Strengthening the Evidence in Exercise Sciences Initiative (SEES Initiative)

Assessment Report for Individual Study

Study title

Effect of a Behavioral Intervention Strategy on Sustained Change in Physical Activity and Sedentary Behavior in Patients With Type 2 Diabetes: The IDES_2 Randomized Clinical Trial

PMID

30835309

Journal

JAMA

Type of Publication and Period of assessment

Randomized Clinical Trials, SEES Pack 3

Component	Item	SEES assessment
Transparency	Registration: Is the study registered in a clinical trial database?	Yes
Transparency	Protocol: Is there referral of a publicly available methodological protocol?	Yes
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 outcomes of interest? (Note: if there is not a directional hypothesis, but there is explanation for an exploratory approach, answer "Yes")	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)	Yes
Outcome	Methods: Are primary and secondary outcomes listed as well as their 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)	Yes
Methodological rigor	Methods: Is there a mention regarding the mechanism for allocation concealment?	Yes
Methodological rigor	Methods: Is there a description of blinding/masking for measurements or analysis of outcomes?	Yes
Methodological rigor	Methods: Is there a description of sample size calculation?	Yes
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
Participants	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, telefone, 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?	Yes
Intervention	Methods/Results-TID11: Is there a description of materials/strategies used in regard to intervention adherence?	Yes

Intervention	Methods/Results-TID12: Is there a description of results of intervention adherence? (i.e., attrition rates)?	Yes
Critical appraisal	Methods: Is there a description of statistical methods used to compare groups for primary and secondary outcomes?	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?	Yes
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: Are baseline data for each group presented?	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")	Yes
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-TID10: Is there a description for non-planned modifications to the intervention during the course of the study? (Note: regards to the study level, and what-why-when for changes should be considered).	Does not apply
Intervention	Results: Is there a description for harm outcomes or adverse events? (Note: whether related or unrelated to interventions)	Yes
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)?	Yes
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, authors declare financial COIs