TBM

Overview of the obesity intervention taxonomy and pooled analysis working group

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Abstract

The National Heart, Lung, and Blood Institute and the National Institutes of Health Office of Disease Prevention convened a meeting on August 29-30, 2013 entitled "Obesity Intervention Taxonomy and Pooled Analysis." The overarching goals of the meeting were to understand how to decompose interventions targeting behavior change, and in particular, those that focus on obesity and to combine data from groups of related intervention studies to supplement what can be learned from the individual studies. This paper summarizes the workshop recommendations and provides an overview of the two other papers that originated from the workshop and that address decomposition of behavioral change interventions and pooling of data across diverse studies within a consortium.

Keywords

Intervention science, Taxonomy, Pooled analysis

Implications

Researchers: Use the behavioral change techniques (taxonomy approach) that decompose each intervention component and determine intervention dose when combining information from studies that employ similar interventions.

Practitioners: Use information from multiple studies rather than individual studies to provide better information regarding behavior change.

Policymakers: Take advantage of information that comes from several studies for data-driven policy decisions.

INTRODUCTION

The National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) have each funded consortia of intervention studies. These consortia include multiple studies, each testing distinct interventions but having a common topic or goal. Examples in the arena of obesity research include the Practice-Based Opportunities for WEight Reduction (POWER) Trials [1], the Early Adult Reduction of weight through LifestYle intervention (EARLY) Trials [2], the Childhood Obesity Prevention and Treatment Research (COPTR) consortium [3], the Lifestyle Interventions for Expectant Moms (LIFE-Moms), the Obesity Related Behavioral Intervention Trials (ORBIT) [4], and the Childhood Obesity Research Demonstration (CORD) projects [5]. Previously funded multiple study consortia targeted smoking and other behaviors [6, 7] or caregiver burden [8]. These studies are typically funded via the Cooperative Agreement mechanism and include as a goal performing cross-study analyses in an effort to learn more about intervention effects than is possible from individual studies. For example, combining information across studies would increase sample sizes such

that it may be possible to gain information on subgroups that are too small in individual studies to obtain meaningful results or to examine effects on less common outcomes than are scientifically justified within individual studies due to limited numbers of outcomes. However, inasmuch as these consortia are constructed such that interventions, target populations, and methods differ by site within a consortium, the use of typical methods for combining information across studies (see, for example, Bangdiwala et al. in this issue) needs to be critically examined or, potentially, other methods need to be applied. With these methods, attention needs to be paid to homogeneity among the studies to be combined with respect to, e.g., eligibility criteria, data collection, and the particular interventions tested within each study. For the EARLY Trials [2], COPTR [3], CORD [9, 10], LIFE-Moms, POWER [1], and REACH [8], substantial effort was put into agreeing upon several protocol issues including common eligibility criteria, measures, and data collection timepoints prior to intervention start with the goal to enhance homogeneity to facilitate cross-study analyses.

Furthermore, by combining information across studies, it may be possible to understand what specific components of a wide variety of complex behavioral interventions lead to favorable outcomes, with the goal to optimize such interventions. One approach

has been demonstrated in the past [11, 12], and the manuscript by Tate et al. in this issue describes an alternative approach to decomposing interventions in an effort to ascertain whether particular aspects of multi-component interventions that are associated with outcome can be identified. Unlike those methods for which interventions should be similar for combining to be meaningful, this method accounts for heterogeneity such that both "active" and "control" interventions are decomposed.

The context for this meeting, then, was the existence of NIH- and CDC-funded consortia comprised of several intervention studies with some common features but with different interventions, populations, and hypotheses under investigation. The meeting, which included investigators from EARLY, COPTR, ORBIT, LIFE-Moms, and CORD, addressed several research questions including the following:

1. Can a taxonomy be developed across diverse interventions to facilitate analysis of common measures and enable better understanding of how complex multi-component intervention content relates to effectiveness?
2. What analytical approaches can be used and how can data be combined across different interventions, populations, and settings?
3. Can data be compared for obesity prevention and treatment studies?
4. What are the best methods for testing differences in subgroup responses to interventions?

The consortia represented at the meeting, briefly described below, are comprised of intervention studies with some commonalities, for example, a common theme is that all are complex, behavioral interventions targeting weight (see Tables 1, 2, 3, 4, and 5).

Early Adult Reduction of weight through LifestYle intervention (EARLY) Trials

This program consists of seven studies that have 17 interventions across the studies, and a Research Coordinating Unit (RCU). The studies are individually funded within a cooperative agreement which includes the NIH. All of the studies are two-phase clinical research studies to refine and test innovative behavioral approaches for weight control in young adults 18–35 years of age at high risk for weight gain. There is also a Resource Coordination Unit to facilitate cross-study activities including logistical and analytical activities. During the first phase of the studies, formative research was conducted to refine the proposed intervention, recruitment, retention, and adherence strategies targeted to young adults. The second phase of each study consisted of a randomized controlled trial to test the efficacy of the interventions. These interventions address weight loss, prevention of weight gain, or prevention of excessive weight gain during pregnancy. Specific target populations include pregnant and postpartum women, community college or university students, and young adults trying to quit smoking. Most of the interventions are technology-driven using novel methods such as mobile phones, social networks, and web-based curricula. EARLY studies are funded by the National Heart, Lung and Blood Institute (NHLBI) and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD).

Childhood Obesity Prevention and Treatment Research Consortium

The purpose of this program is to create and test intervention approaches to prevent excess weight gain in non-overweight and overweight youth and to reduce weight in obese youth. Two obesity prevention trials (University of Minnesota and Vanderbilt University), which target preschoolers (2–5 year olds), are developing and testing approaches that target home, community, and primary care settings for preschool children living in low-income and ethnically diverse neighborhoods. Two obesity treatment trials (Stanford University and Case Western Reserve), which target pre-adolescents or adolescents, are examining novel intervention modalities in overweight and obese children 7–15 years old in school and home settings in collaboration with local youth organizations or schools. A Coordinating Center at the University of North Carolina, Chapel Hill, coordinates the functions of the Consortium. The primary outcome is children's body mass index (BMI); secondary outcomes include waist circumference, body fat, diet, physical activity, psychosocial measures, and cost-effectiveness. COPTR studies are funded by the NHLBI, NICHD, and the NIH Office of Behavioral and Social Sciences Research (OBSSR)

Lifestyle Interventions for Expectant Moms

The LIFE-Moms Consortium is targeting appropriate gestational weight gain among overweight and obese women and is a collaboration of seven independent clinical trials, a Research Coordinating Unit, and the NIH. Each trial is testing a lifestyle intervention designed to control gestational weight gain in overweight or obese women. The primary outcome for the LIFE-Moms Consortium is gestational weight gain above the 2009 Institute of Medicine's guidelines for overweight and obese pregnant women. Secondary outcomes include maternal and neonatal infant anthropometric measures, physical activity, sleep, and complications of pregnancy and delivery. In each trial, weight and metabolic outcomes are being assessed in both mothers and offspring for a minimum of 12 months postpartum. LIFE-Moms is funded by several NIH Institutes and Centers, including the National Institute of Diabetes and Digestive and Kidney

Table 1 | Description of Early Adult Reduction of weight through LifestYle intervention (EARLY) studies

	CHOICES	CITY	e-Moms Roc	IDEA	SMART	SNAP	TARGIT
Institutions, PIs Grant #s	University of Minnesota, L. Lytle	Duke University, L. Svetkey	Cornell University, C. Olson; University of Rochester, I.D. Fernandez	University of Pittsburgh, J. Jakicic S. Belle (RCU)	University of California San Diego, K. Patrick	Brown University, R. Wing University of North Carolina, D. Tate	University of Tennessee, K. Johnson
	U01 HL096767	U01 HL096720	U01 HL 096760	U01 HL 096770	U01 HL 096715	U01 HL 090864	U01 HL096628
Primary outcome (2 years post randomization)	Weight gain prevention BMI change	Weight loss Weight change	Unhealthy gestational weight gain Unhealthy postpartum weight retention	Weight loss Weight change	Weight loss Weight change	Weight gain prevention Weight change (at 3 years, but at 2 years for cross-study analyses)	Weight gain prevention during smoking cessation Weight change
Major inclusion criteria	BMI 20–<35 kg/m^2 Age 18–35 yrs	BMI 25–<40 kg/m^2 Age 18–35 yrs	BMI 18–<35 kg/m^2 Age 18–35 yrs	BMI 25–<40 kg/m^2 Age 18–35 yrs	BMI 25–<40 kg/m^2 Age 18–35 yrs	BMI 21–30 kg/m^2 Age 18–35 yrs	BMI 20–<40 kg/m^2 Age 18–35 yrs
Target Population Description Sample size	Community (2 year) college students 441 (2 arms)	Overweight/obese young adults 365 (3 arms)	Pregnant women 1680 (3 arms)	Overweight/obese young adults 478 (2 arms)	Overweight/obese 4 year college students 404 (2 arms)	Young adults 600 (3 arms)	Young adult smokers 330 (2 arms)
Recruitment Site(s)	2 year colleges: Minneapolis-St. Paul MN	College campuses, community health centers, community: Central NC	Clinics, private practices that deliver in one of 4 hospitals: Rochester, NY	Community: Pittsburgh, PA	College campuses: San Diego County, CA	Community: Providence, RI and Raleigh-Durham-Chapel Hill, NC	Community: Memphis, TN

Interventions: Brief Descriptions	Students are randomized to intervention or control. Intervention begins with a 1-credit college course focused on behaviors important in weight control. A web-based social network site designed for this research and focusing on weight and behavioral tracking and goal setting is introduced during the class and continues for 24 months. The control group receives standard public health information on maintaining a healthy weight.	Participants are randomized to one of three conditions: 1) cell phone based intervention; 2) personal coaching plus cell phones for self monitoring; and 3) control group. The cell phone technology includes self-monitoring weight, diet and physical activity. The coaching condition includes both group and personalized coaching. The control group receives usual care.	Pregnant women are randomized to one of three conditions: 1) standard behavioral weight control program (SBWP) and 2) an enhanced weight loss intervention (EWLI). Both groups receive a previously tested behavioral weight loss treatment involving face to face meetings and supportive phone calls. Participants randomized to the SBWP also receive text messages and access to a website to track behaviors. Participants in the EWLI receive text messages, access to the website and a wearable monitor to assess energy expenditure and activity.	Students are randomized to one of two conditions: intervention and control. Intervention students receive theory-based content on physical activity, diet, calories and weight management strategies through text messaging, emails, Facebook, websites, and apps. Control students receive access to a study website with general health information.	Participants are randomized to one of three conditions: 1) large change intervention; 2) small change intervention; and 3) control. The goal of Large Changes is to lose 5–10 pounds to buffer against the weight gain that often occurs during young adulthood. Small Changes focusses on daily small changes in diet and activity to reduce the chance of weight gain. Both interventions begin with 10 face to face groups followed by a web, and mobile intervention through 3 years. Participants submit weight and receive feedback via web, sms and email. Refresher campaigns are delivered online. The control group receives usual care.	Participants are randomized to either intervention or control. Those randomized to the intervention receive access to a tobacco quit line plus a behaviorally focused weight gain prevention program using interactive technologies that include phone calls, iPod touch with smoking cessation apps and behavioral tracking, webinars and a study website. The control condition receives access to the tobacco quit line.

Table 2 | Description of Childhood Obesity Prevention and Treatment Research (COPTR) studies

	NET-Works	GROW	IMPACT	GOALS
Institutions, PIs Grant #s	University of Minnesota, S. French HealthPartners Institute for Education & Research, N. Sherwood U01 HL 068890	Vanderbilt University, S. Barkin U01 HL 103620	Case Western Reserve University, E. Borawski, L. Cutler, S. Moore U01 HL 103622	Stanford University, T. Robinson U01 HL 103629
Primary outcome	BMI	BMI	BMI slope	BMI slope
Major inclusion criteria	BMI ≥50th percentile 2–4 years old No serious medical problems Speaks English or Spanish Family income <$65,000/year No plans to move within the next 36 months	50th percentile ≤BMI <95th percentile 3–5 years old No serious medical problems Speaks English or Spanish Live in predefined zip codes No plans to move within the next 36 months	BMI ≥85th percentile Rising 6th graders (10–11 years old) No serious medical problems Speaks English or Spanish No plans to move within the next 36 months	BMI ≥85th percentile 7–11 years old No medical problems or medications affecting growth No medical, developmental, or social conditions limiting participation in interventions or assessments Speaks and reads English or Spanish Live in predefined low income neighborhoods No plans to move from SF Bay Area within the next 36 months.
Target population Description Sample size	Child–parent dyads 250/arm	Child–parent dyads 300/arm	Child–parent dyads 120/arm	Children and at least one parent/guardian per family 120/arm
Recruitment site(s)	12 primary care clinics across three health care systems in Minneapolis and St. Paul, MN	Community sites (e.g., daycares, physicians' offices, pre K programs, churches, community service programs) in East Nashville and South Nashville, TN	Public and charter schools in Cleveland, Ohio	Primary care providers and clinics, schools, community centers, churches, and other community locations in low income, primarily Latino neighborhoods near Stanford University (Palo Alto, CA)
Interventions: brief descriptions	Intervention aimed at parents via family connector home visits, community parenting classes, neighborhood and community resource connections and pediatric primary care to improve and reinforce healthy diet and activity patterns.	Intervention aimed at parents and children in classes at community centers. It includes social media and phone coaching to improve dietary patterns, and use of the built environment to enhance physical activity of parent and child.	Intervention aimed at youth and parents in small group sessions and at youth in school based activities through a series of goal setting, skills building, changes in the family environment and daily routines to improve diet and physical activity patterns.	Intervention aimed at children and parents in a home based intervention to reduce screen time, increase physical activity, and alter dietary practices; community-based after school team sports for children, and primary care counseling.

Table 3 | Description of Lifestyle Interventions for Expectant Moms (LIFE-Moms) studies

	Healthy Beginnings	LIFT	PEARLS	MOMFIT	PREGO	Expecting Success	LIFE-Moms Phoenix
Institutions, PIs Grant #s	California Polytechnic Institute State University and Brown University Suzanne Phelan Rena Wing U01 HL114377	St. Luke's–Roosevelt Xavier Pi-Sunyer Dympna Gallagher U01 DK094463	University of Puerto Rico Kaumudi Joshipura Paul Franks U01 HL072834	Northwestern University Linda Van Horn Alan Peaceman U01 HL114344	Washington University in St. Louis Sam Klein Debra Haire-Joshu Kelle Moley U01 DK094416	Pennington Biomedical Research Center Leanne Redman Corby Martin U01 DK094418	Phoenix Indian Medical Center William Knowler HSSN276201300001C
Primary outcome (2 years post randomization)	Weight gain per week within IOM guidelines	Newborn percent body fat	Weight gain per week within IOM guidelines	Weight gain	Weight gain not exceeding IOM guidelines	Weight gain per week exceeding IOM guidelines	Weight gain
Major inclusion criteria	≥18 years Singleton, viable pregnancy BMI ≥25 kg/m² Gestational age 9 weeks 0 days to 15 weeks 6 days	18–40 years Singleton, viable pregnancy 25 kg/m² ≤ BMI ≤35 kg/m² Gestational age 9 weeks 0 days to 15 weeks 6 days	≥18 years Singleton, viable pregnancy BMI ≥25 kg/m² Gestational age 9 weeks 0 days to 15 weeks 6 days	18–45 years Singleton, viable pregnancy 25 kg/m² ≤ BMI <40 kg/m² Gestational age 9 weeks 0 days to 15 weeks 6 days	18–45 years Singleton, viable pregnancy 25 kg/m² ≤ BMI ≤45 kg/m² Gestational age 9 weeks 0 days to 15 weeks 6 days African-American Socioeconomically disadvantaged	18–40 years Singleton, viable pregnancy 25 kg/m² ≤ BMI <40 kg/m² Gestational age 9 weeks 0 days to 13 weeks 5 days	≥18 years Singleton, viable pregnancy BMI ≥25 kg/m² Gestational age 9 weeks 0 days to 15 weeks 6 days
Sample size	175/arm	105/arm	200/arm	150/arm	133/arm	102/arm	100/arm
Recruitment Site(s)	Various OB practices servicing major delivery hospitals in San Luis Obispo and Women and Infants Hospital	Various OB practices and clinics whose patients deliver at St Luke's Roosevelt	University of Puerto Rico Hospital	Prentice Ambulatory Care and other practices whose patients deliver at Prentice Women's Hospital	Women's Health Clinic at Washington University	Various OB practices and clinics whose patients deliver at Women's Hospital Baton Rouge	Women's Clinic at PIMC
Interventions: Brief descriptions	Antepartum Individual counseling sessions; meal replacement product provided; weight graphing with	Antepartum Individual counseling sessions with specific curriculum for diet modification and physical activity, with	Antepartum Individual and group counseling session, phone calls regarding improving diet and promoting regular	Antepartum Group sessions, phone coaching and electronic contact focusing on DASH (Dietary	Antepartum Home visits using the Parents as Teachers Model (PAT), incorporating an integrated diet and exercise lifestyle	Antepartum Group and individual sessions at the clinic with curriculum	Antepartum Group or individual sessions focusing on individualized managed weight gain goals through caloric

feedback; weekly educational/ behavior change materials. Guidance on ways to maintain success postpartum.

behavioral support strategies and social support. additional phone/e-mail contacts for support. Group sessions as needed.

Approaches to Stop Hypertension) and moderate physical activity. Ongoing and electronic contact and feedback from lifestyle coach.

program, focusing on control of weight gain reflecting the philosophy of PAT (family strength, child development, parental modeling, parent–child interaction).

movement and minimizing sedentary behavior; certain food products provided, e.g., brown rice; cooking demo and exercise during group sessions.

Postpartum
Up to 1 year group classes to aid in weight loss, adjust to parenthood, support lactation Individual support as needed

Postpartum
Up to 1 year Group sessions focusing on breastfeeding, physical activity, quality of the diet for the infant, and feeding practices; monthly calls

Postpartum
Up to 1 year 1 group and 2 individual sessions, focusing on weight loss, DASH diet in context of breastfeeding, infant feeding including transition to "Baby DASH"-type diet. Materials e-mailed

Postpartum
Up to 18 months Home visits focusing on goal of returning to pre-pregnancy weight, focusing on issues of relevance and problem-solving Also focus on positive child-feeding behaviors and interactive parent–child activities.

focused on diet and exercise and behavioral principles to foster adherence to the IOM Same lessons delivered by Smartphone; 1st and last sessions in person. Smartphone transmits data which generates feedback to participants.

and fat gram recommendations, daily physical activity such as walking, reducing use of automation and reducing time spent in sedentary behaviors.

Table 4 | Description of Obesity Related Behavioral Intervention Trials (ORBIT)

	SCALE	MAMAS	Snooze to Lose	Claremont	SUNY-Buffalo	WISHFIT	FIT Families
Institutions, PIs Grant #s	Weill Medical College of Cornell University Mary Charlson U01 HL097843	University of California, San Francisco Elissa Epel Barbara Laraia Nancy Adler U01 HL097973	Brown University/ Miriam Hospital, Providence, RI Rena Wing U 0 1 CA150387	Claremont Graduate University Kim Reynolds U01 HL097839	State University of New York at Buffalo Leonard Epstein U01 DK088380	Rush University Medical Center, Chicago Lynda H. Powell U01 HL097894	Wayne State University, Detroit Sylvie Naar-King K.-L. Catherine Jen U01 HL097889
Primary outcome (2 post randomization)	Weight change	Gestational weight gain within IOM guidelines	Weight, eating behavior, physical activity, cognitive performance	Daily servings of high fat snacks, high sugar snacks, and sweetened beverages	Child weight and BMI Parent weight and BMI	Visceral fat (measuring weight weekly as surrogate)	Weight, BMI
Major inclusion criteria							
Gender		Women				Women	
Race/Ethnicity	Black or Latino					Black or White	Black
Weight	Overweight	BMI 25–41	BMI >25		Overweight	<300 lbs.	≥95th percentile BMI
Age		18–45 years	25–55 years	14–17 years	8–12 years	Age >41 years	
Other		Pregnant Low/moderate income	<7 h sleep per night	-Free of major illnesses -Not receiving treatment for obesity or eating disorder -Cell phone with text messaging -Able to speak and write English		Pre-menopausal	
Sample size	Several studies n's range from 67–405	Several studies n's range from 8–212	Several studies n's range from 14–63	Several studies n's range from 34–374	Several studies n's range from 6–94	Several studies n's range from 31–170	Several studies n's range from 6–181
Recruitment site(s)	San Francisco Bay Area hospital-based		Providence, Rhode Island	18 public high schools within 20 miles of Claremont that	Targeted direct mailing, newspaper	Southside communities of	Children's Hospital of

	Medical, community and faith-based settings in Harlem and the South Bronx	prenatal clinics, community health centers, social service organizations, and Craigslist	and surrounding areas	have at least 25 % of student body enrolled in a free or reduced lunch program	ads, flyers around SUNY-Buffalo campuses and neighboring community	Chicago including: Beverly, Morgan Park, Mount Greenwood; and 2 south suburbs: Evergreen Park and Oak Lawn -recruited via local newspapers, direct mailing, and friend/family referral	Michigan, community outreach
Interventions: Brief descriptions	Three pilot trials, Each target the individual, individual + social network, or family. For each trial: Group 1: Self-selected small changes in eating/physical activity behaviors (e.g., small plates, no eating with TV, ½ plate F & V) Group 2: Small change eating/ physical activity + positive affect/ self-affirmation (e.g., induction of positive affect through provision of small items/ gifts, workbook)	Mindfulness and nutrition education intervention to reduce stress and improve awareness of hunger-satiety cues and automatic eating patterns	Three arms, all with standard behavioral weight loss program: -no change in sleep -increase sleep gradually -increase sleep immediately	Intervention uses a cue-removal and implementation intentions based strategy to change habitual dietary behaviors. Primary intervention components include a 90-minute meeting with a trained Health Coach, two 20-min phone calls, four tailored newsletters, and a series of emails and text messages.	Incorporate findings from laboratory and field studies on habituation to high-energy dense foods into family-based intervention that: -reduces variety of high energy dense foods -increases variety of low energy dense foods -compared to nutrition education control	Two-year multi-level program aimed at improving physical activity, depression and diet Small groups meet every other week, social network provides special offerings Motivation and goal-setting for diet, physical activity, and stress behaviors Feedback on goal achievement Phase 2 study, no control group	Community health workers: skills training, motivational conversations, contingency management

Table 5 | Description of Childhood Obesity Research Demonstration (CORD) studies

	California CORD [13]	Massachusetts CORD [14]	Texas CORD [15]
Institutions, PIs Grant #s	San Diego State University and the Institute for Behavioral and Community Health	Massachusetts Department of Public Health Harvard TH Chan School of Public Health Massachusetts General Hospital for Children.	Michael and Susan Dell Center for Healthy Living at University of Texas, UT School of Public Health, UT Health
	Clínicas de Salud del Pueblo, Inc.,	Thomas Land, PhD	Children's Nutrition Research Center, Baylor College of Medicine
	Imperial County Public Health Department	Elsie M. Taveras, MD, MPH	Dell Children's Hospital
	Guadalupe X. Ayala, PhD, MPH	Kirsten K. Davison, PhD	Texas Children's Hospital
	Leticia Ibarra, MPH	Steven Gortmaker, PhD	Deanna Hoelscher, PhD, RD
	Amy Binggeli-Vallarta, MPH, DrPH		Nancy Butte, PhD, MPH, RD
	U1 8DP003377	U1 8DP003370	U1 8DP003367
Primary outcomes	Height, weight, BMI	Height, weight, BMI	Height, weight, BMI
	Behavioral changes	Behavioral changes	Behavioral changes
	-Fruit & vegetable consumption	-Fruit & vegetable consumption	-Fruit & vegetable consumption
	-Sweetened beverage consumption	-Sweetened beverage consumption	-Sweetened beverage consumption
	-Water consumption	-Water consumption	-Water consumption
	-Physical activity	-Physical activity	-Physical activity
	-Screen time	-Screen time	-Screen time
	-Sleep time	-Sleep time	-Sleep time
	Satisfaction with healthcare	Satisfaction with healthcare	Satisfaction with healthcare
	Quality of life	Quality of life	Quality of life
Major inclusion criteria	Child, aged 2–10 years	Child, aged 2–12 years	Primary Prevention:
	Parent able to respond to interviews and questionnaires in English or Spanish.	Parent able to respond to interviews and questionnaires in English, Spanish, or Portuguese.	Preschoolers, 2nd graders, and 5th graders
	Low-income; CHIP eligible	Child has obtained well-child care from the community health center for at least the previous 12 months	Secondary prevention: Children, aged 2–12 years, BMI >85th percentile
		Patient of community health center and plan to remain a patient for the next two years	Parents able and willing to bring their children to the primary healthcare clinic or YMCA sessions over the 12 months.
			Low-income; CHIP eligible
Sample size			

	Total n=1186 children. (328 in Health Care (HC) plus Public Health (PH) condition, 278 in HC only condition, 308 in PH only condition, and 272 in. control condition). Three Clinics. Twenty-six Early Care/Education (ECE). Thirteen Elementary Schools and two School Districts, three Restaurants, and three Community Recreation organizations.	Clinical cohort total n=515 (333 intervention, 182 control). Schools, total students completing evaluation surveys n=7114. Three clinics. Nine ECE. Twenty-eight Schools.	Primary prevention: n=1614 child–parent dyads (807 intervention; 807 control) Secondary prevention: n=549. Eleven clinics. Twenty-three ECE. Sixteen schools.
Recruitment site(s)	Brawley, Calexico and El Centro, California	Fitchburg, New Bedford and Lowell, Massachusetts	Austin and Houston, Texas
Interventions:	Multi-level multi-setting interventions linking primary care and community-wide obesity prevention and control	Multi-level multi-setting interventions linking primary care and community-wide obesity prevention and control	Multi-level multi-setting interventions linking primary care and community-wide obesity prevention and control
Brief descriptions	**Health Care** Policy adoption and practice changes including obesity care clinic days, hiring of patient care coordinator, electronic health record (EHR) modifications, provider trainings, and integration of a CHW-led family wellness program adapted from Entre Familia. **Early Care/Education (ECE)** Policy, Systems and Environment (PSE) assessments with NAPSACC; SPARK to promote active play; water availability; provider toolkit; BMI measurements and parent notification; technical assistance and support **Schools** SPARK for physical education; water jets and containers; BMI measurement and notification; policy adoption through school wellness committee; technical assistance and support	**Health Care** EHR modifications, provider toolkits, Obesity Learning Collaborative (action calls), Be Our Voice Advocacy, CHW (manage/coordinate family care), healthy weight clinic for a select group of children >85th %-tile, Physician Champions, engagement of WIC. **Early Care/Education** PSE assessments with WELLCAT and NAPSACC (enhances policies in childcare settings), I Am Moving I Am Learning (physical activity and healthy food choices) **Schools** Eat Well Keep Moving and Planet Health in public schools (Nutrition and physical activity curriculum), Food and Fun in select afterschool programs(develops healthy eating habits outside of school settings Media competition promoting MA-CORD interventions messages.	**Health Care** 1) Primary Prevention: Next Steps, EHR modifications 2) Secondary Prevention: Next Steps at clinic or MEND/CATCH and transition programs at YMCA (Youth Sports, family support book club, cooking classes, MEND World, text msg; CHW (family liaison) **Early Care/Education** CATCH-Early Childhood (Nutrition and physical health activities) **Schools** CATCH Elementary Plus (Nutrition and physical health activities, child nutrition services, physical education)

Community restaurants:
Introduction of healthy child menus and promotion of said menus through wait-staff training and marketing materials

Community recreation:
SPARK for active play; water containers; community gardens; provider toolkit
Community Advisory Committee
All settings *Our Choice/Nuestra Opción* marketing and branding (consistent messaging and images throughout)

Community
Community activities led by Mass in Motion coalitions, such as social media campaign, Safe Routes to School, Complete Streets, community events, Summer Parks programs, Healthy Dining/Corner Stores, , and *"Mass in Motion Kids"* marketing and branding (consistent messaging and images throughout)

Community
Advisory committee; Your Health Matters: Growing Active Healthy Communities Training, and *"Texas CORD"* marketing and branding (consistent messaging and images throughout)

Disease (NIDDK), NHLBI, NICHD, the Office of Behavioral and Social Sciences Research (OBSSR), the Office of Research in Women's Health (ORWH), and the National Center for Complementary and Integrative Health (NCCIH).

Obesity Related Behavioral Intervention Trials

The goal of ORBIT is to translate findings from basic research on human behavior into more effective clinical, community, and population interventions to reduce obesity. Investigators are developing innovative obesity-reducing strategies that show promise in small-scale early phase trials. Target populations include children and their families, Latino and African-American adults, African-American adolescents, low-income populations, pregnant women, and women in the menopausal transition. The interventions being developed include creative new approaches to promote awareness of specific eating behaviors, decrease responsiveness to high-calorie foods, reduce stress-related eating, increase motivation to adhere to weight loss strategies, engage individual's social networks and communities to encourage physical activity, improve sleep patterns, and change habitual dietary behaviors. A Resource and Coordination Unit (RCU), located at Northwestern University, facilitates collaboration across the studies. ORBIT is funded by NHLBI with co-funding from the National Cancer Institute (NCI), NIDDK, NICHD, and OBSSR.

Childhood Obesity Research Demonstration projects

The CDC Childhood Obesity Research and Demonstration (CORD) project builds on existing community efforts to support children's healthy eating and active living and support obesity prevention. Efforts focus on children 2–12 years old who are eligible for the Children's Health Insurance Program (CHIP). Innovative approaches include combining changes in preventive care at doctor visits with supportive changes in schools, child care centers, and community venues. Community health workers provide a bridge between families and resources in their communities. Overall, the grantees' work focuses on strategies that improve children's health behaviors by involving the children themselves, their parents and other family members, and the communities in which they live. Process, outcome, and sustainability measures are collected. Examples are BMI, behavioral change, quality of life, satisfaction with care, and cost. The three CORD research sites are the University of Texas, Houston; San Diego State University; and the Massachusetts State Department of Health. The Evaluation Center is at the University of Houston. CORD is funded by the Centers for Disease Control and Prevention (CDC).

Investigators within each consortium agreed upon some common features including outcomes and other measures, inclusion/exclusion criteria, and follow-up timepoints (Tables 1, 2, 3, 4, and 5). However, because the component studies within each consortium were separately designed, several differences remain. While the overall goals of the interventions were similar, there were differences with respect to study-specific design issues (e.g., study-specific inclusion/exclusion criteria), target populations, recruitment strategies, intervention content, data collection, and how the interventions were delivered.

The Working Group built on the experience of the Resources Enhancing Alzheimer's Caregiver Health (REACH) consortium which addressed the issue of combining information in a meaningful way across several related studies. This group published articles on the methodology used [11] and the results of the analysis [12]. REACH was comprised of six randomized controlled studies which tested nine "active" interventions against two types of control conditions for family members of people with Alzheimer's Disease or a related disorder with the goal of reducing caregiver burden [8]. Because the REACH interventions, like those represented at the Workgroup meeting, were complex behavioral interventions, REACH investigators wondered whether all components of their multi-faceted interventions were necessary to have an effect on the outcome. This is a question that could be answered across studies, inasmuch as not all interventions had the same components, but not within a study since it is the interventions as a whole that are being compared by each study. The approach adapted by REACH investigators was to decompose the complex interventions, examining who (caregiver, care-recipient, social, or physical environment) and what (knowledge, behavior, skills, affect) the intervention targeted. The combination of the three "whos" and four "whats" resulted in 12 components (e.g., caregiver affect, care-recipient behavior, knowledge about the social environment). Each intervention was "scored" on the basis of these 12 components, and relationships between the components and outcome were examined. As a result, a new intervention (REACH II) was designed that emphasized the components identified as being associated with outcome and subsequently tested in a multi-center randomized, controlled trial [16].

In the process of developing the decomposition methodology, the REACH investigators identified a gap in the literature with respect to how interventions are described and information that is needed to enable the decomposition process to proceed. Thus, an expansion of existing taxonomies for characterizing interventions was proposed [17]. Furthermore, it has been long recognized that the lack of a common nomenclature to describe techniques for behavior change has limited behavior change intervention science [18].

There has been substantial progress in attempting to establish a common language in behavior change intervention research which has resulted in identifying and defining 93 techniques developed by international consensus that have been grouped into 16 higher order domains [19].

Thus, substantial groundwork has been laid to facilitate cross-study intervention research in behavior change, making timely this meeting to discuss the application of a taxonomy and methods for combining information across studies that target obesity. The meeting was initiated with remarks describing research priorities at the National Institutes of Health (NIH) and strategic plans. Two keynote speakers discussed methodologies used to combine results across diverse interventions and a taxonomy that had been developed to describe behavior change techniques. The workgroup members were charged with developing recommendations regarding methods for developing intervention taxonomy and analytical methods for combining data across interventions within a consortium. Keynote speakers met with the represented consortia in breakout groups and the final recommendations were derived by consensus.

The manuscripts that follow address two topics critical for combining information across studies that address behavior change. Tate et al. describe the rationale for decomposing interventions, issues that arise when applying the decomposition process to behavioral interventions, and the need for further development of a common language or taxonomy. In the manuscript by Bangdiwala et al., analytical approaches for combining data across studies are discussed.

The meeting attendees concluded that an investment of time and personnel for developing and applying decomposition methods for cross-study analyses could lead to important information and crucial insights for developing effective interventions. The attendees came to consensus on recommendations to address the research questions articulated above. In general, attendees agreed that a common taxonomy for describing interventions would be useful to better understand those interventions, in particular, aspects of interventions that are related to intervention goals. Several analytical approaches for combining information across interventions, both within a consortium and across consortia, or for investigating treatment response in subgroups, were discussed and are the topic of another manuscript in this issue (Bangdiwala et al.). Attendees agreed that by decomposing interventions (see Tate et al. in this issue) and properly selecting measures, it would be possible to combine data from obesity prevention and treatment studies. The meeting attendees made the following recommendations:

Taxonomy-related recommendations
- Decompose and code content of each intervention utilizing established theory or taxonomy. Examples of taxonomies include behavior change techniques (BCTs) and more extensive taxonomies that address other aspects of studies, such as populations studied, mode of intervention administration, training, measures used, timing of measures, intervention adaptability, and interventionist characteristics.
- If established theory or taxonomy is amended, there should be appropriate scientific rigor to justify the change(s), e.g., calculate inter-rater reliability.
- Determine the intervention components and dose intended to be delivered (according to protocol) per each intervention component (e.g., BCT).
- Determine the intervention components and dose actually delivered per each intervention component (e.g., BCT).
- Determine the intervention components (e.g., BCTs) and dose actually received by participants.

Analysis methodology related recommendations
The methodology should take into account relevant theory and be driven by the research question(s). Issues to consider include variable selection and interactions.

- Pooling results across studies, within or among consortia, must account for heterogeneity among studies.
- In general, pooling is used for exploratory analyses to help identify intervention components (e.g., BCTs) that may work better than others and to identify subsets of participants across studies in which particular components work better. As such, these analyses are not to replace the standard analysis plan for each study. If the analyses were not specified in advance, analyses of pooled data are viewed as "post-hoc" exploratory analyses. If such analyses are to be performed, split-sample or cross-validation techniques should be employed.
- Pooling may also be performed to test hypotheses which were specified a priori.
- Approaches to consider:

– Traditional meta-analysis, with or without meta-regression. Including only study-level covariates in meta-regression limits the number of observations. Using participant level covariates in meta-regression is recommended to the extent possible.
– Ignoring randomization but utilizing intervention components and, potentially, other study or intervention level data rather than indicator(s) of intervention. Participant level covariates should be included with this approach.

- Methodologies to consider

– Linear mixed-effects models (multi-level analysis)

Attendees

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– Non-linear models and approaches (e.g., classification/regression trees/forests)
– Multi-group structural equation modeling
– Latent class models

In conclusion, this paper presents an overview of the workgroup meeting that was convened to discuss, and make recommendations regarding, a taxonomy for obesity intervention research and issues to consider and methods to employ for cross-study analyses. The other two manuscripts in this series (Tate et al, Bangdiwala et al) elaborate on meeting findings and recommendations and together provide useful information to investigators conducting multi-site trials that have different intervention modalities but common primary outcomes.

necessarily represent the official position of the National Institutes of Health or the Centers for Disease Control and Prevention.

Compliance with ethical standards

Conflict of interest: Dr. Cella reports funding from the NHLBI. No other authors reported a potential conflict of interest.

Adherence to ethical principles: This research did not include human subjects or animals.

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