

REVIEW

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Recommendations on self-management interventions for adults living with obesity: COMPAR-EU project

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Summary

Self-management interventions (SMIs) may improve disease management in adults living with obesity. We formulated evidence-based recommendations for SMIs within the context of the COMPAR-EU project. The multidisciplinary panel selected critical outcomes based on the COMPAR-EU core outcome set and established decision thresholds for each outcome. Recommendations were informed by systematic reviews of effects, cost-effectiveness, and a contextual assessment. To assess the certainty of the evidence and formulate the recommendations, we used the GRADE approach

guidance. Overall, SMIs were deemed to have a small impact, but the absence of harmful effects and potential cumulative benefits indicated a favourable balance of effects, despite low certainty. SMIs showed variations in structure, intensity, and resource utilisation, but overall are likely to be cost-effective. Adapting SMIs to local contexts would enhance equity, acceptability, and feasibility, considering patients' values, and availability of resources and teamwork. Consequently, the panel made conditional recommendations favouring SMIs over usual care. The rigorous and explicit recommendations demonstrated the effectiveness of SMIs for adults living with obesity. However, the gaps in the literature influenced the panel to make only conditional recommendations in favour of SMIs. Further research is needed to strengthen the evidence base and improve recommendations' certainty and applicability.

KEYWORDS

guideline, obesity, recommendations, self-management interventions

1 | SUMMARY OF RECOMMENDATIONS

The panel formulated an overarching recommendation for all SMIs compared to usual care (UC) alone, and eight specific recommendations for the selected SMIs compared to UC, see Figure 1.

1.1 | Recommendation for all SMI vs UC (COMPAR-EU platform Recommendations)

Remarks: SMIs should be intensive (more than 10 contact hours with the provider of the SMI or hours of intervention) and should probably include an educational component and monitoring plus a behavioural technique component (either action-based or emotional based).

It is also important to consider people' preferences and needs, as well as the context and setting for implementation, and the potential patient related costs (i.e., vitamins or other supplements not covered by health insurance).

1.2 | Recommendations for selected SMI vs UC

In adults living with obesity, the COMPAR-EU Obesity panel, suggests in favour of using the following SMIs², rather than UC³ (conditional recommendation based on very low certainty of the evidence about the effects), discussing the options and considering people' preferences and needs, see Figure 2. (COMPAR-EU platform Recommendations).

2 | INTRODUCTION

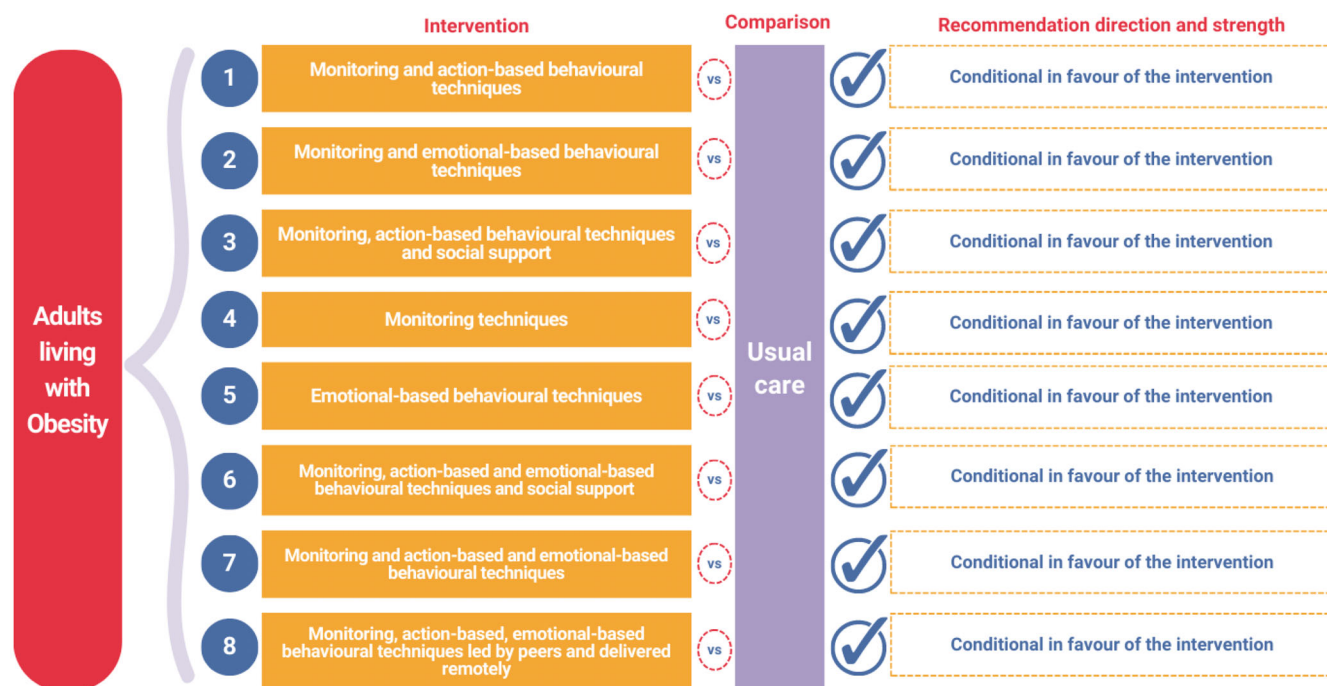
Obesity is a "chronic complex disease defined by excessive adiposity that can impair health".¹ Overweight and obesity are increasing globally affecting nearly 60% of adults in the European region.² The number of global deaths and disability-adjusted life years (DALYs) linked to high body mass index (BMI) has more than doubled in the past 30 years.^{3,4}

Obesity is usually diagnosed by calculating the BMI (weight (kg)/height²(m²)), a surrogate marker of adiposity, in those exceeding a BMI of 30 kg/m². This chronic condition may have multifactorial causes and acts as a gateway disease to a wide variety of other non-communicable illnesses such as type 2 diabetes mellitus, cardiovascular diseases, and cancer among others.^{5,6} Conversely, adverse outcomes such as morbidity, disability, premature death, mental health problems, weight bias, weight stigma, and discrimination are also obesity-related.⁷⁻⁹ Untreated obesity may lead to high costs for treating obesity-related diseases and reduced productivity and human capital, increasing unemployment, and impacting enormously the economy across countries independently of their income or geography.¹⁰⁻¹²

Self-management (SM) support presents an opportunity to enhance obesity management, mainly because of its potential to complement and strengthen clinical and psychological treatment pathways. SM support is defined as "the person's ability to control symptoms, medication, physical and psychosocial issues, and lifestyle changes required by living with a chronic illness to maintain an adequate quality of life".¹³⁻¹⁶ Self-management interventions (SMIs) are supportive strategies designed to empower people (and their



FIGURE 1 General recommendation.



Action-based behavioural techniques: i.e., learn problem-solving skills or goal setting and action planning; **Delivered remotely:** i.e., telephone, smartphone, Internet; **Emotional-based behavioural techniques:** i.e., stress and/or emotional management, or coaching and motivational interviewing; **Led by peers:** i.e., Training and teaching activities provided by peers to guide about a related health care concern; **Monitoring techniques:** i.e., self-monitoring training and feedback; **Social Support:** i.e., encouraging to participate in a local exercise group.

FIGURE 2 Recommendations for selected SMIs ($n = 8$).

BOX 1 Strong versus conditional recommendations and their implications.

Strong recommendation	The panel is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects
Conditional recommendation	The panel concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, but is not confident.
Implications of a strong recommendation	For patients: most people in your situation would want the recommended course of action and only a small proportion would not; request discussion if the intervention is not offered. For clinicians: most patients should receive the recommended course of action. For policymakers: the recommendation can be adopted as a policy in most situations.
Implications of a conditional recommendation	For patients: most people in your situation would want the recommended course of action, but many would not. For clinicians: you should recognise that different choices will be appropriate for different patients and that you must help each patient to arrive at a management decision consistent with his or her values and preferences. For policymakers: policy making will require substantial debate and involvement of many stakeholders.

Chapter 6.1 Recommendations and their strength in Schünemann H, Brozek J, Gyuatt G, Oxman A, editors. GRADE handbook for Grading quality of evidence and strength of recommendations. Updated October 2013. The GRADE working group, 2013. Available from guidelinedevelopment.org/handbook

caregivers) to participate actively in the management of their condition, by increasing their skills and confidence.^{17,18} Several studies suggest that SMIs may improve the health outcomes of people living with obesity.¹⁹ Despite this, there are still gaps in the research on SMIs for adults living with obesity, for example, the scope of research needs to be broadened to include areas important to patients (e.g., emotional and social support) and to include other methods of delivering the interventions, among others.²⁰ Box 1.

The aim of this study is to develop evidence-based clinical recommendations on SMIs for adults living with obesity. These recommendations have been formulated in the context of the COMPAR-EU

project which is a European multimethod and interdisciplinary project aiming to identify, compare, and rank the most effective and cost-effective SMIs for adults living with one of the four priority chronic diseases; Obesity, Type 2 Diabetes Mellitus, Chronic obstructive pulmonary disease and Heart failure²¹ (COMPAR-EU project website).

3 | METHODS

The recommendations were formulated by a multidisciplinary panel, which included endocrinologists, health services

researchers, health economists, general practitioners, certified specialists in obesity, self-management experts, nutritionists, dietitians, clinical psychologists, patient advocates, and guideline methodologists. The panellists applied voluntarily through an online open call and signed a financial and non-financial interest disclosure. Potential panellists with conflict of interests (e.g., working in the industry or for-profit agencies) were not selected. ([Link to read more about panel members](#)).

The COMPAR-EU scientific research team performed several analyses to inform the recommendations. This included a systematic review (SR) on the effectiveness of SMI interventions using standard pairwise meta-analyses, network meta-analyses (NMA)²² and component network meta-analyses (CNMA); a cost-effectiveness analysis; a scoping review of reviews²³ on patients values and preferences; and a contextual analysis to inform about acceptability, feasibility and other implementation considerations.²¹ The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach was used to assess the certainty of the evidence and to formulate the recommendations.^{24–30}

3.1 | Structured question, outcome prioritisation and decision thresholds

3.1.1 | Structured question

The main clinical question was “Which are the most effective and cost-effective SMIs for adults living with Obesity?”. For PICO (Population, Intervention, Comparison and Outcomes) format see Box 2.

BOX 2 Structured clinical question.

Population	Intervention	Comparison	Critical Outcomes ^a
Adults living with obesity/overweight ^b	Self-management intervention (SMIs)	Usual care (UC) ^c	• Self-efficacy • Eating self-efficacy • Exercise self-efficacy • Quality of life • Coping with the disease (stress and depression)^d • Systolic blood pressure • Diastolic blood pressure • Weight management • Body fat • BMI^e • Waist Size

^aCritical outcomes were defined previously in the COS³¹ for Obesity and were validated for the recommendations panel.

^bAdults living with overweight or obesity:

- 100% of patients should have BMI* > than 25 kg/m² and if they are Asian more than 23 kg/m² (according to COMPAR-EU inclusion criteria definition for obesity)
- If BMI is only provided by the mean, we included 2 standard deviations over 25 kg/m² or 2SD over 23 kg/m² for the Asian population.
- If mixed populations (mixed ethnic groups) are included, the threshold over 25 kg/m² was kept.

^cFor the formulation of recommendations, only the results from UC comparisons are presented, although the SR and meta-analyses also use other SMIs as comparators.

^dCoping with the disease: How well a person feels able to cope/manage with stress or other difficulties caused by the disease. The only way studies have measured this outcome is by using scales to assess stress and depression.

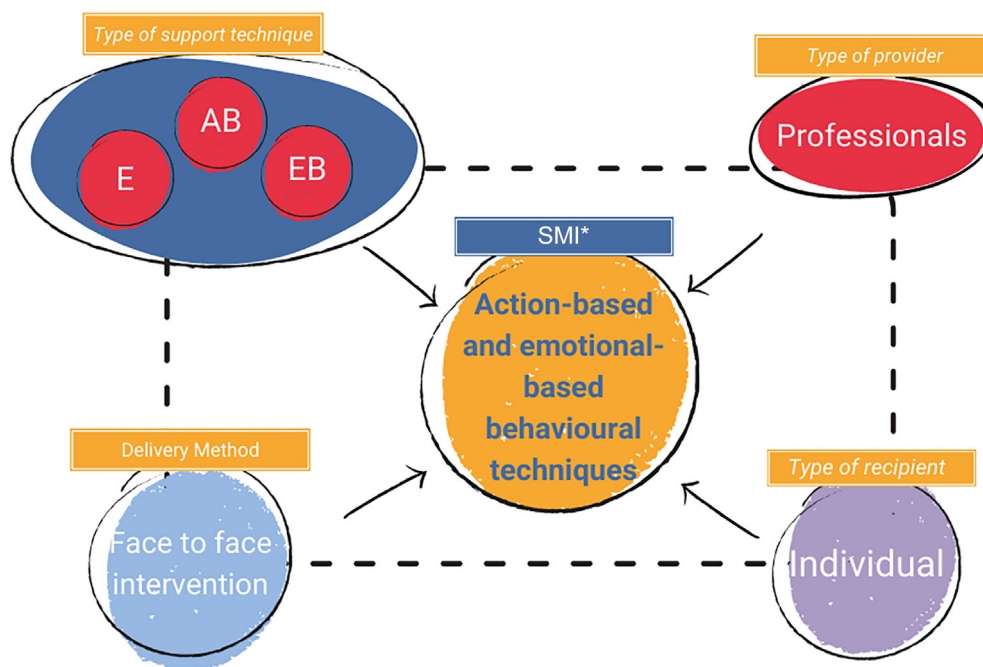
^eBMI not necessarily defines obesity but for the purpose of COMPAREU it was used as a surrogate marker, then in future when available studies better define obesity in their inclusion criteria, more specific definitions can be used.

We included randomised controlled trials (RCTs) that were performed on adults (>18 years) living with obesity or overweight, in which SMIs were compared to UC (generally includes standard of care treatment, and visits plus an educational component) or other SMIs. In Figure 3, we depict an example of an SMI and how we classified it considering all its relevant components. These included type of support technique, type of recipient, type of provider and delivery methods as defined by the COMPAR-EU taxonomy, which includes a general taxonomy for the four chronic conditions assessed by the project.¹⁷ Classifying SMIs in this way deals with the complexity of their multiple components (such as supporting techniques, modalities, targeted behaviours, type of providers delivering interventions, which may interact with each other and with environmental features (setting, health system characteristics, etc.) and facilitates the evidence syntheses).^{31,32} Figure 2.

To understand how a SMI is built (Figure 3), we use as an example the trial entitled “A randomised controlled trial on the effectiveness of a primary healthcare-based counselling intervention on physical activity, diet and CHD risk factors”,³³ that described an SMI including strategies from psychotherapy and behaviour change theory models. Thus, we consider that this intervention was built with the components of Education (E), Action-based (AB) and Emotional-based (EB) behavioural techniques (participants acquire problem-solving skills, set goals, and develop action planning, stress and/or emotional management, and coaching, counselling, collaborative conversations or motivational interviewing) (See Appendix 1: Self-management components).

For the purposes of the project's platform development, the labelling of the SMIs has been simplified, therefore, there may be implicit components in the labels of all the interventions, such as education. Furthermore, if it is not mentioned, SMIs are delivered face to face,

FIGURE 3 Example of self-management intervention.



* SMI: Self-management intervention label according to the taxonomy.

SMI Label: Action-based and emotional-based behavioural techniques

Type of support technique: Education (E), Action-based (AB) and emotional based (EB) behavioural techniques (participants acquire problem-solving skills, set goals, and develop action planning, stress and/or emotional management, and coaching and motivational interviewing).

Example: A randomised controlled trial on the effectiveness of a primary healthcare-based counselling intervention on physical activity, diet, and CHD risk factors (33).

individually or combined (e.g., individual with group sessions), and by a healthcare professional.

3.1.2 | Outcome prioritisation

Regarding the outcomes of the interventions, we worked with those included in the COMPAR-EU core outcome set (COS) for obesity³⁴. This COS was built before the recommendation's development and included 20 outcomes. We surveyed panellist to identify the most critical ($N = 12$), and those considered important but not critical for decision making ($N = 8$) (See Appendix 2: Critical and important outcomes)³⁵. The critical outcomes were considered by the panel to formulate the recommendations, and the important outcomes were included as additional evidence.

3.1.3 | Decision thresholds for the magnitude of the effects

The panel reviewed and agreed on the magnitude of the effects decision thresholds for both critical and important outcomes (i.e., large beneficial effect, moderate beneficial effect, small beneficial effect, trivial to no effect, small harmful effect, moderate harmful effect, and large harmful effect).³⁶ These thresholds were the results of a literature research to

identify studies reporting them that was previously carried out by the project team. We looked for minimal important difference (MID) data for each outcome, and consistent with its description, we considered this value as a small effect. To define the rest of the categories, we estimate that a large effect would be twice the MID. If the MID was not available in the literature, we searched for systematic reviews (SRs) with RCTs reporting a change in cardiovascular events or mortality. We determined the reported risk factor values related to a significant decrease in cardiovascular events or mortality. A value was considered as a small effect if the percentage of the decrease was at least 20%. For the remaining thresholds, we applied the same rules and assumptions explained before. In the case of results reported as standardised mean differences (SMD), we used 'Cohen's effect sizes' (0.2 represents a small effect, 0.5 a moderate effect and 0.8 a large effect)^{37,38} (See Appendix 3: Cut-off points per outcome).

3.2 | Systematic evidence review for effectiveness, values and preferences, economic analyses, and contextual factors

3.2.1 | Effectiveness

In the SR, a total of 8707 unique references retrieved from database searches. After title and abstract screening, 1322 were appraised as full text, and 284 references were excluded due to differences in

population, outcomes of interest, design or were considered as multiple publications of the same RCT. The review evaluated 497 trials that compared a wide spectrum of SMIs to usual care in adults living with obesity²⁰ (Appendix 4: PRISMA flowchart).

We conducted three different types of analyses on the comparative effectiveness and safety of SMIs: pairwise meta-analysis lumping all SMIs and comparing them with UC for all critical and important outcomes, NMA, additive CNMA and a subgroup meta-analysis based on the intensity of the intervention to explore whether the intensity of the intervention impacts on the outcome.^{39–43} For each outcome, we conducted a NMA to explore which combinations of components (interventions) work. In practise, most networks of multicomponent interventions, such as SMIs, are sparse and NMA may fail to estimate accurately the interventions' effects. In such networks, we are also interested to identify the “best” component or the best combination of components. Therefore, we conducted a CNMA to explore the effectiveness of the components and identify the most promising ones. The methods and results of the different meta-analyses are reported separately²¹ (COMPAR-EU platform - NMA).

3.2.2 | Values and preferences

We conducted a mixed methods scoping review of reviews to summarise the preferences and experiences of patients and their caregivers (informal caregivers and healthcare professionals) with SM in four chronic diseases and to identify relevant outcomes for SMIs from these perspectives. Methods and results are published elsewhere.^{23,44}

3.2.3 | Resource use and cost-effectiveness

The methods and results of these analyses are reported elsewhere²¹ (COMPAR-EU platform: Cost-effectiveness). These analyses aimed to assess the cost-effectiveness of SMIs for obesity. A health economic Markov model was used to estimate the long-term health effects of SMIs on obesity. Details of the model can be found elsewhere.⁴⁵ Health states in the model were based on the occurrence of type 2 diabetes mellitus, ischemic heart disease and stroke. The model was used to translate short term clinical outcomes on changes in BMI, observed in the SMI trials into long-term occurrence of the three obesity-related diseases, mortality, and costs. The short-term effects of SMIs (on BMI and quality of life) were derived from the NMA. The disease model was populated by country specific and disease specific data (when possible). The health economic models adopted a societal perspective, including healthcare related costs (related to obesity or unrelated), but also costs for informal care, productivity loss, and non-medical costs.

Due to the lack of detailed information on the resource use related to the SMIs (e.g., number of sessions, duration of sessions, group size), it was not possible to accurately estimate the cost of the SMI interventions. Because intervention costs were missing, it was

also not possible to do a regular cost-effectiveness analysis. Instead, a headroom analysis was conducted to estimate the maximum cost at which a given SMI could still be considered cost-effective. Two threshold values: €20 000 per quality-adjusted life year (QALY) and €50 000 per QALY were used for the headroom analysis. Headroom results were compared with intervention costs in the literature to assess the likelihood that the cost of SMI for obesity is below the headroom result.

3.2.4 | Contextual factors

To describe the most important contextual factor for the implementation of SMIs, the research team conducted a contextual framework to clarify how SMIs work in different settings and specific patient groups. First, they performed a qualitative review of reviews⁴⁶ to identify potential contextual factors and structured them according to the seven domains and (sub) determinants of the Tailored Implementation for Chronic Diseases (TICD) framework.⁴⁷ Then, a Delphi study was also carried out in which different stakeholders identified and prioritised the most relevant contextual factors for the different components of SMIs. The last step was to identify the contextual factors for the most effective SMIs, by reviewing the trials included in the NMA that informed the selected interventions on which the recommendations panel based their judgements.

3.3 | Certainty assessment and selection of the interventions

The four-step NMA GRADE guidance using a partially contextualised framework^{26–30} were used for the evidence of effects assessment and interpretation. To appraise the cost-effectiveness and resource use certainty assessment and the values and preferences evidence we also followed specific GRADE guidance.^{48,49}

3.4 | Prioritisation of Interventions

To select a manageable number of comparisons for the formulation of recommendations, we only presented SMI results versus UC. Then, we sorted the SMIs effect estimates for each critical outcome in a hierarchical order according to effect size (point estimate) into seven categories (large beneficial effect, moderate beneficial effect, small beneficial effect, trivial to no effect, small harmful effect, moderate harmful effect, and large harmful effect). Then, we prioritised those interventions with the greatest benefit and the highest certainty of the evidence, and we checked that results were in agreement with the p-score values, a ranking metric assuming values from zero (worst) to one (best).⁵⁰ Finally, we selected the SMIs with the largest beneficial effects and with the highest certainty in at least two critical independent outcomes.

3.5 | Evidence for recommendations

We used the GRADE Evidence to Decision (EtD) Frameworks^{24,25,51} to formulate the evidence-based recommendations from a population perspective. These recommendations were based on the evaluation of the benefits and harms of the SMIs and considering the costs, patients' values and preferences, acceptability, feasibility, and equity. These frameworks helped the panellists to use the evidence summaries in a more structured and transparent way to develop the recommendations. The discussion on the findings and evidence were organised in four meetings. The technical team formulated draft judgements for each framework and asked the panel if they agree with them using the GRADEpro GDT – Panel Voice online tool. In the final panel meeting the panellists reviewed the voting results of the Panel voice survey and considered the implications of those judgements to formulate the recommendations for the selected SMIs. However, given that the NMA was very sparse and imprecise, the panel also formulated a recommendation using the evidence from the standard pairwise meta-analysis (for the comparison “All SMIs vs UC”).

4 | RESULTS

4.1 | Recommendation for all SMI vs UC

For adults living with obesity, the COMPAR-EU Obesity panel, suggests in favour of using self-management interventions, rather than usual care (Conditional recommendation based on very low certainty in the evidence of effects ⊕○○○).

4.2 | Remarks

SMIs should be intense (more than 10 contact hours) and ideally include education and monitoring techniques plus one or more additional components, like behavioural techniques (either action-based or emotional-based).

For the implementation of the SMIs, it is important to consider the context and setting, the patient's additional related costs, and a definition of obesity that represents the patient itself (Appendix 5. Evidence to Decision Framework for all SMI vs. UC).

4.3 | Summary of the evidence

4.3.1 | Evidence of effects

The analyses demonstrated that most SMIs have trivial or marginal beneficial effects across all outcomes, in relation to the panel's previous validation for the thresholds. Despite the benefits, marginally

relevant for separate outcomes, the recommendations panel agreed that the sum of the effects may result in a small effect on the SMIs and that there were no harmful effects, excluding the possible burden related to the interventions. Consequently, the balance of the effects was probably favourable for the SMIs on the basis of very low certainty in the evidence effects (Table 1).

As additional exploratory analyses, the intensity subgroup analyses showed that overall, a high number of hours (more than 10 contact hours with the provider of the SMI) dedicated to the interventions may impact positively the outcomes (Appendix 7. Intensity subgroup analysis). Additionally, we created component Heat Plots, which allowed us to explore the effectiveness of components (combinations) using the estimates derived by NMA.^{39,52} In these plots, the diagonal elements refer to components, while the off-diagonal elements refer to the two-by-two combinations of components. Each element summarises the z-score of the interventions that include the corresponding component (combination), using the median as a summary measure. Also, the intensity of the colour is proportional to the magnitude of the statistical evidence. For instance, for BMI, all components seem to reduce their levels compared to UC, and the most effective seems to be Monitoring Techniques (MT). On the other hand, for Quality of life, the peers and laypersons or mixed components would be the most promising one (Appendix 8. Heat plots graphs).

4.3.2 | Values and preferences

The self-management process itself and the personal experience with the disease impacts on how patients' and caregivers' value the SMIs, and concomitant comorbidities were considered as barriers to self-management. These were consistent results across all four diseases.

The results of the scoping review of reviews showed that in people living with obesity, coping with the disease, defined as the mental attitude toward obesity or how well a person feels able to cope/manage with stress or other difficulties caused by the disease, appears to be the most influential outcome for most individuals. People with a high sense of obesity stigma experience a strongly devalued physical and moral identity, creating challenges in social interaction, including decision-making. Obesity is associated with weight bias and weight stigma, which affect people's perceptions of the disease, ultimately affecting their ability to gain self-efficacy, adherence to SMIs, patient activation and quality of life.²³

Most people in SM programmes reported that diet and exercise have a significant impact on their physical performance. As they begin earning confidence, skills, and a sense of self-efficacy to carry on activities they experience improvements in their lifestyle and quality of life. On the other hand, there was variability in how individuals experienced this gain in self-efficacy. Some reported having to deal with negative thoughts, along with other comorbidities (causing pain), initial exercise ache and uncomfortable dietary restrictions.²³

Although the COMPAR-EU project involved patients to select which outcomes were considered critical, there are some

TABLE 1 Summary of findings for all SMLs vs. usual care.

Critical outcome	Number of participants (studies)	Anticipated absolute effects (95% CI) difference	Certainty	Plain language statement
Comorbidities management				
Systolic Blood Pressure (SBP)	14923 (86 RCTs)	MD 2.218 mmHg lower (3.074 lower to 1.363 lower)	⊕○○○ Very low ^a	SMLs may reduce/have a marginal effect on systolic blood pressure but the evidence is very uncertain .
Diastolic Blood Pressure (DBP)	14702 (83 RCTs)	MD 1.59 mmHg lower (2.174 lower to 1.021 lower)	⊕○○○ Very low ^b	SMLs may reduce/have a marginal effect on diastolic blood pressure but the evidence is very uncertain .
Quality of life components				
Quality of life	1448 (15 RCTs)	SMD 0.157 SD higher (0.027 higher to 0.288 higher)	⊕⊕○○ Low ^c	SMLs may have a marginal effect on quality of life.
Coping with the disease – Depression	748 (10 RCTs)	SMD 0.21 SD lower (0.369 lower to 0.067 lower)	⊕○○○ Very low ^d	SMLs may reduce/have a marginal effect on depression but the evidence is very uncertain .
Coping with the disease – Stress	536 (7 RCTs)	SMD 0.06 SD lower	⊕○○○ Very low ^e	SMLs may reduce/have a marginal effect on stress, but the evidence is very uncertain.
Basic empowerment components				
Eating self-efficacy	1446 (9 RCTs)	SMD 0.13 SD higher (0.354 lower to 0.233 higher)	⊕○○○ Very low ^f	SMLs may increase/have a marginal effect on eating self-efficacy but the evidence is very uncertain .
Self-efficacy	790 (9 RCTs)	SMD 0.67 SD higher (0.362 higher to 0.994 higher)	⊕○○○ Very low ^g	SMLs may increase/have a marginal effect on self-efficacy but the evidence is very uncertain .
Exercise self-efficacy	521 (9 RCTs)	SMD 0.29 SD higher (0.39 lower to 0.88 higher)	⊕○○○ Very low ^h	SMLs may increase/have a marginal effect on exercise self-efficacy, but the evidence is very uncertain.
Weight management				
Body mass index (BMI)	21696 (142 RCTs)	MD 0.94 kg/m ² lower (0.03 higher to 0.34 higher)	⊕○○○ Very low ⁱ	SMLs may reduce/have a marginal effect on Body mass index (BMI), but the evidence is very uncertain.
Body fat	1843 (14 RCTs)	SMD 0.123 SD lower (0.389 lower to 0.142 higher)	⊕○○○ Very low ^j	SMLs may reduce/have a marginal effect on body fat, but the evidence is very uncertain.
Waist size	19723 (119 RCTs)	MD 3.45 cm lower (4.25 lower to 2.65 lower)	⊕○○○ Very low ^k	SMLs may reduce/have a marginal effect on waist size, but the evidence is very uncertain.
Weight management	32609 (189 RCTs)	MD 2.516 kg lower (2.997 lower to 2.034 lower)	⊕○○○ Very low ^l	SMLs may reduce/have a marginal effect on weight management, but the evidence is very uncertain.

^aWe rated down the certainty of evidence due to very serious risk of bias and serious inconsistency.

^bWe rated down the certainty of evidence due to very serious risk of bias and serious inconsistency.

^cWe rated down the certainty of evidence due to very serious risk of bias.

^dWe rated down the certainty of evidence due to serious inconsistency and very serious risk of bias.

^eWe rated down the certainty of evidence due to serious imprecision and very serious risk of bias.

^fWe rated down the certainty of evidence due to serious inconsistency, serious imprecision and very serious risk of bias.

^gWe rated down the certainty of evidence due to serious imprecision and very serious risk of bias.

^hWe rated down the certainty of evidence due to serious inconsistency, serious imprecision and very serious risk of bias.

ⁱWe rated down the certainty of evidence due to serious inconsistency and very serious risk of bias.

^jWe rated down the certainty of evidence due to serious inconsistency and very serious risk of bias.

^kWe rated down the certainty of evidence due to serious inconsistency and very serious risk of bias.

^lWe rated down the certainty of evidence due to serious inconsistency and very serious risk of bias.

variations in the literature, on how individual patients value some critical outcomes like long-term complications, hypoglycaemia, and weight change. The panel (which also included patients and

patient representatives) considered that there was probably no important uncertainty or variability on how patients value the outcomes.

4.3.3 | Resources required and cost-effectiveness

COMPAR-EU found 11 studies that published the cost of a SMI intervention for obesity. These studies, covering a wide variety of SMIs, showed that the resources required for SMIs are highly variable. The intervention cost presented by the studies ranged from 11€ to 1565€ (all costs transformed to 2020 euros), and the average cost of an SMI per person was about 438€.

Table 2 shows the results of the cost-effectiveness results for obesity. SMIs for obesity result in a gain in QALYs, but also an increase in total costs. The headroom estimate was 1357€ indicating that the SMI intervention could cost a maximum of 1357€ to be considered cost-effective. Because the intervention costs of SMIs found in the literature (438€; range 11 to 1565€) were below the headroom estimates for both thresholds (20 000€ and 50 000€) this indicates that SMIs for obesity are likely to be cost-effective.

In terms of their structure, intensity, and use of resources, SMIs are a complex and very diverse type of intervention. Some of them might be considered as requiring almost no resources, while others can be very resource-consuming. In the same way, SMIs vary widely in their effectiveness and consequently in their cost-effectiveness. However, an overall interpretation could be that there is a possibility that these SMIs are cost-effective, because the average cost of SMI for obesity in the literature (438€; range 11–1565€) is lower than the headroom estimate.

4.3.4 | Equity

The panel agreed that if SMIs are implemented or adapted to the culture and health literacy level of individuals, this could increase health equity. Also, incorporating peers may enhance adaptability, increasing equity. On the other hand, equity could be affected by

geography and accessibility, as well as access to mobile technology.

4.3.5 | Acceptability and feasibility

The obesity recommendations panel considered that SMIs are likely to be acceptable to main stakeholders. Likewise, SMIs are globally acceptable, for patients and/or caregivers. However, this could vary, as they may be affected by the setting, accessibility, adaptation, values (how outcomes are valued) and other factors. The panel acknowledged that, in general, all SMIs are probably feasible, but if there are limited trained human resources or lack of teamwork the implementation could be difficult.

4.4 | Justification of recommendation (all SMIs vs. UC)

The COMPAR-EU Obesity panel made a conditional recommendation in favour of SMIs, rather than UC, due to a probably favourable balance of effects. The panel agreed that resource requirements may vary, but the cost-effectiveness probably favours the interventions, also SMIs probably increase equity, and are possibly acceptable and feasible. SMIs should include the components of education, monitoring techniques and action-based or emotional-based behavioural techniques and SMIs duration should last for at least 10 h (high intensity) in total.

4.5 | Recommendations for selected SMI vs UC

In adults living with obesity, the COMPAR-EU Obesity panel, suggests in favour of using the following eight selected SMIs (see Table 3), rather than UC (conditional recommendation based on very low certainty in the evidence of effects ⊕○○○).

TABLE 2 Cost-effectiveness (All SMIs vs. UC), results for the UK.^a

Outcomes no of participants (studies)	Mean difference	Certainty	Plain language statement
QALYs (1 model; lifetime)	0.083 more QALYs per person	⊕⊕○○ Low ^{b,c}	The intervention may have a small effect on QALYs
Total costs (€ 2021) (1 model; lifetime)	314 to 1868€ more per person	⊕○○○ Very low ^c	The evidence on the incremental cost per person very is uncertain
ICER (1 model; lifetime)	3783 to 22 506€ per QALY	⊕○○○ Very low ^c	The evidence on incremental cost per additional QALY is very uncertain
Headroom ^d (1 model; lifetime)	1357€	⊕⊕○○ low ^{b,c}	The intervention may cost up to 1357 EUR per person and still be considered cost-effective

Abbreviations: ICER, incremental cost-effectiveness ratio; QALY, quality adjusted life years; €: euros.

^aDiscounted results for a lifetime time horizon.

^bRisk of bias: we downgraded two levels due to a low to very low certainty of evidence on the input parameters for the model.

^cThe model used the following input parameters from the NMA: HbA1c, BMI, systolic blood pressure, HDL cholesterol and LDL cholesterol.

^dFor the headroom analysis a threshold of 20 000 EUR per QALY was used to consider an intervention to be cost-effective.

4.6 | Summary of the evidence

4.6.1 | Evidence of effects

NMAs were used to assess 20 outcomes for obesity in seven categories and a total of 11 components were identified. The analyses of the studies reported that our selected SMIs have effects from small to

large in at least one critical outcome (Table 3). The undesirable effects were deemed as trivial or causing no harm by the NMA, except for the potential burden of the interventions, which were highlighted by the panel. Regarding the balance of the effects between benefits and harms, the panel agreed the selected SMIs were probably favourable for the selected SMIs compared to UC (with mostly a very low certainty of the effects ⊕○○○).

TABLE 3 Summary of findings of selected SMIs (Effect and certainty).

SMIs for T2DM	Large beneficial	Moderate beneficial	Small beneficial	Marginal to no effect
Monitoring and action-based behavioural techniques. ⊕○○○ Very low ^a	It may increase adherence, but the evidence is uncertain. ⊕⊕○○ Low	-	It may decrease diastolic blood pressure levels, but the evidence is very uncertain. ⊕○○○ Very low	BMI; Waist; Weight; SBP; Depression; QoL; Eating SE; Exercise SE
Monitoring and emotional-based behavioural techniques. ⊕○○○ Very low ^a	It may increase exercise self-efficacy, but the evidence is very uncertain. ⊕○○○ Very low	It may decrease systolic blood pressure levels, but the evidence is very uncertain. ⊕○○○ Very low	It may decrease diastolic blood pressure levels, but the evidence is very uncertain. ⊕○○○ Very low	BMI; Waist; Weight
Monitoring and action-based behavioural techniques and social support ⊕○○○ Very low ^a	It may increase eating self-efficacy, but the evidence is very uncertain. ⊕○○○ Very low	-	It may decrease depression, but the evidence is very uncertain. ⊕○○○ Very low	BMI; Waist; Weight; SBP; DBP; Stress
Monitoring techniques ⊕○○○ Very low ^a	-	It may decrease depression, but the evidence is very uncertain. ⊕○○○ Very low	It may increase self-efficacy, but the evidence is very uncertain. ⊕○○○ Very low	BMI; Waist; Weight; SBP; DBP; QoL; Eating SE
Emotional-based behavioural techniques. ⊕○○○ Very low ^a	-	-	It may decrease systolic and diastolic blood pressure levels and may increase self-efficacy but the evidence is very uncertain. ⊕○○○ Very low	BMI; Waist; Weight; Depression; QoL
Monitoring, action-based and emotional-based behavioural techniques and social support. ⊕○○○ Very low ^a	-	-	It may decrease stress, and may increase self-efficacy, but the evidence is very uncertain. ⊕○○○ Very low	BMI; Waist; Weight; SBP; DBP; QoL; Exercise SE; Eating SE
Monitoring, action-based and emotional-based behavioural techniques. ⊕○○○ Very low ^a	It may increase weight self-monitoring, but the evidence is uncertain. ⊕⊕○○ Low	-	-	Exercise SE; Eating SE; SE; QoL; depression; Stress; DBP, SBP; Weight
Monitoring, action-based and, emotional-based behavioural techniques lead by peers delivered remotely. ⊕○○○ Very low ^a			It may decrease body mass index, but the evidence is uncertain. ⊕⊕○○ Low	

Abbreviations: BMI, body mass index; DBP, diastolic blood pressure; QoL, quality of life; SBP, systolic blood pressure; SMIs, Self-management interventions; SE, Self-efficacy.

^aThe guideline panel judged the overall certainty of evidence as very low due to very serious risk of bias and very serious imprecision of the evidence.

All selected SMIs for people living with obesity in this project included Education as the main component, and most of them included Monitoring and/or behavioural techniques. Social support was another component that was present in some of the SMIs. Regarding the method of delivering of the interventions most are delivered face-to-face and just one had a remote delivery method. All these SMIs are delivered by professionals and just one may be delivered by peers. Those receiving the intervention are individuals meaning that these selected interventions are not designed to be delivered in groups.

4.6.2 | Values and preferences

An overview of SRs provided information about how patients value several of the outcomes of interest (critical/important) included in this clinical question.

As previously mentioned, coping with the disease (with stress and depression as surrogate markers) is the most influential outcome for most patients. The perceived obesity stigma brings a strongly devalued physical and moral identity, creating challenges in social interaction, including decision-making. A high sense of weight stigma impacts people's perception of the disease and their ability to gain self-efficacy.

Exercise and diet seem to have a substantial impact on physical functioning for people living with obesity experiencing SM programmes. Improvements in lifestyle were noted once people started to gain confidence, skills, and a sense of self-efficacy to perform activities. There could be variability on how individuals experience self-efficacy due to the burden of dealing with negative thoughts, other comorbidities (e.g., pain), the initial discomfort with exercise, and some dietary restrictions.

The analysis of utility values for the outcome of "weight" as assessed in individuals with obesity, revealed that extreme obesity results in a twofold decline in quality of life compared with adults living with obesity or those with overweight.

4.6.3 | Resources required and cost-effectiveness

The panel judged that the resources required varies for the majority of the selected SMIs, and that the cost-effectiveness does not favour either the intervention or the comparison for three interventions, while on the other hand, the cost-effectiveness probably favours the intervention for five of the selected SMIs.

Given the effectiveness and the threshold for cost-effectiveness, known as the headroom value, the maximum amount an intervention can cost varies widely across countries. Headrooms were estimated to range from €379 to €4920 for a threshold of €20 000 per QALY.

The reason for the variation in the headroom between countries was that both the QALY gain per participant and the long-term cost consequences per participant varied considerably between countries. In general, the estimated ranges were lowest for the United Kingdom

and highest for the Netherlands. As the short-term effects of SMI were relatively small, assumptions about the duration of SMIs effects were crucial and had a relatively large impact on the cost-effectiveness results.

4.6.4 | Equity

The panel reasoned that these interventions could increase equity if they are tailored to individual's culture and health literacy level. It is also relevant to consider that equity may be affected by geography and accessibility and in the case of SMIs delivered remotely, equity could be affected by the access to mobile technology.

4.6.5 | Acceptability and feasibility

The panel considered that most of the selected SMIs are probably acceptable and feasible for main stakeholders but may vary since they could be influenced by setting, accessibility, tailoring and other factors. Also, a lack of multidisciplinary work in this context may make the implementation of the SMIs difficult.

Please see Appendix 6: multi comparisons table (selected SMIs) for a summary of the judgements for all EtD criteria, across selected interventions, and Appendix 9: EtD frameworks for the selected SMIs for the complete set of frameworks.

4.7 | Justification of recommendations (selected SMIs)

The COMPAR-EU Obesity panel made conditional recommendations in favour of all selected self-management interventions, rather than UC, because of a probably favourable balance of the effects. The panel agreed that for most interventions, resource requirements vary substantially, and that five of the selected interventions could probably be considered cost-effective, while on the other three SMIs neither the intervention nor UC were favoured. The SMIs also probably increase equity and are probably acceptable and feasible.

As per the recommendation made for all SMIs vs UC, the selected SMIs should be of high intensity (>10 h) and include Education and Monitoring plus one or more additional components, like behavioural techniques (either Action-based or Emotional-based).

5 | DISCUSSION

5.1 | Main findings

The COMPAR-EU Obesity panel formulated rigorous and explicit recommendations in favour of SMIs for adults living with obesity suggesting the use of SMIs instead of UC alone, this recommendation is conditional due to the very limited certainty of the evidence on their

effects. However, the panel concluded that despite the very low certainty, the balance between desirable and undesirable effects probably favours the use of SMIs.

The panel emphasises the inclusion of Education and Monitoring techniques in the selected SMIs, along with one or more additional components, such as behavioural techniques (either Action-based or Emotional-based). These components were identified as the most frequently occurring across the selected SMIs. The panel also highlighted the importance of considering the context, setting, and potential patient-related costs when implementing the SMIs.

Regarding the resources required for implementation, the panel acknowledged that they may vary across interventions. However, five of the SMIs are likely to be cost-effective, while three of them did not show any discernible difference between the intervention and the comparison (UC). Furthermore, the panel concluded that these SMIs probably enhance equity and are generally acceptable, although acceptability may vary depending on factors such as the setting, accessibility, tailoring, and other contextual considerations. SMIs are also likely feasible, but successful implementation requires an adequate proportion of human resources and effective multidisciplinary collaboration. All the recommendations and the corresponding decision-making tools are available on the project's web-based platform (link to COMPAR-EU platform) facilitating access to a wide scope of stakeholders.

5.2 | Our results in the context of previous research

Recent clinical guidelines (CGs), advocate for behavioural interventions as part of obesity management including self-monitoring, education, action and emotional-based techniques, and others, delivered face-to-face, in group sessions by prepared multidisciplinary teams, tailoring these interventions to the patient's background and focusing on reachable outcomes.^{53,54} These guidelines emphasise intensive interventions to improve clinical outcomes, and to reduce the incidence of type 2 diabetes mellitus. Additionally, the CGs highlight the importance of addressing patient motivation for change and suggest the use of behavioural interventions such as cognitive-behavioural therapy incorporating self-monitoring delivered in groups or self-help formats. The multidisciplinary team approach is also highlighted.^{53–56}

COMPAR-EU recommendations align with those of the aforementioned CGs and include factors highlighted by the panel for successful implementation of the SMIs, such as effective multidisciplinary collaboration and tailoring SMIs to the unique background of each individual living with obesity.

Limited SRs have specifically addressed SMIs for obesity as a distinct chronic disease, with most focusing on obesity as an outcome or comorbidity of other conditions such as type 2 diabetes, osteoarthritis, or heart failure. Despite this, previous SRs highlighted the significance of implementing tailored SMIs to improve patient-important outcomes. The therapeutic patient education (TPE) component showed moderate effects in improving biomedical and

biopsychosocial outcomes in obesity, emphasising the need for customization based on patients' preferences.^{57,58} Other SRs have focused on exercise-related interventions, such as Nordic walking, to enhance weight loss, anthropometric outcomes, and comorbidity control. Unfortunately, no NMA studies on SMIs for obesity were identified.^{59,60}

The evidence surrounding the economic perspective of SMIs for obesity is uncertain. Few publications on SMIs have included associated costs, showing high variability depending on the complexity of the intervention. Some SMIs require substantial investment, while others do not. However, for obesity, SMIs seem to be cost-effective since the average costs reported are lower than the headroom estimate. It is important to note that due to limitations in the evidence (such as the description of individual SMI costs and the duration of SMI effects), we could not conduct a comprehensive cost-effectiveness analysis. Therefore, it is crucial for future research to address the quality of reporting of resource use and consider the evaluation of effects over long-term.

Regarding implementation of SMIs in this context, our recommendations support the need for patient-tailored approaches. The selection of the most suitable SMI should be a collaborative decision-making process involving adults living with obesity, considering their preferences, context and needs. Moreover, the healthcare system itself needs to transition from the prevailing traditional model of care to a patient-centred and collaborative approach. It is essential to avoid placing the entire responsibility for obesity management on the individual and instead, a collaborative environment should be fostered.⁶¹ We also consider that it is important to acknowledge that the lack of trained staff to meet the needs of individuals with obesity and the absence of multidisciplinary work can hinder the implementation and success of SMIs.^{61–63}

5.3 | Limitations and strengths

Our recommendations do not address the complete spectrum of challenges associated with implementing SMIs in daily clinical practice, including issues such as inconsistency and insufficient description of SMI measurements, lack of information on patient-relevant outcomes, particularly long-term outcomes, and limited cost data for implementation. Furthermore, the existing literature exhibits certain limitations concerning the reported outcomes, which primarily focused on clinically important outcomes as weight loss, rather than being centred on aspects such as quality of life. Consequently, several evidence gaps identified in earlier reviews persist, making it difficult to draw strong conclusions regarding the real benefits and impact of SMIs on health outcomes. Additionally, a substantial portion of the trials included in the review showed a high risk of bias due to high attrition bias, and the lack of participants, providers and researchers blinding.²⁰

In terms of limitations of the NMA, it is important to note that most networks were sparse (SMIs mostly compared with UC), with few head-to-head comparisons. Hence, the NMA estimates are mainly

driven by direct evidence, increasing the probability of confounding by the study characteristics. Also, there was large uncertainty in the NMA findings due to high levels of heterogeneity; that was addressed through exploratory analyses only. We presume there are multiple factors leading to this unexplained heterogeneity, including clinical diversity of SMI components and the type of UC provided, as well as the contextual factors influencing the implementation of SMIs, etc. Considering all the issues listed above, results should be interpreted with caution.

Our process has several strengths. We followed a rigorous, structured, and transparent methodology for developing recommendations based on the GRADE approach. We prioritised the inclusion of patients' perspectives by considering patient-important outcomes. To ensure the clinical relevance of the effects, we predefined magnitude thresholds for each outcome, based on the existing literature and validated them with the multidisciplinary expert panel.

Additionally, we developed novel health economic models from a societal perspective, and integrate patient's values and preferences, and contextual factors to inform decision-making on the use of SMIs. This comprehensive approach provides robust evidence to guide decision-making and may improve the implementation of the SMIs. Moreover, we have created an online platform featuring a range of decision-making tools, including a decision aid to empower stakeholders with better understanding and facilitate the successful implementation the SMIs in the management of obesity and other priority chronic conditions across Europe.

5.4 | Implementation considerations

When implementing SMI in general, it is crucial for healthcare providers to consider important contextual factors. One key contextual factor is the adaptation of advice, communication or interventions targeted to the patient's personal situation and level of knowledge. This requires adequate communication skills including empathy, providing understandable information, and asking relevant questions. On the other hand, patient's motivation to engage and their attitude toward self-management (e.g., beliefs about the importance of self-management for health, beliefs about the usefulness of certain self-management tasks) plays a significant role as a relevant contextual factor. Additionally, understanding patients' preferences about their own part in treatment is vital (e.g., the degree to which the patient wants to be involved in shared decision making, or expects or wants professional involvement in the day-to-day management of their illness). Considering the context and setting, as well as potential patient-related costs (e.g., nutrient supplements not covered by the health insurance) when implementing SMIs is also important. Furthermore, the presence of trained professionals and effective teamwork can greatly facilitate the successful implementation of SMIs. For specific considerations of selected interventions see Appendix 10: implementation considerations per component.

5.5 | Implications for research

Future studies should prioritise measuring patient-important outcomes, both critical and important outcomes (see Appendix 2. Critical and important outcomes). It is imperative that these studies incorporate an adequate design (sample size and follow-up beyond the intervention phase). Comprehensive reporting is essential, including detailed descriptions of the interventions of interest and their respective comparators. Furthermore, preferences and values of patients in relation to their self-management should be addressed in future research, along with the cost-effectiveness of interventions and exploring sub-categories of SMIs. Additionally, researchers should strive to report long-term effectiveness of the assessed interventions. This will enable a more comprehensive understanding of the sustained impact of SMIs and their implementation.

AUTHOR CONTRIBUTIONS

COMPAR-EU technical research team: MMA and JB and conceptualised this paper, led, and coordinated the recommendations development process and wrote the original draft. MMA, JB, CV, CCA and YS carried out the GRADE assessment of certainty of evidence, the summary of findings, developed the SMIs and outcomes prioritisation and developed the magnitude of decision thresholds and wrote-reviewed and edited the original draft. ENG led and carried out the patient values and preferences studies informing the recommendations and reviewed-edited the original draft. JN and MH led and carried out the contextual factors' studies informing the recommendations and reviewed-edited the original draft. GS, ST, KMK, CC and DM lead and conducted the statistical analyses, metaanalyses, NMA, CNMA and subgroup analyses and reviewed-edited the original draft. MHL lead and carried out the economic analyses and reviewed-edited the original draft. PAC, CO, MB, RS, MH, OG, and DM conceptualised the project and the methodology, secured funding, supervised the development of the recommendations, and reviewed-edited the original draft.

Obesity Panel members: MHL, MGG, SLK, IM, BSM, LPP, JBB, ZSP formed the panel, validated the outcomes and the magnitude of decision thresholds, developed the SMIs recommendations, and reviewed-edited the original draft. All authors were involved in writing the paper and had final approval of the submitted and published version.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflict of interest to declare.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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