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Accumulating Data to Optimally Predict obesity Treatment (ADOPT) Core Measures: Psychosocial Domain

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Abstract

Background—Within the *Accumulating Data to Optimally Predict obesity Treatment (ADOPT) Core Measures* project, the psychosocial domain addresses how psychosocial processes underlie the influence of obesity treatment strategies on weight loss and weight maintenance. The subgroup for the psychosocial domain identified an initial list of high-priority constructs and measures that

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ranged from relatively stable characteristics about the person (cognitive function, personality) to dynamic characteristics that may change over time (motivation, affect).

Objectives—In this paper, we describe (a) how the psychosocial domain fits into the broader model of weight loss and weight maintenance as conceptualized by ADOPT; (b) the guiding principles used to select constructs and measures for recommendation; (c) the high priority constructs recommended for inclusion; (d) domain-specific issues for advancing the science; and (e) recommendations for future research.

Significance—The inclusion of similar measures across trials will help to better identify how psychosocial factors mediate and moderate the weight loss and weight maintenance process, facilitate research into dynamic interactions with factors in the other ADOPT domains, and ultimately improve the design and delivery of effective interventions.

Keywords

psychosocial; weight loss; weight loss maintenance; individual variability; tailored treatment; personalized medicine

Approximately 2/3 of adults in the United States are actively trying to manage their weight either through losing weight or maintaining the same weight (1). Despite this widespread effort to achieve a healthier weight, intervention strategies have had limited success in producing long-term weight loss and maintenance (2). There is also tremendous variability in treatment response, with many treatments effective for some individuals but not others (3). Weight loss/maintenance is the result of a complex web of influences and processes that include psychosocial, biological, behavioral and environmental factors. These pathways are often studied in isolation, but as the ADOPT Core Measures project makes clear (4), understanding how processes within and across these domains interact is critical to identifying targets for treatment and how, when, and with whom to intervene to achieve the greatest success.

The long-term objective of the ADOPT project is to better understand the factors that contribute to individual variability in response to obesity treatment to enable more effective interventions that can be targeted and tailored to the individual. As a step toward this long-term goal, the short-term objectives are to integrate behavioral, biological, environmental, and psychosocial factors into an overarching framework for treatment response, develop an initial list of core constructs¹ within each domain that are critical to the process, and to identify the best measures of these constructs for recommendation for use in weight loss trials. This paper reports the recommendations of the psychosocial domain subgroup of the ADOPT Working Group.

It has long been recognized that psychosocial factors play a role in the effectiveness of obesity treatment. The ADOPT effort seeks to capitalize on this knowledge and address previous limitations, including the need to target similar constructs across studies; use consistent, well-validated measures; and examine these constructs in conjunction with

¹For the purposes of this paper, the word “construct” is used to identify mechanisms, processes, and psychological concepts broadly used and accepted in the research community and defined operationally so they can be tested.

constructs from other domains. In the following sections, we describe (a) the *role of the psychosocial domain* in weight loss and weight management; (b) the *guiding principles* used to select constructs and measures for recommendation; (c) the *initial high priority constructs* recommended for inclusion; (d) *domain-specific issues* for advancing the science; and (e) *recommendations* for future research.

Role of the Psychosocial Domain

In the ADOPT process-oriented model of treatment for weight loss (4), constructs within the psychosocial domain are hypothesized to serve at least one of three functions: predictor, mechanism (i.e., mediator), or moderator. A process-oriented approach, as operationalized by ADOPT, seeks to explicitly model and test the pathways through which these factors lead to successful treatment. As a *predictor*, psychosocial factors are associated with weight loss and weight maintenance, an association that is mediated through behavior or biology. In most cases, predictors will be constructs measured at baseline that predict treatment outcome, regardless of whether the construct changes due to the intervention. Psychosocial factors may also serve as a *mechanism* through which an intervention is effective. Interventions are often designed to target and change specific psychosocial inputs to, in turn, change the behavior that will have a direct effect on weight. For example, self-efficacy is a frequently studied target for treatment that has the potential to trigger a cascade of behaviors leading to weight loss: increasing self-efficacy increases healthy behaviors (e.g., diet, physical activity) that over time lead to successful weight loss (5). A distinction can be made between predictors and mechanisms: psychosocial predictors are constructs that predict treatment outcomes but do not necessarily change as a result of the intervention, whereas psychosocial mechanisms are changes in constructs that contribute to outcomes. It is important to note that a construct can be both a predictor at baseline and a mechanism through which changes in the construct mediate weight loss. For example, higher perceived stress at baseline may predict worse treatment outcomes (predictor), whereas declines in perceived stress in response to treatment may lead to better outcomes (mediator). Finally, factors within this domain may also serve as *moderators* of intervention effectiveness. Just as specific intervention strategies may be more effective for men than women (6), certain interventions may be more effective based on aspects of the individual's psychosocial functioning. Tailored interventions for physical activity based on an individual's motivation, for example, may be more effective for those who show enjoyment toward physical activity at baseline (7). Consistent with a precision medicine approach (8), identifying what type of intervention works best based on psychosocial functioning is critical for applying the most effective treatment approach. Theoretically, nearly all of the identified constructs in the psychosocial domain could operate as predictor, mechanism, and moderator. More extensive datasets generated through the ADOPT approach will help to better identify the specific functions the recommended psychosocial constructs are most likely to serve.

Guiding Principles

The psychosocial domain offers a rich range of constructs to explore individual differences in response to treatment. The inclusion of the same constructs/measures across interventions permits comparisons and will help identify constructs most important for effective

interventions. Since we rarely have the benefit of direct comparisons between constructs, it is expected that this initial list will be refined by the scientific community over time, and these recommendations should not limit investigators to only these constructs/measures.

Construct selection—Constructs were selected based on their hypothesized relevance to weight loss/maintenance and the strength of the current empirical evidence. A construct would ideally be rooted in a theoretical model of processes that underlie weight loss/maintenance and be grounded in evidence of its utility from randomized controlled trials (RCT) of weight loss interventions. Constructs with evidence of predictive validity from either weight loss/maintenance trials or trials that targeted key behaviors implicated in weight loss (e.g., diet, physical activity) were thus selected for inclusion. Some constructs within this domain, however, have a strong theoretical basis for weight loss/maintenance but have not yet been tested in an RCT (e.g., ‘wanting’/‘liking’). Theoretically meaningful constructs with robust evidence from longitudinal studies of body weight and relevant behaviors were also prioritized.

Measure selection—We used another set of guiding principles to evaluate and select candidate measures. Reliability (e.g., test-retest, internal consistency) and validity of the measure were the primary considerations; after that, measures were selected to minimize participant and researcher burden. To reduce participant burden, we prioritized shorter scales that retained strong psychometric properties. Likewise, when possible, measures that are available publicly were chosen over measures under copyright or otherwise proprietary to help minimize cost to the investigator and maximize availability. We also considered ease of administration and scoring. For example, constructs measured with specific tasks may be preferable under some circumstances, but the expertise required to administer and score the task correctly makes it difficult to implement broadly in trials. As such, the self-report measure of a construct was chosen when there was a choice between a psychometrically-sound measure compared to a complex task that would challenge feasible implementation within a clinical trial. There is the expectation, however, that content experts (e.g., researchers knowledgeable about the construct and the scale used to measure it, such as individuals who have published on the construct) need to be consulted to aid with interpretation.

It is important to note that each of the ADOPT domains is not rigidly defined and thus constructs could easily fall into more than one domain. Some eating-related behaviors, for example, include both engagement in the specific behavior and psychological antecedents that are a significant part of the behavior and thus could be placed in either the behavioral domain or the psychosocial domain. Constructs such as perceptions of satiety and hunger, for example, involve internal judgments (psychological) and actions based on those judgments (behavioral). Likewise, the underlying drivers of specific behaviors, such as binge eating, are often psychological in nature. These constructs were placed within the psychosocial domain due to their psychological antecedents. There were also constructs that could be considered within the psychosocial domain that were placed within another domain. Most notably, social support and related social constructs (e.g., social norms) that capture aspects of the individual’s social environment were included under the

environmental domain. These constructs could have been included as part of the psychosocial domain but were placed in the environmental domain because they capture social aspects of the individual's surroundings. There are valid arguments as to why some constructs would be better placed in one domain or another. To reduce redundancy, however, constructs were only included once across the entire ADOPT framework. The complexity of where to place specific constructs highlights the need to consider all four domains within the ADOPT framework simultaneously.

High Priority Constructs and Measures

Through a comprehensive review of the literature, expertise in aspects of psychosocial factors related to body weight, and the guiding principles described, we identified an initial list of high priority constructs and their measures. See Table 1 for the recommended constructs and their associated recommended measures. The recommended constructs/measures are organized into four subdomains: (1) Affect, Stress, and Non-Homeostatic Eating, (2) Executive Function, (3) Motivation, and (4) Personality. Further information regarding each construct and its associated measure described below is available at the ADOPT Core Measures Workspace in GEM (<https://www.gem-measures.org/Public/wsmeasures.aspx?cat=8&aid=1&wid=35>). GEM (www.gem-measures.org) is an electronic database of common measures in clinical research that is publically accessible and easy to use. Workspaces in GEM allow for input and discussion that help to build consensus around common measures.

Affect, Stress, and Non-homeostatic Eating

Non-homeostatic eating, or eating beyond caloric need, includes common eating behaviors that contribute to weight gain. Chronic stress can increase non-homeostatic eating and promote obesity and preferential deposition of visceral fat (9). Thus, it is theoretically important to include measures of distress and non-homeostatic eating behavior (stress eating, binge eating, cravings and reward based eating). Further, stress can increase cravings and impair people's capabilities for adhering to interventions (10).

Affect and subjective stress—Perceived stress has been associated with non-homeostatic eating behaviors in only a few cross sectional studies. Given the theoretical importance of current perceived stress, it is recommended as part of ADOPT. The **Perceived Stress Scale** (11), a 4 or 10 item scale, measures feelings of stress over the last month.

State negative affect or acute stressful events have stronger links to non-homeostatic eating than either perceived stress or trait affect. They tend to trigger overeating episodes in both animals and humans (12). State affect can be measured with the **PANAS**. Studies using ecological momentary assessment (EMA) (13) support the affect regulation model of binge eating, which poses that negative affect precedes binges, and in turn bingeing tends to proximally reduce negative affect (14). Positive affect may trigger overeating episodes rather than binges (15) and needs further study. Daily measures are high in burden but offer promise for understanding individual differences in stress eating and identifying targets for intervention. For researchers able to measure daily (at the end of the day) or momentary (several times a day) responses, it may be helpful to include items for state negative affect

(PANAS), cravings (see below), and episodes of overeating (see below) as intervention targets (e.g., see (16)).

Emotional eating—The Coping subscale of the **Palatable Eating Motives Scale (PEMS)** is a 5-item subscale that measures intentionally using palatable food to cope with negative feelings (17). The trait form has been validated using EMA (16), and both versions are related equally to BMI and changes in emotional eating correlate with changes in BMI over time (18).

Binge eating—Binge eating disorder (BED) is recognized as a psychiatric disorder in the DSM-5. Criteria include eating an objectively large amount of food accompanied by loss of control (LOC) over eating at least weekly for three months. Many people with BED have obesity, and the prevalence of BED increases with increasing BMI and among those seeking weight management treatment. The **Questionnaire on Eating and Weight Patterns-5 (QEWP-5 (19))**, included in the PhenX toolkit (www.phenxtoolkit.org), has been adapted to reflect DSM-5 criteria for BED and can be used to screen for its diagnosis. The item on binge eating frequency, which may reflect severity, can be used to see if change in this measure predicts treatment success. It is optional but strongly suggested that the items measuring subjective binge eating (feeling loss of control without eating an objectively large amount) be used to learn if this also predicts poor treatment response. Further research is needed to determine whether a continuous measurement score of binge eating severity is predictive of outcomes for those who report binge or LOC eating, regardless of whether they meet criteria for BED.

Cravings and Reward based eating—There are many related aspects of non-homeostatic eating such as cravings, lack of control and lack of satiety. We recommend two measures: one for eating behaviors linked to reward drive and one for cravings. The **Reward Based Eating Scale (RED)** is a 13-item scale that assesses preoccupation with food, lack of control over eating, and lack of satiety with one reliable factor. Based on Item Response Theory, it includes items to provide greater coverage of the middle to low levels of reward based eating commonly reported in obesity (20). The RED predicts weight cycling, weight gain over years (21), and in one weight loss trial, improvement in scores on the RED mediated weight (22). Food cravings, in the absence of hunger, are strong stimuli that can interfere with dietary intentions. The **Trait Craving Questionnaire** is a 15-item measure of behavioral, cognitive and physical aspects of cravings for different types of food. High scores predict how much people crave and eat densely caloric snacks in daily life (23) and are associated with self-reported failures in dieting (24).

Executive Function

Executive function (EF) is considered a central concept in behavior control (25) and critical for goal-directed behavior and the control of complex cognition (26). There is general agreement that there are three core executive functions (27): *inhibition*, also called inhibitory control, including self-control (behavioral inhibition) and interference control (selective attention and cognitive inhibition); *working memory* (WM); and *cognitive flexibility* (also called set shifting or mental flexibility). From these core functions, higher order executive

functions are built, including reasoning, decision making, problem solving, and planning (28). EF is necessary for successful weight loss since it facilitates the ability to plan meals and physical activity, organize schedules, follow-through on goals, inhibit desires, choose healthy foods despite prevalence of easily accessible high-calorie foods, problem solve situations that could lead to overeating or lack of physical activity, and diligently self-monitor (29).

It is important to note that obesity could impact cognitive functioning as comorbidities of obesity such as depression, hypertension, dyslipidemia, and type 2 diabetes are associated with cognitive impairment (30–32). Emerging animal and human research, however, suggests an independent contribution of obesity to cognitive impairment via a range of potential mechanisms, including impaired cerebral metabolism (33), elevated leptin (34) and inflammation and neuronal degradation (35).

Research suggests that EF deficits are found among individuals with overweight or obesity compared to those who are healthy weight (35, 36). The evidence suggests individuals with overweight or obesity, compared to those with healthy weight, have impairments in psychomotor performance and speed, verbal memory, set shifting, decision making (including delay discounting), and inhibition (37–39). To date, there is no available evidence to support an independent relationship between obesity and working memory, learning, visual memory and verbal fluency (36). It is important to note that studies have been inconsistent in delineating the effects of obesity versus obesity-related comorbidities, particularly depression and cardiovascular disorders, on cognition. Recent data also suggest that weight loss and/or exercise may improve memory, cognitive flexibility and attention/executive functioning (40).

There are numerous tasks that assess specific aspects of executive functioning and a comprehensive assessment of overall executive functioning would require multiple tasks and take at least a few hours. For this reason, and the goal of maximizing reliability and validity while minimizing participant and researcher burden, and being sensitive to researcher expertise, we recommend the **Behavior Rating Inventory of Executive Function®–Adult Version (BRIEF®-A)**. The BRIEF-A is a questionnaire composed of 75 items within nine clinical scales that can relate to overeating, self-control, physical activity and weight gain: Inhibit, Self-Monitor, Plan/Organize, Shift, Initiate, Task Monitor, Emotional Control, Working Memory, and Organization of Materials. Two broad indexes (Behavioral Regulation and Metacognition), an overall summary score, and three validity scales (Negativity, Inconsistency, and Infrequency) are also computed. The BRIEF-A has strong psychometric properties (41) and has been used in individuals with a range of conditions across a wide age range.

Delay discounting—Delay discounting, or temporal discounting, is a cognitive process that represents decision making, specifically a comparison of values between the immediate and delayed consumption of a determined commodity (42). Delay discounting depicts the tendency of people to give greater value to rewards as they move away from their temporal horizons and towards the present, with high delay discounting suggesting a preference for small, immediately available rewards as compared to larger rewards in the future (43).

Although not typically included as a measure of “executive functioning” per se, decision making is considered a higher order executive function and delay discounting represents a cognitive neuroscience perspective on decision making in the context of reward.

Although delay discounting can be measured in a number of ways, the 27-item **Kirby questionnaire** is most commonly used. This questionnaire is easy to administer, meets psychometric standards for reliability and stability, and has one-year test-retest correlations similar to tests designed to assess personality traits (44). Traditionally, delay discounting is measured using a discounting rate (k -parameter in a hyperbolic discounting function). However, recent studies suggest that a proportion of choices of the delayed rewards is relatively easy to calculate and highly correlated with the k -parameters (45). Reviews suggest that delay discounting could be a promising predictive measure of health behavior, as high discount rates for money are associated with several unhealthy behaviors and markers of health status (46). At this time, there is an emerging relation between delay discounting and weight loss (47), however, the data on a relation between delay discounting and BMI is mixed (48, 49).

Motivation

Based on dual-processing theories (50), motivation can be divided into constructs that are a function of controlled processing (e.g., behavioral intention and self-efficacy) and constructs that are a function of automatic processing (e.g., ‘liking’ and ‘wanting’) (51). Hunger and satiety are psychobiological motivational states that are also important determinants of eating behavior.

Behavioral intention and self-efficacy—Behavioral intention is how much someone wants, plans, or desires to perform a given behavior (52). Self-efficacy is the perceived capability to perform a given behavior (53). Behavioral intention and self-efficacy are a function of controlled cognitive processing regarding the consequences of a given behavior and the perceived facilitators and impediments to the behavior (52, 53). We focus on behavioral intention because it is posited to be the most proximal determinant of behavior and thus a stronger predictor of behaviors that lead to weight loss than causal antecedents, such as attitudes, social norms, and perceived behavioral control (52). Self-efficacy is posited to impact behavior through its effects on outcome expectancies, social support, and perceived barriers (53). Emerging research, however, suggests that self-reported self-efficacy (i.e., what respondents say they “can do”) may reflect *motivation* to perform the target behavior rather than literal *perceived capability* and is thus likely to be—like behavioral intention—a proximal determinant of behavior (54).

Numerous scales have been developed to assess **behavioral intentions** (55) and **self-efficacy** (56) for weight loss or weight-loss-related behaviors. In choosing a measure of behavioral intention or self-efficacy, it is important that the measure be relevant to the particular behavior (e.g., exercise, eating fruits and vegetables), population (e.g., older adults, adults with overweight/obesity), and context (e.g., worksite, grocery shopping, rural, urban). Because of the contextual nature of these measures, the evidence base for predictors of weight loss and weight-loss-related behaviors is best understood on the construct level

(i.e., intention and self-efficacy) rather than specific measures of the construct. Reviews of behavioral intention and self-efficacy have shown that both constructs predict physical activity (57), dietary behaviors such as fruit and vegetable consumption (58), and weight loss (59).

‘Liking’ and ‘Wanting’—The automatic processing aspects of motivation center around the concept of reward, which can be split into the neurobiological distinctions of ‘liking’ and ‘wanting’ (60). ‘Liking’ refers to neurobiological underpinnings of the *immediate* pleasurable response to a stimulus, such as the taste of foods. ‘Wanting’ refers to the neurobiological underpinnings of incentive salience—a specific kind of motivation mediated by the mesolimbic dopaminergic system and automatically triggered by presentation of a relevant behavioral cue. ‘Wanting’ and ‘liking’ are distinct phenomena, with ‘wanting’ occurring before potential consumption of the reward and ‘liking’ occurring during or after consumption. While previous ‘liking’ of a stimulus generally leads to future ‘wanting’ of that stimulus the next time it is cued, this relation is context-dependent such that there are instances where ‘liking’ does not lead to future ‘wanting’ or ‘wanting’ occurs without previous ‘liking’ (60). Similar to the distinction between ‘liking’ and ‘wanting,’ ‘disliking’ and ‘dread’ are the negative poles of affective valence and incentive salience, respectively (60). Reference to these constructs always includes quotation marks to illustrate these terms represent core neurobiological processes and thus may not map directly on to the broader concepts of *liking* and *wanting* (or *disliking* and *dread*).

The concepts of ‘liking’ and ‘wanting’ as components of reward are fundamental to understanding motivation for eating behavior and thus weight loss/maintenance (61) and can be measured with **‘Liking’ and ‘Wanting’ Visual Analog Scales**. These Visual Analog Scales --in which respondents are asked “Do you like [or want] this food?” --can be used to assess self-reported ‘liking’ and ‘wanting’ of foods associated with weight gain and/or targets of a planned weight-loss intervention, such as sugar-sweetened beverages, high-fat snack foods, or high-fat and high-sugar desserts. Higher ratings of ‘liking’ and ‘wanting’ for such foods has been observed in individuals with obesity (62). Additionally, reward value of food is known to increase during short-term energy deficit (63), whereas changes in food ‘liking’ and ‘wanting’ have been shown to differentiate between those susceptible versus resistant to exercise-induced weight loss (64). Moreover, reductions in reward-driven eating have also been shown to account for some of the positive impacts of behavioral interventions on weight-loss (22). Likewise, several studies have shown that assessment of ‘liking’/ ‘disliking’ is predictive of adherence to physical activity programs (65).

Hunger and satiety—Hunger is a subjective sensation that reflects a conscious motivation to eat; satiety is the suppression of hunger during the inter-meal period that inhibits further eating (66). These processes are conceptualized through the satiety cascade, which provides a theoretical framework that maps the underlying biological mechanisms of appetite onto the psychological experience and behaviors that influence food intake (67). Subjective hunger and satiety are measured using horizontal **visual analog scales** anchored at each end using the extremes of a unipolar question relating to subjective hunger, fullness,

desire to eat or prospective food consumption (68). Within-subject ratings are sensitive to experimental manipulation of food ingestion and display good test-retest reliability (69).

Measures of subjective hunger and satiety can be used to help explain eating behavior and susceptibility to weight loss or gain. An inability to recognize and respond to internal sensations of hunger (70) or a weakened satiety response to food consumption (71) are risk factors for overconsumption and weight gain. Hunger, which increases following weight loss and may remain elevated during weight loss maintenance (72), is also predictive of successful long-term weight loss maintenance (71).

Personality

Psychological dispositions are stable characteristics that describe a person's typical ways of thinking, feeling, and behaving. The Five-Factor Model of personality (FFM (73)), also known as the Big Five, operationalizes these characteristics along five broad dimensions: Conscientiousness, Neuroticism, Extraversion, Openness, and Agreeableness.

Of the five traits, Conscientiousness is associated most consistently with body weight and weight-related behaviors. Conscientiousness is defined as the general tendency to be organized, disciplined, and dutiful (74). Individuals who score high in Conscientiousness are at less risk of weight gain and lower risk of obesity across adulthood (75, 76). There is likewise a consistent association between Conscientiousness and greater engagement in physical activity (77–79), consumption of a healthier diet (80–82), and healthier eating patterns (82). Of note, the associations between Conscientiousness and BMI and behavior tend to be similar regardless of the measure used and tend to be similar across different demographic groups (76, 78).

Neuroticism is the general tendency to experience negative emotions and greater vulnerability to stress (83). Neuroticism has been associated with greater weight gain in adulthood, particularly among women (75) but evidence is mixed (76). Neuroticism is, however, associated consistently with physical activity and eating patterns: Individuals higher in Neuroticism are less physically active (77, 78) and more likely to engage in disordered eating behavior (82, 84). As such, although the evidence for a direct association between Neuroticism and weight outcomes is somewhat equivocal, there is a clear association between Neuroticism and behaviors conducive to obesity.

The other traits are more consistently associated with behaviors related to diet and physical activity than to body weight itself. There are very consistent associations, for example, between Extraversion (the tendency to be outgoing and sociable) and more physical activity (77–79), less engagement in sedentary behavior (78), and consumption of a healthier diet (80–82). Openness (the tendency to be creative and unconventional) is likewise associated with more frequent physical activity (77, 78) and, of the FFM traits, is the one associated most consistently and most strongly with consuming a healthy diet (80–82). There is not strong evidence that Agreeableness (the tendency to be sympathetic and trusting) is related consistently with diet, physical activity, or weight outcomes (76, 78, 81), but it is strongly related to adherence in other behavioral domains (85). Thus, although not directly relevant to

weight, it may be extremely consequential for identifying individuals who are most (and least) likely to adhere to an intervention.

There are many reliable and valid measures of FFM personality traits. Common scales include the suite of NEO measures (e.g., NEO-PI-3, NEO-FFI (86)), the International Personality Item Pool (IPIP (87)), the Big Five Inventory (BFI (88)), the Midlife Development Inventory (MIDI (89)), and the Ten Item Personality Inventory (TIPI (90)). Each of these inventories is an excellent choice to measure personality traits. In keeping with our goal of maximizing reliability and validity while minimizing participant and researcher burden, we recommend the **mini-IPIP** as a measure of personality to include in adult weight loss trials. The mini-IPIP is brief (it measures five traits with 20 items), has good psychometric properties (91), and is associated reliably with body weight (76), behaviors implicated in effective weight loss (78), and adherence (92). When time permits, we recommend the BFI-2. As with the mini-IPIP, the BFI-2 has excellent psychometric properties and predictive validity (88). The advantage of the BFI-2 is that it allows for the scoring of more specific aspects, or facets, of the broad traits. Facet-level analyses are able to help pinpoint exactly which aspects of the traits are associated with weight loss outcomes and will thus help to both identify potential intervention targets and better understand the mechanisms through which personality traits lead to specific outcomes. The BFI-2 is a 60-item measure and thus should be used when the investigator and participants have more time to complete questionnaires.

Domain-specific Considerations for Advancing the Science

We identified an initial list of high-priority constructs with a strong evidence base, but there is still much to be learned about how these constructs operate within trials, how they relate to each other, and how they relate to other key biological, behavioral, and environmental factors. The key next step is the consistent, coordinated measurement of these constructs (and those in the other domains) in trials for weight loss/maintenance. Such an approach will bring us closer to understanding individual and sub-group differences in response to treatment and to developing more targeted, and thus more effective, interventions. Addressing gaps in knowledge will provide a roadmap for future research that will help better identify how psychosocial factors contribute to weight loss/management and how to match interventions to the individual to increase the likelihood of success.

Evidence—Across the psychosocial domain, there is variability in the strength of evidence for specific constructs. Some constructs have substantial evidence from prospective longitudinal studies but lack evidence from RCTs. Conscientiousness, for example, is a consistent predictor of healthier weight trajectories across the lifespan (75, 93), but the effect of this trait has not been tested in randomized trials. Constructs were recommended because of their theoretical relevance to weight and the strength of the evidence from observational studies. Still, their utility needs to be tested in the context of RCTs. The evidence from these RCTs will provide essential guidance for future recommendations regarding high priority constructs and measures in this domain.

Sociocultural factors—There are sociocultural factors that may contribute to the success or failure of interventions. The experience of interpersonal aggression, for example, has been associated with worse weight management. There is growing evidence that unfair treatment on the basis of body weight (94) and unfair treatment more generally (95) are associated with greater weight gain over time. Weight stigma in particular has been implicated in both weight gain and behaviors conducive to obesity and thus should be included in future work in clinical trials to determine its utility in the context of weight loss and maintenance. Such work will also be helpful in identifying the best measure of stigma to be recommended to be included in trials. In addition, other constructs within the psychosocial domain are present across a wide range of populations but vary in their association with weight-related outcomes by population (e.g., body image, attitudes toward weight (96)). Such constructs need to be tested further to determine their utility in weight loss trials.

More generally, even when targeting the same construct or behavior, the intervention needs to take into account the sociocultural context of the individual being treated. Interventions that are culturally sensitive and tailored to a population tend to be more effective than interventions designed for other populations or treatment as usual (97). Several of the recommended constructs have been associated with weight-related factors in multiple populations (e.g., personality, stress), but the effectiveness of interventions based on these constructs may vary across populations and needs to be explicitly tested.

Health disparities—There are well-documented disparities in obesity prevalence across demographic groups, including racial and ethnic minority, rural, and low-income populations (98). And yet, these groups are underrepresented in clinical trial research (99); especially weight loss trials (100). RCTs tend to focus on white, urban, middle-class individuals. It is critical to include more diverse populations, especially populations that have the greatest disparities in obesity, in clinical trials. Weight loss trials are also needed that test interventions tailored to hypothesized population-specific needs. These efforts will allow for a more robust scientific base explaining the predictors, mediators, and moderators unique to groups at the highest risk for obesity and help identify targets to improve treatment approaches for these populations. Although ADOPT encourages use of consistent measures across studies, testing whether constructs important for weight loss in one group generalize to others is also critical.

Feasibility of measures/technology—As technology progresses, there will be more opportunities to integrate sophisticated assessments into weight loss trials. This issue is usually of concern in domains such as biology and behavior but also applies to psychosocial constructs. For example, as the ability to more easily incorporate EMA into trials increases, there are more opportunities to measure constructs in real-time and intervene on aspects of psychological functioning that fluctuate regularly throughout the day (e.g., affect, stress). Such advances in technology may also facilitate study into interactions across domains, such as how psychosocial functioning and biology reciprocally influence each other. An example is the potential for use of sensor cueing used to direct individuals to alternative strategies rather than eating to self-soothe in response to stress.

Process/mechanisms—In the development and delivery of obesity treatments, knowledge of psychosocial processes is important for understanding which intervention strategies modify the behavioral and biological factors that have a direct effect on weight loss and weight maintenance. These constructs also represent the thoughts and feelings people have in response to changes in their weight; responses that, in turn, affect people's ability to engage in behaviors that enable them to maintain a weight-reduced state. Because of the dynamic and interactive nature of these constructs across domains, the ADOPT initiative encourages investigators to include low burden measures from each psychosocial subdomain when possible. This approach will facilitate research into the dynamic relation between domains to identify how to best intervene for weight loss. The ADOPT effort is a step toward an integrated process model that explicitly recognizes and encourages research into interconnections to advance the science of effective intervention for weight loss.

Recommendations for Research

Measurement schedule—How frequently a construct needs to be measured in a trial depends on how the construct is hypothesized to operate. Constructs hypothesized to be predictors or moderators should be measured at the beginning of the trial. Constructs that are hypothesized to be mediators of intervention effectiveness need to be measured at multiple points throughout the trial. Further, some constructs are hypothesized to be predictors but may also change over the course of the trial because of either the intervention or through the process of weight loss, and that change may be the mechanism that explains the effectiveness of the intervention. Even constructs hypothesized to be predictors or moderators may turn out to be mediators if change in the construct contributes to better outcomes. Thus, the constructs often need to be measured multiple times over the course of the trial. Table 1 shows the suggested measurement schedule for the recommended measures. These recommendations are based on the current state of the evidence; future work needs to better specify these schedules and ground them in a better understanding of how these constructs change over time.

Promising constructs—In addition to our initial set of recommended measures, it is imperative to continue to identify how psychosocial factors contribute to effective weight loss/management. Our recommendations are meant to help bring consistency to weight loss trials to promote comparisons and integration across trials. These recommendations should not, however, limit investigations into additional psychosocial factors implicated in weight loss.

Conclusion

The purpose of this paper was to describe the psychosocial domain and its importance to the ADOPT project, to define the constructs and measures recommended for inclusion in trials, and to place this domain within the broader weight loss/maintenance process. The complexity of weight loss underscores the importance of addressing the multiple factors that contribute independently and in combination to healthy weight regulation. The inclusion of similar measures across different weight loss trials will help bring coherence to the literature and facilitate comparisons and integration of data across trials. An added benefit is that by

including measures from the four domains in a single trial, hypotheses about connections and interactions across domains can be tested to identify how different domains function together to improve or hinder intervention effectiveness. Such evidence is critical to advance the design and delivery of more effective treatments for weight loss and weight loss maintenance.

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What is already known about this subject?

- Psychosocial factors help shape behaviors related to eating and physical activity that are critical for successful weight loss outcomes.
- The high level of individual variability in the response to obesity treatments may be due, in part, to variability in aspects of psychosocial functioning.
- Despite the importance of psychosocial constructs, there is not a consensus on the constructs and measures most important for successful weight loss outcomes; such an evidence base would inform the development of effective tailored treatments.

What does our study add?

- The Psychosocial Domain Subgroup of the ADOPT Core Measures Project provides an initial list of high priority psychosocial constructs and associated measures that could be feasibly employed in weight loss trials.
- Consistent use of the high priority measures in future studies will facilitate meta-analyses to identify the psychosocial processes that predict successful treatment response.
- The consistent use of ADOPT Psychosocial Domain measures in weight loss trials, along with key measures from the other ADOPT domains, will help identify predictors of treatment responses and inform the development of effective tailored interventions.

Table 1
Initial List of Recommended Constructs and Measures from the Psychosocial Domain Subgroup of the ADOPT Working Group

| Construct | Measure | Measure Type ¹ | Logistics | | | Source of Evidence ³ |
|--|--|---------------------------|-----------------|-------------------------------|-----------------------------------|---------------------------------|
| | | | Number of Items | Administration Time (minutes) | Measurement Schedule ² | |
| <u>Affect, Stress, and Non-homeostatic eating</u> | | | | | | |
| State Affect | PANAS (state) | EMA, SA | 20 | <5 | B, MA | L |
| Perceived Stress | Perceived Stress Scale | SA | 4, 10 | <5 | B, F | C |
| Emotional Eating | Palatable Eating Motives: Coping Subscale | EMA, SA | 4/full | <5/<10 | B, MA, F | L |
| Binge Eating | Questionnaire on Eating and Weight Patterns | SA | 11 | <5 | B, F | C |
| Trait Food Craving | Trait Food Craving Questionnaire-Reduced | SA | 15 | <5 | B, F | C |
| Reward-Related Eating | Reward Based Eating Drive | SA | 13 | <5 | B, F | RCT |
| <u>Executive Function</u> | | | | | | |
| Executive Function | Behavior Rating Inventory of Executive Function-Adult | SA | 75 | <30 | B | C |
| Delay Discounting | Kirby Questionnaire | SA | 27 | <10 | B | C |
| <u>Motivation</u> | | | | | | |
| Behavioral Intention | Behavioral Intention Scale(s) | EMA, SA | Variable | Variable | B, MA | L |
| Self-Efficacy | Self-Efficacy Scale(s) | EMA, SA | Variable | Variable | B, MA | L |
| Hedonic Response to ('liking') and Motivation ('wanting') for Food | 'Liking' and 'Wanting' Visual Analog Scales | EMA, SA | 2 | <5 | B, MA | L |
| Hunger and Satiety | Hunger and Satiety Visual Analog Scales | EMA, SA | 2 | <5 | B, MA | L |
| <u>Personality</u> | | | | | | |
| Personality: Big Five Factors | Mini-International Personality Item Pool (Short form)/Big Five Inventory-2 (Long form) | SA | 20/60 | <5/<10 | B, F | L |

¹EMA=ecological momentary assessment; SA=self-administered.

²B=baseline; MA=multiple assessments across the trial; F=follow-up.

³C=cross-sectional; L=longitudinal; RCT=randomized controlled trial.

Evidence included both weight-related outcomes (e.g., weight loss) and behaviors related to weight loss (e.g., physical activity).