Development of a core patient-centred outcome set for adults living with obesity: a modified delphi-based international consensus

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Summary

Background **Obesity is a chronic disease linked to over 200 health conditions, reduced quality of life, and increased mortality. Despite the availability of multimodal treatments, there is a lack of standardised, patient-centred outcome measures to effectively assess and improve clinical care. This project aimed to define a core set of standardised**

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outcome measures for adults with obesity, incorporating both patient-reported and clinician-reported outcomes. Additional objectives included determining the optimal measurement frequency and identifying case-mix variables essential for risk adjustment.

Methods The International Consortium for Health Outcomes Measurement (ICHOM) established the Obesity Working Group (OWG), composed of 29 international experts and individuals living with obesity. Members were selected based on their expertise in obesity care and research and represented 21 countries. The development process, conducted from May 2023 to July 2024, began with a kick-off meeting to define scope, followed by eight virtual meetings. A comprehensive literature review informed the identification of relevant clinical outcomes, patient-reported outcomes, treatment-related complications, and case-mix variables. A three-round Delphi process was used to reach consensus on key outcomes and follow-up intervals. Outcomes were included in the final set if at least 80% of OWG members rated them between 7 and 9 on a 9-point scale. Validation was conducted through surveys with 95 patients and 106 healthcare professionals from fields such as dietetics, obesity medicine, and general practice.

Findings The OWG developed a standardised set of 20 outcome measures, comprising 17 core measures and 3 population-specific measures. These span domains including physical health, psychosocial well-being, health behaviours, body functioning, and adverse events. Specific measures were also developed for bariatric surgery and female reproductive health (both pregnant and non-pregnant individuals). Key case-mix factors and appropriate follow-up periods were defined to support global consistency in reporting.

Interpretation Adoption of this standardised outcome set enables clinicians, patients, and stakeholders to identify care gaps, monitor outcomes, and evaluate the quality of obesity care against global benchmarks. Implementation can support the creation of a robust international data resource to guide research, inform clinical practice, and shape policy and guidelines for adult obesity treatment. Limitations include limited geographical diversity in validation surveys, the exclusion of internalised weight bias due to a lack of validated measurement tools, and limited applicability to individuals with obesity and multiple comorbidities.

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Keywords: ICHOM; Adult obesity; Clinical practice; Outcome measures; Patient-centred outcomes

Introduction

Obesity, a chronic disease, is associated with over 200 adverse health conditions impacts quality of life and mortality, impacts quality of life and mortality.[1–4] The global prevalence of obesity and its associated disability, morbidity and mortality has risen alarmingly, prompting the World Health Organization (WHO) to declare it a global epidemic.[2,5] Current obesity management outcomes are primarily focused on measuring BMI and weight loss.[6] However, relying on BMI as the primary measure for diagnosing and managing obesity can result in significant challenges, including the misclassification of individuals due to its inability to distinguish between fat and muscle mass. This limitation not only undermines accurate risk assessments and appropriate treatment but also contributes to stigmatisation and psychological distress.[7–9] Importantly, due to these limitations and lack of consistent approaches in obesity care, people living with obesity (PwO) frequently experience poor access to effective care. For instance, a recent international survey reported that while most PwO understand that it is a disease, the majority still assume personal responsibility for its management. This often leads to delays in initiating the conversation about obesity with a healthcare professional. Furthermore, healthcare professionals often dismiss the biological and physiological underpinnings of obesity, contributing to poor access to evidence-based treatments. This is also likely due to the inherent bias and stigma in the healthcare system that still exists around the treatment of obesity.[10] These limitations highlight the urgent need for a comprehensive, non-judgmental approach to obesity care that aligns with current scientific knowledge and prioritises outcomes that matter most to PwO.[11]

A key strategy for improving quality of care is the implementation of value-based health care (VBHC),[12] where value is defined as the health outcomes that matter most to patients, relative to the cost of achieving those outcomes. However, in obesity, current outcomes of success are often measured only by metrics such as BMI and weight loss, overlooking the broader physical

Research in context

Evidence before this study

Value-Based Health Care (VBHC), which emphasises outcomes that matter most to patients relative to cost, is a key strategy for improving care. In obesity, however, success is often measured by limited metrics like BMI and weight loss, overlooking important physical, psychological, and social factors. Although there is growing support for a more patient-centred approach, current outcome measures remain fragmented and inconsistently used across healthcare systems. This lack of standardisation highlights the need for a comprehensive, condition-specific set of outcomes that reflects the lived experiences and priorities of people with obesity (PwO). We searched PubMed, Web of Science, EMBASE, PsycINFO, Cochrane, clinical trial databases, and the Core Outcome Measures in Effectiveness Trials (COMET) databases up to the time where the project was initiated (i.e., May 1, 2023); however, there are no published obesity standard set among adults.

Added value of this study

We developed a consensus-based core set of outcome measures for adult obesity care through a global, multidisciplinary collaboration across five continents and 21 countries. Using a modified Delphi method, the group identified key outcomes and appropriate measurement intervals, validated through surveys with people with obesity (PwO) and healthcare professionals (HCPs). Led by the ICHOM, this is the first coordinated, multinational effort to establish a standardised, clinically meaningful set of outcomes that reflect what matters most to both PwO and HCPs, aiming to support their use in routine practice.

Implications of all the available evidence

A standardized set of 20 outcome measures of which 17 core and 3 population-specific—covering physical health, psychosocial well-being, health behaviours, body functioning, and complications related to bariatric surgery and female reproductive health were identified. The set also includes recommended case-mix factors and follow-up intervals to support consistent global reporting. This consensus-based outcome set, shaped by the priorities of both PwO and HCPs, is designed to improve quality, support benchmarking, and guide continuous improvement in obesity care. Its adoption enables clinicians, patients, and healthcare systems to monitor outcomes, identify gaps, and align care with international standards.

and psychosocial dimensions of health and health risks, both of which are critical in understanding the full impact of obesity. Although there is increasing recognition of the need for a more patient-centred approach - one that encompasses both clinical and mental health outcomes in addition to social dimensions of health,[13] existing outcome metrics remain fragmented and lack standardisation across diverse healthcare settings. This inconsistency highlights the need for a condition-specific, complete, standardised, measurable set of outcomes that reflects the lived experiences of individuals with obesity.

To address this gap and advance the transition towards VBHC, the International Consortium for Health Outcomes Measurement (ICHOM) convened a multidisciplinary Adult Obesity Working Group (OWG) to develop a standardised Set of Patient-Centred Outcome Measures that measure what matters most to PwO and reflects evidence-based knowledge. The primary aim of this project was to define a standardised minimum set of outcome measures for obesity among adults, including patient-reported outcome measures (PROMs) and clinician reported outcome measures (CROMs). Additionally, the project sought to establish the optimal frequency for measuring these outcomes and identify specific case-mix variables critical for risk adjustment.

This initiative aims to enhance shared decision-making between HCPs and PwO, support continuous quality improvement, ensure that outcomes are assessed based on what matters most to PwO, and appropriately place screening measures such as BMI as one among many required to assess and understand the disease, rather than a singular, isolated metric.

Methods

Obesity standard set initiation and composition of working group

The development of the Obesity Standard Set took place between May 2023 and July 2024. To ensure a standardised approach, the EQUATOR Delphistar checklist for reporting delphi studies in health and social sciences was adhered to. ICHOM established a geographically diverse, international, and multidisciplinary working group—referred to as the Obesity Working Group (OWG)—comprising 29 members from 21 countries (Supplementary Table S1). The OWG included a broad range of subspecialties within the obesity community, as well as individuals living with obesity. Countries represented were Argentina, Australia, Brazil, Canada, Chile, Denmark, Finland, India, Ireland, Italy, Jamaica, Malaysia, Mexico, the Netherlands, Nigeria, South Africa, Spain, Sweden, the United Arab Emirates (UAE), the United Kingdom (UK), and the United States of America (USA). Members were selected based on their expertise and relevant

contributions to the field, including publications and clinical experience in obesity care and management. Members were identified through their published work, ICHOM's professional network, or recommendations from experts in the field. A core project team (TM, LS, AS, SC) was established to guide and coordinate the efforts of the OWG.

Development of the obesity standard set

A modified Delphi process was followed in line with ICHOM methods and adopted in previous ICHOM sets. The development of the Obesity Standard Set followed a structured process consisting of distinct phases. The process began with a project kick-off meeting that defined the project's scope, followed by subsequent eight video conference meetings, where the OWG identified and defined relevant outcomes, appropriate outcome measurement tools, and relevant case mix variables. Final phases included prioritisation of a primary subset of measures, as well as external validation surveys to test real-world feasibility and validity. Fig. 1 depicts the phases of Obesity Set development (Fig. 1).

Search strategy and selection criteria

Following consensus on the Set scope, comprehensive literature search was conducted to identify relevant clinical outcomes, patient-reported outcomes, treatment related complications, and case-mix variables. The search strategy focused on extracting studies and clinical guidelines published between January 1, 2005, and May 30, 2023. A database-specific search strategy was developed and conducted by two investigators. A systematic search of the literature across PubMed, Web of Science, EMBASE, PsycINFO, Cochrane, clinical trial databases, and the Core Outcome Measures in Effectiveness Trials (COMET) databases was performed. The supplementary tables (Supplementary Tables S2–S6) present the search terms. Search terms for both quantitative and qualitative studies, as well as specialised databases such as clinical trial databases, the COMET database, and Cochrane databases, were also considered in addition to the commonly searched databases. In order to guide the identification of relevant clinical outcomes, patient-reported outcomes, treatment-related complications, and case-mix variables, we followed the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines,[14] and included studies of people aged older than 18 years with obesity. The searched articles were exported to Rayyan software for screening of relevant studies[15] The project team members (LS, TM, SC, IM) independently screened all articles for eligibility criteria to extract candidate outcomes, which were then discussed during each virtual meeting. All potential outcomes were extracted into Microsoft Excel for data management, with all duplicated records excluded. For each eligible article, the abstract was initially reviewed, followed by a full-text review as needed to determine inclusion. Any disagreements between reviewers were discussed and resolved by the project team.

Outcome selection process

The outcome selection process was facilitated using a structured Delphi method, a consensus-building approach, where each OWG member rated each outcome on a Likert scale ranging from 1 (least essential) to 9 (most essential). Outcomes were included in the final set if at least 80% of OWG members rated them 7 to 9. Inconclusive outcomes (rated 4 to 6) were re-evaluated in a second round, while outcomes rated 1

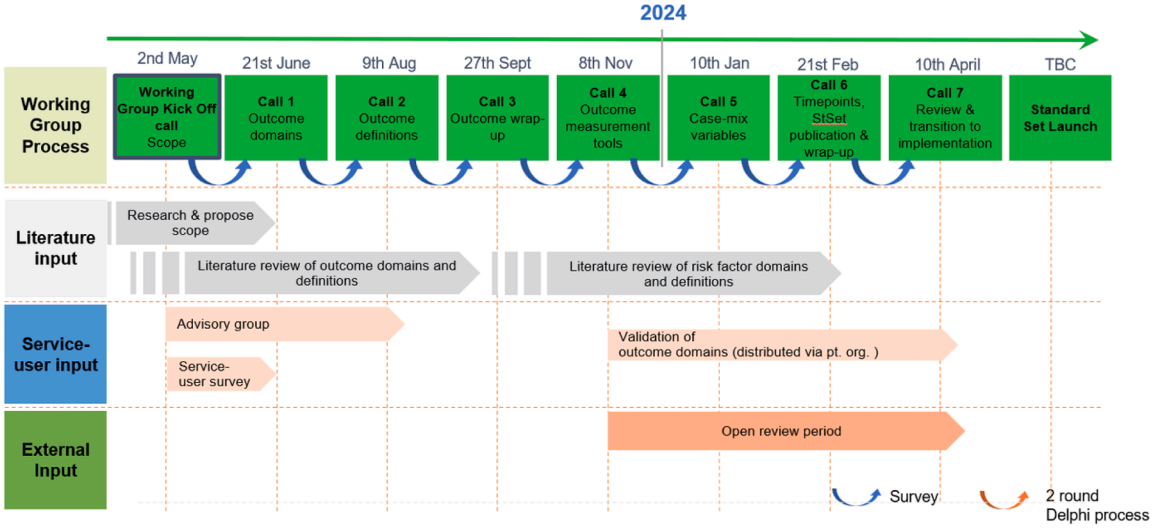

Fig. 1: Project timeline.

to 3 were excluded. Domains unresolved after the second round were further discussed jointly with the OWG, before being submitted to a third and final consensus process, where inclusion/exclusion was determined by majority rule based on binary voting. After reaching consensus, outcomes were included in the final standard set and unanimously approved by all members of the OWG. Following each virtual meeting, detailed minutes were circulated among OWG members along with a survey and slide deck containing discussion points. The core project team was not involved in the outcome decisions or the Delphi voting process.

The OWG considered the following six criteria when ratifying outcomes for inclusion:

(i) Importance to PwO - outcomes that reflect the priorities and needs of PwO, particularly those impacting their quality of life and long-term health.
(ii) Clinical relevance: Outcomes that are directly relevant to clinical decision-making and management of obesity and associated comorbidities.
(iii) Sensitivity to changes in healthcare delivered: Outcomes that are responsive to improvements or changes in obesity care, such as various effective treatment modalities.
(iv) Feasibility in data collection: Practicality of collecting the outcome in routine and diverse clinical settings without causing significant burden on patients or clinicians.
(v) Cross-cultural and psychometric validity: Outcomes that are applicable and meaningful across diverse healthcare settings, ensuring global relevance.
(vi) Practicality over aspiration: Prioritising outcomes that are practical and feasible for implementation rather than an ideal that would be challenging to measure.

For PROM tool selection, additional criteria were also considered such as domains covered, clinical interpretability of detected changes and comparison with other existing PROM tools to ensure validation and ease of implementation.

After the final Set of Patient-Centred Outcome Measures was completed and validated by external patients and HCPs (see 'Open Review Survey' below), the OWG conducted a final round of voting to define a Primary Subset. The Primary Subset are the 'essential, must have' data elements to serve as a starting point for implementers to begin measuring the outcomes that matter most to PwO, transitioning to full set implementation if recommended.

To define the Primary Subset, the OWG was asked to rank each outcome variable from the final Core Outcome Set on a 9-point Likert scale (1 = Not important 5 = Somewhat important 9 = Most important). The OWG was asked to rank the 38 outcome variables in the final ICHOM Set of Patient-Centred Outcome Measures for PwO in order to define further the most essential metrics that any implementing site, regardless of geography or resources, would be able to use to begin outcome measurement collection. Additionally, all case-mix variables ratified into the final Set were included in the Primary Subset.

For an outcome to be included in the Primary Subset, at least 80% of the OWG members had to agree, with each member rating the outcome as 7.0 or higher. For other variables, at least 70% agreement was required, based on clinical implementation feasibility. After voting, the results were reviewed with the OWG where clinical feasibility was discussed to ensure the Primary Subset may be applied practically regardless of treatment setting.

Psychometrics of patient-reported outcome measures (PROMs)

The assessment of the psychometric properties of PROMs included in the Set was conducted by searching relevant studies, following a modified search strategy based on Terwee et al.'s recommendations.[16] Additional manual searches of references from systematic reviews were conducted to identify studies on the psychometric properties or validation studies of relevant PROMs. The PROMs were evaluated for their psychometric quality based on validity, reliability, sensitivity to change/responsiveness, and feasibility (i.e., cost, language coverage, time to complete). Since the target population was PwO, only tools validated for this population were selected. The inclusion of PROMs in the Set was determined by the OWG, based on comprehensive coverage of outcomes, prior validation with PwO, availability in at least three languages, free access, and a completion time of less than 20 min or fewer than 40 items.

Identification of case mix variables

Relevant case mix variables were extracted by the core project team through a comprehensive review of the literature, focused on studies that identified relevant outcome domains, clinical and patient-reported outcomes, and treatment-related complications in PwO. In this standard set, case mix variables (also called risk adjustment variables) are patient characteristics that are not outcomes themselves but can influence outcomes. These case-mix variables were then presented to the OWG to decide for inclusion or exclusion. The relevance (strength of causal linkage between the case-mix variable and the outcome), the independency (improves predictive power over variables already included), the practicality of measurement (not harmful, expensive, or uncomfortable) and the ability for international comparison were criteria used to assess inclusion of case

mix variables. In total, 18 variables were included for case mix adjustment (Table 1).

Open review survey

Before launching the final Standard Set, an open review process was conducted with the following aims: (i) to assess whether the selected outcomes reflected the health priorities and quality of life aspects most important to PwO; (ii) to ensure the feasibility of data collection in routine clinical practice; (iii) to verify the validity of the outcomes for clinical decision-making; and (iv) to incorporate feedback to improve the alignment of the outcomes with patients and clinical needs. This involved circulating the final set of proposed outcome measures to a broad group of stakeholders, including HCPs, researchers, patient advocates and PwO.

Ethical approval was obtained prior to conducting the online survey from the local ethical and regulatory bodies in each country. The North Star Review Board found the ICHOM Patient Validation Survey to be exempt from further requirements of the common rule under criteria at 45 CFR 46.104(d) (2) in the United States. The NHS Health Research Authority confirmed exemption for the ICHOM Patient Validation Survey. Informed consent was provided to all participants informing the purpose of the survey, all risks and benefits, voluntary participation, confidentiality and anonymity of the results, the opportunity to withdrawal at any time, and ask questions at any point. Informed consent was collected from all individual participants in the survey. No identifiable participant data, including specific location information, was collected as part of the survey.

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. All authors had full access to the data in the study and reviewed the final manuscript. LS, TM, SC, and AS had final responsibility for the content and made the decision to submit the paper for publication.

Results

Condition scope

The ICHOM Set of Patient-Centred Outcome Measures for Adults Living with Obesity is aimed at adults aged 18 years and older, with obesity being the primary reason for care. Obesity is defined as a BMI $\geq$ 30 kg/m^2 or obesity diagnosed using ICD-10: E66 or ICD-9: 278 or previously diagnosed with/treated for obesity at any point in a patient's lifetime. This Set is intended to be treatment agnostic, including behavioural interventions, psychosocial care, pharmacological, non-pharmacological, and surgical interventions, with the exclusion of experimental treatments. The outcome selection process, outcomes included, consolidation of the chosen outcomes and details of the core outcome domains and core outcomes has been presented in Figs. 2–4, and Supplementary Table S7, respectively. The Set aims to assess outcomes across different health dimensions in diverse health care settings. Outcomes have been grouped to include physical health, clinical status, wellbeing, health behaviours, body functioning, adverse outcomes, surgery specific adverse outcomes, and obstetric and gynaecological outcomes (Fig. 3).

Patient Population	Measurement grouping	Measure	Timing points to be measured at	Clinical or patient reported data
All patients	Demographic	Year of birth	Baseline	Clinical
		Sex	Baseline	Clinical
		Race	Baseline	Clinical
		Ethnicity	Baseline	Clinical
		Gender identity	Baseline + annual follow-up (FU)	Patient-reported
		Education level	Baseline + annual FU	Patient-reported
		Employment status	Baseline + annual FU	Patient-reported
		Financial burden	Baseline + annual FU	Patient-reported
All patients	Clinical and health status factors	BMI	Baseline + annual FU	Clinical
		Weight	Baseline + annual FU	Clinical
		Height	Baseline + annual FU	Clinical
		Smoking status	Baseline + annual FU	Clinical
		Alcohol intake	Baseline + annual FU	Clinical
		Comorbidities	Baseline + annual FU	Clinical
All Patients	Treatment related factors	Non-pharmacological treatment	Baseline + annual FU	Clinical
		Pharmacological treatment	Baseline + annual FU	Clinical
		Specific pharmacological treatment	Baseline + annual FU	Clinical
		Cardiovascular procedure	Baseline + annual FU	Clinical

Table 1: **Description of case-mix variables and measurement timepoints.**

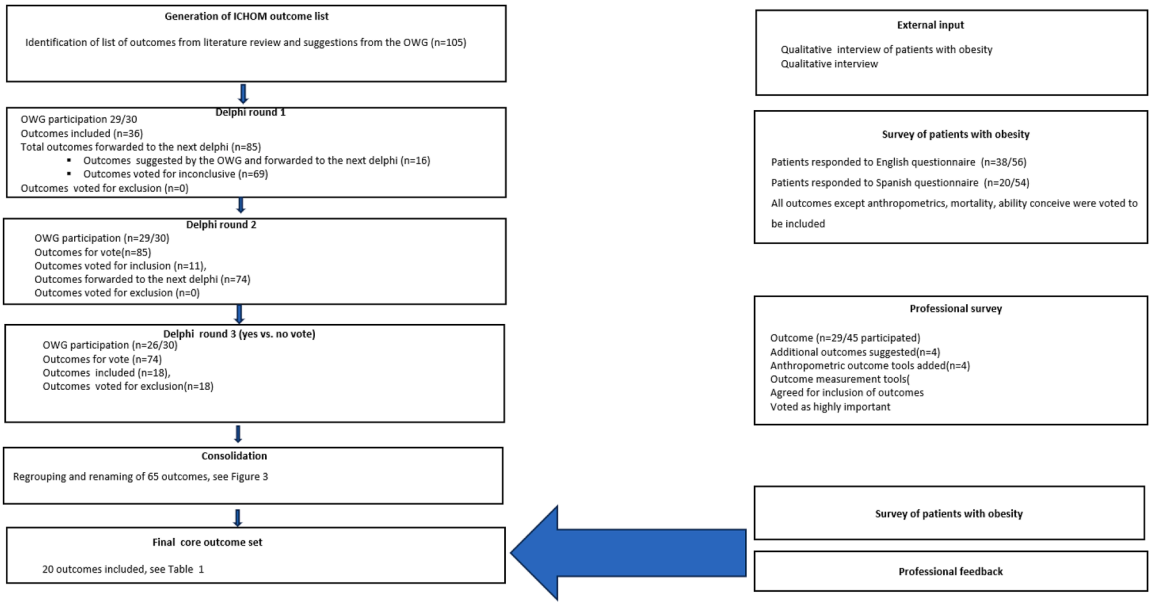

Fig. 2: Overview of outcome selection process.

Outcomes in the set

The final Set of 20 outcomes was developed and approved by all members of the OWG. Seventeen of these outcomes were recommended to be measured in all patients, while three population-specific outcomes were developed for particular sub-populations. These are surgery-specific adverse events related to complications from metabolic bariatric surgery, gynaecological outcomes associated with reproductive health with and without pregnancy. Outcomes were categorised into the five domains detailed in Fig. 3.

Detailed timelines for data collection were agreed upon by the OWG (Table 2). These were structured to enable longitudinal tracking of both short-term and long-term changes in patient health and treatment outcomes.

Clinical reported outcomes

Across the five outcome domains, the OWG ratified a blend of clinical- and patient-reported outcome measures into the final Set. The OWG recommended that clinical outcomes such as cardiometabolic risk (blood

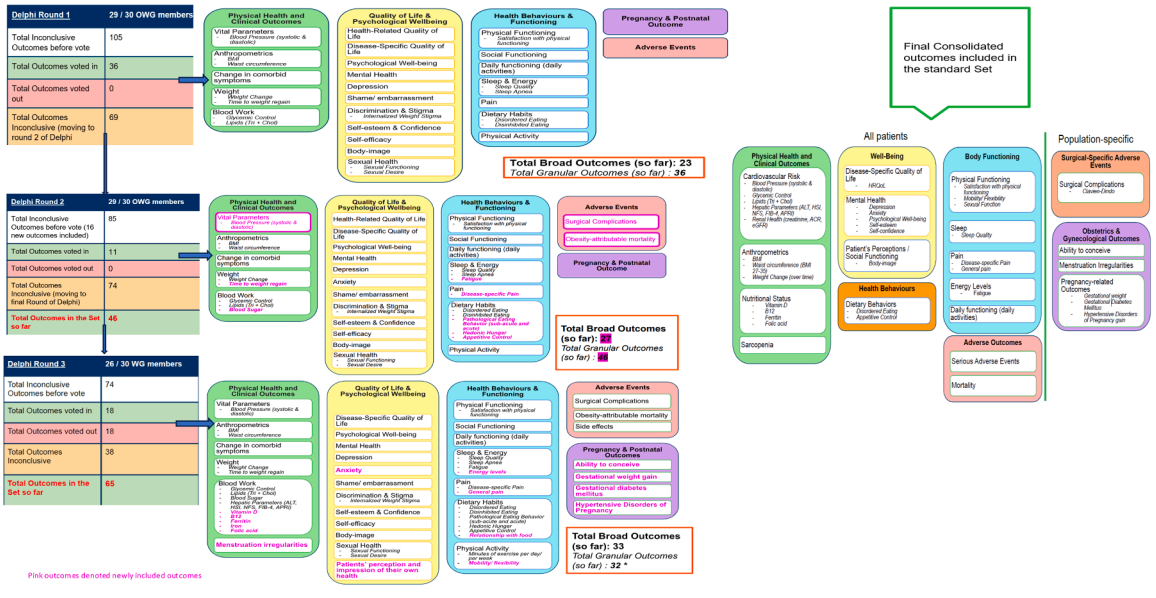

Fig. 3: Outcomes included at each phase of the selection process.

Fig. 4: Details of Core outcome domains and core outcomes in the standard set.

pressure, glycaemic control, lipids, hepatic parameters, and renal function) and anthropometric measures (height, weight and waist circumference) be measured at baseline, six-month follow-up and then annually. Nutritional status, including vitamin D, vitamin B12, ferritin and folic acid should also be monitored, with similar measurement timelines. Additionally, OWG recommended screening for sarcopenia, an important indicator for muscle health, using grip strength tests, at baseline and every six months thereafter.

Patient-reported outcome measures (PROMs)

The OWG identified key outcomes that could be captured using PROMs. These included general quality of life, mental health, body image, social function and body functioning (sexual function, physical function, sleep, pain, energy levels and daily activities). It was agreed that health behaviours should reflect dietary behaviours as an outcome measure. The selected tools for measuring these outcomes included the EQ-5D-5L for measuring generic quality of life, mental health, and physical function. The BODY-Q Obesity Modules were used for capturing social function, dietary behaviour, sexual function, physical function, and psychological wellbeing.[17] The BODY-Q Obesity Module is a patient-reported outcome measure designed to assess the impact of obesity and its treatments—such as bariatric surgery or lifestyle changes—using 48 questions across six scales: eating behaviour, body image, social function, psychological function, sexual function, and physical function. In addition, the STOP-BANG Questionnaire for evaluating sleep quality. PROMs were recommended to be collected at baseline and six-month intervals thereafter (Table 2).

During the PROM selection process, the OWG initially considered 33 tools through a comprehensive literature review. This was followed by an in-depth evaluation of 11 generic and 10 obesity-specific tools.

Patient population	Core outcome group	Core outcome variable	Measurement point(s)	Clinical or patient-reported
All patients	Cardiometabolic risk	Blood pressure	Baseline + every 6 mths	Clinical
		Glycemic control	Baseline + every 6 mths	Clinical
		Lipids	Baseline + every 6 mths	Clinical
		Hepatic parameters	Baseline + every 6 mths	Clinical
		Renal function	Baseline + every 6 mths	Clinical
All patients	Anthropometrics	BMI	Baseline + every 6 mths	Clinical
		Waist circumference weight change	Baseline + every 6 mths	Clinical
			Baseline + every 6 mths	Clinical
All patients	Nutritional status	Vitamin D	Baseline + every 12 mths	Clinical
		Vitamin B12	Baseline + every 12 mths	Clinical
		Ferritin	Baseline + every 12 mths	Clinical
		Folic acid	Baseline + every 12 mths	Clinical
All patients	Sarcopenia	Grip strength	Baseline + every 6 mths	Clinical
All patients	Survival	Mortality	Baseline + every 12 mths	Clinical
All surgical patients	Surgical complications	Surgical complications	Baseline + every 6 mths	Clinical
All patients	Obesity related quality of life	Social functioning	Baseline + every 6 mths	Patient-reported
		Physical function	Baseline + every 6 mths	Patient-reported
		Sexual function	Baseline + every 6 mths	Patient-reported
		Disease-specific	Baseline + every 6 mths	Patient-reported
		Pain	Baseline + every 6 mths	Patient-reported
		Psychological function	Baseline + every 6 mths	Patient-reported
		Body image	Baseline + every 6 mths	Patient-reported
		Dietary behavior		Patient-reported
All patients	General quality of life	Depression	Baseline + every 6 mths	Patient-reported
		Anxiety	Baseline + every 6 mths	Patient-reported
		Mobility/Flexibility	Baseline + every 6 mths	Patient-reported
		Energy levels	Baseline + every 6 mths	Patient-reported
		Daily functioning (ADLs)	Baseline + every 6 mths	Patient-reported
		Physical function	Baseline + every 6 mths	Patient-reported
All patients	Sleep	Sleep quality	Baseline + every 6 mths	Patient-reported
All patients	Adverse events	Serious adverse events	Baseline + every 6 mths	Patient-reported
All Females	Reproductive health	Ability to conceive	Baseline + every 6 mths	Patient-reported
		Menstruation irregularities	Baseline + every 6 mths	Patient-reported
All Females	Pregnancy	Gestational weight gain	Baseline + every 12 mths	Patient-reported
		Gestational diabetes mellitus	Baseline + every 12 mths	Patient-reported
		Hypertensive disorders of pregnancy	Baseline + every 12 mths	Patient-reported

Table 2: **Details of core outcomes and measurement time points.**

The final selection of the EQ-5D-5L, and the BODY-Q Obesity Module was based on criteria such as psychometric robustness, availability in multiple languages, validation across multiple settings, and the practicality of use in a clinical setting. The selected tools provide comprehensive coverage of five core domains: mental, social, sexual, physical functioning and pain.

Recognising variation among healthcare organisations operational and contextual requirements, the OWG also identified alternative tools that could be used to assess health-related quality of life. These alternatives include PROMIS Global Health, VR-12 or SF-12. These tools provide robust coverage of quality-of-life measures, though they may lack the obesity specific areas of focus provided by BODY-Q Obesity Modules. The OWG did not include common depression and anxiety measures, in an effort to reduce question burden on HCPs and PwOs.

The OWG agreed that these PROMs should be administered at baseline, and then at six-month intervals to ensure comprehensive and consistent tracking of patient outcomes over time. The OWG acknowledges the recommended outcome measures include currently available, validated tools that may not be ideal; therefore, as more specific and concise tools are developed and validated may be considered in future iterations of this Set.

Adverse events

The OWG agreed that serious adverse events related to obesity treatment, agnostic to treatment type, should be systematically recorded. Therefore, the OWG adopted a Serious Adverse Event (SAE) variable from the ICHOM Atrial Fibrillation (Afib) Set[18] and made minor modifications to reflect SAEs associated with different treatment modalities in obesity care. This was done to allow harmonisation across sets to reduce redundancy and question burden in the event a PwO also has Afib, and to improve internal consistency across ICHOM sets.

Population specific outcomes

For specific sub-populations, the OWG included Obstetrics and Gynaecological and surgical-specific outcomes. This includes tracking fertility issues, menstrual irregularities, and pregnancy-related outcomes. The OWG agreed upon single questions that could be asked to assess these outcomes (Supplementary Table S8) and recommended that clinicians record pre-gestational weight for pregnant patients, and among women of childbearing potential, outcomes reflecting reproductive health should be assessed at baseline and annually. For surgical complications from metabolic and bariatric surgery, the OWG opted for the Clavien-Dindo Classification System.

Case mix variables

Case mix variables ensure that meaningful comparisons between institutions and regions are fair. The 18 case mix variables included demographic data, baseline clinical and health status data, and treatment related factors detailed in Table 1 alongside measurement points for the case mix variables (Table 1).

Open review results

The open review survey to professionals was deployed through social media which reached the ICHOM network of over 42,000 providers in over 150 countries. Additionally, snowball sampling from the professional network of OWG members was leveraged to branch out from the diverse working group professional networks. Overall, the strategy would be considered successful as we reached 106 professionals from 11 different countries encompassing high-, middle-, and low-resource settings.

Two external validation surveys were deployed to incorporate external feedback and validation into the outcomes and outcomes measures selected for the Set. The first survey was deployed to PwO to garner insights into whether the outcomes proposed by the OWG were truly the elements that matter most to PwO. A total of 95 participants completed the English version of the patient validation survey including individuals with lived experience of obesity (84%) and caregivers of adults living with obesity (16%). Around two thirds of participants were females (68%) and 29% were males. Over a third of participants were aged 46–60 years old (38%); 28% were 61–75 years old; 28% were 31–45 years old and 6% were 21–30 years old.

The second survey was deployed to HCPs to validate the clinical relevance and feasibility of the patient- and clinical-reported data elements. A total of 106 HCPs from various subspecialties, including obesity medicine practitioners (23.6%), dieticians (24.5%), general practitioners (11.3%), nurses (7.5%), industry/commercial representatives (2.8%), as well as policy advisors, healthcare administrators, and physician assistants, participated in the survey. The geographic distribution of respondents included Europe (37.7%), Asia (21.7%), Australia and New Zealand (14.2%), North America (16%), Africa (6.6%), South America (1.9%), and the Middle East (1.9%).

Feedback from patients and healthcare professionals

For the 20 domains included in the Set of outcomes over three quarters of patient and/or carer respondents valued the core domains as highly important to be included in the set. Response rate for the patient validation survey was not captured due to the nature of how the survey was deployed via social media and newsletters in patient organizations. Only anthropometrics were valued as lower with 45% of respondents valuing them as highly important, 42% suggesting moderate importance and 13% of respondents ranking anthropometrics as low importance. Over three quarters of the respondents agreed that having this information would be helpful to support care for themselves or the person for whom they care for (Supplementary Table S9).

Healthcare professionals valued the proposed Set as highly important (Supplementary Table S10). Additional outcomes were suggested including sleep apnea, bone health, body composition, internalized weight bias, and visceral fat. Over 90% of professionals agreed on the inclusion of key PROMs domains, and obstetrics and gynaecological outcomes (96%).

For case-mix variables, 97% of respondents agreed on the relevance of demographic case-mix variables, and 84% agreed with the inclusion of baseline clinical and health status data. Suggested changes included using waist-to-hip ratio or Edmonton Obesity Staging System (EOSS)[19] instead of BMI and tracking weight status over time. Implementation feedback revealed over 90% of professional respondents indicated they would like access to the final set, and 78.6% expressed interest in implementing the Set in their local clinical contexts.

No significant changes were made to any validated outcome measures based on external feedback. There were some minor amendments to verbiage (e.g., expanding the various types of procedures under the Cardiovascular Procedure variable or adding notation to collect waist circumference in PwO with BMI < 35). One reoccurring suggestion from the Professional Open Review survey was to include Internalised Weight Stigma as an outcome with a subsequent measure. This was already voted as an essential outcome by the OWG; however, there are no valid existing tools that safely collect this information as an outcome in adults living with obesity yet.

Primary subset

The OWG was asked to vote on a Primary Subset from the finalised Set of Patient-Centred Outcome Measures for adults living with obesity. This is intended as a

recommended starting point for the ICHOM Set implementers. The outcomes voted to be included in the primary dataset were blood pressure (92.3% agreement), glycaemic control (96.2% agreement), lipids (80.8% agreement), disease-specific quality of life (96.2% agreement), dietary behaviours - appetitive control (80.8% agreement), sleep quality (88.5% agreement), activities of daily living (88.46% agreement), and serious adverse events (92.31% agreement). The project team then decided which remaining variables, with ≥70% agreement, should be in the Primary Subset based on clinical feasibility in most treatment settings. This included waist circumference (76.9% agreement), dietary behaviours - disordered eating (76.9% agreement), weight change over time (76.9% agreement), and BMI (76.9% agreement).

In the final Set, the BODY-Q Questionnaire Obesity Modules are recommended for use in the Primary Subset due to its utility measuring comprehensive obesity-specific quality of life (96.2% agreement) and the various sub outcomes with varying degrees of importance according to the OWG. The BODY-Q Obesity Module is a 48-item questionnaire with six modules capturing the sub-outcomes associated with obesity-specific quality of life (15): psychological function (73.1% agreement), physical function (61.5% agreement), social function (69.2% agreement), dietary behaviours (78.8% agreement), sexual function (50% agreement), and body image (69.2% agreement).

Data collection and implementation

The next step will be the adoption and implementation of the ICHOM Set of Patient-Centred Outcome Measures for Treatment of Adults living with Obesity. A reference guide and data dictionary has been developed by ICHOM to facilitate implementation and minimise variability and inconsistency in the collection of data (https://www.ichom.org/patient-centered-outcome-measure/adult-obesity/).

The next phase of ICHOM's work driving adoption of the Set will be initiating the first cohort for a Learning Collaborative (OBE LC). The ICHOM OBE LC will involve five obesity treatment sites from various geographic regions and clinical settings, including LMIC, who will be collecting the Primary Subset outcome measures, at a minimum, and using those findings to engage in shared learning to explore variations in care pathways, and define best practices in Obesity treatment. The OBE LC will leverage ICHOM's partner network to enable a standardised approach to outcomes measurement implementation, data analysis, and change management or quality improvement.

Discussion

This study describes the selection of a set of outcome measures for monitoring the quality of obesity treatment care in adults living with obesity. To the best of our knowledge, this ICHOM-led initiative is the first coordinated multinational effort to establish a standardised and clinically meaningful set of metrics that matter most to PwO and HCPs for use in routine clinical practice.

The consensus among the experts and PwO was to include twenty outcomes across five domains. Recent studies have highlighted the limitations of focussing solely on weight loss as a measure of success in obesity treatment. For instance, a recent study underscored the importance of a non-weight focused approach in obesity care, highlighting improvements in quality of life and mental health as critical indicators of treatment efficacy.[20] The outcomes identified in this set - ranging from cardiometabolic risk factors to body image and mental health, align with this emerging need in obesity care, capturing the complexity and heterogeneity of obesity as a multifactorial chronic condition.

Moreover, consistent with various clinical practice guidelines (CPGs) this set recommends inclusion of waist circumference (WC) alongside BMI, as WC serves as an indirect measure of metabolic health and reduction can reduce the risk of adverse health events.[21] The inclusion of cardiovascular-related outcome measurements for the Set (i.e., blood pressure, glycaemic control, lipids, hepatic and renal) is crucial for shifting the focus from solely weight-related metrics to overall health improvements. Findings highlight the importance of monitoring nutritional outcomes as an essential component of obesity treatment irrespective of treatment modality to understand the impact of treatment interventions on nutritional changes. This is specifically important after metabolic and bariatric surgery to ensure patients are absorbing enough nutrition through a healthy dietary regimen and appropriate supplementation with necessary vitamins and minerals.[22] This Set reflects the importance of including patient-reported outcomes alongside clinical weight related outcomes.[23] In addition, it developed a core set of outcomes for quality of life specifically, acknowledging the need to recognise outcomes important to the patient. Three PROMs were selected: the Impact of Weight on Quality of Life-Lite to measure self-esteem; the BODY-Q to capture physical function, physical symptoms, psychological function, social function, eating behaviour, and body image, and the Quality of Life for Obesity Surgery questionnaire. Findings in the current study conducted by ICHOM build on this set, supporting the use of the BODY-Q Obesity Modules to capture the core dimensions but identifying CROMs and PROMs that the OWG considered important to measure. Alternative outcome measurement tools were also provided to acknowledge pragmatic issues which might warrant the use of other measures.

Findings here are in congruence with previous research suggesting the need to include a general and obesity specific HRQoL measure.[24,25] Previous literature and OWG input recommend using the general EQ-5D-5L and BODY-Q Obesity Modules to measure dimensions of QoL. This current Set and other core outcome sets for obesity treatment have all acknowledged and included PROMs[23,26] providing further support for the inclusion of PROMs alongside clinical outcome measures.[27] The value of including PROMs is well recognized by regulators, clinicians, and patients to allow the consideration of the patient perspective[27] also highlighted the need to select appropriate PROMs to capture the patient perspective and allow transparent reporting of PROMs.[27] This current standardised set of obesity treatment outcomes provides guidance on what PROMs to use to allow valid, reliable and pragmatic measurement of the PROMs included.

This study directly involved patient representatives in the design and development of the Set. The OWG (n = 29) was in line with typical numbers involved in ICHOM Set Development processes with the goal of 20–30 experts to balance geographic, gender, professional and cultural diversity. The OWG contained 17% patient representatives with another 10% being multidisciplinary professionals with lived experience and were fully involved in the decision-making process taking part in all stages of the obesity treatment set development. Additional feedback from service users and professionals working in the field was sought toward the end of the Sets development through dedicated, open review surveys. The patient and HCP survey responses were supportive of the Set development and feedback reflected points that had already been discussed by the OWG. Additional comments provided from the surveys mostly aligned with what was put in the Set, thus no major changes were made around this feedback. Some recommended changes were considered yet refinements were not made as they did not fit the purpose of the Set.

This Set was developed to be used and applied in the context of all obesity treatments including metabolic and bariatric surgery, pharmacotherapy, or with combined obesity treatments. Furthermore, there is additional guidance on applying the Set to specific patient populations including pregnancy. The scope of the obesity Set is limited to adults; thus, a different Set will need to be developed for child and adolescent populations. The Set is intended for patients being treated with a primary focus on obesity; however, obesity is commonly experienced alongside other comorbidities like type 2 diabetes mellitus and coronary artery disease. Although internalised weight bias was ratified as an "essential outcome" by the OWG, given that there are no psychometrically valid tools that can feasibly capture this in clinical practice, it could not be included in the Set. The Set is a minimum recommendation of outcomes to measure, and the OWG recommends that, where feasible, clinicians complement the obesity treatment Set with other outcome measures of importance to each individual patient and clinic environment. For example, if a setting wishes to utilise the PHQ-9 or GAD-7 for depression or anxiety respectively, they should do so in tandem with the measures encompassed in this Set.

It was difficult to identify appropriate tools to measure outcomes across several of the domains recommended by the OWG (e.g., physical activity). Decisions were made on PROMs by considering the validity, reliability, and for pragmatic reasons like availability in different languages, time to complete (acceptability and feasibility) and whether it was freely available. Therefore, PROMs that were recommended were prioritised to be as globally generalisable as possible to accommodate the largest number of implementers for each PROM as possible. It is recognised that implementation of the full Set may be difficult or infeasible for a variety of reasons; however, the Primary Subset was developed with this challenge in mind. The Primary Subset serves as a consensus-based starting point for implementers to focus efforts before scaling to include other outcome measures from the broader Set. It might be difficult to feasibly implement the Set in some clinical settings globally but if clinicians can measure as many outcomes as are clinically feasible it is working towards this VBHC approach.

Whilst a strength of the ICHOM method is the validation surveys, the patient survey was limited to western samples given ethical approval only being granted in the US and UK. It is acknowledged that a modest sample size and English-only survey may limit the representativeness of the broader global population. The HCP survey was more geographically representative yet could have benefitted from further representation from South American and Middle Eastern populations. However, a range of HCP roles were represented in the survey from Obesity Medicine practitioners, dieticians, policy advisors, and psychologists. Sample sizes for the patients (n = 95) and HCPs survey (n = 106) were in line with similar sample sizes from previous ICHOM sets and above the minimum sample size of 40 set out in the ICHOM methodology.

The broad range of outcomes included in the Set is aligned with the recent guidelines on reframing obesity to look beyond weight at an individual's holistic health status. Using this Set to measure broad health outcomes can allow consideration of different clinical presentation of PwO and thus lead to better management and understanding.[28] It is acknowledged that definitions of obesity across geographic regions remain in flux and the panel therefore did not specify exact diagnostic criteria for obesity, a discussion of which would have been beyond the scope of this paper. Rather the consensus was that the recommended set of

outcome measures should apply to any patient undergoing obesity management. The geographic range of feedback from HCPs was not representative. Patient feedback was only available to those who spoke English.

The adoption of the ICHOM Set of Patient-Centred Outcome Measures for Adults living with Obesity will empower HCPs to ensure that evidence-based obesity care and key aspects of PwO lives are being measured and addressed in routine clinical practice which will ensure treatments meet the needs of those seeking it. It will also allow HCPs to benchmark performance against other treatment approaches internationally, track patient outcomes over time acknowledging the potential impact of case-mix variables on patient outcomes and identify areas for quality improvement. Global adoption of the Set by clinicians would signal the importance of measuring and acknowledging the value of non-weight-related outcomes in obesity treatment, highlighting the importance of the patient voice and measuring outcomes that matter most to them. In turn, the recognition of the importance of PROMs by clinicians globally could reduce stigma and bias faced by PwO. Standardised reporting of outcome measures in evaluations of adult obesity treatment interventions will contribute to more rigorous evaluations, providing comparable data across diverse settings internationally. This will also allow researchers to draw more meaningful conclusions regarding which treatment options work best, for which patients, and in what context. It will also aid in shared decision making while treating PwO.

Future research needs to focus on validating the Set in different settings and geographies, including Small Island Developing States which have the highest prevalence of obesity. Evidence from implementation of the Set can be used to update and improve it. Further research is also needed to explore the utility of the core outcome set in driving improvements in health outcomes and developing a reliable and valid measure of internalised weight bias, as this is a critical outcome in the assessment and management for PwO. Qualitative research with both treatment providers and patients in obesity treatment settings will help determine if their perspectives align with the shift toward value-based healthcare. As our understanding of obesity as a chronic disease continues to develop, treatment modalities will evolve. Therefore, the inclusion of long-term follow-up of outcome measures, as recommended in the ICHOM implementation guide (https://www.ichom.org/patient-centered-outcome-measure/adult-obesity/), is vital for evaluating the sustained impact of interventions on both CROMs and PROMs.

This study represents a broad international consensus across clinicians, researchers and patient representatives of a standardised Set of outcomes for PwO. The ICHOM Obesity Set covers outcomes considered most essential to patients and caregivers, including physical, clinical and psychosocial impact, body functioning, health behaviours and adverse events. The ICHOM Set has the potential to improve clinical practice and research and overall patient care. The implementation of the Set can contribute to the adoption of value-based and patient-centred healthcare frameworks, policies and payment approaches, subsequently improving obesity care and value for all stakeholders involved. In the future, the OWG will assess the level of implementation and work to update the ICHOM Set when advances in outcome measurements are made. The widespread implementation of the Set can contribute to developing a large database of evidence that will provide an invaluable resource for researchers, clinicians and experts contributing to the development of policies and guidelines for adult obesity treatment.

Contributors

TM: Responsible for conceptualisation, investigation, and validation, including the preparation of both the original and final drafts of the manuscript. Duties also included conducting literature reviews, screening articles based on eligibility criteria to identify candidate outcomes for discussion by the Obesity Working Group (OWG), and extracting potential outcomes that were subsequently reviewed during each virtual meeting and reviewing of the final manuscript.

LS: Responsible for conceptualisation, investigation, and validation, including the preparation of both the original and final drafts of the manuscript. Duties also included conducting literature reviews, screening articles based on eligibility criteria to identify candidate outcomes for discussion by the OWG and extracting potential outcomes that were subsequently reviewed during each virtual meeting and reviewing of the final manuscript.

SC: Responsible for project management, conceptualisation, investigation, and validation, including, screening articles based on eligibility criteria to identify candidate outcomes for discussion by the OWG, and extracting potential outcomes that were subsequently reviewed during each virtual meeting, and reviewing the manuscript draft and reviewing of the final manuscript. SC had access had access to and verify the underlying study data.

ZDG: Conceptualisation, investigation, validation, reviewing the manuscript draft and reviewing of the final manuscript.

UD: Conceptualisation, investigation, validation, reviewing the manuscript draft and reviewing of the final manuscript.

YS: Conceptualisation, investigation, validation, reviewing the manuscript draft and reviewing of the final manuscript.

IM: Conceptualisation, investigation, validation, reviewing the manuscript draft and reviewing of the final manuscript.

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MCS: Conceptualisation, investigation, validation, reviewing the manuscript draft and reviewing of the final manuscript.

SHT: Conceptualisation, investigation, validation, reviewing the manuscript draft and reviewing of the final manuscript.

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TZ: Conceptualisation, investigation, validation, reviewing the manuscript draft and reviewing of the final manuscript.
MAA: Conceptualisation, investigation, validation, reviewing the manuscript draft and reviewing of the final manuscript.
VVV: Conceptualisation, investigation, validation, reviewing the manuscript draft and reviewing of the final manuscript.
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MC: Conceptualisation, investigation, validation, reviewing the manuscript draft and reviewing of the final manuscript.
BH: Conceptualisation, investigation, validation, reviewing the manuscript draft and reviewing of the final manuscript.
DB: Conceptualisation, investigation, validation, reviewing the manuscript draft and reviewing of the final manuscript.
LP: Conceptualisation, investigation, validation, reviewing the manuscript draft and reviewing of the final manuscript.
OMAH: Conceptualisation, investigation, validation, reviewing the manuscript draft and reviewing of the final manuscript.
AMS: Conceptualisation, investigation, validation, reviewing the manuscript draft and reviewing of the final manuscript and supervision of the primary authors. AMS had access to and verify the underlying study data.

Data sharing statement

The datasets used and/or analysed during the current study are available from the corresponding author upon reasonable request and with prior permission from ICHOM.

Declaration of interests

SN received funding from Medtronic for grants unrelated to this project and the Dutch Audit for Treatment of Obesity unrelated to this project and, reports no conflicts of interest with the funders of this project.

MP has received compensation in the form of consulting fees and support for travel from Novo Nordisk, Bausch Health, Rhythm Pharmaceuticals, Shoppers Drug Mart, CCRN, Antibody Solutions, CPSO London Health Science, obesity Canada and Eli Lilly for work unrelated to this project and reports no conflicts of interest.

VCD has received compensation in the form of honoraria and grants from Novo Nordisk and Eli Lilly for work unrelated to this project and reports no conflicts of interest.

MCS has received compensation in the form of honoraria, support for travel, and compensation for participation on a data safety monitoring board or advisory board from Novo Nordisk for work unrelated to this project and reports no conflicts of interest.

SHT has received compensation from Novo Nordisk for speaking engagements unrelated to this project and reports no conflicts of interest.

SS has received compensation in the form of honoraria from Novo Nordisk for presentations unrelated to this work and reports no conflicts of interest.

EH has received compensation in the form of consulting fees from Eli Lilly, Novo Nordisk, Vivus BV, The Finnish heart Association, Merck, Exeltis, Orion Pharma, Gedeon Richter, Novartis, The Finnish Association for the Study of Obesity (FASO) and Boehringer Ingelheim for work unrelated to this project and reports no conflicts of interest.

PS has received compensation from Novo Nordisk, Eli Lilly, Amryt (Chiesi), Pfizer, and Boehringer Ingelheim for work unrelated to this project and reports no conflicts of interest.

RL has received funding from Johnson & Johnson, Olympus, Medtronic, IFSO, Dutch Audit for Treatment of Obesity, Federation of Medical Specialists in the Netherlands, Nederlandse Obesitas Kliniek West (The Hague & Gouda) unrelated to this work and reports no conflict of interest related to this project.

MV has received compensation in the form of honoraria, consulting fees, and grants from Novo Nordisk for work unrelated to this project, and in the form of consulting fees and honoraria Eli Lilly and Boehringer Ingelheim for work unrelated to this project reports no conflicts of interest.

KC has received compensation in the form of consulting fees and honoraria from Novo Nordisk for work unrelated to this project, and in the form of consulting fees from Eli Lilly and Boehringer Ingelheim for work unrelated to this project and reports no conflicts of interest.

KC has received funding from National Institute for Health Research (NIHR), NIHR School for Primary Care Research, Health Education England (now NHS England), NIHR Oxford Medical Products, National Institute of Academic Anaesthesia and Health Education England/NIHR for work unrelated to this project and reports no conflicts of interest.

VVV has received compensation in the form of grants or contracts, honoraria, consulting fees, and support for travel from Novo Nordisk, in the form of consulting fees and honoraria from Eli Lilly, and in the form of honoraria from Boehringer Ingelheim.

YPC has received compensation from Novo Nordisk presentations unrelated from this project and Nerthus Laboratory, reports no conflicts of interest related to this project. YPC also reports serving as a board member at the Ministry of Health for the commission of Obesity.

MFTM has received compensation in the form of support for travel from Novo Nordisk for work unrelated to this project and reports no conflicts of interest.

IP has received compensation in the form of consulting fees from Novo Nordisk for work unrelated to this project, and in the form of consulting fees and support for travel or attending meetings from Boehringer Ingelheim for work unrelated to this project and reports no conflicts of interest.

XRS has received compensation in the form of grants and honoraria from Novo Nordisk, European Association for the Study of Obesity, European Coalition for People Living with Obesity, Sociedad Mexicana de Nutrición y Endocrinología Canadian Cardiovascular Society, Consorci de Salut de Catalunya, Globalport LLC., Medscape, Sociedad Mexicana de Nutrición y Endocrinología, Chair, Bias 180 and Owner, K&X Ramos AB, Sweden for work unrelated to this project and reports no conflicts of interest.

MC has received funding from Novo Nordisk, NIPC, Med Learning Group, Obesity Canada, Medscape Consilient Health, Novo Nordisk, Johnson & Johnson Association for the Study of Obesity in Ireland, Irish National Obesity Management Clinical Advisory Group, my best weight clinic for work unrelated to this project and reports no conflicts of interest.

BH has received compensation in the form of honoraria, support for travel, and participation on a data safety monitoring board or advisory board from Novo Nordisk and Eli Lilly. BH also reports being a Primary Investigator for clinical studies sponsored by Eli Lilly, Novo Nordisk, and Boehringer Ingelheim for work unrelated to this project and reports no conflicts of interest.

DB has received compensation in the form of grants or contracts from Novo Nordisk, Eli Lilly, NIH and obesity society for work unrelated to this project and reports no conflicts of interest.

TAS has received compensation from consulting, advisory, and leadership roles with organizations including the Ministry of Health Jamaica, Caribbean Public Health Agency, Healthy Caribbean Coalition, and NCD Child, among others. TAS reports no conflicts of interest related to this project.

AMS has received compensation in the form of consulting fees, honoraria, and support for travel from Novo Nordisk, Eli Lilly, and Boehringer Ingelheim for work unrelated to this project.

SC, ZDG, UD, YS, IM, MM, JV, AU, MEGSL, GR, LP, OMAH, MAA, and TZ declare no competing interests.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.eclinm.2025.103422.

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