Received: 2 January 2022 | Revised: 7 March 2022 | Accepted: 8 March 2022

DOI: 10.1111/obr.13452

OBESITY TREATMENT/RESEARCH

OBESITY Reviews WILEY

Outcomes of the first global multidisciplinary consensus meeting including persons living with obesity to standardize patient-reported outcome measurement in obesity treatment research

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Abbreviations: BARIACT, BARIAtric and metabolic surgery Clinical Trials; BOSS, bariatric and obesity-specific survey; COMET, Core Outcome Measures in Effectiveness Trials methodology; COS, Core Outcomes Set; COSMIN, COnsensus-based Standards for the selection of health Measurement INstruments; ICHOM, International Consortium for Health Outcomes Measurement; IWQOL-Lite, Impact of weight on quality of life-Lite; OP-Scale, Obesity-related Problems Scale; PRO, Patient-reported outcomes; PROMIS, Patient-Reported Outcome Measurement Information System; PROMs, patient-reported outcome measures; QoL, quality of life; QOLOS, quality of life for obesity surgery; S.Q.O.T., Standardize Quality of life measurement in Obesity Treatment; SF-36, Short Form-36; STAR-LITE, STAndardized Reporting of Lifestyle Weight Management InTerventions to Aid Evaluation.

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Funding information
Bart Torensma; Castor EDC; Johnson and Johnson; Medtronic; Novo Nordisk; Philips Vital Health

Summary

Quality of life is a key outcome that is not rigorously measured in obesity treatment research due to the lack of standardization of patient-reported outcomes (PROs) and PRO measures (PROMs). The S.Q.O.T. initiative was founded to Standardize Quality of life measurement in Obesity Treatment. A first face-to-face, international, multidisciplinary consensus meeting was conducted to identify the key PROs and preferred PROMs for obesity treatment research. It comprised of 35 people living with obesity (PLWO) and healthcare providers (HCPs). Formal presentations, nominal group techniques, and modified Delphi exercises were used to develop consensus-based recommendations. The following eight PROs were considered important: self-esteem, physical health/functioning, mental/psychological health, social health, eating, stigma, body image, and excess skin. Self-esteem was considered the most important PRO, particularly for PLWO, while physical health was perceived to be the most important among HCPs. For each PRO, one or more PROMs were selected, except for stigma. This consensus meeting was a first step toward standardizing PROs (*what* to measure) and PROMs (*how* to measure) in obesity treatment research. It provides an overview of the key PROs and a first selection of the PROMs that can be used to evaluate these PROs.

KEYWORDS
obesity treatment, patient-reported outcome measures, patient-reported outcomes, quality of life

1 | INTRODUCTION

There is substantial variability in treatment options for obesity, ranging from diet and lifestyle interventions to pharmacological treatment and surgical procedures.[1,2] With increasing numbers of people undergoing obesity treatment annually, determination of the comparative effectiveness of different treatment options is important.[3] Although the clinical endpoints of obesity treatments have been well defined and evaluated, the effectiveness of these interventions has not been as adequately assessed from the patient's perspective.[4–6]

Patient-reported outcomes (PROs) directly capture the patient's perspective about the effectiveness of interventions, which are evaluated using PRO measures (PROMs).[7] Although there are many obesity-related PROMs, there has been a lack of standardization in the use of these measures.[4–6,8] A systematic review by Coulman et al. demonstrated that in 86 bariatric surgery trials, 1,897 different PROs were measured, with 68 different PROMs.[5] In weight loss interventions for patients with type 2 diabetes, 20 different PROMs were used in 19 trials.[6] Both studies were limited in synthesis of PRO data in their meta-analyses. Moreover, de Vries et al. showed that the measurement properties of many of the PROMs used in bariatric surgery were largely unknown.[8] Thus, a wide variety of PROMs have been used in obesity treatment research, and many PROMs developed for this population have not been thoroughly validated.

International initiatives, such as the International Consortium for Health Outcomes Measurement (ICHOM) and the Core Outcome Measures in Effectiveness Trials (COMET) initiative, encourage standardization of outcome measurement in clinical practice and clinical trials, respectively.[9,10] Two studies aimed at standardizing outcome assessment in research of obesity treatment and these studies developed Core Outcomes Sets (COSs) following the COMET methodology.[11] A COS represents an agreed minimum set of outcomes that should be measured and reported in all clinical trials in a specific area of health.[12] The BARIAtric and metabolic surgery Clinical Trials (BARIACT) study developed a COS for bariatric and metabolic surgery and overall quality of life (QoL) was one of the nine selected core outcomes.[13] The STAndardized Reporting of Lifestyle Weight Management InTerventions to Aid Evaluation (STAR-LITE) study developed a COS for behavioral weight management interventions, and QoL was one of the 24 outcomes prioritized for inclusion in the final COS.[14] The BARIACT group did not make recommendations for PROMs; in the STAR-LITE study, they agreed to measure QoL with the EQ-5D-5L. However, both initiatives did not obtain consensus on which specific key aspects of QoL should be measured. Because QoL is a broad multidimensional concept that encompasses the emotional, social, and physical well-being of people's life, it is important to obtain consensus on which of these outcomes matter most to people living with obesity (PLWO) before selecting PROMs.[15] Additionally, these measures should be selected based on evidence that has been validated with patients undergoing obesity treatment.[11]

Standardization of PRO measurement in obesity treatment research will reduce the heterogeneity of outcomes, enabling the comparison of results across studies and data synthesis. This will improve the quality of evidence used to make well-informed decisions about obesity treatment. Therefore, building on the two aforementioned consensus efforts, the Standardize Quality of life measurement in Obesity Treatment—S.Q.O.T. initiative—was founded by researchers who focus on the measurement of PROs in obesity treatment. The S.Q.O.T. initiative aims to improve the relevance and consistency of PROs (*what* to measure) and PROMs (*how* to measure) in obesity treatment research. This study reports the results of the first S.Q.O.T. consensus meeting involving PLWO and healthcare providers (HCPs). The objectives of this meeting were twofold: (i) to identify key aspects of QoL (PROs) relevant to be measured in studies on treatment of obesity and (ii) to standardize the future collection of patient-reported data in such studies by agreeing on preferred PROMs.

2 | METHODS

This study involved two steps. First, "*what* to measure," that is, achieving consensus over the relevant PROs in obesity treatment research. Second, "*how* to measure," that is, achieving consensus on the preferred PROMs to measure the PROs that were considered most relevant. Ethical approval was obtained by the regional institutional review board (Medical research Ethics Committees United, The Netherlands, reference number W21.227).

2.1 | Systematic review and updated systematic review

The results of a systematic review by de Vries et al. and an update of this review were used as a base for selecting PROs and PROMs.[8] The first systematic review was performed in 2018 and described the quality of existing PROMs developed and/or validated for QoL measurement in bariatric and body contouring surgery. The update was conducted in 2019 and focused on PLWO undergoing any type of treatment. Only studies with full-text papers written in English language that aim to describe the development and/or evaluation of measurement properties of PROMs that measure QoL were included. The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guideline for systematic reviews of measurement instruments was used to evaluate the methodological quality of the included studies and the quality of the PROMs was evaluated by applying quality criteria.[16] The search for the update was conducted on April 22, 2019. Details of the search are provided in Supporting Information 1. Because the consensus meeting and its prioritization work were conducted in English, only PROMs that were available in the English language and available as full copy were used for the meeting. From the systematic review of de Vries et al., 11 eligible PROMs were identified, and PROs measured with these PROMs were extracted.[8] The updated search resulted in five additional PROMs, and additional PROs measured with these PROMs were extracted. The results of the updated search are shown in Supporting Information 1. One PROM was brought to our attention by one of the

members of the consensus meeting panel.[17] A total of 25 PROs and 17 PROMs were extracted and discussed in the consensus meeting.

2.2 | Prioritization surveys

Before the consensus meeting, two prioritization surveys were sent to PLWO and HCPs from North America, South America, Europe, Asia, and Australia: first, to determine which PROs among participants were the most important, and second, to select PROMs that could be eligible for measuring selected PROs. Convenience samples were recruited through national and international healthcare provider federations and patient organizations. The surveys were administered by email with a link to a Web-based survey (Qualtrics, Provo, UT).[18] The surveys were sent without an a priori decision about the number of PROs or PROMs that would be included. However, in concordance with previous research, an a priori cut-off of more than 70% voting "definitely include" or "definitely exclude" was defined to either include or exclude a PRO or PROM for the consensus meeting.[19,20]

The Wilson and Cleary model was used as a conceptual model to provide essential structure to conceptualization of PROs.[21] This model distinguishes between biological and physiological factors, symptom status, functional status, general health perceptions, and overall quality of life and shows how these outcomes may interrelate. Additionally, the Patient-Reported Outcome Measurement Information System (PROMIS) conceptual model was used to differentiate between physical, mental, and social aspects of health. PROMIS is a new measurement system for PROs, which is expected to be used more and more worldwide.[22] PROMIS has developed its own conceptual model of PROs, distinguishing physical, mental, and social aspects of health.[23]

The survey consisted of the 25 PROs extracted from the systematic reviews, and all participants were asked to vote on the PROs ("definitively include," "possibly include," or "definitively exclude") (Supporting information 2). The survey also included a free-text field to allow the participants to nominate additional PROs not included in the prioritization survey.

The second survey included the PROMs informed by the systematic review described above.[8] All participants were asked to decide if each PROM was important to be included in the consensus meeting ("definitively include," "possibly include," or "definitively exclude") (Supporting information 2).

2.3 | Face-to-face consensus meeting

A two-day face-to-face consensus meeting was held with PLWO and HCPs. The PLWO were identified through patient organizations or patient representative networks (including participants who participated in the survey), and the HCPs were identified through the professional networks of the organizers. The participants were sent an email invitation describing the objectives of the S.Q.O.T. initiative and meeting. It was ensured that the participants of the consensus meeting were geographically diverse, included a broad range of recognized HCPs and a representative sample of PLWO. The HCPs had expertise in patient-centered outcomes research, outcome measurement, clinical trials, registries, quality improvement, or healthcare policy. An independent moderator with experience in COS development (CT) led the meeting. The moderator works independently from the S.Q.O.T. initiative and was not involved in the development of any of the PROMs that were included in the meeting. The consensus process was an orientation with formal presentations, a group discussion using nominal group techniques, and Delphi exercises. Nominal group technique and Delphi technique are both established consensus methods that involve a group of stakeholders to generate ideas and establish consensus.[24,25] Nominal group technique is used to explore ideas in relation to a question to come to an agreement using face-to-face discussion and voting, although the Delphi is used to come up with a final decision using anonymous voting and feedback.[26] The moderator led the group discussion using nominal group techniques. In the Delphi exercise, participants were anonymously asked for their opinion on PROs and PROMs and repolled with controlled and anonymized presentation of results to establish consensus. After each voting round, the combined and stratified analysis (PLWO versus HCPs) of the survey was conducted. The number of rounds in the Delphi exercise was not a pre-determined, but a dynamic process. All voting was captured electronically and anonymously by using VoxVote.[27] The organizers (CV, BW, RL, IJ, and VM) and moderator only functioned as facilitators during the consensus meeting and were not permitted to influence the discussions or voting rounds.

2.3.1 | Part 1: Orientation

During orientation participants attended a presentation concerning the background and objective of the S.Q.O.T. consensus meeting. Relevant terminology and clarification on the definition of the candidate PROs extracted from the systematic reviews were provided. Furthermore, definitions of measurement properties were explained to enable full participation in the meeting by a methodological expert (CT). In addition, outcomes of the systematic review and the online surveys were presented.

2.3.2 | Part 2: What to measure

The results of the prioritization survey on the selection of PROs were first presented and discussed. A group discussion was then held to elicit opinions on the importance of each PRO. The group discussion started with a brainstorm session in which all participants could suggest PROs deemed important. This was to ensure that PROs used in the consensus process were comprehensive from the perspective of different stakeholders (PLWO and HCPs). PROs were generated until saturation was reached. All PROs that were considered important

were presented on a list to all participants. The definition of each PRO was also discussed to ensure clarity among all participants and to understand their interpretation. The group discussion informed the list of PROs that were used for the first voting round. After the group discussion, participants were invited to vote on the question "Which three PROs are most relevant to be measured in each research study on obesity treatment?". The top PROs by average ranking were included in the following voting rounds.

2.3.3 | Part 3: How to measure

Subsequently, the PROMs identified in the systematic review and updated version described above that were available for each selected PRO were discussed with the whole group. Participants were provided with a full paper copy of the PROMs for each PRO (labeled according to the outcome of the second prioritization survey), and a paper summary of the measurement properties and feasibility aspects of the PROMs.

Each PROM was discussed separately. First, participants individually assessed the face validity ("the degree as to which the items of an instrument indeed look as though they are an adequate reflection of the construct to be measured") for each PROM. Second, the group anonymously voted on whether the PROM had sufficient face validity for the specific PRO. Only PROMs that the participants voted as having sufficient face validity were included in the voting round of the respective PRO.

Subsequently, the participants anonymously voted on each of the PROMs separately to the question "Is [PROM name] adequate to measure [PRO] in obesity treatment research?". On the basis of the COSMIN methodology, professionals were asked whether each PROM (and all of its content) was relevant ("Are the questions relevant to measure [PRO] in persons living with obesity?") and comprehensive ("With regard to [PRO] in persons living with obesity, are there any key aspects missing?").[28] In addition to the relevance and comprehensiveness, PLWO were also asked whether the PROMs were comprehensible ("Are the questions and response options understandable?").[28] An a priori cut-off of more than 70% of the participants or more than 70% of the PLWO was needed to endorse a PROM to be included for that specific PRO. This cut-off has been considered appropriate in similar consensus studies.[19,20] Participants involved in the development of one of the eligible PROMs were excluded from the voting round.

3 | RESULTS

3.1 | The face-to-face consensus meeting

On September 1 and 2 in 2019, 35 participants from North America, South America, Europe, Asia, and Australia participated in the face-to-face consensus meeting in Amsterdam, the Netherlands. The participants included 16 PLWO and 19 HCPs (surgeons, endocrinologists, other physicians specialized in obesity treatment, dieticians, physiotherapists, and clinical psychologists). Three participants canceled just before the meeting due to personal reasons ($n = 1$) or flight cancelation ($n = 2$).

3.2 | *What* to measure

The prioritization survey to rank the PROs was completed by 111 PLWO and HCPs. The following six PROs were selected for discussion in the consensus meeting (>70% "definitely include"): physical health, psychological health, physical symptoms, mental health, self-esteem, and pain. The results of this survey are shown in Table 1 and Supporting Information 3.

During the presentation of the online survey on the identified PROs, concerns emerged about how the PROs should be defined. Therefore, the moderator started the day with a discussion about the definition of PROs and which of the PROs participants perceived to be the most important. Afterwards, participants were asked to select and rank their top 3 PROs anonymously.

Self-esteem was considered the most important PRO, particularly for PLWO, although physical health was perceived to be the most important among HCPs. The voting resulted in the inclusion of the following PROs: self-esteem, physical health, mental health, social health, stigma, eating, body image, and excess skin (see Figure 1). After the group discussions, participants agreed that the list of PROs was a comprehensive list that captured all PROs relevant to PLWO.

3.3 | *How* to measure

The second prioritization survey to rank the PROMs was completed by 63 PLWO and 23 HCPs. Only the BODY-Q and the bariatric and obesity-specific survey (BOSS) were voted on for inclusion, whereas none of the PROMs were voted upon for exclusion. Therefore, all PROMs were discussed in the consensus meeting (Supporting Information 4). The results of the second survey can be found in Supporting Information 5.

TABLE 1 Patient-reported outcomes (PROs) that were endorsed (>70% "definitely include") based on the online prioritization survey

Domain	%	Definition
Physical health	95.7	Overall condition of the body at a given time
Psychological health	90.6	Well-being of mental and emotional state
Physical symptoms	86.5	Departure from normal function or feeling from the body
Mental health	80.2	Cognitive, behavioral, and emotional well-being
Self-esteem	75.8	Own worth, ability and value
Pain	71.3	Unpleasant sensory and emotional experience

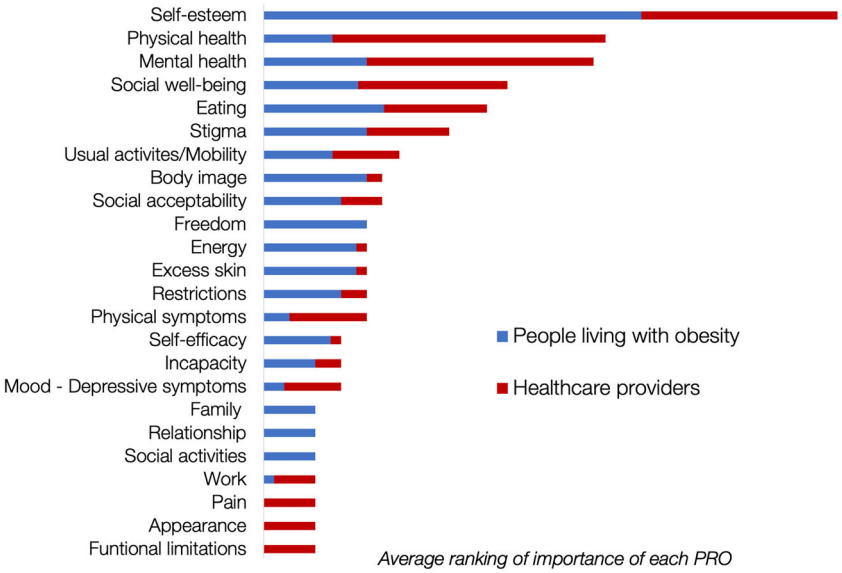

FIGURE 1 Ranking of the patient-reported outcomes (PROs) in the face-to-face consensus meeting, showing results for people living with obesity and healthcare providers

Participants of the consensus meeting voted on PROMs to be included for each specific PRO. The PROMs selected based on face validity and the selected PROMs from the voting rounds are summarized for each PRO in Table 2. For each PRO, one or more PROMs were selected, but no PROM could be selected for stigma due to the lack of PROMs validated with PLWO. The following PROMs were at least once selected: impact of weight on quality of life (IWQOL)-Lite, Short Form (SF)-36, BODY-Q, Obesity-related Problems (OP)-Scale, and Quality of Life for Obesity Surgery (QOLOS). No consensus was reached during the meeting on the most adequate PROM for the PROs physical health, social health, body image, and excess skin.

4 | DISCUSSION

The goal of the S.Q.O.T. I multi-professional, international meeting including PLWO was to obtain consensus on PROs (*what* to measure) and PROMs (*how* to measure) to be used in obesity treatment research. Formal presentations, nominal group techniques and modified Delphi exercises were used to develop consensus-based recommendations.

The results demonstrated that PLWO and HCPs consider different PROs to be the most important. PLWO and HCPs selected eight PROs: self-esteem, physical health, mental health, social health, eating, stigma, body image, and excess skin. HCPs voted on broad PROs including physical or mental health, while PLWO voted on more specific PROs such as self-esteem, body image or excess skin. Furthermore, more HCPs voted on symptoms, including depressive symptoms, physical symptoms, and pain. For each PRO, one or more PROMs were selected, but there is currently no validated PROM available to assess obesity stigma. The selected PROs are in line with a previous qualitative study of patient perspectives in persons who had undergone bariatric surgery.[29] The main differences were that self-esteem and stigma were not described in the qualitative study, and that the participants from the current study did not vote sexual life to be among the most important PROs.

This was the first consensus meeting that identified which PROs should be collected as a minimum in obesity treatment and how these PROs should be measured, following a rigorous and patient-centered methodology. We used the previous work of two different COSs developed for obesity treatment research (BARIACT study and STAR-LITE study) as a starting point. There are, however, some differences with the STAR-LITE study that are important to mention. In the STAR-LITE study, "self-confidence and self-esteem" were selected separately from QoL in the optional outcome set with a corresponding PROM that was not included in our consensus meeting due to the lack of validation evidence in the treatment of obesity (the Warwick-Edinburgh Mental Well-being Scale).[14] The EQ-5D-5L that was recommended to measure QoL in the STAR-LITE study was not selected in our consensus meeting because it does not capture the PROs considered most important by PLWO.[14] A next S.Q.O.T. consensus meeting will focus on the selection of one PROM for each PRO, and it should be discussed if items reflecting stigma are represented in other PROMs. If this is not the case, a literature review should be undertaken to identify existing PROMs that measure stigma (e.g., developed for other populations) and whether these can be used in obesity treatment, or such PROMs may need to be developed if none is available. Given that stigma toward PLWO is pervasive,[30] and the negative impact of experiencing and internalizing weight stigma,[31,32] there is a need to adequately measure both in obesity treatment research.

A strength of this study is the high number of PLWO that participated. The HCPs included academics from different disciplines and continents. There are no definite guidelines on the sample size of a consensus meeting, but the COMET handbook describes that an adequate number of people attending the in-person meeting is helpful to fully represent the patient's view.[11,33] In this consensus meeting, the ratio of PLWO and HCPs was nearly 1:1. This was to reflect the input

TABLE 2 The most important domains and the selected PROMs

Domain	PROM(s) available	PROM(s) selected based on face validity	PROM(s) that were selected after the vote[a]
Self-esteem	IWQOL-Lite, IWQOL-Lite CT, PROS, WHO-QOL BREF	IWQOL-Lite, IWQOL-Lite CT	IWQOL-Lite
Physical health/ functioning/symptoms	BAROS, BODY-Q, BOSS, BQL-Index, EQ-5D-5L, GIQLI, IWQOL-Lite, IWQOL-Lite CT, M-A QOL QII, OP-scale, PBOT, PROS, QOLOS, SF-36, TRIM, WHO-QOL BREF	BODY-Q, BOSS, IWQOL-Lite, IWQOL-Lite CT, PBOT, QOLOS, SF-36, TRIM	BODY-Q, IWQOL-Lite, SF-36,
Mental/psychological health	BAROS, BODY-Q, BQL-Index, IWQOL-Lite CT, M-A QOL QII, SF-36, TRIM, WHO-QOL BREF	BODY-Q, BQL-Index, IWQOL-Lite CT, SF-36	BODY-Q
Social health	BAROS, BODY-Q, BOSS, BQL-Index, EQ-5D-5L, GIQLI, IWQOL-Lite, IWQOL-Lite CT, M-A QOL QII, OP-Scale, PBOT, PROS, QOLOS, SF-36, TRIM, WHO-QOL BREF	BODY-Q, BOSS, BQL-Index, GIQLI, IWQOL-Lite, OP-Scale, SF-36	BODY-Q, IWQOL-Lite, OP-Scale
Stigma	—	—	—
Eating	BODY-Q, BOSS, M-A QOL QII, QOLOS, TRIM	BODY-Q, BOSS, QOLOS	BODY-Q
Body image	BODY-Q, QOLOS	BODY-Q, QOLOS	BODY-Q, QOLOS
Excess skin	BODY-Q, QOLOS	BODY-Q, QOLOS	BODY-Q, QOLOS

Abbreviations: BAROS, Bariatric Analysis and Reporting Outcome System; BOSS, bariatric and obesity-specific survey; BQL Index, Bariatric Quality of Life Index; GIQLI, Gastrointestinal Quality of Life Index; IWQOL-Lite, Impact of Weight Quality of Life-Lite; IWQOL-Lite CT, Impact of Weight Quality of Life-Lite Clinical Trials; M-A QoLQII, Moorehead-Ardelt Quality of Life Questionnaire II; OP-Scale, Obesity-related Problems Scale; PBOT, Post Bariatric Outcome Tool; PROS, patient-reported outcomes in obesity; QOLOS, Quality of Life for Obesity Surgery; SF-36 Short Form Health Survey 36; TRIM, Treatment Related Impact Measure; WHOQOL-BREF, World Health Organization Qualitiy of Life Questionnaire-BREF.
[a]PROMs were selected if >70% of the participants (people living with obesity and healthcare providers) or >70% of the persons living with obesity selected the PROM for that specific domain.

from PLWO and HCPs equally, which may ensure that the PROs and PROMs chosen are suitable and well accepted. This meeting showed the importance of including PLWO and HCPs, as the selected key PROs were different in these groups.

There are limitations to this study. First, the majority of PLWO were from the United Kingdom and Ireland. The PLWO from the Netherlands had to be fluent in English, through which it was weighted toward higher educated individuals. It is important to note that the HCPs comprised representatives from all continents, except Africa. Second, a few of the participants participated in the development of a PROM that was selected for the consensus meeting. Participants who had a conflict of interest were not excluded, as the number of participants with a conflict of interest was too low to influence the results. Third, the prioritization survey for the selection of PROs lacked relevance due to disagreements by the participants because no clear definitions were given on the PROs and too many different PROs were considered relevant. Therefore, the moderator decided to start the consensus meeting with a group discussion on the definition and selection of PROs. Finally, at the very beginning, the group discussion led to a broad discussion with little consensus. Many domains were deemed important by the different stakeholders. Even though the group discussion was time-consuming, it was very important for the group dynamic and to reach an agreement on the meaning of the specific PROs. Furthermore, PROs emerged in the group discussion that were not covered in the PROMs identified in the systematic reviews. These PROs would otherwise not have been considered in the voting rounds.

5 | CONCLUSION

PROs are crucial endpoints in clinical trials and prospective studies of any modality of obesity treatment. To enable data evidence synthesis including outcomes that reflect the views of PLWO, standardized data collection of PROs is key. This consensus meeting was a first step toward standardizing PROs (*what* to measure) and PROMs (*how* to measure) in obesity treatment research. It provides an initial presentation of key PROs and preferred PROMs for obesity treatment research.

ACKNOWLEDGMENTS

The S.Q.O.T. meeting was funded by Medtronic, Johnson & Johnson, Philips Vital Health, Novo Nordisk, Castor and Bart Torensma. The funders of the meeting were not involved in the selection of the domains and questionnaires included in this meeting. These sponsors played no role in the selection of participants of the meeting, in the selection of the domains and questionnaires included in this meeting, the voting rounds, or the writing of this paper.

CONFLICT OF INTEREST

None of the members of the organizing committee (C.V., V.M., B.W., I.J., and R.L.) and none of the participants received payment for their participation. Travel expenses and the hotel overnight for the face-to-face meeting of the S.Q.O.T. were supported by Medtronic, Johnson & Johnson, Philips Vital Health, Novo Nordisk, Castor and Bart Torensma. C.V. and V.M. are the founders of the S.Q.O.T. initiative, B.W., I.J., and R.L. are cofounders of the S.Q.O.T. initiative. R.C. received lecture, presentations, speakers bureaus, manuscript writing, or educational events fees for Johnson & Johnson, Medtronic, Jansen Pharmaceutical, Novo Nordisk, BAriatec, and GI Dynamics; a research grant from Medtronic; consulting fees from Johnson & Johnson and Medtronic. X.R.S. received lecture, presentations, speakers bureaus, manuscript writing, or educational events fees for Obesity Canada, the European Association for the Study of Obesity, and the World Health Organization Regional Office for Europe; conference travel fees from Obesity Canada, the European Association for the Study of Obesity, the World Health Organization Regional Office for Europe, World Obesity Federation, The Obesity Society, and Novo Nordisk consulting fees from Obesity Canada, the European Association for the Study of Obesity, and the World Health Organization Regional Office for Europe; is co-chair of the World Obesity Federation Working Group on Weight Bias and Stigma, member of The Obesity Society Policy and Advocacy Committee, and founding member of the Obesity Canada EveryBODY Matters Collaborative (unpaid); owns a research and communications company through which she conducts her consulting work (K&X Ramos AB). R. L. received lecture, presentations, speakers bureaus, manuscript writing, or educational events fees for Johnson & Johnson, Medtronic. S. F. received academic conference attendance fees from Johnson & Johnson and Novo Nordisk. B.B. received from Monash University funding support for attendance, as the main account holders of the funding received from the Department of Health, Commonwealth of Australia. Monash University did not provide any additional funding or financial support for the attendance outside of the grant funding money as explained above. W.B. received lecture, presentations, speakers bureaus, manuscript writing, or educational events fees for Merck Sharpe and Dohme, Novo Nordisk, and Gore; research grants from Medtronic, Johnson & Johnson, Gore, Applied Medical, Novo Nordisk, and Commonwealth Government of Australia; conference travel fees from Novo Nordisk. All other authors declare that they have no conflict of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

How to cite this article: de Vries CEE, Terwee CB, Al Nawas M, et al. Outcomes of the first global multidisciplinary consensus meeting including persons living with obesity to standardize patient-reported outcome measurement in obesity treatment research. *Obesity Reviews*. 2022;e13452. doi:10.1111/obr.13452

Supporting Information 1: Details of systematic review

Eligibility criteria

All instruments developed for patients with obesity undergoing any type of treatment were eligible. Only studies with full text papers and with the aim to describe the development and/or evaluation of measurement properties of instruments that measure quality of life were included. Since the consensus meeting was held in English only instruments available in the English language were used for this review.

Literature search

On 22 april 2019, a systematic literature search was conducted in PubMed, EMBASE, Ebsco/PsycINFO, Ebsco/CINAHL, Cochrane Database Systematic Reviews and CENTRAL. The search included, but was not limited to the following terms:

- Obesity
- Patient-reported outcome measures
- Quality of Life
- Lifestyle intervention
- Nutrition
- Movement therapy
- Cognitive behavioral therapy
- Pharmacological treatment
- Endoscopic treatment
- Clinimetrics/psychometrics

Using Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia. Available at www.covidence.org) two reviewers (CV and VM) independently screened titles and abstracts and, at a second stage, assessed the full-text articles retrieved by the literature search. Conflicts were resolved by consensus of the two reviewers.

Evaluation of methodological quality

The same two reviewers (CV and VM) independently evaluated the methodological quality of included studies. The COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) guideline for systematic reviews of measurement instruments was used to evaluate the methodological quality of the included studies (1). Conflicts were resolved by consensus of the two reviewers. For each included instrument development studies were searched to complete quality evaluation.

Since one reviewer (CV) worked in the department of one of the included instruments (the BODY-Q), this instrument was rated by another reviewer (MN).

Selection of instruments

The previous review included 26 articles with 24 instruments (2). After exclusion of instruments focused on body contouring surgery (n=1) and instruments in other languages then English (n=12), a total of 11 instruments could be used in the consensus meeting. Studies on development and/or evaluation of measurement properties of these 11 instruments were described in 14 publications.

The updated search resulted in seven additional instruments, two of these instruments were not available in English and hence not included (3,4).

In addition, one instrument was brought to our attention via a of the member of the consensus meeting panel (5).

Figure 1: Flow diagram of search.

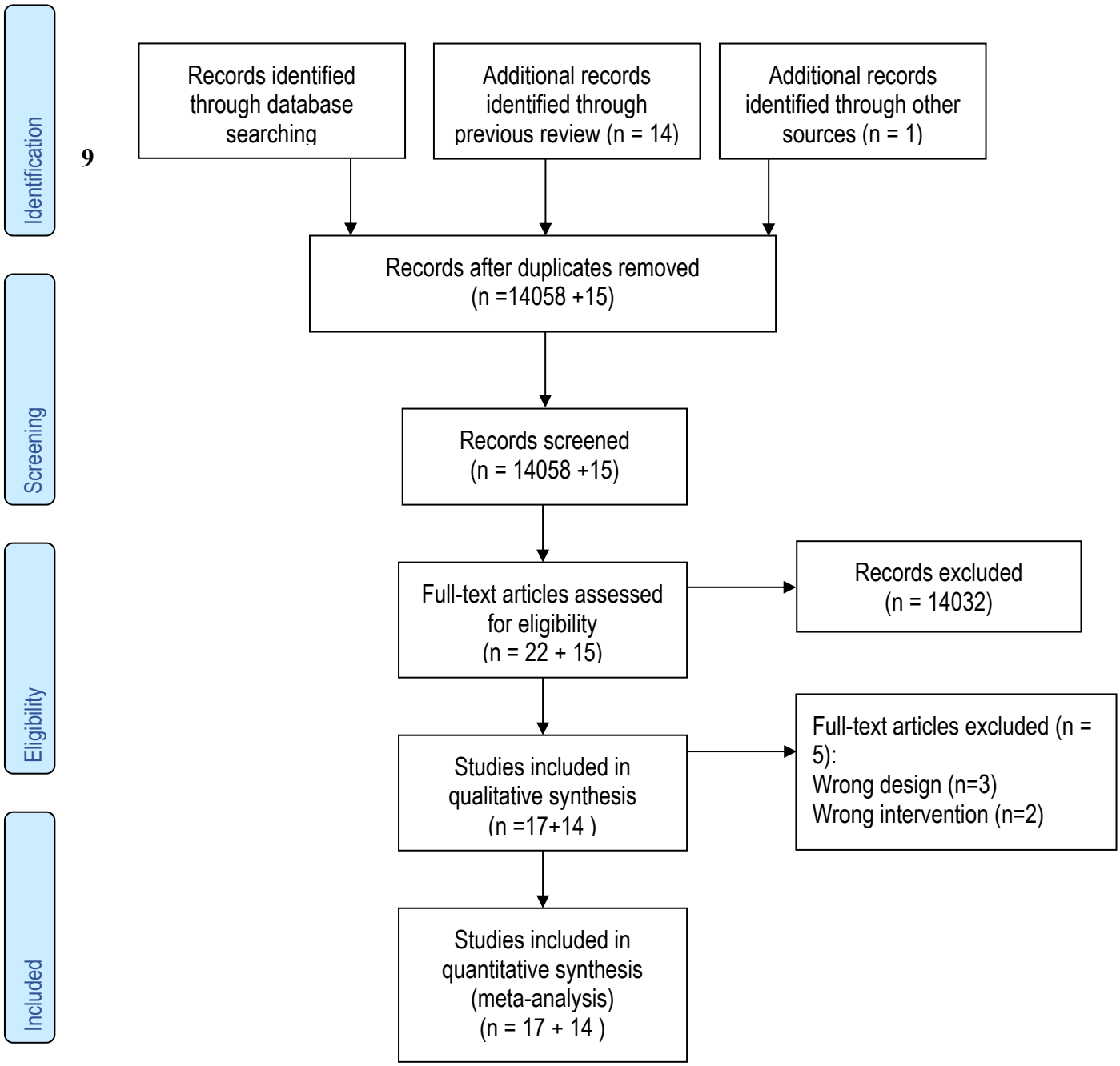

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Table 1: Characteristics of the included studies

Instrument	author	Year of publication	Geographic location(s)	Language	Population	Number of participants	Age, years	Percentage of women	BMI, kg m^2
M-A QoLQ (BAROS)	Oria HE	1998	US	English	n.a.	n.a.	n.a.	n.a.	n.a.
BOSS	Tayyem RM	2014	UK	English	Pre and postbariatric patients	236	45.3±10.7	77.1%	48.4±9.2
Laval	Donini	2017	Italy	Italian	Patients in treatment for obesity	273	46.2 ± 14.2 (m) 46 ± 13.5 (f)	72,9%	40.4 ± 8.3 (M) 34.8 ± 6.2 (F)
TRIM	Brod et al	2010	US, Australia, and Canada	English	Patients who use anti-obesity medication	208	20-76 years	78.4%	30-45
SF-36	Corica	2016	Italy	Italian	obese subjects seeking treatment	1735	44.7 ± 11.0	77.6%	30-45

IWQOL-lite	Kolotkin	1997							
	De Mariano	2010	Brazil	Portugese	Premenopausal women in weight loss program (excluded: chronic diseases physical disabilities and smokers.)	89 clinical 156 community	36.0 (±7.8) (clinical) 34.0 (±7.6) community	?	29.3 ±5.3 (clinical) 24.4 ±5.0 community
	Engel	2005	Portugal	Portugese	Outpatient lifestyle weight management programme & overweight/obese volunteers (all women) exclu: pre-menopausal, free from	138 clinical 250 community			

					current major chronic and without limiting physical disability.				
IWQOL-lite Clinical trial version	Kolotkin	2017	US	English	Pts with obesity only	42	19-70	52.4%	30.4-51.6
					Pts with obesity and diabetes	29	21-75	16/29	27.1–45.7
Obesity-related Problems scale	Karlsson	2003	Sweden	Swedish	Obese subjects	6863	37-57	4264	
	Karlsson	1995	Sweden	Swedish		709	47-48 per group on average	312	
Moorhead-Ardelt Quality of life Questionnaire II	Oria	2009	US	English					

QOLOD	Ziegler	2005	France	French	Pts with obesity, excluded those with obesity of endocrine origin	128 & 212	42.5 ± 12.1 & 43.3 ± 12.2	83.6% & 77.7%	34.5 ± 2.8 & 35.8 ± 7.5

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Supporting Information 2: Prioritization surveys

Prioritization survey 1:

Please indicate for each domain if you think this domain should be definitively included, possibly included or definitively excluded in quality of life measurement for obesity treatment.

	Definitively include	Maybe include	Definitively exclude
Appearance			
Physical Health			
Physical Symptoms			
Psychological Health			
Sexual Well-being			
Social Health			
Body Image			
Self Esteem			
Work Function			
Eating			
Incapacity			
Personal Hygiene			
Emotional distress			
Anxiety			
Pain			
Digestive symptoms			
Family			

	Definitively include	Maybe include	Definitively exclude
Positive activities			
Partnership			
Excess skin			
Usual activities			
Self care			
Fatigue			
Mental Health			
Self-Efficacy			

Is there a domain that is not in the list, but should be according to you?

Thank you for filling in the survey!

Prioritization survey 2:

Dear Participant,

Thank you for assisting the SQOT initiative to rank PROMs that measure Quality of Life in obesity. As explained in the e-mail, this survey will be used as a basis for the consensus meeting on Quality of Life measurement in obesity treatment.

Recently, our team performed a systematic review on PROMs in surgery for obesity. We will ask you the rate the PROMs included in that survey.

At the end of the survey you will be able to add additional instruments that are not listed in the survey. Please add the instrument along with why you think that it is important.

For each PROM (ordered based on their category of recommendation in the systematic review by de Vries et al.):

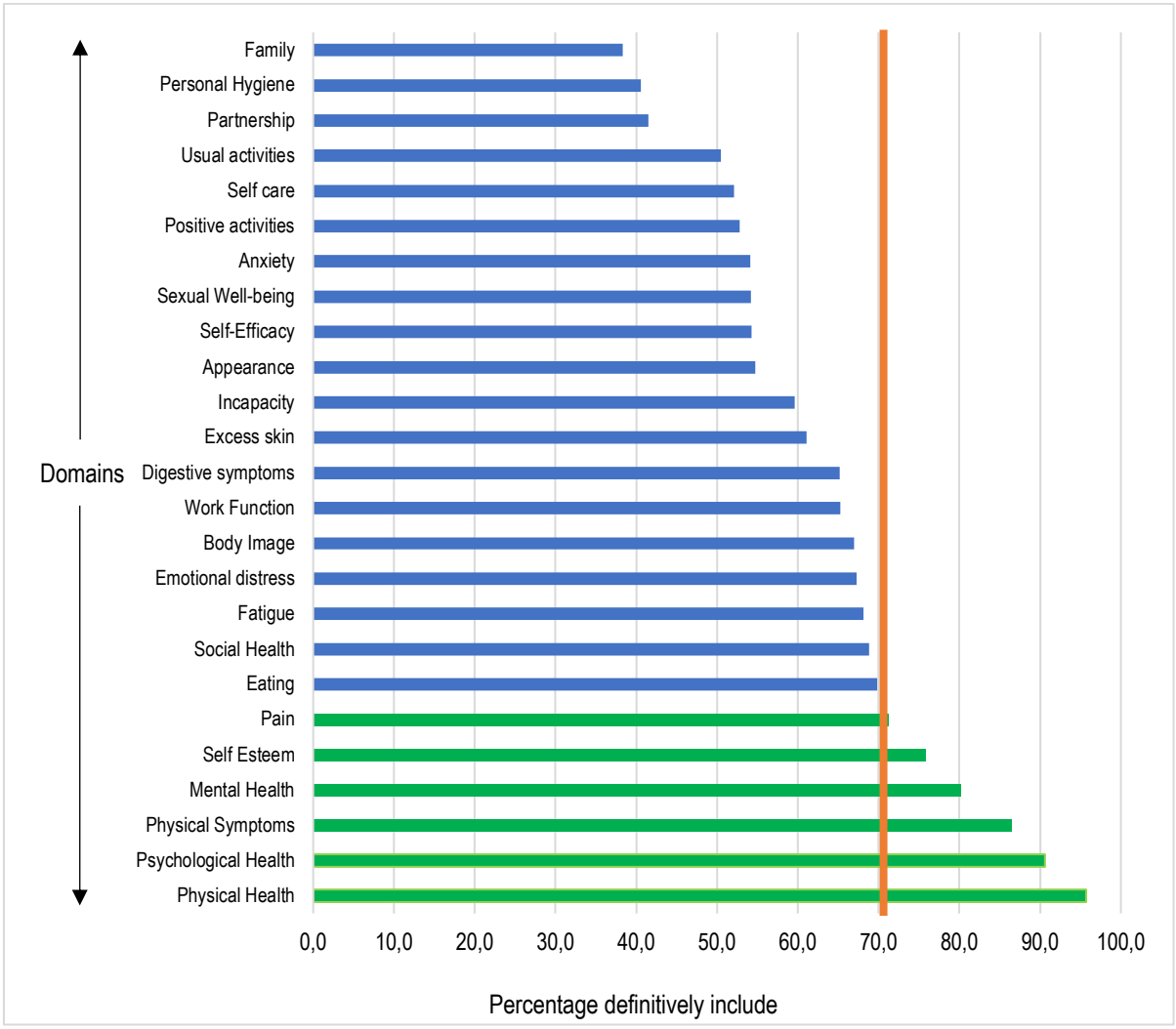
Categorization of this PROM:

- Definitively include
- Possibly include
- Definitively exclude

Comment:

Supporting Information 3: Prioritization surveys: ranking of domains

Figure 1: Results of the online survey assessing which domains that should be included in QoL measurement



Supporting Information 4: PROMs included in the consensus meeting

1. BAROS
2. BODY-Q
3. BOSS
4. BQL-Index
5. EQ-5D-5L
6. GIQLI
7. IWQOL-Lite
8. IWQOL-Lite CT
9. M-A QOL QII
10. OP-scale
11. ORWELL-97
12. PBOT
13. PROS
14. QOLOS
15. SF-36
16. TRIM
17. WHO-QOL BREF

BAROS, Bariatric Analysis and Reporting Outcome System; BOSS, bariatric and obesity-specific survey; BQL Index, Bariatric Quality of Life Index; GIQLI, Gastrointestinal Quality of Life Index; IWQOL-Lite, Impact of Weight Quality of Life-Lite; M-A QoLQ, Moorehead-Ardelt Quality of Life Questionnaire; M-A QoLQII, Moorehead-Ardelt Quality of Life Questionnaire II; OP-scale, Obesity-related Problems scale; ORWELL-97, Obesity-Related WELL-being-97; PBOT, Post Bariatric Outcome Tool; PROS, Patient-Reported Outcomes in Obesity; QOLOS, Quality of Life for Obesity Surgery; SF-36, Short-Form-36; TRIM,

Treatment Related Impact Measure; WHO-QOL BREF, World Health Organization Qualitiy of Life Questionnaire-BREF

155 **Supporting Information 5: Ranking of PROMs in the first prioritization survey**
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PROM	Survey option	Percentage, %
BAROS	Definitely include Possibly include Definitely exclude	38 17 45
BODY-Q – Domain: Quality of Life	Definitely include Possibly include Definitely exclude	77 17 6
BODY-Q – Domain: Appearance	Definitely include Possibly include Definitely exclude	56 26 18
BOSS	Definitely include Possibly include Definitely exclude	73 22 4
BQL-Index	Definitely include Possibly include Definitely exclude	35 33 33
EQ-5D-5L	Definitely include Possibly include Definitely exclude	38 38 24
GIQLI	Definitely include Possibly include Definitely exclude	43 28 30
IWQOL-Lite	Definitely include Possibly include Definitely exclude	59 31 10
M-A QOL QII	Definitely include Possibly include Definitely exclude	34 29 37
OP-scale	Definitely include Possibly include Definitely exclude	43 30 27

PBOT	Definitely include Possibly include Definitely exclude	59 28 14
QOLOS	Definitely include Possibly include Definitely exclude	64 23 13

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158 BAROS, Bariatric Analysis and Reporting Outcome System; BOSS, bariatric and obesity-
159 specific survey; BQL Index, Bariatric Quality of Life Index; GIQLI, Gastrointestinal Quality
160 of Life Index; IWQOL-Lite, Impact of Weight Quality of Life-Lite; M-A QoLQ, Moorehead-
161 Ardelt Quality of Life Questionnaire; M-A QoLQII, Moorehead-Ardelt Quality of Life
162 Questionnaire II; OP-scale, Obesity-related Problems scale; PBOT, Post Bariatric Outcome
163 Tool; QOLOS, Quality of Life for Obesity Surgery

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165