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THE EFFECT OF ACCEPTANCE AND COMMITMENT THERAPY ON VALUE CONSISTENCY DURING A WEIGHT LOSS PROGRAM

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THE EFFECT OF ACCEPTANCE AND COMMITMENT THERAPY ON VALUE
CONSISTENCY DURING A WEIGHT LOSS PROGRAM

BY

LEAH DORFMAN

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE
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ABSTRACT

In the last decade, the prevalence of obesity has increased significantly in populations worldwide. It is well established that overweight and obesity are associated with a host of deleterious health consequences. Standard Behavioral Therapy (SBT) for weight loss has been demonstrated to yield only modest outcomes with poor long-term maintenance. Therefore, efforts must be made to improve upon what is currently considered to be best practices in weight loss interventions, especially with a goal of improving retention and long-term maintenance. Acceptance and Commitment Therapy (ACT) is a behavioral and cognitive intervention that implements both acceptance and mindfulness processes, and commitment and behavior change processes with the purpose of increasing psychological flexibility to allow an individual to live a value-driven life. To date little is known about the effects of improving one's consistency of values regarding weight loss and weight loss maintenance. The purpose of this secondary data analysis of a randomized controlled trial (N=162) aimed to model weight and values scores during 12 months of intervention and 12 months of follow-up and to conduct a mediation analysis to identify if, and how much, values scores mediated change in weight over time. Longitudinal modeling demonstrated the SBT arm exhibited a slightly larger decrease in weight during the study intervention, but also exhibited a larger rebound in weight gain post-intervention compared to the ACT arm ($p=0.0277$). The longitudinal modeling of participant values suggests that both arms exhibited an increase in the value score throughout the study intervention; however, after the study intervention, the SBT arm saw a drop in the value score whereas the ACT arm appeared to maintain the gain in value score on average ($p=0.0003$). Finally, the mediation analysis suggests that change

in value score at 18 months partially mediates (50.7%) between study treatment arm and weight loss at 24 months. Future research needs to replicate this finding, and to examine the mechanisms of change (specifically values clarity) with more sophisticated statistical analyses and larger sample sizes, to further understand the proposed mechanisms of change contribution.

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CHAPTER 1

DEFINITION AND SIGNIFICANCE OF THE PROBLEM

The Problem of Obesity.

In the last decade, the prevalence of obesity has increased significantly in populations worldwide (Withrow & Alter, 2011). Obesity is defined as an unhealthy excess of body fat that increases risk for both morbidity and mortality (Villareal, Apovian, Kushner, & Klein, 2005). Obesity increases risk for a variety of conditions including heart disease, stroke, type 2 diabetes, and certain types of cancer. These are among the leading causes of preventable, premature death. Using body mass index (BMI), which considers both height and weight, overweight is defined as having a BMI ≥ 25.0 kg/m² and obesity is defined as a BMI ≥ 30.0 kg/m². With obesity reaching epidemic proportions, and Standard Behavioral Therapy (SBT) yielding only modest outcomes with poor long-term maintenance, efforts must be made to improve upon what is currently considered to be best practices for behavioral weight loss therapy. Therefore, improving weight loss interventions, especially with a goal of improving retention and long-term maintenance, should be a high public health priority.

Justification and Significance.

It is estimated that two-thirds of adults in the United States are overweight or obese (Flegal, Carroll, Ogden, & Curtin, 2010). Overweight and obesity are associated with a host of deleterious health consequences including hypertension, dyslipidemia, diabetes mellitus, coronary heart disease, congestive heart failure, stroke, metabolic syndrome, degenerative joint disease, and increased mortality (Lillis, Hayes, & Levin, 2011; Lillis et al., 2015). Additionally, obesity confers negative consequences on both the

physical and psychosocial aspects of quality of life, as well as psychological outcomes such as depression and perceived stigma (Cattivelli et al., 2015; Kushner & Foster, 2000). In addition to perceived stigma, actual stigma, discriminatory acts, and ideologies targeted towards individuals because of their weight and size, can add a host of deleterious health consequences. Stigma and discrimination toward obese persons are pervasive and pose numerous consequences for both psychological and physical health (Puhl & Heuer, 2010). Obesity also produces large economic consequences, both directly (hospitalization, medication, and health procedures) and indirectly through loss of productivity (absenteeism and disability), as well as placing a significant burden on healthcare systems (Finkelstein, Trogdon, Cohen, & Dietz, 2009; Lillis et al., 2011; Withrow & Alter, 2011). Each year, obesity-related medical conditions are estimated to cost the U.S. an estimated \$75 billion and take the lives of 365,000 Americans (Finkelstein et al., 2009). All of this taken together demonstrates the severity of overweight and obesity as a significant public health problem in the United States.

CHAPTER 2

REVIEW OF LITERATURE

Standard Behavioral Therapy for Obesity.

Standard Behavioral Therapy (SBT) for obesity aim to produce 1-2 pounds of weight loss per week which is often achieved through a combination of caloric restriction, physical activity, and behavioral modification (Lillis et al., 2015). Traditional SBT programs for obesity stem from Social Cognitive Learning Theory and aim to modify behavior by replacing maladaptive behaviors (sedentary behavior and high caloric diets) with reinforcing positive behaviors (exercise and calorie restricted diets). These lifestyle modification programs typically include a combination of dietary and physical activity treatments (Forman et al., 2013; Forman, Butryn, Manasse, & Bradley, 2015). In addition to dietary education, and physical activity prescription these treatments include behavioral skills such as self-monitoring, goal setting, and stimulus control (Forman & Butryn, 2015). Self-monitoring and goal setting are intended to aid the individual in adhering to caloric goals, exercise prescriptions, and regular weighing (Lillis & Kendra, 2014). Stimulus control, specifically changing cues in the environment, is also taught to increase the likelihood of healthy behaviors. Overall, SBT for weight loss is primarily skills based with a goal of training and ingraining habits.

One upgrade to SBT for weight loss has been the addition of cognitive change strategies (Forman, Butryn, Hoffman, & Herbert, 2009). Typically, SBT includes two to three sessions which address overeating in response to stress and negative thoughts and emotions. During these sessions participants are taught to “control” or attempt to “change” their negative emotions and thoughts through techniques such as distraction,

thought stopping, and refocusing strategies (Lillis et al., 2015; Niemeier, Leahey, Palm Reed, Brown, & Wing, 2012). However, recent studies suggest that employing such control strategies may actually exacerbate the difficulties for obese individuals to cope with food cravings, difficult thoughts, and emotions, which may in turn lead to an even greater consumption of craved food (Forman, Hoffman, Juarascio, Butryn, & Herbert, 2013; Forman et al., 2007; Hoffman, 2010).

Standard behavioral weight loss treatments, even with the addition of addressing cognition, have shown to yield, at best, modest weight losses, typically yielding weight losses between 5% and 10% of baseline body weight over six to 12 months (Forman et al., 2009). It is important to note that there is considerable variability between participants in regards to weight loss outcomes, with some participants achieving significantly better weight loss than others (Loveman et al., 2011). Additionally, long-term weight loss maintenance is often not achieved (Lillis et al., 2011). It has been shown that participants regain about a third of their lost weight within the first year of weight loss, and by five years post weight loss more than half of participants have either returned to or even exceeded their baseline weight (Butryn, Forman, Hoffman, Shaw, & Juarascio, 2011; Gifford & Lillis, 2009; Lillis & Kendra, 2014).

Historical Context of Behavioral Treatment.

To understand the current trajectory of behavioral treatment more fully it is important to consider the historical context of behavioral therapy. Behavioral therapy can be broadly categorized into three separate waves of dominant assumptions, methods, and goals. The first wave of behavior therapy focused directly on problematic behavior and emotion, based on conditioning and neo-behavioral principles. Early behaviorists asserted

that theories should be built upon well-established scientific basic principles. The failure of this first wave of behavior therapy was that it did not adequately deal with cognition. The second wave of behavior therapy aimed to deal with thoughts in a more direct way. In this wave behavioral principles were de-emphasized, and the focus was placed on cognitive concepts. Rather than focusing on simple direct associative concepts, the second wave focused on more mediational constructs. While the second wave made efforts to account for the shortcomings of the first wave, it did so at the expense of embracing a more clinically based approach. More specifically, in the second wave the goal would be to eliminate or weaken maladaptive thoughts or emotions by detecting and correcting them. Cognitive-Behavior Therapy (CBT) emerged as a tool for the second wave to in some way assimilate the first wave. In CBT, behavioral principles are less emphasized as compared to cognitive constructs, but empirically supported methods aimed at overt behaviors, emotions, and cognitions can all be employed depending on context. The belief that direct cognitive change is a necessary or effective method of clinical improvement remains controversial and has been criticized.

The third wave of behavior therapy is grounded in empirical research, acknowledges the important role of behavior just as much if not more so than traditional CBT, and additionally acknowledges the important role of cognitions. However, the novelty in this third wave approach lies in how cognitions are treated. Third wave therapies assert that attempting to control or change cognitions and other internal experiences may be maladaptive. Rather than employing the second wave approach of focusing on changing internal states, third wave therapies instead seek to change the function of those internal states. More specifically, they aim to change not the internal

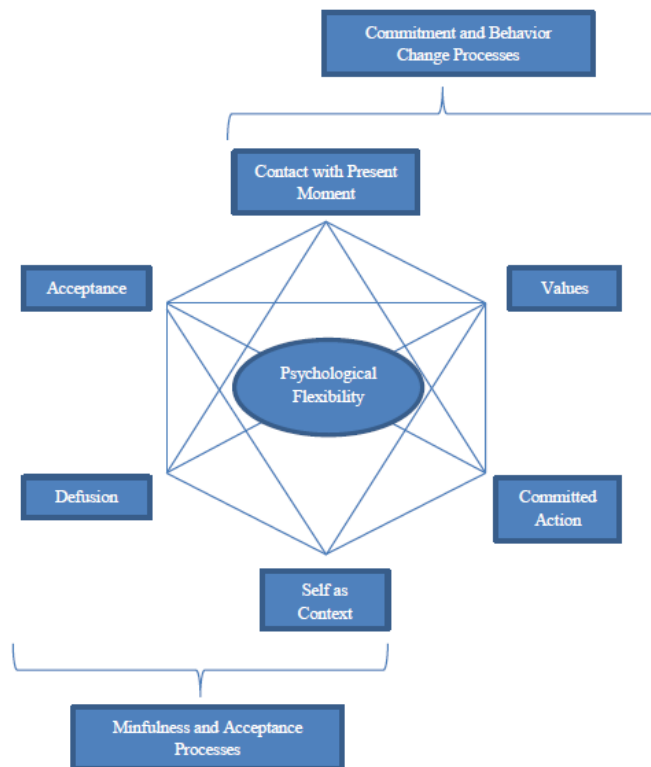
state itself, but instead the way one relates to those states in a way that helps their behavior to be more adaptive (Hayes, Luoma, Bond, Masuda, & Lillis, 2006; Hayes, 2004).

Acceptance and Commitment Therapy.

Acceptance and Commitment Therapy (ACT (Hayes, Strosahl, & Wilson, 1999)) is one such third wave therapy gaining support across a broad range of outcomes. Acceptance and Commitment Therapy can be thought of as a behavioral and cognitive intervention that implements both acceptance and mindfulness processes, and commitment and behavior change processes with the purpose of increasing psychological flexibility to allow an individual to live a value-driven life (Hayes, Levin, Plumb-Villardaga, Villatte, & Pistorello, 2013; Hayes et al., 2006). In ACT, psychological flexibility is targeted through six core processes, which interconnect to create a “hexaflex” and are labeled as: acceptance, defusion, self as context, contact with the present moment, committed action, and values (Figure 1). Psychological flexibility is best defined as the ability to contact the present moment more fully, with the ability to either change or persist in a behavior to be consistent with and in the service of self-stated values (Hayes et al., 2013; Hayes et al., 2006). More specifically, ACT strategies are designed to facilitate identification of values and nurture a lasting commitment to behaving consistently with these values, even in the presence of various aversive states (Hayes, et al., 2006). From an ACT perspective, it is believed that internal events such as thoughts and feelings do not cause overt behaviors or actions without the interaction of context. Therefore, rather than changing internal states to change overt behavior, ACT seeks to change the context that links internal states to maladaptive overt behaviors. From

this view, the content of cognitions themselves is not directly problematic, unless contextual factors lead cognitions to regulate overt behaviors/actions in maladaptive ways. This further supports why ACT does not seek to train or change thoughts, but instead attempts to de-couple thoughts from unhealthy actions.

Figure 1. The ACT ‘Hexaflex’ outlining the relationship between the six core processes and psychological flexibility (Hayes, 2006).



The first four processes collectively are mindfulness and acceptance processes, and the last four processes are commitment and behavior change processes. Acceptance is taught as an alternative to the maladaptive behavior of experiential avoidance. Specifically, acceptance involves active reception of private internal events without any attempt to

change either their frequency or form. Cognitive defusion techniques are taught along with acceptance to alter the negative functions of thoughts and other private internal events, but just like acceptance, without changing the form or frequency. One goal of cognitive defusion is to create distance from unhelpful thoughts. Together, acceptance and defusion aim to change the way one interacts with private internal events, rather than changing the internal events themselves. The self as context fosters both defusion and acceptance by being aware of personal experiences (internal and external), but without being invested in those experiences. Being present is a process targeted by ACT which promotes ongoing and non-judgmental contact with internal and external events and states as they occur. Committed action encourages the individual to develop patterns of adaptive behaviors that are in alignment with self-identified values. Committed action is fostered through a variety of exercises, one of which being goal setting. Goals are concrete, measurable, attainable, and consistent with one's values.

One of the six core process which is targeted in ACT is values clarity. Values are self-identified, and unlike goals can never be fully attained, but instead can be embodied and epitomized by moment-to-moment action that is consistent with values. Acceptance and Commitment Therapy focuses specifically on increasing one's ability to live a fulfilling and meaningful life, even in the presence of challenges and aversive states that will inevitably occur. Therefore, ACT is theoretically appealing for individuals who endorse emotional or stress related eating in response to such aversive states. Having clearly defined values that would constitute a fulfilling and meaningful life is inherently important in ACT. More specifically, values clarification is an important process throughout ACT, and committed action is an important extension, so that individuals can

form patterns of values directed behavior. In ACT values are defined as a “special class of reinforcers that are verbally constructed, dynamic, ongoing patterns of activity, for which the predominant reinforcement is intrinsic in the correspondence between the individuals’ behavior and the valued behavior pattern” (Wilson, Sandoz, Kitchens, & Roberts, 2010). In this context, goals become important because they are in the service of the larger underlying values. It is really only within the context of one’s identified values that committed action, acceptance, and defusion come together to form a meaningful connection (Hayes, 2004). Analogue studies have identified that values increase acceptance of aversive experiences in laboratory settings (Dahl, 2015; Zettle, Rains, & Hayes, 2011). Additionally, applied research has shown that those who are clearest on their values are better able to maintain long lasting behavior changes (Dahl, 2015). One study examined mediators of change in producing positive outcomes for self-management of epilepsy and found engaging in valued activities to mediate changes in a host of outcomes (including quality of life) (Lundgren, Dahl, Melin, & Kies, 2006). To date, value consistency has yet to be explicitly examined as a mediator or process variable in achieving or maintaining weight loss.

Regarding weight loss specifically, effortful choices, especially those which may produce aversive states, are unlikely to occur unless the individual has clearly linked committed actions to specific goals, which are in turn linked to deep-seated values. Many individuals feel they need to put their lives on hold until the desired weight loss is achieved. From an ACT perspective it would be important to complete behaviors and actions that are values-based, even if they cause aversive internal states now, instead of waiting. For example, it would be important to engage in physically active play outdoors

with their children now in the process of losing weight, rather than saying “I need to lose weight in order to then be a good parent to my children”. In ACT it is important to demonstrate committed action to those values now, instead of believing that losing the weight would then allow them to be more physically active thereby making them a better parent.

In summary, it is plausible to hypothesize that targeting values clarity and consistency in ACT interventions can increase quality of life (Wilson et al., 2010), improve psychological flexibility, and improve values clarity as well. Thus, performing committed actions that are connected to values has the potential to generalize to various aspects of adaptive functioning, beyond those directly targeted by the intervention (Dahl, 2015). Applied research is needed to further examine value consistency as a mediating or process variable in randomized controlled trials of values-based interventions such as ACT (Dahl, 2015). Acceptance and Commitment Therapy has the potential to overcome some of the limitations of SBT. More specifically, ACT can improve quality of life by clarifying values and promoting committed actions above and beyond SBT. Additionally, in SBT participants are taught to “control” or attempt to “change” their negative emotions and thoughts through techniques such as distraction, thought stopping, and refocusing strategies (Lillis et al., 2015; Niemeier et al., 2012). However, recent studies suggest that employing such control strategies may actually exacerbate difficulties for obese individuals coping with food cravings, difficult thoughts, and emotions, which may in turn lead to an even greater consumption of craved food (Forman, Hoffman et al., 2013; Forman et al., 2007; Hoffman, 2010). On the other hand, ACT, does not seek to change the form or frequency of aversive states or negative thoughts or emotions, but instead

uses acceptance and compassion to change how the individual relates and responds to these internal events.

Acceptance and Commitment Therapy and Non-Weight Loss Outcomes.

Thus far, ACT has shown promising results across a broad range of health-related behaviors, including smoking cessation (Gifford et al., 2004), self-management of diabetes (Gregg et al., 2007) chronic pain (McCracken & Yang, 2006; Vowles and McCracken, 2008; Vowles & Wetherell, 2009), HIV medication adherence (Moitra, Herbert, & Forman, 2011), cancer (Feros et al., 2013), epilepsy (Lundgren, Dahl, & Hayes, 2008), and a host of other conditions (Bach & Hayes, 2002; Davis et al., 2014; Powers, Vording, & Emmelkamp 2009). Results from these studies, along with other lab paradigms (Masedo & Esteve, 2007; Branstetter-Rost, Cushing, & Douleh, 2009; Ivanova et al., 2015), provide strong support that acceptance-based interventions improve levels of distress tolerance, and commitment to actions and values, which subsequently result in better treatment outcomes. While not directly targeting weight loss in overweight and obese populations, a variety of studies have examined ACT on various weight-related outcomes and behaviors. For example, ACT has demonstrated support in improving physical activity levels (Butryn et al., 2011), weight gain prevention (Katterman et al., 2014), decreasing eating pathology (Juarascio, Forman, & Herbert, 2010), and food cravings (Hooper et al., 2012; Forman et al., 2007; Forman et al., 2013; Hoffman, 2010). Initial trials are currently building strong support for the efficacy of ACT on weight loss (Forman et al., 2013; Forman et al., 2009; Niemeier et al., 2012; Tapper et al., 2009; Lillis et al., 2009).

Acceptance and Commitment Therapy for Weight Loss.

Acceptance and Commitment Therapy has shown promise in inducing positive behavioral outcomes across a broad range of conditions (Hayes et al., 2006). Specifically, in regards to weight loss, only a few open and pilot trials (Forman et al., 2009; Niemeier et al., 2012) and only one full-scale randomized controlled trial (Lillis et al., 2016) have been conducted to evaluate the effectiveness of full-scale Acceptance-based behavioral treatment for weight loss as compared to the current gold standard of SBT. In this first randomized controlled trial, Forman and colleagues (2009) randomized 128 overweight participants to a one-year group-based weight loss treatment of either SBT or ACT. Participants were randomly allocated to SBT or ACT and treatment consisted of group-based sessions which were held weekly during weeks 1-20 and bi-weekly during weeks 21-40, for a total of 30 75-minute sessions. The SBT and ACT group had many shared components including nutritional education, self-monitoring goals, and calorie and exercise prescriptions. Additionally, they covered topics such as stimulus control, behavior shaping, relapse prevention, identifying triggers and barriers, and problem-solving strategies. The SBT only components included cognitive behavioral techniques such as: cognitive restructuring, building self-efficacy, and learning to cope with food cravings by distraction. The ACT only components had a heavy focus on acceptance and commitment-based strategies to facilitate dietary and physical activity adherence. These included value identification, sustained exposure to unpleasant experiential states, and commitment to difficult behavioral goals. Overall participants achieved a $10.17 \pm 8.36\%$ weight loss by post treatment and an $8.16 \pm 8.57\%$ weight loss by 6-month follow-up. Weight loss at 6 months follow-up post-intervention between groups did not reach statistical significance but was trending towards being greater for those who received the

acceptance-based therapy. Of primary interest, moderation analyses revealed that the advantage conferred by the acceptance-based group was significantly greater for participants who endorsed high disinhibition, emotional eating, and susceptibility to the food environment (Forman, Butryn et al., 2013).

Lillis and colleagues conducted the first full-scale randomized controlled trial that has been conducted to compare the current gold-standard SBT to a program which combined both SBT components with acceptance-based strategies from ACT for weight loss in overweight and obese individuals who reported high internal disinhibition (Lillis et al., 2016). This study produced the data for this current secondary data analysis. A total of 162 participants were randomly allocated to one of the two treatment groups: SBT or ACT. Description of full methods were published previously (Lillis et al., 2015). Both intervention conditions included group-based weekly meetings (approximately one-hour long sessions) for 6 months, followed by bi-weekly meetings for three months, and then monthly meetings for three months. After the completion of this twelve-month intervention, participants attended follow-up assessments for an additional year. Assessments occurred as baseline, three months, mid-way through intervention at six months, nine months, at the completion of intervention at 12 months, and additional follow-up at 18 and 24 months. Both the SBT and ACT conditions shared some components which constitute the current “gold standard” of behavioral weight loss treatment. Participants were encouraged to lose one to two pounds per week, with a goal of achieving and maintaining a weight loss of 10% of their baseline body weight. Additionally, all participants were encouraged to gradually increase their physical activity until they reached the goal of exercising at least 250 minutes per week at a

moderate intensity (moderate intensity being defined as 50-75% of maximal heart rate or a perceived exertion of 13 on the Borg Rating of Perceived Exertion Scale). Typically, this exercise goal was achieved by brisk walking, but participants were able to choose alternative desired activities. Regarding diet, participants were placed on a standard calorie and fat restricted diet, with a goal of 1200-1800 kcals/day and 33-42 grams of fat/day (with 25% of calories from fat). The individual goal for a participant within those calories and fat-gram ranges depended on their baseline weight. All participants received a fat/calorie guidebook and were instructed at the beginning of the intervention on how to self-monitor their daily calorie and fat intake in food diaries. All participants received weekly food diaries which were reviewed each week by a group leader who would provide written feedback to each participant. All participants were taught various standard behavioral weight loss strategies regarding both eating and exercise behaviors. Examples of these topics include self-monitoring, stimulus control, problem-solving, social support, goal setting, improving diet quality through volumetrics, and adding variety to an exercise routine. Later lessons included topics about weight maintenance, dealing with loss of motivation, and relapse prevention.

The main discrepancy between the two intervention groups was their approach towards negative thoughts, stress, and emotions. SBT utilized more traditional cognitive behavioral techniques to help participants change those internal events, while ACT focused on making healthful choices in the presence of those internal events. The SBT intervention addressed negative thoughts and emotions during three sessions during the weekly groups, and then later the core skills are reviewed again during the reduced contact phases. Regarding negative thoughts, especially those that would impede weight

loss, participants were taught to identify negative thoughts and then to actively stop and replace those thoughts with positive ones. In terms of stress, participants were taught to engage in behaviors to reduce stress, as well as to change their eating responses to stress and negative emotions. For example, participants were encouraged to increase participation in pleasurable (non-eating related) activities to distract from negative emotions. Additionally, relaxation and other distraction techniques were also presented.

In contrast to the “change-focused” SBT view towards maladaptive thoughts, emotions, and stress the ACT intervention can be considered “acceptance-focused”. The ACT intervention taught acceptance, mindfulness, and values-based techniques to address negative thoughts, emotions, and food cravings. Each of these techniques was presented individually for two sessions each (each of the three primary components was addressed for two sessions each), in addition to being integrated across topics in each session throughout the treatment. Broadly speaking, the ACT intervention aimed to present the concept of being aware of negative states and making a conscious choice to make healthful-value driven behavioral choices in the presence of those thoughts, feelings, and emotions rather than a change-focused SBT perspective of combatting those negative states to distract, suppress, or remove them.

Of primary interest for the secondary analysis, the values work taught in the ACT condition helped participants to identify how weight-related behaviors fit with their self-identified core values. More specifically, weight influencing behaviors and actions were seen as ways to support broader desired life actions as defined by their own self-identified values. If goals are specific and attainable which support more aspirational and intangible values (i.e. you can achieve a goal, and that goal can and should be congruent

with your values, but a value is a lifelong pursuit and never a “completed” goal that can be checked off). In this sense, goals support values by serving as tangible markers along an intangible journey. For example, a goal of exercising five times a week is achievable and is congruent with a stated value of setting a good example of health for family members or increasing longevity and quality of life to spend more time with loved ones. Those previously mentioned values of setting a good example or increasing longevity would never be reached but are instead something continually demonstrated with actions (i.e., you wouldn’t ever reach a state of completing being a good example). Therefore, while goals are measurable markers of values, these goals would have no meaning outside the context of one’s stated values. The continual connection of weight-influencing actions and behaviors to one’s stated core values was emphasized repeatedly and presumed to sustain motivation to persevere in weight-loss behaviors even in the presence of adverse states.

In addition to values work the other two core components included mindfulness and acceptance. Mindfulness techniques were introduced to aid participants in increasing their awareness of their thoughts and feelings. Of particular importance in the ACT intervention was the concept of cognitive defusion. The aim of cognitive defusion is to allow an individual to distance themselves from unhelpful thoughts, but without trying to change them or get rid of them. In this sense, a thought can be seen as a thought you are having rather than as a fact or “truth”. The primary goal of cognitive defusion is therefore to de-couple maladaptive thoughts and unhealthy behaviors (i.e., behaviors that are not congruent with stated values). Mindfulness is presented to ACT participants in a variety

of ways including meditation, thought labeling, guided imagery, thought exposure, and metaphors.

Acceptance strategies were presented through experiential exercises to demonstrate that efforts to either avoid or control internal experiences have not been successful in the past, nor will they be moving forward, and instead are coupled with unhealthy behaviors for weight control. Examples of this include emotional eating to reduce stress or sadness in short-term, but at a long-term expense of poor health, and possibly increased stress and sadness along with weight gain and the dissonance between behaviors and values. More specifically, efforts to control unwanted thoughts or feelings in the moment can often result in even more amplified negative thoughts or feelings later. A variety of exercises were used to expose participants to unwanted physiological and psychological states, such as guided imagery and presentation of highly craved foods, and then distress tolerance skills were taught with the negative thoughts and emotions present.

CHAPTER 3

PURPOSE OF THE PRESENT STUDY

The primary outcomes from the original study of this intervention (Lillis et al., 2016) indicated that an ACT program achieved better weight loss at 24 months compared to those allocated to the SBT condition. At month 24, participants in the ACT condition had a mean weight change of -4.1% (SE = 0.88) compared with -2.4% (SE = 0.87; $p = 0.204$) for SBT participants (24.3 vs. 22.6 kg). Although overall weight change at month 24 did not differ between groups, the time x condition interaction in the model approached significance ($p = 0.067$). Thus, secondary analyses were conducted to compare the weight changes in ACT versus SBT during the intervention phase (0-12 months) and during post-treatment follow-up phase (12-24 months). The interaction was not significant during the treatment phase ($p = 0.680$), but there was a significant time by condition interaction ($p = 0.005$) during the post-treatment phase, where participants in the ACT condition gained an average of 4.6 kg versus 7.1 kg for SBT participants.

Additionally, participants in the ACT condition reported greater reductions in weight-related experiential avoidance. Internal disinhibition decreased significantly over time (time variable, $p < 0.001$), but the changes did not differ by condition (time x condition interaction, $p = 0.777$). Although the largest reductions in internal disinhibition occurred during treatment, at 24 months both groups had lower internal disinhibition scores than at baseline. Changes in internal disinhibition from baseline were significantly correlated (all p values < 0.01) with changes in weight in both conditions at 6 months ($r = 0.52$ in ACT and $r = 0.37$ in SBT) and 12 months ($r = 0.50$ in ACT and $r = 0.53$ in SBT); at 18 and 24 months internal disinhibition change was significantly correlated with weight

change in the ACT group ($r=0.25$, $r=0.28$ respectively, $p's<0.05$) but was not significantly correlated with weight change in the SBT group ($r= -0.07$, $r= 0.18$ respectively, $p= NS$). The primary outcomes paper did not examine changes in values-consistent behavior over time, nor how the various subdomains of valued behavior changed over time. Therefore, the purpose of these analyses is to further understand if, and how much values consistency and clarity contributes as a mechanism of change.

Thus far acceptance-based interventions have not yet been tested in regards to long-term weight loss maintenance, which is the time when failure to adhere to a behavioral weight loss intervention is most common (Forman & Butryn, 2015). Also, an ACT-based weight loss treatment program has not yet been compared to SBT in a population which specifically endorses high internal disinhibition, the very population potentially benefiting the most from an ACT treatment (Forman et al., 2009).

Additionally, studies have begun to examine not only whether these treatments work, but whether they work through the proposed mechanisms of the model (i.e., six core processes). Initial research suggests that the process variables targeted by ACT are at least partially responsible for the ACT intervention outcomes (Hayes et al., 2006). The research on ACT mechanisms of change has been short in duration and limited in scope. Acceptance and psychological flexibility (or reductions in avoidance and inflexibility) (Gifford & Lillis, 2009; Lillis, Hayes, Bunting, & Masuda, 2009) and mindfulness and defusion (Goodwin, Forman, Herbert, Butryn, & Ledley, 2012) have received the majority of attention as process variables to date. Treatment outcome differences alone are insufficient to evaluate how each treatment works. Until these process variables are

better understood, it will be impossible to definitively state whether either treatment (ACT versus SBT) operates in a truly different way (Hayes et al., 2013).

If well-designed randomized controlled trials can demonstrate ACT to be more effective than the current SBT for weight loss, this would have potentially important implications for the current best practices for behavioral weight loss therapy.

Additionally, if studies can demonstrate that ACT can potentially improve adherence or improve long-term maintenance, this would further support the integration of ACT principles into the current SBT for weight loss. Furthermore, if certain subgroups, for instance those who endorse high internal disinhibition, are found to benefit more from ACT than SBT relative to those who do not endorse high disinhibition, more personalized and tailored programs can be administered in such populations. Finally, and of most relevance to this paper, further identifying process variables (such as values clarity and consistency) and understanding the mechanisms of change within this model is of importance both to further refine the model, and to better design interventions to target process variables that induce the most change. As the hypotheses from the primary outcomes paper were at least partially confirmed, there were two aims for this current project to further understand the process of change variable of values consistency and how it relates to weight loss between groups and over time.

Primary Aim One. To longitudinally model weight and values scores during the 12 months of intervention and 12 months of follow-up. More specifically, to explore a variety of different longitudinal models, with the goal of exploring if greater care in model selection would impact the findings of the initial outcomes paper.

Primary Aim Two. To conduct a mediation analysis to identify if, and how much, values scores mediated change in weight over time.

CHAPTER 4

METHODS

Secondary data analysis was conducted to address the research questions of the current study. Permission has been granted from Weight Control and Diabetes Research Center (WCDRC), a joint research institution of The Miriam Hospital and the Warren Alpert Medical School of Brown University, in Rhode Island to analyze this de-identified dataset. Both the Institutional Review Boards at The Miriam Hospital, which approved the original trial, as well as the University of Rhode Island's Institutional Review Board approved this current study. Full and detailed methods of the original study have been published elsewhere (Lillis et al., 2015), as well as the primary outcomes paper (Lillis et al., 2016).

Participants and Sampling.

A total of 162 participants were enrolled and randomly allocated to treatment (ACT or SBT). For a full explanation of the behavioral weight loss interventions employed refer to methodological design (Lillis, et al., 2015) and primary outcomes (Lillis, et al., 2016) papers. Randomization was completed using number generation software in a 1:1 allocation. However, given the expected low rate of participation of males as compared to females, randomization was stratified by sex to ensure near equal numbers of males and females in each treatment condition. Eligibility criteria included being a man or woman between 18 and 70 years of age, a BMI between 25 and 50 kg/m², and a score of a 5 or higher on the internal disinhibition subscale of the Eating Inventory (EI). A more detailed list of inclusion and exclusion criteria are available (Lillis, et al., 2015).

Measures.

All assessments were administered by research assistants who were blinded to the treatment assignment of participants. Data on participant weight (procedures detailed in anthropometric measures) and ordinal value scores (procedure detailed in psychosocial measures) from four values domains were measured at seven time points: baseline, three months, six months, nine months, 12 months, 18 months, and 24 months. A detailed description of measures is available (Lillis et al., 2015), and the primary outcomes paper is also available (Lillis et al., 2016).

Demographics. At baseline only, a demographic questionnaire was administered to collect the following information: sex, age, race, ethnicity, marital status, age, and income.

Anthropometrics. At all assessments, weight was measured to the nearest 0.1 kg using a digital scale while participants wore light indoor clothing without shoes and with empty pockets. At baseline only, height was measured to the nearest millimeter with a wall-mounted stadiometer using standard procedures. From these measures of height and weight BMI was calculated using the standard formula (weight in kg/ height in meters²).

Eating Behavior. The EI is a well-established measure of eating behavior (Westenhoefer, Stunkard, & Pudel, 1999). For purposes of the current analysis it was used solely to screen at the time of enrollment/baseline. The purpose of this was to specifically recruit and enroll participants who endorsed high amounts of emotional and stress related eating behaviors. To meet eligibility requirements, a potential participant needed to score 5 or higher on the internal disinhibition subscale (demonstrating disinhibited eating behavior). Previous research has shown that individuals who score

five or higher (out of eight) on the internal disinhibition subscale lose significantly less weight in a standard behavioral weight loss program over 18 months (4.8 versus 7.6kg) (Niemeier et al., 2012). The EI has demonstrated sufficient internal consistency and test-retest reliability (Shearin, Russ, Hull, Clarkin, & Smith, 1994; Westenhoefer, et al., 1999).

Psychosocial Measures. All psychosocial measures were assessed at all assessment points, and a full description of each follow.

Bull's Eye: The Bull's Eye Value Survey (BEVS) is designed to assess one's ability to take action in a manner consistent with one's self-identified values and goals (Lundgren, Luoma, Dahl, Strosahl, & Melin, 2012). In completing the BEVS participants are asked to identify their personal values and goals in four specific domains of life (health, relationships, work/education, and leisure). Once their values have been established in each of the four domains, participants then indicate on a dartboard with seven rings how consistently their actual behavior corresponds to the previously self-stated values and goals in each of the four domains. Marks drawn closer to the center of the dartboard (i.e. bull's eye) indicate greater consistency between behavior and values. Marks for each of the four domains are then converted into a Likert scale from 1-7 (1 corresponding to a mark on the outermost ring of the dartboard, and each subsequent number moving in a ring closer on the dartboard). Therefore, a higher score indicates greater consistency between behavior and stated values in each domain. The BEVS has been shown to be sensitive to treatment effects and able to differentiate between clients who receive values-based interventions and those who do not. Additionally, the BEVS

has demonstrated acceptable temporal stability as well as internal consistency (Dahl, 2015; Lundgren et al., 2012).

Data Analysis. Baseline characteristics were presented as means \pm standard deviations or percentages, as appropriate. All data were checked for statistically significant baseline differences. To describe the data on raw participant weight and the value score, as well as change in weight and value score, distributional summaries, boxplots, and scatterplots with smoothed loess line (a smoothed line using local regression) to show the longitudinal trends were utilized. For values, the overall 28-point ordinal value score was reported and used in the analyses.

Primary Aim One. To longitudinally model weight and values scores during the 12 months of intervention and 12 months of follow-up. This aim was addressed by longitudinally modeling participant weight and the value score using both linear mixed models and covariance pattern models. Time was treated as both continuous (see appendices A and B for weight and the value score, respectively), and nominal (i.e., categorical). Given the balanced nature of the data, where there was uniformity in the timing of the visits across all participants, it was appropriate to treat time as nominal. While a correctly specified continuous model, for example using polynomial terms, would generally have more statistical power to detect a longitudinal difference in participant weight or values by study arm, such a model may not capture the true underlying mean trend. Conversely, a nominal time model does not have the same concern as to the potential for model misspecification in the functional form of the fixed effects. Hence, analyses were conducted using both models.

Care was taken in model selection, particularly as to functional form of time for the continuous time model, and to the structure of the variance-covariance matrix for the nominal time model. Competing models were compared using the Akaike Information Criteria (AIC) based on ordinary maximum likelihood, as the models were non-nested. Model assumptions and adequacy of fit were assessed through residual plots (not shown). Final model estimates and standard errors were based on restricted maximum likelihood (REML), which is recommended when reporting model estimates as ordinary maximum likelihood can underestimate variance components especially in small to modest samples (Fitzmaurice, 2011). All longitudinal models presented are valid under the missing at random (MAR) assumption. The following models were fit:

Model 1: Longitudinal model of participant weight with continuous time (results shown in Appendix A):

$$\begin{aligned} \text{Weight} = & \mathbf{B0} + \mathbf{B1}*\text{ACT} + \mathbf{B2}*\text{Time} + \mathbf{B3}*\text{Time}^2 + \mathbf{B4}*\text{Time}^3 + \mathbf{B5}*\text{ACT}*\text{Time} \\ & + \mathbf{B6}*\text{ACT}*\text{Time}^2 + \mathbf{B7}*\text{ACT}*\text{Time}^3 + \mathbf{b0} + \mathbf{b1}*\text{Time} + \mathbf{error} \end{aligned}$$

Where ACT is a binary indicator for randomized ACT, Time is continuous in months, Time² is a quadratic term, Time³ is a cubic term, $\mathbf{b0} \sim N(0, \sigma_1^2)$ is a random intercept term, $\mathbf{b1} \sim N(0, \sigma_2^2)$ is a random slope term, and $\mathbf{error} \sim N(0, \sigma^2)$ is a random error term. The random intercept and random slope are subject-specific parameters which allow each subject to have his or her own intercept and slope. This is a flexible model that allows both the variance and covariance terms of the within-subject variance-covariance matrix to vary as a function of time and allows for curvature over time with separate longitudinal curves by study arm due to the interaction between the treatment parameter and time.

Model 2: Longitudinal model of the value score with continuous time (results shown in Appendix B):

$$\begin{aligned} \text{Value score} = & \mathbf{B0} + \mathbf{B1}*\text{ACT} + \mathbf{B2}*\text{Time} + \mathbf{B3}*\text{Time}^2 + \mathbf{B4}*\text{Time}^3 + \\ & \mathbf{B5}*\text{ACT}*\text{Time} + \mathbf{B6}*\text{ACT}*\text{Time}^2 + \mathbf{B7}*\text{ACT}*\text{Time}^3 + \mathbf{b0} + \mathbf{b1}*\text{Time} + \text{error} \end{aligned}$$

Where ACT is a binary indicator for randomized ACT, Time is continuous in months, Time² is a quadratic term, Time³ is a cubic term, $\mathbf{b0} \sim N(0, \sigma_1^2)$ is a random intercept term, $\mathbf{b1} \sim N(0, \sigma_2^2)$ is a random slope term, and $\text{error} \sim N(0, \sigma^2)$ is a random error term. Refer to the comments for **Model 1**.

Model 3: Longitudinal model of participant weight with nominal time (random intercept):

$$\begin{aligned} \text{Weight} = & \mathbf{B0} + \mathbf{B1}*\text{ACT} + \mathbf{B2}*\text{T3} + \mathbf{B3}*\text{T6} + \mathbf{B4}*\text{T9} + \mathbf{B5}*\text{T12} + \mathbf{B6}*\text{T18} + \\ & \mathbf{B7}*\text{T24} + \mathbf{B8}*\text{ACT}*\text{T3} + \mathbf{B9}*\text{ACT}*\text{T6} + \mathbf{B10}*\text{ACT}*\text{T9} + \mathbf{B11}*\text{ACT}*\text{T12} + \\ & \mathbf{B12}*\text{ACT}*\text{T18} + \mathbf{B13}*\text{ACT}*\text{T24} + \mathbf{b0} + \text{error} \end{aligned}$$

Where ACT is a binary indicator for ACT, Ti is a binary indicator for the ith-month time point, $\mathbf{b0} \sim N(0, \sigma_1^2)$ is a random intercept term and $\text{error} \sim N(0, \sigma^2)$ is a random error term. The random intercept is a subject-specific parameter which allows each subject to have his or her own intercept. Separate means by study arm at each time point are secured by the interaction terms.

Model 4: Longitudinal model of participant weight with nominal time (Toeplitz model):

$$\begin{aligned} E(\text{Weight}) = & \mathbf{B0} + \mathbf{B1}*\text{ACT} + \mathbf{B2}*\text{T3} + \mathbf{B3}*\text{T6} + \mathbf{B4}*\text{T9} + \mathbf{B5}*\text{T12} + \mathbf{B6}*\text{T18} + \\ & \mathbf{B7}*\text{T24} + \mathbf{B8}*\text{ACT}*\text{T3} + \mathbf{B9}*\text{ACT}*\text{T6} + \mathbf{B10}*\text{ACT}*\text{T9} + \mathbf{B11}*\text{ACT}*\text{T12} + \\ & \mathbf{B12}*\text{ACT}*\text{T18} + \mathbf{B13}*\text{ACT}*\text{T24} \end{aligned}$$

Where ACT is a binary indicator for ACT randomization and T_i is an indicator for the i^{th} -month time point. Further, as opposed to using a random intercept, which enforces a compound-symmetry variance-covariance matrix, **Model 4** is a covariance pattern model using a Toeplitz variance-covariance matrix, which assumes equal variance at each time point, but allows the covariance to vary over time, with any pair of responses that are equally separated in time having the same covariance. Again, separate means by study arm at each time point are secured by the interaction terms.

Model 5: Longitudinal model of the value score with nominal time (Toeplitz model):

$$E(\text{Value score}) = \mathbf{B0} + \mathbf{B1}*\text{ACT} + \mathbf{B2}*T3 + \mathbf{B3}*T6 + \mathbf{B4}*T9 + \mathbf{B5}*T12 + \\ \mathbf{B6}*T18 + \mathbf{B7}*T24 + \mathbf{B8}*\text{ACT}*T3 + \mathbf{B9}*\text{ACT}*T6 + \mathbf{B10}*\text{ACT}*T9 + \\ \mathbf{B11}*\text{ACT}*T12 + \mathbf{B12}*\text{ACT}*T18 + \mathbf{B13}*\text{ACT}*T24.$$

Where ACT is a binary indicator for ACT randomization and T_i is an indicator for the i^{th} -month time point. Refer to the comments for **Model 4**.

Primary Aim Two. Weight change from baseline to 24 months was considered as the outcome. The putative mediator was defined as the change in value score from baseline to 18 months (baseline to 12 months was also examined). It is generally recommended that the presumed mediator and outcome not be assessed at the same time, but that the mediator be measured prior to the outcome, since it is posited that treatment causes a change in the presumed mediator which in turn causes a change in the outcome (Maxwell, 2011). The mediation analysis approach suggested by Baron and Kenny (1986) was employed, where a series of three models were fit: the outcome regressed on treatment, the outcome regressed on the putative mediator, and the outcome

regressed on treatment and the putative mediator (see **Model 6** through **Model 8** below). If the value score mediates weight loss, then the **B1** coefficient under **Model 8** should be smaller than the **B1** coefficient under **Model 6** (models shown below).

In addition, the mediation package in R was used to calculate the average causal mediation effect (ACME), average direct effect (ADE), and proportion mediated, with variance estimation conducted via nonparametric bootstrapping with N=50,000 simulations. To estimate these causal effects, the assumption is that the mediator is ignorable given the observed treatment and pretreatment confounders (also referred to as sequential ignorability) (Tingley, 2014). In other words, among subjects who share the same treatment status and the same pretreatment characteristics, the analysis assumes that the mediator can be regarded as if it were randomized. It should be noted that this is a strong assumption.

Model 6: Outcome regressed on Treatment

$$\text{Diff in weight at 24 months} = B0 + B1*ACT + \text{error}$$

Model 7: Putative Mediator regressed on Treatment

$$\text{Diff in value score at 18 months} = B0 + B1*ACT + \text{error}$$

Model 8: Outcome regressed on Treatment and Mediator

$$\text{Diff in weight at 24 months} = B0 + B1*ACT + B2*\text{Diff in value score at 18 months} + \text{error}$$

Where for each model, ACT is a binary indicator for randomized ACT and **error** ~ N(0,σ²) is a random error term.

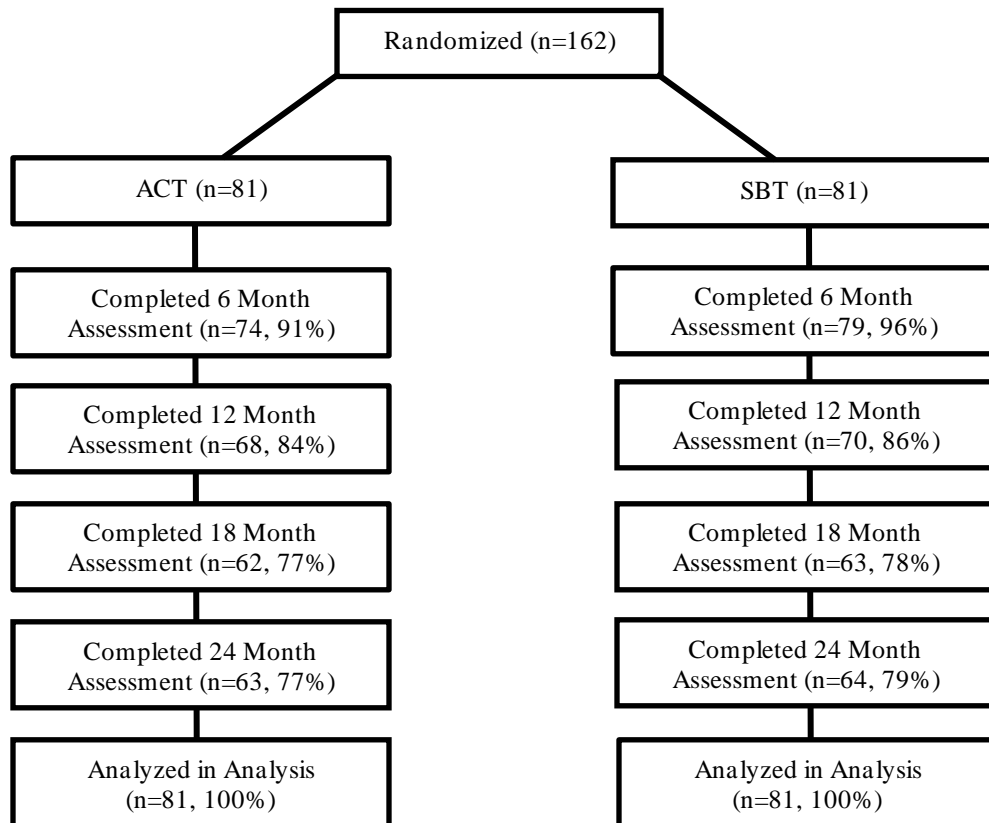
CHAPTER 5

RESULTS

Enrollment and retention.

A total of 748 potential participants contacted the WCDRC for information about the study. Of those, 162 were randomized after being found eligible and completing all pre-randomization study procedures. Participants who stopped attending treatment sessions continued to be followed/contacted for assessments. See Figure 2 for details on participant flow.

Figure 2. Participant Flow from randomization through intervention, assessment, and analysis.



Baseline characteristics.

The sample was predominantly middle-aged (50.2 ± 10.9), Caucasian (88%), and female (85%). The mean BMI was $37.6 \pm 5.3 \text{ kg/m}^2$. Table 1 presents the baseline characteristics of participants in the total sample as well as the ACT and SBT groups separately (Lillis et al., 2016). At baseline, as compared to the ACT group the SBT group scored significantly higher on both leisure time value consistency (2.5 ± 1.3 vs. 3.1 ± 1.6 , $p=0.02$) and total value consistency (12.0 ± 4.3 vs. 13.6 ± 4.4 , $p=0.01$).

Table 1. Baseline Characteristics of Participants.

	ACT (n=81)	SBT (n=81)	TOTAL (n=162)
Sex, N(%)			
Female	69 (85)	69 (85)	138 (85)
Male	12 (15)	12 (15)	24 (12)
Race/Ethnicity, N(%)			
Black/African American	6 (7.5)	2 (2.5)	8 (5)
Hispanic	5 (6)	5 (6)	10 (6)
Asian	2 (2.5)	0 (0)	2 (1)
Caucasian (non-Hispanic)	68 (84)	74 (91.5)	142 (88)
Education, N(%)			
High School	6 (7)	6 (7)	12 (7.5)
Some College/Vocational	24 (30)	20 (25)	44 (28)
Bachelor's Degree	29 (37)	29 (37)	58 (36.5)
Graduate or Professional	21 (26)	24 (31)	45 (28)
Age (years)	50.7 ± 11.3	49.8 ± 10.7	50.2 ± 10.9
Weight (kg)	102.5 ± 17.3	102.2 ± 17.7	102.3 ± 17.4
BMI (kg/m²)	37.5 ± 5.4	37.7 ± 5.3	37.6 ± 5.3
Values			
Health	2.0 ± 1.2	2.3 ± 1.5	2.2 ± 1.3
Relationships	3.8 ± 1.8	4.1 ± 1.7	3.9 ± 1.7
Leisure**	2.5 ± 1.3	3.1 ± 1.6	2.8 ± 1.5
Work/Education	3.8 ± 1.9	4.1 ± 1.5	3.9 ± 1.7
Total*	12.0 ± 4.3	13.6 ± 4.4	12.8 ± 4.4

* Denotes statistical significance at $p < 0.05$. ** Denotes statistical significance at $p < 0.01$.

Weight.

Distributional summaries of weight and of raw change from baseline for weight are shown in Tables 2 and 3, respectively (Lillis et al., 2016). Overall, across both study arms and all time points, 165/1134 (15%) of responses were missing for weight. No missing data occurred at the baseline visit, and missing data rates were higher for later time points (9-month time point and beyond).

Table 2 Distributional summaries of weight (kg) by study arm and time point.

Timepoint	Study arm			
	ACT (n=81)		SBT (n=81)	
	M (SD) Median (Min, Max)	Number missing (%)	M (SD) Median (Min, Max)	Number missing (%)
Baseline	102.5 (17.3) 100.6 (74.9, 150.8)	0 (0%)	102.2 (17.7) 97.7 (73.1, 152.9)	0 (0%)
3 months	95.7 (17.0) 92.1 (65.8, 150.2)	8 (10%)	93.9 (17.0) 90.8 (65.5, 140.7)	8 (10%)
6 months	92.8 (16.9) 89.8 (64.7, 153.1)	7 (9%)	91.9 (16.9) 91.2 (61.1, 135.0)	2 (2%)
9 months	90.1 (16.0) 88.6 (64.9, 150.5)	21 (26%)	89.2 (17.7) 86.8 (54.3, 133.2)	18 (22%)
12 months	93.4 (18.3) 90.2 (61.9, 149.9)	14 (17%)	92.0 (17.5) 90.2 (57.0, 133.0)	12 (15%)
18 months	96.4 (19.5) 91.5 (64.5, 155.1)	20 (25%)	95.4 (18.2) 90.3 (63.8, 137.4)	18 (22%)
24 months	98.2 (19.6) 96.0 (61.6, 152.2)	19 (23%)	98.3 (19.1) 90.5 (69.2, 150.7)	18 (22%)

Table 3 Distributional summaries of raw change in weight (kg) from baseline by study arm and time point

Timepoint	Study arm			
	ACT (n=81)		SBT (n=81)	
	M (SD) Median (Min, Max)	Number missing (%)	M (SD) Median (Min, Max)	Number missing (%)
Baseline	-	-	-	-
3 months	-8.0 (4.6) -7.8 (-19.2, 2.5)	8 (10%)	-8.1 (4.4) -8.3 (-21.5, 4.2)	8 (10%)
6 months	-9.9 (6.5) -8.7 (-30.0, 5.4)	7 (9%)	-10.4 (7.1) -10.3 (-31.4, 7.4)	2 (2%)
9 months	-11.0 (8.9) -9.3 (-36.6, 6.8)	21 (26%)	-12.9 (8.8) -11.8 (-38.5, 3.4)	18 (22%)
12 months	-9.4 (9.0) -7.0 (-37.6, 6.2)	14 (17%)	-9.7 (9.5) -8.1 (-37.3, 9.4)	12 (15%)
18 months	-6.4 (8.9) -6.1 (-38.7, 12.0)	20 (25%)	-6.5 (8.0) -5.7 (-30.3, 12.0)	18 (22%)
24 months	-5.4 (7.9) -4.4 (-31.9, 7.4)	19 (23%)	-3.4 (6.8) -3.2 (-23.8, 10.9)	18 (22%)

Exploratory plots of the longitudinal trend in weight are depicted by a boxplot of weight by timepoint and study arm (Figure 3), and scatterplots of weight (Figure 4) and change in weight (Figure 5) by timepoint and study arm. For the scatterplots, in each row, the plot on the right shows a zoomed-in version. The scatterplots have smoothed loess line to demonstrate the longitudinal trend. These plots suggest that the SBT arm exhibited a slightly larger decrease in weight during the study intervention (i.e. through 12 months), but also exhibited a larger rebound in weight gain post-intervention (12 through 24 months).

Figure 3 Boxplot of weight (kg) by time and treatment group

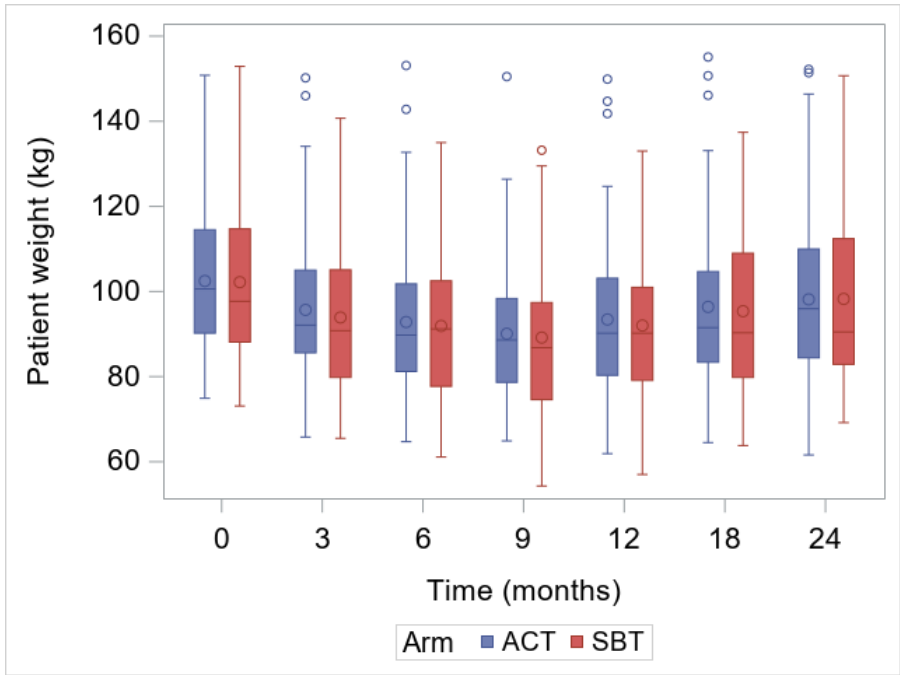


Figure 4 Scatterplot of weight (kg) over time by treatment group. The right is the zoomed-in version.

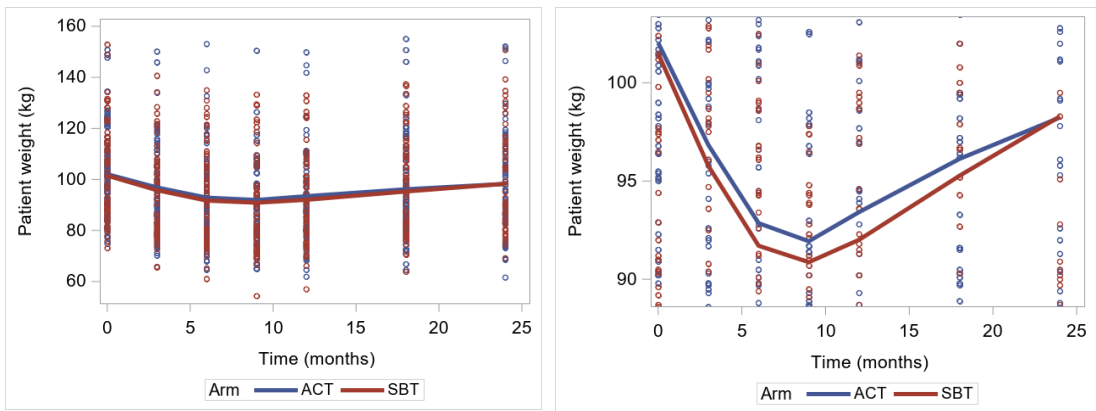
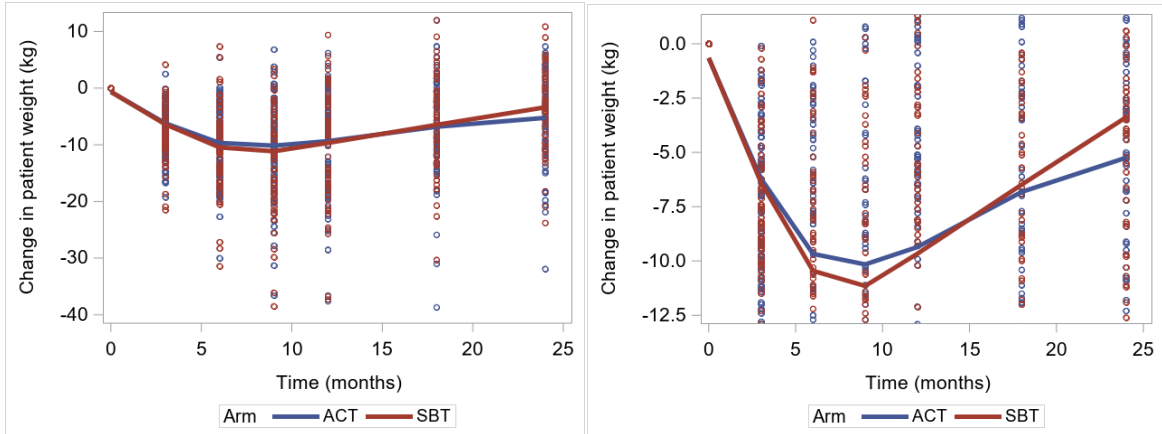


Figure 5 Scatterplot of change in weight (kg) over time by treatment group. The right is the zoomed-in version.



Value Scores.

Distributional summaries of values scores and of raw change from baseline for values are shown in Tables 4 and 5, respectively. Overall, across both study arms and all time points, 163/1134 (14%) of responses were missing for value score. No missing data occurred at the baseline visit, and missing data rates were higher for later time points (9-month time point and beyond). In addition, there was some imbalance noted in the value score at baseline (mean 12.0 ACT vs. mean 13.6 SBT); this can occur with small sample sizes despite randomization.

Table 4. Distributional summaries of the value score by study arm and time point.

Timepoint	Study Arm			
	ACT (n=81)		SBT (n=81)	
	M (SD) Median (Min, Max)	Number missing (%)	M (SD) Median (Min, Max)	Number missing (%)
Baseline	12.0 (4.3) 11 (5, 23)	0 (0%)	13.6 (4.4) 13 (4, 24)	0 (0%)
3 months	13.8 (4.2) 14 (4, 25)	8 (10%)	14.5 (4.3) 14 (6, 24)	8 (10%)
6 months	15.6 (4.0) 16 (6, 24)	8 (10%)	15.9 (4.5) 16 (5, 25)	3 (4%)
9 months	15.5 (4.2) 16 (5, 23)	21 (26%)	16.1 (4.7) 16 (7, 26)	18 (22%)
12 months	16.2 (4.8) 16 (7, 26)	14 (17%)	17.0 (5.1) 17 (4, 26)	12 (15%)
18 months	15.4 (5.1) 15 (5, 26)	19 (23%)	15.7 (4.7) 16 (6, 26)	18 (22%)
24 months	15.8 (4.8) 16 (5, 26)	17 (21%)	15.3 (4.8) 15.5 (6, 26)	17 (21%)

Table 5. Distributional summaries of raw change in the value score from baseline by study arm and time point.

Timepoint	Study Arm			
	ACT (n=81)		SBT (n=81)	
	M (SD) Median (Min, Max)	Number missing (%)	M (SD) Median (Min, Max)	Number missing (%)
Baseline	-	-	-	-
3 months	1.9 (4.2) 2 (-9, 12)	8 (10%)	1.0 (4.0) 1 (-6, 10)	8 (10%)
6 months	3.7 (4.3) 3 (-8, 14)	8 (10%)	2.3 (4.7) 2 (-10, 12)	3 (4%)
9 months	3.6 (5.1) 3 (-12, 13)	21 (26%)	2.6 (4.7) 2 (-7, 12)	18 (22%)
12 months	4.3 (5.3) 4 (-7, 21)	14 (17%)	3.1 (5.1) 3 (-7, 14)	12 (15%)
18 months	3.5 (4.9) 4 (-10, 16)	19 (23%)	1.6 (4.3) 1 (-7, 12)	18 (22%)
24 months	4.1 (4.5) 5 (-4, 13)	17 (21%)	1.2 (4.3) 1 (-12, 9)	17 (21%)

Exploratory plots of the longitudinal trend in values are depicted by a boxplot of values by timepoint and study arm (Figure 6), and scatterplots of values (Figure 7) and change in values (Figure 8) by timepoint and study arm. For the scatterplots, in each row, the plot on the right shows a zoomed-in version. The scatterplots have smoothed loess line to demonstrate the longitudinal trend. These plots suggest that both arms exhibited an increase in the value score throughout the study intervention (i.e. through 12 months); however, after the study intervention (12 through 24 months), the SBT arm saw a drop in the value score whereas the ACT arm appeared to maintain the gain in value score on average.

Figure 6 Boxplot of values by time and treatment group

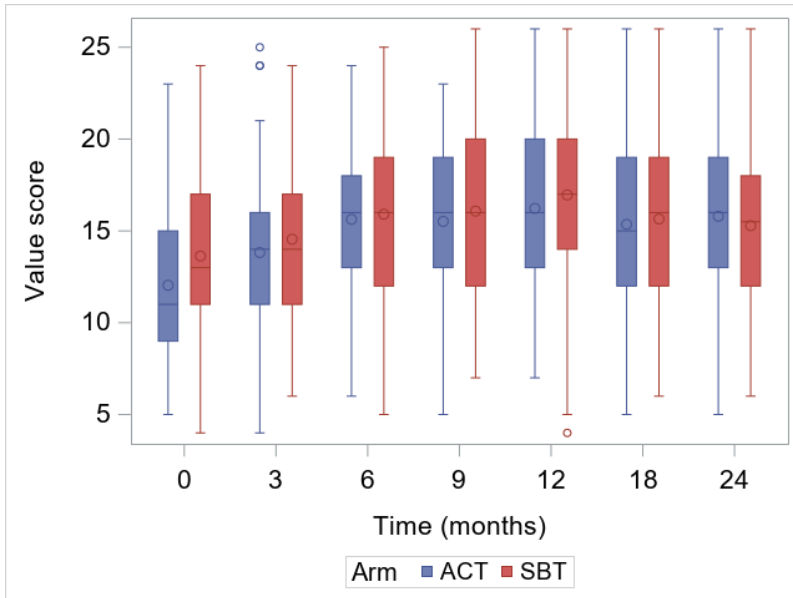


Figure 7 Scatterplot of values over time by treatment. The right is a zoomed-in version.

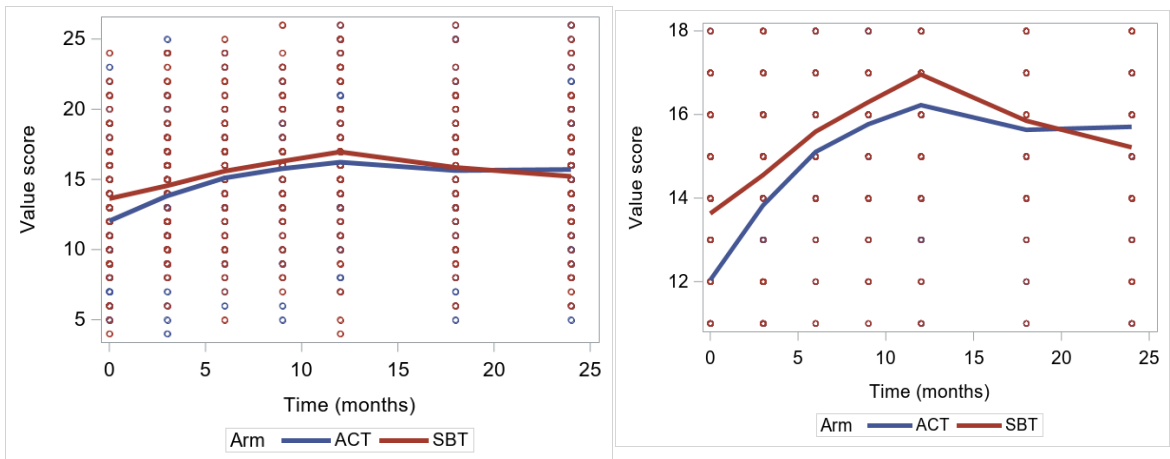
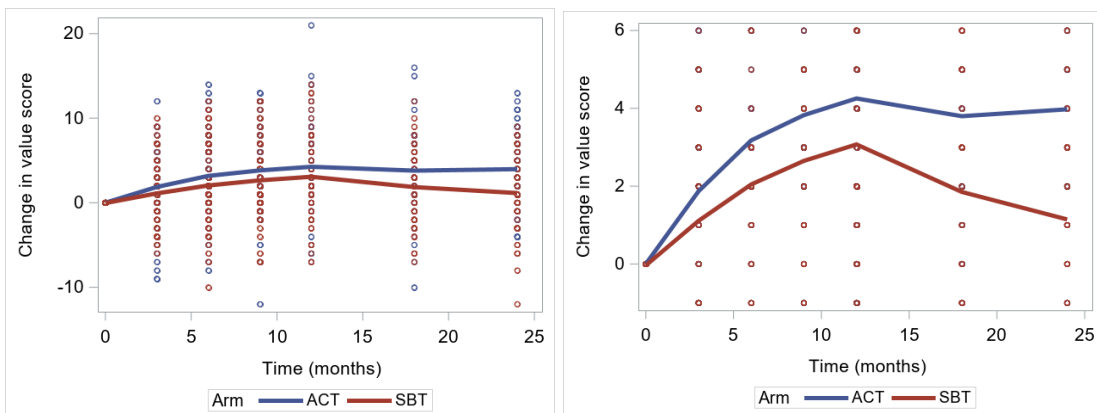


Figure 8 Scatterplot of change in value score over time by treatment. The right is a zoomed-in version.



Nominal Longitudinal Modeling of Weight.

As previously stated, if the continuous model (**Model 1** in Appendix A) is correctly specified, then it will generally have more statistical power to detect a longitudinal difference in participant weight by study arm. However, a polynomial may not capture the true underlying mean trend, and a nominal time model does not have the same concern as to the potential for model misspecification in the form of the fixed effects. Therefore, nominal models were also fit and compared using AIC.

Model 3 (detailed on page 27) is a linear mixed model including nominal time and a random intercept and is given by $Weight = \mathbf{B0} + \mathbf{B1} * ACT + \mathbf{B2} * T3 + \mathbf{B3} * T6 + \mathbf{B4} * T9 + \mathbf{B5} * T12 + \mathbf{B6} * T18 + \mathbf{B7} * T24 + \mathbf{B8} * ACT * T3 + \mathbf{B9} * ACT * T6 + \mathbf{B10} * ACT * T9 + \mathbf{B11} * ACT * T12 + \mathbf{B12} * ACT * T18 + \mathbf{B13} * ACT * T24 + \mathbf{b0} + error$. Note that this corresponds to a compound symmetry within-subject variance-covariance matrix. The null hypothesis of no difference by study arm in the longitudinal profiles of participant weight is $\mathbf{H0: B8=B9=B10=B11=B12=B13=0}$, which can be assessed by means of a joint significance test using a chi-square test with six degrees of freedom based on the corresponding estimable contrast. Model estimates are shown in Table 7. Note that it is best statistical practice to use the six degree of freedom omnibus test: if this test is not significant (which is the case here, $p=0.1622$), then no further differences are explored.

However, note that the assumed compound symmetry variance-covariance matrix in this model is very restrictive; namely, within a subject, it assumes that the covariance between any two observations is the same no matter how far apart in time. Instead, one can fit a covariance pattern model that allows for a more flexible variance-covariance matrix. Given that there are seven observations per subject, and thus a 7x7 within-subject

variance-covariance matrix is required, an unstructured model would require 28 variance and covariance parameters, which is probably too many for this modest size sample.

Instead, the analysis considered variance-covariance matrices that impose some structure on the matrix, but at the same time are more flexible.

Table 6. AIC of Competing Models for Participant Weight

Continuous time polynomial model:	AIC=6267.1
Compound symmetry model (equivalent to random intercept model):	AIC=6352.6
First-order autoregressive model:	AIC=6152.7
Heterogenous autoregressive model:	AIC=6105.8
Toeplitz model:	AIC=6001.8

Table 6 compares various models using the AIC based on ordinary maximum likelihood, where smaller AIC indicates a better fit, and the continuous time model (**Model 1** from Appendix A) is added for reference. Using a Toeplitz variance-covariance matrix arrives at an alternative model, which requires only 6 covariance parameters and has the lowest AIC. This corresponds to **Model 4** (detailed on page 27) and is given by

$$E(\text{Weight}) = \mathbf{B0} + \mathbf{B1}*\text{ACT} + \mathbf{B2}*T3 + \mathbf{B3}*T6 + \mathbf{B4}*T9 + \mathbf{B5}*T12 + \mathbf{B6}*T18 + \mathbf{B7}*T24 + \mathbf{B8}*\text{ACT}*T3 + \mathbf{B9}*\text{ACT}*T6 + \mathbf{B10}*\text{ACT}*T9 + \mathbf{B11}*\text{ACT}*T12 + \mathbf{B12}*\text{ACT}*T18 + \mathbf{B13}*\text{ACT}*T24.$$

In this model, the within-subject variance-covariance matrix assumes equal variance at each time point, but allows the covariance to vary over time, where any pair of responses that are equally separated in time have the same covariance. Note that the fixed effects remain the same. The null hypothesis of no difference by study arm in the longitudinal profiles of participant weight is again **H₀: B₈=B₉=B₁₀=B₁₁=B₁₂=B₁₃=0**, which can be assessed by means of a joint significance test using a chi-square test with 6 df based on the corresponding estimable contrast.

Model estimates for the Toeplitz model (**Model 4**) are shown in Table 8. The null hypothesis of no difference by study arm (omnibus test) was rejected ($p=0.0059$). It appears that there was a difference between arms at the 24-month time point, where the ACT arm exhibited a larger decrease from baseline to 24 months compared to the SBT arm ($p=0.0277$). Thus, the trend noted in the exploratory plots of a greater rebound in weight gain in the SBT arm post-intervention to month 24 was confirmed to be statistically significant using the Toeplitz model. Estimated least squares (i.e. model-based) means are presented in Table 9. Note that as a sensitivity analysis, an autoregressive model was also fit, which also showed a significant difference by study arm at month 24 (results not shown).

Table 7. Parameter Estimates for **Model 3**.

Covariate	Level	Parameter estimate (SE)	p-value
Intercept	(parameter B0)	102.20 (1.9346)	<0.001
Study arm	SBT	-ref-	-ref-
	ACT (parameter B1)	0.2741 (2.7360)	0.9202
Time point	Baseline	-ref-	-ref-
	3-month (parameter B2)	-7.5525 (0.7181)	<0.001
	6-month (parameter B3)	-10.4014 (0.6992)	<0.001
	9-month (parameter B4)	-11.9961 (0.7536)	<0.001
	12-month parameter (B5)	-9.3559 (0.7327)	<0.001
	18-month (parameter B6)	-6.2803 (0.7542)	<0.001
	24-month (parameter B7)	-3.1363 (0.7542)	<0.001
Interaction between time point and study arm	SBT*Baseline	-ref-	-ref-
	SBT*3-month	-ref-	-ref-
	SBT*6-month	-ref-	-ref-
	SBT*9-month	-ref-	-ref-
	SBT*12-month	-ref-	-ref-
	SBT*18-month	-ref-	-ref-
	SBT*24-month	-ref-	-ref-
	ACT*Baseline	-ref-	-ref-
	ACT*3-month (parameter B8)	-0.1037 (1.0167)	0.9188
	ACT*6-month (parameter B9)	0.5518 (1.0026)	0.5822
	ACT*9-month (parameter B10)	1.5637 (1.0765)	0.1468
	ACT*12-month (parameter B11)	0.2337 (1.0431)	0.8228
	ACT*18-month (parameter B12)	0.3297 (1.0743)	0.7590
	ACT*24-month (parameter B13)	-1.7194 (1.0715)	0.1089

Estimable contrast	Num DF	Chi-Square	<i>p</i>-value
Joint significance test of no longitudinal difference by study arm (Ho: B8=B9=B10=B11=B12=B13=0)	6	9.21	0.1622

Estimated Within-Subject Correlation Matrix							
	Baseline	3 months	6 months	9 months	12 months	18 months	24 months
Baseline	1.0000	0.9363	0.9363	0.9363	0.9363	0.9363	0.9363
3 months	0.9363	1.0000	0.9363	0.9363	0.9363	0.9363	0.9363
6 months	0.9363	0.9363	1.0000	0.9363	0.9363	0.9363	0.9363
9 months	0.9363	0.9363	0.9363	1.0000	0.9363	0.9363	0.9363
12 months	0.9363	0.9363	0.9363	0.9363	1.0000	0.9363	0.9363
18 months	0.9363	0.9363	0.9363	0.9363	0.9363	1.0000	0.9363
24 months	0.9363	0.9363	0.9363	0.9363	0.9363	0.9363	1.0000

Table 8. Parameter Estimates for **Model 4**.

Covariate	Level	Parameter estimate (SE)	p-value
Intercept	(parameter B0)	102.20 (1.9355)	<0.001
Study arm	SBT	-ref-	-ref-
	ACT (parameter B1)	0.2741 (2.7372)	0.9204
Time point	Baseline	-ref-	-ref-
	3-month (parameter B2)	-7.5948 (0.5738)	<0.001
	6-month (parameter B3)	-10.4002 (0.7526)	<0.001
	9-month (parameter B4)	-11.3202 (0.8707)	<0.001
	12-month (parameter B5)	-9.2431 (0.8680)	<0.001
	18-month (parameter B6)	-6.5650 (0.7665)	<0.001
	24-month (parameter B7)	-3.4075 (0.5529)	<0.001
Interaction between time point and study arm	SBT*Baseline	-ref-	-ref-
	SBT*3-month	-ref-	-ref-
	SBT*6-month	-ref-	-ref-
	SBT*9-month	-ref-	-ref-
	SBT*12-month	-ref-	-ref-
	SBT*18-month	-ref-	-ref-
	SBT*24-month	-ref-	-ref-
	ACT*Baseline	-ref-	-ref-
	ACT*3-month (parameter B8)	-0.1051 (0.8141)	0.8973
	ACT*6-month (parameter B9)	0.6094 (1.0759)	0.5712
	ACT*9-month (parameter B10)	1.2583 (1.2445)	0.3123
	ACT*12-month (parameter B11)	0.2671 (1.2365)	0.8291
	ACT*18-month (parameter B12)	0.8485 (1.0894)	0.4363
ACT*24-month (parameter B13)	-1.7302 (0.7846)	0.0277	

Estimable contrast	Num DF	Chi-Square	p-value
Joint significance test of no longitudinal difference by study arm (Ho: B8=B9=B10=B11=B12=B13=0)	6	18.12	0.0059

Estimated Within-Subject Correlation Matrix							
Row	Baseline	3 months	6 months	9 months	12 months	18 months	24 months
Baseline	1.0000	0.9586	0.9262	0.9070	0.9090	0.9334	0.9670
3 months	0.9586	1.0000	0.9670	0.9334	0.9090	0.9070	0.9262
6 months	0.9262	0.9670	1.0000	0.9670	0.9334	0.9090	0.9070
9 months	0.9070	0.9334	0.9670	1.0000	0.9670	0.9334	0.9090
12 months	0.9090	0.9090	0.9334	0.9670	1.0000	0.9670	0.9334
18 months	0.9334	0.9070	0.9090	0.9334	0.9670	1.0000	0.9670
24 months	0.9670	0.9262	0.9070	0.9090	0.9334	0.9670	1.0000

Table 9. Model-based Least Squares Means for Participant Weight from **Model 4**.

Study arm	Time point	Estimate	Standard Error
ACT	Baseline	102.47	1.94
ACT	3-month	94.77	1.94
ACT	6-month	92.68	1.95
ACT	9-month	92.41	1.96
ACT	12-month	93.50	1.96
ACT	18-month	96.76	1.96
ACT	24-month	97.34	1.95
SBT	Baseline	102.20	1.94
SBT	3-month	94.61	1.94
SBT	6-month	91.80	1.94
SBT	9-month	90.88	1.95
SBT	12-month	92.96	1.95
SBT	18-month	95.64	1.96
SBT	24-month	98.79	1.95

Nominal Longitudinal Modeling of Values.

When considering the value score as the outcome of interest instead of weight, similar model considerations can be made. The model could be fit continuously, as seen with **Model 2** in Appendix B. Conversely, given the balanced nature of the data, where there was uniformity in the timing of the visits across all participants, one could also fit a longitudinal model where time is treated as nominal. Again, it is important to note, similarly to weight, if the continuous model from Appendix B was correctly specified, then it will generally have more statistical power to detect a longitudinal difference in the value score by study arm. However, again it is important to note that a polynomial may not capture the true underlying mean trend, and a nominal time model does not have the

same concern as to the potential for model misspecification in the functional form of the fixed effects.

As with participant weight, covariance pattern models were entertained. Again, given that there are seven observations per subject, and thus a 7x7 within-subject variance-covariance matrix is required, an unstructured model would require 28 variance and covariance parameters, which is probably too many for this modest size sample. Instead, the analysis considered variance-covariance matrices that impose some structure on the matrix, but at the same time are more flexible.

Table 10. AIC of Competing Models for the Value Score

Continuous time polynomial model:	AIC=5283.8
Compound symmetry model (equivalent to random intercept model):	AIC=5299.0
First-order autoregressive model:	AIC=5335.4
Heterogenous autoregressive model:	AIC=5335.7
Toeplitz model:	AIC=5273.2

Table 10 compares various models using the AIC based on ordinary maximum likelihood, where smaller AIC indicates a better fit, and the continuous time model (**Model 2** from Appendix B) is added for reference. Again, like the weight model, using a Toeplitz variance-covariance matrix provides the lowest AIC, and requires only 6 covariance parameters. This corresponds to **Model 5** (detailed on page 28) and is given by $E(\text{Value score}) = \mathbf{B0} + \mathbf{B1} * \text{ACT} + \mathbf{B2} * \text{T3} + \mathbf{B3} * \text{T6} + \mathbf{B4} * \text{T9} + \mathbf{B5} * \text{T12} + \mathbf{B6} * \text{T18} + \mathbf{B7} * \text{T24} + \mathbf{B8} * \text{ACT} * \text{T3} + \mathbf{B9} * \text{ACT} * \text{T6} + \mathbf{B10} * \text{ACT} * \text{T9} + \mathbf{B11} * \text{ACT} * \text{T12} + \mathbf{B12} * \text{ACT} * \text{T18} + \mathbf{B13} * \text{ACT} * \text{T24}$. The null hypothesis of no difference by study arm in the longitudinal profiles of the value score is $\mathbf{H0: B8=B9=B10=B11=B12=B13=0}$, which can be assessed by means of a joint significance test using a chi-square test with 6 df based on the corresponding estimable contrast.

Model estimates are shown in Table 11. The null hypothesis of no difference by study arm was rejected using the omnibus test ($p=0.0367$). It appears that there is a difference between arms at the 24-month time point, where the ACT arm exhibited a larger increase in the value score from baseline to 24 months compared to the SBT arm ($p=0.0003$); the difference between arms at 18 months was marginally significant ($p=0.0518$). Thus, the trend noted in the exploratory plots of a decline in the value score post-intervention in the SBT arm compared to the ACT arm was confirmed to be statistically significant using both the continuous and nominal (Toeplitz) models. Estimated least squares (i.e. model-based) means are presented in Table 12. Note that as a sensitivity analysis, an autoregressive model was also fit, which also showed a significant difference by study arm (results not shown).

Table 11. Parameter estimates for **Model 5**

Covariate	Level	Parameter estimate (SE)	p-value
Intercept	(parameter B0)	13.6296 (0.5130)	<0.001
Study arm	SBT	-ref-	-ref-
	ACT (parameter B1)	-1.5926 (0.7254)	0.0296
Time point	Baseline	-ref-	-ref-
	3-month (parameter B2)	0.8400 (0.4821)	0.0818
	6-month (parameter B3)	2.3117 (0.5332)	<0.001
	9-month (parameter B4)	2.2259 (0.5667)	<0.001
	12-month parameter (B5)	3.1320 (0.5282)	<0.001
	18-month (parameter B6)	1.7178 (0.5305)	0.0013
	24-month (parameter B7)	1.2999 (0.4832)	0.0073
Interaction between time point and study arm	SBT*Baseline	-ref-	-ref-
	SBT*3-month	-ref-	-ref-
	SBT*6-month	-ref-	-ref-
	SBT*9-month	-ref-	-ref-
	SBT*12-month	-ref-	-ref-
	SBT*18-month	-ref-	-ref-
	SBT*24-month	-ref-	-ref-
	ACT*Baseline	-ref-	-ref-
	ACT*3-month (parameter B8)	1.0514 (0.6822)	0.1237
	ACT*6-month (parameter B9)	1.1809 (0.7616)	0.1214
	ACT*9-month (parameter B10)	1.3723 (0.8082)	0.0899
	ACT*12-month (parameter B11)	1.1168 (0.7513)	0.1376
	ACT*18-month (parameter B12)	1.4663 (0.7530)	0.0518
ACT*24-month (parameter B13)	2.4751 (0.6839)	0.0003	

Estimable contrast	Degrees of freedom	Chi-Square	p-value
Joint significance test of no longitudinal difference by study arm (Ho: B8=B9=B10=B11=B12=B13=0)	6	13.43	0.0367

Estimated Within-Subject Correlation Matrix							
	Baseline	3 months	6 months	9 months	12 months	18 months	24 months
Baseline	1.0000	0.5883	0.4747	0.4662	0.5220	0.5466	0.6291
3 months	0.5883	1.0000	0.6291	0.5466	0.5220	0.4662	0.4747
6 months	0.4747	0.6291	1.0000	0.6291	0.5466	0.5220	0.4662
9 months	0.4662	0.5466	0.6291	1.0000	0.6291	0.5466	0.5220
12 months	0.5220	0.5220	0.5466	0.6291	1.0000	0.6291	0.5466
18 months	0.5466	0.4662	0.5220	0.5466	0.6291	1.0000	0.6291
24 months	0.6291	0.4747	0.4662	0.5220	0.5466	0.6291	1.0000

Table 12. Model-based least square means for the value score from **Model 5**

Study arm	Time point	Estimate	Standard Error
ACT	Baseline	12.04	0.51
ACT	3-month	13.93	0.53
ACT	6-month	15.53	0.53
ACT	9-month	15.64	0.56
ACT	12-month	16.29	0.55
ACT	18-month	15.22	0.56
ACT	24-month	15.81	0.55
SBT	Baseline	13.63	0.51
SBT	3-month	14.47	0.53
SBT	6-month	15.94	0.52
SBT	9-month	15.86	0.55
SBT	12-month	16.76	0.54
SBT	18-month	15.35	0.55
SBT	24-month	14.93	0.55

Mediation Analysis.

Using the change in value score at 18 months as a putative mediator for weight loss at 24 months, the ACME was significantly different from 0 ($p=0.018$), and the proportion mediated was over 50% (50.7%), which equates to a 50.7% decrease in the ACT coefficient between Model 6 and Model 8, as seen in Table 16. This suggests that change in value score at 18 months partially mediated between study treatment arm and weight loss at 24 months. However, the effect using change in value score at 12 months was weaker ($p=0.14$), with proportion mediated of 27.2%, as seen in Table 17.

Results of the three models are shown below, as well as the estimated ACME, ADE and proportion mediated; however, note that regression models are only shown for change in value score at 18 months.

Table 13. Results of the Outcome (weight loss at 24 months) regressed on Treatment (**Model 6**).

Variable	Parameter Estimate	Standard Error	t value	p-value
Intercept	-3.24194	0.93711	-3.46	0.0007
ACT	-2.25806	1.33627	-1.69	0.0937

Table 14. Results of the Putative Mediator (change in value score at 18 months) regressed on Treatment (**Model 7**).

Variable	Parameter Estimate	Standard Error	t value	p-value
Intercept	1.64516	0.58752	2.80	0.0060
ACT	1.98817	0.83777	2.37	0.0192

Table 15. Results of the Outcome (weight loss at 24 months) regressed on the Putative Mediator (change in value score at 18 months) and Treatment (**Model 8**).

Variable	Parameter Estimate	Standard Error	t value	p-value
Intercept	-2.29382	0.90568	-2.53	0.0126
ACT	-1.11227	1.28025	-0.87	0.3867
Change in value score at 18 months	-0.57630	0.13634	-4.23	<0.0001

Table 16. Estimated ACME, ADE, and proportion mediated for change in value score at 18 months. Putative Mediator: Change in value score at 18 months. Outcome: Change in weight at 24 months.

Causal Mediation Analysis				
Nonparametric Bootstrap Confidence Intervals with the Percentile Method				
	Estimate	Lower	Upper	p-value
ACME	-1.146	-2.350	-0.19	0.018
ADE	-1.112	-3.578	1.35	0.377
Total Effect	-2.258	-4.906	0.36	0.091
Prop. Mediated	0.507	-1.417	3.07	0.100
Sample Size Used: 122				
Simulations: 50000				

Table 17. Estimated ACME, ADE, and proportion mediated for change in value score at 12 months. Putative Mediator: Change in value score at 12 months. Outcome: Change in weight at 24 months.

Causal Mediation Analysis				
Nonparametric Bootstrap Confidence Intervals with the Percentile Method				
	Estimate	Lower	Upper	p-value
ACME	-0.488	-1.287	0.16	0.14
ADE	-1.307	-3.880	1.16	0.30
Total Effect	-1.795	-4.437	0.78	0.18
Prop. Mediated	0.272	-1.458	2.22	0.26
Sample Size Used: 122				
Simulations: 50000				

CHAPTER 6

CONCLUSION

Discussion. The findings of these analyses confirmed and strengthened the findings in the primary outcomes paper while modeling weight and values longitudinally (Lillis et al., 2016). More importantly, a unique aspect of the current analysis was that greater care was taken in the modeling process regarding model selection. Improving model selection led to a better-fitting model which showed a clear significant difference in weight loss between the study arms at 24 months. This is in contrast to the main Lillis paper which only found marginal significance from baseline to 24 months and stated “Although overall weight change at month 24 did not differ between groups, the time X condition interaction in the model approached significance ($p=0.067$) (Lillis et al., 2016).”

This secondary analysis contributes to the previous findings by beginning to understand one mechanism of change (values) that may mediate the primary outcome (weight loss). Although a simplistic approach, this mediation analysis is a significant contribution as ACT is a rather new modality for weight loss therapy and limited research exists to better understand its effectiveness, and more specifically, which of the six processes of change proposed by ACT explain the effects of the entire treatment modality. While ACT posits a “hexaflex” of six processes of change, limited research to date explains these processes. More specifically, of the six processes, no research to date has looked at the process of values alignment and values clarity, and its contribution as a process of change variable. Therefore, an examination of values as a mediator, and

confirming that it does at least partially mediate the outcome moves forward the general understanding of ACT as a treatment modality.

Many Social Cognitive based Theories hold onto the assumption that behavior is driven by a product of an individual's expectations of the outcome and the value that they place on that outcome. Therefore, values exist in a plethora of other theories in some shape or form. The "values" we discuss in ACT are different as they are about broad life values that the person identifies as being personally important to them. Furthermore, ACT does not just identify these broad life values (values clarity) but also looks at how individual's behavioral actions align, or not, with these said values (values alignment). This is now very different than the values discussed in Social Cognitive Theories that examine values that people place on specific outcomes. Therefore, the measurement of "values" needs to be specifically considered for clarity and alignment in the context of ACT values. ACT is not unique in including the concept of values into the theory, but it is unique in how it used values as broader intangible life goals versus placing value on a specific outcome. Also, it is unique in considering how daily behaviors align, or not, with said values. Furthermore, values can exist in a very broad number of domains. The BEVs for example chooses to examine values in the four subdomains of: work, leisure, health, and relationships. From an ACT perspective, it is possible to then hypothesize that values clarity and values alignment may be more or less important in some domains versus others to create subsequent behavior change (and which values are most important are likely highly dependent on what the outcome behavior of interest is). For weight loss, one could hypothesize that values clarity and alignment in the health domain might be very important. Cases could be made for someone with better alignment in the work

domain (being a good employee would mean to miss less work, be able to do physically demanding duties better, etc) to be helpful in the service of weight loss. Additionally, in relationships- being a good partner or parent requires being able to do shared common interests together that may require physical fitness or health, or to be free of disease, and just remain alive for major life events and memories. As examined in Appendix C, initial examinations of the BEVS data indicates that individual domains of values changed differently over the course of the intervention in both ACT and SBT arms. It is not a large leap to hypothesize change in health values potentially driving a weight loss behavior. But again, cases could be made for changes in other domains also helping to drive this same outcome.

Strengths. This study had many strengths, including a randomized design, a gold standard comparison group, objective measurement of weight, blinded assessors, and the recruitment of a clinical sample of individuals who typically demonstrate poor response to treatment. Specifically, this study targeted perhaps the biggest problem in behavioral weight loss, long-term maintenance, and tested a novel intervention incorporating innovative acceptance-based strategies that theoretically target barriers to maintenance. While some studies have begun to examine not only whether these treatments work, but whether they work through the proposed mechanisms of the model (i.e., six core processes), the research on these mechanisms of change has been short in duration and limited in scope. Of the proposed six core processes, acceptance and psychological flexibility (or reductions in avoidance and inflexibility) (Gifford & Lillis, 2009; Lillis, Hayes, Bunting, & Masuda, 2009) and mindfulness and defusion (Goodwin, Forman, Herbert, Butryn, & Ledley, 2012) have received the majority of attention as process

variables to date over values consistency and clarity. Therefore, a strength of this analysis is that it demonstrates a strong attempt at better understanding a proposed mechanism of change that has been under-represented thus far in research. Treatment outcome differences alone are insufficient to evaluate how each treatment works. Until these process variables are better understood, it will be impossible to definitively state whether either treatment (ACT versus SBT) operates in a truly different way (Hayes, et al., 2013). One important strength of this analysis therefore is that to date this is the first analyses to begin to explain, understand, and identify process variables (specifically values clarity and consistency) to further refine the model, and to better design interventions to target process variables that induce the most change.

Another strength of this analysis was the use of AIC to choose the best fitting models to longitudinally model both weight and values. The use of Toeplitz appears to be superior to the modeling techniques applied in the original outcomes paper (Lillis et al., 2016). The Toeplitz model provided greater power to detect significance as it assumes equal variance at each time point, but allows the covariance to vary over time, with any pair of responses that are equally separated in time having the same covariance. Models 1 and 2 (Appendices A and B) closely replicates what was done in the primary outcomes paper, using the AIC criterion the Toeplitz model (Models 4 and 5) had a lower AIC indicating a better fit for the weight and values data temporally.

Limitations. This study was of course not without limitations. The sample was primarily middle aged, Caucasian women, limiting the generalizability of the findings. Although the training of therapist pairs was standardized, the study did not include an assessment of the skill of the therapists. Acceptance Commitment Therapy itself is a

newer therapy modality. While initial evidence for this modality is promising, there is limited evidence accumulated thus far across a broad range of health behaviors, and very limited evidence specifically in behavioral weight loss. Within this limited amount of accumulated evidence in weight loss, there is a paucity in previous evidence for values acting as a mediator, and none using this same measurement tool (BEVS).

One limitation of the statistical analysis was that the mediation analysis was somewhat simplistic in that it ignored missing data. In particular, the analysis uses 122 of 162 participants which had non-missing weight at 24 months and non-missing value score at 18 months, and 122 of 162 participants (differing subset) which had non-missing weight at 24 months and non-missing value score at 12 months. Another limitation was that only the overall combined value score was examined in this analysis. One could also analyze the scores individually (see preliminary analysis of this in Appendix C). Future analysis should power their studies to have a sample size large enough to analyze the subdomains as well as the total score. Furthermore, this analysis also did not make full use of all the longitudinal data, as for example in longitudinal structural equation models. But the current analysis can serve as a starting point and demonstrated that the value score significantly mediated between treatment arm and weight loss.

Final Conclusions and Future Directions. The longitudinal modeling of participant weight demonstrated that the SBT arm exhibited a slightly larger decrease in weight during the study intervention (i.e. through 12 months), but also exhibited a larger rebound in weight gain post-intervention (12 through 24 months). The trend noted in the exploratory plots of a greater rebound in weight gain in the SBT arm post-intervention to month 24 was confirmed to be statistically significant using the Toeplitz model. The

longitudinal modeling of participant values suggests that both arms exhibited an increase in the value score throughout the study intervention (i.e. through 12 months); however, after the study intervention (12 through 24 months), the SBT arm saw a drop in the value score whereas the ACT arm appeared to maintain the gain in value score on average. Similarly, as with weight, the trend noted in the exploratory plots of a decline in the value score post-intervention in the SBT arm compared to the ACT arm was confirmed to be statistically significant using both continuous and nominal (Toeplitz) models. Finally, the mediation analysis suggests that change in value score at 18 months partially mediated (about 50%) between study treatment arm and weight loss at 24 months.

Initial research is promising, including the primary outcomes paper (Lillis et al., 2016) of the entirety of ACT as an efficacious treatment modality for behavior change, and specifically behavior change for weight loss. Furthermore, initial research suggests that the process variables targeted by ACT are at least partially responsible for the ACT intervention outcomes (Hayes, et al., 2006). As previously stated, the research on ACT mechanisms of change has been short in duration and limited in scope and values has not yet been a primary focus. Therefore, the mediation analysis conducted in this manuscript is a significant outcome, as one of six proposed mechanisms of change explaining about 50% of the outcome is an important finding. Firstly, because of the six proposed mechanisms of ACT, values have been the most underexamined, and this analysis demonstrates its utility. Secondly, if values really are such a significant contributing mediator, then significant time and attention should be given to values work during the intervention to achieve the most optimal outcomes. This would require understanding the best methods and means of helping individuals clarify their personal values and making

connections between seemingly unrelated behavioral daily behaviors and said long term values. Further, this would require refining mechanisms for measuring both values clarity and values alignment differently.

While this analysis was a promising first attempt at understanding the mediating relationship of values on ACT treatment outcomes, future research needs to replicate this finding, and to examine the mechanisms of change (specifically values clarity) with more sophisticated statistical analyses and larger sample sizes, to further understand the proposed mechanisms of change contribution. By doing so, future interventions can better explore the most effective use of acceptance-based strategies (specifically values clarity) for improving weight control and achieving long term weight loss maintenance.

Additionally, further work needs to be done in refining the actual measurement of values. The BEVS has been shown to be sensitive to treatment effects and able to differentiate between clients who receive values-based interventions and those who do not. Additionally, the BEVS has demonstrated acceptable temporal stability as well as internal consistency (Dahl, 2015; Lundgren et al., 2012). While this is promising information for the BEVS, limited measurement tools exist for values, and few studies have used such tools. Values alignment and clarity in a ACT context have been superficially examined in epilepsy and pain management, but never in behavioral weight loss. Further, the BEVs was not a common measurement tool between these analyses nor was the mediating effect of values examined. With such sparse data it is very challenging to determine if the BEVS is optimally developed, and if it is the best method or means of collecting information about values clarity in ACT.

APPENDIX A:

LONGITUDINAL MODEL OF WEIGHT WITH CONTINUOUS TIME

A longitudinal linear mixed model was used to model participant weight treating time as continuous. Comparing the AIC across different models, suggested incorporating both random slopes and random intercepts with a cubic polynomial. This corresponds to **Model 1** (detailed on page 26) and is given by $\text{Weight} = \mathbf{B0} + \mathbf{B1}*\text{ACT} + \mathbf{B2}*\text{Time} + \mathbf{B3}*\text{Time}^2 + \mathbf{B4}*\text{Time}^3 + \mathbf{B5}*\text{ACT}*\text{Time} + \mathbf{B6}*\text{ACT}*\text{Time}^2 + \mathbf{B7}*\text{ACT}*\text{Time}^3 + \mathbf{b0} + \mathbf{b1}*\text{Time} + \text{error}$.

Model estimates are shown in Appendix Table A1. The covariance estimates for both the random intercept and the random slope were both significantly different from 0 ($p < 0.001$), indicating differences across participants in both starting baseline weight and in the trend over time. The difference in longitudinal curves by study arm was marginally significant ($p = 0.085$), but not statistically significant at the 0.05 level. Estimated model-based marginal mean curves by study arm are shown in Appendix Figure A1. As a sensitivity analysis, a quadratic model was also fit (omitting the cubic terms), which yielded the same conclusion ($p = 0.064$, results not shown).

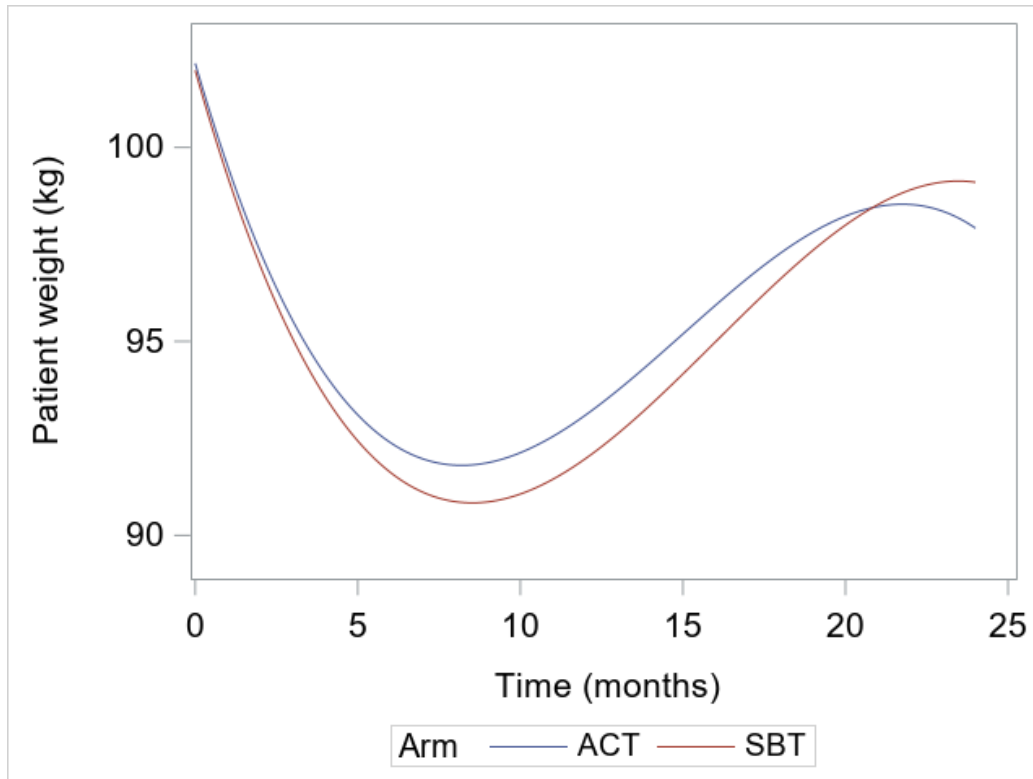
Table A1. Parameter estimates for **Model 1.**

Covariate	Level	Parameter estimate (SE)	p-value
Intercept	(parameter B0)	101.98 (1.8705)	<0.001
Study arm	SBT	-ref-	-ref-
	ACT (parameter B1)	0.1833 (2.6454)	0.9448
Time (slope term)	(parameter B2)	-2.9764 (0.1704)	<0.001
Time ² (quadratic term)	(parameter B3)	0.2380 (0.01812)	<0.001
Time ³ (cubic term)	(parameter B4)	-0.00496 (0.000509)	<0.001
Interaction between Time (slope term) and study arm	SBT	-ref-	-ref-
	ACT (parameter B5)	0.08451 (0.2435)	0.7287
Interaction between Time ² (quadratic term) and study arm	SBT	-ref-	-ref-
	ACT (parameter B6)	0.004845 (0.02586)	0.8514
Interaction between Time ³ (cubic term) and study arm	SBT	-ref-	-ref-
	ACT (parameter B7)	-0.00045 (0.000725)	0.5375

Estimable contrast	Degrees of freedom	Chi-Square	p-value
Joint significance test of no longitudinal difference by study arm (Ho: B5=B6=B7=0)	3	6.62	0.0850

Estimated covariance parameters	Estimate	Standard Error	Z Value	p-value
Random intercept	270.56	30.9481	8.74	<0.001
Covariance	0.3416	0.4709	0.73	0.4682
Random slope	0.07723	0.01515	5.10	<0.001
Residual	14.4891	0.8067	17.96	<0.001

Figure A1. Estimated model-based marginal means of participant weight over time by study arm from **Model 1**.



Model-based curves:

$$\text{ACT: Weight} = 102.1633 - 2.89189 \cdot \text{Time} + 0.242845 \cdot \text{Time}^2 - 0.00541 \cdot \text{Time}^3$$

$$\text{SBT: Weight} = 101.98 - 2.9764 \cdot \text{Time} + 0.2380 \cdot \text{Time}^2 - 0.00496 \cdot \text{Time}^3$$

APPENDIX B:

LONGITUDINAL MODEL OF VALUES WITH CONTINUOUS TIME

A longitudinal linear mixed model was used to model the value score treating time as continuous. Comparing the AIC across different models (results not shown), suggested incorporating both random slopes and random intercepts with a cubic polynomial. This corresponds to **Model 2** (detailed on page 27) and is given by Value score = **B0** + **B1***ACT + **B2***Time + **B3***Time² + **B4***Time³ + **B5***ACT*Time + **B6***ACT*Time² + **B7***ACT*Time³ + **b0** + **b1***Time + **error**.

Model estimates are shown in Table B1. The covariance estimates for both the random intercept and the random slope were both significantly different from 0 ($p < 0.001$ and $p = 0.0256$, respectively), indicating differences across participants in both starting value score and in the trend over time. The difference in longitudinal curves by study arm was statistically significant ($p = 0.0394$), where the SBT arm demonstrated a decline in the value score during the post-intervention period compared to the ACT arm. Estimated model-based marginal mean curves by study arm are shown in Figure B1.

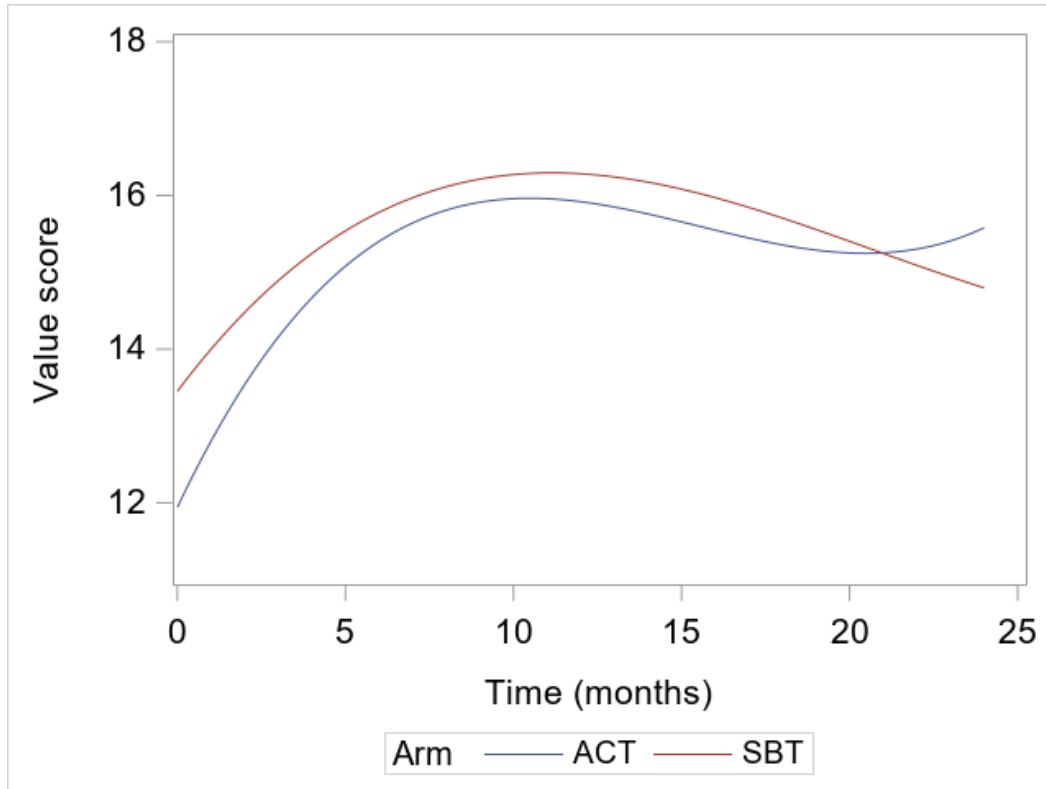
Table B1. Parameter estimates for **Model 2**.

Covariate	Level	Parameter estimate (SE)	p-value
Intercept	(parameter B0)	13.4515 (0.4651)	<0.001
Study arm	SBT	-ref-	-ref-
	ACT (parameter B1)	-1.5101 (0.6578)	0.0220
Time (slope term)	(parameter B2)	0.5818 (0.1323)	<0.001
Time ² (quadratic term)	(parameter B3)	-0.03575 (0.01423)	0.0123
Time ³ (cubic term)	(parameter B4)	0.000577 (0.0004)	0.1494
Interaction between Time (slope term) and study arm	SBT	-ref-	-ref-
	ACT (parameter B5)	0.3437 (0.1885)	0.0687
Interaction between Time ² (quadratic term) and study arm	SBT	-ref-	-ref-
	ACT (parameter B6)	-0.03101 (0.02026)	0.1263
Interaction between Time ³ (cubic term) and study arm	SBT	-ref-	-ref-
	ACT (parameter B7)	0.000861 (0.000568)	0.1303

Estimable contrast	Degrees of freedom	Chi-Square	p-value
Joint significance test of no longitudinal difference by study arm (Ho: B5=B6=B7=0)	3	8.35	0.0394

Estimated covariance parameters	Estimate	Standard Error	Z Value	p-value
Random intercept	9.5310	1.5469	6.16	<0.001
Covariance	0.1021	0.05847	1.75	0.0808
Random slope	0.007606	0.003902	1.95	0.0256
Residual	9.0148	0.4959	18.18	<0.001

Figure B1. Estimated model-based marginal means of the value score over time by study arm from **Model 2**.



Model-based curves:

$$\text{ACT: Value score} = 11.9414 + 0.9255 * \text{Time} - 0.06676 * \text{Time}^2 + 0.001438 * \text{Time}^3$$

$$\text{SBT: Value score} = 13.4515 + 0.5818 * \text{Time} - 0.03575 * \text{Time}^2 + 0.000577 * \text{Time}^3$$

APPENDIX C:

MEAN TABLES FOR VALUES SCORES

The original analyses from the primary outcomes paper included the planned analysis which were used to calculate the power for the sample size. This secondary data analysis used data from this sample to understand the mediating effects of values on weight loss. As this was not a planned analysis in the primary outcomes paper, but rather a secondary analysis decided upon after data collection, the sample was not appropriately powered to complete all the possible analyses to better understand the values survey data. More specifically, looking at each of the value's subdomains separately rather than only as a summative values score would not be sufficiently powered with this given sample size.

While conducting more analyses on the individual values subdomains would be an important future direction, an initial step could be to examine the means and standard deviations of total values and values subdomains over time. Additionally, another step would be to not only examine the mean scores at each timepoint, but also the change in these scores at each timepoint.

	Baseline		6 Month		12 Month		24 Month	
	ACT	SBT	ACT	SBT	ACT	SBT	ACT	SBT
Relationship Value Consistency	3.8 ± 1.8	4.1 ± 1.7	4.3 ± 1.5	4.2 ± 1.7	4.5 ± 1.5	4.5 ± 1.7	4.2 ± 1.5	4.2 ± 1.6
Health Value Consistency	2.0 ± 1.2	2.3 ± 1.5	3.7 ± 1.4	3.8 ± 1.4	3.7 ± 1.6	3.8 ± 1.6	3.5 ± 1.6	3.3 ± 1.4
Leisure Value Consistency	2.5 ± 1.3 p=0.01	3.1 ± 1.6 p=0.01	3.6 ± 1.4	3.8 ± 1.5	3.8 ± 1.6	4.2 ± 1.5	3.6 ± 1.6	3.7 ± 1.5
Work Value Consistency	3.8 ± 1.9	4.1 ± 1.5	4.0 ± 1.6	4.2 ± 1.5	4.2 ± 1.6	4.5 ± 1.6	4.4 ± 1.6	4.1 ± 1.6
Total Value Consistency	12.0 ± 4.3 p=0.02	13.6 ± 4.4 p=0.02	15.6 ± 4.0	15.9 ± 4.5	16.2 ± 4.8	17.0 ± 5.1	15.8 ± 4.8	15.3 ± 4.8

The above table shows total value score (note a “perfect” score in this would be 28) as well as subdomain scores (a “perfect” score in each domain being 7), and weight at each assessment timepoint. Of importance to note here, health and leisure were very low at baseline, and therefore had significant room for improvement over time. Both ACT and SBT improved in these domains over time, but SBT seemed to regress back towards their baseline scores during post-intervention while ACT maintained their improved scores. Additionally, it is important to note that all domains, and both groups generally improved over time during the treatment phase. Both groups generally declined from 12 month through post intervention follow-up, but ACT less dramatically. Interestingly, at 12 months SBT actually had a higher total score as compared to ACT, but at the 24 month follow up assessment ACT had a higher total score, meaning that they were better able to maintain their values gains.

The table below demonstrated changes in values scores (both total and subdomains), as represented as means and standard deviations from baseline to 6, 12, and 24 months, as well as change form end of intervention (12 months) to end of follow-up (24 months). It is important to note here that form baseline to 6, 12, and 24 months in any of the subdomains or in the total score that the ACT group had a larger change in values consistency as compared to their SBT counterparts. Additionally, it is of importance to note that from 12 month to 24 month (i.e. post-intervention) that in every subdomain and in total score the SBT group declined their values consistency at a greater amount than their ACT counterparts. Most interestingly perhaps, note that leisure and health improved more dramatically than the other two subdomains during intervention, and that

in the ACT group these improvements were maintained as compared to their SBT counterparts.

	Baseline – 6 Month		Baseline – 12 Month		Baseline – 24 Month		12 Month – 24 Month	
	ACT	SBT	ACT	SBT	ACT	SBT	ACT	SBT
Relationship Value Consistency	0.6 ± 1.8	0.1 ± 1.6	0.7 ± 1.9	0.4 ± 1.7	0.5 ± 1.6	0.0 ± 1.4	-0.4 ± 1.6	-0.4 ± 1.4
Health Value Consistency	1.7 ± 1.5	1.5 ± 1.8	1.7 ± 1.8	1.4 ± 2.0	1.6 ± 1.7	0.88 ± 1.7	-0.3 ± 1.5	-0.6 ± 1.7
Leisure Value Consistency	1.2 ± 1.5	0.7 ± 1.8	1.3 ± 1.9	1.0 ± 1.6	1.2 ± 1.7	0.5 ± 1.7	-0.2 ± 1.8	-0.5 ± 1.5
Work Value Consistency	0.4 ± 2.0	0.1 ± 1.8	0.6 ± 2.1	0.3 ± 1.7	0.9 ± 1.9 p<0.001	-0.2 ± 1.7 p<0.001	0.2 ± 1.9	-0.4 ± 1.6
Total Value Consistency	3.7 ± 4.3	2.4 ± 4.7	4.3 ± 5.3	3.1 ± 5.1	4.1 ± 4.5 p<0.0001	1.2 ± 4.3 p<0.0001	-0.7 ± 4.9	-2.0 ± 4.7

While this is a rather simplistic analysis of values subdomains. It really helps clarify and paint the picture of what was being demonstrated in the mediation analysis in this manuscript. The mediation analysis suggested that values scores at 18 months at least partially mediated weight at 24 months. These above tables highlight the trend in change not only values scores, but the underexamined individual subdomains of this total values score. These tables demonstrate that health and leisure improved most significantly over time (as compared to other subdomains) and that in the ACT group they did not diminish much during post-intervention. The fact that both groups improved their health and leisure values, but that the ACT group alone maintained these improved values scores may explain what drove the significant findings of the mediation analysis.

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