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(Kg-Free): A randomized controlled trial

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Abstract

This randomized-controlled trial aims to test the efficacy of a group intervention (Kg-Free) for women with overweight or obesity based on mindfulness, ACT and compassion approaches. The intervention aimed to reduce weight self-stigma and unhealthy eating patterns and increase quality-of-life (QoL). Seventy-three women, aged between 18-55 years old, with BMI \geq 25 without binge-eating seeking weight loss treatment were randomly assigned to intervention or control groups. Kg-Free comprises 10 weekly group sessions plus 2 booster fortnightly sessions, of 2h30 hours each. The control group maintained Treatment as Usual (TAU). Data was collected at baseline and at the end of the Kg-Free intervention. Overall, participants enrolled in Kg-Free found the intervention to be very important and helpful when dealing with their weight-related unwanted internal experiences. Moreover, when compared with TAU, the Kg-Free group revealed a significant increased health-related QoL and physical exercise and a reduction of weight self-stigma, unhealthy eating behaviors, BMI, self-criticism, weight-related experiential avoidance and psychopathological symptoms at post-treatment. Results for self-compassion showed a trend towards significance, whereas no significant between-groups differences were found for mindfulness. Taken together, evidence was found for Kg-Free efficacy in reducing weight-related negative experiences and promoting healthy behaviors, psychological functioning, and QoL.

Keywords: Overweight and Obesity; Weight-self-stigma; Obesity-related Quality-of-life; RCT; Kg-Free Intervention.

1. Introduction

One of the most serious worldwide health problems is obesity, especially as it is associated with several health problems (e.g., diabetes, hypertension, high cholesterol, heart and liver disease, sleep apnea, osteoarthritis, depression and anxiety disorders) and diminished quality-of-life (e.g., Franz et al., 2007). Obesity treatments typically include dietary restriction and physical activity prescriptions, usually producing significant short-term weight losses (e.g., Lasikiewicz, Myrissa, Hoyland, & Lawton, 2014). However, the majority of the individuals regain their initial weight within 5-years (Wilson & Brownell, 2002). A growing body of empirical data suggests that not only diet-focused interventions may be ineffective and counterproductive, but may also pose significant unwanted harmful effects such as increased body dissatisfaction, disordered eating behaviors (e.g., chronic dieting, overeating), shame and self-criticism, and have a damaging impact on individuals' health and well-being (e.g., Bacon et al., 2002; Tylka et al., 2014).

Literature has been emphasizing the role of shame and self-criticism as important transdiagnostic processes involved in several psychological and health-related medical conditions, including eating psychopathology and obesity (Gilbert et al., 2014; Kelly & Carter, 2013). Additionally, the impact of weight stigma may reach almost every life domain of people with overweight and obesity. Weight stigma may be internalized reflecting personal experiences of shame, negative self-evaluations as well as perceived discrimination, that have been related to medical noncompliance, avoiding seeking medical care and has been considered a major predictor of poorer outcomes (Latner, Durso, & Mond, 2013; Lillis, Luoma, Levin, & Hayes, 2010; Palmeira, Pinto-Gouveia, & Cunha, 2016a). Thus, it seems that focusing only on weight loss is not sufficient to promote health and well-being of those living with a chronic illness such as obesity. Therefore, targeting the psychological processes that are linked to weight gain is crucial to help people to develop a healthier and more accepting relationship with their eating, weight, and weight-related experiences in order to increase quality-of-life (Hilbert, Braehler, Haeuser, & Zenger, 2013; Tapper et al., 2009; Tylka et al., 2014). Research has shown that health-focused interventions promote healthy eating behaviors and physical activity, improve health, (including the reduction of well-known risk factors such as elevated blood pressure, cholesterol and glucose), even without significant weight changes (e.g., Blaine, Rodman, & Newman, 2007; Tylka et al., 2014).

In fact, several psychological factors associated with weight regain (e.g., avoidance-based motivations, emotional eating, impulsivity and rigid control of eating) might reflect weight-related experiential avoidance patterns, which in turn have been related to poorer outcomes and diminished quality-of-life (Lillis, Hayes, Bunting, & Masuda, 2009; Palmeira et al., 2016a).

Weight-related experiential avoidance relates to being unwilling to stay in contact with difficult, weight and eating-related internal experiences (such as craving for food, fatigue, weight self-stigma) and attempts to avoid, control or change them (Lillis et al., 2009). Acceptance and Commitment Therapy (ACT; Hayes, Strosahl, & Wilson, 2012) specifically aims to reduce experiential avoidance patterns by increasing willingness and acceptance towards one's unwanted internal experiences. ACT fosters cognitive defusion (i.e., the ability to recognize thoughts as simply products of the mind and not necessarily the truth) and distress tolerance skills in order to promote committed actions driven by one's core life values.

Furthermore, the development of mindfulness skills is key for all ACT processes (Hayes et al., 2012). Mindfulness involves present moment experiences awareness with an open, accepting and non-judgmental attitude. Particularly regarding food and eating, the practice of mindfulness enhances awareness and clarity of emotional and sensory cues (e.g. hunger and satiety) and the ability to make healthier choices (Kristeller & Wolever, 2011). It may also help to create a more positive and accepting relationship with food, which in turn could lead to weight changes (O'Reilly, Cook, Spruijt-Metz, & Black, 2014).

Efficacy studies showed that ACT interventions can be effective to reduce weight self-stigma, disinhibit and emotional eating, psychological distress, weight loss and increase physical activity and health-related QoL (Forman et al., 2013; Lillis et al., 2009; Niemeier, Leahey, Reed, Brown, & Wing, 2012; Tapper et al., 2009). In addition, a recent literature review (O'Reilly et al., 2014) concluded that mindfulness-based interventions can be effective in reducing binge eating, emotional and external eating, food cravings, body image concerns and showed promising results for weight management.

Concomitantly, there is an increasing interest in developing self-compassion to promote wellbeing and decrease shame and self-criticism patterns (e.g., Gilbert, 2010). Self-compassion involves cultivating a kind, accepting and reassuring relationship with oneself, especially during challenging times (Gilbert, 2010; Neff & Dahm, 2015). It includes the sensitivity to one's suffering and a desire to prevent or alleviate it (Goetz, Keltner, & Simon-Thomas, 2010). Mindfulness is one of the key components of self-compassion, as one needs to be aware, open and able not to become overidentified with one's own suffering in order to be self-compassionate (Neff & Dahm, 2015). However, the concept of self-compassion goes beyond mindfulness as it involves an attitude of support and kindness towards oneself, instead of being critical and disparaging, as well as the recognition that suffering is an inherent part of the human condition. Individuals may need to learn mindfulness skills before practicing loving-kindness or other compassion exercises, given that mindfulness is required for compassion and that both skills

mutually enhance one another (Hofmann, Grossman, & Hinton, 2011; Kabat-Zinn, 1990; Neff & Dahm, 2015).

Research shows that self-compassion is associated with decreased body dissatisfaction and increased global mental health (Albertson, Neff, & Dill-Shackleford, 2015) and may buffer the relationship between weight self-stigma and health of individuals with overweight and obesity (Hilbert et al., 2015). Nevertheless, results from a qualitative study (Gilbert et al., 2014) suggest that people struggling with their weight find it hard (if not impossible) to be self-compassionate when dealing with relapses. In fact, when facing setbacks, many dieters tend to see themselves as failures, feeling shame and becoming self-critical rather than self-reassuring, which hinders the maintenance of healthy lifestyles and eating habits (Adams & Leary, 2007; Gilbert et al., 2014). Thus, developing self-compassion skills with people struggling with their weight and eating seems particularly relevant (Gilbert et al., 2014). Additionally, self-compassion has been linked to perceived self-efficacy and intrinsic motivation (e.g., Neff, Rude, & Kirkpatrick, 2007), less fear of failure and a higher tendency to try again when facing failures (Neely, Schallert, Mohammed, Roberts, & Chen, 2009).

It seems that all the above-mentioned skills (acceptance, cognitive defusion, distress tolerance, values and committed actions, mindfulness and self-compassion) may be key to maintain healthy behaviors in the current obesogenic environment where food is abundant and easily accessible and where sedentary lifestyles are common (Forman et al., 2015; Lillis et al., 2015).

ACT, mindfulness, and compassion-based interventions share a common ground, as they focus on promoting a more aware, kind, accepting and non-judgmental relationship with a person's experiences and oneself (Neff & Dahm, 2015; Neff & Tirsch, 2013). ACT and self-compassion both emphasize that mindfulness is crucial to develop cognitive defusion, acceptance and self-compassion abilities (Hayes et al., 2012; Neff & Tirsch, 2013). Moreover, compassion training (e.g., loving-kindness, Compassion Focused Therapy - CFT) may be combined with several cognitive-behavioral therapeutic techniques (Gilbert, 2010; Hofmann et al., 2011). Furthermore, some authors (Luoma & Platt, 2015; Neff & Tirsch, 2013) argue that most ACT protocols may benefit from explicitly targeting self-compassion, as it improves the ability to stick to health-related behaviors and decreases weight-stigma, shame, and self-criticism.

Although growing interest in integrating self-compassion in ACT and mindfulness-based interventions exists (Neff & Dahm, 2015; Neff & Tirsch, 2013), research on how these different yet related approaches might be integrated into comprehensive interventions is still scant. So far, only one pilot study found promising results integrating ACT and CFT to increase self-compassion and diminish HIV-related stigma (Skinta, Lezama, Wells, & Dilley, 2015). Thus, we

developed a 12-session group intervention (Kg-Free) for women with overweight and obesity that integrates mindfulness, ACT and self-compassion components.

This randomized controlled trial main goal was to test the efficacy of Kg-Free with women with overweight and obesity without binge eating. Kg-Free specifically aims at promoting quality-of-life and reducing weight self-stigma and unhealthy eating behaviors (emotional and uncontrolled eating) by targeting weight-related experiential avoidance and self-criticism. Our hypothesis is that after Kg-Free, participants will be more open, accepting and compassionate towards themselves and their unwanted internal experiences (especially those related to eating and weight), which will increase their well-being and quality-of-life. If a change occurs at this level, it is likely that participants will be increasingly able to engage in healthier behaviors even in the face of difficulties, which may influence their weight and obesity-related biochemical risk factors (e.g., cholesterol).

2. Methods

2.1. Participants and procedures

Previously to data collection, ethical approval was obtained from all institutions involved. Participants were adult women, aged between 18 and 55 years old, with overweight and obesity ($BMI \geq 25$) without binge eating, enrolled in nutritional treatment for weight loss in primary care units and Hospitals from Coimbra's district, Portugal. Participants were recruited directly at the medical care units in the day of their appointment by a clinical psychologist (member of the research team), using an existent spare room. A brief overview of the treatment program was presented and participants were individually informed about the voluntary and confidential nature of the data.

Power analysis was calculated a priori using G*Power 3.1 (Faul, Erdfelder, Lang, & Buchner, 2007) for ANCOVA analysis. Results indicated that a sample size of 26 per group ($N = 52$) was needed, using a significance level of 05 and a power of 80% to detect significant fixed effects, main effects, and interaction effects, with a large effect size ($f = 0.40$). Overall, 108 women were invited to take part in the study and six declined. Those who accepted to take part in the study signed a written informed consent. Only then, participants were screened for eligibility. Exclusion criteria included: a) Binge Eating Disorder assessed through EDE interview; b) Severe psychiatric problems (severe depressive episode, substance abuse, Bipolar disorder and Borderline Personality Disorder) assessed through SCID-I and SCID-II; c) medical conditions that affect weight; d) medication that can cause significant weight or appetite changes. From the 102 that accepted to participate, 16 did not meet inclusion criteria. Fig. 1 displays the flow of participants throughout the study in detail. To guarantee confidentiality a numerical unique code

was assigned to each participant. Only one of the researchers (L.P.) had access to the participant's research code.

2.2. Study design

This is a randomized controlled trial, parallel group study conducted in Portugal from September 2014 to June 2016. After baseline assessment, 73 participants were randomly assigned to an experimental or to control conditions by a member of the research team, using a computer-based random allocation.

Participants in the experimental group received Kg-Free while maintaining their Treatment As Usual (TAU), which includes medical and nutritional appointments. At the same time, the control group maintained only TAU, at their local medical care units. The medical appointment in TAU includes a physical examination and addressing comorbidities. In nutritional appointments individuals are weighed, receive tailored dietary recommendations (according to one's needs and food preferences) and physical activity prescriptions (at least 3 times per week of moderate to high intensity physical exercise is usually recommended). Difficulties regarding weight loss plans are also addressed in both appointments. TAU does not include any psychological intervention. Data collection was carried out by clinical psychologists (blinded to participants' treatment condition). From the initial 36 participants allocated to Kg-Free, four failed to attend any session, one became severely depressed between the baseline assessment and program's first session, one was submitted to bariatric surgery and three dropped out after the first sessions. These nine participants were excluded from further analysis because it was not possible to obtain any data at post-treatment assessment. From the initial 37 participants allocated to TAU, one moved to another city, one was submitted to bariatric surgery and three more were scheduled but did not attend the second assessment. These five participants were also excluded from analysis. After the post-intervention assessment, participants in the TAU group were given the possibility to receive the intervention.

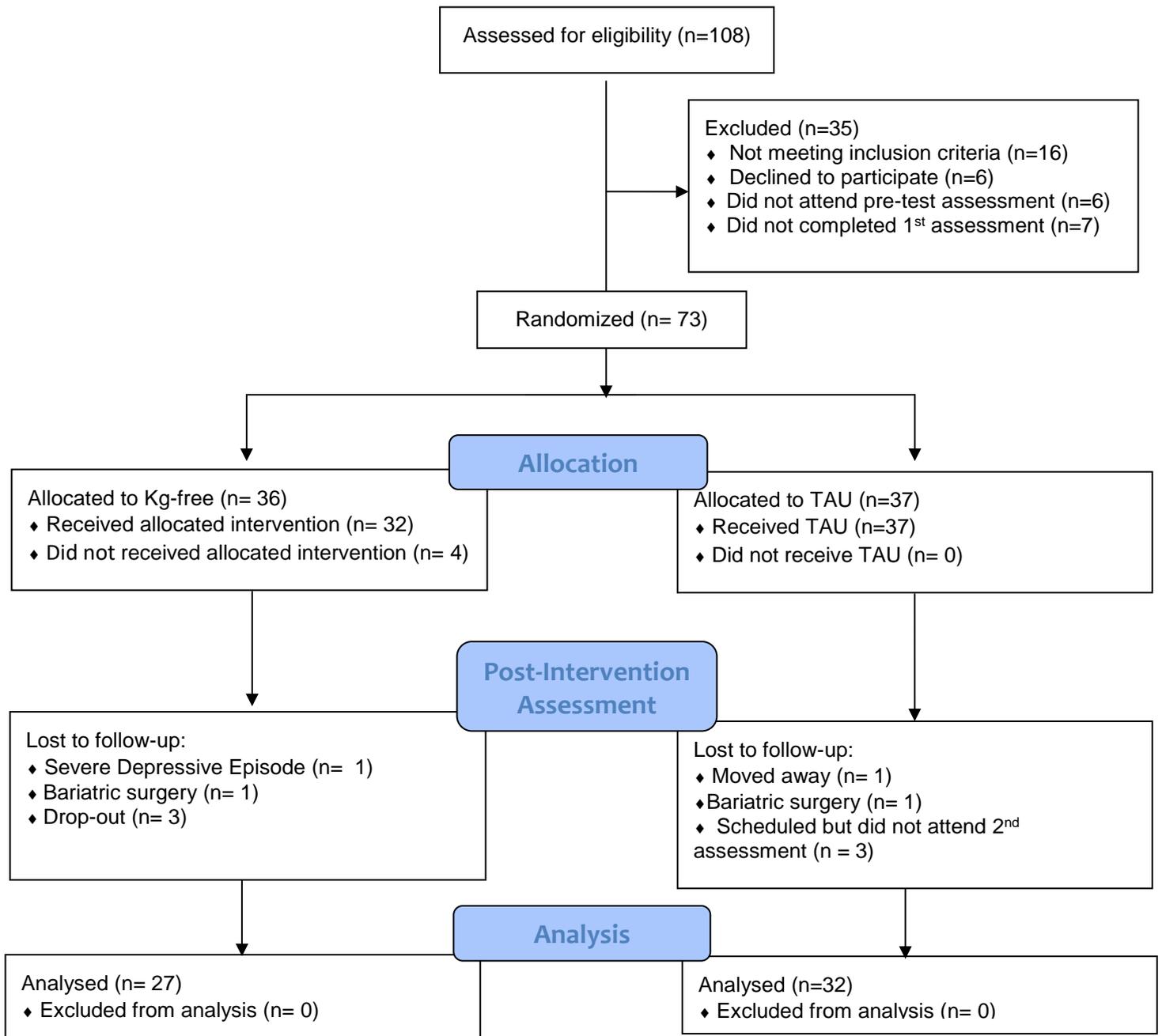


Fig. 1. Flow of participants throughout the randomized controlled trial.

Table 1 displays baseline demographic characteristics across intervention and control groups after randomization.

	Kg-Free (n=36)		TAU (n=37)	
	M	SD	M	SD
Age	41.97	8.79	42.73	8.36
Years of education	14.94	3.03	15.35	3.45
BMI	34.82	5.26	33.65	4.83
	N	%	N	%
Marital status				
Single	7	19.8	4	10.8
Married	26	72.2	27	73
Divorced	3	8.3	6	16.2
Socioeconomic status				
Low	8	22.2	4	10.8
Medium	22	61.1	31	83.8
High	6	16.7	2	5.4
Number of previous diet attempts				
None	3	8.3	5	13.5
Less than 5	19	52.8	20	54.1
From 5 to 10	9	25	10	27
More than 10	5	13.9	2	5.4

Note. Kg-Free = treatment group; TAU = control group

2.3. Kg-Free intervention

Kg-free is a manualized group intervention based on mindfulness, ACT and compassion-based approaches for women with overweight and obesity developed by the three authors. It comprises 10 weekly group sessions plus 2 booster fortnightly sessions (3^{1/2}months) 2h30 hours each, run in small groups (from 10 to 12 participants). The intervention was designed to reduce weight self-stigma and unhealthy eating behaviors and promote quality-of-life by targeting weight-related experiential avoidance and self-criticism. A clinical psychologist with previous training in contextual-behavioural therapies and one clinical psychology master student delivered the sessions for all groups.

The intervention was designed to integrate distinct yet related components that have showing promising results with people that are have weight and eating difficulties (e.g., Goss, 2011; Kristeller & Wolever, 2011; Forman et al., 2013; Lillis et al., 2009; Tapper et al., 2009). Table 2 displays a session-by-session overview of Kg-Free intervention. Kg-free included the

following main components: a) psychoeducation regarding eating, weight and emotions using an evolutionary approach to decrease shame and self-criticism (Gilbert, 2010; Goss, 2011); b) values and committed actions towards a healthier life were promoted to enhance motivation; c) acceptance of unwanted internal experiences, cognitive defusion and distress tolerance skills were used to diminish experiential avoidance patterns and promote a more accepting and flexible relationship with one's eating and weight; d) mindfulness was promoted in all sessions to cultivate present moment awareness, as well as a nonjudgmental attitude towards one's experiences, particularly concerning eating; and e) self-compassion was included to tackle weight self-stigma and self-criticism patterns, to enhance individual's motivation to kindly take care of themselves and to explicitly promote well-being and positive affect.

Experiential exercises and key concepts from ACT were adapted from pre-existent ACT books (Hayes & Smith, 2005) and manuals for eating and weight issues (Forman et al., 2013; Lillis et al., 2009). The mindfulness exercises scripts used were adapted from Teasdale, Williams, and Segal (2014). Particularly, the mindfulness eating practices (mindful eating and mindful eating awareness) included in all sessions were adapted from MB-EAT (Kristeller & Wolever, 2011). Finally, the self-compassion component included a loving-kindness meditation (Salzberg, 1995), as well as several self-compassion exercises (adapted from CFT; Gilbert, 2010; Goss, 2011), given that both are frequently combined in many Buddhist practices and psychological studies (Kabat-Zinn, 1990).

All sessions shared the same basic structure, starting with 30 minutes of shared experience, followed by a five-minute mindfulness practice (e.g., eating a raising meditation, mindfulness of breathing, physical sensations). The session content was delivered, followed by a mindful eating practice to train the ability to pay attention to food and eating physical sensations. Finally, the session content was briefly revised and practices for the week were established (e.g., audio mindfulness and self-compassion practices). Participants received a manual that included the targeted constructs, examples, and exercise sheets. Audio files were provided to ensure the practice of mindfulness and compassion exercises between sessions.

Table 2

Overview of Kg-Free intervention session-by-session.

Sessions	Aims	Key Metaphors and Exercises
1.Introduction	Participants' presentations, Programs' structure and methodology; Promote creative hopelessness; Introducing mindful eating.	Group dynamics; Man in the hole metaphor; Eating a raisin meditation.
2. Psychoeducation I	Promote mindfulness skills; Understanding our relationship with food; The multiple functions of food; Deshaming and diminishing self-criticism. Develop mindful eating.	Mindfulness of breathing; Videos and discussion about your relationship with food; Mindful eating exercise.
3. Psychoeducation II	Understand the role of different emotions in our lives; Deshaming and diminish self-criticism. Enhance awareness of hunger and satiety cues.	Mindful looking at your hand; Videos and discussion; Exploring emotional regulation systems; Mindfulness eating awareness.
4.Values and committed action	Promote mindfulness skills; Promote values clarification; Enhance motivation towards healthy valued actions; Creating obtainable goals towards a healthier life.	Mindfulness of breathing; Passengers on the bus metaphor; Attending your own funeral exercise; Goals, barriers and actions worksheet.
5.Acceptance and defusion	Promote mindfulness skills; Understanding why language lead to suffering; Control as the problem; Introduce the importance of acceptance; Thoughts are not facts.	Mindfulness of physical sensations; Debate language as a double-edged sword; Clipboard exercise; Defusion exercises (e.g., Labeling your thoughts);
6.Willingness and distress tolerance	Promote mindfulness skills; Promote acceptance and willingness of unwanted internal experiences; Enhance distress tolerance;	Mindfulness of the present moment; Taking the mind for a walk exercise; Eyes On exercise; Urge surfing.
7.Descriptions vs evaluations	Promote mindfulness skills; The mind as an evaluating machine; Distinguish between descriptions and evaluations towards your bodies; Promote acceptance of unwanted internal experiences;	Mindfulness of physical sensations; Defusion in front of a mirror; Leaves on a stream; Mindfulness of a difficult experience.
8.Shame and self-criticism	Promote mindfulness skills; The role of shame and self-criticism; Self-compassion as an antidote for shame and self-criticism;	Mindful eating exercise; Role play; Two-teachers metaphor; Soothing rhythm breathing and safe place exercises.
9.Self-compassion	Promote mindfulness skills; Understand what is compassion; Why do we need compassion?; Cultivate loving-kindness and compassion for self;	Mindfulness of the present moment; Loving-Kindness meditation; Compassionate friend exercise.
10.Self-compassion	Promote mindfulness skills; Explore obstacles for self-compassion; Cultivate compassion for self.	Mindfulness of physical sensations; Compassionate self exercise; Compassionate letter writing.
11.Booster session I	Change what you can and accept what you cannot change; Foster acceptance of unwanted internal experiences; Smashing patterns and building flexible actions	Mindfulness of breathing; Mindfulness of a difficult emotion;
12.Booster session II	Sticking to committed actions; Coping with relapses; Develop a personalized action plan.	Mindful walking; Mountain path metaphor; Willingness and action plan worksheet

2.4. Measures

Participants were assessed at baseline and after the *terminus* of the intervention program (or the equivalent period for the control group).

Demographic Data. In the initial screening interview, participants were asked about their age, educational level, and previous weight history.

Qualitative Data. After the intervention, participants allocated to Kg-Free intervention completed a brief self-reported questionnaire designed to assess program's acceptability.

2.4.1 Main outcome measures

The intervention targeted specifically two main areas of outcomes: health-related (including quality-of-life and weigh self-stigma) and eating-related (emotional and uncontrolled eating) outcomes.

Weight self-stigma Questionnaire (WSSQ; Lillis et al., 2010; Palmeira, Cunha, & Pinto-Gouveia, 2017) was designed to assess weight self-stigma in people with overweight and obesity. The 12 items are rated on a 5-point Likert scale (1 = strongly disagree to 5 = strongly agree), with higher scores reflecting the presence of more weight self-stigma. WSSQ original version showed good psychometric properties ($\alpha = 0.88$), similar to the ones found in the Portuguese version (Palmeira et al., 2017). In the present study only WSSQ total score was used and revealed high internal consistency ($\alpha = 0.90$).

Obesity Related Well-Being Questionnaire (ORWELL-97; Mannucci et al., 1999; Silva, Pais-Ribeiro, & Cardoso, 2008) is an 18items measure that assesses obesity-related quality-of-life (QoL). Participants are asked to rate all items on a four-point scale (0 = "not at all" to 3 = "much"), with higher scores indicating diminished QoL. Orwell-97 has revealed good internal consistencies both the original and the Portuguese version ($\alpha = 0.83$ and $\alpha = 0.85$ respectively). In this study, ORWELL-97's Cronbach alpha was 0.91.

Three Factor Eating Questionnaire-21R (TFEQ-R21; Cappelleri et al., 2009; Duarte, 2015) measures three types of eating behaviors: cognitive restraint, uncontrolled eating, and emotional eating. Twenty items are rated on a 4-point scale (1= "completely true" to 4= "completely false"). Item 21 is answered through an 8-point scale (1= "I eat everything I want and when I want" and 8=" I constantly confine my food intake"). Higher scores indicate higher tendency to engage in those eating behaviors. In this study, only emotional and uncontrolled eating dimensions were used and presented good internal consistency ($\alpha = 0.86$ for uncontrolled eating; and $\alpha = 0.94$ for emotional eating).

2.4.2 Secondary outcome measures

BMI. All participants were weighted with their street clothes (without shoes) using the same Body Composition Analyzer (Tanita TBF-300) accurate to 0.1kg.

Waist circumference was measured, by the same researcher, using a tape measure at the umbilicus.

Total Cholesterol. Participants consented and provided blood samples. The samples were collected and analysed by the clinical analysis laboratory from the Pharmacy department¹. Confidentiality was assured hence only the research code for each participant was provided to the laboratory.

General health Questionnaire (GHQ-28; Goldberg & Hillier, 1979; Pais-Ribeiro & Antunes, 2003) measures current mental health and screen for non-specific psychiatric morbidity. It assesses four main areas: somatic symptoms, anxiety, depression, and social dysfunction. Items are rated on a 4-point scale (0 = better than usual to 3 = worse than usual). GHQ has been shown to be valid in screening for psychiatric problems in both clinical and general populations. In this study, GHQ internal consistency was 0.91.

Physical exercise. Participants were asked three different questions: 1) Do you currently do physical exercise? (Yes responses were considered if participants engage in physical exercise for more than 30min at a time); 2) What kind of exercise do you do?; 3) How frequently do you do physical exercise? (Responses ranged from 0 = “less than once a week” to 4 = “6/7 days a week”)

2.4.3 Process measures

Acceptance and Action Questionnaire for Weight-Related Difficulties-Revised (AAQW-R; Palmeira, Cunha, Pinto-Gouveia, Carvalho, & Lillis, 2016b) is a 10 items version of the original AAQW, that measures the tendency to avoid, control or suppress unwanted internal experiences related to one’s weight. Participants are asked to rate all items on a 7-point scale (1 = “never true” or “not at all believable” and 7 = “always true” or “completely believable”), with higher scores reflecting more experiential avoidance. In this study AAQW-R showed good internal consistency ($\alpha = 0.87$).

Forms of Self-Criticizing/Attacking & Self-Reassuring Scale (FSCRS; Gilbert, Clark, Hempel, Miles, & Irons, 2004; Castilho, Pinto-Gouveia, & Duarte, 2015a) assesses the tendency to criticize or reassure the self when things go wrong. It comprises three subscales: inadequate, hated and reassured self. The 22 items are rated on a 5-point scale (0 = “Not at all like me” to 4 = “Extremely like me”). The FSCRS presented good internal consistencies in clinical and non-clinical samples ranging from 0.83 to 0.91 (Gilbert et al., 2004). In this study, only inadequate and hated-self dimensions were used and presented adequate internal consistencies ($\alpha = 0.79$ for inadequate-self, $\alpha = 0.64$ for hated-self).

¹ All costs were supported by the first author's Ph.D. grant.

Self-Compassion Scale (SCS; Neff, 2003; Castilho, Pinto-Gouveia, & Duarte, 2015b) is a 26 items questionnaire assessing compassion for self. The instrument comprises six subscales that measure three self-compassion components (self-kindness/self-judgment; common humanity/isolation and mindfulness/ over-identification). Items are rated on a 5 point Likert scale (1 = almost never; to 5 = almost always). In the original study, SCS showed good internal consistency ($\alpha = 0.92$; Neff, 2003), similar to the one found in the current study ($\alpha = 0.91$).

Five Facet Mindfulness Questionnaire - 15 (FFMQ-15, Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006; Gregório, Pinto-Gouveia, Palmeira, & Carvalho, in preparation) is a shorter version of the original FFMQ with 15 items that measures the dispositional mindfulness characteristics. Participants rate how mindful they feel in daily life on a 5-points Likert scale (1 = “never or very rarely true” to 5 “very often or always true”). In the present study only FFMQ-15 global score was used and it showed low but still acceptable internal consistency ($\alpha = 0.52$).

2.5. Data analysis

All data analyses were performed using SPSS Statistics 20 and alpha level was set at 0.05. *Independent sample t tests* were used in order to compare intervention and control groups at baseline. To test between-group differences at post-treatment ANCOVAs with baseline as covariate and condition as a fixed factor were performed. The effect sizes were calculated using d_{corr} as it allows testing the effect size controlling for unequal sample sizes and baseline differences (Morris, 2008). According to Cohen's guidelines (1988 cited in Tabachnick & Fidell, 2007), Cohen's d between 0.2 and 0.4 represent small effects; between 0.5 and 0.7 medium effects and above 0.8 large effects. Independent samples t-tests and ANCOVA assumptions were verified through skewness and kurtosis. Also, ANCOVA's assumption of homogeneity of variance assumption (Levene's test of the homogeneity) and homogeneity of regression slopes was also tested.

Finally, to explore within-group differences from pre to post-treatment, *paired samples t-tests* were performed for each group separately. Bonferroni correction for multiple comparisons was calculated in order to reduce type I errors ($\alpha = .05/14$). Effect sizes were calculated using Cohen's d .

3. Results

3.1. Kg-Free feasibility and acceptability

Overall, the intervention had high attendance rate. From the 27 participants that completed the Kg-free intervention, 24 attended the majority of the 12 sessions ($M = 10.89 \pm$

1.12). Intervention acceptability was assessed at post-treatment on a 5-point rating scale (from 1 = “not at all” to 5 “extremely”). Participants rated the program as very important ($M = 4.37 \pm 0.49$) and helpful ($M = 4.00 \pm 0.39$). Likewise, participants found the intervention to have a significant impact on their quality-of-life ($M = 3.96 \pm 0.76$) and to be very important to help them deal with difficult thoughts ($M = 4.11 \pm 0.58$), emotions ($M = 3.89 \pm 0.70$) and urges ($M = 3.89 \pm 0.51$). Lastly, sessions that promoted acceptance and defusion (63%) and self-compassion (52%) were considered the most useful.

3.2. Baseline differences

Baseline differences between groups were explored for all outcome measures. At baseline the intervention group revealed higher levels of weight-related experiential avoidance ($t_{(71)} = -2.251, p = 0.027, \text{Cohen}' d = 0.53$) and self-criticism (inadequate-self: $t_{(71)} = -2.307, p = 0.024, \text{Cohen}' d = 0.54$; hated-self: $t_{(71)} = -2.438, p = 0.017, \text{Cohen}' d = 0.57$). Moreover they reported diminished obesity-related quality-of-life ($t_{(17)} = -2.138, p = 0.036, \text{Cohen}' d = 0.50$), and fewer abilities be compassionate towards themselves ($t_{(57)} = 2.216, p = 0.030, \text{Cohen}' d = 0.52$) in comparison with TAU group. All differences represent medium effect sizes. No differences at the onset of the study were found for all other study's variables. We also compared the characteristics of those who dropped with those who remained in the study at baseline. Only one significant difference was found. When compared to those who remained in the study, those who drop-out presented less years of education ($t_{(71)} = -2.482, p = 0.015, \text{Cohen}' s d = 0.74$ – medium effect size).

3.3. Intention to treat analysis

Initially, an intention to treat analysis was conducted. Missing data were replaced by calculating the mean change from previous observations in the group and adding or subtracting this value from the existent previous observation. Table 3 displays the results found for the intention to treat analysis. Results showed that weight self-stigma, diminished quality-of-life, emotional and uncontrolled eating decreased in both groups. Physical activity frequency and self-compassion increased in the Kg-Free group compared to a decrease in the control group (see Table 3). Conversely, changes in BMI, waist circumference and cholesterol were relatively minor. Psychological distress and hated-self decreased in the intervention group compared to an increase in the TAU group. Both groups also showed a reduction in weight-related experiential avoidance and inadequate-self and an increase in mindfulness abilities. ANCOVA analyses with the condition as a fixed factor and baseline scores as covariate were executed (Table 3). Levene's test

of the homogeneity were non-significant for all study's variables indicating that group variances were equal. Likewise, the homogeneity of regression slopes was also non-significant for all variables, which means that the relationship between the outcome and the covariate is the same in both groups. Results showed that the intervention has significant effects for almost all variables, with small to medium effect sizes. The significant effect for BMI was very low, with a non-significant effect size (Cohen's $d = 0.09$). Lastly, no significant effects of the intervention were found for waist circumference, total cholesterol, mindfulness and self-compassion skills.

3.4. Intervention efficacy analyses

As in the intention to treat analysis, ANCOVA assumptions were satisfied. Thus, ANCOVA with baseline scores as covariate and condition as a fixed factor were performed in order to test between-group differences at post-treatment. As can be seen in Table 3, when compared with the control group, participants in Kg-Free group presented a significant decrease in weight self-stigma, emotional and uncontrolled eating and increased quality-of-life. All effect sizes reflect medium effects.

Regarding secondary outcomes, those allocated to Kg-Free revealed a significant decrease in BMI, less psychological distress and increased physical exercise frequency. At post-intervention, the intervention group presented was practicing physical exercise 4 or 5 times a week, whereas on average the TAU group practiced once a week. Moreover, no significant between groups' differences were found regarding waist circumference and cholesterol. Likewise, significant between-group differences were found for process variables with participants from the Kg-Free group presenting lower levels weight-related experiential avoidance, inadequate-self, and hated-self. These results reflect medium to large effect sizes. Results for self-compassion were on the edge of statistical significance, reflecting a medium effect size. No between-groups difference at post-intervention was found for mindfulness abilities.

Finally, and given that the intervention was delivered in groups, additional ANCOVA analyses controlling for group allocation were performed to explore between groups differences in all outcomes. Results resembled the ones found above, with no differences between the intervention groups being found.

Table 3.

Mean change score (and SDs) for all outcome and process variables by group, Analysis of Covariance and effect size for the intention to treat and intervention efficacy analyses.

	Intention to treat			Intervention efficacy						
	<i>Kg-Free</i> (<i>n=36</i>)	<i>TAU</i> (<i>n=37</i>)	<i>F</i>	<i>p</i>	<i>d</i>	<i>Kg-Free</i> (<i>n=27</i>)	<i>TAU</i> (<i>n=32</i>)	<i>F</i>	<i>p</i>	<i>d</i>
	<i>M (SD)</i>	<i>M (SD)</i>				<i>M (SD)</i>	<i>M (SD)</i>			
Main outcomes										
Weight self-stigma	-5.27 (6.83)	-0.19 (4.13)	11.294	0.001	0.58	-6.96 (7.14)	-0.19 (.81)	14.790	<0.001	0.74
Quality-of-life	-8.47 (12.31)	-0.56 (10.18)	5.110	0.027	0.50	-11.11 (13.23)	-0.56 (10.97)	5.346	0.024	0.68
Emotional eating	-0.32 (.54)	-0.02 (.36)	8.003	0.006	0.44	-0.41 (.60)	-0.05 (.35)	6.837	0.011	0.52
Uncontrolled eating	-0.28 (.37)	-0.05 (.28)	10.245	0.002	0.46	-0.35 (.41)	-0.06 (.30)	9.801	0.003	0.61
Secondary outcomes										
BMI	-0.54 (.92)	-0.07 (.76)	5.506	0.022	0.09	-0.69 (.95)	-0.33 (.81)	8.323	0.006	0.13
Waist Circumference	-1.56 (3.73)	-0.70 (4.26)	0.894	0.348	0.08	-1.74 (4.28)	-0.67 (4.58)	0.824	0.368	0.09
Total Cholesterol	-12.07 (21.37)	-11.56 (24.96)	0.250	0.619	0.29	-12.76 (19.47)	-11.57 (25.53)	.598	0.531	0.28
Physical Exercise	+1.06 (1.71)	-0.62 (1.91)	24.534	<0.001	1.11	+1.52 (1.74)	-0.56 (1.95)	31.609	<0.001	2.00
GHQ	-6.29 (10.56)	+2.58 (10.37)	11.790	0.001	0.85	-9.00 (10.91)	+2.31 (10.90)	16.718	<0.001	1.18
Process measures										
AAQW-R	-7.96 (9.99)	-0.46 (4.67)	8.127	0.006	0.61	-10.56 (10.32)	-0.19 (8.08)	9.884	0.003	0.96
Mindfulness	+3.44 (6.39)	+0.84 (4.45)	2.042	0.158	0.48	+4.35 (7.23)	+0.84 (4.80)	1.722	0.195	0.70
Inadequate self	-3.97 (5.76)	-0.02 (5.01)	6.151	0.016	0.63	-5.30 (6.11)	+0.03 (5.41)	6.194	0.016	0.94

Hated self	-1.94 (2.59)	+0.16 (2.45)	7.744	0.007	0.62	-2.63 (2.66)	+0.16 (2.65)	9.467	0.003	0.87
Self-compassion	+0.22 (.47)	-0.03 (.33)	3.458	0.067	0.38	+0.38 (.50)	-0.03 (.36)	3.774	0.052	0.71

Note. Kg-Free = treatment group; TAU = control group; BMI = Body Mass Index; GHQ = General Health Questionnaire; AAQW-R = Acceptance and Action Questionnaires for Weight-Related Difficulties-Revised.

3.5. Post-hoc analyses

As participants from the intervention group lost more weight than those in the control group, a supplementary set of ANCOVA were conducted for the study's main outcomes (weight self-stigma, unhealthy eating behaviors, and quality-of-life), using baseline scores and BMI at post-intervention as covariates. This allowed testing whether reductions in BMI accounted for changes in intervention's main outcomes. Results showed that the effect due to condition increased slightly for all outcomes, this suggests that the impact of the intervention was direct and not due to changes in weight. At post-intervention participants from Kg-free group presented decreased levels of weight self-stigma ($F(1, 57) = 16.943, p \leq 0.001, \eta_p^2 = 0.24$ – large effect), emotional ($F(1, 57) = 8.151, p = 0.006, \eta_p^2 = 0.13$ – medium effect) and uncontrolled eating ($F(1, 57) = 11.348, p = 0.001, \eta_p^2 = 0.17$ – large effect) and increased quality-of-life ($F(1, 57) = 6.487, p = 0.014, \eta_p^2 = 0.11$ – medium effect).

3.6. Within-group t-tests of changes

To explore significant changes within each group, paired samples t-tests were also performed, comparing baseline to post-treatment scores for each group. Table 4 presents the means, standard deviations from baseline and post-treatment assessments, paired samples t-tests and within-group effect sizes for both groups. Using Bonferroni correction for multiple corrections significant results were considered when $p \leq 0.004$. As can be seen in Table 4, in the Kg-Free group, significant differences were found from baseline to post-treatment. At post-treatment, the Kg-Free group presented significantly lower BMI and an important increase in physical activity frequency. Although effect size for BMI was rather small, the effect size for physical activity frequency large. In addition, results from the self-reported measures showed the same pattern (Table 4), with differences representing moderate to large effect sizes. Results also showed that there was a significant improvement in self-compassion in the Kg-Free group. Given the Bonferroni correction, differences from baseline to post-intervention in the Kg-free group concerning waist circumference, cholesterol levels, and mindfulness abilities remained non-significant. Finally, no statistically significant differences were found for the TAU group (Table 4).

Table 4.

Means, standard deviations, within-group t-test of changes from pre to post-treatment and Cohen's d for effect size for each group.

	Kg-Free Group (n = 27)					TAU Group (n = 32)				
	<i>Pre-treatment</i>	<i>Post-treatment</i>	<i>t</i>	<i>p</i>	<i>d</i>	<i>Pre-treatment</i>	<i>Post-treatment</i>	<i>t</i>	<i>p</i>	<i>d</i>
	<i>M (SD)</i>	<i>M (SD)</i>				<i>M (SD)</i>	<i>M (SD)</i>			
Main outcomes										
Weight self-stigma	40.81 (6.71)	33.85 (7.72)	5.068	<0.001	0.96	35.84 (5.97)	35.66 (10.54)	0.232	0.813	0.02
Quality-of-life	62.70 (14.31)	51.59 (13.02)	4.364	<0.001	0.81	51.63 (16.32)	51.06 (17.30)	0.290	0.774	0.03
Emotional Eating	2.88 (0.66)	2.48 (0.52)	3.551	0.001	0.67	2.67 (0.77)	2.62 (0.70)	0.854	0.400	0.07
Uncontrolled Eating	2.26 (0.44)	1.91 (0.38)	4.523	<0.001	0.85	2.14 (0.57)	2.08 (0.51)	1.180	0.276	0.11
Secondary outcomes										
BMI	34.76 (5.44)	34.07 (5.68)	3.732	0.001	0.12	33.40 (5.03)	33.37 (5.07)	0.232	0.818	0.01
Waist Circumference	106.26 (12.52)	104.51 (12.89)	2.115	0.044	0.14	105.84 (11.38)	105.17 (10.40)	0.829	0.413	0.06
Total Cholesterol ^a	203.48 (28.96)	186.14 (22.84)	3.004	0.007	0.67	208.26 (41.06)	196.70 (38.45)	2.173	0.041	0.29
Physical Exercise	1.26 (1.61)	2.78 (0.16)	-4.534	<0.001	1.33	1.31 (1.86)	.75 (1.39)	1.632	0.113	0.34
GHQ	26.00 (10.31)	17.00 (9.43)	4.287	<0.001	0.91	22.78 (10.86)	25.09 (9.09)	-1.200	0.239	0.23
Process measures										
AAQW-R	46.26 (11.10)	35.70 (10.17)	5.317	<0.001	0.99	38.00 (10.66)	37.81 (11.17)	0.131	0.896	0.02
Mindfulness	44.59 (4.74)	48.96 (7.11)	-3.064	0.005	0.72	48.16 (5.19)	49.00 (5.84)	-0.994	0.328	0.15
Inadequate self	19.93 (5.25)	14.63 (5.46)	4.506	<0.001	0.99	15.53 (5.97)	15.71 (7.36)	0.033	0.974	0.03
Hated self	5.74 (2.84)	3.11 (3.11)	5.132	<0.001	0.88	3.65 (3.30)	3.77 (3.45)	-0.339	0.737	0.04
Self-compassion	2.80 (0.47)	3.16 (0.37)	-3.699	0.001	0.81	3.21 (0.61)	3.18 (0.46)	0.514	0.611	0.06

Note. ^an = 22 for Kg-Free group and n = 23 for TAU group; BMI = Body Mass Index; GHQ = General Health Questionnaire; AAQW-R = Acceptance and Action Questionnaires for Weight-Related Difficulties-Revised.

4. Discussion

The present study main goal was to test the efficacy of Kg-Free – an acceptance, mindfulness and compassion-based group intervention for women with overweight and obesity. As far as we know, this is the first study to test the efficacy of an intervention that integrates ACT, mindfulness, and self-compassion components to reduce weight self-stigma and unhealthy eating patterns and improve health-related quality-of-life. The intervention specifically targeted weight-related experiential avoidance and self-criticism, two important psychological processes associated with poorer outcomes and diminished quality-of-life (Gilbert et al., 2014; Latner et al., 2013; Lillis et al., 2009).

Overall, participants enrolled in Kg-Free found the intervention to be very important and helpful when dealing with unwanted internal experiences (thoughts, emotions and urges). Cognitive defusion, urge surfing, mindfulness and compassion skills were rated as the most useful, which supports the importance of integrating component from different but complementary perspectives.

Results highlighted several differences between groups at post-intervention. When compared with the TAU group, the Kg-Free group revealed a significant increase in health-related quality-of-life and psychical exercise frequency (from 1 to 4/5 times a week) and lower levels of weight self-stigma, unhealthy eating patterns, and psychopathological symptoms. Moreover, participants from Kg-Free group also revealed decreased levels of self-criticism and weight-related experiential avoidance. All differences represented medium to very large effect sizes. These findings support the efficacy of the Kg-Free intervention on the targeted health and eating-related main outcomes and psychological processes. This is relevant given the detrimental role of weight self-stigma, weight-related experiential avoidance and self-criticism patterns have on the health and well-being of people living with obesity (e.g., Gilbert et al., 2014; Latner et al., 2013; Lillis et al., 2010). It seems that the intervention helped participants to develop a more accepting relationship with their weight and eating-related internal experiences and to decrease the tendency to be harsh and critic with oneself, particularly when facing mistakes and failures. This might have led to decrease their weight self-stigma and helped participants to engage and maintain healthy behaviors, which in turn, may have an impact on their BMI and cholesterol levels.

Furthermore, at post-treatment, participants from Kg-Free had a significant decrease in BMI, when compared with TAU. Nevertheless, the effect size was small. In fact, participants in Kg-Free lost 1.15kg more than participants allocated to TAU at post-treatment. This result is in line with findings from previous acceptance and mindfulness-based interventions (O'Reilly et al., 2014; Tapper et al., 2009). Although between-groups differences for waist circumference was non-significant, participants from Kg-Free intervention showed a decrease, whereas the TAU group did not. Likewise, there was no difference between groups in total cholesterol, with both

groups showing improvements at post-intervention. Remarkably, total Cholesterol values were at optimal levels (< 200 mg/dl) for both groups at post-treatment. These findings are similar to the ones from Bacon et al. (2002) that compared a diet and non-diet program and found that both improved individuals' metabolic fitness.

Results for self-compassion failed to reach statistical significance, when comparing changes in both groups from baseline to post-treatment. However, within-groups results suggested that participants in Kg-Free did show improved self-compassion skills at post-treatment. In fact, self-compassion was only explicitly promoted in the program last sessions, which gave participants less time to practice. It is possible that the development of self-compassion requires more time and practice. Another explanation may rely on the instrument used to assess self-compassion. It is possible that SCS did not capture (at least completely) what was promoted in the intervention. Nevertheless, at the time no other validated measure of self-compassion was available.

On the other hand, there were no between-group differences regarding mindfulness, which was not expected. At least partially, this result may be due to the difficulty in assessing mindfulness through self-report questionnaires in individuals without meditation experience (Baer et al., 2006). Also, the FFMQ version used had internal consistency problems. Moreover, and although mindfulness was promoted in all session, between sessions the majority of the participants practiced less than three times a week, which may also explain the results found.

Additionally, post-hoc analyses highlighted that changes in our main outcomes (weight self-stigma, emotional and uncontrolled eating and quality-of-life) did not depend on whether participants lost weight at post-treatment or not. This is particularly relevant as weight loss is hard to achieve and maintain. In addition, it supports the importance of delivering an intervention aimed at reducing weight self-stigma and unhealthy eating behaviors and improving people's quality-of-life regardless of the amount of weight lost.

Within-group changes from baseline to post-intervention assessment further supported the results found, with the Kg-Free revealing significant improvement in almost all outcomes (with the exception of waist circumference, cholesterol levels, and mindfulness). The effect sizes were mostly large, with the exception of emotional eating and BMI that presented moderate and small effect sizes, respectively. In contrast, no significant changes occurred in the TAU group.

Despite the encouraging findings, this study encloses some limitations that should be taken into consideration and addressed in future studies. Firstly, the sample comprised only adult women seeking nutritional treatment, which does not allow to generalize the results for men or adolescents' samples. Secondly, the control group remained with TAU, which did not include any psychological intervention. Thus, we can only state that adding Kg-Free to TAU seems to be useful for women struggling with weight and eating issues. Future studies with larger samples are needed to replicate these findings and test the efficacy of Kg-Free in comparison to other

psychological interventions. Thirdly, despite randomization, our groups were not equal at baseline in all outcome variables. Thus, we cannot assure with absolute certainty that the improvements observed in the Kg-Free group derived solely from the intervention. Moreover, given that participants were not blind to their group allocation and that Kg-Free was a group intervention, at least partially, the group support might have played a role on the changes we observed.

Nevertheless, this is still an ongoing research that includes two follow-up assessments. The next step will be to analyze the clinical changes maintenance at 3- and 6-months follow-up and explore the mechanisms responsible for those changes.

Overall, this study provides an important contribution to psychological interventions with people struggling with their weight. It is one of the first studies that integrates different but yet related approaches (based on ACT, mindfulness, and compassion) to tackle weight self-stigma and promote healthy behaviors and quality-of-life in women living with overweight and obesity. It also reinforces the importance of promoting well-being and quality-of-life and not only weight loss. Finally, Kg-Free revealed itself as an effective and feasible intervention in reducing weight self-stigma and increasing health-related indicators in women struggling with their eating and weight.

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Intervention manual: Information regarding the Kg-Free intervention can be found at: <http://www.uc.pt/en/fpce/research/CINEICC/interventionprograms>. The program includes a therapist and a participant manual written in Portuguese. Manuals are available upon request through the first author email. Moreover, to have access to the intervention session-by-session overview in English please contact the first author by email.

Trial register: This trial was registered at clinicaltrials.gov with the Identifier code: NCT02850796 following data collection and analysis.

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