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Narrative Review

The usefulness of randomized trials of lifestyle interventions for overweight, obesity, or metabolic syndrome: A systematic review

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SUMMARY

Background: Randomized controlled trials (RCTs) widely considered the gold standard for evidence-based healthcare may be limited in their clinical usefulness in lifestyle interventions for adults with overweight, obesity, or metabolic syndrome.
Objective: In this systematic review of lifestyle intervention RCTs we delineated trial usefulness.
Methods: Following prospective registration in PROSPERO (CRD4202347896), we conducted a comprehensive search across Medline, Scopus, Web of Science, and the Cochrane Library databases, covering the period from inception to December 2023. RCTs involving dietary interventions, with or without physical activity, and with or without behavioural support were included. Two reviewers independently performed study selection and data extraction. Study usefulness was assessed using a multidimensional 14 item questionnaire. Percentage compliance with usefulness items was computed.
Results: Of 1175 records, 30 RCTs (12,841 participants) were included. Among these, 13 (43%) RCTs complied with half of the usefulness items and only 3 (10%) complied with two-thirds of the items. For each usefulness item individually: 30 (100%) reported the burden of the problem addressed, 15 (50%) contextualized the trial through a systematic review, 18 (60%) presented an informative trial with clinically meaningful outcomes evaluated at a stated statistical power, 17 (57%) had low risk of bias, 2 (7%) exhibited pragmatic features pertaining to the trial methodologies and outcomes relevant to real-world application.18 (60%) were patient centred with formal patient involvement, none (0%) demonstrated value for money, 17 (57%) were completed according to their feasibility assessment achieving at least 90% of the estimated sample size, and 30 (100%) reported at least one of five transparency or openness features.
Conclusion: Only one in 10 lifestyle RCTs met two-thirds of the usefulness features. It is imperative to meet these criteria when devising future trials within the field of nutrition to reduce research waste.

1. Introduction

Nutrition plays an important role in promoting human health, serving as a critical factor in preventing and managing non-communicable diseases as overweight, obesity and metabolic syndrome [1]. As awareness of nutrition's importance in health grows, publications in nutritional epidemiology have increased in recent years. Nutrition research has arisen as a discipline aimed at

Abbreviations: (GRIPP), Guidance for Reporting Involvement of Patients and the Public checklist; (PPI), patient and public involvement; (RCTs), Randomized controlled trials; (SR), Systematic Review.

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furnishing empirical data population-level research to guide dietary recommendations, employing cross-sectional, longitudinal or retrospective case–control studies. Nevertheless, among the methodologies mentioned above, randomized controlled trials (RCTs) are the mainstay of evidence-based practice in medicine [2].

Although RCTs are positioned at the top of the evidence hierarchy, the clinical significance of their findings often remains limited [3]. This is in part due to the emphasis on reporting statistically significant results in biomedical literature without validated usefulness [4]. Research usefulness contributes to the advancement of knowledge, considering not only pragmatic aspects such as the relevance of the research question, but also factors like transparency, efficiency in resource utilization, and the patient-centred approach. Enhancing the usefulness of RCTs in nutrition can reduce wastage in medical research budgets and guide effective interventions [5]. The scarcity of usefulness assessment during the question, design, and planning phase of a study has been previously highlighted in clinical research [6]. While some recent publications in literature have recognized the research usefulness of RCTs for specific biomedical research fields like paediatric [7] or obstetrics and gynaecology [8], our scoping literature searches found no prior study has assessed the main factors comprising the usefulness of research in nutrition.

By employing a research instrument developed by a steering group to enhance clinical usefulness and minimize research inefficiency [9], our study examined the main usefulness criteria causing research futility in a sample of RCTs for lifestyle modification in patients with overweight, obesity and/or metabolic syndrome.

2. Materials and methods

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement [10]. The protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) under the registration number CRD4202347896.

2.1. Literature search

We conducted an extensive literature review in major electronic databases (Medline, Scopus, Web of Science, and Cochrane Library) for lifestyle randomized trials on overweight, obesity and/or metabolic syndrome patients from their inception to December 2023 without any search filters or language restrictions. We developed a comprehensive and inclusive search strategy using MeSH search terms and combined them using the Boolean "AND" and "OR" (Supplementary Table 1: Table S1), as part of previously published systematic reviews [11]. We manually searched the bibliographies of relevant studies to identify any additional trials not captured by our electronic database search.

2.2. Study selection

The study screening and inclusion process were completed in two stages by two independent reviewers (A.M.T. and A.B-H). First, titles and abstracts were scrutinized to identify potentially relevant studies. Then, the full texts of these pertinent articles were evaluated against our inclusion criteria. We included all RCTs focusing on dietary interventions, whether coupled with physical activity and behavioural support, within the adult population characterized by metabolic syndrome, obesity and/or overweight. We excluded studies that involved pregnant women, adolescents, children, as well as participants with eating disorders, established cardiovascular disease, diabetes, bariatric surgery, cancer or kidney disease. Studies were also excluded if they failed to provide weight change outcome data for the control group or if the control group did not receive standard care. Exclusion criteria extended to study designs other than RCTs and interventions beyond lifestyle modification like supplements or pharmacological treatment. Disagreements regarding citation inclusion were resolved by consulting another researcher (N.C-I). All identified citations were transferred to Endnote software, where duplicates were eliminated.

2.3. Data extraction

Two reviewers (A.M.T and A.B-H.) independently extracted the main characteristics from the selected studies in duplicate after a comprehensive examination of the full texts. Data including the author, year of publication, country, sample characteristics and follow-up period were summarized. Our primary outcome was usefulness score, which was independently, and blindly assessed among the selected RCTs using a published and validated tool [12]. This tool (originally encompassing 8 criteria and combining 13 total items of clinical usefulness) was modified adding one feature related to risk of bias and modifying one feature 'patient centeredness' by including the reporting of patient and public involvement (PPI). It formed the basis for our extraction form. Our extraction form was composed of 14 unique usefulness criteria (we added the item "patient and public involvement reported" to the predefined tool); all unique criteria can be found in (Supplementary table 2: Table S2). The extraction was piloted and double-checked on a few RCTs for completeness and accuracy before complete data extraction. Where disagreements or doubts existed, consensus of the entire authorship was deployed to maximise reliability.

We assessed the quality of the RCTs in duplicate (A.M.T. and A.B-H.) using the JADAD scale (score range 0–5) [13]. This scale includes key elements correlated with bias and establishes reliability and external validity. Each RCT was assessed based on methodological quality of randomization, blinding and patient withdrawals or dropouts. RCTs with a score of $\geq$3 was of high quality. Disagreement was resolved by discussion between both reviewers and consultation with the third reviewer (N.C.-I).

2.4. Data synthesis

The key features of the included RCTs were synthesized and organized in Table 1, encompassing details such as author, year, country, randomized population, follow-up period, and participant characteristics. For the usefulness checklist, a content analysis was conducted to categorize and quantify the information gathered. We extracted data on characteristics of the publication's usefulness, including the problem base, context placement, information gain and power calculations, risk of bias, pragmatism, patient centeredness including PPI, value for money, transparency, protocol preregistration, funding statement, conflicts of interest statements, and free data availability. A data coding method of NA (not applicable), 0 (no) or 1 (yes), was developed to provide a total score for each study. Each RCT was graded out of a total score of 14 points, with 1 point being awarded for each unique criterion. Compliance with usefulness items was reported through percentage and number (n, %). The summary of usefulness assessment was expressed as compliance with 50% (half) or 67% (two-thirds) of the usefulness items (7 out of 14 points, and 9 out of 14 points; respectively).

Given the limitations imposed by the small sample size, it is important to document modifications to the registration process. Specifically, it should be clarified that due to the limited number of RCTs a direct comparison between the PPI group and the non-PPI

Table 1
Characteristics of the selected studies included in the systematic review of lifestyle randomized controlled trials for overweight, obesity, or metabolic syndrome.

Author, year	Country	Randomized population (n)	Personnel conducting intervention	Follow-up period (months)	Patients' characteristic		
					Age Years range/average (SD)	BMI	Other characteristics
Greaves, 2015	UK	108	Nurse and coaches	12	40–74	>28	High CV risk
Lin, 2015	USA	124	Dietitian and physician	12	>21	>27	African American with text-messaging capability
Weinhold, 2015	USA	78	Dietitians	3	18–65	25–50	Prediabetes
Oh, 2008	South Korea	32	Nurses	1	>20	>25	Rural women with MetS
Alghamdi, 2017	Saudi Arabia	70	Nurses	3	>20	≥30	Arab nationality
Blackford, 2016	Australia	401	Web based	6	50–69	>25	Rural people with or at risk of MetS
Fernández-Ruiz, 2018	Spain	74	Physicians, nurses, nutritionists and psychologists	24	Not reported	>25	MetS
Bo, 2007	Italy	335	Family physicians and dietitian	12	45–64	>25	MetS
Duijzer, 2017	Netherlands	316	General practitioners, practice nurses, dieticians and physiotherapists, sport coaches	18	40–70		High risk of type 2 diabetes
Christensen, 2011	Denmark	144	Sport instructors	12	18–40 >40	>25 >34	Female health care workers
Kandula, 2015	USA	63	Dietitians	6	50 (8)	>25	High atherosclerotic CV risk including obesity
Thiabpho, 2018	Thailand	60	Nurses	4	30–50	⩾27.5	With no non-communicable disease
Cai, 2019	China	480	Dietitians	24	≥60	≥28	Obese Chinese adults
Nanri, 2012	Japan	107	Nurses	6	53 (6.8)	Not reported	Men with MetS
Maruyama, 2010	Japan	111	Dietitian and physical trainer	4	30–59	≥25	Male office workers with MetS
Share, 2015	Australia	43	Qualified exercise Scientist and dietitian	3	18–30		Women with abdominal obesity [waist circumference (WC) ≥ 80 cm], and physically inactive.
Moss, 2014	UK	60	Exercise physiologist	9.5	18–85	>30	With at least moderate OSAHS.
Puhkala, 2015	Finland	113	Nutritionists and physiotherapist	24	30–62		Male truck or bus driver, waist circumference ≥100 cm, absence of diabetes and little PA
Anderson, 2021	UK	560	Nurses	12	50–70	>25	Women attending, or invited to attend, routine breast screening clinics (not recall clinics)
Röhling, 2020	Germany	30	Nutritionists, exercise scientists, biologists, physicians and psychologists	12	>18	≥25	Occupational healthcare employees with overweight or obesity
Salas-Salvadó, 2019	Spain	626	Doctors, dietitians and nurses	12	55–75	>27- <40	Patients without CVD, overweight/obese and with MetS.
Pablos, 2017	Spain	97	Doctors, nutritionists, nurses, psychologists and trainers	8	20–70	>25	Adults with no regular PA living in a low median household income census tract.
Lopes, 2022	Brazil	3414	Nutritionists, educators, and psychologists.	48	>20	Not reported	Participants in a primary health care service
Lugones-Sanchez, 2022	Spain	650	Nurses	12	20–65	27.5–40	Adults physically inactive
Muilwijk, 2021	Netherlands	3684	Nurses and dietitians	12	40–70	≥22	Without Type 2 Diabetes but with raised haemoglobin A1c (HbA1c) and/or waist circumference.
Ross, 2022	Canada	320	Web- based	36	25–70	25–39.9	Adults physically inactive
Liampeng, 2023	Thailand	107	Nurses	5	18-60 (43.1 ± 9.9)	>27.5	Adults with obesity living in remote rural areas
Kohl, 2023	Germany	153	Web-based	6	18–65	27.5–34.9	Adults with overweight and obesity that participate in a web-based health program
Chang, 2023	Taiwan	103	Nurse investigator and one trained community health volunteer	18	≥50	>30	Adult women with MetS and low education
Maddison, 2023	New Zealand	378	Dietitians	13	30–65	≥28	Overweight and obese men able to safely undertake PA

BMI Body mass index; CVD Cardiovascular disease; MetS Metabolic syndrome; OSAHS Obstructive sleep apnoea hypopnoea syndrome; PA Physical activity.

group was not possible. This revision to the registration aims to enhance transparency regarding the encountered constraints and ensures the accurate interpretation of the findings within the confines of the research parameters.

3. Results

3.1. Selection of studies

The initial search identified 1175 records and after applying the eligibility criteria 30 lifestyles RCTs reporting on 12,841 participants with overweight, obesity and/or metabolic syndrome (see Fig. 1 for details**).** A compilation of 102 studies that could seem to fulfil the criteria for inclusion but were omitted, along with the primary rationale for their exclusion is shown in Supplementary Table 3: Table S3.

3.2. Characteristics of the studies included

A summary of the key characteristics of the included studies is provided in Table 1. Most studies were conducted in countries in Europe (50%) [14–28], followed by Asia (24%) [29–35], North America (20%) [36–41], and two articles reported on patients from Brazil (3%) [42], and Saudi Arabia (3%) [43]. In total, only one study was published before 2010 [29]. Sample sizes of the included RCTs ranged from 32 [29] to 3684 [26]. Regarding the follow-up of lifestyle intervention, the periods ranged from 1 to 36 months, with an average of 12,6 months. According to the patient's characteristics, mean age range spanned from 18 to 70 years with a BMI $\geq$22 kg/m^2. Five studies exclusively included female participants (17%) [18,21,29,35,40], while four studies focused solely on male participants (13%) [20,28,32,33].

The focus of lifestyle interventions was dietary adjustments and physical activity prescription. These interventions were administered by dietitians or nutritionists, either independently or in partnership with various healthcare professionals such as nurses, physicians, psychologists, sports coaches, or trainers. Control groups either received standard or usual care or were placed on a waiting list to receive the lifestyle program after the completion of data collection.

3.3. Quality of the studies included

The evaluation of the methodological quality of each RCT according to JADAD criteria is shown in Fig. 2. Out of the total number of studies, 17 were of high quality (17/30, 57%) and 13 (13/30, 43%)

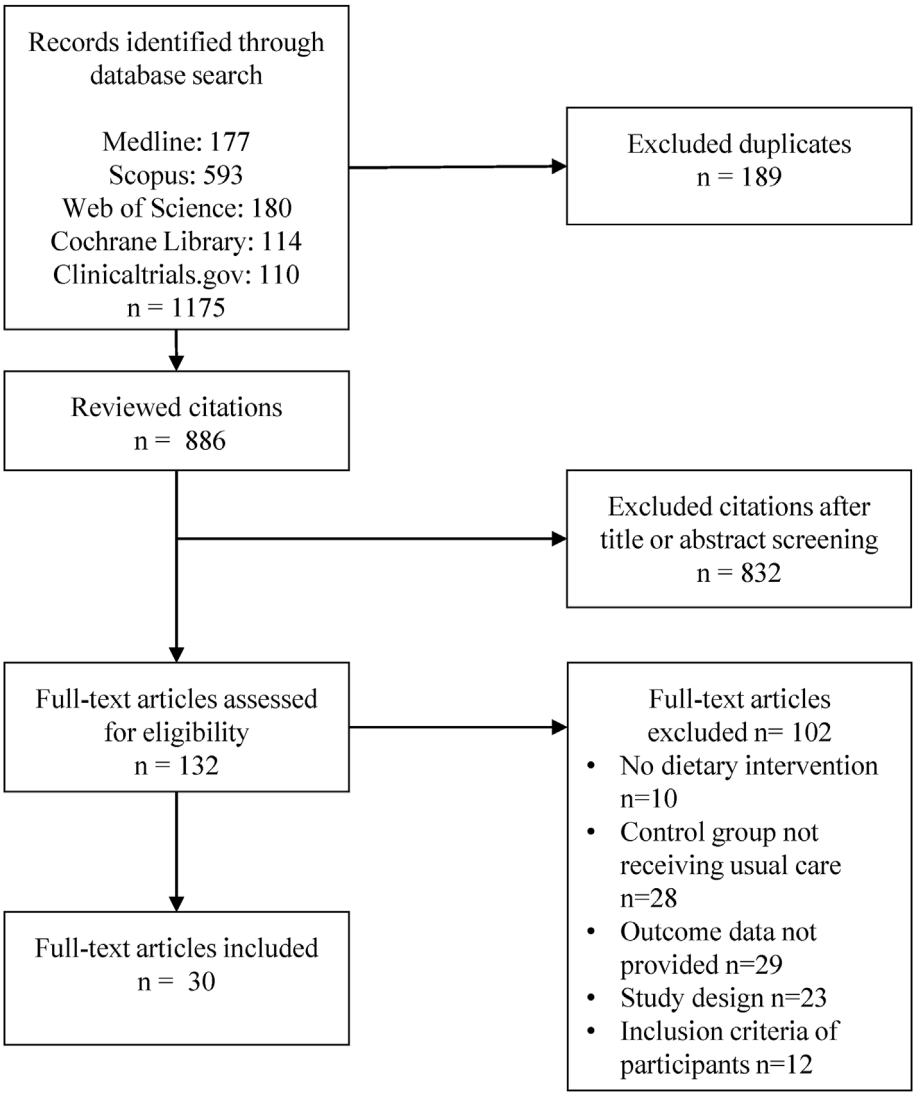

Fig. 1. Flow chart of study selection process of trials included in the systematic review of lifestyle randomized controlled trials for overweight, obesity, or metabolic syndrome.

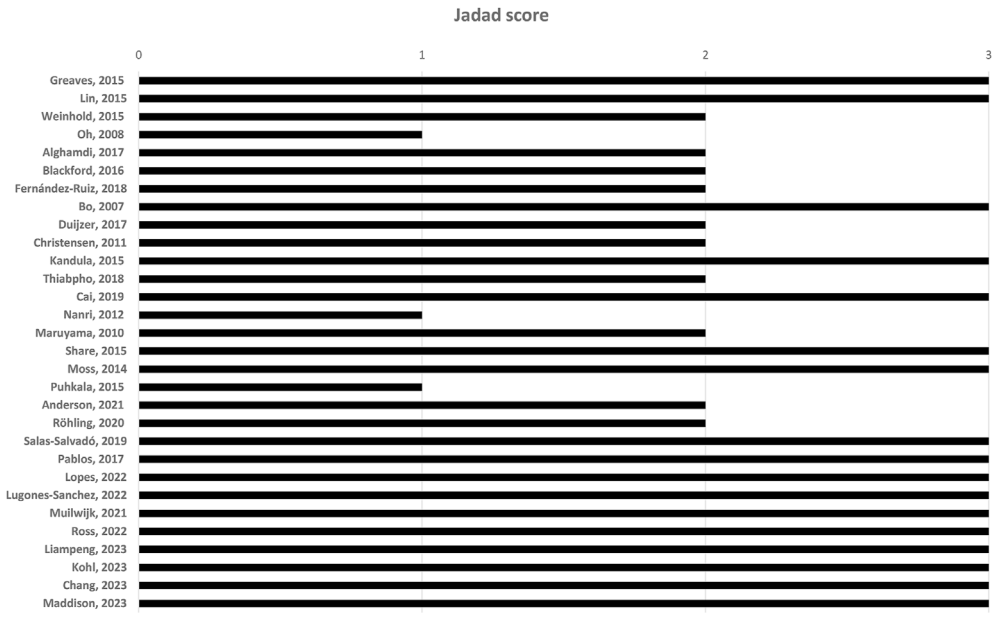

Fig. 2. Quality assessment of trials included in the systematic review of lifestyle randomized controlled trials for overweight, obesity, or metabolic syndrome.

were of low quality. The most common problem identified was the inability of double blinding lifestyle interventions.

3.4. Usefulness assessment

The characteristics of usefulness criteria of lifestyle interventions for overweight, obesity or/and metabolic syndrome patients are presented in Table 2. The compliance with half or 2/3 of the usefulness items was 43% (13/30) and 10% (3/30), respectively. For criterion 1, problem base, 30 RCTs (100%) emphasized the burden of the problem. For criterion 2, context placement, 14 RCTs (47%) contextualized the trial. For criterion 3, information gain, 18 RCTs (60%) presented an informative trial. The main reason for no information gain was no power calculation in 8 RCTs (27%). For criterion 4, risk of bias, 17 RCTs (57%) had low risk of bias. For criterion 5, pragmatism, 2 (7%) had pragmatism features. For criterion 6, patient centeredness 18 RCTs (60%) were patient centred, including PPI 18 RCTs (60%) direct or indirectly reported. 2 out 18 RCTs including PPI (7%) complies with Guidance for Reporting Involvement of Patients and the Public checklist (GRIPP). None of the RCTs included (0%) demonstrated value for money (criterion 7). For criterion 8, 17 RCTs (57%) were completed according to their feasibility assessment. Finally, for criterion 9, transparency and integrity, trial registration was showed in 21 RCTs (70%). All the RCTs included (100%), reported at least one of five transparency features: Preregistration trial (6, 20%), protocol published (14, 47%), adherence to protocol (4, 13%), funding (30, 100%), conflict of interest (27, 90%), availability of data (8, 27%).

4. Discussion

The main goal of assessing usefulness is to prevent researchers from contributing to a significant waste of research evidence, aligning with optimising potential patient benefits upon study completion [44]. This study was performed to evaluate the usefulness of lifestyle RCTs involving overweight, obesity or metabolic syndrome patients based on their compliance with a predefined checklist [12]. One of the main findings of our study was that only 10% of the reviewed RCTs met two-thirds of the usefulness criteria.

Table 2
Assessment of usefulness of trials included in the systematic review of lifestyle randomized controlled trials for overweight, obesity, or metabolic syndrome.

Usefulness	n (% of 30 studies in total)
Usefulness item assessment	
1. Problem base (disease burden)	30 (100)
2. Context placement reference to SR	14 (47)
3. Information gain present	18 (60)
Reasons for no information gain	
No power calculation	8 (27)
Retrospective power calculation	1 (3)
Composite outcome	1 (3)
Surrogate outcome	3 (10)
Power <80%	1 (3)
Combination of the above	3 (10)
4. Study quality high (risk of bias low)	17 (57)
5. Pragmatism	2 (7)
Obvious violation of pragmatism (yes)	1 (3)
6. Patient centeredness	18 (60)
Use of core outcome set	0 (0)
Patient priority assessed	0 (0)
Patient and Public Involvement reported	18 (60)
Complies with GRIPP statement	2 (7)
7. Value for money	0 (0)
8. Feasibility	
Not reported	6 (20)
Yes	17 (57)
Reasons for no feasibility	
Pilot study	4 (13)
Funding	1 (3)
<90% of a priori calculated sample size	2 (7)
9. Transparency and Integrity	
Trial registration	21 (70)
9a. Preregistration trial	6 (20)
9b. Protocol published	14 (47)
9c. Any comment on adherence to protocol	4 (13)
9d. Funding stated	30 (100)
9e. Statement on conflict of interest	27 (90)
9f. Statement on availability of data	8 (27)
Summary of usefulness assessment	
Compliance with 50% of the usefulness items	13 (43%)
Compliance with 67% of the usefulness items	3 (10%)

Abbreviations: (GRIPP): Guidance for Reporting Involvement of Patients and the Public checklist; (n): number; (PPI): patient and public involvement; (SR): systematic review.

This result is somewhat better than that obtained for randomized trials in preterm birth prevention [9], several factors may contribute to the observed gap. Methodological limitations, such as inadequate sample sizes, insufficient reporting of outcomes, and lack of patient-centered outcomes, can diminish the relevance and applicability of study findings [45,46]. Additionally, publication bias towards studies with positive outcomes may skew the perception of overall effectiveness and utility in clinical practice [47].

Also, there is one evaluation of 600 RCTs related to Child Health Research [7], where the authors assessed eleven usefulness items. The rate of compliance was under 20% for 6 out 11 items, showing areas that need a great deal of improvement in order to maximize clinical usefulness and reduce research waste.

Exploring the usefulness items, all studies successfully addressed the problem base and funding statement, reflecting a thorough understanding of both items. The CONSORT statement highlights the crucial role of rigorous justification for Randomized Controlled Trials (RCTs) in biomedical research, emphasizing the magnitude and relevance of the condition under scrutiny, along with transparent disclosure of conflicts of interest [48]. This adherence to CONSORT guidelines likely accounts for the compliance of all evaluated RCTs in our review. However, only a minority of studies (47%) appropriately placed their context reference to systematic reviews (SR), potentially indicating a gap in literature review methodology. This finding underscores the importance of a robust and comprehensive approach to literature review, particularly in the incorporation of systematic reviews which provide a synthesized and rigorous analysis of existing evidence. Nevertheless, it's common to overlook integrating systematic reviews into primary studies, despite gaps in understanding existing knowledge, which may compromise research reliability [49].

In terms of information gain, a 60% of the studies examined yielded pertinent findings. However, the absence of information gain in the remaining studies was attributed to various factors. These encompassed deficiencies such as inadequate power calculation, reliance on composite or surrogate outcomes, and insufficient statistical power. Rates slightly lower than our results showed an examination of RCTs indexed in PubMed for the years 2000–2006 carried out by Hopewell S et al. This study highlighted that sample size calculation were reported in only 27% of 519 trials in 2000 and 45% of 616 trials in 2006 [50]. These gaps underscore the importance of methodological robustness in research design and analysis. In particular, the accurate estimation of statistical power and careful consideration of outcome measures are crucial for ensuring the validity and interpretability of study findings.

Inclusion of perspective in patient centeredness in research is mandatory across any stage of the development process, aiding in the prioritization of research questions, development of methodology, selection of outcomes, recruitment, implementation, and dissemination of scientific results [51]. In our study, patient-centeredness was moderately addressed, with 60% of studies reporting PPI, although none utilized core outcome sets or assessed patient priorities systematically. Additionally, only a small proportion of studies complied with the GRIPP (Guidance for Reporting Involvement of Patients and Public) statement, highlighting potential gaps in reporting standards for patient engagement. Similar to our findings, Bouzalmate-Hajjaj et al. reported that 65% included PPI in any stage of lifestyle RCT [52]. The recognition of PPI in health research is increasing [53]. However, patient engagement in patient-oriented interventional research remains notably inadequate [54], accompanied by low-quality reporting [55]. Therefore, more rigorous reporting guidelines are necessary to ensure transparency and accountability in PPI. Greater awareness and adoption of existing guidelines, such as GRIPP2, along with clearer guidance and training for researchers on effective PPI engagement and reporting, as well as journals mandating adherence to standardized reporting frameworks in submission criteria, can significantly enhance transparency and accountability in research practices.

The convergence of limited resources and escalating healthcare demands underscores the pivotal role of priority setting in health policy. In spite of this, the usefulness item namely "value of money" was absent in all studies. The absence of a budget impact calculation of all studies has implications for policy and clinical practice. Economic assessments, such as a budget impact analyses, are essential for decision-makers to prioritize and allocate resources efficiently among competing studies on healthcare interventions. Without such evaluations, there is a risk of misallocation of resources, potentially leading to suboptimal use of healthcare budgets [56,57]. A value of information analysis is a method to provide insights on the expected benefits from clinical research by characterizing the uncertainty of the effects of interventions on health outcomes. This information is then used to inform decisions about the design and priority of those studies. Failure to incorporate economic evaluation may limit the ability to make informed decisions regarding resource allocation and the optimization of healthcare delivery [58]. Schawb S. et al., informed about ten simple rules for good research practices informing about the main areas to enhance research reproducibility [59]. Among them, Pre-registration, and data availability were reported as critical items. Pre-registration of trials and publication of protocols serve as critical measures to mitigate bias and ensure the integrity of research findings by providing transparency regarding study design and methodology before data collection begins [60]. Likewise, statements regarding data availability facilitate reproducibility and promote scientific rigor by allowing other researchers to verify study results and conduct further analyses [61]. Although, transparency and integrity were generally well-maintained, with high rates of trial registration, funding disclosure, and conflict of interest statements. The pre-registration trial, protocol publication and data availability statements were less frequent, indicating potential areas for improvement in nutrition research transparency.

Non-compliance with usefulness criteria in research studies can impact the reliability and applicability of findings in clinical practice and policymaking. Future research efforts should prioritize enhancing methodological rigor, transparency in reporting, and alignment with established guidelines such as CONSORT and GRIPP2 [45,62]. By doing so, researchers can improve the quality and relevance of study outcomes, facilitating informed decision-making and enhancing the translational impact of research findings.

4.1. Strengths and limitations

To our knowledge this study is pioneer in the application of a practical tool to evaluate the usefulness of RCTs in the field of nutritional research, specifically in the context of lifestyle interventions. Despite of this, there are some limitations to consider. First, RCTs included in the databases analysed may not capture all lifestyle prevention trials. Nevertheless, the selection of these databases warranted to cover at least 75% of rates in research in biomedical sciences. Furthermore, we conducted an unrestricted search with a substantial sample size, free from language or time span limitations across databases, to ensure the inclusion of a large number of significant studies. The search, selection, and quality assessments of studies demonstrated high reviewer agreement, enhancing the reliability of the reviewers. Second, the accuracy of usefulness data collection relies on the reporting in published articles. Therefore, an underestimation or overestimation of the prevalence of some item is possible. Third, the usefulness criteria tool was not developed to simply serve as a checklist for ensuring

high quality and low bias. For this reason, a study that scores low on some usefulness criteria can still contribute valuable information to the nutrition-based evidence. Fourth, the potential for publication bias may have influenced the findings, affecting the interpretation of results. However, we conducted a comprehensive and systematic search across multiple major databases, ensuring broad and complete coverage of relevant studies.

The findings of this systematic review highlight critical areas for improvement in the design and reporting of lifestyle intervention RCTs. Future research should prioritize adherence to the usefulness criteria to enhance their clinical applicability. Specifically, ensuring that trials are pragmatic, patient-centered, and demonstrate value for money could significantly improve their relevance to real-world settings. Moreover, incorporating comprehensive feasibility assessments and achieving high retention rates will strengthen the validity and reliability of trial outcomes. Enhanced trial design can yield more robust findings that inform effective public health strategies targeting overweight, obesity, and metabolic syndrome. By focusing on clinically meaningful outcomes and maintaining methodological rigor, future RCTs have the potential to significantly contribute to sustainable public health interventions and improve overall health outcomes at a population level.

5. Conclusion

Lifestyles RCTs in overweight, obesity and metabolic syndrome patients lacked most usefulness criteria. By incorporating these criteria into trial design, researchers can optimize the utility and impact of their findings. Significant gaps were noted in pragmatic trial features, addressing value for money, and integrating patient-centered outcomes. Prioritizing clinically meaningful outcomes, optimizing sample sizes for statistical power and practical relevance, including patient-centered outcomes, integrating budget impact analyses from inception, involving stakeholders in trial design, and adhering to reporting guidelines can enhance the utility of RCTs.

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Author contributions

A.B.C., K.S.K. and J.V.H. conceived the research question and designed the study; A.B.H. and A.M.T. conducted the literature search, study selection, and data extraction; A.B.H. and A.M.T. performed the quality assessment. N.C.I. resolved the study selection discrepancies, carried out the data analysis, and wrote the main draft of the manuscript. All the authors contributed to the design of the figures, tables and supplementary materials. All the authors approved the final version of the manuscript.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.clnesp.2024.08.026.

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