

Sex/gender in intervention studies

1 **ABSTRACT:**

2 **Background:** Physical inactivity is often reported in youth and differs among boys and girls.
3 The aim of this study is to assess sex/gender considerations in intervention studies promoting
4 Physical Activiyy (PA) and reducing Sedentary Behaviour (SB) in youth using a sex/gender
5 checklist.

6 **Methods:** A systematic search was conducted in August 2018 to identify all relevant controlled
7 trials. Studies screened must have reported a quantified measure of PA and/or SB, and
8 identified participants by sex/gender at baseline. For evaluation of the sex/gender consideration
9 we used a sex/gender checklist developed by expert consensus.

10 **Results:** We reviewed sex/gender considerations in all aspects of intervention development,
11 implementation and evaluation in 217 studies. Sex/gender aspects were only rudimentarily
12 taken into account, most frequently during statistical analyses such as stratification or
13 interaction analysis.

14 **Conclusions:** Sex/gender effects are not sufficiently reported. To develop guidelines that are
15 more inclusive of all girls and boys, future interventions need to document sex/gender
16 differences and similarities, and explore whether sex/gender influences different phases of
17 intervention programs. The newly developed sex/gender checklist can hereby be used as a tool
18 and guidance to adequately consider sex/gender in the several steps of intervention planning,
19 implementation and evaluation.

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24 **TEXT**

25 **Background**

26 A large body of evidence is available showing that physical activity (PA) in children and
27 adolescents is positively associated, and sedentary behaviour (SB) negatively associated, with
28 physical, social, psychological and emotional health.^{1,2} Nevertheless, children are insufficiently
29 active and differences in PA and SB between girls and boys exist. As the foundation for an
30 active lifestyle is developed in childhood and adolescence and tracks into adulthood, children
31 and adolescents are high priority target groups for PA promotion and SB reduction.^{3,4}

32 There is a strong tradition of gender and health research that conceptualizes health behaviours
33 (such as PA and SB) as both shaped by and as expressions of societal constructions of gender
34 (e.g., masculinity, femininity).⁵⁻⁷ Increasingly, theoretical approaches to gender and health
35 acknowledge that sex-based biological factors and gendered social factors are entangled in the
36 sense that it is not always possible to theoretically or empirically isolate the influences of the
37 biological and the social.⁸ In recognition of this complexity, in this article we use the term
38 sex/gender.⁹

39 A systematic review by Mears, Jago¹⁰ on the effectiveness of after-school programs to enhance
40 moderate-to-vigorous physical activity (MVPA) in children and adolescents, reported that a
41 small minority of studies had conducted subgroup analyses in boys and girls with some
42 evidence of greater effects on MVPA in boys but too few studies to draw conclusions. They
43 also highlight that very few studies focused on exploring sex/gender differences or similarities
44 and the underlying causes or mechanisms of any observed differential effects.¹⁰

45 Tools such as the Equity Extension of the Preferred Reporting Items in Systematic Reviews and
46 Meta-analysis (PRISMA-E) or PROGRESS-plus can aid researchers in considering sex/gender
47 in systematic reviews. PRISMA-E specifies items to report that are essential to understanding
48 issues of equity and fairness. The PROGRESS-plus acronym identifies gender and other socio-

49 demographic factors (e.g., race/ethnicity, education, and socio-economic status) that may
50 impact health equity and potentially intersect with gender.^{11,12} However, because both of these
51 tools are comprehensive in their treatment of equity-related issues, neither focus on sex/gender
52 consideration in depth and there is no specific tool to analyse sex/gender in PA or SB primary
53 studies.

54 Two PA reviews analysed equity issues according to PROGRESS-Plus items but only in adult
55 populations.^{13,14} Both reviews concluded that sex/gender was the most often studied variable
56 regarding equity in reviews as well as in primary studies. A majority of the intervention studies
57 reported that baseline characteristics differed between men and women and different
58 interventions had different effects on men and woman. Some of the studies had a bigger impact
59 on women and some on men.¹⁴ It was suggested that features, such as intervention content,
60 setting as well as outcome measures, might have been responsible for differential findings by
61 sex/gender.¹³ However, the authors did not delve further into these findings and the findings
62 were inconsistent, so this does not allow one to draw conclusions that there are significant
63 differential effects.

64 To examine possible sex/gender differences and to minimise any potential sex/gender related
65 inequities, a tool for assessment and consideration of sex/gender in all stages of the design,
66 implementation and evaluation of an intervention, as well as for the conduct of systematic
67 reviews, is required. This includes identifying if and how intervention studies take sex/gender
68 into account when formulating research questions and in any underpinning theories, in study
69 design, sample recruitment and measurement instruments, and in all aspects of the reporting of
70 sex/gender related data.¹⁵⁻¹⁷ Therefore, the aim of this study was to evaluate sex/gender
71 considerations in a comprehensive way in intervention studies aimed at promoting PA and/or
72 reducing SB in children and adolescents.

73 **Evidence Acquisition**

74 This systematic review is reported according to Preferred Reporting Items for Systematic
75 Reviews and Meta-Analyses (PRISMA) (see Appendix Table 1). The protocol for the review
76 was published previously and also registered with PROSPERO (ref CRD 42018109528).¹⁸
77 There were no substantial changes to the protocol. As part of a systematic review, termed the
78 genEffects project, we examined the sex/gender considerations of all included studies.¹⁸ The
79 genEffects project had two goals: to determine whether PA and SB interventions targeting
80 children and adolescents had similar or differential effects on boys and girls, and to determine
81 how studies took sex/gender into account; the latter findings are the focus of this paper.¹⁸
82 Effectiveness results will be reported in separate papers. We searched eleven electronic
83 databases from January 2000 to August 2018 and with a search strategy based on Cochrane
84 standards (see Appendix Table 2).

85 Two researchers performed the study selection process independently using Covidence
86 software and followed the inclusion criteria (Table 1). All discrepancies were resolved by a
87 third, senior researcher. After removal of duplicates, titles and abstracts were screened and any
88 potentially relevant article or those of indeterminate relevance were subsequently retrieved and
89 screened against eligibility criteria.

90 For each included intervention study, specific details were extracted by two reviewers
91 independently, using a piloted data extraction form to ensure consistency. Data extraction
92 covered information about general study characteristics, sample size for intervention and
93 control groups stratified by sex/gender and dropout rate, details about intervention content as
94 well as intervention approaches and settings. For additional information, study protocols and

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97 *Table 1 Eligibility criteria for the genEffects systematic review*

	Included
Population	Healthy children and/or adolescents within the average age range of three to 19 years
Intervention	Aim of the intervention must be the promotion of PA and/or reduction of SB by any type of quantified measure
Study design	Controlled intervention studies
Control group	no PA or SB intervention
Outcomes	<p>PA and/or SB in all domains assessed by any type of measure (subjective/ objective)</p> <p>Descriptive or inferential statistical outcomes of PA / SB must be reported</p> <ul style="list-style-type: none"> • for sex/gender disaggregated at baseline and/or follow-up and displayed in text and/or tables and/or • for sex/gender disaggregated in relation from baseline to follow-up and displayed in text and/or tables and/or • that there were no differences in the outcome when looking at sex/gender and no further analyses were carried out and/or • how they dealt with sex/gender in measuring the outcomes (e.g., adjustment)

Publication type	Peer reviewed journal articles published after year 2000 in English
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100 supplementary material were used and in the case of missing information, authors were
101 contacted (maximum of two contact attempts).

102 To evaluate the degree to which sex/gender was considered in the included intervention studies,
103 we developed a comprehensive sex/gender checklist in a three-step procedure. First, the
104 existing literature and tools that appraise sex/gender in health research were collated, including
105 guidelines for systematic review authors.¹⁹⁻³⁰ Second, we summarized existing instruments and
106 checked them for applicability to our objectives. Third, a draft sex/gender checklist was
107 developed in collaboration with 16 international multidisciplinary researchers with expertise in
108 the field of sex/gender methodology (e.g., members of the Cochrane Sex/Gender Methods
109 Group, a subgroup of the Campbell and Cochrane Equity Methods Group). The final sex/gender
110 checklist consists of ten items (see Appendix file 1). The items were rated using five
111 classifications, guided by item-specific definitions, to determine the extent to which the primary
112 study took sex/gender into account for each item. The main ratings are categorized broadly as
113 *detailed*, *basic*, or *no information provided*. Studies are rated with *detailed* when they
114 considered sex/gender in the specific item in a comprehensive and extensive way (for item
115 specific description of the detailed classification see Appendix file 1). *Basic* is rated when
116 studies mentioned sex/gender in context of the specific item and did not elaborate the topic
117 further (for item specific description of the basic classification see Appendix file 1). *No*
118 *information* is rated when studies did not provide any information about sex/gender in context
119 of the respective item. For studies that recruited only boys or girls, a fourth classification, *not*
120 *relevant*, was used for items that were considered less applicable to single sex/gender studies
121 e.g., provision of sex/gender-disaggregated data for participant flow (items 4, 5, 8 and 9). Some
122 single sex/gender studies have nevertheless provided additional information, which we then
123 rated as basic or detailed. For the first item only (*Definition and use of sex and/or gender*

124 *terminology) poor* was also a rating for those studies that used the terms sex and gender
125 interchangeably. Two researchers independently assessed studies for the ten items of the
126 sex/gender checklist. When multiple publications reported the same trial, the trial was assessed
127 only once, using all available information.

128 **Evidence Synthesis:**

129 The search identified 24,835 records after removing duplicates (see Figure 1). During the
130 review of titles and abstracts, 683 articles were included for detailed assessment via full text
131 screening. A total of 217 unique studies (in 244 articles) met eligibility criteria (see Appendix
132 Table 3). Sixteen studies had more than one identified publication.

133 **[PLEASE INSERT HERE]** *Figure 1. PRISMA Flowchart*

134 The identified studies measured different outcomes regarding PA and SB, which we divided in
135 the following subgroups: overall PA (n=97), PA in school (n=62), leisure-time PA (n=31),
136 active commuting (n=12) and SB (n=71). We sorted all study results that did not fit in these
137 groups in a third category “other outcomes” (e.g. physical fitness or nutrition) (n=28). The most
138 frequently used measurement instruments were accelerometers (n=173) and/or questionnaires
139 (n=113).

140 In the primary studies, the methods for addressing sex/gender varied. A single sex/gender
141 sample was included in 34 studies. Sixty-seven studies reported results disaggregated by
142 sex/gender. Thirty studies investigated whether a significant interaction existed between group,
143 sex/gender and time. Thirty-seven studies examined whether differences existed between boys
144 and girls, but quantitative results were not displayed. Finally, 76 studies adjusted for sex/gender.

145 The sex/gender checklist rating procedure was carried out for all included 244 articles. When
146 multiple publications reported the same trial they were included only one time resulting in 217

147 evaluations per item. The highest rating across all publications provided was achieved. In total,
148 159 conflicts were resolved during our application of the sex/gender checklist through
149 discussion amongst two independent reviewers. These represent 7.3% out of all rated items.

150 The results of the checklist show that with regard to the background, planning and
151 implementation of the intervention (items 3-7 of the checklist), no information was provided in
152 the majority of the studies. Primary studies increasingly dealt with sex/gender in the results
153 section. Forty-one studies (19%) reported the number of girls and boys in intervention and
154 control groups at all measurement points. In the results 113 studies (52%) reported sex/gender,
155 that they were rated *detailed* for and 49 studies (23%) discussed their findings with regard to
156 sex/gender. The rating of each individual study for each item is presented in Appendix Figure
157 1. The highest rating on the sex/gender checklist was a study that was rated *detailed* on six
158 different items ³¹. Three studies (1%) were rated *detailed* on four different items ³²⁻³⁴. In
159 contrast, 77 studies (35%) had no *detailed* ratings. There was no study that reported information
160 across all 10 checklist items. Ten studies (4.6%) were rated *no information provided* on eight
161 different items.

162 **[PLEASE INSERT HERE]** Figure 2 Summary of the results of the sex/gender Checklist

163 The first item of the sex/gender checklist describes whether the use of sex and/or gender
164 terminology was defined in the study. Of the 217 studies, none defined and used consistently
165 one of the terms “sex”, “gender” or “sex/gender” which was required for a rating of *detailed* for
166 this item. In 134 studies (62%), “sex” or “gender” was used consistently and not
167 interchangeably, with 66 studies using the term “sex” and 68 using the term “gender”. These
168 studies were rated as *basic* for item 1. Sixty-eight (31%) of the studies used the terms “sex” and
169 “gender” interchangeably without any explanation, earning the rating “poor”. Fifteen (7%) of
170 the studies provided no information about sex/gender terminology.

171 The second item examines whether sex/gender background information was identified as a
172 consideration when formulating the research question. Contextual information regarding
173 sex/gender differences and/or similarities was provided in the background and introduction of
174 only 7 studies (3%) that were, therefore, categorized as *detailed*. For example, Taymori, et al.,
175 described the cultural difficulties for Iranian girls in meeting recommendations for PA.³⁵ In 60
176 studies (28%), sex/gender background was considered at a *basic* level, meaning that these
177 studies only mentioned sex/gender considerations regarding the research questions. In total, 150
178 studies (69%) did not provide any sex/gender background information on the research question.

179 The last item within *background and concepts* considered *theoretical and/or conceptual*
180 *linkages with sex/gender (Item 3)*. This relates to whether studies used an underlying
181 behavioural theory in relation to sex/gender. One study (0.5%), by Sigmund, El Ansari,
182 Sigmundova, did this in a *detailed* fashion by considering the theory of co-education in terms
183 of sex/gender by coeducating boys and girls in the same school, in the same class³¹. Taymoori,
184 et al. and Rosenkranz, et al. included conceptual linkages of connecting the intervention with
185 sex/gender and were rated as *basic*, so conducted Rosenkranz, et al. their intervention in
186 collaboration with the Girl Scout non profit organization, which is devoted to building the
187 courage, confidence, and character of girls.^{35,36} The vast majority of studies (99%) did not
188 provide any information regarding theoretical and/or conceptual linkages with sex/gender.

189 The item *Measurement instruments (Item 4)* evaluates the degree to which the measurement
190 instruments are tested to be valid and reliable for girls and boys. As for example boys tend to
191 be more active in vigorous physical activity and pedometers underestimate vigorous physical
192 activity, pedometers tend to underestimate physical activity of boys.³⁷ Therefore, to avoid
193 measurement instruments measuring PA differently for boys and girls, the measurement
194 instrument should be tested valid and reliable for sex/gender. Five intervention studies (2.3%)

195 by Babic, et al.³⁸, Pate, et al.³⁹, Sigmund, et al.³¹, Story, et al.⁴⁰ and Young, et al.⁴¹ reported
196 validated measurement instruments for sex/gender groups. In 10 studies (5%), this item was
197 rated *basic* because measurement instruments used are not developed for sex/gender groups
198 (reliable or valid), but reasons for this decision are given. In 27 (12%) studies as *not relevant*,
199 because of single sex/gender studies. Additionally, 175 (81%) of the interventions did not
200 provide any information about the measurement instrument concerning sex/gender.

201 In item *Study sample recruitment (Item 5)* we examined how study investigators took
202 sex/gender into account in sampling. Thirty studies (14%) recruited only one sex/gender group
203 (boys or girls) so this particular item was rated as *not relevant* although we acknowledge study
204 investigators may have been prompted to enrol only one sex/gender group for sex/gender
205 considerations. No study reported on inclusion of gender diverse participants. Of the 187
206 mixed-sex/gender studies, no study included a power calculation with respect to sex/gender and
207 was rated as *detailed*. The 10 studies (5%) that described how sex/gender was taken into account
208 during sampling were rated as *basic*. For example, in the UP4FUN research, in which teachers
209 were equipped with materials about e.g. PA, SB and activity breaks, “schools were paired
210 according to size, gender and socio-economic status”.⁴² None of the remaining 177 (82%)
211 studies reported information about sex/gender considerations in sampling.

212 The third category of the sex/gender checklist was *Intervention planning and delivery*. This
213 comprises two items (Item 6&7), *intervention content and materials* (e.g. brochures, leaflets,
214 plans of sessions) and *intervention delivery, location and interventionists*. Six (3%) studies
215 described content/materials in terms of sex/gender. For example, the “Dads And Daughters
216 Exercising and Empowered” program by Morgan, et al. had a primary focus on education,
217 "redefining gender norms, developing the girls’ critical thinking skills, and eliciting meaningful
218 support from their fathers as gender equity advocates".⁴³ Girls were taught to resist, question,

219 and negotiate real-world PA barriers in empowering ways. Another 11 (5%) studies described
220 the intervention content/materials in terms of sex/gender-inclusiveness, but did not report on
221 implementation. For the remaining 200 (92%) studies, no information was provided on whether
222 the intervention content/materials were considering sex/gender.

223 Item 7 (Intervention delivery, location & interventionists) rated whether the intervention was
224 sex/gender-inclusive regardless of the mode of intervention delivery, location and the person(s)
225 carrying out the intervention and 3 (1%) studies were rated *detailed*. Sigmund, et al. gave
226 sex/gender attention by offering specific programs for girls and boys.³¹ In addition, PA with
227 boys and girls together was fostered by the teachers. Twelve (6%) studies in which the
228 importance of a sex/gender-inclusive intervention delivery, location or person carrying out the
229 intervention was mentioned were rated *basic*. For example, Cui, et al. intentionally sex/gender-
230 balanced the eight peer leaders, who conducted parts of the intervention but no further
231 explanations regarding this procedure were given⁴⁴. *No information was provided* about
232 sex/gender-inclusive modes of intervention delivery, location or the person carrying out the
233 intervention in 202 (93%) studies.

234 Item 8 (Participant flow) of the sex/gender checklist assessed whether participant flow
235 provides information about sex/gender as part of trial participant accounting.⁴⁵ At all
236 measurement points, 41 (19%) studies provided the sample size for boys and girls and were
237 therefore rated *detailed*. A *basic* rating was given to the 126 (58%) that provided sample size
238 for girls and boys separately at least once while in 20 studies (9%), no information about the
239 sex/gender of participants was provided for any measurement. In the 34 (14%) studies that
240 enrolled a single sex/gender group, this item was rated as *not relevant*.

241 *Statistical results (Item 9)* was the second item of the category *Presentation of findings* and it
242 relates to whether sex/gender differences and/or similarities in outcomes were described. This

243 item was addressed in *detail* by 113 (52%) studies because they included sex/gender statistics
244 on main outcomes and looked for possible sex/gender differences and/or similarities in
245 intervention effects (using e.g., sex/gender disaggregated analyses, stratified analyses,
246 interactions). Another 72 studies (33%) reported statistical analyses for sex/gender differences
247 and/or similarities regarding the main outcomes but did not report the effect sizes for
248 sex/gender. In two studies (1%) there was *no information provided*. In 30 studies (14%), this
249 item was rated as *not relevant*.

250 The last category *Interpretation of findings* consists of only one item *Discussion (Item 10)*.
251 Rated as *detailed* were 49 (23%) studies because study investigators reflected on their findings
252 and future directions with respect to sex/gender. Dudley, et al. also describe the importance of
253 adapting environmental conditions to facilitate girls' physical activity and to enable making
254 self-effective decisions.⁴⁶ In the intervention study of Parrish, et al., it was observed that the
255 physical activity behaviour in recess differs between boys and girls, with girls spending more
256 time in sedentary time and boys being active in ball play at baseline.⁴⁷ The intervention worked
257 better for girls than boys. They discussed if their introduced portable equipment (e.g., ropes or
258 hoops) may change the behaviour of girls in more active behaviour. Seventy (32%) studies were
259 rated *basic*, as sex/gender findings were discussed without any consideration of future
260 directions. Ninety-eight (45%) studies did not provide any information on this subject.

261 **Discussion**

262 This review approach assessed the sex/gender considerations made in all steps of an
263 intervention development, implementation and evaluation in 217 intervention studies aiming to
264 promote PA and/or reduce SB in children and adolescent. Overall, sex/gender aspects were only
265 rudimentarily considered in the included primary studies. Our eligibility criteria required that

266 trials report, as a minimum, sex/gender-disaggregated characteristics at baseline, which resulted
267 in exclusion of 125 studies.

268 Only during the statistical analyses of the intervention effects, sex/gender was likely to be
269 addressed in more detail. Even this finding is a result of our exclusion of studies that did not
270 report at a minimum, disaggregated findings for boys and girls for at least one timepoint. In
271 addition, in the discussion sections of the included studies, sex/gender was often considered.
272 These findings lead us to conclude that researchers are more likely to take sex/gender into
273 account in analyses of intervention effectiveness and discussions instead of considering
274 sex/gender related aspects confirmatory during all steps of intervention study.

275 Also to find out what kind of samples (mixed sex/gender or single sex/gender studies) are more
276 effective for boys and girls, we need more information on how sex/gender was taken into
277 account during sampling. In relation to the intervention content and materials, we need evidence
278 of whether it is more effective to use different materials (e.g. brochures, leaflets, plans of
279 sessions) for girls and boys or whether the same materials should be used for all. It is also
280 essential to report intervention delivery, location and personnel and consider how each might
281 have a gendered impact. For example, if the person carrying out the intervention was trained to
282 be sex/gender inclusive in language that could alter outcomes. The findings of the sex/gender
283 assessment and agenda items for guiding future studies are in line with systematic reviews that
284 include sex/gender as a discriminating variable.^{13,14} With regard to the planning and
285 implementation of interventions, it is important to consider the extent to which sex/gender is
286 accounted for in content, materials, training of staff and delivery in order to draw conclusions
287 about what works how for who. Studies and systematic reviews should also present the number
288 of participants disaggregated by sex/gender at each time of measurement when reporting results
289 of the interventions.

290 Reporting sex/gender-disaggregated data alone does not actually constitute a sex/gender-based
291 analysis and is still very rudimentary. This is just a first step to determining whether differences
292 or similarities exist. Even if sex/gender-disaggregated data show a difference, it is far from clear
293 whether the issue is based exclusively on sex/gender or other social determinants of health that
294 intersect with sex/gender. Mixed-methods studies or qualitative studies are required to explore
295 reasons for any differential effects in addition to quantitative studies. With our approach we are
296 going to take a next step to objectively illuminate different aspects for the adequate
297 consideration of gender/sex. With more researchers using the sex/gender checklist, when
298 planning, conducting and evaluating an intervention or systematic review we can achieve more
299 information about how these aspects function in primary research before deciding on best
300 interventions to promote PA and SB equitably.

301 The sex/gender checklist used in this systematic review approach could be a helpful tool for
302 researchers to address sex/gender in intervention studies. Sex/gender considerations in
303 individual studies should be part of systematic reviews. For this purpose, the sex/gender
304 checklist developed in this project could be used. Additionally, the effectiveness of
305 interventions must be examined regarding key sex/gender elements during the entire process
306 from theory underlying research to intervention design, implementation and evaluation. The
307 key strength of this systematic review approach is our innovative method for considering
308 sex/gender using a novel sex/gender checklist. The checklist could help researchers focus on
309 new ways of planning, conducting and evaluating future intervention studies to adequately
310 integrate sex/gender in other areas of health. Furthermore, our comprehensive literature search
311 and screening based on standards for systematic reviews can be counted among the strengths
312 of this study. The strengths of the sex/gender checklist developed lie in the comprehensive
313 evaluation of sex/gender in intervention studies from intervention planning, development,

314 implementation, and delivery to evaluation. Additionally, by calculating a high level of
315 agreement of the raters of the checklist is an appropriate tool. The primary purpose of the
316 sex/gender checklist was for appraisal of sex/gender in systematic reviews; nevertheless, the
317 checklist can be used for guidance when planning, conducting and evaluating an intervention
318 study.

319 **Limitations**

320 Although we used a comprehensive search unrestricted by language, a limitation of the study
321 is restriction of eligibility to English language articles and peer reviewed publications. One
322 limitation of the checklist is the fact that this was just identifying whether sex/gender was
323 discussed, but not the quality and the extent of the discussion. Another potential limitation is
324 that there is no meaningful summative score from it. Such a score could aid in comparing
325 studies. However, the development of such a score is challenging and necessitates a relative
326 weighting of included items. There is no established weighting at present. In the future, it might
327 be useful to additionally explore how a sex/gender score might developed.

328 For future intervention studies, we recommend considering sex/gender in all aspects of
329 intervention planning and implementation. It is important to consider in the first step how to
330 use sex/gender terminology and whether to focus consciously on the biological, social, or
331 connectedness of the two components. Furthermore, it is important to consider sex/gender with
332 regard to the research question in order to keep the effects and characteristics of sex/gender in
333 mind from the beginning. A theoretical concept that takes sex/gender into account with regard
334 to the research question can help to adequately consider sex/gender. Additionally, it is important
335 to select measurement instruments that are equally valid for all sex/gender as there are
336 measurement instruments that measure differently for girls than for boys.^{37,48,49} In order to
337 determine the effectiveness of interventions and possible differences in effectiveness with

338 respect to sex/gender, it is important that statistical power calculations have been performed
339 with respect to sex/gender. Only in this way can the effectiveness or non-effectiveness of
340 interventions be attributed or denied to sex/gender. In order to find out how the content,
341 materials, the intervention implementation, the location and the implementing persons affect
342 the different sex/gender, it is important that considerations are made in advance and that the
343 implemented intervention is precisely documented with all components. This is an important
344 step forward to find out whether a certain place works better for girls or boys, whether girls
345 benefit more from female or male interventionists or whether this does not matter. Furthermore,
346 it is important that sex/gender and the dropout rate are documented at all measurement points
347 in order to find out whether an above-average number of persons of a sex/gender dropped out
348 at a measurement point and to find possible reasons for this. To interpret the results in relation
349 to sex/gender, statistical analyses should also be carried out, e.g. disaggregated or stratified, or
350 interaction analyses should be carried out. All of these points need to be discussed in relation
351 to sex/gender to develop further recommendations for the future.

352 Sex/gender considerations in interventions promoting PA and/or reducing SB among children
353 and adolescents are rarely reported. Policies and guidelines to best address promotion of PA
354 and reduction of SB should be informed by intervention evidence that adequately takes
355 sex/gender into account. In order to develop policies, guidelines and programs that are more
356 inclusive of all girls and boys, future intervention studies aiming to increase PA and reduce SB
357 need to document sex/gender differences and similarities, and to explore whether sex/gender
358 influences different phases of intervention programs, including implementation, acceptability,
359 and perceived or actual barriers to participation. The newly developed sex/gender checklist
360 could be a useful tool to facilitate documentation of sex/gender in future studies.

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368 The researchers are independent of the funders who have no influence on study design, conduct,
369 analyses, or interpretation of the data, the decision to submit the results or the preparation of
370 the manuscript.

371

372 **List of abbreviations**

373 SB: Sedentary Behaviour; MVPA: moderate-to-vigorous physical activity; PA: physical
374 activity;

375 **Declarations**

376 Not applicable.

377 **Ethics approval and consent to participate**

378 Not applicable

379 **Consent for publication**

380 Not applicable.

381 **Availability of data and materials**

382 All data analysed during this study are included in the supplementary information files of this
383 article.

384

385 **Authors' contributions**

386 AS prepared the first draft of the manuscript. All authors were involved in a priori protocol
387 development including the development of the sex/gender-checklist, and the search strategy.
388 AS, CV, CS performed the searches, with search strategies devised in consultation with
389 Douglas M. Salzwedel, information specialist with Cochrane Hypertension, University of
390 British Columbia, Canada, and LP. AS, CV and CS conducted the screening of the search,
391 extracted the data, appraised the study quality and conducted the grading with the sex/gender-
392 checklist. AKR, JB, YD supervised this process. All authors contributed to the interpretation
393 of the results, critically reviewed the manuscript and approved the final manuscript. AKR, JB
394 and YD secured the funding for the study and conceived the genEffects project.

395

396 **Appendix**

397 Appendix Table 1: PRISMA Checklist

398 Appendix Table 2: file name: Appendix_Table_2_Search strategy

399 Appendix Table 3: file name: Appendix_Table_3_all_included_studies_responsepaper;

400 Appendix file 1: file name Appendix_File_4_Sex_Gender_Checklist

401 Appendix Figure 1: file name: Appendix_Figure_1_S-G rating of included studies

402

403 References

- 404 1. Chaddock-Heyman L, Erickson KI, Chappell MA, et al. Aerobic fitness is associated with
 405 greater hippocampal cerebral blood flow in children. *Dev Cogn Neurosci*. 2016;20:52-58.
 406 <https://doi.org/10.1016/j.dcn.2016.07.001>.
- 407 2. Powell KE, King AC, Buchner DM, et al. The Scientific Foundation for the Physical Activity
 408 Guidelines for Americans, 2nd Edition. *J Phys Act Health*. 2018:1-11. 10.1123/jpah.2018-
 409 0618.
- 410 3. Bouchard C, Blair SN, Haskell WL. *Physical activity and health*. 2nd ed. Champaign, IL [u.a.]:
 411 Human Kinetics; 2012.
- 412 4. Telama R, Yang X, Leskinen E, et al. Tracking of physical activity from early childhood through
 413 youth into adulthood. *Med Sci Sports Exerc*. 2014;46(5):955-962.
 414 10.1249/MSS.0000000000000181.
- 415 5. Courtenay WH. Constructions of masculinity and their influence on men's well-being: a
 416 theory of gender and health. *Soc Sci Med*. 2000;50(10):1385-1401. 10.1016/s0277-
 417 9536(99)00390-1.
- 418 6. Johnson JL, Repta R. Sex and gender: Beyond the binaries. In: Oliffe JL, Greaves L, eds.
 419 *Designing and conducting gender, sex, and health research*. Thousand Oaks: Sage
 420 Publications; 2012:17-37. Doi
- 421 7. Saltonstall R. Healthy bodies, social bodies: Men's and women's concepts and practices of
 422 health in everyday life. *Soc Sci Med*. 1993;36(1):7-14. [https://doi.org/10.1016/0277-
 423 9536\(93\)90300-S](https://doi.org/10.1016/0277-9536(93)90300-S).
- 424 8. Springer KW, Mager Stellman J, Jordan-Young RM. Beyond a catalogue of differences: a
 425 theoretical frame and good practice guidelines for researching sex/gender in human health.
 426 *Soc Sci Med*. 2012;74(11):1817-1824. 10.1016/j.socscimed.2011.05.033.
- 427 9. Cochrane Methods Group. Why sex and gender matter in health research synthesis.
 428 <http://methods.cochrane.org/equity/sex-and-gender-analysis>. Accessed 10 Jul 2019.
- 429 10. Mears R, Jago R. Effectiveness of after-school interventions at increasing moderate-to-
 430 vigorous physical activity levels in 5- to 18-year olds: a systematic review and meta-analysis.
 431 *Br J Sports Med*. 2016;50(21):1315-1324. 10.1136/bjsports-2015-094976.
- 432 11. Welch V, Petticrew M, Petkovic J, et al. Extending the PRISMA statement to equity-focused
 433 systematic reviews (PRISMA-E 2012): explanation and elaboration. *Int J Equity Health*.
 434 2015;14:92. 10.1186/s12939-015-0219-2.
- 435 12. O'Neill J, Tabish H, Welch V, et al. Applying an equity lens to interventions: using PROGRESS
 436 ensures consideration of socially stratifying factors to illuminate inequities in health. *J Clin
 437 Epidemiol*. 2014;67(1):56-64. 10.1016/j.jclinepi.2013.08.005.
- 438 13. Attwood S, van Sluijs E, Sutton S. Exploring equity in primary-care-based physical activity
 439 interventions using PROGRESS-Plus: a systematic review and evidence synthesis. *Int J Behav
 440 Nutr Phys Act*. 2016;13:60. 10.1186/s12966-016-0384-8.
- 441 14. Humphreys DK, Ogilvie D. Synthesising evidence for equity impacts of population-based
 442 physical activity interventions: a pilot study. *Int J Behav Nutr Phys Act*. 2013;10:76.
 443 10.1186/1479-5868-10-76.
- 444 15. Gupta GR, Oomman N, Grown C, et al. Gender equality and gender norms: framing the
 445 opportunities for health. *The Lancet*. 2019;393(10190):2550-2562. 10.1016/S0140-
 446 6736(19)30651-8.
- 447 16. Liwander A, Pederson A, Boyle E. Why the Canadian sedentary behaviour guidelines should
 448 reflect sex and gender. *Can J Public Health*. 2013;104(7):e479-481. 10.17269/cjph.104.4108.

- 449 17. Schriver B, Mandal M, Muralidharan A, et al. Gender counts: A systematic review of
450 evaluations of gender-integrated health interventions in low- and middle-income countries.
451 *Glob Public Health*. 2017;12(11):1335-1350. 10.1080/17441692.2016.1149596.
- 452 18. Demetriou Y, Vondung C, Bucksch J, et al. Interventions on children's and adolescents'
453 physical activity and sedentary behaviour: protocol for a systematic review from a
454 sex/gender perspective. *Syst Rev*. 2019;8(1):65. 10.1186/s13643-019-0963-2.
- 455 19. De Castro P, Heidari S, Babor TF. Sex and gender equity in research (SAGER): reporting
456 guidelines as a framework of innovation for an equitable approach to gender medicine.
457 *Annali dell'Istituto superiore di sanita*. 2016;52(2):154-157.
- 458 20. Jahn I, Börnhorst C, Günther F, Brand T. Examples of sex/gender sensitivity in epidemiological
459 research: results of an evaluation of original articles published in JECH 2006–2014. *Health
460 Research Policy and Systems*. 2017;15(1):11.
- 461 21. Johnson JL, Greaves L, Repta R. Better science with sex and gender: Facilitating the use of a
462 sex and gender-based analysis in health research. *Int J Equity Health*. 2009;8(1):14.
463 10.1186/1475-9276-8-14.
- 464 22. Pederson A, Greaves L, Poole N. Gender-transformative health promotion for women: a
465 framework for action. *Health promotion international*. 2014;30(1):140-150.
- 466 23. Welch VA, Petticrew M, O'Neill J, et al. Health equity: evidence synthesis and knowledge
467 translation methods. *Syst Rev*. 2013. 10.1186/2046-4053-2-43.
- 468 24. Doull M, Runnels V, Tudiver S, Boscoe M. Sex and gender in systematic reviews: A planning
469 tool. *Presentation at Combining forces to improve systematic reviews: Gender, equity and
470 bias, Ottawa, ON*. 2011.
- 471 25. Doull M, Runnels VE, Tudiver S, Boscoe M. Appraising the evidence: applying sex- and
472 gender-based analysis (SGBA) to Cochrane systematic reviews on cardiovascular diseases. *J
473 Womens Health*. 2010;19(5):997-1003. 10.1089/jwh.2009.1626.
- 474 26. European Commission. Toolkit - Gender in EU-funded research. 2009. 10.27777/12256.
- 475 27. Jahn I. Gender Mainstreaming im Gesundheitsbereich–Materialien und Instrumente zur
476 systematischen Berücksichtigung der Kategorie Geschlecht. *Das Gesundheitswesen*.
477 2005;67(07):V32.
- 478 28. Nieuwenhoven L, Bertens M, Klinge I. Gender. Awakening tool: Bibliography: sex and
479 gender in research. In: Maastricht University; 2007.Doi
- 480 29. Doull M, Welch V, Puil L, et al. Development and evaluation of 'Briefing Notes' as a novel
481 knowledge translation tool to aid the implementation of sex/gender analysis in systematic
482 reviews: a pilot study. *PLoS One*. 2014;9(11):e110786.
- 483 30. Welch V, Puil L., Shea B., Runnels V., Doull M., Tudiver S., Boscoe M. for the Sex/Gender
484 Methods Group. Addressing Sex/Gender in Systematic Reviews: Cochrane Musculoskeletal
485 Group Briefing Note. Version 2014-01.
486 https://methods.cochrane.org/sites/methods.cochrane.org/equity/files/public/uploads/KBriefingNote_MSKFINAL.pdf. Accessed 10/12/2018.
- 487
488 31. Sigmund E, El Ansari W, Sigmundova D. Does school-based physical activity decrease
489 overweight and obesity in children aged 6-9 years? A two-year non-randomized longitudinal
490 intervention study in the Czech Republic. *BMC Public Health*. 2012;12:570.
491 <https://dx.doi.org/10.1186/1471-2458-12-570>.
- 492 32. Smith JJ, Morgan PJ, Lonsdale C, Dally K, Plotnikoff RC, Lubans DR. Mediators of change in
493 screen-time in a school-based intervention for adolescent boys: findings from the ATLAS
494 cluster randomized controlled trial. *J Behav Med*. 2017;40(3):423-433.
495 <https://dx.doi.org/10.1007/s10865-016-9810-2>.
- 496 33. Vasickova J, Groffik D, Fromel K, Chmelik F, Wasowicz W. Determining gender differences in
497 adolescent physical activity levels using IPAQ long form and pedometers. *Ann Agric Environ
498 Med*. 2013;20(4):749-755.

- 499 <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med7&AN=2>
 500 [4364448](http://dx.doi.org/10.1016/j.yjmed.2014.04.023).
- 501 34. Pardo BM, Bengoechea EG, Julian Clemente JA, Lanaspá EG. Empowering adolescents to be
 502 physically active: three-year results of the Sigue la Huella intervention. *Prev Med*. 2014;66:6-
 503 11. <https://dx.doi.org/10.1016/j.yjmed.2014.04.023>.
- 504 35. Taymoori P, Niknami S, Berry T, Lubans D, Ghofranipour F, Kazemnejad A. A school-based
 505 randomized controlled trial to improve physical activity among Iranian high school girls. *Int J*
 506 *Behav Nutr Phys Act*. 2008;5:18. 10.1186/1479-5868-5-18.
- 507 36. Rosenkranz RR, Behrens TK, Dzewaltowski DA. A group-randomized controlled trial for health
 508 promotion in Girl Scouts: healthier troops in a SNAP (Scouting Nutrition & Activity Program).
 509 *BMC Public Health*. 2010;10:81. <https://dx.doi.org/10.1186/1471-2458-10-81>.
- 510 37. Rowlands AV, Eston RG. Comparison of accelerometer and pedometer measures of physical
 511 activity in boys and girls, ages 8-10 years. *Res Q Exerc Sport*. 2005;76(3):251-257.
 512 10.1080/02701367.2005.10599296.
- 513 38. Babic MJ, Smith JJ, Morgan PJ, et al. Intervention to reduce recreational screen-time in
 514 adolescents: Outcomes and mediators from the 'Switch-Off 4 Healthy Minds' (S4HM) cluster
 515 randomized controlled trial. *J Prev Med*. 2016;91:50-57.
 516 <https://dx.doi.org/10.1016/j.yjmed.2016.07.014>.
- 517 39. Pate RR, Ward DS, Saunders RP, Felton G, Dishman RK, Dowda M. Promotion of physical
 518 activity among high-school girls: a randomized controlled trial. *Am J Public Health*.
 519 2005;95(9):1582-1587.
 520 <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med5&AN=1>
 521 [6118370](http://dx.doi.org/10.118370).
- 522 40. Story M, Sherwood NE, Himes JH, et al. An after-school obesity prevention program for
 523 African-American girls: the Minnesota GEMS pilot study. *Ethnic Dis*. 2003;13(1 Suppl 1):S54-
 524 64.
 525 <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med4&AN=1>
 526 [2713211](http://dx.doi.org/10.1183211).
- 527 41. Young DR, Phillips JA, Yu T, Haythornthwaite JA. Effects of a life skills intervention for
 528 increasing physical activity in adolescent girls. *Arch Pediatr Adolesc Med*. 2006;160(12):1255-
 529 1261.
 530 <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med5&AN=1>
 531 [7146023](http://dx.doi.org/10.1187146023).
- 532 42. Verloigne M, Bere E, Van Lippevelde W, et al. The effect of the UP4FUN pilot intervention on
 533 objectively measured sedentary time and physical activity in 10-12 year old children in
 534 Belgium: the ENERGY-project. *BMC Public Health*. 2012;12:805.
 535 <https://dx.doi.org/10.1186/1471-2458-12-805>.
- 536 43. Morgan PJ, Young MD, Barnes AT, Eather N, Pollock ER, Lubans DR. Engaging Fathers to
 537 Increase Physical Activity in Girls: The "Dads And Daughters Exercising and Empowered"
 538 (DADEE) Randomized Controlled Trial. *Ann Behav Med*. 2018:10.
 539 <https://dx.doi.org/10.1093/abm/kay015>.
- 540 44. Cui Z, Shah S, Yan L, et al. Effect of a school-based peer education intervention on physical
 541 activity and sedentary behaviour in Chinese adolescents: a pilot study. *BMJ Open*. 2012;2(3).
 542 <https://dx.doi.org/10.1136/bmjopen-2011-000721>.
- 543 45. Schulz KF, Altman DG, Moher D, CONSORT Group. CONSORT 2010 statement: updated
 544 guidelines for reporting parallel group randomized trials. *Ann Intern Med*. 2010;152(11):726-
 545 732. 10.7326/0003-4819-152-11-201006010-00232.
- 546 46. Dudley DA, Okely AD, Pearson P, Peat J. Engaging adolescent girls from linguistically diverse
 547 and low income backgrounds in school sport: a pilot randomised controlled trial. *J Sci Med*
 548 *Sport*. 2010;13(2):217-224. <https://dx.doi.org/10.1016/j.jsams.2009.04.008>.

- 549 47. Parrish AM, Okely AD, Batterham M, Cliff D, Magee C. PACE: A group randomised controlled
550 trial to increase children's break-time playground physical activity. *J Sci Med Sport*.
551 2016;19(5):413-418. <https://dx.doi.org/10.1016/j.jsams.2015.04.017>.
- 552 48. Sloomaker SM, Schuit AJ, Chinapaw MJ, Seidell JC, van Mechelen W. Disagreement in
553 physical activity assessed by accelerometer and self-report in subgroups of age, gender,
554 education and weight status. *Int J Behav Nutr Phys Act*. 2009;6:17. 10.1186/1479-5868-6-17.
- 555 49. Bornstein DB, Beets MW, Byun W, McIver K. Accelerometer-derived physical activity levels of
556 preschoolers: a meta-analysis. *J Sci Med Sport*. 2011;14(6):504-511.
557 10.1016/j.jsams.2011.05.007.
- 558