TBM

ORIGINAL RESEARCH

The EARLY trials: a consortium of studies targeting weight control in young adults

Leslie A Lytle, PhD, MS,[1] Laura P Svetkey, MD, MHS,[2] Kevin Patrick, MD, MS,[3] Steven H Belle, PhD, MSHyg,[4] I Diana Fernandez, MD, MPH, PhD,[5] John M Jakicic, PhD,[10] Karen C Johnson, MD, MPH,[6] Christine M Olson, PhD, MS,[7] Deborah F Tate, PhD, MS,[1] Rena Wing, PhD, MA,[8] Catherine M Loria, PhD, MS[9]

[1]Department of Health Behavior, University of North Carolina, Campus Box 7440, Chapel Hill, NC 27599-7440, USA
[2]Duke University, Durham, NC, USA
[3]University of California, San Diego, CA, USA
[4]University of Pittsburgh, Pittsburgh, PA, USA
[5]University of Rochester, Rochester, NY, USA
[6]University of Tennessee Health Science Center, Memphis, TN, USA
[7]Cornell University, Ithaca, NY, USA
[8]Alpert Medical School of Brown University and The Miriam Hospital, Brown University, Providence, RI, USA
[9]National Heart, Lung, and Blood Institute, Bethesda, MD, USA
[10]Department of Health and Physical Activity, Physical Activity and Weight Management Research Center, University of Pittsburgh, Pittsburgh, PA, USA

Correspondence to: L A Lytle
llytle@email.unc.edu

Cite this as: *TBM* 2014;4:304–313
doi: 10.1007/s13142-014-0252-5

Abstract

Young adulthood has been identified as a high-risk period for the development of obesity but few interventions have been tested in this population. One way to escalate our learning about effective interventions is to test a number of interventions simultaneously as a consortium of research trials. This paper describes the Early Adult Reduction of weight through LifestYle intervention (EARLY) trials. Seven research sites were funded to conduct intervention trials, agreeing to test similar primary outcomes and cooperating to use a set of common measurement tools. The EARLY consortium was able to work cooperatively using an executive committee, a steering committee, workgroups and subcommittees to help direct the common work and implement a set of common protocol and measurement tools for seven independent but coordinated weight-related intervention trials. Using a consortium of studies to help young adults reach or maintain a healthy weight will result in increased efficiency and speed in understanding the most effective intervention strategies.

KEYWORDS

Young adults, Obesity, Intervention trials, Research consortium

Implications

Researchers: A common protocol and set of measurement tools to assess the same primary outcome across seven studies allows researchers to pool data and to make comparisons in efficacy across a variety of intervention strategies.

Practitioners: Standardizing elements of independent studies while testing a variety of intervention approaches allows practitioners to evaluate a wide set of strategies for weight management and to make better decisions about the most effective and appropriate strategies for their population.

Policy-makers: Evaluating the comparative efficacy of a variety of approaches to weight management for young adults allows a more rapid translation of actionable strategies for policy makers.

BACKGROUND

Obesity has reached epidemic proportions in American adults and youth and accounts for nearly 10 % of all annual medical spending [1, 2]. By 2030, between 35 and 51 % of the population will be obese [3, 4]. Young adults (18–35 years) are at higher risk for weight gain than older adults. According to a recent National Health and Examination Survey (NHANES) for US adults ages 25–74, major weight gain over 10 years (a gain in body mass index (BMI) $\geq$5 kg/m^2) was highest at ages 25–34 [5]. Between 2004 and 2010, the prevalence of overweight and obesity rates for men ages 20–39 increased from 62.2 to 67.1 % and the prevalence for women in the same age range increased from 51.7 to 55.8 % [6]. The Coronary Artery Risk Development in Young Adults (CARDIA) study, sponsored by the National Heart, Lung, and Blood Institute (NHLBI), showed peak aging-related weight gain over 10 years was highest in the early to mid-twenties [7].

After many years of declining coronary heart disease (CHD) mortality rates, recent national age-specific data suggest a possible increase in the CHD death among young adults. While CHD and its risk factors have been rare at age 20, these new data suggest that these conditions may be increasing, and recent successes in reducing CHD mortality may be reversed in future years [8, 9]. Data from the CARDIA Study suggest that excess weight gain in early adulthood adversely impacts development of multiple CHD risk factors, such as hypertension, dyslipidemia, and diabetes. Mean CHD risk factor levels remained relatively unchanged in adults, initially aged 18–30, who maintained a stable

weight over 15 years even if already overweight at baseline, whereas risk factor levels steadily increased in weight gainers [10]. These data suggest that if further weight gain is avoided early in adulthood, risk factor progression may be reduced or prevented and more adults will enter middle age at lower CHD risk. Lower CHD risk status in middle age is linked to lower CHD morbidity and mortality, lower health care costs, increased life expectancy, and higher quality of later life [11].

The prevalence of overweight and obesity in young adults and findings from the CARDIA Study, led the NHLBI to initiate clinical trials of behavioral weight control interventions targeting young adults using a consortium approach. The trials were charged with conducting clinical research studies to, "… develop, refine, and test innovative behavioral and/or environmental approaches for weight control in young adults at high risk for weight gain." [12]. The consortium approach involves funding multiple studies in a specific research area, each of which conducts a unique intervention, shares a common primary outcome and agrees on a set of common elements and measurement protocol. Testing several approaches simultaneously has the potential to advance knowledge regarding what works and how to engage this high-risk age group in achieving and maintaining a healthy weight more rapidly than independent trials. This approach also facilitates making cross-study and intervention strategy comparisons [13].

In 2009, seven institutions were awarded funds to participate in this research with the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) joining NHLBI to help fund the trials. The investigators and staff from NHLBI and NICHD formed the Early Adult Reduction of weight through LifestYle intervention (EARLY) Trials (www.earlytrials.org). The purpose of this paper is to describe the EARLY trials, including the studies involved, EARLY's organization, and the development of common elements that are intended to provide cross-study insights into weight control strategies for young adults.

METHODS

Common elements across the trials

The trials include a set of parameters to be consistent across all studies. The interventions are to be 24 months in duration, focusing on weight control defined as weight loss, prevention of weight gain, or prevention of excessive weight gain during pregnancy. The interventions all incorporate media and technologies commonly used by this age group, such as the Internet, chat rooms, iPods, or cell phones, in order to facilitate recruitment and retention and to appeal to young adults. In addition, interventions are designed to be practical, cost-effective, sustainable, and easily disseminated on a broad scale. Change in weight or BMI are the primary outcome. A set of common data elements was agreed upon and included specific protocols for assessing height, weight, waist circumference and blood pressure and the collection and storing of blood samples as well as a common set of questions to describe behavioral, psychosocial, demographic, and clinical factors. The process for identifying the common elements and the final set of common elements are described in a following section. A set of common inclusion and exclusion criteria for participants was also established for the trials (Table 1).

Overview of the research partners

Table 2 identifies the institution and principal investigator, and describes study characteristics. All studies received approval from their institution's human subjects and internal review boards and are monitored by Data and Safety Monitoring Boards (DSMB). A brief description of each study follows.

(CHOICES) (Minneapolis-St. Paul, MN)

The goal of the Choosing Healthy Options In College Environment Settings (CHOICES) study is to develop and test innovative strategies to help prevent unhealthy weight gain in students attending 2-year community or technical colleges (www.choicesstudy.org). The CHOICES sample is made up of 441 students randomized to an intervention or control condition. The CHOICES intervention is based on social ecological and social networks models [14]. Students randomized into the intervention condition participate in a one-credit course offered through their 2-year college that

Table 1 | EARLY common inclusion and exclusion criteria

Common inclusion criteria:
• Age 18–35 years
• Intending to be available for a 24-month intervention
Common exclusion criteria:
• Unable to provide informed consent
• BMI<20 kg/m^2 (E-Moms<18.5 kg/m^2)
• BMI≥40 kg/m^2 (E-Moms<40 kg/m^2)
• Household member on study staff
• Past or planned weight loss surgery; current participation in a commercial weight loss program; current or planned enrollment in another diet/PA/ weight loss intervention study
• Regular use of systemic steroids, prescription weight loss drugs, and/or diabetes medications
• Current treatment for an eating disorder
• Lost more than 15 lb within the last 3 months
• Cardiovascular event within the last 6 months
• Current treatment for a malignancy
• Currently pregnant or gave birth within the last 6 months, currently lactating or breastfeeding within the last 3 months, actively planning pregnancy within the next 24 months (E-MomsRoc not included in this exclusion)
• Systolic BP≥160 mmHg or diastolic BP≥100 mmHg at screening
• Investigator discretion

Table 2 | Description of individual studies in the EARLY trials

Study	CHOICES	CITY	E-MomsRoc	IDEA	SMART	SNAP	TARGIT
Institution(s), PI(s)	U Minnesota, L Lytle	Duke U, L Svetkey	Cornell U, C Olson; U Rochester, ID Fernandez	U Pittsburgh, J Jakicic	U California—San Diego, K Patrick	Brown U, R Wing; U North Carolina, D Tate	U Tennessee, K Johnson
Primary outcome All outcomes are evaluated at 24 months post randomization	Change in BMI	Change in weight	Difference in proportion of unhealthy gestational weight gain; Difference in proportion of unhealthy postpartum weight retention	Change in weight	Change in weight	Change in weight	Change in weight
Target population							
Description	Community college students	Overweight/obese young adults	Pregnant women	Overweight/obese young adults	Overweight/obese 4-year college students	Young adults	Young adult smokers
Sample size	441	365	1691	471	404	600	330
Recruitment by race							
% White/ Caucasian	72.8	56	62.4	76.2	41.8	75.4	57
% Black/ African American	15	36	23.4	17.2	3.7	11.4	37
% Asian	6.1	3	2.1	1.9	23.8	4.3	0.3
% Multiple	4.8	0	2.8	3.4	9.2	8.7	5.2
% Other[a]	1.3	1	0.5	1.3	21.5	0	0.5
% Unknown	0	4	8.8	0	0	0.2	0
% Female	67.6	70	100	71.1	70	78.3	48.8
Recruitment site	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 Chapel Hill, NC	Community; Memphis, TN

Table 2 (continued)

Study	CHOICES	CITY	E-MomsRoc	IDEA	SMART	SNAP	TARGIT
Technologies used	Online curriculum; Web-based social network	Cell phone; Bluetooth-enabled bathroom scale	Cell phone; internet	Cell phone; text messaging; wearable monitor; web-based interface supports wearable technology.	Cell phone (text messages, Smartphone apps); Facebook, web, email	Cell phone; internet	Internet, phone, iTouch, webinars
Intervention							
Brief descriptions	Students are randomized to two conditions: Intervention and control. Intervention arm begins with a one-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; (3) control group. The cell phone technology includes self-monitoring of weight, diet and physical activity. Both group and personalized coaching are used in the coaching condition. The control group receives usual care	Pregnant women are randomized to one of three conditions: (1) intervention only during pregnancy; (2) intervention during pregnancy and post partum; and (3) control group. Both intervention arms receive intervention strategies through cell phones and internet. Key elements include: motivators to encourage goal setting with incentives and reinforcement; tools for self-monitoring of weight gain and associated behaviors and informational tips and action-oriented behavioral messages. Control group receives non-weight-related health information on a website	Participants are randomized to one of two 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 as well as a wearable monitor to assess energy expenditure and activity	Students are randomized to 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. Apps are developed by college-age tech designers. 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. Two intervention groups test the differences in making large changes or small changes in diet and physical activity to avoid unhealthy weight gain. The goal of the large change group is to lose 5-10 lb to buffer against the weight gain that often occurs during young adulthood. The small change group makes small changes in diet and activity to reduce the chance of weight gain. The control group receives usual care	Participants are randomized to one of two conditions: (1) intervention and control. The control condition receives a tobacco quit line while those randomized to the intervention receive the tobacco quit line plus a behaviorally focused weight gain prevention program using interactive technologies. The interactive technologies include phone calls, iPod touch with smoking cessation apps and behavioral tracking, webinars and a study website

[a] "Other" race/ethnicity category includes American Indian/Alaskan native; Native Hawaiian/Pacific Islander; and self-described as "other" race

focuses on eating, activity, sleep, and stress management as ways to help maintain or achieve a healthy weight. Three course sections (online, face-to-face, and a hybrid course option) are offered to accommodate students' scheduling needs and learning preferences. A study-designed website component is introduced as part of this course and continues for 20 months following the one-credit course. The goal of the CHOICES website is to reinforce behaviors related to healthy weight maintenance and to encourage exchange and support among all intervention participants. Students track their weight and weight-related behaviors on the website, and intervention staff interact with participants electronically or through phone calls offering encouragement and helping with problem solving. Control students receive their health assessments, existing public health information on maintaining a healthy weight, and information on health services offered on their school's campus. Change in BMI over 2 years is the primary outcome for this study and secondary outcomes examine the impact of the intervention on behavioral and psychosocial outcomes and on the formation of social networks.

CITY (Durham, NC)

The Cellphone InTervention for You (CITY) study is a randomized control trial (RCT) in which a diverse population of 365 overweight/obese, generally healthy adults are randomly assigned to one of three groups: (1) a behavioral weight loss intervention delivered almost entirely via an interactive "smart" phone application designed by the investigators; (2) a behavioral weight loss intervention delivered via group and individual personal coaching, using cell phones for self-monitoring of weight, dietary intake, and physical activity; or (3) a usual care, advice-only control group. CITY is testing the hypothesis that each active intervention will lead to more weight loss than occurs in the control group. A secondary analysis will compare weight loss in the cell phone intervention to weight loss in the personal contact intervention. Other outcomes to be compared among the three treatment groups include health behaviors (diet and physical activity), obesity-associated risk factors (e.g., blood pressure, insulin resistance), psychosocial variables (e.g., body image), and costs of implementation. Subgroup analyses will determine treatment effects in race, sex, and age subgroups. Other secondary analyses will attempt to identify predictors of successful weight loss in this study population.

E-MomsRoc (Rochester, NY)

The goal of E-MomsRoc is to decrease the prevalence of excessive pregnancy weight gain and excessive weight retention in the first 18 months postpartum in a socioeconomically and racially/ethnically diverse sample of women who are normal weight (BMI 18.5–24.9), overweight (BMI 25–29.9), and obese class 1 (BMI 30–34.9) in early pregnancy (below 14 weeks gestation) using electronically mediated patient intervention programs. The sample of 1,691 women are randomized in the first 20 weeks of pregnancy to one of three groups: (1) receipt of an electronically mediated intervention program only during pregnancy; (2) receipt of an electronically mediated intervention both during pregnancy and for 18 months postpartum; and (3) a control condition in which women receive non-weight-related health information and resources at the project website and through their cell phones. A project website and cell phones are the electronic media that are used for communicating with the women. Analyses will examine if intervention during pregnancy prevents excess weight gain and, additionally, whether intervention during pregnancy and postpartum has a greater effect on overall weight retention than intervention during pregnancy only. Subgroup analyses will examine treatment effects in income and weight subgroups.

IDEA (Pittsburgh, PA)

The primary aim of the Innovative Approaches to Diet, Exercise, and Activity (IDEA) study is to examine whether an enhanced weight loss intervention (EWLI) that includes advanced technology components results in improved weight loss in young adults compared to a standard behavioral weight control program (SBWP) over a period of 24 months. The sample includes 471 overweight and obese young adults. All participants are engaged in a 24-month behavioral weight loss program that includes weekly intervention meetings for the initial 6 months with monthly sessions from months 7–24, and brief monthly intervention-based telephone calls from months 7–24 with a goal to reduce energy intake and increase moderate-to-vigorous intensity exercise. During months 1–6, weekly sessions are conducted in a group format by trained staff. Each session incorporates feedback and problem solving, includes a formal lesson on weight loss, nutrition, physical activity, or behavior change and allows for group interaction. Each session lasts between 30 and 60 min and precedes a weekly weigh-in performed by staff. In addition, participants are randomized to receive one of two additional treatments (SBWP or EWLI). Participants randomized to SBWP also receive modest technology enhancements from months 7–24 that include periodic targeted text messages and access to a study website where the participant can self-monitor diet and activity behaviors. Participants randomized to EWLI also receive text messaging from months 7–24, intervention materials posted to a website from months 7–24, and the BodyMedia Fit System® that includes a wearable monitor and display to provide real-time feedback on energy expenditure, physical activity goals, dietary intake. While the primary outcome is change in body weight, secondary outcomes include examining the interventions' effect on BMI, body

composition, fitness, and behavioral/psychosocial measures that may be predictive of obesity risk.

SMART (San Diego, CA)

Social/Mobile Approach to Reduce weighT (SMART) is a theory-based intervention that utilizes web, cell phone and social media to provide an engaging weight loss program for young adults. Participants are 404 college and university students with BMI between 25 and 34.9 kg/m^2 from three institutions in San Diego County. Participants are randomized to the SMART intervention or the comparison arm. SMART is comprised of the following components: (1) a brief (30 min) health educator session at program onset; (2) over the course of 24 months, up to 10 (as needed) brief (5–10 min) phone contacts with the health educator via phone, email, Skype, or instant messaging chats; (3) study-specific smartphone apps (accessible on either Android or iPhone) and interactive text messages that support improved weight-related behaviors; (4) study-specific Facebook campaigns and games supporting improved weight behaviors; and (5) access to the SMART intervention website for updated study-related content and news. For the full 24 months of the study, participants are asked to visit the intervention website on a weekly basis and interact with intervention content via text messages and through Facebook applications several times per week. They are encouraged to engage their social network via Facebook, sharing specific SMART related apps with their friends. Control participants are assigned to a website with general health information for college students. Change in weight is the primary outcome with additional analyses examining influences of SMART intervention components and social network characteristics on weight-related behaviors and other aspects of health important for young adults.

SNAP (Providence, Rhode Island and Raleigh/Durham NC)

The purpose of Study of Novel Approaches to Weight Gain Prevention (SNAP) is to test two interventions to prevent weight gain in young adults. The project involves two clinical centers (The Miriam Hospital/Alpert Medical School of Brown University and the University of North Carolina at Chapel Hill) and a Data Coordinating Center (Wake Forest University School of Medicine). The interventions are based on a self-regulation approach that has been shown to help prevent weight regain in recent weight losers [15]. Key aspects of this approach include daily self-weighing, use of the information from a scale to know when adjustments in eating and activity are needed, behavioral skills to modify these behaviors, and small reinforcements for successful prevention of weight gain. One self-regulation intervention is focused on making small consistent changes in eating and exercise behavior to prevent weight gain; the other emphasizes periodic larger changes in eating and exercise behavior that result in small weight losses. These interventions will be compared to each other and to a control condition in a three-armed RCT. The study involves 600 adults (300 at each clinical site), with a BMI of 23–30, who are randomly assigned to (1) control; (2) self-regulation intervention with small behavior changes or (3) self-regulation with large behavior changes. Both interventions include ten face-to-face group meetings delivered during the initial 4 months; subsequently participants use the Internet, email or cell phones to submit their weight at least monthly and are sent monthly feedback on their weight via email. Both groups are offered periodic refresher classes and assistance (via email, phone or in person) if weight gain is observed. Participants will be followed from randomization until the end of the grant, resulting in 24–48 months of follow-up (mean=3 years). The primary hypothesis is that the magnitude of weight gain across an average planned follow-up of 3 years will differ among the three groups; the a priori hypothesis is that weight gain will be greatest in control, intermediate in small changes, and least in the large change condition. The trial will also examine the association among changes in behaviors, weight, and cardiovascular disease risk factors and examine potential moderators and mediators.

TARGIT (Memphis, Tennessee)

The purpose of the Treating Adults at Risk for weight Gain with Interactive Technology (TARGIT) study is to develop and test a behavioral weight loss/weight gain prevention intervention delivered through interactive technology. This intervention will be used in conjunction with an efficacious tobacco quit line in young adult smokers to determine if it can prevent weight gain associated with smoking cessation. TARGIT's primary hypothesis is that the behavioral intervention using interactive technology will significantly attenuate or prevent weight gain associated with smoking cessation at 2 years after enrollment compared to a tobacco quit line in young adult smokers. The TARGIT study also plans to test whether the behavioral intervention using interactive technology combined with a tobacco quit line compared to a tobacco quit line alone results in increased biochemically verified smoking cessation, increased healthy eating, and increased physical activity as secondary outcomes. A total of 330 participants are randomly assigned to the intervention group or the comparison group in a 1:1 ratio and followed for 24 months to assess outcomes. TARGIT offers a variety of interactive technologies including phone calls (quit line), TARGIT study website (www.targitstudy.org), and iPod Touch with a smoking cessation application (app) for both groups and weight loss-related apps for the intervention group.

EARLY trials organizational structure and subcommittees

In addition to the seven trials, one institution (University of Pittsburgh, Steven Belle, PI) was also selected to serve as the Resource and Coordination Unit (RCU). The RCU is responsible for facilitating cross-study activities, such as coordinating meetings and committee work, supporting the identification of common elements (e.g., eligibility criteria and measures) across studies, and serving as a data repository for measures common to all the trials. The EARLY trials are governed by a Steering Committee (SC) comprised of each study's Principal Investigator (PI), the RCU PI, and NHLBI and NICHD scientists. An Executive Committee, made up of the elected SC Chair and Vice Chair, RCU PI and two NHLBI project scientists, facilitates direction and coordination of the trials. The EARLY trials have three NIH-appointed DSMB that advise the NHLBI on the execution and safety of the trial. DSMB members, with specific expertise relevant to the EARLY trials, are external to the trial. Additional EARLY trials subcommittees include: Design and Analysis (D&A), Safety, Recruitment and Retention (R&R) and Intervention. These subcommittees include investigators from each of the studies as well as NIH program office scientists (Table 3).

Common elements

Although each of the EARLY studies will publish it own results, the EARLY investigators also plan to engage in cross-study analyses based on a pooled database. Hypothesis testing for primary study aims can only occur in the context of single studies; however, the pooled data can address additional questions of interest with a larger sample. In order to maximize comparability and facilitate cross-study analysis, the SC agreed to measure elements that would be common across studies.

In the first year, working groups were created to establish measures and protocols that would be common across all seven trials. The EARLY working groups included: Physical Measures, Diet Assessment, Physical Activity, and Survey. The working groups' activities occurred prior to baseline data collection and representation from each study was encouraged on each working group. The chairs of the working groups convened conference calls that reviewed each study's measurement and evaluation plans put forth in their individual grant application. Similarities and differences in plans were examined and a list of potential common elements was proposed to the SC. The SC amended and approved the list of common elements based on the potential cost, feasibility and impact of adoption.

The EARLY SC made all final decisions on the common elements to be collected by all EARLY studies and on the measurement protocols to be used. In addition, the EARLY SC specified that data collection visits would occur, at a minimum, at baseline, 12, and 24 months; some studies included additional interim data collection visits depending on study design. For E-MomsRoc, the data collection time points are: baseline (enrollment to 28 weeks gestation), 32 weeks gestation to delivery, delivery and 6 weeks postpartum and 6, 12, and 18 months postpartum. Table 4 outlines the common elements related to measurement agreed upon for the EARLY trials, the number of questions included for assessing each construct on survey

Table 3 | EARLY subcommittees

Subcommittee name	Purpose
Design and Analysis (D&A)	• Define a list of common eligibility criteria for all studies
	• Agree on common analytic approaches, such as handling of missing data and rules for censoring data
	• Make recommendations for the primary outcome for cross-study analyses
	• Provide guidance on all issues related to study design and analyses
	• Assist in standardizing responses to requests and recommendations made by the DSMBs
Safety	• Make recommendations to SC concerning safety alerts (e.g., elevated blood pressure, high depression score, too rapid weight loss) and safety procedures (e.g., Serious Adverse Event reporting)
	• Develop procedures for surveillance, detection and reporting of safety alerts, and common protocols for responding to an alert
	• Conduct regular webinar training throughout the trial
Recruitment and Retention (R&R)	Share ideas about the best ways to recruit and retain young adults into the studies
Intervention	• Identify common intervention strategies used across the studies
	• Develop common process measures to assess the engagement of participants in the interventions
	• Identify and share strategies for maintaining engagement with the intervention
	• Help studies problem-solve intervention-related issues
Publications and Presentations	Develop and implement a process and procedure for proposing manuscripts and presentations that use data from multiple studies

Table 4 | Common elements: demographic information, physical and dietary measures and constructs and sources

Physical Measures (collected using a standardized protocol)		
Height		
Weight		
Arm circumference		
Waist circumference		
Resting systolic blood pressure		
Resting diastolic blood pressure		
Resting heart rate		
Dietary intake (from 24-h recalls or food frequency questionnaires)		
Total calories		
Grams of fat		
Grams of protein		
Grams of carbohydrate		
Grams of alcohol		
Healthy Eating Index Score		
Demographic information on survey	# of items	Source
Ethnicity/Hispanic	1	NIH
Race	1	NIH
Gender	1	NIH
Date of birth	1	NA
Age at randomization	1	NA
Highest grade finished	1	NIH
Children under 18 living at home	1	Original
Adults 18 or older living at home	1	Original
Income for the past 12 months	1	Adapted from CARDIA [20]
Current relationship status	1	Adapted from Boynton College Student Health Survey [21]
Common constructs from survey	# of items	Source
Sugar sweetened beverage consumption	6	Diet History Questionnaire III, NCI [22]
Fast food consumption	3	Nelson and Lytle, 2009 [23]; Original
Meals prepared at home	1	Adapted from CITY [24]
Behaviors to lose weight/prevent weight gain	1	Adapted from French et al. [25] and Linde et al. [26]
Frequency of self-weighing	1	Adapted from French et al. [25] and Linde et al. [26]
Access to a scale	1	Original
Daily meal patterns	7	Adapted from Raynor et al. [27]
Smoking/tobacco use	6	BRFSS; NYTS [28,29]
Alcohol intake	4	BRFSS [28]
Depression	10	Andresen et al., CES-D [30,31]
Sleep	6	Adapted from Lytle et al. [32]; original; adapted from Buysse et al., PSQI [33]; adapted from NHANES [34]
Neighborhood environment	8	Sallis et al., PANES [35]
Exercise Habits	8	Paffenbarger et al. [36]
Physical activity	22	Adapted from GPAC [37]
Sedentary behavior	16	CARDIA [38]; Original; Rosenberg et al., SBQ [39]
Satisfaction with intervention	3	Adapted from Van Wormer [40] and Baldwin [41]

BRFSS Behavioral Risk Factor Surveillance System; *CARDIA* Coronary Artery Risk Development In Young Adults; *CES-D* Center for Epidemiologic Studies Short Depression Scale; *CITY* Cellphone InTervention for You; *DHQ* Diet History Questionnaire; *FAB* Food, Attitudes and Body; *GPAQ* global physical activity questionnaire; *NHANES* National Health and Nutrition Examination Survey; *NYTS* National Youth Tobacco Survey; *PANES* Physical Activity Neighborhood Environment Scale; *POP* pound of prevention; *PSQI* Pittsburgh Sleep Quality Index; *SBQ* Sedentary Behavior Questionnaire; *TREC-IDEA* Transdisciplinary Research in Energetics and Cancer—Identifying Determinants of Eating and Activity

instruments, and the source of the assessment methodology.

DISCUSSION

The EARLY trials are testing seven unique 2-year behavioral interventions in young adults that address weight loss, prevention of weight gain or prevention of excessive weight gain during pregnancy. The trials target a variety of racially- and ethnically diverse populations, including 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 to appeal to young

adults. The EARLY trials are some of the first to evaluate the effectiveness and efficacy of a variety of technology-based approaches to reach and engage young adults and to have an impact on health-related outcomes such as obesity treatment and prevention.

The EARLY trials are an example of a research consortium funded by NHLBI. Another example of this type of trial is the POWER trials that included three centers independently evaluating the effectiveness of weight loss interventions in primary care settings. Each of the POWER studies conducted unique interventions but agreed on a common primary outcome and a set of common measures, inclusion and exclusion criteria and a common analysis plan for the primary outcome. Yeh et al.13 identify three advantages to this type of model that includes: (1) the ability to test several interventions simultaneously; (2) the ability to draw on expertise from the larger group of investigators representing each site; and (3) the potential to learn more because of the ability to conduct pooled analyses and to make comparisons across studies.

Another benefit of this approach is the shared expertise of investigators from across the studies. Collaborative trials such as POWER and EARLY are examples of team science in action [16]. In a team science approach researchers who traditionally would work independently come together to form collaborative centers or groups. The advantage of team science is to create opportunities for innovations and advancement that are not possible when investigators work independently. Working as a transdisciplinary team allows researchers to draw on techniques, approaches and perspectives unavailable in any single discipline, providing great potential to impact the most complex health issues that we face.

In EARLY, this team science approach encouraging shared expertise was helpful as we chose the common elements and the most rigorous protocol to use. This approach also facilitates continued problem solving involving a wide range of issues that the individual trials faced including issues related to recruitment, retention and sustaining engagement in the intervention. The pooled sample size of more than 4,200 young adults represented in the EARLY trials greatly increases the generalizability of what we learn and yields greater statistical power. In addition, the EARLY investigators plan to use a process described by Belle et al. [17] that will allow us to compare the efficacy of a wide variety of intervention strategies, by pooling data from each study and using a taxonomy to integrate results across the diverse interventions. For this process, we are using the weight management strategies described by Michie et al. [18, 19] to provide structure for combining diverse interventions.

Yeh et al. [13] also describe challenges faced by the POWER trials in conducting independent but coordinated trials that have been shared by EARLY. Those challenges include: (1) allocating resources for the increased time required and complexity involved in the decision-making process; (2) designing and agreeing on strategies that maximize the potential for pooling data; and (3) monitoring the trial. For the EARLY trials, a great deal of work went into identifying and agreeing upon the set of common elements. Having adequate time in the trial to make these difficult decisions was imperative; studies generally underestimated the resources required for fully participating in coordinating across the studies. Creating the system for pooling data has also been challenging and relies largely on the EARLY's RCU to create the protocol and process for receiving data from each study. Unlike a multicenter trial with a single coordinating center that provides statistical and data management support, this model requires collaboration and consensus among statisticians and data managers across all studies. In addition, data managers in each study must have the time and expertise to provide the RCU with common data and, at the same time, manage the data that are unique to the study-specific research questions.

Several additional challenges have been encountered with the EARLY trials. One issue has been to make the trials as comparable as possible without overburdening the individual studies and their participants. Coordinating timelines has also been difficult. Individual studies have their own timelines for pilot work, recruitment, measurement and intervention activities that often differ from other studies. Analyzing common elements across studies for any one measurement period requires all studies to wait until the last study has finished data collection and cleaning. A final challenge has been respecting the unique research aims of each study. While all of the EARLY trials focus on weight control in young adults, approaches and samples differ and direct comparisons across studies are not possible. Nevertheless, the EARLY trials will provide the opportunity to test hypotheses from individual trials and to combine results and data to provide a cross-cutting perspective of behavioral weight control approaches that work well for young adults.

CONCLUSION AND IMPLICATIONS

The article describes the development, organization and implementation of the EARLY research consortium that includes seven independent but coordinated research trials funded to evaluate innovative strategies to help young adults achieve and maintain a healthy weight. This type of research consortium represents a useful approach in research areas at an earlier stage of development in which the state-of-the-science has not yet identified a single approach ready to be evaluated through a large single protocol, multicenter trial. By funding multiple independent trials with a common primary outcome

that test a variety of potential behavioral interventions using common protocol and measurement tools for at least a subset of measures, the ability to pool data and to make comparisons in efficacy in intervention strategies is greatly increased. If this model is successful in expanding what we can learn from single, smaller intervention studies, this may have implications for the future design of larger behavioral intervention trials that impact research design, clinical practice, and national policy.

Acknowledgments: The EARLY trials are funded by National Heart, Lung, and Blood Institute: HL096760-02 (Fernandez and Olson), HL096770-01 (Jakicic), HL096628-01 (Johnson), HL096767-01 (Lytle), HL096715-01 (Patrick), HL096720-01 (Svetkey), HL090864 (Wing), and HL090875 (Espeland). All of the trials are registered as clinical trials: NCT01134783 (CHOICES), NCT01092364 (CITY), NCT01331564 (e-MomsRoc), NCT01121871 (IDEA), NCT01200459 (SMART), NCT01183689 (SNAP), and NCT01199185 (TARGIT). The authors would like to acknowledge all of the investigators involved in the EARLY trials and Megan Treziok and Helena Knego for their help with tables and formatting the manuscript.

1. Finkelstein E, Trogdon J, Cohen J, et al. Annual medical spending attributable to obesity: payer-and service-specific estimates. *Health Aff*. 2009; 28(5): w822-w831.
2. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of obesity and trends in body mass index among US children and adolescents, 1999-2010. *JAMA J Am Med Assoc*. 2012; 307(5): 483-490.
3. Finkelstein EA, Khavjou OA, Thompson H, et al. Obesity and severe obesity forecasts through 2030. *Am J Prev Med*. 2012; 42(6): 563-570.
4. Wang YC, McPherson K, Marsh T, Gortmaker SL, Brown M. Health and economic burden of the projected obesity trends in the USA and the UK. *Lancet*. 2011; 378(9793): 815-825.
5. Williamson DF, Kahn HS, Remington PL, Anda RF. The 10-year incidence of overweight and major weight gain in US adults. *Arch Intern Med*. 1990; 150: 665-672.
6. Flegal KM, Carroll MD, Kit BK, Ogden CL. Prevalence of obesity and trends in the distribution of body mass index among US adults, 1999–2010. *JAMA J Am Med Assoc*. 2012; 307(5): 491-497.
7. Lewis CE, Jacobs DR Jr, McCreath H, et al. Weight gain continues in the 1990s: 10-year trends in weight and overweight from the CARDIA study. Coronary artery risk development in young adults. *Am J Epidemiol*. 2000; 151(12): 1172-1181.
8. Ford E, Capewell S. Coronary heart disease mortality among young adults in the U.S. from 1980 through 2002. Concealed leveling of mortality rates. *J Am Coll Cardiol*. 2007; 50: 2128-2132.
9. Jones DS, Greene JA. The decline and rise of coronary heart disease: understanding public health catastrophism. *Am J Public Health*. 2013; 103(7): 1207-1218.
10. Lloyd-Jones DM, Liu K, Colangelo LA, et al. Consistently stable or decreased body mass index in young adulthood and longitudinal changes in metabolic syndrome components: the Coronary Artery Risk Development in Young Adults Study. *Circulation*. 2007; 115(8): 1004-1011.
11. Daviglus ML, Liu K, Pirzada A, et al. Cardiovascular risk profile earlier in life and Medicare costs in the last year of life. *Arch Intern Med*. 2005; 165(9): 1028-1034.
12. Loria CM, Signore C, Arteaga SS. The need for targeted weight-control approaches in young women and men. *Am J Prev Med*. 2010; 38(2): 233-235.
13. Yeh HC, Clark JM, Emmons KE, et al. Independent but coordinated trials: insights from the practice-based opportunities for weight reduction trials collaborative research group. *Clin Trials*. 2010; 7(4): 322-332.
14. Lytle LA, Nanney MS, Laska MN, Linde JA, Sevcik SM, Petrich, CA. Designing a weight gain prevention trial for young adults: the CHOICES study. American Journal of Health Education. 2014; in press.
15. Wing RR, Tate DF, Gorin AA, Raynor HA, Fava JL. A self-regulation program for maintenance of weight loss. *N Engl J Med*. 2006; 355(15): 1563-1571.
16. Bennett LM GH, Levine-Finley S. Collaboration & Team Science: A field guide. 2010.
17. Belle SH, Czaja SJ, Schulz R, et al. Using a new taxonomy to combine the uncombinable: integrating results across diverse interventions. *Psychology Aging*. 2003; 18(3): 396-405.
18. Michie S, Johnston M, Abraham C, et al. Making psychological theory useful for implementing evidence based practice: a consensus approach. *Qual Saf Health Care*. 2005; 14(1): 26-33.
19. Michie S, Ashford S, Sniehotta FF, Dombrowski SU, Bishop A, French DP. A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: the CALO-RE taxonomy. *Psychol Health*. 2011; 26(11): 1479-1498.
20. CARDIA Study. CARDIA III Year 5 (1990–1991): Sociodemographic Questionnaire. CARDIA III Year 5 (1990–1991). Accessed 28 July 2010.
21. Boynton Health Service at the University of Minnesota. College Student Health Survey 2008. http://www.bhs.umn.edu/health-data/surveys. Accessed 28 July 2010.
22. NCI. Diet History Questionnaire: National Cancer Institute. National Institutes of Health; 2007.
23. Nelson MC, Lytle LA. Development and evaluation of a brief screener to estimate fast-food and beverage consumption among adolescents. *J Am Diet Assoc*. 2009; 109(4): 730-734.
24. CITY Study. From formative work/focus group questions. Personal communication with Pao-Hwa Lin ed. August 4, 2010.
25. French S, Jeffery R, Murray D. Is dieting good for you? Prevalence, duration, and associated weight and behaviour changes for specific weight loss strategies over four years in US adults. *Int J Obes*. 1999; 23: 320-327.
26. Linde J, Jeffery R, French S, Pronk N, Boyle R. Self-weighing in weight gain prevention and weight loss trials. *Ann Behav Med*. 2005; 30: 210-216.
27. Raynor D, Phelan S, Hill J, Wing R. Television viewing and long-term weight maintenance: Results from the national weight control registry. *Obes Res*. 2006; 14: 1816-1824.
28. Centers for Disease Control and Prevention. Behavioral Risk Factor Surveillance System Survey Questionnaire. 2009.
29. American Legacy Foundation. National Youth Tobacco Survey 2002 Questionnaire. http://www.legacyforhealth.org/1106.aspx. Accessed 19 August 2010.
30. Radloff LS. The CES-D scale: A self-report depression scale for research in the general population. *Appl Psychol Meas*. 1977; 1: 385-401.
31. Andresen EM, Malmgren JA, Carter WB, Patrick DL. Screening for depression in well older adults: evaluation of a short form of the CES-D (Center for Epidemiologic Studies Depression Scale). *Am J Prev Med*. 1994; 10(2): 77-84.
32. Lytle LA, Pasch KE, Farbakhsh K. The relationship between sleep and weight in a sample of adolescents. *Obesity*. 2011; 19: 324-331.
33. Buysse D, Reynolds C, Monk T, Berman S, Kupfer D. The Pittsburg sleep quality index (PSQI): a new instrument for psychiatric research and practice. *Psychiatry Res*. 1989; 28: 193-213.
34. Centers for Disease Control and Prevention. NHANES 2007–2008. http://www.cdc.gov/nchs/nhanes.htm. Accessed 28 July 2010.
35. Sallis J, Kerr J, Carlson J, et al. Evaluating a brief self-report measure of neighborhood environments for physical activity research and surveillance: Physical activity neighborhood environment scale (PANES). *J Phys Act Health*. 2010; 7: 533-540.
36. Paffenbarger R, Wing A, Hyde R. Physical activity as an index of heart attack risk in college alumni. *Am J Epidemiol*. 1978; 108: 161-175.
37. World Health Organization. Global Physical Activity Questionnaire version 2. http://www.who.int/chp/steps/GPAQ. Accessed February 2010.
38. CARDIA Study. CARDIA VIII, year 25, Sedentary Behavior Questionnaire. E-mail communication with John Jakicic. February 11, 2010.
39. Rosenburg D, Norman G, Wagner N, Patrick D, Calfas K, Sallis J. Reliability and validity of the sedentary behavior questionnaire (SBQ) for adults. *J Phys Act Health*. 2010; 7(6): 697-705.
40. VanWormer J, Martinez AM, Cosentino D, Pronk NP. Satisfaction with a weight loss program: what matters? *Am J Health Promot*. 2010; 24(4): 238-245.
41. Baldwin AS, Rothman AJ, Hertel AW, Keenan NK, Jeffery RW. Longitudinal associations between people's cessation-related experiences and their satisfaction with cessation. *Psychol Health*. 2009; 24(2): 187-201.