An ACT-Based Physician-Delivered Weight Loss Intervention

Study Protocol

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The study was approved by the Research Ethics Board (REB-II) at McGill University (Montreal, Canada). Participants provided written informed consent prior to commencing the intervention.

Trial Design

The present study was a two-arm pilot randomized controlled trial conducted from May 7, 2016 to March 7, 2018. Participants were randomized to eight sessions of either an ACT-based intervention aimed at reducing emotional eating or standard care, which involved diet and exercise counselling. All outcomes were assessed at baseline and post-intervention. The present study aimed to recruit 128 participants (64 per condition), similar to the trial protocol outlined by Knäuper et al. (2014).

Participants

Participants were adults over the age of 18 with overweight or obesity who were seeking treatment for weight loss at a clinic in Toronto, Ontario. Only participants considered to be emotional eaters, as assessed by a score of 3.25 or higher on the Dutch Eating Behavior Questionnaire (DEBQ), were recruited for the study (van Strien, Herman, Anschutz, Engels, & de Weerth, 2012). In addition, participants who did not speak, write, and read in English fluently were excluded from the study, as well as those who were pregnant.

Study Procedures

Participants were recruited upon initial registration at the weight loss clinic. Those who expressed interest to participate were assigned a participant ID number and asked to complete a brief prescreen questionnaire to determine their eligibility based on the criteria described above. Eligible participants were randomly assigned to either the ACT intervention or control condition

based on the ID number they had initially received. Participants completed a battery of questionnaires both baseline and Session 8. Weight was measured every session.

Randomization and Blinding

Participants were randomized in 1:1 sequence using a random number generator (randomizer.org). Two hundred participant ID numbers (1-200) were randomized prior to study commencement and assigned to patients who were prescreened. Due to a high number of ineligible participants, an additional 100 ID numbers (201-300) were randomized during the recruitment process. Participants retained the same ID number throughout, regardless of their eligibility, to simplify the process for administrative staff at the clinics. Participants were blind to their condition, but physicians and administrative staff were not blind to participant condition. Physicians were not blind to participant condition because they were responsible for delivering the ACT intervention or standard care. They were thus required to know the participant's condition in order to deliver the adequate treatment. Administrative staff was responsible for providing physicians with this information and organizing study paperwork and thus needed to be aware of participant condition as well.

Physician Training

Physicians were trained in the delivery of the weight loss interventions in a 1-hour Skype training session delivered by a clinical psychology PhD student. During this training session, each physician was taught how to administer the manualized ACT intervention and provided the opportunity to ask questions pertaining to the various skills that they would be required to teach their patients. Copies of the manual were provided to physicians to follow during sessions. Follow-up training sessions were conducted as necessary to ensure treatment fidelity and clarify questions that arose as physicians began delivering the interventions.

Intervention

Participants in the standard care condition were provided with diet and exercise counselling and psychoeducation from their physicians over the course of 8 sessions, as was routinely done at the clinic. Physicians were responsible for facilitating this counselling at their discretion, and thus what "standard care" entailed differed based on the physician who was administering it. However, standard care did not involve any targeted intervention to reduce emotional eating. Thus, in addition to standard care, participants in the ACT condition were taught techniques to reduce their emotional eating. All sessions were approximately 5-10 minutes in length and weight was assessed at each visit. Three overarching skills were taught over the course of the ACT intervention: (1) values clarification and commitment, (2) metacognitive awareness, and (3) distress tolerance. ACT participants were first taught values clarification and commitment techniques, where they reflected on their reasons for losing weight and how this would improve their quality of life. Participants were taught the BOLD technique (Breathe, Observe sensations, Listen to values, Decide on actions that are in line with values) to use their values to make discussions pertaining to avoiding emotional eating (Ciarrochi, Bailey, & Harris, 2013). Next, participants were introduced to the concept of metacognitive awareness, or recognizing and identifying one's thoughts, feelings, and emotions. Specifically, participants were trained in mindful eating, in order to increase awareness of hunger and satiety cues and avoid eating when not physically hungry (Kristeller & Wolever, 2011). Lastly, participants were taught to increase distress tolerance in the face of negative emotions that typically led to emotional overeating. Participants were taught acceptance techniques (dropping the rope, urge surfing) to use when experiencing triggering emotions or cravings (Bowen & Marlatt, 2009). An

intervention summary can be found in Table 1 and the intervention manual is available upon request.

Throughout the sessions, physicians formed if-then plans with the patients to specify how to habitually use the ACT techniques to reduce emotional eating in their everyday lives. At the end of each session, participants were given a one-page homework sheet that asked them to monitor their behavior and their use of the ACT techniques during the week. Participants were instructed to bring the homework back with them for the next session so that it could be reviewed with their physician.

Measures

Demographics. At baseline, participants reported basic demographic information including gender, age, English fluency, ethnicity, marital status, educational attainment, employment status, household income, and whether or not they smoked.

Anthropomorphic measures. Weight was measured at each of the eight sessions (primary outcome). Participant body fat percentage was assessed and recorded by their physician at baseline and at completion of the eight sessions (secondary outcome).

Emotional, restrained, and external eating. Participants were pre-screened for emotional eating using the Dutch Eating Behavior Questionnaire (DEBQ; van Strien et al., 1986). The DEBQ is a 33-item questionnaire that assesses three dimensions of eating behaviors: emotional eating (primary outcome), restrained eating (secondary outcome), and external eating (secondary outcome). The emotional eating subscale assesses the reported desire to eat under specific negative emotional conditions such as stress, anxiety, and depression. The DEBQ has high internal consistency and factorial validity (van Strien et al., 1986). The DEBQ was administered again post-intervention.

Distress tolerance. The Distress Tolerance Scale (DTS; Simons & Gaher, 2005), a brief self-report questionnaire that assesses one's ability to tolerate distressing emotions, was completed at baseline and post-intervention (secondary outcome). The scale is made up of items that assess the dimensions of distress tolerance, absorption, appraisal, and regulation. The DTS has high reliability and high discriminant, convergent, and criterion validity (Leyro, Bernstein, Vujanovic, McLeish, & Zvolensky, 2011; Simons & Gaher, 2005).

Mindfulness. At both time points (i.e. baseline, post-intervention) participants completed the Philadelphia Mindfulness Scale (PHLMS; Cardaciotto, Herbert, Forman, Moitra, & Farrow, 2008), a 20-item self-report questionnaire that assesses two components of mindfulness: present-moment awareness and acceptance (secondary outcome). The scale has been shown to have good internal consistency and construct validity (Cardaciotto, Herbert, Forman, Moitra, & Farrow, 2008).

ACT application. At baseline and post-intervention participants filled out a self-report questionnaire designed to assess the extent of the participant's use of ACT strategies to reduce emotional eating (secondary outcome). This questionnaire was developed for the present study to evaluate participants' real world application of the intervention. Participants were asked to indicate their level of agreement on a 5-point scale (1 = strongly agree and 5 = strongly disagree) to prompts such as "My values motivate me to lose weight" and "I am able to accept negative emotions and don't have to eat when I'm feeling bad".

Treatment satisfaction. After the eighth session, participants completed a brief, self-developed questionnaire to assess their overall satisfaction with the intervention. Participants were asked to indicate their level of agreement on a 5-point scale (1 = strongly agree and 5 = strongly disagree). Physicians were also asked to complete a similar questionnaire at various

points throughout the intervention to obtain their input on its feasibility and efficacy of the intervention. Open-ended feedback was also collected from physicians, asking for their suggestions on ways to improve the intervention, and to provide insight on patient dropout/non-responsiveness.

Data Analysis

All analyses were conducted in SPSS version 24. 2 Two separate 2 (Condition: Standard Care, ACT Intervention) x 2 (Time: Baseline, Session 8) repeated measures MANOVAs were conducted for the anthropomorphic and questionnaire data outlined above, respectively, with follow-up *t*-tests conducted as necessary. Two separate MANOVAs were conducted to not lose data from incomplete cases (i.e., participants who had completed anthropomorphic but not questionnaire data). Independent samples *t*-tests were conducted for treatment satisfaction data collected at Session 8, whereas chi-square tests were conducted to compare recruitment rates, attrition rates, questionnaire completion, and intervention completion time between conditions. Missing data were not imputed because of the large drop out rates: Imputation with small sample sizes and high rates of missingness has been shown to be highly prone to Type I error (McNeish, 2016).

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Table 1. Intervention summary

Session	Session Content	Homework
1 – Emotional eating	The patient and physician discussed emotional eating and what emotions lead to the patient overeating, and what situations in the patient's life lead to these emotions. They went over the patient's DEBQ results to determine what emotions they scored the highest on.	The patient kept an emotional eating diary for 1 week, where each time the patient overate they wrote down the emotions they felt before and after overeating, as well as whether or not they were truly hungry.
2 – Values	The patient and physician discussed what core values are. They discussed why the patient wanted to lose weight and why weight loss is important to them, as well as how their values are related to emotional eating and how emotional eating may hinder their weight loss progress.	The patient wrote down their reasons for wanting to lose weight and how these reasons are related to emotional eating.
3 – Using values to make decisions	The patient and physician briefly reviewed the patient's values related to losing weight. The physician taught the patient the BOLD technique and how to use it to reduce emotional eating, as well as introduced if-then plans and how they can be used to reduce emotional eating.	The patient practiced following if-then plans (IF I want to eat when I experience _____ emotion, THEN I will use the BOLD technique). They journaled their observations from a time when the BOLD technique was used to reduce emotional eating.
4 – Acceptance	The patient and physician discussed the concept of accepting and tolerating negative emotions. The tug-of-war metaphor and the concept of dropping the rope in the face of negative emotions was introduced. They brainstormed alternative ways to respond to negative emotions (instead of eating).	The patient practiced dropping the rope and finding alternatives to eating in response to negative emotions. The patient used the if-then plan "IF I feel _____ emotion, then I will practice dropping the rope and do (alternate behaviour) instead of eating". They journaled a time when this occurred doing the week and what the experience was like.

5 – Urge surfing	The patient and physician discussed the concept of urge surfing and how it can be used when experiencing emotions or cravings to prevent overeating.	The patient practiced urge surfing using the if-then plan "IF I feel _____ emotion, THEN I will practice urge surfing". They journaled a time during the week when urge surfing was used and what the experience was like.
6 – Mindful eating	The physician explained the concept of mindful eating and how to do it. They completed a mindful eating exercise to train the patient in how to prevent mindless eating.	The patient practiced mindful eating at home. They used the if-then plan "IF I want to eat my favourite treat, THEN I will practice eating it mindfully". They journaled a time during the week when mindful eating was used and what the experience was like.
7 – Establishing habits	The physician reviewed the skills taught in the first six sessions to help reduce emotional eating and promote long-term weight loss. They discussed the techniques that the patient found most useful and emphasized the importance of practicing these skills routinely to establish a habit.	The patient chose the if-then plans that worked best for reducing their own emotional eating and wrote them down. They tailored them to the emotions the patient finds most triggering.
8 – Commitment to values	The patient and physician discussed setbacks, loss of motivation, and how they are a normal and inevitable part of the weight loss journey. They discussed ways to stay committed to values and goals despite setbacks. The if-then plans the patient had chosen as the most effective were reviewed. The patient wrote those plans on a summary card.	The patient was encouraged to keep the summary card of if-then plans somewhere accessible to act as a constant reminder of values when feeling a lack of motivation.