


The development of a core outcomes set for self-management interventions for patients living with obesity

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Summary

Self-management interventions (SMIs) can improve the life of patients living with obesity. However, there is variability in the outcomes used to assess the effectiveness of SMIs and these are often not relevant for patients. In the context of COMPAR-EU, our aim was to develop a core outcome set (COS) for the evaluation of SMIs for patients with obesity. We followed a four steps multimethod approach: (1) the development of the initial catalogue of outcomes; (2) a scoping review of reviews on patients' values and preferences on outcomes of self-management (SM); (3) a Delphi survey including patients and patient representatives to rate the importance of outcomes; and (4) a 2-day consensus workshop with patients, patient representatives, healthcare professionals and researchers. The initial catalogue included 82 outcomes. Ten patients and patient's representatives participated in the Delphi survey. We identified 16 themes through the thematic synthesis of the scoping review that informed 37.80% of the outcomes on initial catalogue. Five patients, five healthcare professionals, and four researchers participated in the consensus workshop. After the consensus process, 15 outcomes were selected to be part of the final COS, and five supplementary outcomes were also provided. We developed a COS for the evaluation of SMIs in obesity with a significant involvement of patients and other key stakeholders. This COS will help improving data synthesis and increasing the value of SM research data in healthcare decision making.

KEYWORDS

core outcome set, obesity, patients, self-management interventions

What is already known about this subject

- The appropriate selection of outcomes is an essential stage of research aimed to guide decision-making and inform policy.

Abbreviations: COMET, core outcome measures in effectiveness trials; COS, core outcome set; EMPATHIE, empowering patients in the management of chronic diseases; EU, European Union; ICF, International Classification of Functioning, Disability and Health; PRO-STEP, Promoting Self-Management for Chronic Diseases in the EU; SMIs, self-management interventions; SRs, systematic reviews.

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- Various consensus processes have previously been used to develop core outcome set (COS), but it is uncertain, which are the most appropriate.
- Two previous studies have developed COS for the evaluation of interventions in patients living with overweight and obesity. One of them was restricted to the United Kingdom, including members of the public but not specifically persons with this condition, whereas the other COS was specific for patients undergoing bariatric and metabolic surgery.

What this study adds

- This work is the first to develop a COS specifically for self-management interventions for patients living with obesity in Europe by following an innovative, evidence-based multi-method approach.
- This study identified which outcomes are most important to adult people with obesity.
- This set of outcomes will be helpful to develop and address future intervention trials for patients living with obesity.

1 | INTRODUCTION

Obesity is an increasingly common public health issue; the worldwide prevalence of obesity nearly tripled between 1975 and 2016.¹ In 2016, more than 1.9 billion adults aged 18 years and older were overweight worldwide. Of these, over 650 million adults were obese. Overall, about 13% adult population (11% of men and 15% of women) were obese in 2016.¹ Obesity is a major risk for non-communicable diseases such as cardiovascular diseases; diabetes; musculoskeletal disorders; and some cancers (including endometrial, breast, ovarian, prostate, liver, gallbladder, kidney and colon).² Obesity is associated with many adverse outcomes, including morbidity, disability, premature death,¹ poor mental health,³ stigma and discrimination.⁴

Self-management (SM) is a dynamic, interactive, and daily activity in which individuals engage to manage their chronic illness.⁵ For the purpose of this study, we defined SM as 'actions that individuals, families, and communities engage in to promote, maintain, or restore health and cope with illness and disability, with or without the support of health professionals, and including but not limited to self-prevention, self-diagnosis, self-medication, and coping with illness and disability'.⁶ Optimal SM can help patients to manage symptoms, treatments, lifestyle changes and address emotional strategies to maintain a satisfactory quality of life.⁷ Self-management interventions (SMIs) are supportive interventions systematically delivered or led by healthcare staff or other patients with the aim of building patients' confidence and equipping them with the necessary skills. Their purpose is to actively engage patients (and informal caregivers where appropriate) in the management of their disease.⁸ Research evidence suggests that SMI can improve clinical outcomes in chronic conditions, such as body weight in patients with obesity,⁹ and patient-reported outcomes such as quality of life, self-efficacy and adherence.¹⁰

However, outcomes that measure effectiveness of an intervention often do not reflect what matters most to patients.¹¹ This is

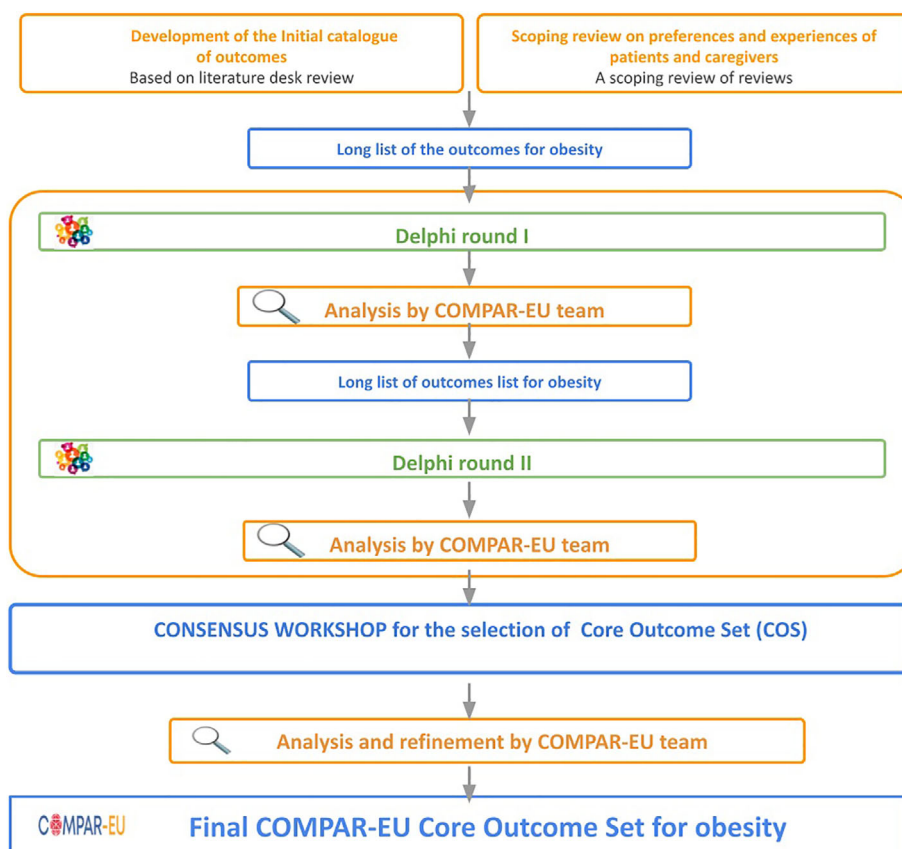
probably because most used measurement tools were not co-developed by involving patients.¹² Therefore, the appropriate selection of outcomes is an essential stage of research aimed to guide decision-making and inform policy.¹³ Research results can only be optimally compared if similar outcomes are used across studies. To overcome this, researchers are beginning to develop core outcome sets (COS); defined as '*agreed, standardised set of the outcomes that should be measured and reported at a minimum in clinical trials and studies of specific conditions and interventions, and are also suitable for research other than randomised trials*'.¹⁴

Therefore, the aim of this study was to develop the first COS for SMIs for patients living with obesity, from the perspective of patients and other stakeholders dealing with this condition. This work was conducted as part of the COMPAR-EU project; an EU-funded project that aims to bridge the gap between current knowledge and practice on SMIs for patients living with four high-priority chronic conditions: type 2 diabetes, obesity, chronic obstructive pulmonary disease and heart failure.⁶ Three other COS specific to type 2 diabetes mellitus, chronic obstructive pulmonary disease and heart failure have also been developed in the context of this project, in which manuscripts are under preparation.

2 | METHODS

We developed and published our protocol in *BMJ Open*.⁶ The COS-STAR guidelines were used to ensure the reporting of this study.¹⁵ The development of this COS for SMIs for patients living with obesity included four steps: (1) Development of the initial catalogue of outcomes; (2) Scoping review on preferences and experiences of patients and caregivers; (3) Delphi survey (two rounds) with patients and patients' representatives; and (4) Consensus workshop with patients, patient representatives, healthcare professionals and researchers (Figure 1).

FIGURE 1 Core outcomes set development process



2.1 | Development of the initial catalogue of outcomes

2.1.1 | Data sources and searches

Following methods used in previous COS studies including literature reviews,^{16,17} we reviewed selected references of two EU funded projects: *Promoting Self-Management for Chronic Diseases in the EU (PRO-STEP)* and *Empowering patients in the management of chronic diseases (EMPATHIE)* that included the development of several overviews of systematic reviews focusing on SMLs for chronic diseases.^{18,19} We additionally searched for COS in relevant organization databases such as Core Outcome Measures in Effectiveness Trials (COMET) (<http://www.comet-initiative.org/Resources/Database>) (Table S1), and also in Medline (via PubMed) by using specific search terms such as ‘core outcome set’; ‘Obesity’ (MeSH terms); ‘patient preference’ (MeSH terms); and ‘Outcome Assessment, Health Care’ (Mesh). We restricted the search to studies published in English, published from 2012 onward.

2.1.2 | Study selection

We included systematic reviews and individual studies that reported outcomes on SMLs for patients living with obesity. We excluded studies if the included outcomes were not related to obesity or when the outcomes were not developed considering the perspective of patients. Pairs of authors (RS, CO, MB and EC) conducted

independently title and abstract screening and full-text assessment. Disagreements were solved by consensus or with the help of a third author. We also checked references from included studies.

2.1.3 | Data extraction

For each included study, pairs of authors (RS, CO, MB and EC) independently extracted the following data: (i) name of the database source, (ii) the type of publication (i.e., published COS, literature reviews or systematic reviews), (iii) age groups, and (iv) list of outcomes and definitions.

2.1.4 | Data synthesis

We synthesized and classified outcomes into seven subdomains using a predefined taxonomy developed in the COMPAR-EU project²⁰: (i) basic empowerment components, (ii) adherence to expected SM behaviours, (iii) clinical-related outcomes, (iv) quality of life of patients and caregivers, (v) perceptions and satisfaction with care, (vi) healthcare use, and (vii) costs. Outcomes of the initial list and their definitions were iteratively reviewed and discussed by the research team and when outcomes were similar to others were merged. An external review process included a review by an external clinician and researcher (VP), followed by a discussion with multidisciplinary experts of the COMPAR-EU consortium. The list was edited in plain language by experts in health

literacy and patient representatives. This list of outcomes was used for the first round of the Delphi process (Step 3).

2.2 | Scoping review on preferences and experiences of patients and caregivers

We conducted a scoping review of reviews using the methodology proposed by Arksey and O'Malley's²¹ to identify and describe key concepts related to outcomes exploring patients' and caregivers' preferences and experiences with SM for the evaluation of SMIs for people living with obesity.

2.2.1 | Data sources and searches

We applied a content search strategy for values and preferences²² in combination with terms specific to obesity and searched in MEDLINE, CINAHL, and PsycINFO (from inception to February 2018).

2.2.2 | Study selection

We included quantitative, qualitative and mixed-methods reviews that explored preferences and experiences of patients or caregivers through a systematic search.

2.2.3 | Data extraction

Using a previously pilot-tested data extraction form, pair of authors collected the general characteristics and main findings of each review.

2.2.4 | Data synthesis

Finally, we conducted a descriptive thematic synthesis including identification of codes, descriptive themes, and main themes relevant to SMI outcomes.^{23,24} In addition, we developed an infographic to illustrate the themes by outcome. The infographic included the outcomes of the initial catalogue of outcomes informed by the scoping review, classified according to the preliminary version of the outcome taxonomy. This material was sent to participants 1 week in advance to inform and facilitate the selection of the final COS during the consensus workshop (Appendix S2, Infographic).

2.3 | Delphi survey

Following standard methodologies used in previous studies,^{25,26} we conducted a two-round modified Delphi online survey with a convenience sample to investigate and obtain consensus on what outcomes were important to participants living with obesity to measure the success of SMIs.

2.3.1 | Study population and recruitment strategy

Patients with obesity, caregivers and patients' representatives, who were able to understand and speak English, provided informed consent to participate. Participants were identified by the European Patients' Forum network of more than 70 patient organizations (<https://www.eu-patient.eu/about-epf/about-us/>) and other patient groups (e.g., those involved in the International Consortium for Health Outcomes Measurement) (<https://www.ichom.org/>). Recruitment started in February 2018 and ended in May 2018.

2.3.2 | Two-round Delphi survey

We administered a Delphi online survey in two separate rounds. In both rounds, participants were asked to rate the importance of outcomes using a 9-points Likert scale (1 being the least and 9 being the most important). In addition, in the second round, participants were able to see the ratings of participants in the first round. All participants received weekly reminders to complete the questionnaire.

All outcomes were then categorized into three groups based on the level of agreement participants reached. If an outcome reached a 70% level of agreement on importance with a Likert-scale mean score larger or equal to 7, meant the outcome was considered important to measure the success of an SMI, and it was categorized in the 'high consensus and high support outcomes' group. If less than 70% of participants agreed on the importance of one outcome, it was categorized in the group 'low consensus and mixed support'; finally, if an outcome reached a 70% level of agreement on non-importance with a Likert-scale mean score smaller or equal to 6, the outcome was categorized in the 'high consensus of moderate and low support'.

2.4 | Consensus workshop and final COS development

The final stage of the obesity COS development process was a 2-day consensus workshop. In the workshop patients and patients' representatives, healthcare professionals, researchers and project members participated. We aimed to invite a group of participants balanced in terms of gender, socioeconomic status, nationality and professional experience. Participants were provided with the results of the two-round Delphi survey (Step 3), and with the synthesis of results from the scoping review together with the infographic (Step 2).

The list of the outcomes was presented into the same seven sub-domains as for the Delphi survey, and sorted by level of agreement as described above. Participants were first presented with the outcomes of the 'low consensus mixed support' category, which were individually discussed and voted for inclusion (yes or no answers by raising hands) using the same criteria of importance and non-importance described above (i.e., at least of 70% level of agreement on importance). In the same way, participants reviewed the outcomes from the 'high consensus of moderate and low support', and from the 'high

consensus and high support' groups to determine which outcomes to include in the final COS. During this process, participants had the opportunity to discuss results, propose new outcomes and when outcomes were similar to others were merged. These data were entered by one author into a Microsoft Excel computer file and checked by a second author at the time of the voting. Those outcomes with at least 70% of agreement on high importance were included as part of the draft COS. After all outcomes had been voted on, and the draft COS was reviewed, participants were asked to select a maximum of 15 outcomes for the final COS following the same inclusion criteria previously described. Outcomes that reached a vote of 'high consensus and high support' but were not included in the final COS, became 'supplementary outcomes' (maximum 10 outcomes). The COMPAREU research team led step-by-step the discussion and addressed discrepancies across stakeholders (Figure 2).

3 | RESULTS

3.1 | Development of the Initial catalogue of outcomes

3.1.1 | Study selection

The review of previous EU funded projects identified 257 records focusing on SMI in chronic diseases in general. We included

44 systematic reviews specific to obesity (see references in Appendix S1, Systematic Reviews References). The search in MEDLINE (via PubMed) and COMET yielded 21 articles of which six were considered eligible. After full-text screening, we included five studies.²⁷⁻³¹ Figure S1 presents the study flowchart with the search results and study selection process.

3.1.2 | Study characteristics

Five studies included a COS,²⁷ a comprehensive International Classification of Functioning, Disability and Health (ICF) Core Set,²⁸ two systematic reviews^{29,30} and a protocol of a clinical trial design.³¹ Three of the studies were on outcomes related to surgery, and one was about a specific drug. The 44 SR included 948 individual studies with a total of 323 303 patients. The individual studies were conducted between the years 1950 and 2006, and were published between 2010 and 2016. Thirty-two of 44 SR (72.73%) included at least one European study.

3.1.3 | Catalogue of outcomes and outcomes classification

We identified 82 outcomes, which were categorized into the seven predefined subdomains and 24 elements (Table 1). The majority of outcomes were either 'Clinical related outcomes' ($n = 24$, 29.3%), or

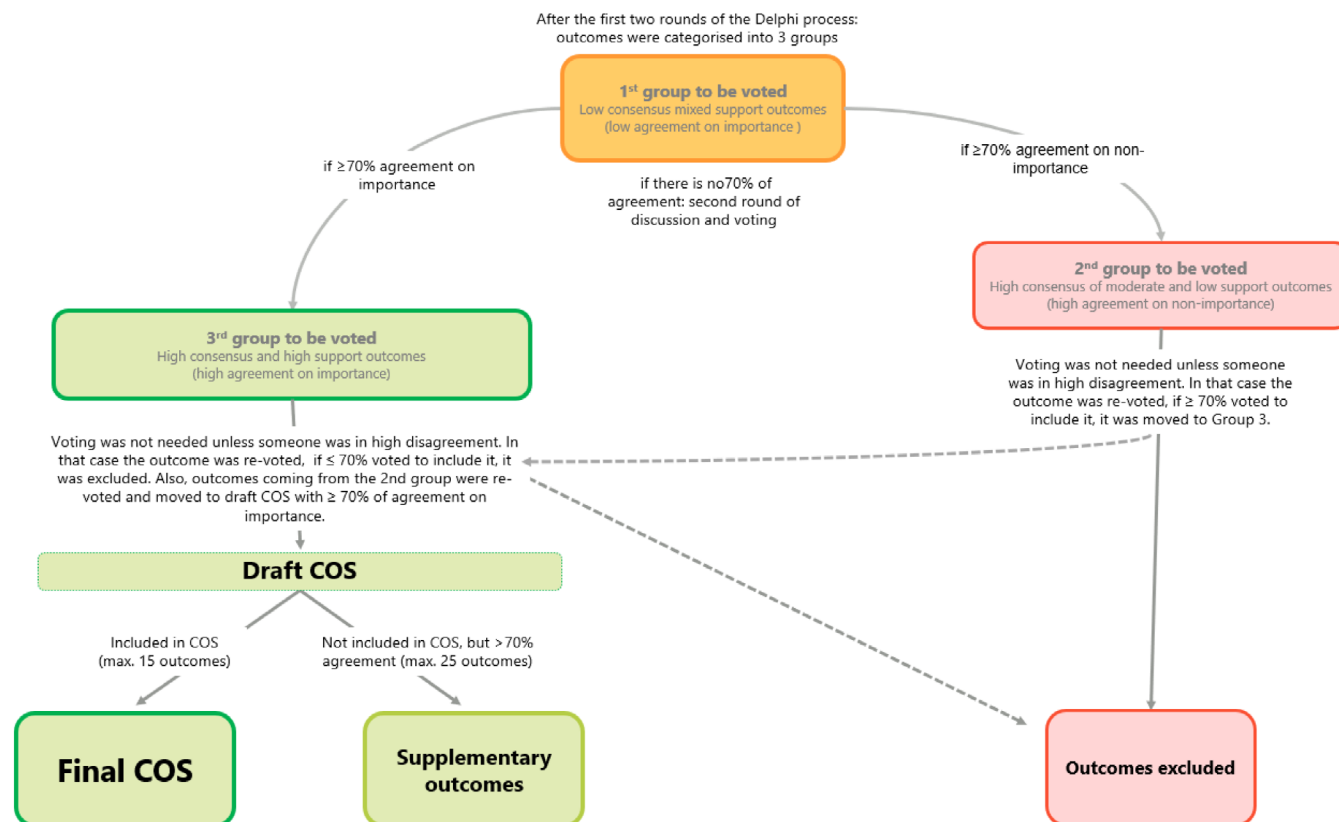


FIGURE 2 Consensus workshop process

TABLE 1 Initial catalogue of outcomes

Subdomains	Elements	Outcome	
Basic empowerment components	Patient activation level	1. Patient activation	
	Level of self-efficacy	2. Self-efficacy	
	Level of knowledge	3. Knowledge	
	Level of health literacy	4. Health literacy	
Level of adherence to expected SM behaviours	Clinical self-management behaviours	5. Adherence to programme	
		6. Taking medication or other treatment as advised (adherence)	
		7. Self-monitoring (Including self-recording)	
		8. Dietary planning	
	Lifestyle-related measures	9. Eating management	
		10. Energy intake	
		11. Dietary journal	
		12. Sugar-sweetened beverages consumption	
		13. Calorie burn	
		14. Physical Activity	
		Psychological self-management	15. Addictive behaviours
			16. Bingeing
			17. Purging
	18. Adverse events		
	Clinical-related outcomes	Complications	19. Complications
			20. Blood pressure control
		Disease progression	21. BMI
22. Bowel motion issues			
23. Breathing problems during sleep			
24. Breathlessness (dyspnoea)			
25. Cardiac rhythm			
26. Heat waves			
27. Lipid control			
28. Nausea			
29. Numbness			
30. Physical fatigue			
31. Sleep quality			
32. Snoring			
33. Stable weight			
34. Swallowing disorders			
35. Symptoms (general)			
Mortality	36. Waist size		
	37. Weight loss		
	38. Cardiovascular risk		
	39. Chance of developing other diseases		
	40. General metabolic functions		
	41. Mortality		
Quality of life of patients and caregivers	Caregivers' quality of life and competences	42. Caregiver quality of life	
		43. Caregiver burden	
		44. Caregiver knowledge	
		45. Caregiver self-efficacy	
		46. Caregiver anxiety and/or depression	

TABLE 1 (Continued)

Subdomains	Elements	Outcome
	Physical functioning	47. Usual activities 48. Mobility 49. Work 50. Physical activities 51. Sex life 52. Normality 53. Pain
	Psychological functioning	54. Depression 55. Anxiety 56. Stress 57. Coping 58. Hostility 59. Happiness 60. Self-esteem
	Social relations and activities	61. Family relationships 62. Friends 63. Social activities
Perceptions and satisfaction with care	Overall satisfaction with self-management interventions	64. Care satisfaction 65. Consultation time
	Perception of being well and sufficiently informed (quality of information provision)	66. The patient feels s/he has enough information
	Personalized care	67. Participation and decisions making
	Perception of patient-provider relationship	68. Patient healthcare provider relation 69. Communication with healthcare professionals
Healthcare use	Number of visits or contacts with healthcare providers	70. (Number of) primary care or outpatient (ambulatory) visits 71. (Number of) nurse visits 72. (Number of) visits to specialist doctors 73. Number of visits with other healthcare professionals 74. (Number of) virtual visits or contacts with healthcare providers
	Emergency departments visits	75. (Number of) emergency department visits (hospital)
	Hospital admissions and length of stay	76. (Number of) hospital admissions 77. The length of time spent in hospital 78. (Number of) re-hospitalizations, unexpected return to hospital
Costs	Cost for the healthcare system	79. Impact on healthcare costs for the healthcare system 80. Cost savings for the healthcare system as a result of the self-management intervention
	Cost for patient (out of pocket payments)	81. Direct medical costs for patient (out of pocket expenses)
	Cost-effectiveness	82. Value for money of the self-management intervention

were included in the 'Quality of life of patients and caregivers' subdomain ($n = 22$, 26.8%). The remaining were distributed in: 'Adherence to expected self-management behaviours' ($n = 13$, 15.9%),

'Health care use' ($n = 9$, 11.0%), 'Perceptions and satisfactions with quality of care' ($n = 6$, 7.3%); 'Basic empowerment components' ($n = 4$, 4.9%), and 'Costs' ($n = 4$, 4.9%).

TABLE 2 Identified themes according to the COMPAR-EU taxonomy subdomains

Taxonomy subdomains	Themes
Basic empowerment components	Health knowledge ^{39,41} Help-seeking behaviour ^{34,35} Technological literacy ³⁷
Level of adherence to expected SM behaviours	Adherence to treatment ^{32,33,36} The perceived benefit of the intervention ^{36,37} Weight control ^{33,41}
Clinical-related outcomes	Progression of disease ^{33,38}
Quality of life of patients and caregivers	Physical functioning ³⁹ Psychological distress ^{33-35,37,39-41} Social support ^{36,41}
Perceptions and satisfaction with care	Patient-provider interaction ^{34,35,42} Perceived quality of care ³⁵
Healthcare use	Access to healthcare ^{35,44} Visits or contacts with healthcare professionals ³⁵
Costs	Cost for patients (out of pocket) ³² Cost-effectiveness ³³

3.2 | Scoping review on preferences and experiences of patients and caregivers

3.2.1 | Study selection

After removing duplicates, searches yielded 2154 unique references resulting in 67 records selected for full-text screening, and 15 reviews finally included.³²⁻⁴⁶ Figure S2 presents the study selection flow diagram.

3.2.2 | Study characteristics

Of the 15 reviews included, seven were published between 2015 and 2017 (46.6%). The majority were qualitative evidence synthesis ($n = 8$, 53.3%) and the number of included studies ranged from 6⁴¹ to 29 primary studies.⁴³ Most of the reviews ($n = 14$, 93%) addressed patients' perspectives, except for one review⁴⁴ (7%) that addressed only the perspective of healthcare providers. Most reviews ($n = 10$, 66.6%) explored the experiences of patients in the process of SM, four explored the experiences with SM_I,^{36,37,39,46} and one review explored the patients' preferences regarding weight change.³⁸

3.2.3 | Identified themes

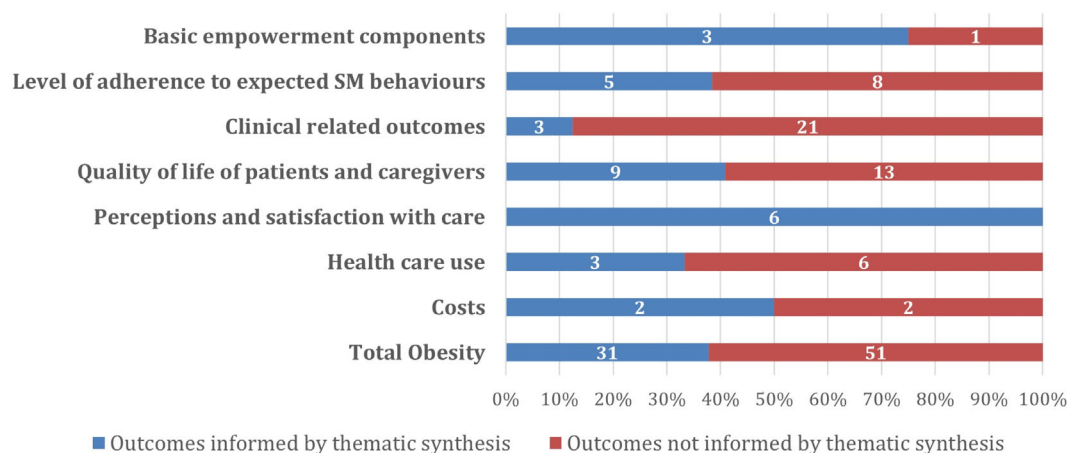
We identified 16 themes according to the COMPAR EU taxonomy subdomains (Table 2).

3.2.4 | Mapping of themes

Of the 82 outcomes of the initial catalogue of outcomes, 31 were covered in the thematic synthesis, meaning nearly one out of four were informed by the scoping review ($n = 31$, 37.80%). All outcomes of the subdomain 'Perception and satisfaction with care' were informed by the scoping review findings ($n = 6$, 100%), while the 'Clinical outcomes' subdomain had the least number of outcomes informed ($n = 3$, 12.50%). Figure 3 reports the number of outcomes informed by the thematic synthesis of the scoping review.

3.2.5 | Infographics

One infographic on obesity was developed for the final consensus workshop. The infographic included a summary of the main findings and topic-related images (Appendix S2, Infographic).

**FIGURE 3** Mapping of themes per COMPAR-EU taxonomy subdomains

3.3 | Delphi survey

Ten participants participated in the two-round Delphi online survey and only one participant did not complete the second round of the survey. The majority of the participants were women (70%) and were patient advocates or patient representatives. Five of the included participants (50%) were between 45 and 54 years

old and the majority had a bachelor's degree or a higher education (masters' or equivalent; doctoral or equivalent) (Table S2).

After the Delphi survey, of the 82 included outcomes, 27 were categorized in the 'high consensus and high support outcomes' group, 49 in the 'low consensus mixed support outcomes' group and five in the 'high consensus of moderate and low support'.

TABLE 3 Outcomes included in the core outcome set

Outcome	Definition
Self-efficacy	A person's belief that s/he is capable of doing something, often related to a specific goal s/he wants to achieve; feeling of confidence and of being in control. According to the group health, literacy is a prerequisite and can be included here
Participation and decisions making	Feeling able to participate actively in her/his own care and treatment decisions (as much as s/he wishes)
Patient activation	The knowledge, skills and confidence a person has in managing their own health and healthcare, including a feeling of being responsible for taking care of their own health
Adherence to programme ^a	(1) Adherence to programme: Adherence to diet, exercise plan, etc. (as a whole) The extent to which a patient follows the prescribed treatment, such as taking medication as advised and following lifestyle advice. (2) Taking medication or other treatment as advised: The extent to which a patient follows the prescribed treatment, such as taking medication as advised and following lifestyle advice. (3) Direct medical costs for patient: Out of pocket expenses
Self-monitoring (including self-recording)	The extent to which a patient (regularly) monitors herself/himself as agreed with her/his healthcare professionals, for example her/his symptoms or her/his weight
Healthy nutrition habits/personalized nutrition ^a	(1) Dietary planning: Having a healthy/balanced eating pattern. (2) Eating management: Healthy eating (personalized nutrition). (3) Sweet tasting beverages consumption: Sugary drinks with sugar or artificial sweetened. (4) Mindful eating: Being able to stop eating when feeling full
Quality of life—Physical and psychological functioning ^a	(1) Usual activities: Being able to do usual activities, such as personal hygiene, housework, managing finances. (2) Normality: Feeling able to live a 'normal' life. (3) Mobility: Being able to walk, climb stairs, bend, cross legs, get up from chairs). (4) Work: Being able to do work tasks, or to take up work/paid employment. (5) Physical Activities: Being able to participate in and enjoy physical activities. (6) Depression: Feeling depressed. (7) Anxiety: Feeling anxious. (8) Stress: Feeling stressed
Coping with the disease ^a	(1) Coping: How well a person feels able to cope/manage with stress or other difficulties caused by the disease. (2) Attitude: Mental attitude toward the condition
Social interactions ^a	(1) Friends: Relationship with friends. (2) Social activities: Having the confidence/energy/motivation to participate in social activities. (3) Family relationships: Relationship with partner/spouse and/or ability to care for children. (4) Coping: Coping with family and friends
Integration at work ^b	Being able to do work tasks, or to take up work/paid employment
Physical activity	Physical activity/exercise as advice (adherence to the exercise plan)
Weight management ^a	(1) Weight loss: Reduction in weight. (2) Stable weight: Being able to keep a stable weight. (3) Waist size: Measure of waist circumference
Comorbidities management ^a	(1) Blood pressure control: Lowering of blood pressure or needing to use less blood pressure medication. (2) Reduce the chance of developing other diseases: Such a heart disease, diabetes, coronary artery disease, metabolic syndrome
Patient-healthcare provider relationship ^a	(1) Patient-healthcare provider relation: Patient's confidence (trust) in the healthcare provider (professional). (2) Communication with healthcare professionals: How good the communication is between the patient and healthcare professional(s). (3) Consultation time. (4) Care satisfaction: How satisfied the patient is generally/overall with her/his care. (5) Information: The patient feels s/he has enough information
Cost-effectiveness for the health system—value-based outcomes ^a	(1) Impact on health care costs for the healthcare system: Impact on healthcare costs for the healthcare system. (2) Cost savings for the healthcare system as a result of the self-management intervention: Cost savings for the healthcare system as a result of the self-management intervention. (3) Value for money of the self-management intervention: Cost-effectiveness. (4) Overall treatment burden including comorbidities

^aMerged outcomes.

^bNew outcome proposed by the participants.

TABLE 4 Supplementary outcomes

Outcome	Definition
Addictive behaviours	For example, alcohol, drugs, gambling, shopping...
Sleep quality ^a	(1) Breathing problems during sleep: Being able to breathe easily when sleeping/not needing the sleep mask as much as before (obstructive sleep apnoea). (2) Sleep quality: Overall quality of sleep
Medication-adverse events	Problems or injuries related with the treatment or with care (e.g., medication side effects)
Pain	Feeling pain or discomfort
Sex life	Being able to have a satisfactory sex life

^aMerged outcomes.

3.4 | Consensus workshop and final COS development

Ten participants attended the consensus workshop, five were patients living with obesity who participated in the Delphi survey and five were healthcare professionals who were informed on the Delphi results before the workshop took place. Of the 10 participants, there was only one male and the age of all participants ranged from 25 to 65. Four members of the COMPAR-EU team (CV, RS, VS, NA) also participated.

Participants selected and prioritized 15 outcomes for the final COS, five supplementary outcomes were also provided. The COS included five individual outcomes originally discussed and voted during the Delphi, nine composed outcomes resulting from the merging of 22 'high consensus and high support outcomes' with 14 'low consensus mixed support outcomes' and finally, one new outcome 'Integration at work' proposed by the participants. None of the outcomes included in the final COS were from the 'high consensus of moderate and low support' group. The five supplementary outcomes included: (1) Addictive behaviours; (2) Sleep quality; (3) Medication adverse events; (4) Pain; and (5) Sex life. Table 3 presents the final list of outcomes and Table 4 presents the five supplementary outcomes.

4 | DISCUSSION

4.1 | Main findings

Our study produced a COS for SMIs for patients (aged 18 years or older) living with obesity including 15 outcomes important to patients.

4.2 | Our results in the context of previous research

According to the COMET database, an increasing number of COSs have been developed over the years across a range of health areas.⁴⁷

For example, several studies have looked at developing COS in childhood asthma using different methods and proposing slightly different COS.⁴⁸⁻⁵⁰ One study employed an expert panel approach⁴⁹; another study used literature reviews and expert opinion⁵⁰; whereas another combined results from a Delphi survey with clinicians and interviews with parents and children.⁴⁸ Various consensus processes have also been used to develop COS, but it is uncertain, which are the most appropriate.^{51,52} Our COS was developed specifically for SMIs for patients living with obesity in Europe through a multimethod approach, including an extensive search of the literature, a Delphi survey, and a consensus workshop with main stakeholders. Two previous studies have developed COS for the evaluation of interventions in patients living with overweight and obesity.^{27,53} One of them identified outcomes important to patients in the context of behavioural weight management intervention programmes for overweight and obesity, and the most appropriate instruments for measuring each outcome.⁵³ This COS was developed through a multistep approach including members of the public with lived experience of weight management programmes but restricted to the United Kingdom. They identified eight outcomes partially different from the ones we identified (e.g., diabetes status or they have reported weight and BMI as two separate outcomes, whereas we merged them into one category 'weight management'). The other study, developed a COS for patients undergoing bariatric and metabolic surgery and included nine outcomes, some similar to ours (e.g., weight, quality of life) but others were focused specifically on the surgical procedure (i.e., 'technical complications of the specific operation', and 'any reoperation/reintervention').²⁷

4.3 | Strengths and limitations

Our study has several strengths. To our knowledge, this is the first attempt to produce a COS for SMIs for patients (aged 18 years or older) living with obesity. According to Gargon et al.,⁴⁷ during the last years, there has been an improvement in COS development and reporting. However, concerns remain around the adequate reporting criteria of the methods employed and on the appropriateness of the methods needed to reach consensus among participants. Our study addresses these difficulties by following a four steps evidence-based approach involving patients' representatives, health professionals, researchers and most importantly patients living with obesity. Furthermore, a protocol has been previously developed and published explicitly reporting our a priori methodology.⁶

As potential limitations, although Delphi processes have been recommended to identify which outcomes to measure in clinical trials,⁵⁴ they have also been criticized for the use and selection of experts, raising a debate around the issue of defining consensus and expertise.^{54,55} Another limitation, it is the limited generalizability of the COS due to the use of a convenience sample and the inclusion of a small number of participants with only one male participant and the majority being highly educated. In addition, social and peer pressures may have influenced the consensus process, as voting was not anonymous.

4.4 | Implications for practice and research

The COS for patients living with obesity will help standardize outcome reporting in this area, and facilitate comparison of data across studies, to guide clinical practice. This COS will be useful to develop and address future intervention trials for patients living with obesity, and it will support and structure future research in the area. We recommend that future research evaluating SMI for obesity should consider at least these outcomes. Further work is needed to identify and provide guidance on the most appropriate outcome measures for the included outcomes in this COS. Also, future research is needed to replicate the findings from this COS study, and study its generalizability in different settings.

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CONFLICT OF INTEREST

The authors report no conflict of interest.

AUTHOR CONTRIBUTIONS

Study concept and design: All authors. Initial catalogue of outcomes: Rosa Suñol, Carola Orrego and Marta Ballester. Delphi survey: Rosa Suñol, Carola Orrego, Valentina Strammiello, Kaisa Immonen, Lyudmil Ninov and Marta Ballester. Scoping review: Ena Niño de Guzmán and Pablo Alonso-Coello. Consensus workshop: Claudia Valli, Rosa Suñol, Valentina Strammiello and Nina Adrion. Drafting of the article: Claudia Valli, Ena Niño de Guzmán and Pablo Alonso-Coello. Critical review of the manuscript: Claudia Valli, Rosa Suñol, Carola Orrego, Ena Niño de Guzmán, Kaisa Immonen, Lyudmil Ninov, Marieke van der Gaag, Marta Ballester and Pablo Alonso-Coello. Final approval: All authors.

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REFERENCES

- World Health Organisation. Obesity and overweight. Accessed May 13, 2020. <https://www.who.int/en/news-room/fact-sheets/detail/obesity-and-overweight>
- Kyrou I, Randeve SH, Tsigos C, Grigorios Kaltsas G, Weickert OM. Clinical problems caused by obesity. In: Feingold KR, Anawalt B, Boyce A, et al., eds. *Endotext*. MDText.com, Inc.; 2000.
- Atlantis E, Baker M. Obesity effects on depression: systematic review of epidemiological studies. *Int J Obes (Lond)*. 2008;32:881-891.
- Puhl RM, Moss-Racusin CA, Schwartz MB, Brownell KD. Weight stigmatization and bias reduction: perspectives of overweight and obese adults. *Health Educ Res*. 2008;23:347-358.
- Lorig KR, Holman H. Self-management education: history, definition, outcomes, and mechanisms. *Ann Behav Med*. 2003;26(1):1-7.
- Ballester M, Orrego C, Heijmans M, et al. Comparing the effectiveness and cost-effectiveness of self-management interventions in four high-priority chronic conditions in Europe (COMPARE-EU): a research protocol. *BMJ Open*. 2020;10(1):e034680.
- Schulman-Green D, Jaser S, Martin F, et al. Processes of self-management in chronic illness. *J Nurs Scholash*. 2012;44(2):136-144.
- Tattersall RL. The expert patient: a new approach to chronic disease management for the twenty-first century. *Clin Med (Lond)*. 2002;2(3):227-229.
- Hartmann-Boyce J, Johns DJ, Jebb SA, Summerbell C, Aveyard P, Behavioural Weight Management Review Group. Behavioural weight management programmes for adults assessed by trials conducted in everyday contexts: systematic review and meta-analysis. *Obes Rev*. 2014;15(11):920-932.
- Chiarotto A, Terwee CB, Deyo RA, et al. A core outcome set for clinical trials on non-specific low back pain: study protocol for the development of a core domain set. *Trials*. 2014;15:511.
- Young B, Bagley H. Including patients in core outcome set development: issues to consider based on three workshops with around 100 international delegates. *Res Involv Engagem*. 2016;2:25.
- Williamson PR, Altman DG, Blazeby JM, et al. Developing core outcome sets for clinical trials: issues to consider. *Trials*. 2012;13:132.
- Moloney RM, Messner DA, Tunis SR. The increasing complexity of the core outcomes landscape. *J Clin Epidemiol*. 2019;116:150-154.
- Williamson PR, Altman DG, Bagley H, et al. The COMET handbook: version 1.0. *Trials*. 2017;18(suppl 3):280.
- Kirkham JJ, Gorst S, Altman DG, et al. Core outcome set—STAndards for reporting: the COS-STAR statement. *PLoS Med*. 2016;13(10):e1002148.
- Webbe J, Brunton G, Ali S, Duffy JM, Modi N, Gale C. Developing, implementing and disseminating a core outcome set for neonatal medicine. *BMJ Paediatr Open*. 2017;1(1):e000048. <https://doi.org/10.1136/bmjpo-2017-000048>
- Schlessinger DI, Iyengar S, Yanes AF, et al. Development of a core outcome set for clinical trials in basal cell carcinoma: study protocol for a systematic review of the literature and identification of a core outcome set using a Delphi survey. *Trials*. 2017;18(1):4-9.
- EU-PROSTEP Project Promoting Self-Management for Chronic Diseases in the EU-PROSTEP Project. European Commission. Pilot project on the promotion of self-care in chronic diseases in the European Union. Final report 2018. Accessed September 14, 2020. <https://www.eu-patient.eu/globalassets/projects/prostep/pro-step-final-report.pdf>
- EMPATHIE Consortium. *EMPATHIE Empowering patients in the management of chronic diseases. Final summary report*. 2014. Accessed September 14, 2020. https://ehff.eu/wp-content/uploads/2015/10/empathie_frep_en.pdf
- Orrego C, Ballester M, Pacheco-Barrios K, et al. Development and external validation of a comprehensive taxonomy of self-management interventions in chronic conditions: the COMPARE-EU taxonomy. 2019. Accessed September 14, 2020. https://self-management.eu/wp-content/uploads/2019/11/7863_Taxonomy_GIN_Poster.pdf

21. Arksey H, O'Malley L. Scoping studies: towards a methodological Framework. *Int J Soc.* 2005;8(1):19-32.
22. Selva A, Sola I, Zhang Y, et al. Development and use of a content search strategy for retrieving studies on patients' views and preferences. *Health Qual Life Outcomes.* 2017;15(1):126.
23. Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in systematic reviews. *BMC Med Res Methodol.* 2008; 8(1):45.
24. Campbell R, Pound P, Morgan M, et al. Evaluating meta-ethnography: systematic analysis and synthesis of qualitative research. *Health Technol Assess.* 2011;15(43):1-164.
25. Hsu C-C, Sandford BA. The Delphi technique: making sense of consensus. *Pract Assess Res Eval.* 2007;12:10.
26. Akins RB, Tolson H, Cole BR. Stability of response characteristics of a Delphi panel: application of bootstrap data expansion. *BMC Med Res Methodol.* 2005;5:37.
27. Coulman KD, Hopkins J, Brookes ST, et al. A core outcome set for the benefits and adverse events of bariatric and metabolic surgery: the BARIACT project. *PLoS Med.* 2016;13(11):e1002187.
28. Weigl M, Cieza A, Andersen C, Kollerits B, Amann E, Stucki G. Identification of relevant ICF categories in patients with chronic health conditions: a Delphi exercise. *J Rehabil Med.* 2004;36(suppl 44): 12-21.
29. Coulman KD, Abdelrahman T, Owen-Smith A, Andrews RC, Welbourn R, Blazeby JM. Patient-reported outcomes in bariatric surgery: a systematic review of standards of reporting. *Obes Rev.* 2013; 14(9):707-720.
30. Hopkins JC, Howes N, Chalmers K, et al. Outcome reporting in bariatric surgery: an in-depth analysis to inform the development of a core outcome set, the BARIACT study. *Obes Rev.* 2015;16(1):88-106.
31. Anderson JW. Clinical trial design for obesity agents: a workshop report. *Obes Res.* 1998;6(4):311-315.
32. Garip G, Yardley L. A synthesis of qualitative research on overweight and obese people's views and experiences of weight management. *Clin Obes.* 2011;1(2-3):110-126.
33. Ohsiek S, Williams M. Psychological factors influencing weight loss maintenance: an integrative literature review. *J Am Acad Nurse Pract.* 2011;23(11):592-601.
34. Henderson E. Obesity in primary care: a qualitative synthesis of patient and practitioner perspectives on roles and responsibilities. *Br J Gen Pract.* 2015;65(633):e240-e247.
35. Mold F, Forbes A. Patients' and professionals' experiences and perspectives of obesity in health-care settings: a synthesis of current research. *Health Expect.* 2013;16(2):119-142.
36. Archibald D, Douglas F, Hoddinott P. A qualitative evidence synthesis on the management of male obesity. *BMJ Open.* 2015;5:e008372.
37. Lyzwinski LN, Caffery LJ, Bambling M, Edirippulige S. Consumer perspectives on mHealth for weight loss: a review of qualitative studies. *J Telemed Telecare.* 2018;24(4):290-302.
38. Doyle S, Lloyd A, Moore L, Ray J, Gray A. A systematic review and critical assessment of health state utilities: weight change and type 2 diabetes mellitus. *Pharmacoeconomics.* 2012;30(12):1133-1143.
39. McIntosh T, Hunter DJ, Royce S. Barriers to physical activity in obese adults: a rapid evidence assessment. *J Res Nurs.* 2016;21(4): 271-287.
40. Greaves C, Poltawski L, Garside R, Briscoe S. Understanding the challenge of weight loss maintenance: a systematic review and synthesis of qualitative research on weight loss maintenance. *Health Psychol Rev.* 2017;11(2):145-163.
41. Malterud K, Ulriksen K. Obesity, stigma, and responsibility in health care: a synthesis of qualitative studies. *Int J Qual Stud Health Well-Being.* 2011;6(4):8404.
42. Papadopoulos S, Brennan L. Correlates of weight stigma in adults with overweight and obesity: a systematic literature review. *Obesity.* 2015;23(9):1743-1760.
43. Brown I, Gould J. Decisions about weight management: a synthesis of qualitative studies of obesity. *Clin Obes.* 2011;1(2-3):99-109.
44. Dewhurst A, Peters S, Devereux-Fitzgerald A, Hart J. Physicians' views and experiences of discussing weight management within routine clinical consultations: a thematic synthesis. *Patient Educ Couns.* 2017;100(5):897-908.
45. Sherson EA, Yakes Jimenez E, Katalanos N. A review of the use of the 5 A's model for weight loss counselling: differences between physician practice and patient demand. *Fam Pract.* 2014;31(4):389-398.
46. Moredich CA, Kessler TA. Physical activity and nutritional weight loss interventions in obese, low-income women: an integrative review. *J Midwifery Womens Health.* 2014;59(4):380-387.
47. Gargon E, Gorst SL, Williamson PR. Choosing important health outcomes for comparative effectiveness research: 5th annual update to a systematic review of core outcome sets for research. *PLoS ONE.* 2019;14(12):e0225980.
48. Sinha IP, Smyth RL, Williamson PR. Using the Delphi technique to determine which outcomes to measure in clinical trials: recommendations for the future based on a systematic review of existing studies. *PLoS Med.* 2011;8(1):e1000393.
49. Reddel HK, Taylor DR, Bateman ED, et al. An official American Thoracic Society/European Respiratory Society statement: asthma control and exacerbations: standardizing endpoints for clinical asthma trials and clinical practice. *Am J Respir Crit Care Med.* 2009;180(1):59-99.
50. Busse WW, Morgan WJ, Taggart V, Togias A. Asthma outcomes workshop: overview. *J Allergy Clin Immunol.* 2012;129(3 suppl):S1-S8.
51. Kirkham JJ, Gorst S, Altman DG, et al. Core outcome set-STAR standards for reporting: the COS-STAR statement. *PLoS Med.* 2016; 13(10):e1002148.
52. Williamson PR, Altman DG, Blazeby JM, et al. Developing core outcome sets for clinical trials: issues to consider. *Trials.* 2012;13:132.
53. Mackenzie RM, Ellis LJ, Simpson SA, Logue J. Core outcome set for behavioural weight management interventions for adults with overweight and obesity: standardised reporting of lifestyle weight management interventions to aid evaluation (STAR-LITE). *Obes Rev.* 2020;21(2):e12961.
54. Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. *J Adv Nurs.* 2008;32(4):1008-1015.
55. McKenna HP. The Delphi technique: a worthwhile research approach for nursing? *J Adv Nurs.* 1994;19(6):1221-1225.

SUPPORTING INFORMATION

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