 Canada.

23 16
24 17 ³ Department of Surgery and The Wilson Centre, University of Toronto and
25 18 University Health Network, Canada

26 19
27 20 ⁴ Department of Family and Community Medicine and The Wilson Centre,
28 21 University of Toronto and University Health Network, Canada

29 22
30 23 ⁵ Department of Medicine and The Wilson Centre, University of Toronto and
31 24 University Health Network, Canada

32 25
33 26 ⁶ Surgical Divisions, Neuroscience, & Medical Education, Health Sciences Library,
34 27 University Health Network, Toronto General Hospital, Canada.

35 28
36 29 ⁷ Department of Anesthesia and The Wilson Centre, University of Toronto and
37 30 University Health Network, Canada

38 31
39 32 Running head: Quality of randomised controlled trials in medical education.

40 33
41 34 | Conflicts of interest: None of the authors report any conflicts of interest.

42 35
43 36 Corresponding author:

44 37 Martin G. Tolsgaard, MD, PhD

45 38 Postdoctoral research fellow, Centre for Clinical Education and the Juliane Marie
46 39 Center, Copenhagen University Hospital Rigshospitalet

47 40 9 Blegdamsvej, 2100 Copenhagen-O

48 41 Denmark

49 42 Tel: +456103072

50 43 martintolsgaard@gmail.com

51 44
52 45
53 46 Word count: XXX

54 47 Keywords: Randomised controlled trials, medical education

Abstract

Introduction: Research in medical education has increased in volume over the last decades but concerns have been raised regarding the quality of trials conducted within this field. Randomised controlled trials (RCTs) involving educational interventions that are reported in biomedical journals have been criticised for insufficient conceptual, theoretical framework. RCTs published in journals dedicated to medical education, on the other hand, have been questioned regarding their methodological rigor.

The aim of this study is therefore to assess the quality of RCTs of educational interventions reported in 2012 and 2013 in journals dedicated to medical education compared to biomedical journals with respect to objective quality criteria.

Methods and analysis: RCTs published between 1 January 2012 and 31 December 2013 in English are included. The search strategy is developed by the help of experienced librarians to search online databases for key terms. All of the identified RCTs are screened based on their titles and abstracts individually by the authors and then compared in pairs to assess agreement. Data is extracted from the included RCTs by independently scoring each RCT using a data collection form. The data collection form consists of four steps. Step 1 includes confirmation of RCT eligibility; Step 2 consists of the CONSORT checklist; Step 3 consists of the MERSQI framework; Step 4 consists of a Medical Education Extension (MEdEx) to the CONSORT checklist. The MEdEx includes the following elements: Description of scientific background, explanation of rationale, quality of research questions and hypotheses, clarity in the description of the use of the intervention and control as well as interpretation of results.

Ethics and Dissemination: This review is the first to systematically examine the quality of RCTs conducted in medical education. We plan to disseminate the results through publications and presentation at relevant conferences. Ethical approval is not sought for this review.

Article summary

Strengths and Limitations of this study

Strengths:

- The first systematic review of the quality of randomised controlled trials in medical education.
- The use of duplicate, independent, and reproducible data coding of quality measures pertaining to research methodology and reporting.

Limitations:

- To provide a current state of evidence on trial quality, only studies reported from 2012 to 2013 are included in this review.
- Only articles in English are included in this systematic review.

93 Introduction

94 Medical education as a field has grown during the past twenty years. It has
95 become a billion dollar industry accounting for about US\$100 billion per year
96 worldwide¹ and increasing awareness of linking education to patient outcomes
97 has brought focus on evidence-based medical education.² The growing interest is
98 reflected in the rise in number of publications within this area over the past
99 several decades.³ However, this is not unproblematic, as several scholars have
100 warned that the medical education research lacks methodological rigor.³ In a
101 study of randomised controlled trials (RCTs) published between 2000 and 2003,
102 a large proportion fell short of the criteria developed by the International
103 Committee of Medical Journal Editors for reporting RCTs.⁴ Meanwhile, some
104 argue that judging the quality of research being performed in medical education
105 by any 'objective' checklist is insufficient.⁵ Instead, quality of medical education
106 research should be based on ~~how well the~~ the advancement of our theoretical
107 ~~understanding of a problem becomes~~, rather than on how well a particular
108 research methodology has been adopted.⁵ Other viewpoints state that whatever
109 method is used should comply with the highest standards of practice for that
110 design.⁶ Thus, two discourses of evaluating quality have been promoted. One is
111 assessing quality against 'gold-standards' such as the checklists and guidelines,
112 and another is judging the advancement of theory.

113 In clinical epidemiological research, RCTs take on a central role when evaluating
114 health care interventions. Since 2000, the CONSORT group has provided
115 guidelines to improve the transparency and rigor when reporting randomised
116 trials within biomedicine.⁷ Although the CONSORT statement does not include

Formatted: Superscript

1
2
3
4
5
6 117 recommendations for designing, conducting, and analysing trials, it indirectly
7
8 118 affects design and conduct as transparent reporting may expose deficiencies in
9
10 119 research if they exist⁷ Furthermore, CONSORT is informed by methodological
11
12 120 theorists and practitioners in clinical epidemiology as well as biostatistics.
13
14 121 Assessing quality of RCTs in medical education using the CONSORT statement
15
16 122 may, however, not capture advancement of theory. Insufficient use of a
17
18 123 conceptual theoretical framework may lead to failure to identify the active
19
20 124 component of training interventions. ~~Furthermore, and~~ poor description of
21
22 125 context of the study as well as trainee characteristics limit the external validity in
23
24 126 terms of generalizability to other settings and populations. Reporting should
25
26 127 therefore also relate the study to a relevant theoretical context to justify how it
27
28 128 uses and advances existing theory⁵ including thorough descriptions of context,
29
30 129 educational intervention and control circumstances, and trainee characteristics.⁸
31
32 130 However, these aspects are not assessed using the CONSORT statement and
33
34 131 other measures to evaluate study quality within medical education research may
35
36 132 be warranted. To further evolve our understanding of quality of RCTs conducted
37
38 133 in medical education, we aim to explore the adherence to standardised quality
39
40 134 criteria as well as the use of theory in recent literature. The research question of
41
42 135 this review is:
43
44 136
45
46 137 In randomised controlled trials in medical education reported between 2012 and
47
48 138 2013, what characterises the quality of papers published in journals dedicated to
49
50 139 medical education compared to papers published in biomedical journals with
51
52 140 respect to objective quality criteria?
53
54 141
55
56
57
58
59
60

142 Methods

143 This systematic review is designed according to the seven-step approach
144 recommended for conducting systematic reviews in medical education² and
145 reported according to the PRISMA statement.⁹

147 Study eligibility

148 Broad inclusion criteria are used to obtain a broad range of randomised trials in
149 medical education. Studies published between 1 January 2012 and 31 December
150 2013 in English are included. This period is chosen as new guidelines for
151 reporting randomised trials were published in June 2010 and previous studies
152 argued that the evaluation of reporting guidelines should first be evaluated 18-
153 24 months following publication.¹⁰⁻¹¹ All research papers in medical education
154 using randomised designs are included. Medical education research is defined as
155 “any original research study pertaining to medical students, residents, fellows,
156 faculty development, or continuing medical education for physicians.”¹² Using
157 this definition, studies on veterinary-, nursing-, pharmacist-, physiotherapist-
158 and dentistry education research are not eligible. Parallel group studies, cross-
159 over studies, non-inferiority and equivalence studies are all included whereas
160 pseudo-randomised studies are not.

162 Search

163 The search strategy is developed by the help of experienced librarians to search
164 MEDLINE, EMBASE, CINAHL, PsychINFO, ERIC, Web of Science, and Scopus for
165 key terms. These terms include truncated search on random* and MeSH terms

1
2
3
4
5
6 166 relating to medical education (e.g. "Education, Professional"). Related domains
7
8 167 are also included in the search to account for research not categorised under
9
10 168 medical education (e.g. health professions education, simulation, undergraduate
11
12 169 medical education, technology-enhanced education, clinical reasoning, skills
13
14 170 assessment, education professional, student health occupation, internship and
15
16 171 residency, curriculum planning, instructional method, self-directed learning etc.).
17
18 172 The search is supplemented by adding the reference-lists of recent reviews in
19
20 173 simulation-based medical education and with authors' records of studies
21
22 174 published in the period of interest. The authors' records are used to refine the
23
24 175 search strategy in an iterative way so that as many relevant randomised studies
25
26 176 as possible are included in the online search.
27

28 177

31 178 **Study selection**

32
33 179 All of the identified studies are screened based on their titles and abstracts
34
35 180 individually and compared in pairs to assess agreement so that all studies have
36
37 181 been screened by two authors. Potential disagreement is solved by discussion
38
39 182 until consensus is reached. If the title or abstract is insufficient for determining
40
41 183 eligibility, the full text is reviewed. If consensus cannot be reached by two of the
42
43 184 co-authors, the whole author team will decide whether to include the paper or
44
45 185 not. The agreement between the raters is determined using intra-class
46
47 186 correlation coefficients (ICCs).
48

49 187

1
2
3
4
5
6 188 **Data collection process**
7

8 189 Data is extracted from included studies by duplicate and independent scoring of
9
10 190 each study using a data collection form. The data collection form consists of four
11
12 191 steps. Step 1 includes confirmation of study eligibility; Step 2 consists of the
13
14 192 CONSORT checklist; Step 3 consists of the Medical Education Research Study
15
16 193 Quality Instrument (MERSQI) framework; Step 4 consists of a Medical Education
17
18 194 Extension to the CONSORT statement developed by the review group.
19

20 195

21
22 196 *Step 1.* The first step includes confirmation of study eligibility, extraction of
23
24 197 Study ID (created by review author) as well as name and focus of journal
25
26 198 (medical education/biomedical).
27

28 199 *Step 2.* The dichotomous CONSORT checklist is completed by ticking off each
29
30 200 item when either present (=1), absent (=0), or not applicable (N/A). The
31
32 201 CONSORT statement recommends that researchers provide a scientific
33
34 202 background for the study as well as present specific objectives and hypothesis,
35
36 203 thoroughly describe the intervention and control conditions, randomisation
37
38 204 procedure, data analysis and interpretation of results.

39
40 205 Step 3. The Jadad Scale for reporting randomised trials¹³ is used to assess the
41
42 206 methodological rigor of the included studies. The Jadad scale consists of three
43
44 207 items pertaining to randomisation procedure, blinding, and participant
45
46 208 withdrawal or dropouts.
47

48 209 *Step 4.* The Medical Education Research Study Quality Instrument (MERSQI)¹² is
49
50 210 used to provide an established measure of study quality and scores are
51
52 211 compared in pairs and discussed until consensus. Evidence of validity of the
53
54 212 MERSQI framework has been established in a previous study.¹² The MERSQI
55
56
57
58
59
60

Formatted: Superscript

213 framework provides a measure of trial size (single- or multiple institutions),
 214 validity of assessment instruments used, and the Kirkpatrick level of outcome
 215 measures used (a taxonomy for classifying training programmes). Hence, studies
 216 of a certain size and focusing on patient outcomes would receive higher scores
 217 than single-institution studies that assess the impact of interventions on health
 218 care professionals' knowledge or behaviour in a simulated setting.

219 *Step 54.* The Medical Education Extension (MEdEx) is developed by the study
 220 group through a literature review of relevant quality research in medical
 221 education. To further advance our understanding of the use of theory in the
 222 scientific background of the RCTs, the reporting of specific hypotheses, clarity of
 223 description of interventions¹⁴³ and controls, and the use of theory in the
 224 interpretation of the observed results, we chose to include these factors in a
 225 medical education extension (MEdEx) to the CONSORT checklist. In step 4, the
 226 following items are therefore included: 1) Scientific background,⁵ 2) Explanation
 227 of rationale,⁵ 3) Objectives or research question,^{4, 6} 4) Hypotheses,^{4, 6} 5)
 228 Description of the intervention and control circumstances,^{6, 8, 14} 6)
 229 Interpretation^{4, 5, 12} of results (see Appendix).

230

231 **Statistical analysis**

232 Inter-rater reliability is calculated using Intra-Class Correlation Coefficients. In
 233 the event of disagreement, the assessments will be solved by consensus.

234 Descriptive statistics for each of the three different quality measures will be
 235 performed. Logistic regression will be performed using journal type as
 236 dependent and The CONSORT-scores, MERSQI-scores, and and-MEdEx-scores as

Formatted: Superscript

Formatted: Superscript

Formatted: Superscript

Formatted: Superscript

Formatted: Superscript

Formatted: Superscript

Formatted: Superscript

1
2
3
4
5
6 237 ~~predictor variables.- Multiple regression using the same predictor variables and~~
7
8 238 ~~journal impact factor will also be performed to assess the relation between~~
9
10 239 ~~quality measures and journal impact factor. are correlated to each other, to~~
11
12 240 ~~journal impact factor, and compared across papers published in journals~~
13
14 241 ~~dedicated to medical education and biomedical journals using parametric~~
15
16 242 ~~statistics if the conditions are met.~~
17
18 243

20 244 Discussion and dissemination

21
22
23 245 In parallel with the rise in publications in medical education over the last
24
25 246 decades, increasing interest is being paid to systematically evaluate the quality of
26
27 247 research conducted within this field. We chose to include three different quality
28
29 248 measures in the data collection form for this systematic review. To evaluate the
30
31 249 quality of reporting, the CONSORT checklist is included as a measure of the
32
33 250 degree to which current medical education research adhere to the guidelines
34
35 251 endorsed by the *World Association of Medical Editors, the International*
36
37 252 *Committee of Medical Journal Editors (ICMJE), and the Council of Science*
38
39 253 *Editors.*¹⁵⁴ The second quality measure includes the MERSQI framework, which
40
41 254 has been used extensively in several recent reviews.¹⁶⁵⁻¹⁸⁷ Although MERSQI-
42
43 255 scores have been shown to correlate with journal impact factor,¹² it provides
44
45 256 limited information on the use of theory or clarity in the description of
46
47 257 interventions. Hence, to account for the use of conceptual theoretical
48
49 258 frameworks in medical education RCTs, we plan to include a third quality
50
51 259 measure in terms of the MEdEx framework.
52
53 260

1
2
3
4
5
6 261 We hypothesise that this review may demonstrate differences between different
7
8 262 quality measures in RCTs reported in biomedical journals compared to those
9
10 263 published in journals dedicated to medical education. We expect that RCTs
11
12 264 reported in biomedical journals adhere more strictly to the CONSORT statement
13
14 265 and use outcome measures that relate to the upper Kirkpatrick levels than RCTs
15
16 266 reported in medical education journals. Finally, we hypothesise that RCTs
17
18 267 published in medical education journals use theory in the rationale for their
19
20 268 research question, methods, and in their interpretation of the results, whereas
21
22 269 this may be missing in research published in biomedical or clinical journals.

23
24 270 The review results will be submitted for publication in a peer-reviewed general
25
26 271 medical journal and will be disseminated through relevant international
27
28 272 conferences.

29
30 273 The results of this review will help clarify the state of quality of education
31
32 274 research by using common quality standards. The comparative analysis with
33
34 275 clinical epidemiology will provide feedback for ~~the medical education~~
35
36 276 ~~community~~ medical education researchers and contribute to raising the quality of
37
38 277 research and improve the reporting of studies within this field.

39
40
41 278

42 279 *Funding statement:* This review has been supported by the Laerdal Foundation.

43
44 280

45
46 281 *Competing interest statement:* None disclosed.

47
48 282

49
50 283 *Contribution statement:* All authors contributed to the design of the review and
51
52 284 all authors contributed and approved the final manuscript. Everyone listed as an
53
54 285 author fulfils all three of the ICMJE guidelines for authorship. MGT and CR were

1
2
3
4
5
6 286 responsible for conception of the review. CK, KMK, RB, NW, MGT, and CR were
7
8 287 responsible for designing the review and the MEdEx. MGT drafted the first
9
10 288 version of the protocol and CK, RB, NW, KMK, and CR were critically revised the
11
12 289 paper.

13
14 290 ~~Contributors: All authors contributed to the design of the review and all authors~~
15
16 291 ~~contributed and approved the final manuscript.~~
17
18 292
19
20 293
21
22 294
23
24 295
25
26 296
27
28 297
29
30 298
31
32 299

33 34 299 References

35
36 300
37
38
39 301 1) Frenk J, Chen L, Bhutta ZA, Cohen J, Crisp N, Evans T, Fineberg H, Garcia P, Ke
40
41 302 Y, Kelley P, Kistnasamy B, Meleis A, Naylor D, Pablos-Mendez A, Reddy S,
42
43 303 Scrimshaw S, Sepulveda J, Serwadda D, Zurayk H. Health professionals for a new
44
45 304 century: transforming education to strengthen health systems in an
46
47 305 interdependent world.Lancet. 2010 Dec 4;376(9756):1923-58.
48
49 306

- 1
2
3
4
5
6 307 2) Cook DA, West CP. Conducting systematic reviews in medical education: a
7
8 308 stepwise approach. *Med Educ*. 2012 Oct;46(10):943-52. doi: 10.1111/j.1365-
9
10 309 2923.2012.04328.x.
11
12 310
13
14 311 3) Lee K, Whelan JS, Tannery NH, Kanter SL, Peters AS. 50 years of publication in
15
16 312 the field of medical education. *Med Teach*. 2013 Apr 22
17
18 313
19
20 314 4) Todres M, Stephenson A, Jones R. Medical education research remains the
21
22 315 poor relation. *BMJ* 2007;335:335-5.
23
24 316
25
26 317 5) Eva KW. *Med Educ*. Broadening the debate about quality in medical education
27
28 318 research. 2009 Apr;43(4):294-6. doi: 10.1111/j.1365-2923.2009.03342.x.
29
30 319
31
32 320 6) Stephenson A, Todres M, Jones R. Reply to Dornan et al.'s 'On evidence'. *Med*
33
34 321 *Educ*. 2009 Apr;43(4):390-1. doi: 10.1111/j.1365-2923.2009.03306.x.
35
36 322
37
38 323 7) Schulz KF, Altman DG, Moher D; CONSORT Group .CONSORT 2010 statement:
39
40 324 updated guidelines for reporting parallel group randomized trials. *Ann Intern*
41
42 325 *Med*. 2010 Jun 1;152(11):726-32. doi: 10.1059/0003-4819-152-11-201006010-
43
44 326 00232. Epub 2010 Mar 24.
45
46 327
47
48 328 8) Frambach JM, van der Vleuten CP, Durning SJ. AM last page. Quality criteria in
49
50 329 qualitative and quantitative research. *Acad Med*. 2013 Apr;88(4):552. doi:
51
52 330 10.1097/ACM.0b013e31828abf7f.
53
54 331
55
56
57
58
59
60

1
2
3
4
5
6 332 9) Prisma statement, available at www.prisma-statement.org. Accessed 5
7
8 333 January 2014.

9
10 334

11 335 10) Prady SL, Richmond SJ, Morton VM, et al. A Systematic evaluation of the
12
13 336 impact of STRICTA and CONSORT recommendations on quality of reporting for
14
15 337 acupuncture trials. *PLoS One* 2008;3:e1577.

16
17
18 338

19
20 339 11) Fuller T, Pearson M, Peters JL, Anderson R. Evaluating the impact and use of
21
22 340 Transparent Reporting of Evaluations with Non-randomised Designs (TREND)
23
24 341 reporting guidelines. *BMJ Open*. 2012 Dec 19;2(6). pii: e002073. doi:
25
26 342 10.1136/bmjopen-2012-002073. Print 2012.

27
28 343

29
30 344

31
32 345 ~~122~~) Reed DA, Cook DA, Beckman TJ, Levine RB, Kern DE, Wright SM. Association
33
34 346 between funding and quality of published medical education research. *JAMA*.
35
36 347 2007 Sep 5;298(9):1002-9.

37
38 348

39
40 349 [13\) Jadad AR1, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ,](#)

41
42 350 [McQuay HJ. Assessing the quality of reports of randomized clinical trials: is](#)

43
44 351 [blinding necessary? *Control Clin Trials*. 1996;17\(1\):1-12.](#)

45
46 352

47
48 353 ~~143~~) Hoffmann TC, Eructi C, Glasziou PP. Poor description of non-

49
50 354 pharmacological

51
52 355 interventions: analysis of consecutive sample of randomised trials. *BMJ*. 2013

53
54 356 Sep 10;347:f3755. doi: 10.1136/bmj.f3755

1
2
3
4
5
6 357
7

8 358 | 154) Altman DG. Endorsement of the CONSORT statement by high impact
9
10 359 | medical journals: survey of instructions for authors. BMJ. 2005 May
11
12 360 | 7;330(7499):1056-7.
13

14 361

15
16 362 | 165) Cook DA, Hatala R, Brydges R, Zendejas B, Szostek JH, Wang AT, Erwin PJ,
17
18 363 | Hamstra SJ. Technology-enhanced simulation for health professions education: a
19
20 364 | systematic review and meta-analysis. JAMA. 2011 Sep 7;306(9):978-88. doi:
21
22 365 | 10.1001/jama.2011.1234. Review.
23

24 366

25
26 367 | 176) Cook DA, Brydges R, Zendejas B, Hamstra SJ, Hatala R. Mastery learning for
27
28 368 | health professionals using technology-enhanced simulation: a systematic review
29
30 369 | and meta-analysis. Acad Med. 2013 Aug;88(8):1178-86. doi:
31
32 370 | 10.1097/ACM.0b013e31829a365d. Review.
33

34 371

35
36 372 | 187) Cook DA, Levinson AJ, Garside S. Method and reporting quality in health
37
38 373 | professions education research: a systematic review. Med Educ. 2011
39
40 374 | Mar;45(3):227-38. doi: 10.1111/j.1365-2923.2010.03890.x.

41
42 375

43
44 376
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Appendix 1.

Extension to the CONSORT statement

The column on the left-hand side is selected CONSORT elements. The column on the right represents the coding extensions specific for this study. All of these additional items are rated on three-point scales.

<p>2a Scientific background and explanation of rationale</p>	<ul style="list-style-type: none"> • <u>Scientific background</u> (maximum score = 3) include the use of <ol style="list-style-type: none"> 1) Educational instruments. Score = 1.0 <i>Example: Simulation-based medical education, use of assessment instruments with validity evidence.</i> 2) Educational concepts. Score = 1.0 <i>Example: Deliberate practice, self-directed learning.</i> 3) Educational theories. Score = 1.0 <i>Example: Cognitive load theory, developmental frameworks.</i> • <u>Explanation of rationale</u> is the clinical rationale or justification for conducting the study. Maximum score = 3. <ol style="list-style-type: none"> 1) Clinical background. Score = 1.5. <i>Example: "laparoscopic surgery has long learning curves and complications occurs more frequently with inexperienced surgeons."</i> 2) Justification of the use of intervention. Score = 1.5. <i>Example: "Simulation-based training has been shown to be useful for initial training and may therefore reduce the number of complications..."</i>
<p>2b Specific objectives or hypotheses</p>	<ul style="list-style-type: none"> • <u>Objectives or research question</u> (maximum score = 3) include specifications of <ol style="list-style-type: none"> 1) Setting and population (Each = 0.5) 2) Intervention and control (Each = 0.5) 3) Outcome measures (Each = 0.1) • <u>Hypotheses</u> are proposed effects or mechanisms of action. <ol style="list-style-type: none"> 1) Score = 3 if stated clearly as a hypothesis <i>Example: Our hypothesis was that...</i> 2) Score 1.5 if potential mechanisms of actions are stated but not explicitly called a hypothesis <i>Example: "Simulation-based training has previously shown improved operative performances and may therefore also reduce complications..."</i> 3) Score=0 if no mechanism of action is proposed or no specific hypothesis is suggested.

	<p>Example: Effective communication is difficult. We aimed to explore if a simulated patient programme improved students' confidence in...</p>
<p>5 The interventions for each group with sufficient details to allow replication, including how and when they were actually administered</p>	<ul style="list-style-type: none"> • <u>Description of the use of the intervention and control</u> (maximum score = 3) include <ol style="list-style-type: none"> 1) Detailed description of the type of intervention and control conditions. Score = 1 <i>Example: Type of simulation or type of learner interaction.</i> 2) Detailed description of instructions/information available to participants. Score = 1 <i>Example: Verbal or written instructions available prior to and during the intervention and additional resources such as textbooks, web-based learning material etc.</i> 3) Detailed description of the supervision/ assessment/ feedback provided, the amounts available and the qualifications/training of the persons providing supervision/ assessment /feedback. Score = 1. <i>Example: How much feedback was provided, how was it provided, by whom and for how much time?</i>
<p>Interpretations</p>	<ul style="list-style-type: none"> • <u>Interpretation of results</u> (maximum score = 3) includes <ol style="list-style-type: none"> 1) Reported consistent with the observed results (Score = 1.5). <i>Example: "These significantly higher performance-scores suggest that simulation-training of junior surgeons may lead to superior performance in the OR".</i> 2) Integration of results and interpretation into existing educational theory. (Score = 1.5) <i>Example: "These results are consistent with cognitive load theory suggesting that..."</i>



PRISMA 2009 Checklist

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A – not subject for registration with PROSPERO as this is a methodological review.
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	6
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	8



PRISMA 2009 Checklist

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49

Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	8
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	8
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	N/A

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	8
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	N/A
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	N/A
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	N/A
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	N/A
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	N/A
FUNDING			



PRISMA 2009 Checklist

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49

Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	10
---------	----	--------------------------------------------------------------------------------------------------------------------------------------------	----

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

Page 2 of 2

For peer review only