



**Pharmacotherapy and
Intensive Health Behavior and Lifestyle Treatment:
*Creating Expert Recommendations for Research and Practice***

***NOPREN Pediatric Obesity Health Services Research
Work Group Meeting
May 29, 2024***

Today's Agenda



- Work group updates
- Subgroup updates - Primary Care Survey, Tertiary Care Survey
- AAP Clinical Practice Guidelines for IHBLT and pharmacotherapy
- Group Discussion

**Today's Goal: To begin creating expert recommendations
on co-therapy in research and practice**

Product Resulting from April WG Meeting

Pediatric Obesity Treatment Interest Groups

The NOPREN Pediatric Obesity Health Services Research Work Group provides the following list and descriptions of pediatric obesity interest groups and how to get involved in each.
Updated May 2024

Nutrition, Obesity, Policy, Research and Evaluation Network (NOPREN) Pediatric Obesity Health Services Research Network Work Group

NOPREN Pediatric Obesity Health Services Research Work Group Aims to:

- Advance the study and implementation of pediatric obesity treatment and research methodologies.
- Advance the equitable prevention and treatment of childhood obesity and co-occurring conditions in the United States.
- Build a network of interdisciplinary members to synergize efforts, identify and answer gaps, and advance implementation of evidence-based practices and policies for pediatric obesity prevention and treatment.

Co-Chairs: Amanda Staiano, PhD; Sam Pierce, MPH; Aly Goodman, MD

Fellow: Alyssa Button, PhD

Contact us to join:

Dr. Alyssa Button;
alyssa.button@pbrc.edu



[Pediatric Obesity Health Services Research Work Group](https://www.pbrc.org/Pediatric-Obesity-Health-Services-Research-Work-Group)

Meeting Frequency

- Workgroup: Virtually for 1-hour every 1-2 months
- Subcommittees set their own frequency
- Networking/social gatherings at annual conferences

Childhood Obesity Multi-Program Analysis and Study System (COMPASS)

About COMPASS:

- COMPASS is a practice-based national research network with a focus on better understanding the etiology of childhood obesity and improving its treatment through translational research.
- Research projects are member driven with recent study topics ranging from patient risk factors, to assessments of novel treatment approaches.

Co-Chairs: Jared Tucker, PhD; Bob Siegel, MD

Contact us to join:



Dr. Jared Tucker;
jared.tucker@helendevoschildrens.org

Meeting Frequency:

- COMPASS meets virtually every month
- Research subcommittees set their own meeting frequency
- Network/social dinner (combined with POWER) at PAS and TOS meetings

National Collaborative on Childhood Obesity Research (NCCOR)

NCCOR's Goals:

- Support researchers and practitioners with tools that help build the capacity for research and surveillance.
- Maximize outcomes from research and supporting evaluations.
- Use innovation to stimulate broad thinking to generate fresh, synergistic ideas.
- Increase knowledge to find solutions by promoting new

Contact us to join:



nccor@thi360.org

American Academy of Pediatrics Section on Obesity (AAP SOOB)

About AAP SOOB:

- Provides members with resources needed to deliver obesity prevention, assessment, and treatment.
- Creates a community of pediatricians who learn from each other and receive support from the Section.
- Authors policy statements, technical reports, and clinical reports.
- Finds opportunities to comment and advocate for legislation and policies proposed that influence child health.
- Improves the health and well-being of children and families by reducing the prevalence of childhood obesity and promoting healthy active living.



Visit to join:

[Contact SOOB \(aap.org\)](https://www.aap.org/soob)

Pediatric Obesity Weight Evaluation Registry (POWER)

About POWER:

- POWER is a centralized data repository for the on-going collection and maintenance of demographic and clinical data from hospital-based pediatric weight management programs (WMPs) across the country.

POWER's Mission is

- To better understand and improve the health outcomes of children and adolescents with overweight and obesity who are participating in multi-component weight management programs.

Contact us to join:



Dr. Shelley Kirk;
shelley.kirk@cchmc.org



[Join/Contact I POWER \(powerregistry.org\)](https://www.powerregistry.org)

The Obesity Society's (TOS) Pediatric Obesity Task Force

About TOS Task Force:

- Provides innovative thought leadership.
- Catalyzes initiatives aimed at increasing the quality and scope of pediatric obesity treatment in the United States and beyond.
- Facilitates meaningful collaborative partnerships formed with related TOS committees and with key external societies and organizations to advance the mission of the task force.

Contact us to join:



Dr. Aaron Kelly;
kelly105@umn.edu



Dr. Anja Jastreboff;
anja.jastreboff@yale.edu

Society of Pediatric Psychology Obesity Special Interest Group:

Contact: Eileen A. Chaves, PhD;
eileen.chaves@nationwidechildrens.org

Academic Pediatric Association Obesity Special Interest Group:

Contacts: Steve Cook, MD, MPH;
Stephen_Cook@URMC.Rochester.edu;
Christine SanGiovanni MD, MSCR: sangiova@musc.edu;
Amy Beck MD, MPH: amy.beck@ucsf.edu

National Association of Pediatric Nurse Practitioners:

Contact: Laura Roettiger, PhD, APRN, CPNP-PC;
lea82@yahoo.com

Institute for Healthy Childhood Weight:

Contact: Jeanne Lindros, MPH; jlindros@aap.org

Obesity Action Coalition:

Home Page - Obesity Action Coalition
www.obesityaction.org

Intensive Health Behavior and Lifestyle Treatment KAS

KAS 11. Pediatricians and other PHCPs should provide or refer children 6 y and older (Grade B) and may provide or refer children 2 through 5 y of age (Grade C) with overweight (BMI \geq 85th percentile to $<$ 95th percentile) and obesity (BMI \geq 95th percentile) to intensive health behavior and lifestyle treatment. Health behavior and lifestyle treatment is more effective with greater contact hours; the most effective treatment includes 26 or more hours of face-to-face, family-based, multicomponent treatment over a 3- to 12-mo period

More about IHBLT



WHEN

- Upon diagnosis



WHAT

- Health education
- Skill building
- Behavior modification & counseling



FORMAT

- Group
- Individual, or
- Both



WHO:

- Patient & family
- Multidisciplinary treatment team



WHERE

- Healthcare setting
- Community –based setting with linkage to medical home



DOSAGE

- Longitudinal (3-12 months long)
- At least 26 contact hours



CHANNEL

- Face-to-face or
- Virtual

When IHBLT is not available

Deliver the best available intensive treatment to all children with overweight and obesity.

Build collaborations with other specialists and programs in their communities.

Expert Consensus: Behavioral Strategies



Reduction of sugar-sweetened beverages



60-minute of daily physical activity



Balance meals and portion sizes
MyPlate



Reduction of Screen time



Appropriate sleep



Stoplight diet



Exergaming & screen-based physical activity

Pharmacotherapy

KAS 12. Pediatricians and other PHCPs should offer adolescents 12 y and older with obesity (BMI \geq 95th percentile) wt loss pharmacotherapy, according to medication indications, risks, and benefits, as an adjunct to health behavior and lifestyle treatment.

Pharmacotherapy

Consensus Recommendation: PHCPs may offer children ages 8 through 11 y of age with obesity wt loss pharmacotherapy, according to medication indications, risks, and benefits, as an adjunct to health behavior and lifestyle treatment.

Pharmacotherapy

"No current evidence supports weight loss medication use as a monotherapy; thus, pediatricians and other PHCPs who prescribe weight loss medication to children should provide or refer to intensive behavioral interventions for patients and families as an adjunct to medication therapy."

CPG

Limitations of Each Approach



Limitations of IHBLT	Limitations of Pharmacotherapy
Often insufficient alone for achieving and maintaining clinically significant BMI reduction	Often insufficient alone to alter psychosocial or other non-biological outcomes of importance to families
Does not directly address biological and physiological aspects of obesity (e.g. appetite, enhanced palatability, reduced satiety, energy dysregulation)	Does not directly address influences external to biology/physiology (e.g. health behaviors, skills, emotional eating, disordered eating, parenting practices, environment, etc)
Practicality and feasibility (e.g. 26 contact hours)	Potentially life-long treatment; do not know long-term effects

Gaps in Scientific Evidence



- In pharmacotherapy research studies, lifestyle interventions are often poorly described, with variation in components across sites, participants, and studies
 - Lack of standard guidance for “lifestyle treatment” across and within trials
 - Limited resources and staffing in research & clinical practice
 - Many pharmacological trials resort to **handouts only / self-directed**
- Lack of studies that capture/monitor non-weight outcomes
 - E.g. health behaviors, household/environmental changes, parenting practice changes, coping with bullying/teasing, changing eating patterns, changing emotional eating, psychosocial health, etc.
 - Evidence that addition of lifestyle does not outperform AOM effectiveness on BMI, but does show improvements in metabolic risk factors (e.g., Clarson et al., 2009; Casteels et al., 2010; Kelly et al., 2022)

Practicality: Payers and Coverage



- Payers don't know what to cover, leaving their language vague, which can allow for "complications" for coverage.
- Language examples:
 - "Our weight management program offers one on one time with a coach to help you reach your goals. This is available to any Medicaid enrollee 12 years or older."
 - "Services: Obesity in Children and Adolescents. The **USPSTF** recommends that clinicians screen for obesity in children and adolescents 6 years and older **and offer or refer them** to comprehensive, **intensive behavioral interventions** to promote improvements in weight status."

Evaluating the Evidence in the AAP CPG



- Pennington Biomedical Research Center team reviewed the studies included in the pharmacotherapy section of the CPG
- Compared the description of the dietary/behavior/lifestyle counseling to the AAP CPG guidelines for IHBLT
- Identified areas of vagueness in the description

Rubric for Categorizing Descriptions

Components
Included

1-3: Vague

4-6: Somewhat
descriptive

7-8: Adequately
descriptive

Frequency/duration	<ul style="list-style-type: none"> Clearly defines how many visits Average or target duration of each session Frequency of visits across the intervention and at what time points
Nutritional component	<ul style="list-style-type: none"> Provides objective goals of dietary counseling (e.g., 250-500 cal deficit, Traffic Light Diet, increase F/V, decrease SSB) Evidence-based dietary intervention used Describes nutritional counseling content
Behavioral component	<ul style="list-style-type: none"> Describes psychosocial components of intervention Goal setting
Physical activity component	<ul style="list-style-type: none"> Provides guidance on PA goals Describes PA content
Participants	<ul style="list-style-type: none"> Describes who attends/is invited to sessions (e.g., parents, group setting, family-based)
Content	<ul style="list-style-type: none"> Additional content (e.g., theoretical approach) described
Interventionist	<ul style="list-style-type: none"> Role described (e.g., research team, embedded within clinic) Training background (e.g., degree, research protocol, etc.)
Format	<ul style="list-style-type: none"> Describes delivery modality (e.g., in-person, telehealth)

Evidence Cited in the AAP CPG

- TODAY Study Group. (2012). A clinical trial to maintain glycemic control in youth with Type 2 Diabetes. *New England Journal of Medicine*.
 - Lifestyle treatment description: [nejmoa1109333_appendix.pdf](#) (Appendix B)
 - **Energy balance behaviors** (dietary [TLP] & physical activity) and **family involvement/support** through self-monitoring, goal setting, reinforcement, stimulus control, problem solving, motivational techniques
 - Delivered by trained interventionists with psychologist supervision
 - Three phases: Lifestyle Change (6-9 mos, 60-90 mins weekly in-person), Lifestyle Maintenance (6-8 mos, 60 mins biweekly in-person), continued Contact (through y2, 45-60 mins in-person)
 - This study *meets criteria* for IHBLT



Vague

Somewhat Descriptive

Adequately Descriptive

Evidence Cited in the AAP CPG

- Kelly, A.S. et al., (2020). A randomized, controlled trial of liraglutide for adolescents with obesity. *New England Journal of Medicine*
 - In-person “series of” visits during the first 2 years, continued contact at quarterly medical visits
 - Individualized counseling in healthy nutrition by a certified dietician
 - Individualized counseling in physical activity by site staff trained in physical activity counseling
 - Encouraged to engage in 60 minutes of moderate- to high-intensity physical activity daily
 - “Limited power to detect significant differences with regard to secondary outcomes of cardiometabolic markers and results on quality-of-life assessments”
 - This study *meets criteria* for IHBLT



Vague

Somewhat Descriptive

Adequately Descriptive

Evidence Cited in the AAP CPG



- Kelly, A.S., et al., (2022). Phentermine/topiramate for the treatment of adolescent obesity. *New England Journal of Medicine Evidence*
 - Family-based lifestyle modification program for adolescents, as tolerated
 - Diet modification of 500-kilocalorie/day deficit, physical activity, behavior change, and family support.
 - Routine study visits by a study coordinator or dietician (5-15 mins lifestyle training)
 - This study **meets IHBLT criteria**, but **not recommended contact hours** based on AAP guidelines



Vague

Somewhat Descriptive

Adequately Descriptive

Evidence Cited in the AAP CPG

- Clarson, C.L., et al. (2009). Metformin in combination with structured lifestyle intervention improved body mass index in obese adolescents, but did not improve insulin resistance. *Endocrine*
 - "Lifestyle intervention, with or without metformin, improved metabolic risk factors..."
 - "Structured 6-month individualized lifestyle intervention..."
 - Individualized goals
 - Commitment of a parent "coach"
 - Regular contact with multidisciplinary team (weekly telephone calls, monthly clinic visits, family education sessions)
 - *This study **may** meet IHBLT criteria, not enough information is provided*



Vague

Somewhat Descriptive

Adequately Descriptive

Evidence Cited in the AAP CPG

- Wilson, D.M., et al. (2010). Metformin extended release treatment of adolescent obesity: a 48-week randomized, double-blind, placebo-controlled trial with 48-week follow-up. *Archives of Pediatrics & Adolescent Medicine*.
 - Weigh of Life LITE program developed at Texas Children's Hospital, Houston used across all sites
 - Unable to locate article for this program for description
 - 10 individualized "intensive" sessions at weekly intervals, following a specific curriculum
 - Monthly follow-up sessions for the remainder of the study
 - A trained health specialist led the sessions and parents/guardians were invited to attend
 - This study *may meet* IHBLT criteria, not enough information is provided



Evidence Cited in the AAP CPG



- Casteels, K., et al. (2010). Metformin therapy to reduce weight gain and visceral adiposity in children and adolescents with neurogenic or myogenic motor deficit. *Pediatric Diabetes*
 - Lifestyle intervention = “standard advice on a healthy diet and - if possible - exercise was given to all patients”
 - This **does not** meet criteria for IHBLT



Vague

Somewhat Descriptive

Adequately Descriptive

Evidence Cited in the AAP CPG

- Yanovski, J.A., et al. (2011). Effects of metformin on body weight and body composition in obese insulin-resistant children: a randomized clinical trial. *Obesity Studies*
 - Monthly meetings with a dietitian who administered a weight-reduction lifestyle modification program
 - Individualized prescriptions for a “traffic light” style (42) 500 kcal/day–deficit diet that reduced fat and energy intake
 - Exercise prescription encouraging 30 min of aerobic exercise every day and inclusion of lifestyle exercise, monitored by pedometer
 - Self-monitoring of medication, intake, activity, inactive time, and pedometer readings logged and reviewed monthly
 - “...because the weight loss intervention was intended to model to some extent what might be available in clinical practice, it consisted solely of monthly visits with a dietitian, and the magnitude of metformin-associated weight reduction that might occur among children treated with an intensified behavioral modification regimen is not established.”
 - This study **does not** meet criteria for IHBLT



Vague

Somewhat Descriptive

Adequately Descriptive

Evidence Cited in the AAP CPG



- Rynders, C., et al. (2012). Lifestyle intervention improves fitness independent of metformin in obese adolescents. *Medicine & Science in Sports & Exercise*
 - Dietary counseling weekly for first 4 weeks, monthly until 3 months, and then again at 6 months
 - Recommended caloric deficit of ~250-500/day
 - Daily food records
 - Free membership to local YMCA, for use at least 3/week for 30 minutes/session
 - Structured exercise sessions including aerobic and strength training
 - “Exercise consisted of 5–10 min for warm-up and stretching, followed by 15–30 min of cardiovascular exercise (i.e., treadmill, bicycle ergometer, rower, NuStep (NuStep Inc., Ann Arbor, MI), etc.), 10–20 min of strength training (supervised using weight stack equipment), and 5–10 min of cooldown and stretching. Participants were started at 15 min of cardiovascular exercise and 10 min of strength training exercise and encouraged to progress by 2–3 min every week until 30 and 20 min, respectively, was achieved.”
 - “Metformin did not provide benefits above lifestyle modification for improving cardiorespiratory fitness in obese adolescents... associated with more favorable metabolic outcomes”
 - *This study does not meet criteria for IHBLT*



Vague

Somewhat Descriptive

Adequately Descriptive

Evidence Cited in the AAP CPG



- Pu, R., et al. (2020). Effects of metformin in obesity treatment in different populations: a meta-analysis. *Therapeutic Advances in Endocrinology and Metabolism*
 - Out of 21 studies, lifestyle Tx was the control in 9, in 11 participants in the metformin and control groups received lifestyle Tx, and lifestyle Tx outcomes was not mentioned in 8 studies
 - Different degrees of lifestyle intervention and variance in standards
 - *The studies in this review do not meet criteria for IHBLT*



Summary of Evidence Cited in the AAP CPG



Does Not Meet IHBLT Criteria	May Meet IHBLT Criteria	Meets IHBLT Criteria
Casteels 2010 (metformin)	Clarson 2009 (metformin)	Kelly 2020 (liraglutide)
Pu 2020 (systematic review/metformin)	Wilson 2010 (metformin)	TODAY Study Group 2012 (metformin)
Kelly 2022 (phentermine/topiramate)		
Rynders 2012 (metformin)		
Yanovski 2011 (metformin)		

Discussion



- Are there core components of nutrition/lifestyle/behavioral counseling for AOM research trials? For clinical practice?
 - What can be added/modified, or what would be considered minor components (finding balance between fidelity and adaptation)
- Guidance for **researchers** on implementing and reporting lifestyle/behavioral treatment in conjunction with AOMs
 - Exemplars?
 - Recommendations?
 - Feasibility/utility of a checklist for describing lifestyle/behavioral treatment
 - What outcomes can be addressed through lifestyle intervention in conjunction with AOMs that are not measured and reported currently?
- Guidance for **clinicians** on implementing behavioral treatment in conjunction with AOMs
 - Safety considerations
 - IHBLT as a strategy for healthy and sustained weight loss

What You Can Do: **Balance Fidelity and Adaptations**

Making too many changes to an intervention can reduce its original effectiveness, or worse, introduce unintended and harmful outcomes.

Before making adaptations to the intervention, you should think about how the change to the original intervention can improve the fit to your community, setting, or target population, and at the same time, maintain fidelity to the core components of the original intervention. Think of possible adaptations as you would a green, yellow, or red traffic light: green light changes are usually OK to make; yellow light changes should be approached with caution; and red light changes should be avoided when possible.¹²

GREEN LIGHT CHANGES

- » Usually minor
- » Made to increase the reach, receptivity, and participation of the community
- » May include:
 - Program names
 - Updated and relevant statistics or health information
 - Tailored language, pictures, cultural indicators, scenarios, and other content

YELLOW LIGHT CHANGES

- » Typically add or modify intervention components and contents, rather than deleting them
- » May include:
 - Substituting activities
 - Adding activities
 - Changing session sequence
 - Shifting or expanding the primary audience
 - Changing the delivery format
 - Changing who delivers the program

RED LIGHT CHANGES

- » Changes to core components of the intervention
- » May include:
 - Changing a health behavior model or theory
 - Changing a health topic or behavior
 - Deleting core components
 - Cutting the program timeline
 - Cutting the program dosage

Next Up



- Subgroups to meet later this summer
- Email Alyssa.button@pbrc.edu to join the expert recommendations writing group on co-therapy
 - Be on the lookout for surveys
- Submit your ideas for future speakers/topics and project ideas to alyssa.button@pbrc.edu