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Accumulating Data to Optimally Predict obesity Treatment (ADOPT) Core measures: Behavioral Domain

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Abstract

Background—The ability to identify and measure behaviors that are related to weight loss and prevention of weight regain is crucial to understanding variability in response to obesity treatment and the development of tailored treatments.

Objectives—The overarching goal of the ADOPT Core Measures project is to provide obesity researchers with guidance on a set of constructs and measures that are related to weight control and that span and integrate obesity-related behavioral, biological, environmental and psychosocial domains. This article describes how the behavioral domain subgroup identified the initial list of high priority constructs and measures to be included, and describes practical considerations for assessing the four behavioral areas: eating, activity, sleep and self-monitoring of weight. We also

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discuss challenges and considerations for advancing the science related to weight loss and maintenance behaviors.

Significance—Assessing a set of core behavioral measures in combination with those from other ADOPT domains is critical to improve our understanding of individual variability in response to adult obesity treatment. The selection of behavioral measures is based on the current science although there continues to be much work needed in this field.

Keywords

Obesity; behaviors; measurement; weight loss; weight loss maintenance; individual variability; tailored treatment; personalized medicine

Introduction

The risk of weight gain leading to obesity is determined by myriad and highly complex factors including genetics, biology, psychological factors and the social and physical environments with which individuals interact. These factors influence behavior (defined here as observable patterns or actions that individuals exhibit), and weight-related behaviors are among the most mutable, and therefore, most important factors related to obesity risk. Behaviorally focused interventions are the primary non-pharmaceutical and non-surgical way to treat obesity; therefore, the ability to identify and measure behaviors that are related to weight loss and prevention of weight regain during participation in a behavior change program is crucial to the advancement of obesity treatment.

In the Accumulating Data to Optimally Predict obesity Treatment (ADOPT) Core Measures Project's conceptual model(1) individual behavior is the most proximate domain related to energy intake and expenditure, directly impacting energy balance, weight loss and weight maintenance. Within the behavioral domain, eating behaviors directly impact energy intake, while physical activity and sedentary behaviors directly impact energy expenditure. Sleep duration and timing are coupled to energy metabolism at multiple levels, and affect appetite and hunger, nutrient preference, calorie intake, and overall energy expenditure. In addition to behavior's most proximal relationship to energy intake and expenditure, behaviors can also serve as mediators for factors within other domains impacting energy balance (specifically, environmental, psychosocial and biological domains) and past behaviors related to adherence to obesity treatments including self-monitoring of one's weight are also important behaviors that link the psychosocial and biological domains with other weight-related behaviors. Therefore, assessing behavior is a critical element of understanding individual variability in response to adult obesity treatment.

The overarching goal of the ADOPT Core Measures project is to provide obesity researchers with guidance on a set of constructs and measures that are related to weight control and that span and integrate obesity-related behavioral, biological, environmental and psychosocial domains. The ADOPT project is the first step in creating a research base that can be used to develop more effective, personalized treatment for adult obesity, thereby advancing the state of the science needed to optimize the design and delivery of adult obesity treatments(1). The

behavioral domain subgroup of the ADOPT Working Group was charged with identifying the behaviors that are associated with weight loss and maintenance and to identify a set of high priority constructs and measures to recommend as a starting place for other obesity researchers. The purpose of this paper is to 1) describe the process used by the behavioral domain subgroup to identify the initial list of high priority constructs and measures to be included; 2) describe practical considerations for assessing the four behavioral areas including: eating, activity, sleep and self-monitoring of weight; and 3) discuss challenges and considerations for advancing the science related to weight loss and maintenance behaviors.

Identification of Core Constructs and Measures: Process and insights gained

The charge for the behavioral domain subgroup was to identify and recommend an initial list of behaviorally-related constructs (identified in the ADOPT project as any type of explanatory factor) and measures that may be predictors, mediators, or moderators of adult response to obesity treatment, including maintenance of weight loss after treatment(1). The initial list was to be created considering the strength and source of evidence related to weight loss outcomes or weight-related behaviors, the psychometric quality of the measures, the feasibility of using the measure within a clinical trial, and the participant burden posed by the measure. In addition, the behavioral domain subgroup was to consider what facets of behaviors should be measured as well as consider construct overlap with an intent to recommend a parsimonious list of recommended constructs. The behavioral domain subgroup was made up of obesity researchers with specific expertise in the areas of diet and eating behaviors, activity, and sleep.

This initial step resulted in a list of 19 potential constructs; the next step was for the group to subjectively evaluate each of those constructs based on a set of criteria (Table 1). The working group discussed each proposed construct and measure based on those criteria and worked to reduce the list to include those with the highest priority. As an example, the initial list of possible behavioral constructs included "daily meal patterns". The corresponding measure was a set of questions developed for the Early Adult Reduction of weight through LifestYle intervention (EARLY) trials(2) that asked participants to estimate how many times per week they eat breakfast, lunch, and dinner, mid-morning, mid-afternoon or evening snacks, and eat within an hour of bedtime. The construct was rated high based on its feasibility related to cost and logistics, ease of use with large number of study participants, and modest level of researcher or analytical expertise required to use the measure; however, the quality of the measure, the source of evidence, and the strength of evidence were all rated as modest. The behavioral domain subgroup decided that this construct should not be ranked as a top priority until the psychometric properties of the measure and strength of evidence were demonstrated. Likewise, food frequency questionnaires (FFQ) were not ranked as a top priority even though usual dietary intake is an extremely important weightrelated behavior. FFQs have several important limitations including their ability to only capture information on the foods listed in the questionnaire, potentially resulting in the omission of important dietary patterns across a range of economic, cultural and ethnic

population groups. In addition, validation studies comparing the FFQ and intervieweradministered 24-h multiple pass recalls to doubly labeled water assessments of energy intake(3-6) indicate that the FFQs may underestimate dietary intake to a greater extent than 24 hour recalls and be more susceptible to bias from factors such as participant weight and gender(7, 8). In considering sleep measures to include, overnight polysomnography (PSG) is a gold-standard method for quantifying sleep duration, quality, and breathing difficulty during sleep (e.g., sleep apnea), via use of multiple EEG, EMG and respiratory sensors(9). However, cost, technical requirements of research personnel to collect and analyze the data, and the high burden of performing multiple PSGs during some significant limitations for most population-based trials; therefore, PSG was not included as a high priority construct in ADOPT.

Important insights were gained through this activity, including the realization that a single behavioral measurement tool could sometimes be used to assess multiple constructs. As an example, wrist-worn accelerometers can be used to assess physical activity, sedentary behavior and sleep duration and timing. Obesity researchers can take advantage of these types of multi-use tools, creating efficiency and reducing the costs of their measurement activities. However, while data collection protocol may be the same for all behaviors, protocols for identifying missing data, cleaning data and calibrating data may differ based on the purpose of the data collection, calling attention to the need for highly skilled personnel for analysis of accelerometry data.

In addition, this activity helped the behavioral domain subgroup realize that some of the constructs originally placed in the behavioral domain fit better in another domain. As an example, the behavioral domain subgroup decided that constructs on the original list measuring food preferences, perceptions of satiety and hunger, and appetite are internal judgments or preferences that precede a behavioral response and more accurately represent the psychosocial domain. Therefore, the constructs of "Food Hedonics and Preferences" (as measured with the Leeds Food Preferences Questionnaire(10) and "Subjective Appetite Sensations" (as measured with the Visual Analogue Scales for Appetite measurement(11), the Satiety Quotient(12) or the Three Factor Eating Questionnaire(13) originally in the behavioral domain's list of possible high priority items were all referred to the psychosocial domain subgroup for their consideration.

Practical considerations for assessing each of the four behavioral areas

The result of the behavioral domain subgroup's deliberations was a set of 14 constructs representing four metaconstructs: eating behavior, activity behavior, sleep behavior, and self-monitoring of weight (Table 2). The following section highlights some of the practical considerations for the constructs in each of the behavioral areas.

Eating behavior

Eating behavior refers to foods, beverages and calories consumed as well as usual eating patterns. Eating behaviors, both preceding intervention activities as well as during interventions, have been found to predict weight loss or prevention of weight gain; however, their power to predict change is quite modest (14). Eating is highly complex behavior that

can be considered and assessed through a variety of metrics, including, but not limited to, the intake of calories and nutrients consumed; types and amounts of foods and beverages consumed; source of food (i.e., home versus full service or fast food restaurant); timing and meal patterns related to intake; and the frequency of consuming specific foods and beverages related to obesity risk. Each facet of eating behavior provides different types of information and requires different types of methodology for data collection. While caloric intake is most proximately related to weight gain, difficulties in collecting unbiased energy intake information are well known(3, 5, 7) and have led to an examination, testing, and use of food intake and dietary patterns as proxies for diet-related obesity risk.

The constructs included under eating behavior include: usual dietary intake; overall diet quality as measured with the healthy eating index; eating away from home; and sugar sweetened beverage consumption (SSB).

Usual Dietary Intake—An assessment of usual dietary intake is an attempt to identify the foods and beverages one consumes, the quantity consumed, and the methods used to prepare those foods over a prescribed period of time for the purpose of assessing energy and nutrient intake and the quality of one's usual diet. Assessing usual dietary intake is critically important in weight loss studies since negative energy balance is required for weight loss; likewise, weight maintenance requires caloric intake to be in balance with energy expenditure. In addition, many dietary interventions attempt to modify the nutrient content of the diet or the proportion of calories coming from energy-contributing nutrients, such as consuming more protein or fewer carbohydrates to assist with weight loss(15-17).

The behavioral domain subgroup recommends that usual dietary intake be collected using interview-assisted, multiple pass, 24-hour recalls. Several studies and meta analyses indicate that, while all dietary methodology is susceptible to error, the 24-h recall method may be the most accurate available currently (18, 19). In spite of its limitations, we recommend the use of 24-hour recalls until more accurate methods that are feasible in RCTs are available. Furthermore, 24-h recall data can be used to calculate a Healthy Eating Index (HEI) score(20). At least three recalls are recommended with at least one recall representing intake on a weekend day(21). The preferred protocol for a 24-h dietary recall involves a 5step multiple-pass approach, and recalls are conducted in person or by telephone. Each recall takes approximately 20 minutes to administer. Recall data are entered into software that links with a nutrient database for automated food coding. The behavioral domain subgroup recommends an interviewer assisted recall rather than the self-administered web-based such as the ASA 24(22). While using a self-administered 24h recall provides savings with data collection costs, more frequent missing data and the inability to query missing or unreasonable data entered by the respondent are significant drawbacks. Participant burden is a relatively minor issue for the interviewer-administered 24-h recall but this method is relatively expensive to conduct as it requires well trained interviewers and sophisticated nutrition software. Because the process of administering the recall is highly specified and because data coding, particularly how missing data are handled, can influence the reported nutrients, formal training or consultation with a research center experienced in the methodology is highly recommended.

Overall Dietary Quality—The Healthy Eating Index-2010 (HEI-2010)(23) is a dietary quality index that is based on federal dietary guidelines including the 2010 Dietary Guidelines for Americans and the USDA Food Patterns. The HEI-2010 includes 12 components, 9 of which assess adequacy of the diet, including 1) total fruit; 2) whole fruit; 3) total vegetables; 4) greens and beans; 5) whole grains; 6) dairy; 7) total protein foods; 8) seafood and plant proteins; and 9) fatty acids. Refined grains, sodium, and empty calories (i.e., energy from solid fats, alcohol, and added sugars) make up the other three components and assess dietary components that should be consumed in moderation. Higher scores of the HEI-2010 reflect better diet quality because the moderation components are scored such that lower intakes receive higher scores. The scores of the 12 components are summed to yield a total score, which has a maximum value of 100. The HEI-2010 has been shown to have good internal consistency (alpha=0.68) and to have good construct and concurrent criterion validity (19). However, construct validity between HEI scores and total energy intake has not been demonstrated likely due to the lack of estimates of quantities of foods consumed(20). However, HEI scores have been shown to be related to weight loss and are also sensitive to change(24-26) and, therefore, useful to collect in obesity intervention studies. An HEI score can be calculated from the information collected from the recalls (self-administered or interviewer administered) or from some food frequency questionnaires.

Eating Away from Home and Consumption of sugar-sweetened beverages-

Eating away from home and the consumption of sugar-sweetened beverages are two constructs representing behavioral patterns of eating that have been associated with obesity risk. **Eating away from home**, particularly eating at fast food restaurants, has been associated with obesity risk in adults and is likely due to the fact that highly affordable fast food tends to be energy dense, poor in micronutrients, low in fiber, high in glycemic load and excessive in portion size (23). A systematic review of the literature examining crosssectional, longitudinal and experimental studies showed good evidence for a cross sectional and longitudinal relationships between fast food consumption and body mass index in adults(27). As an example, in a prospective cohort study following adults for fifteen years, those who consumed fast food frequently regularly gained an extra 4.5 kg of body weight compared with those who reported infrequent consumption(28).

Likewise, the consumption of **sugar-sweetened beverages** (**SSB**) has consistently been shown to be associated with obesity risk and is likely due to the added sugar content, low satiety, and incomplete compensation for total energy with fluid intake. In a review of the literature, Malik et al (2013) identified 32 original articles that examined the association between the consumption of sugar sweetened beverages and weight gain through prospective cohort or randomized control trials; twelve of these reported on studies with adults. In both cohort and randomized control trials, intakes of SSB were shown to have a direct relationship with weight gain. The authors conclude that there is substantial evidence for an association between the consumption of SSB and obesity risk(29).

The measures for the constructs of eating away from home and consumption of SSB are both self-reported. Although such information can be collected as part of a 24-hour recall protocol, these consumption patterns may not occur every day and may be missed using recalls. Therefore, the use of questionnaires to assess these constructs is desirable since

questionnaires can ask about usual intake that might include the last week or last month. The recommended questionnaires are relatively short (6 questions or less), require minimal time for the respondent to complete, and require minimal study resources to enter the data and create variables. The measures recommended for both eating away from home and consumption of SSB have been used in randomized control trials with multiple data points(30, 31).

Physical activity and sedentary behavior

There is evidence that physical activity is related to modest weight loss in addition to what is achieved with modest dietary restriction, and there is evidence of weight loss with physical activity even without dietary restriction(32, 33). The magnitude of weight loss achieved may occur in a dose-response manner based on the magnitude of physical activity performed(33). Moreover, there is consistent evidence that physical activity is associated with improved weight loss maintenance(33) and the primary prevention of weight gain(34, 35). Within the spectrum of physical activity, sedentary behavior has become an important consideration for a variety of health-related outcomes. Considering body weight, there are inconsistent relationships reported, with some studies reporting an association between sedentary behavior and weight loss(14, 32) and others not reporting this association(36).

Physical Activity (PA) and sedentary behavior (SB) may be measured objectively using devices such as **actigraphy** (also referred to as **accelerometry**) or by self-report using validated questionnaires. With regard to objective monitoring of SB, using a device that allows for the assessment of posture will permit assessment of SB based on the accepted definition that the individual be in a seated or reclined position. Whenever possible, objective measurement of PA and SB should be conducted; however, particular study designs and applications may make the use of objective monitoring logistically or financially unfeasible. Moreover, objective monitoring techniques such as actigraphy do not provide information on specific categories of physical activity that one may be engaging in (i.e., housework, transportation, or recreational activities such as team sports). As this type of categorical, self-report information provides additional insight that could be used for development of tailored interventions the use of both self-report techniques and actigraphy should be considered, if time and resources permit.

Objective measurement of physical activity involves the use of devices that assess human motion through acceleration, with more contemporary devices incorporating inclinometers to assess body positioning. These devices have become more widely used in research, with actigraphy being the most widely used form of objective monitoring. Actigraphs are worn on the hip, wrist, or thigh for a period of time that is representative of typical physical activity and sedentary behaviors, typically a period of 4-7 days in succession. Note that wrist-worn actigraphy can also assess sleep behaviors (see below). Additional instructions specify situations when the device can be removed to optimize data collection and to minimize damage to the device (e.g., during water-based activities should the device not be water resistant). Research grade, as opposed to consumer-based devices, limit the participant's ability to obtain feedback on their physical activity and sedentary behavior from the device, which is critical for assessment of physical-activity-related behavioral outcomes. In addition

to limiting recall bias, actigraphy can also provide more precise information on patterns of physical activity, which enhances the value of using objective monitoring within the context of understanding this important area human behavior. Challenges for the use of actigraphy include cost (devices typically cost between \$100-\$500 per unity, plus costs for additional required software or hardware), participant burden (remembering to wear and return the devices to the research team), and staff burden (issuing and activating the device and assuring that devices are collected post-wear). Specific analytical expertise of these data is also required for actigraphy.

Several self-report measures are also recommended, including the Global Physical Activity Questionnaire (GPAQ)(37-39), the Paffenbarger Exercise Habits Questionnaire(40), and a sedentary behavior questionnaire developed by the EARLY consortium (Early Adult Reduction of weight through LifestYle intervention (EARLY) Trials(2). In general, the GPAQ was recommended because it is useful for assessing a variety of domains of physical activity, including occupational physical activity, transport-related physical activity, and physical activity during discretionary or leisure time as well as time spent in sedentary behaviors. The Paffenbarger Exercise Habits Questionnaire is a frequently used tool that focuses specifically on moderate-to-vigorous physical activity, including common activities such as stair climbing and walking, along with other sport, fitness, or recreational activities that occur during leisure-time. Both of the GPAQ and Paffenbarger questionnaires are validated tools that have been widely used in adults throughout the age spectrum in many cross-sectional and interventional clinical studies. The EARLY sedentary behavior questionnaire, modified from a questionnaire developed for the CARDIA Study (Coronary Artery Risk Development in Young Adults)(41) with additional questions added to include contemporary forms of sedentary behavior, was developed with young adults in mind; however, most of the queried sedentary behaviors likely apply to the majority of adults. At a minimum, studies that are unable to collect actigraphy data should assess PA and SB with the GPAQ; however, if time and resources permit, use of all three questionnaires is recommended. These questionnaires are publicly available and at no cost to investigators for use in research studies. Scoring algorithms are available and do not require extensive expertise for data analysis(42).

To obtain the most comprehensive perspective of PA and SB a combination of objective monitoring, GPAQ (to assess time each of the domains of physical activity), the Paffenbarger Questionnaire (to assess specific forms of leisure-time physical activity), and the EARLY Questionnaire (to assess types of SB) should be used when sufficient time and resources are available. At a minimum, however, it is recommended that objective monitoring be used and combined with at least one of these questionnaires, with the questionnaire chosen based on the specific domain of interest to the investigator within the context of the research that is being conducted.

The contribution of physical activity to total daily energy expenditure can also be represented by the Physical Activity Level (PAL), which has been recommended by the ADOPT Biological domain subgroup. The PAL is computed as: PAL = total daily energy expenditure/resting energy expenditure. Thus, because the GPAQ or actigraphy may provide a measure of total daily energy expenditure, it is possible to compute an estimate of the PAL

if a measure or estimate of resting energy expenditure is also available. Future research could explore whether any of the methods recommended provide a valid and reliable measure of the PAL, which may inform which of these methods if preferred and thereby reducing the number of activity measures that are included in research studies.

SLEEP BEHAVIOR

An accumulation of evidence demonstrates that insufficient sleep duration and timing are associated with obesity, and that chronic sleep restriction mediates important aspects of energy balance, including hunger and appetite, calorie intake, glucose/lipid metabolism, cellular nutrient sensing, and the ability to reduce fat mass in response to weight loss intervention(43-45). Recent studies indicate that the timing of meal consumption in relation to sleep phase is also an important factor for weight regulation(46). Therefore, an assessment of sleep duration and timing may contribute important behavioral phenotype and mechanistic information for predicting the ability to lose or maintain weight loss in obesity trials.

Wrist-worn actigraphy is a wearable technology recommended as an objective surrogate measure of sleep duration and timing. For sleep monitoring, actigraphs are normally worn on the non-dominant wrist for a minimum of 7 days, but can be used for longer periods of data collection. A variety of actigraph devices are available, each applying a particular algorithm to activity count data, to determine when an individual is asleep or awake(47). Actigraphy is validated against gold-standard PSG technology for determining overall sleep duration and timing, however, may be less accurate at identifying specific sleep stages (e.g., light non-rapid eye movement (NREM), slow wave sleep, REM). Advantages of actigraphy include the relative ease of collecting many nights/days of reliable sleep/wake data in a participant's natural environment. When actigraphy is used to evaluate sleep duration and timing, the additional use of sleep questionnaires is not required, unless other aspects of sleep need to be obtained (e.g., self-reported daytime sleepiness, insomnia, sleep apnea symptoms, circadian rhythm chronotype), or unless there is a specific objective to evaluate the association between objective and self-report sleep data. Challenges of actigraphy for sleep assessment are similar to those described for physical activity (see above), including cost, participant and research staff requirements related to device use and tracking, and some level of technical expertise of research staff to obtain and analyze the data.

Sleep duration and timing also can be estimated based on participant self-report. For example, the Munich Chronotype Questionnaire (MCTQ)(48, 49) is recommended as a self-report instrument for adults, providing data on usual sleep duration and timing on both weekdays and weekends, individual chronotype (i.e., morning or evening preference), and the degree to which one's chronotype differs from actual sleep timing (i.e. circadian misalignment). The MCTQ allows for multiple sleep/circadian phenotypes to be derived from a relatively short set of questions, with low cost, low participant burden, and moderate analytic requirements. Self-reported sleep duration is generally less accurate compared to objective measures (e.g., actigraphy, PSG), however, is still widely used in clinical research due to feasibility and for use in examining sleep deficiency-related risks. A common approach is to stratify sleep duration into categories, e.g., short (<6 hrs.), normal (7-9 hrs.),

and long (>9 hrs.) sleep, rather than analyze hours and minutes of sleep on a continuous scale. The decision to use an objective (e.g., actigraphy) vs. self-report (e.g., MCTQ) measure to evaluate sleep will depend on multiple factors, including cost, feasibility, and research and analytic objectives of the obesity trial. Of course, both methods can be used in combination, which would ultimately maximize data harmonization across multiple obesity trials.

Sleep disordered breathing is a prevalent co-morbidity of obesity, associated with daytime sleepiness, impaired neurocognitive performance and mood, altered nutrient metabolism, and increased risk of obesity-related cardiovascular disease(50). The Berlin Sleep Apnea Questionnaire is a recommended self-report instrument to evaluate sleep apnea risk via the presence of core symptoms, such as snoring, gasping for air during sleep, and daytime sleepiness(51). While sleep apnea has not been investigated as an effect modifier of obesity intervention, the high prevalence and overlap with obesity-related risks suggests its potential importance for research to evaluate apnea in the context of weight loss and maintenance interventions.

Self-monitoring of weight

The act of self-monitoring likely reflects an individual's motivation to lose or maintain their weight and provides feedback on the individual's recent attempts to modify weight-related behavior. Self-monitoring of weight consistently has been shown in RCTs and longitudinal studies to predict weight loss, weight gain prevention, and positive response to treatment(52, 53). The EARLY Self Weighing Questionnaire is a 2-item screener that asks about frequency of self-weighing and access to a bathroom scale. It requires minimal burden for the participant and the researcher.

Limitations and future directions

Measuring behavior objectively, with sufficient frequency and duration at a reasonable cost and with low participant and study burden, is one of the greatest challenges that we have in obesity research. At present, choices in assessing behavior are limited to 1) direct observation of behaviors by research staff; 2) report of behaviors of research participants by others in their environment (for example, parents reporting on their children's behaviors); 3) self-report of behaviors by research participants; or 4) using data collected in an objective manner in real time. To date, the only measurement tool that we have that collects objective behavioral data in real time is actigraphy, which can assess physical activity, sedentary time, and sleep duration and timing. As previously mentioned, some of these approaches are not feasible in population-based studies and these approaches carry significant challenges and limitations.

At present, the majority of behavioral measures are collected using self-report tools and such tools suffer from a range of problems that include missing data (as respondents forget to record some aspect of their behaviors, particularly habitual behaviors) as well as biased reporting (as respondents misreport their behaviors either purposefully or unintentionally). Therefore, self-report data typically include both random error as well a potential systematic bias. The reliance on self-report remains a particular concern for measures of dietary intake

and eating behavior. Energy intake is a construct that is directly related to energy balance and weight gain but numerous studies have demonstrated that self-report tools to assess intake, including food frequency questionnaires, 24 hour recalls, and food records and diaries, provide biased estimates of caloric intake(3, 5, 7). While doubly-labeled water can provide unbiased estimates of caloric intake(7), the cost and data collection-related burden of using doubly labeled water makes it unfeasible for larger, population based studies.

The use of technology to assess dietary intake is in its infancy. While commercial diet apps have been developed and promoted for monitoring dietary intake, they still rely on the user to input data about what they have consumed. Therefore, while technology may facilitate the data entry and feedback, diet apps are a form of food record and still rely on self-report. In addition, app developers may or may not fully document the source of food composition data and their algorithms making it difficult for obesity researchers to fulling understand the data obtained. Technology-based approaches to more objectively assess dietary intake are being developed that include the use of camera-phone based methods or wearable video cameras that record foods and beverages consumed in real time(54-56). However, there is much to be learned about the potential bias that comes with these methods including whether the use of such devices impact intake. In addition, unless users can enter or annotate dietary intake, the technology will not provide the ability to accurately assess the composition of the foods or beverages consumed (for example, a photo of food provides no information on the fat content of the meat or whether the beverage consumed was a regular soda or diet soda). Camera-phone based methods are equivalent to a food record, and are subject to the same biases. While video may be the most objective if the camera is always on, the processing of video data is difficult to automate and concerns regarding privacy exist(55). Therefore, even with camera-based methods to record intake in real time, inaccurate caloric and nutrient assessment will still likely be a problem. The field is still far from having good solutions to these important problems and much more research is needed in order to have a valid and cost-effective measure of energy intake.

Another challenge with self-reported behavioral measures is determining and adapting the time frame to be queried. For behaviorally-based obesity research, a key goal is assessment of usual patterns (rather than infrequent behaviors) of eating, activity and sleep over time as it is habitual behaviors that impact weight. Often, self-report measures are challenged by a lack of clear guidance on what time period should be queried to represent 'usual' behavior. As an example, early work in nutritional epidemiology provided guidance on the number of days of dietary recalls that were needed to assess an individual's usual intake of nutrients; fewer days of recalls were needed to get an estimate of typical macronutrient intake that did not vary as much within individuals (for example, carbohydrates, protein, fat) but many more days were needed to get an estimate of micro nutrients that may vary greatly within the individual based on specific food intake (for example, Vitamin D intake)(57, 58). We have little guidance of the timeframe to query to understand "usual" eating patterns such as usual consumption of sugar sweetened beverages or fast food and those estimates may vary by population groups (for example, young adults versus older adults). Nutritional epidemiologic work is needed across population groups to help determine the time frames to query to characterize usual behavior.

The frequency with which to collect behavioral data is also a consideration. Collecting behavioral data throughout the trial would help researchers understand how behaviors may change during weight loss treatment and also provide more information on how behavior change mediates weight change. A consideration of the crucial times to assess behaviors is important and likely includes data collection at baseline, immediately following the intense intervention period, after booster sessions and at a follow-up period. However, the increased frequency of data collection needs to be balanced with the additional costs of data collection, data coding and analysis as well with response burden.

Construct overlap also needs to be considered. Multiple measures may be used to assess the same construct and doing so may have advantages. For example, a researcher may choose to use a questionnaire as well as using actigraphy to assess sleep duration at one or more assessment periods. Including multiple measures that assess the same construct to test associations with weight loss may enhance the robustness of findings, providing evidence that the effect of the intervention on sleep duration was strong enough to be seen across different measures. In addition, the use of multiple measures to assess the same construct may provide an opportunity for an assessment of criterion validity, e.g., establishing the relationship between a more objective measure of sleep duration (e.g., actigraphy) and a self-report measure of sleep duration (e.g., MCTQ). By establishing that the sleep questionnaire has good criterion validity, the researcher may have more confidence in using a self-report questionnaire for additional data points during the study. However, there is little guidance on the associations to be expected when different tools are used to assess the same construct; for example, how large would we expect the association between sleep duration as measured via actigraphy and self-report to be across different populations of participants (e.g., race/ethnicity, age, gender, disease condition)? How do different measurement tools differ on estimates predicting changes in sleep duration over time (e.g., actigraphy pre- and post-obesity intervention) or in predicting weight loss/maintenance in obesity trials?

Conclusions

The ADOPT project begins the important step of providing guidance for obesity researchers on the factors and constructs that are related to weight loss and weight loss maintenance and suggests ways to measure those constructs (MacLean et al, submitted). This is a first step in the process and dialogue between obesity researchers and emerging evidence will guide future decisions about important constructs to consider and measures to be used. These constructs and measures will continue to evolve and improve as our science and methods become more sophisticated. Also, inherent in this process is the recognition that each obesity researcher will need to balance their use of these recommendations with the resources available to them and the specific goals of their research.

Importantly, ADOPT attempts to provide guidance across multiple domains with the realization that successful weight loss and weight maintenance requires attention to the biological, behavioral, environmental and psychosocial factors that impact weight regulation. Working through the process of identifying the core set of constructs and measures with a group of obesity researchers approaching the problem using different lenses was both challenging and exciting. We were challenged to sift through the many factors that

are considered important in obesity treatment to identify those that, currently, are most robust in predicting response to treatment. Through the process we needed to justify our assumptions about the constructs and measures that we typically use as well as have an eye toward being parsimonious in our selection of high-priority constructs and measures. More is not always better; suggesting more data to be collected typically reduces the time, energy and resources that can be used to enhance and be innovative in our intervention approaches.

The ADOPT project also helped clarify the need for interdisciplinary collaboration. It is impossible for a single researcher to be an expert in all the aspects of measurement related to weight-related eating, activity and sleep behaviors much less be an expert on all of the biological, psychosocial and environmental factors that contribute to obesity risk. To enhance the success in weight loss and weight maintenance programs embracing the need for interdisciplinary collaboration will be vitally important.

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What is already known about this subject?

- The risk of weight gain leading to obesity is determined by myriad and highly complex factors that influence weight-related behaviors.
- Eating behaviors directly impact energy intake, and physical activity and sedentary behaviors directly impact energy expenditure. Sleep duration and timing affect both energy intake and energy expenditure.
- The ability to identify and measure key behaviors that are related to weight loss and prevention of weight regain is crucial to understanding variability in response to obesity treatment and the development of tailored treatments.

What does our study add?

- The ADOPT Core Measures Project recommends an initial list of common core behavioral constructs and associated measures related to eating, activity, sleep, and self-monitoring of weight, which could be feasibly employed in weight loss trials.
- The high priority measures suggested in this project hope to significantly enhance the value of future studies by facilitating the integration of multiple data sets to deepen our understanding of the individual variability in obesity treatment responses.
- The consistent use of ADOPT Behavioral Domain core measures in adult weight loss trials, along with measures from biological, environmental, and psychosocial domains, could help to identify predictors of treatment responses and inform tailored interventions.

Table 1

Metrics used to help identify high priority constructs and measures for the Behavioral Domain

Importance or impact of the construct: a subjective assessment of the importance of the construct in increasing the understanding of behavioral factors and their association with weight loss or maintenance

<u>Potential role of the construct</u>: an assessment of how the construct has previously been used in the analysis for weight change or maintenance research; specifically, has the construct been used as a predictor, moderator, mediator or for multiple analytic purposes?

Quality of measure: the extent to which the psychometric properties (including estimates of reliability and validity) of the constructs are reported in the literature and the robustness of the properties within and across studies

<u>Source of evidence</u>: the types of weight loss or maintenance studies that have used the construct. Randomized control trials (RCTs) with a weight-related primary outcome provide the strongest evidence for using the constructs; followed by RCTS with weight-related behaviors as the primary outcome; followed by longitudinal studies using weight or weight-related behavioral outcomes; followed by cross-sectional studies with weight or weight-related behavioral outcomes. Studies that posit a theoretical relationship (T) between the construct and weight or a weight related outcome but with no empirical evidence provide the weakest evidence.

<u>Strength of evidence</u>: a subjective rating of the strength of the evidence for the construct including considerations of effect size between the construct and the weight related outcome, the robustness of the associations found and the extent to which associations have been replicated across studies.

<u>Feasibility-Researcher expertise</u>: a subjective rating of the need for specialized training for researchers using the measure, including specialized training related to data collection or data analyses

<u>Feasibility-Cost and logistics</u>: a subjective rating of the cost (including financial, specialized training for staff required, participant burden) and the logistics (including measurement schedule required, special equipment or space needs, special needs to maximize participant participation such as transportation or child care)

Suitable study size: an estimate of the how many participants are required in the sample (large study-(>200 participants; medium study-100–200 participants; or small study-<100 participants) for a meaningful estimate of the construct being measured

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Table 2

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Behavioral Core Measures

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CARDIA/EARLY ² Questionnaire Self-administered 16 10 minutes Conduct at baseline and repeat after conclusion of intensive intervention phase, and every 3–6 months Actigraphy Wearable device N/A- miniuum 7 days, worn Conduct at baseline and repeat after conclusion of intensive intervention phase, and every 3–6 months Munich Chronotype Questionnaire (MCTQ) Self-administered 31 10 minutes Conduct at baseline and repeat after conclusion of intensive intervention phase. Berlin Questionnaire for Sleep Apnea Self-administered 6-10 5 minutes Conduct at baseline and repeat after conclusion of intensive intervention phase. EARLY Self Weighing Questionnaire Self-administered 2 2 minutes Conduct at baseline and repeat after conclusion of intensive intervention phase.	Sedentary Behavior	Global Physical Activity Questionnaire	Self-administered	21	10 minutes	Conduct at baseline and repeat after conclusion of intensive intervention phase, and every 3–6 months	Questionnaire, regular programmer	IJ
Actigraphy Wearable device N/A- minimum 7 days, worn phase, and every 3-6 months Monter at baseline and repeat after conclusion of intensive intervention phase, and every 3-6 months Munich Chronotype Questionnaire (MCTQ) Self-administered 31 10 minutes Conduct at baseline and repeat after conclusion of intensive intervention phase Berlin Questionnaire for Steep Apnea Self-administered 6-10 5 minutes Conduct at baseline and repeat after conclusion of intensive intervention phase EARLY Self Weighing Questionnaire Self-administered 2 2 minutes Conduct at baseline and repeat after conclusion of intensive intervention phase	Sedentary Behavior	CARDIA/EARLY ² Questionnaire	Self-administered	16	10 minutes	Conduct at baseline and repeat after conclusion of intensive intervention phase, and every 3–6 months	Questionnaire, regular programmer	Γ
ActigraphyWearable deviceN/A-minimum 7 days, worn continuouslyConduct at baseline and repeat after conclusion of intensive intervention phase, and every 3–6 monthsMunich Chronotype Questionnaire (MCTQ)Self-administered3110 minutesConduct at baseline and repeat after conclusion of intensive intervention phaseBerlin Questionnaire for Sleep ApneaSelf-administered6–105 minutesConduct at baseline and repeat after conclusion of intensive intervention phaseEARLY Self Weighing QuestionnaireSelf-administered22 minutesConduct at baseline and repeat after conclusion of intensive intervention phase	Sleep behavior							
Munich Chronotype Questionnaire (MCTQ) Self-administered 31 10 minutes Conduct at baseline and repeat after conclusion of intensive intervention phase Berlin Questionnaire for Sleep Apnea Self-administered 6–10 5 minutes Conduct at baseline and repeat after conclusion of intensive intervention phase EARLY Self Weighing Questionnaire Self-administered 2 2 minutes Conduct at baseline and repeat after conclusion of intensive intervention phase	Sleep Duration	Actigraphy	Wearable device	- W /N	minimum 7 days, worn continuously	Conduct at baseline and repeat after conclusion of intensive intervention phase, and every 3–6 months	Actigraphs, software, analyst	Γ
Berlin Questionnaire for Sleep Apnea Self-administered 6–10 5 minutes Conduct at baseline and repeat after conclusion of intensive intervention phase - - - - 2 - <td< td=""><td>Sleep Duration and Timing</td><td>Munich Chronotype Questionnaire (MCTQ)</td><td>Self-administered</td><td>31</td><td>10 minutes</td><td>Conduct at baseline and repeat after conclusion of intensive intervention phase</td><td>Questionnaire, regular programmer</td><td>C</td></td<>	Sleep Duration and Timing	Munich Chronotype Questionnaire (MCTQ)	Self-administered	31	10 minutes	Conduct at baseline and repeat after conclusion of intensive intervention phase	Questionnaire, regular programmer	C
EARLY Self Weighing Questionnaire Self-administered 2 2 minutes Conduct at baseline and repeat after conclusion of intensive intervention phase, and every 3–6 months	Sleep Disorders (Sleep Apnea)	Berlin Questionnaire for Sleep Apnea	Self-administered	6-10	5 minutes	Conduct at baseline and repeat after conclusion of intensive intervention phase	Questionnaire, regular programmer	C
EARLY Self Weighing Questionnaire Self-administered 2 2 minutes Conduct at baseline and repeat after conclusion of intensive intervention phase, and every 3–6 months	Self-monitoring							
	Self-Weighing Behavior	EARLY Self Weighing Questionnaire	Self-administered	2	2 minutes	Conduct at baseline and repeat after conclusion of intensive intervention phase, and every 3–6 months	Questionnaire, regular programmer	RCT

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/RCT=Randomized Control Trial; C=Cross-sectional; L=longitudinal

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