



STRENGTHENING THE EVIDENCE IN EXERCISE SCIENCES

The SEES Initiative

Journal Reports 2019

Journal of the American Medical Association

Randomized Clinical Trials



www.sees-initiative.org

About SEES Initiative

We are a group of academics, including faculty, post-doctoral fellows, graduate, and undergraduate students, highly compelled to do meta-research in publications featuring interventions of exercise and physical activity applied to several health conditions.

Our primary goal is to promote surveillance of published evidence in exercise sciences, fostering a culture of respectful and critical appraisal for the published evidence in our field. We attempt to do so as transparently and collaboratively as possible.

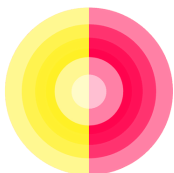
Further, we ultimately aim to increase the awareness regarding the need for transparent and informative scientific reports that should be valued by a complete reporting, carefully designed methods, and well-reasoned claims on the pursued research question.

About this collection

The present journal collection displays assessment reports generated by us as a result of continuous and systematic surveillance of published articles by the featured journal. Such publications reported either randomized clinical trials or systematic reviews with meta-analysis. All of our assessment reports were sent by email to the corresponding authors. Whenever requested by authors, we were prone to proceed required revisions and self-correction (whenever applicable), disseminating the corrected assessment reported.

©2020 SEES Initiative: Textbook content produced by SEES Initiative is licensed under a Creative Commons. Attribution 4.0 International License (CC BY 4.0)

DOI: 10.17605/OSF.IO/NTW7D



Contents



Journal: Journal of the American Medical Association

Editor in Chief: Howard Bauchner, MD

Associated Professional Society: American Medical Association

Website: <https://jamanetwork.com/journals/jama>

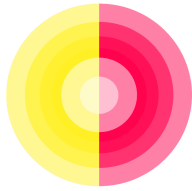
Number of randomized clinical trials assessed by the SEES Initiative

03 articles

Information for individual publication reports

Title	Pack*	Links
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	03	SEES link: https://sees-initiative.org/pmid30835309/
Effect of a Multicomponent Home-Based Physical Therapy Intervention on Ambulation After Hip Fracture in Older Adults: The CAP Randomized Clinical Trial	09	SEES link: https://sees-initiative.org/pmid31503309/
Effect of a Nutritional and Behavioral Intervention on Energy-Reduced Mediterranean Diet Adherence Among Patients With Metabolic Syndrome: Interim Analysis of the PREDIMED-Plus Randomized Clinical Trial	12	SEES link: https://sees-initiative.org/pmid31613346/

*Pack: (place where each month's articles are archived).



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

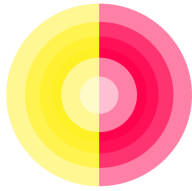
JAMA

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, 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?	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")	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-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).	No
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



Strengthening the Evidence in Exercise Sciences Initiative (SEES Initiative)

Assessment Report for Individual Study

Study title

Effect of a Multicomponent Home-Based Physical Therapy Intervention on Ambulation After Hip Fracture in Older Adults: The CAP Randomized Clinical Trial.

PMID

31503309

Journal

JAMA

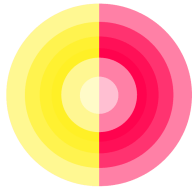
Type of Publication and Period of assessment

Randomized Clinical Trials, SEES Pack 9

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?	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?	No
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, 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?	Yes
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)?	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).	Yes
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 and non-financial COIs



Strengthening the Evidence in Exercise Sciences Initiative (SEES Initiative)

Assessment Report for Individual Study

Study title

Effect of a Nutritional and Behavioral Intervention on Energy-Reduced Mediterranean Diet Adherence Among Patients With Metabolic Syndrome: Interim Analysis of the PREDIMED-Plus Randomized Clinical Trial

PMID

31613346

Journal

JAMA

Type of Publication and Period of assessment

Randomized Clinical Trials, SEES Pack 12

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?	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)	No
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)	No
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, 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?	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).	No
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)?	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 and non-financial COIs

Our team

Akemy Neubert Kamitoyo

Pontifícia Universidade Católica do Rio Grande do Sul

Andresa Ignácio

Universidade Federal do Rio Grande do Sul

Angélica T. De Nardi

Universidade Federal do Rio Grande do Sul

Bruna Goés Moraes

Pontifícia Universidade Católica do Rio Grande do Sul

Cíntia E. Botton

Universidade Federal de Pelotas

Daniel Umpierre

Universidade Federal do Rio Grande do Sul

Douglas dos Santos Soares

Universidade Federal do Rio Grande do Sul

Leony Morgana Galliano

Hospital de Clínicas de Porto Alegre

Lucas Helal

Universidade do Extremo Sul Catarinense

Lucas P. Santos

Hospital de Clínicas de Porto Alegre

Luiza Isnardi Cardoso Ricardo

Universidade Federal de Pelotas

Marcelo R. dos Santos

Instituto do Coração – FMUSP

Nórton L. Oliveira

Hospital de Clínicas de Porto Alegre

Raíssa Borges Monteiro

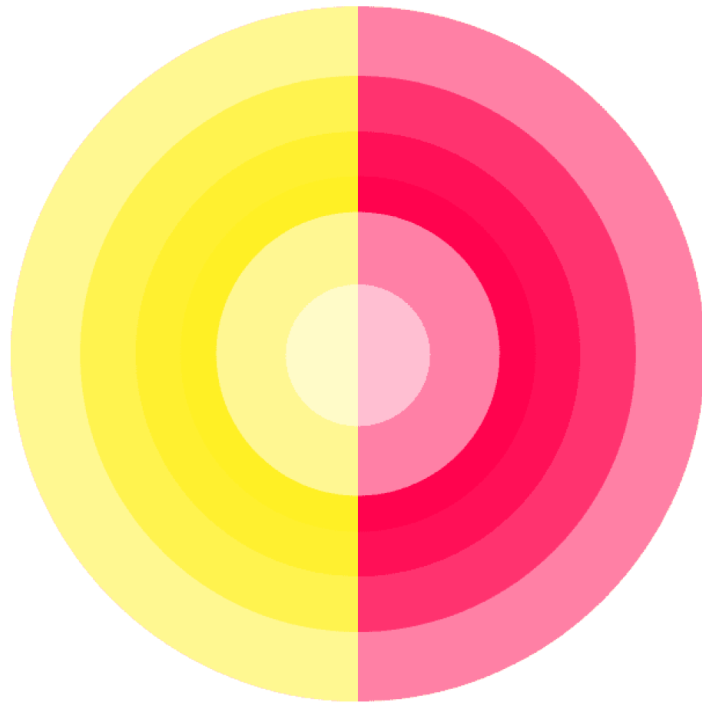
Universidade do Vale do Rio dos Sinos

Tainá Silveira Alano

Universidade Federal de Ciências da Saúde de Porto Alegre

Faculty director - **Daniel Umpierre**

Technical director - **Nórton L. Oliveira**



STRENGTHENING THE EVIDENCE IN EXERCISE SCIENCES
The SEES Initiative

Universidade Federal do Rio Grande do Sul
Hospital de Clínicas de Porto Alegre
sees.initiative@gmail.com

www.sees-initiative.org