

Appendix I:

Research Protocols

This checklist is designed to be used by studies investigating obesity medications (OMs) in youth when describing their research protocols (e.g., in manuscripts), with the goal of enhancing accurate, thorough, and transparent reporting. These suggested reporting details may be included in the main manuscript text or appendices/supplementary materials. The table was inspired by the consolidated criteria for reporting qualitative research (CORE-Q).

The columns represent the major potential domains that research protocols may address. The checklist was derived from workshop attendees' responses to the following question: "For studies that address the prioritized research questions, are there specific details about clinical protocols that would particularly inform clinical care?" These responses were iteratively modified by the workshop organizers and co-chairs. It is expected that only a subset of protocols will be applicable to any given study.

Topic	Major Potential Domains	Clinical Protocol Details
Obesity Medication Treatment and Supports		
Medication Dose	Medical	Did you report the dose of medication? • Dose escalation schedule • Discontinuation schedule • Criteria for increasing, maintaining, decreasing, or discontinuing
Frequency and Follow-Up	Medical, Nutrition, Physical Activity, Behavioral and Mental Health	Did you report the frequency of contact points for each intervention component? • Whether participants received clinical or research contact in between visits • How and by whom were participants contacted (e.g., enrollment, initiation, dose escalation, maintenance, post study/follow up plan) • Research protocol or implementation timeline
Modality	Medical, Nutrition, Physical Activity, Behavioral and Mental Health	Did you report on the delivery modality (in-person or telehealth) of the contact points for each component? • Tools utilized • Best practices used for telehealth • Was the intervention individual or group-based (e.g., classes, group chat)? • Was the contact synchronous (e.g., audio, video, facilitated/hybrid, in-person)? • Was the contact asynchronous (e.g., email, texting, message portal)?
Type of Practitioner	Medical, Nutrition, Physical Activity, Behavioral and Mental Health	Did you report on the type of provider delivering lifestyle treatment components (e.g., nutrition education, behavioral support, PA education)? • E.g., registered dietitian, exercise physiologist, psychologist, medical provider, health coach, community health worker, research coordinator

Topic	Major Potential Domains	Clinical Protocol Details
Training	Medical, Nutrition, Physical Activity, Behavioral and Mental Health	Did you report on the training provided to all providers who deliver OM treatment/support? • Training content • Training duration/frequency • Assessment of mastery (e.g., include tool used for assessment) • Follow-up/booster training provided (if any)
Protocol Implementation Fidelity	Medical, Nutrition, Physical Activity, Behavioral and Mental Health	How was the fidelity of protocol implementation assessed for providers who deliver OM treatment/support? • Description of any fidelity measurements/tools • Appointment attendance • Specific modifications allowed for children with special needs (if any)
Inclusion and Exclusion Criteria	Medical, Nutrition, Physical Activity, Behavioral and Mental Health	Did you list the specific inclusion and exclusion criteria for OMs? • E.g., age, complex health care needs, mental health, eating disorder
Engagement and Retention	Medical, Nutrition, Physical Activity, Behavioral and Mental Health	Did you report how participant engagement was measured and how retention was achieved? • Objective measures of adherence (e.g., wearable health trackers, pill counting) • Definitions of adherence differ for youth with special health care needs (if applicable) • Retention strategies
Goals/Targets of Health Behavior and Lifestyle Treatment with OM	Medication, Nutrition, Physical Activity, Behavioral and Mental Health	Did you report whether there were any goals or targets related to OM treatment and supports? • Obesity related comorbidities • Nutrition education and activities • Eating behaviors • Physical activity • Sleep • Emotional health • Stress management • Screen time • Overall (e.g., weight loss, such as reduction of binge eating episodes by 50%) • Mental health improvements • Improvements in self-internalization of weight stigma, body shape/size satisfaction or acceptance, and externalized weight bias.
Statistical Analysis and Data Processing	Medical, Nutrition, Physical Activity, Behavioral and Mental Health	• Intent-to-treat analyses • Wearable health trackers used for monitoring (if any) • Timing and frequency of labs

Topic	Major Potential Domains	Clinical Protocol Details
Safety and Monitoring	Medical, Nutrition, Physical Activity, Behavioral and Mental Health	Did you report on screening and monitoring tools used to assess adverse events? • Frequency of labs, vitals • Validated instruments/questionnaires (e.g., eating disorder, mental health) and protocol used for baseline; threshold for rescreening • Pre-specified “red flags” (e.g., excess weight loss/gain, minimum nutrition/hydration requirements) • Adverse event monitoring and reporting approach (e.g., checklist, diary) • Next steps after a red flag or adverse event occurs (e.g., referrals, increased intensity of follow-up, documentation of subsequent decision points and resolution)
Patient Experience and Shared Decision Making	Medical, Nutrition, Physical Activity, Behavioral and Mental Health	Did your protocol include any shared decision-making strategies with the patient and family? • Details on how communication and shared decision making occurred in real-world scenarios • Decision-making process for multidisciplinary teams and how that could translate to primary care providers • Details on targets and medical outcomes • Strategies for shared decision making when the goals of the patient, family, and/or medical team do not align
Clinical Decisions and Integration into Care Plans	Medical, Nutrition, Physical Activity, Behavioral and Mental Health	Did you report on the clinical decisions and tools that were used? • Algorithm or clinical protocol used (e.g., dosing changes, imaging modality, consults) • Implementation and clinical decision supports that facilitate adoption • Details on care coordination in the clinic, community, or research site (e.g., who, what, where, when, and how did it work?)
Health behavior and lifestyle treatment with OMs		
Structured Health Behavior and Lifestyle Intervention	Nutrition, Physical Activity, Behavioral and Mental Health	If your study used a structured lifestyle intervention, did you report the content with enough detail to be replicated? • Lifestyle component details for nutrition, sleep, screen-time, emotional health, the specific physical activity protocol, etc. (e.g., physical activity protocol: 15-minute guided videos of body weight-based resistance exercises, twice weekly) Format: • Audience(s) (e.g., parent/caregiver only, parent/caregiver +child) • MI or other behavior change techniques (e.g., SMART goal-setting, tracking, problem-solving) • Resources provided to the patient/family (e.g., study backpack including a food guide, accelerometer (model, company), and sleep diary) • Timing (e.g., when intensive phases are delivered, when intervention delivered related to OM treatment phases)

Topic	Major Potential Domains	Clinical Protocol Details
		Delivery modality (in-person or telehealth) of the health behavior and lifestyle intervention: • Tools utilized • Best practices used for telehealth • Was the intervention individual or group-based, caregiver involvement (e.g., classes, group chat)? • Was the contact synchronous (e.g., audio, video, facilitated/hybrid, in-person)? • Was the contact asynchronous (e.g., email, texting, message portal)? Type of health behavior and lifestyle interventionist (e.g., registered dietitian, exercise physiologist, psychologist, medical provider, health coach, community health worker, research coordinator) • Training provided to all interventionists • Training content • Training duration/frequency • Assessment of mastery (e.g., include tool used for assessment) • Follow-up/booster training provided (if any) Duration of each of the behavioral intervention components? • Length of each contact • # of contact points for each component • Length of time over which contact points were provided Dose of behavioral intervention • Total contact hours • Dose escalation, maintenance, discontinuation • Resources provided to the patient/family (e.g., study backpack including a food guide, accelerometer (model, company), and sleep diary)
Goals/Targets of Health Behavior and Lifestyle Treatment with OM	Medication, Nutrition, Physical Activity, Behavioral and Mental Health	Did you report whether there were any goals or targets related to any of the intervention components? • Obesity related comorbidities • Nutrition education and activities • Eating behaviors • Physical activity • Sleep • Emotional health • Stress management • Screen time • Overall (e.g., weight loss, such as reduction of binge eating episodes by 50%) • Mental health improvements • Improvements in self-internalization of weight stigma, body shape/size satisfaction or acceptance, and externalized weight bias