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7 Perspectives on the application of CONSORT guidelines to randomised controlled trials in
8 nutrition

9

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52 Abstract

53

54 Purpose:

55 Reporting guidelines facilitate quality and completeness in research reporting. The CONSolidated
56 Standards Of Reporting Trials (CONSORT) statement is widely applied to dietary and nutrition
57 trials but has no extension specific to nutrition. Evidence suggests poor reporting in nutrition
58 research. The Federation of European Nutrition Societies led an initiative to make
59 recommendations for a nutrition extension to the CONSORT statement towards a more robust
60 reporting of the evidence base.

61 Methods:

62 An international working group was formed of nutrition researchers from 14 institutions in 12
63 different countries and on five continents. Using meetings over a period of one year, we
64 interrogated the CONSORT statement specifically for its application to report nutrition trials.

65 Results:

66 We provide new nutrition-specific recommendations or emphasized recommendations for the
67 reporting of the introduction (three), methods (twelve), results (five) and discussion (eight). We
68 also added two additional recommendations that were not allocated under the standard
69 CONSORT headings.

70 Conclusion:

71 We identify a need to provide guidance in addition to CONSORT to improve the quality and
72 consistency of the reporting and propose key considerations for further development of formal
73 guidelines for the reporting of nutrition trials. Readers are encouraged to engage in this process,
74 provide comments and conduct specific studies to inform further work on the development of
75 reporting guidelines for nutrition trials.

76

77 Keywords: Guidelines, CONSORT, nutrition trials, dietary interventions, reporting, expert opinion

78 Statements and declarations

79

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86

87 Competing interests:

88 Financial interests: Sanne Ahles receives a salary from BioActor BV. Janet Cade is Director of

89 Dietary Assessment Ltd.

90 Non-financial interests: Janet Cade and Carl Lachat were involved in developing the STROBE-

91 nut statement for reporting observational studies in epidemiology focussing on nutrition. Lukas

92 Schwingshackl is a member of the GRADE working group. Connie Weaver was a member of the

93 NURISH group that published reference 2, 12, and 13.

94 All other authors have no relevant financial or non-financial interests to disclose.

95

96 Author contributions

97 All authors contributed to the drafting of the manuscript. JRF and CW were responsible for review

98 and editing. All authors read and approved the final manuscript.

99

100 Introduction

101

102 Randomized controlled trials (RCTs) are needed to generate causal evidence. Too often,
103 however, causal relationships and underpinning mechanisms are poorly defined and reported.
104 Well-conducted trials with a robust design can overcome some of these limitations and improve
105 the quality of evidence regarding nutrition, diet and human health relationships [1].

106

107 There are specific challenges to conducting high quality dietary and / or nutrition intervention trials.
108 Lichtenstein et al. [2] have previously summarised key concerns related to implementation of such
109 trials. In addition, even if well-conducted, trials need to be reported accurately, with sufficient detail
110 for correct interpretation and application of research findings. If data generated by nutrition trials
111 are to be appropriately transcribed into health-related actions, it is critical that the results are
112 written up completely and transparently. This is also an important requirement for comparability
113 of trials and accumulation of findings for systematic reviews, which are crucial for health decision-
114 making and used in drafting of programme guidance and policy. There is evidence that points
115 towards poor reporting of nutrition research [3–6].

116

117 Reporting guidelines are widely used to improve quality and completeness of reporting research.
118 Previous efforts, organised as an extension of the STrengthening the Reporting of OBservational
119 studies in Epidemiology (STROBE) statement of nutritional epidemiology, have focused on the
120 reporting of dietary assessment and observational studies [3]. However, the CONSolidated
121 Standards Of Reporting Trials (CONSORT) statement [7, 8] for RCTs does not have an extension
122 specific to nutrition. CONSORT details the minimum requirements for reporting RCTs, with
123 additional guidance provided by the Template for Intervention Description and Reporting (TIDieR)
124 checklist [9]. It remains unclear, however, if additional guidance is necessary to improve

125 CONSORT adherence and the utility of CONSORT guidelines in nutrition trials, and consequently,
126 reporting quality of nutrition RCTs.

127

128 To this end and as part of the Improving Standards in the Science of Nutrition Initiative, the
129 Federation of European Nutrition Societies (FENS) led an effort to evaluate and identify key
130 elements of nutrition intervention trials which should be reported in a standardised way in order
131 to provide a more robust evidence base. The present opinion piece summarises the findings from
132 this consultation. It serves to initiate and inform further discussion on efforts to improve reporting
133 of nutrition trials and ultimately to contribute to a better evidence base in diet, nutritional status,
134 and health.

135

136 Methods

137

138 Responding to a call from FENS [10], a working group of nutrition experts was assembled and
139 enlarged by recruitment of international and geographically diverse experts to ensure that the
140 committee included a range of nutrition trial specialties and expertise and the local/national
141 context. The working group convened nutrition researchers from 14 institutions from 12 different
142 countries and five continents, including a representative from the American Society for Nutrition.
143 Members of the working group were invited through contacts of existing members, or via
144 identification as being a known expert in a trial methodology and in particular, nutrition intervention
145 (e.g., whole diet, supplement, eating behaviour, etc.) trials. Within the expertise of the working
146 group and calling on previous research around reproducibility, quality, and transparency of
147 nutrition trial reporting [11–15], we applied an iterative process to interrogate the 2010 CONSORT
148 guidelines as they relate to nutrition trials. This was achieved through a series of regular online
149 consultations over 12 months.

150

151 We reviewed the CONSORT items specifically as applied to all types of nutrition intervention trials
152 and where additional guidance for nutrition trials would be advantageous. Since the 25-item
153 CONSORT checklist provides basic elements to describe, this opinion piece sets out the findings
154 of the working group under the CONSORT framework, and proposes either enhancements to
155 existing CONSORT items, or clear items in addition. We define “nutrition trial” as an intervention
156 that include feeding studies that provide all foods and beverages to be consumed, or one that
157 provide single foods or supplements, dietary advice, and/or behavioural modifications, with or
158 without placebo or control in a nutrition or nutrition-related setting. The present considerations
159 hence apply to both primary trials and secondary analyses of such trials. Agreement was reached
160 on the main points. Additional considerations for diet-related trials beyond the standard
161 CONSORT checklist identified are elaborated upon with a summary for each section provided in
162 Boxes 1 to 5.

163

164 Results

165

166 1. Title

167 For nutrition trials, the title should include details of the food bioactives, food/food group, dietary
168 pattern or eating behaviour intervention. For interventions where it is implemented by food choice
169 guidance rather than the provision of foods or supplements or via a multi-domain eating behaviour
170 modification approach (see below) this should be obvious from the title. For example, if the trial
171 is investigating the impact of adopting the Mediterranean Dietary Pattern (MDP) on a health
172 outcome, and the intervention is food choice guidance or a more holistic eating behaviour
173 approaches (to provide individuals with the capability, opportunity, or motivation to adopt a MDP)
174 then this should be indicated in the title with phrases such as *MDP guidance*, *MDP dietary*
175 *intervention* or a *MDP eating behaviour intervention*.

176

177 Where nutritional status, dietary intake or eating behaviour is the primary outcome this should
178 also be clearly stated in the title, with information on the intervention targeting these also given.

179

180 Where possible, the type of dietary comparator should be described in the title, specifically “RCT”
181 for trials with a control group, “trial” where two intervention groups are used and “placebo-
182 controlled trial” where a placebo is used as comparator. Furthermore, the design of the trial should
183 be specified, e.g., cluster, cross-over, parallel, non-inferiority. Likewise, if the manuscript is
184 reporting a secondary RCT analysis, this should always be stated in the title.

185

186 2. Abstracts

187 Abstracts should be clear, transparent, and sufficiently detailed to be stand-alone, given that not
188 all health care, policy or commercial professional readers have access to the full papers with
189 decisions often made on the abstract, e.g., the decision to include RCTs in systematic reviews is
190 typically based initially on a title and abstract review. Though it is recognised that due to journal
191 abstract word limit, the addition of all the information relating to RCTs is not possible, the abstract
192 should include as much information as possible under the following standard headings: (i)
193 background: should specify the nutrition research question; (ii) Methods: should clearly present
194 the trial design, details of the intervention (detailed composition of the food / supplement / dietary
195 pattern / behaviour change; whether the intervention is a (isocaloric) replacement or add on
196 intervention), duration of the intervention, and how the intervention is delivered (supplements,
197 food, guidance, etc.), and any details on the (dietary) comparator or control group. Methods used
198 to assess dietary adherence should be given. The PICO (Population, Intervention, Comparator
199 and Outcome) criteria should be clearly identifiable; (iii) Results: Main findings (including dietary
200 adherence) based on intention-to-treat analysis with effect estimates and 95% CI or other
201 assessment of variance; (iv) Conclusion: General scientific interpretation of the results; (v)
202 Implementation, impact or relevance: In addition to the conclusion, an explicit statement on

203 implementation, impact or relevance, including to public health policy, is recommended. Although
204 a large amount of high-quality nutrition research is conducted, this is often not effectively
205 translated into policy and practice, such as improved population eating behaviour and nutrition
206 status, the availability of affordable, widely consumed food products with improved composition,
207 or effective therapeutic use of nutrition approaches in clinical medicine. Therefore, to enhance
208 translation of findings, it is recommended the authors conclude the abstract (and highlights
209 section of the paper if offered by the journal) with this summary on the impact, relevance, and
210 possible implementation approach to apply the findings.

211

212 3. Keywords

213 To enhance visibility of information in literature reviews keywords should include the bioactive
214 compound, food, (non) nutrient or dietary behaviour being tested, using the Medical Subject
215 Headings (MeSH) term with preference.

216

217 4. Introduction

218 Although CONSORT recommends that the introduction include scientific background and
219 explanation of rationale, reporting of the justification for undertaking nutrition trials is incomplete
220 if all of the points described below are not clear. The introduction should clearly describe the
221 nutrition research question and justification for undertaking the trial. This should include a
222 summary of relevant research with reflections on effect estimates, consistency of the evidence,
223 and its certainty [16]. This could be derived from previous well-conducted RCTs, high quality
224 systematic reviews of RCTs, interrupted time series analyses and/or observational studies (with
225 a focus, where available on prospective cohort data), and pre-clinical evidence (high-quality
226 animal, *in vitro*, *ex vivo*, and *in silico* studies). For preclinical evidence, the physiological relevance
227 to humans should be considered with a reflection on the human equivalent dose of the intervention
228 and its chemical form [17].

229

230 If relevant RCT findings are available, a statement should be provided as to their scope and
231 limitations to justify the need for further RCTs. If it is not obvious, a statement on the biological
232 plausibility [18] of the intervention and the likely behavioural, physiological, or molecular
233 mechanism underpinning the impact of intervention on the primary outcome measures should be
234 provided. The introduction should provide a justification for the length of the intervention, based
235 on the time-lag required to explore differences in change between intervention and control for
236 primary and key secondary outcomes, which will also inform study design. An intervention period
237 that is too short runs the risk of an underestimated treatment effect. Too long an intervention is
238 unethical as it misuses participants, research, and financial resources. For example, when looking
239 at the impact of supplementation with EPA+DHA on plasma triglyceride levels, an intervention
240 period of 4-6 weeks is sufficient to achieve maximal effect (20) high-quality, whereas the maximal
241 LDL-cholesterol lowering effect of a diet enriched with plant sterols is already visible within 1-2
242 weeks [19], with a cross-over study design optimal for such short intervention periods. However,
243 if focused on a more functional endpoint, e.g., the impact of DHA on cognitive function, when the
244 proposed mechanisms are dependent on enrichment of neuronal or glial cells with DHA, then an
245 intervention period of one year or more, with a parallel design, should be considered, given the
246 half-life of DHA in the brain is more than 2 years [20, 21].

247

248 Where relevant, the dietary intervention and comparator should be directly compared to current
249 dietary recommendations or food intake in the population of interest. Where appropriate a
250 discussion of any possible harm should also be included, particularly in vulnerable groups or in
251 combination with other lifestyle or phenotype characteristics, such as medication use or disease
252 status. Moreover, the studied population needs to be justified, i.e., including sex, age, morbidities
253 (e.g., type 2 diabetes), socioeconomic status, etc. In addition to the scientific background and

254 rationale, the introduction should refer to any health/food/nutrition policy priorities the proposed
255 research is addressing.

256

257 With the pleiotropic nature of food bioactives affecting multiple physiological processes, numerous
258 secondary outcomes are typically captured. For validity and transparency, the main objectives
259 and/or hypotheses of the research should be clearly stated at the end of the introduction.

260

261 Given the complexity of well conducted RCTs, their cost and the research-staff and participant
262 'burden' of completing the intervention, which may take several years to design, deliver, analyse,
263 and publish, the publication of manuscripts based on well-conducted secondary analyses is highly
264 encouraged. However, as with the primary analysis, such secondary analyses should be well
265 rationalised, with a clear indication given in the introduction (and throughout the paper) that the
266 RCT design is suitable to address the secondary research question.

267

268 Box 1: Proposed additions to CONSORT checklist for "Introduction" in manuscripts describing
269 diet-related and nutritional trials

- State the biological plausibility of the nutrition intervention and behavioural, physiological, or molecular mechanism underpinning the intervention impact on the primary outcome measures.
- Justify the length of nutrition intervention with respect to the primary outcome
- Provide contextualisation to current dietary recommendations or food intake in the population of interest. Justify the population chosen giving details. Ensure PICO criteria are clearly identifiable.

270

271

272 5. Methods

273 *Trial design*

274 Overall design. A figure to visually explain the intervention(s) and methods is often informative,
275 particularly if interventions are complex. CONSORT guidelines recommend a description of the
276 trial design (such as parallel, crossover, cluster, factorial) including the allocation ratio [22].
277 Extensions have expanded on how to report on specific RCT designs including non-
278 pharmacological treatments, multi-arm parallel groups, cluster, crossover, adaptive design,
279 routinely collected data, within-person, pilot and feasibility, non-inferiority and equivalence trials,
280 and using web-based and mobile health interventions [23–33]. Extensions for reporting
281 effectiveness trials in communities rather than efficacy trials in controlled settings have been
282 developed [34]. Diet-related trials can use any of these designs and should follow the relevant
283 reporting guidelines for describing them. Properly designed RCTs reduce trial contamination and
284 allow causal inference to be assessed. As pointed out by Lichtenstein et al. [2], the choice of the
285 design should align with the question being asked and be part of the trial protocol. If the paper is
286 a secondary analysis of an intervention, that should be made clear in the methods.

287

288 Length of intervention. An important aspect of the design for addressing efficacy (effect under
289 controlled conditions) or effectiveness (pragmatic effect under real world conditions) is the
290 duration of the intervention. The biological response of interest to an intervention may reach a
291 stable level following exposure to the intervention that could take hours, days, weeks, or even
292 years, which may also depend on the exposure dose, or the response may be progressive. For
293 example, serum 25(OH)D may peak within one day following a large, acute dose [35] or it may
294 reach a plateau after 4 or more weeks of chronic lower dose supplementation [36]. Different types
295 of dietary interventions may require different durations to see the entire effect for the same
296 outcome measure. For example, in a re-analysis of a four-week randomised controlled feeding
297 study to compare the effects of a Dietary Approaches to Stop Hypertension (DASH)-style diet

298 high in fruits, vegetables, and low-fat dairy with a typical Western diet higher in fat, especially
299 saturated fat, Juraschek et al. [37] found the DASH diet intervention lowered blood pressure after
300 the first week with no subsequent further decreases, whereas, low sodium diets did not yet reach
301 a plateau after 4 weeks, suggesting the full effects had not been achieved by 4 weeks.

302

303 Health outcomes. Health outcome measures for diet-related interventions are typically a specific
304 validated and reliable physiological, structural, functional, or biochemical measure used to
305 establish a causal link between the dietary intervention and the health outcome (e.g., macular
306 pigment optical density as an indicator of eye structure associated with normal visual function,
307 endothelium-dependent vasodilation related to healthy blood flow, bone mineral density as an
308 indicator of fracture risk, etc.). Intermediate biomarkers should be selected that are on the causal
309 pathway to disease. Changes in disease outcomes are difficult to achieve in diet-related
310 interventions because of the usual long latency to see an effect, but surrogate outcomes along
311 the causal pathway must be validated as described by Yates et al. [38]. Further, diet-related
312 interventions typically affect many systems which may have different responses for efficacy and
313 risk and at different doses.

314

315 Protocol modifications. Any important changes to the methods made after trial commencement
316 should be disclosed with justification and ethical approvals. For example, in a crossover RCT
317 evaluating the efficacy of dietary supplements for reducing bone loss in postmenopausal women
318 compared to a positive control, the option for choosing the positive control was altered mid-study
319 [39]. The originally approved positive control was oestradiol plus progesterone, but during the trial
320 the results of the Women's Health Initiative hormone trial were released which led to large-scale
321 withdrawal of hormone replacement therapy in clinical practice. The investigators received
322 approval to offer a bisphosphonate positive control instead of oestrogen and reported the change
323 as "Subjects were initially offered oestradiol plus medroxyprogesterone as the positive control,

324 but after publicity surrounding the premature termination of the Women's Health Initiative
325 hormone trial, a bisphosphonate was offered instead."

326

327 *Participants*

328 The CONSORT checklist includes describing eligibility criteria for participants [8], but provides
329 little more guidance. The population selected for study should align with the aims of the study. If
330 the population may benefit from the intervention or if maximal efficacy of the intervention is of
331 interest, the population to be studied may reflect a relatively homogenous and specific group. The
332 broader the inclusion of the population, the more generalizable the results which may be desirable
333 for public health recommendations compared to guidelines for treating patients. There is recent
334 attention on including pregnant women in trials as well as underrepresented minorities. Studies
335 with more generalizable results using a heterogeneous population come with the disadvantages
336 of higher cost and effort as power to see an effect is reduced [2].

337

338 Eligibility criteria for diet-related interventions should include baseline nutritional consumption or
339 status of components relating to the intervention that would influence the outcomes of interest,
340 which should be reported This may include an objective biological assessment related to the
341 intervention (e.g., serum ferritin for iron, serum 25(OH)D for vitamin D; red blood cell
342 docosahexaenoic acid (DHA) for DHA intake, serum or urine metabolite specific to intake of a
343 certain food or class of foods), or if no good biomarker of exposure exists which is the case for
344 many nutrients, related characteristics, food and nutrient intakes or functional biomarkers may be
345 useful, e.g., anthropometrics, clinical measures, dietary/nutrient/bioactive intake assessment.
346 Statements to show whether exposure measurements are valid should be included. For example,
347 in relation to iron, clinical measures such haemoglobin levels or dietary intakes of haem and non-
348 haem iron related to iron status should be in the population under study. Consideration should be
349 given to potential confounders of exposure; in the case of iron this could be other dietary factors

350 which enhance or inhibit absorption. Also, the presence of metabolic conditions, such as for the
351 iron example, haemochromatosis, which could affect status need to be assessed. Clear
352 statements of methods used to assess the nutritional exposure are required with a justification of
353 method selection.

354

355 Assessing background nutritional exposure or status is an important factor in nutrition trials, that
356 often is not considered to be a factor in other types of trials, including those outside of the nutrition
357 field. This is important because baseline status for a given nutrient(s), can affect the response or
358 nutritional status related to the intervention being investigated. People must consume essential
359 nutrients; therefore, there is rarely a zero-background starting status as there is for an intervention
360 of a xenobiotic that is absent prior to the trial. In fact, it is unethical to chronically deplete humans
361 of an essential nutrient to determine a functional deficiency [40], making the use of placebo
362 difficult. Moreover, standard of care has differing definitions. If the intervention has a dose
363 threshold for an effect and the background status of the population being studied exceeds that
364 threshold, benefits are unlikely and erroneous conclusions about the relationship of diet and
365 physiological response may occur. This should be considered in the inclusion/exclusion criteria.
366 This occurred in the Women's Health Initiative calcium and vitamin D trial where average status
367 of calcium intake and serum 25(OH)D were approximately the recommended levels of these
368 nutrients. When data were re-analysed to exclude participants who were taking their own calcium
369 and vitamin D supplements and were compliant with the intervention, calcium and vitamin D
370 supplementation resulted in a clinically meaningful reduction in hip fracture [41]. Too often, studies
371 are conducted without assessing baseline status or the threshold status is unknown. Nutrient
372 recommendations based on dose-response studies with a physiological outcome such as
373 maximal retention have been conducted for calcium [42, 43], but for very few other nutrients. If a
374 food allergy or avoidance is an exclusion criterion, this should be disclosed. When relevant,

375 disclosure of the training or characteristics (vegan, clinical, etc.) of those delivering the
376 intervention should be disclosed.

377

378 *Settings and locations*

379 The CONSORT checklist includes settings and locations where the data were collected [8]. The
380 study settings that might influence the intervention for diet-related studies that should be given
381 further consideration include supervised, or free-living settings and their implementation (clinical
382 or population-based settings). Setting and location are essential information to assess potential
383 bias arising from the randomisation process in nutrition assessment. The STROBE-nut guidance
384 document contains specific recommendations to report characteristics of the participants or
385 contextual variables (season, festivities) that may influence the validity of the dietary recall [3].

386

387 *Intervention*

388 CONSORT recommends that interventions for each group be described in sufficient detail to allow
389 replication, including how and when they were actually administered [8]. Nutrition related
390 interventions and RCTs in which interventions are influenced by nutritional status or co-ingested
391 nutrients or food patterns require comprehensive documentation and reporting to interpret causal
392 relations and to support food guidance. Nutrition interventions can include feeding studies,
393 providing all foods and beverages to be consumed or those that provide single foods or
394 supplements, dietary guidance, or behavioural modifications. The intervention for diet-related
395 studies should be rigorously monitored and reported. The TiDieR checklist can be used to guide
396 elements to include about an intervention for better replication on why, what, who provided, how,
397 where, when and how much, tailoring, and modifications [9], but it is not specific to nutrition. Not
398 only should sufficient details of the intervention be described to be able to reproduce the study,
399 but validation of the presence of the active constituents and validation of its stability throughout
400 the course of the intervention should be determined and reported, and where possible, verification

401 of consumption. Whether foods were manufactured commercially or were developed for research
402 purposes should be noted. Details of food preparation, cooking, and storage conditions as well
403 guidance as to when throughout the day, with or without food, the intervention should be
404 consumed, as these variables may affect the composition/biological activity of the intervention
405 should be reported as relevant.

406

407 If the intervention is given via dietary advice, diet assessment is needed to provide relevant
408 context for interpreting the effect of the intervention on outcome variables, the methods used, and
409 their validation need to be described. For example, if dietary counselling is used, fidelity measures
410 to ensure the consistency of delivery of the intervention should be included. Determination of diet
411 composition should be described when assessments are used to determine intake. Further
412 information on documentation and reporting of diet-related interventions can be found in Weaver
413 et al. [12] and Health Canada [44].

414

415 Assessing and reporting on dietary adherence to the intervention has some unique opportunities
416 and challenges in diet-related trials. Assessment of dietary adherence in nutrition trials using food
417 supplement(s) may not differ substantially from drug trials. Objective biochemical assessment of
418 exposure of an intervention with a known bioactive component or related biomarker may be
419 feasible. In contrast, human diets are complex with well characterised difficulties with self-
420 reporting if not provided in a controlled setting. Best practices for diet assessment and reporting
421 were given by Kirkpatrick et al. [45].

422

423 A particular challenge in diet-related interventions is the comparator which often requires as much
424 thought and detailed explanation as the intended intervention. This is especially true of
425 manipulation of macronutrients or whole diet interventions. If the level of a macronutrient such as
426 fat is being altered, the replacement (control) may have unexpected effects on the health

427 outcomes being measured. Such contamination has led to confusion. One recent example is the
428 debate over whether saturated fatty acids *per se* are associated with increased risk of markers of
429 cardiovascular disease, or whether it is their replacement with polyunsaturated fats in the
430 comparator groups of trials that is responsible for the observed cardiovascular benefits [46–49].
431 Replacement foods that are thought to be neutral in their effect on the outcome measure being
432 studied have also come under scrutiny. For example, an apple was given as the control to a plum
433 intervention for arresting bone loss in postmenopausal women [50], but subsequently, the apple
434 comparator was found to contain polyphenolic compounds that also benefited bone composition.
435

436 An example of documenting a whole blueberry freeze-dried powder intervention is described by
437 Weaver and Hodges [51]. This paper discusses many elements for reporting nutrition trials using
438 food bioactives, including description of the intervention, monitoring stability of the polyphenol
439 bioactives, monitoring compliance through serum polyphenol metabolite biomarkers, and safety
440 considerations.

441
442 Full reporting on the intervention may also include ethical and cultural acceptability of the
443 product(s) being tested or used as controls. Authors should disclose any ingredients that might
444 be prohibited for consumption for religious or cultural reasons, which therefore might introduce
445 bias.

446
447 *Outcomes*

448 Nutrition trials need to report primary and secondary outcomes transparently. The selection of
449 outcome needs to be clearly justified with a research hypothesis that provides a clear added value
450 to science and/or society. Nutrition trials, however, are typically complex interventions, which
451 present some specific challenges with regard to the multiplicity of tests and inflation of false
452 negative findings [52], and risk of bias should be considered [53]. Specific attention is hence

453 required to indicate which outcomes are defined a priori, well-powered, and based on a robust
454 hypothesis, and any other outcomes that are secondary and for which the assessment is rather
455 exploratory. Outcomes should be adequately defined, described as “objective” (e.g., mortality) or
456 “subjective” (e.g., quality of life), and reported at pre-specified timepoints. When reporting
457 secondary analyses, a *post-hoc* power calculation should be included.

458

459 *Randomisation*

460 The CONSORT checklist requires details on the method used to generate the random allocation
461 sequence and the type of randomization including restrictions. For nutrition trials, baseline nutrient
462 status should be considered as a basis for randomization when relevant (e.g., when sample size
463 is small), and risk of bias arising from randomisation, and in particular, allocation concealment,
464 should be considered [53].

465

466 *Blinding*

467 The CONSORT checklist requires details on who was blinded and how, and whether the trial was
468 single, double, or triple blinded should be clearly described [8]. Measures undertaken to reduce
469 risk of bias such as concealed allocation strategies should be provided, including any measure
470 taken in the case of deviations from intended interventions (e.g., blinding of participants, carers
471 and people delivering the interventions, using appropriate analysis to estimate the effect of
472 assignment to intervention) [53].

473

474 Blinding can be particularly challenging in diet-related trials, however. With interventions involving
475 dietary supplements, the placebo may be well matched to the intervention, but not if commercially
476 available dietary supplements with different packaging are being compared, as was the case with
477 different sources of plant isoflavones [39]. Blinding of manipulations of diet or foods may be
478 especially difficult because of their appearance, taste, smell, and texture. The participant may not

479 be able to see a difference in salt level if that is the only variable, but they can taste the difference
480 between high and low salt levels. Weaver and Hodges [51] describe the problems with blinding
481 of intensely coloured products. Even when the intervention or comparator cannot be blinded from
482 the participants or those who deliver the intervention, the staff who perform testing and the
483 analyses can be blinded, and this should be described. This may be particularly true for
484 measurements that are vulnerable to observer bias such as cognitive testing or even to decide
485 which pixels to include on an image.

486

487 *Statistical Methods*

488 Guidelines for developing an *a priori* statistical analysis plan specific to diet-related trials were
489 recently reported [54]. The statistical analysis plan should be finalised before unblinded outcome
490 data become available for analysis. The design and adjustments should match the appropriate
491 analyses, and also consider measurement error. Measurement error is always a consideration in
492 nutrition-related trials in relation to exposure or outcome measures; statistical techniques can be
493 used to reduce the impact of this error [55]. The primary analysis should be based on the intention-
494 to-treat principle. Compliance cut offs for per protocol analyses should be reported and defined
495 a-priori. Methods for additional analyses such as the statistical method used to combine dietary
496 or nutritional data, intake modelling, use of weighting factors should be identified and justified.
497 Stratifications and adjustments as relevant should be described. Considerations of per protocol
498 compared to intention to treat analysis and baseline nutritional status are especially important in
499 diet related trials.

500

501 A particular challenge in nutrition research is to consider the independent effect of specific
502 nutrients on disease outcomes. As nutrient intake can be associated with increased energy intake,
503 adjustment for energy intake can be essential. There are various methods to make statistical
504 adjustments and the statistical section needs to justify and report the method used [56].

505

506 In addition, description of the analysis should contain specific detail on participants that were
507 excluded based on possible misreporting. Discuss potential effects on study power and report
508 any data imputation or sensitivity analysis to assess potential bias of such exclusion on the
509 findings.

510

511 Finally, methods for secondary analyses should not just refer to the primary paper when
512 describing methods, rather include a brief summary of the key points of the methods in addition.

513

514 Box 2: Proposed additions to CONSORT checklist for “Methods” in manuscripts describing diet-
515 related and nutritional trials

- The trial design should align with the scientific question being addressed
- Duration of the trial should be appropriate for the primary and key secondary nutritional sensitive outcomes
- Potential contaminations should be measured, including baseline nutritional status (especially for the nutrient, bioactive, diet being tested to determine if participants are already adequate) and factors that could influence nutrition trial outcomes (habitual diet, season, physical activity, knowledge of participants and interventionists, especially for education interventions), carry-over effects in crossover trials
- Target populations- efficacy vs effectiveness, clinical vs healthy population, specify particular dietary, physiological or nutritional characteristics targeted. List eligibility criteria related to baseline nutritional status (anthropometric, biochemical, clinical, diet, food allergies)

- Dietary comparators should be well described, including details if isocaloric or not, as applicable.
- Dietary adherence assessment should be clear
- Details of the diet-related intervention should be given. If given, how was it prepared, stored, checked for bioactive constituent(s), evaluated for storage stability, and biological exposure monitored? For behavioural interventions, describe the protocol that includes how it was developed and administered and by whom and when. Description of assessment of background diets is needed as relevant.
- Randomization based on nutrient intake or status (especially important in small trials) and allocation concealment should be described
- Describe any limits to blinding and who was blinded (participants, staff who delivered the intervention, analytical staff), as well as details of concealed allocation
- An a priori statistical analysis plan that aligns with the study design should be described, and primary analysis should be based on intention-to-treat, with per-protocol analysis described in addition where relevant.
- Comparisons between intention-to-treat and per protocol analysis should be considered. Additionally, per protocol compliance cut-offs should be reported, including possible exclusion criteria for misreporting
- Identify and justify data analysis choice (e.g., statistical method used to combine dietary or nutritional data, energy adjustments, intake modelling, use of weighting factors). Define stratifications and adjustments.

517 6. Results

518 Transparent, accurate and complete reporting of results is critical if data are to be considered for
519 further use, be it in research, inclusion in systematic reviews, or to influence health policy.
520 CONSORT guidelines provide a rigorous framework, including a strong recommendation for
521 inclusion of a flow diagram to document the number of participants included and who finished the
522 trial with completeness. Such flow diagrams are now considered as standard practice also in
523 nutrition trials, though they are rarely included in those reported earlier than 2010. For example,
524 the reputed DASH trial [57], published in 2001 may have benefited from inclusion of a flow
525 diagram. Though the authors describe the number and percent of participants completing the
526 study in each arm and specify that withdrawals were similar between groups, they do not
527 elaborate on reasons for withdrawal, which is particularly relevant in nutrition trials evaluating
528 different dietary interventions, to inform on acceptability of these interventions. Flow diagrams
529 may be integrated with information on study design and flow, as presented by Jongstra et al. [58],
530 who provide clear detail on ineligibility or withdrawal between screening and baseline, and then
531 reasons for non-completion between enrolment and endpoint.

532

533 Additional detail on the flow diagram relative to nutrition trials should specify the actual
534 interventions (i.e., treatment(s) and comparator(s)) as they were implemented, especially if
535 differing from the described methods. Numbers of and reasons for losses and exclusions (e.g.,
536 missing, incomplete or implausible dietary/nutritional data) should be additionally present. Authors
537 should include dates defining recruitment periods and any follow-up periods as applicable and
538 specify if the trial ended as planned or was stopped early, providing reasons, particularly if loss
539 of participants was due to intervention-related reasons such as adverse reactions to the
540 intervention such as intolerability, or lack of adherence e.g., too strong restriction (unrealistic) of
541 carbohydrate intake with very low carbohydrate diets. Details of results of adherence monitoring,

542 such as collection of supplement containers at points during the intervention period, should be
543 clearly described.

544

545 The CONSORT guidelines stipulate inclusion of a table showing baseline demographic and
546 clinical characteristics for each group. In particular, nutrition trials should provide details of where
547 baseline differences between intervention and/or control groups may be relevant to defining the
548 nutritional status or response to dietary intervention. This may be particularly relevant in small or
549 underpowered trials e.g., pilot trials.

550

551 The baseline characteristics table should, as a minimum, include an assessment of variability
552 (e.g., standard deviation, 95% CI, interquartile range), measures of status and/or recent or long-
553 term intake of the food or bioactive of interest. Measures of status may also include proxy
554 measures for nutrient intake, particularly if being used as a primary or secondary outcome
555 measure. Examples might include stunting prevalence alongside serum zinc assessment [59] or
556 household uptake of iodized salt alongside urinary iodine concentration [60]. Furthermore, though
557 most trials seek to eliminate contamination bias, the uptake of any permitted dietary habits, in
558 particular the use of nutritional supplements beyond that in the intervention, should be clearly
559 recorded. Where applicable, medication use should also be considered. For example, if subjects
560 are using statins and the trial seeks to examine the effect of diet on vascular function.

561

562 As with any trial, outcomes reported in the results should match the methods, and be strictly based
563 on intention-to-treat analysis. It is common in systematic reviews to detect bias in selection of the
564 reported result, which may lead to the over- or underestimation of treatment effects or harms [61].

565 For outcomes and estimation, reports of nutritional trials should provide details about whether
566 measurement or ascertainment of the outcome differed between intervention groups. Further, if
567 Bayesian analyses were performed, 'credibility intervals' should be reported. This is in addition to

568 existing CONSORT recommendations for outcomes and estimation, which state that for each
569 primary and secondary outcome, results for each group, and the estimated effect size and its
570 precision (e.g., 95% CI), are given, as well as presentation of both absolute and relative effect
571 sizes for binary outcomes.

572

573 An important consideration for nutrition trials in addition to response to the intervention, is
574 reporting of adherence. Although some level of detail may be included in the flow diagram, a
575 specific discussion on dietary adherence is desirable, to understand how participants could
576 adhere to the intervention, which in turn, can indicate acceptability, feasibility, and possible entry
577 points for error. In a systematic review, Kehoe and colleagues [62] assessed the adequacy of
578 reporting of participant adherence in RCTs investigating the effect of maternal nutritional
579 supplements on infant outcomes. Out of 58 included RCTs, almost a third did not describe how
580 participant adherence was assessed. Nearly half of the papers failed to report participant
581 adherence numerically and differences in adherence data between treatment arms were not
582 reported in 52% of publications. Soofi et al. [63] in their assessment of micronutrient powders with
583 and without zinc on several primary outcomes including growth, diarrhoeal episodes and
584 respiratory morbidity, report mean consumption of micronutrient powder sachets per group, but
585 do not elaborate if data were collected on reasons why compliance was approximately half the
586 intended dose (mean of about 16 sachets per month per group, for a daily dose intervention).

587

588 Where additional ancillary analyses, such as per-protocol, as-treated, sensitivity, subgroup and
589 adjusted analyses are included, these should be distinguished as being pre-specified (and should
590 thus match the methods) or exploratory. In addition to these CONSORT recommendations,
591 nutrition trial reports should, in particular, document any interaction terms, sensitivity analysis
592 (e.g., exclusion of under/over reporters or outliers) and data imputation, if applicable.

593

594 Finally, all unintended effects, and/or adverse outcomes beyond the incidental events that are
595 unlikely to be associated with the intervention and possible with normal food and beverage intake,
596 e.g., choking, minor gastrointestinal disturbances, gagging, vomiting, etc., in each group should
597 be described.

598

599 Box 3: Proposed additions to CONSORT checklist for “Results” in manuscripts describing diet-
600 related and nutritional trials

- Consistent use of CONSORT flow chart, including, where relevant, detail on interventions as administered, especially if different to the protocol/methods, and detail on loss to follow up due to intervention-related reasons e.g., adverse reactions to the intervention, lack of adherence, etc.
- Tabulate baseline demographic and clinical characteristics per group, highlighting nutritionally relevant differences between intervention and/or control groups and stating the participant N included in per protocol/intention to treat analyses.
- Present primary outcomes first, then secondary outcomes per trial registration, and details on whether outcomes differed between groups. If Bayesian analyses were performed, present credibility intervals in addition to usual CONSORT reporting. Results should be based on intention-to-treat analyses.
- Declare ancillary analyses as pre-specified or exploratory, reporting interaction terms, sensitivity analyses and data imputation where relevant.
- For each group, report all unintended or adverse events/outcomes beyond incidental events unlikely to be associated with normal food and beverage intake.

601

602

603 7. Discussion

604 As per general recommendations for the reporting of trials, limitations of the study, generalizability
605 of the findings and interpretation are key sections of the discussion section of nutrition trials.

606

607 The discussion should clearly state the main findings of the paper, using intention-to-treat
608 principles [53], with per protocol interpretations given in addition, depending on the objective of
609 the study, e.g., if the trial outcome was to assess the effect of adhering to the intervention. The
610 discussion should also put findings clearly into context with the research objectives and
611 differentiate these clearly from findings from ancillary analysis. A discussion of fidelity of the
612 intervention should follow, i.e., if the intervention as intended was feasible and/or adhered to with
613 a discussion of the solutions where this was not possible. Dietary adherence is also essential to
614 understand in nutrition studies, and authors should describe if an adherence assessment was
615 conducted and include an evaluation of its adequacy. Also included here should be a discussion
616 on how many participants were lost due to poor adherence, and how this affects statistical
617 analyses.

618

619 Common limitations such as potential sources of bias e.g., selection bias based on uneven
620 distribution of prognostic factors such as nutritional status, data sources or assessment methods,
621 imprecision, and multiple testing, can also affect nutrition trials. Of particular concern for nutrition
622 trials, however, is the potential bias due to lack of (or partial) blinding and quality control of the
623 intervention, including the assessment of adherence, the active constituent(s) of the intervention
624 and its stability/feasibility over time, interaction with food matrix and diet, duration of intervention.
625 Potentially false discoveries due to the type of adjustments used in statistical analysis need to be
626 acknowledged, as well as a consideration of the likely impact of habitual intake or nutrition status
627 of the participants on the response to the intervention.

628

629 Authors should discuss the generalizability of the findings, considering the background diet of the
630 participants, the likely variations in nutrition in other populations and the comparator used in the
631 control group. Authors need to describe to the reader if the findings apply to the general population
632 or to specific groups. A clear separation needs to be made between research findings from
633 efficacy or effectiveness studies when inferring implications of the study findings on nutrition or
634 health benefits of other populations.

635

636 Finally, the interpretation of the findings is a key concern. A clear separation needs to be made
637 between statistical and findings of clinical significance as they refer to clinical/biological or health
638 effects, e.g., a reduction in systolic blood pressure of 10 mmHg, and including both relative (risk
639 ratio) and also absolute effects (x cases per /1000) for binary outcomes. Interpretation of effects
640 in general needs to consider the precision of the assessment of the outcomes and whether the
641 effects are clinically meaningful from an individual or population perspective. For example, a small
642 risk ratio (RR, 0.95) can have a considerable absolute effect for a common disease (e.g., type 2
643 diabetes) at population level. Furthermore, a distinction should be made between whether the
644 effect is from the intervention itself or food or supplement use during the intervention period. The
645 manuscript should discuss how the findings affect clinical practice, dietary guidance, or public
646 health recommendations. Further discussion of the findings should consider how nutritional
647 interventions can be achieved in practice considering dietary habits, culture, socio-economic
648 barriers, and concerns regarding environmental footprints. The feasibility of implementing the
649 intervention in different settings should be discussed, deliberating on how each of the afore-
650 mentioned factors can affect adherence.

651

652 Box 4: Proposed additions to CONSORT checklist for “Discussion” in manuscripts describing diet-
653 related and nutritional trials

- Cover generalizability of the findings, interpretation, and limitations of the study clearly in key sections of the discussion.
- State the main findings of the paper, using intention-to-treat principles, with per protocol interpretations given in addition, depending on the objective of the study. Provide a clear differentiation for these findings from ancillary analyses.
- Discuss the choice of comparator, including whether isocaloric exchange was used or not, and any bias introduced.
- Discuss any assessment of dietary adherence.
- Discuss any relevant aspects on the active constituent of the intervention as revealed by the trial.
- Describe any potentially false discoveries due to any adjustments used in statistical analyses.
- Clearly discuss generalizability with consideration to background diet and any variation in other populations, ensuring a differentiation between efficacy and effectiveness.
- Distinguish clearly between statistical and clinically relevant findings, with detailed interpretation on how the findings affect clinical practice, dietary guidance, or public health recommendations, as relevant.

654

655 8. Other information

656 CONSORT guidelines refer to trial and protocol registration and declaration of sources of funding.

657 The conflict of interest statement may require additional detail for nutrition trials. Rowe et al. [64]

658 previously summarised the challenges and good practices to carry out research funded by the

659 private sector and food industry, in particular. The International Committee of Medical Journal
660 Editors (ICJME), as well as many nutrition journals to date, provide instructions on how to identify
661 and report conflicts of interest. Despite this, however, there are concerns and emerging evidence
662 that findings of nutrition trials are affected by the funding source [65, 66]. It is essential that authors
663 ensure transparency in sources of funding (including provision of resources such as food or food
664 products for the trial) and potential sources of conflict. This will facilitate correct interpretation of
665 findings, synthesis of evidence and overall transparency in reporting research.

666

667 There might be additional personal factors relating to the researchers (e.g., food preferences,
668 restrictions,) that could induce confirmation bias and affect research findings. Authors should
669 consider disclosing these and any other conflicts of interest that are considered essential for
670 external readers to assess the study findings and determine potential bias.

671

672 Availability of study material is an essential aspect of reporting completeness for nutrition trials.
673 In addition to CONSORT recommendation to share study protocol however, there is increasing
674 attention to make other research products available i.e., questionnaires, standard operating
675 procedures (SOP), statistical analysis plans, syntax for data manipulation and analysis, and
676 (meta)data. Most journals have clear instructions and policies on availability of data, including
677 provisions to handle data on a sensitive patient level. Repositories such as Github
678 FAIRSHARING, the Open Science Framework (OSF) are at hand to enhance Findability,
679 Accessibility, Interoperability and Re-use of resources from nutrition trials.

680

681 Box 5: Proposed additions to CONSORT checklist for “Other Information” in manuscripts
682 describing diet-related and nutritional trials

- Include additional details in the conflict of interest statement where relevant.

- Where possible, make research products such as questionnaires, standard operating procedures, data syntax and metadata available.

683

684 Discussion

685

686 We propose important considerations that need to be addressed when assessing the
687 CONSORT checklist to improve the rigour of reporting nutrition RCTs. The exercise illustrates
688 the relevance and potential value of a nutrition extension to CONSORT and illustrates the extent
689 of gaps in reporting for reproducibility and interpretation of results. In a second step, we will
690 obtain peer feedback on our findings from the nutrition community and relevant stakeholders via
691 (i) a workshop for attendees at the International Union of Nutritional Sciences (IUNS)
692 conference 2022, (ii) an online forum to capture comments on this manuscript, and (iii) feedback
693 from editors of targeted nutrition-related journals.

694

695 Further work remains to draft, test and propose authoritative reporting guidance. To date, the
696 Enhancing the QUALity and Transparency Of health Research (EQUATOR) network hosts
697 hundreds of guidelines to facilitate reporting of research findings. A programme, Securing
698 Transparency And Reproducibility in studies of NUTritional interventions (STAR-NUT), is
699 implemented to consolidate reporting standards for randomised controlled trials and systematic
700 reviews of nutritional interventions [67]. STAR-nut involves a comprehensive review of literature
701 and consultation of stakeholders including journal editors to determine what guidance for nutrition
702 trials is most appropriate, which will provide further input for drafting potential future guidelines.

703

704 It is important that care is taken to ensure consistency among reporting guidelines. The FENS
705 working group maintains close contact with EQUATOR, the STAR-NUT study team, and the
706 STROBE-nut development group to ensure a consistent message is presented. Care should

707 equally be taken to incorporate revised versions of CONSORT and SPIRIT, for which guidance
708 is presently updated and consolidated [68]. To further improve and increase adoption of the final
709 guidelines, we encourage readers to engage in this process, provide comments and conduct
710 specific studies to inform further work on the development of reporting guidelines for nutrition
711 trials.

712

713 Conclusion

714

715 We identify the need to develop guidance for the reporting of nutrition trials to increase
716 consistency and transparency in reporting, the overall quality of the conduct of trials, and
717 ultimately the evidence base in diet nutritional status and health. Using CONSORT as a
718 framework, we report here the first output of this iterative process to develop such guidelines for
719 the nutrition community. The FENS working group acknowledges the challenges to reporting of
720 other nutrition research findings including policy interventions for nutrition-sensitive interventions
721 that are, in essence, not specifically focused on nutrition but have a large potential to improve
722 nutrition and diets of populations [69]. Nevertheless, as a discipline and in terms of research
723 integrity, it is very important that the nutrition field embraces robust and consistent reporting of
724 dietary studies and nutrition trials.

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