



Strengthening the Evidence in Exercise Sciences Initiative (SEES Initiative)

Assessment Report for Individual Study

Study title

The "11 for Health in Denmark" intervention in 10- to 12-year-old Danish girls and boys and its effects on well-being-A large-scale cluster RCT

PMID

32353906

Journal

Scand J Med Sci Sports

Type of Publication and Period of assessment

Randomized Clinical Trials, SEES Pack 4

Note: The COVID-19 pandemics we are going through is very challenging and totally unprecedented. However, through it we can see that science conducted in an open, transparent and reproducible way is more than an ideal, it is a necessity. In this sense, we decided to keep our activities. However, we emphasize this evaluation was possibly not reviewed/questioned by the article authors due to the moment we are all going through. Thank you for your time and consideration.
SEES Initiative team.

Component	Item	SEES assessment
Transparency	Registration: Is the study registered in a clinical trial database?	No
Transparency	Protocol: Is there referral of a publicly available methodological protocol?	No
Completeness	Title: Is the study identified as a randomized?	Yes
Intervention	Abstract: Does the abstract list the study interventions?	Yes
Outcome	Abstract: Does the abstract inform the primary outcome (variable of interest)?	Yes
Outcome	Abstract: If any quantitative result is reported, is it accompanied by the respective precision estimate (e.g., standard deviation, confidence intervals, etc)?	Yes
Completeness	Intro/Methods-TID2: Is there a rationale, theory, or goals described to present the essential elements of the intervention?	Yes
Critical appraisal	Introduction: Is there a hypothesis stated for the outcome(s) of interest? (Note: if there is not a directional hypothesis, but there is explanation for an exploratory approach, answer "Does not apply")	Yes
Completeness	Introduction: Is there a description of specific objectives?	Yes
Completeness	Methods: Is there a description for the trial design (e.g., parallel, factorial, cluster)?	Yes
Participants	Methods: Is there a detailed description of eligibility criteria for participants? (i.e., information that would allow to replicate the inclusion and exclusion decisions)	No
Outcome	Methods: Are primary and secondary outcomes listed?	Yes
Outcome	Methods: Are outcome measurements specified?	Yes
Methodological rigor	Methods: Is the type of randomization sufficiently described? (Note: (i) type, such as computer; (ii) allocation ratio; and (iii) methods of restriction (if any) such as stratification or blocking should be considered)	Partially yes
Methodological rigor	Methods: Is there a mention regarding the mechanism for allocation concealment?	No
Methodological rigor	Methods: Is there a description of blinding/masking for measurements or analysis of outcomes?	No
Methodological rigor	Methods: Is there a description of sample size calculation?	No
Completeness	Methods/Intro-TID1: Is there a brief name or a phrase that describes the intervention?	Yes
Intervention	Methods-TID3: Is there a description of physical and information materials used as part of the intervention? (i.e., information that would allow to replicate the intervention with materials for participants or intervention providers)	Yes
Intervention	Methods-TID4: Is there a description of activities or procedures used to carry out the intervention? (i.e., information that would allow to replicate the necessary steps to run the intervention)	Yes
Intervention	Methods-TID5: Is there a description of individuals involved in providing the intervention? (i.e., information that would allow to replicate the necessary workforce to run the intervention)	Yes

Intervention	Methods-TID6: Is there a description of modes of delivery of the intervention? (i.e., information that would allow to replicate the delivery to run the intervention, such as face-to-face, telephone, individually or in a group)	Yes
Intervention	Methods-TID7: Is there a description of location(s) where the intervention occurred? (Note: infrastructure and relevant features should be considered)	Yes
Intervention	Methods/Results-TID8: Is there a description regarding the period, amount, intensity and schedule of delivery? (i.e., information that would allow to replicate 'when' and 'how much')	Yes
Intervention	Methods/Results-TID9: If any form of individual tailoring for the intervention was used (such as, variable exercise intensity), is there a description for the rationale and guide for tailoring?	No
Intervention	Methods/Results-TID11: Is there a description of materials/strategies used in regard to intervention adherence?	No
Intervention	Methods/Results-TID12: Is there a description of results of intervention adherence? (i.e., attrition rates)?	No
Critical appraisal	Methods: Is there a description of statistical methods used to compare outcomes between groups? (i.e., at least for primary outcome)	Yes
Participants	Results: Is there a participant flow (in text or diagram) reporting the numbers of participants who were assigned, received intervention, and were analyzed for the primary outcome?	No
Completeness	Results: Is there a description regarding the dates/periods of recruitment? (Note: if the follow-up has a variable length, the min-median-max durations should be considered)	Yes
Outcome	Results: Is there a table showing baseline demographic and clinical characteristics for each group?	Yes
Outcome	Results: Is there a description on the actual number of participants analyzed? (Note: if numbers are reported only for the primary outcome, we choose "Yes")	No
Outcome	Results: Are the effect sizes described along with their precision measures? (e.g., continuous outcomes with standard deviation and binary outcomes with risk measures and absolute numbers)	Yes
Intervention	Results: Is there a description for harm outcomes or adverse events? (Note: whether related or unrelated to interventions)	No
Critical appraisal	Discussion: Is there a discussion of potential bias, imprecision, multiplicity of analyses or other limitations?	Yes
Critical appraisal	Discussion: Is there a potential spin bias based on a specific reporting strategy to highlight that the experimental treatment is beneficial?	No
Transparency	Is there a statement regarding the data availability (data sharing plan)?	No
Completeness	Is there a statement regarding the sources of funding?	Yes
Completeness	Did the trial authors declare whether they had any conflicts of interest (COI)?	Yes