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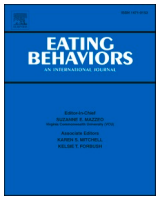

Body weight change during a smoking cessation intervention for individuals with overweight or obesity

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ABSTRACT

Introduction: A more comprehensive understanding of the factors regarding weight control in individuals with overweight or obesity after quitting smoking is needed. The study aimed to analyze the changes of in-treatment variables during a smoking cessation intervention and examine their impact on weight.
Methods: A total of 120 individuals who smoke with overweight or obesity (M_{BMI} = 31.75 ± 4.31; 54.16 % female) participated in a cognitive-behavioral therapy for smoking cessation and weight control or the same treatment plus contingency management. Weight, smoking variables (cotinine and continuous abstinence), eating behaviors (appetite, grazing), exercise, and sleep were assessed weekly throughout the treatment.
Results: More participants gained weight over time with reduced nicotine use or abstinence. There was a tendency during treatment to increase appetite and exercise time, while grazing episodes and sleeping hours remained stable. Higher baseline weight ($p < .001$), greater cotinine reduction ($p = .021$) and time ($p = .009$) were associated with greater weight gain, while more hours of exercise ($p = .003$), no appetite changes ($p = .003$) and diminished appetite ($p < .001$) were associated with less gain over the treatment. Both treatment conditions showed similar results in all in-treatment variables.
Discussion: Individuals with overweight and obesity with higher baseline weight and higher baseline cotinine levels during smoking cessation interventions may require special attention to improve weight outcomes. Exercise and appetite regulation may be useful for mitigating weight gain in smoking cessation interventions for individuals with overweight or obesity.

1. Introduction

Tobacco use and excessive body weight often occur concurrently, leading to significant serious health problems (Chatkin et al., 2015, 2010) which increase morbidity and mortality risks (Freedman et al., 2006; Koster et al., 2008). Although quitting smoking leads to improvements in health (Jha, 2020), post-cessation weight gain may attenuate these benefits (Bush et al., 2016; Choi et al., 2020). Individuals within the healthy weight range gain an average of 7.8 kg in the eight years after quitting, while individuals within the overweight range increase their weight by 10.2 kg, and people with obesity gain 19.5 kg (Lycett et al., 2011). Weight concerns are highly prevalent among individuals with overweight and obesity and, therefore, post-cessation weight gain is an extended barrier for smoking cessation in this population (Beebe & Bush, 2015; Levine et al., 2013).

Cognitive-behavioral therapy (CBT) and contingency management (CM) for smoking cessation have proved effective with the combination of CBT and CM obtaining superior smoking outcomes than CBT alone (Fonseca Pedrero et al., 2021; González-Roz & Secades-Villa, 2022; Notley et al., 2019). Several studies targeting smoking cessation among individuals with overweight and obesity have also included weight management during the treatment (García-Fernández et al., 2022; Hurt et al., 2017; Krotter et al., 2024; Love et al., 2011; Svendsen et al., 2021; White et al., 2019; Wilcox et al., 2010). Particularly, the present study is a secondary and exploratory analysis of a recent randomized controlled trial for both quitting smoking and weight control that found that addressing smoking cessation and weight control simultaneously was effective for quitting smoking among individuals with overweight or obesity but smoking abstinence rates declined over time and participants who attained abstinence showed a slight weight gain at EOT and a

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greater weight gain over time (Krotter et al., 2024). However, studies typically report smoking cessation outcomes and weight gain outcomes at post-treatment and follow-ups, but do not report other key clinical smoking and weight markers collected throughout treatment (i.e., in-treatment variables). Indeed, none of these studies targeting smoking cessation and weight management reported weekly changes in smoking, weight, or health-related variables while participants were still receiving the intervention. In-treatment behaviors are clinically relevant due to their association with successful treatment outcomes. For example, in-treatment smoking-related variables, such as the number of tobacco abstinence days and weekly decrease in cotinine levels, are predictors for smoking cessation in CBT and CM based-treatments among the general population and specific populations such as individuals with substance use disorders (Aonso-Diego et al., 2021; López-Núñez et al., 2016). Despite post-cessation weight gain being associated with smoking relapse (Krotter et al., 2023; Salk et al., 2019), the impact of changes in smoking or other in-treatment behaviors (such as eating or exercising) on weight has not yet been studied. This area of research could enhance weight management methods within the context of quitting smoking, which is relevant considering the limited evidence found in previous meta-analysis of interventions aimed at controlling post-cessation weight gain (García-Fernández et al., 2023; Hartmann-Boyce et al., 2021).

There is a considerable amount of scientific literature on the mechanisms underlying weight gain upon smoking cessation, but these mechanisms are still not fully understood and there is evidence for numerous contributing factors (Chao et al., 2019). Evidence points out that the suppression of nicotine's metabolic effects (Audrain-Mcgovern & Benowitz, 2011) and behavioral changes (e.g., eating behaviors, exercise, or sleep) could account for this weight gain. Regarding eating behaviors, literature notes that caloric intake, snacking and appetite increase after smoking cessation (Bacha et al., 2016; Kadota et al., 2010; Kos et al., 1997; Yannakoulia et al., 2018), and that the increase in the caloric intake is greater among women with higher body mass index (BMI $\geq$ 27) (Saules et al., 2004). However, one study found that the reinforcer nature of food increases when individuals are abstinent (Lerman et al., 2004) while another study concluded it remained stable (Betts & Tiffany, 2019). Therefore, additional research is required on changes in eating behaviors during smoking cessation treatments, particularly among individuals with overweight and obesity, who frequently present with disordered eating behaviors (Nightingale & Cassin, 2019).

Additionally, prior research has found that individuals who smoke and individuals with overweight and obesity tend to exercise less than individuals who do not smoke and individuals with a healthy weight (Cassidy et al., 2017; Laredo-Aguilera et al., 2019). Individuals with a sedentary lifestyle, prior to quitting smoking, are at greater risk of post-cessation weight gain (see e.g., Kmetova et al., 2014). A previous meta-analysis on interventions for preventing weight gain after smoking cessation (Hartmann-Boyce et al., 2021) concluded that exercise interventions did not significantly impact on weight at the end of treatment (EOT) but weight was reduced at 12 months. Moreover, smoking cessation is associated with a mean increase of 4–5 kg after 12 months of abstinence, and most weight gain occurs within the first three months after quitting (Aubin et al., 2012). In this line, further research is needed to analyze the impact of exercise on weight gain during smoking cessation treatments, particularly among individuals with overweight and obesity.

Lastly, excessive body weight is a risk factor for sleep-related problems (e.g., poor sleep duration; Cassidy et al., 2017; Patel et al., 2008), and in turn, sleep deprivation is associated with appetite increase (Taheri et al., 2004) and weight gain (Rodrigues et al., 2021; Wu et al., 2014). Additionally, nicotine stimulation can lead to sleep disturbances (Costa & Esteves, 2018) and smoking cessation is often followed by a deterioration of sleep patterns (Htoo et al., 2004; Jaehne et al., 2014) that is associated to a higher likelihood of smoking relapse (Patterson et al., 2019). However, to our knowledge, no studies have examined sleep changes along a smoking cessation treatment and its effects on weight changes.

Given this background, this study included a sample of individuals with overweight and obesity receiving a smoking cessation intervention with a component of weight gain prevention, and aimed to analyze: (1) changes in body weight during the intervention; (2) changes in smoking behavior (i.e., adherence to nicotine reduction treatment guidelines, participants' quit day, evolution of urine cotinine levels, and days of continuous abstinence); (3) other health-related variables changes, specifically eating behaviors (i.e., appetite and grazing episodes), exercise and sleep, (4) the impact of these changes on weight over the course of treatment, and (5) whether CM changes the variables under investigation.

2. Material and methods

2.1. Study design and participants

This is a secondary and exploratory analysis from a randomized controlled trial (RCT) (Clinical trial ID: NCT04332029) in which individuals who smoke with overweight or obesity were assigned to a CBT for smoking cessation and weight gain prevention (CBT; $n = 60$), or the same treatment alongside CM for smoking cessation (CBT + CM; $n = 60$). The main goal of this RCT is to assess smoking abstinence rates and weight change in each treatment condition at EOT, and at 1-, 3-, 6- and 12-month follow-ups in order to analyze the efficacy of the interventions and the contribution of CM to CBT (see Krotter et al., 2024). In the present study, we examined the evolution and impact of in-treatment changes on weight gain throughout the treatment, while participants were receiving the intervention. This secondary study is crucial because there are few studies that monitor weekly in-treatment participants' behaviors during smoking cessation treatments and it is important to identify in-treatment predictors of post-cessation weight gain among individuals with overweight or obesity. Participants' randomization was performed by means of a computer-generated list of random numbers which allocated individuals to interventions on a 1:1 ratio. The study was conducted at the Clinical Unit of Addictive Behaviors of the University of Oviedo (Spain). The protocol was approved by the local Ethical Committee of Research of the Principality of Asturias (n° 329/19).

Participants were recruited from the community by local advertisements from September 2020 to October 2021, and all of them provided informed consent. Inclusion criteria were being $\geq$18 years of age, presenting with overweight or obesity (BMI $\geq$ 25), having smoked $\geq$10 cigarettes per day over the past year, and meeting the diagnostic criteria for tobacco use disorder (American Psychiatric Association, 2013). Individuals were excluded for being pregnant, breastfeeding or in the six-month postpartum period; having received a treatment for smoking cessation or for weight control (either behavioral or pharmacological) in the last 30 days; having been diagnosed during the last year with a severe mental disorder (e.g., psychotic disorder), eating disorder (except binge eating disorder) or substance use disorder (other than tobacco use disorder); presenting any health condition which affects feeding or requires a specialized diet (e.g., uncontrolled diabetes); or taking medication that affects weight. Those unable to attend all sessions were also excluded. Fig. 1 displays the participants' flowchart, and participants' baseline characteristics are shown in Table 1. No significant differences were found between individuals assigned to CBT compared to those assigned to the CBT + CM condition, with the exception of individuals from CBT group being older than participants in the CBT + CM group ($p = .009$).

2.2. Interventions

All participants enrolled received eight therapy session (each session

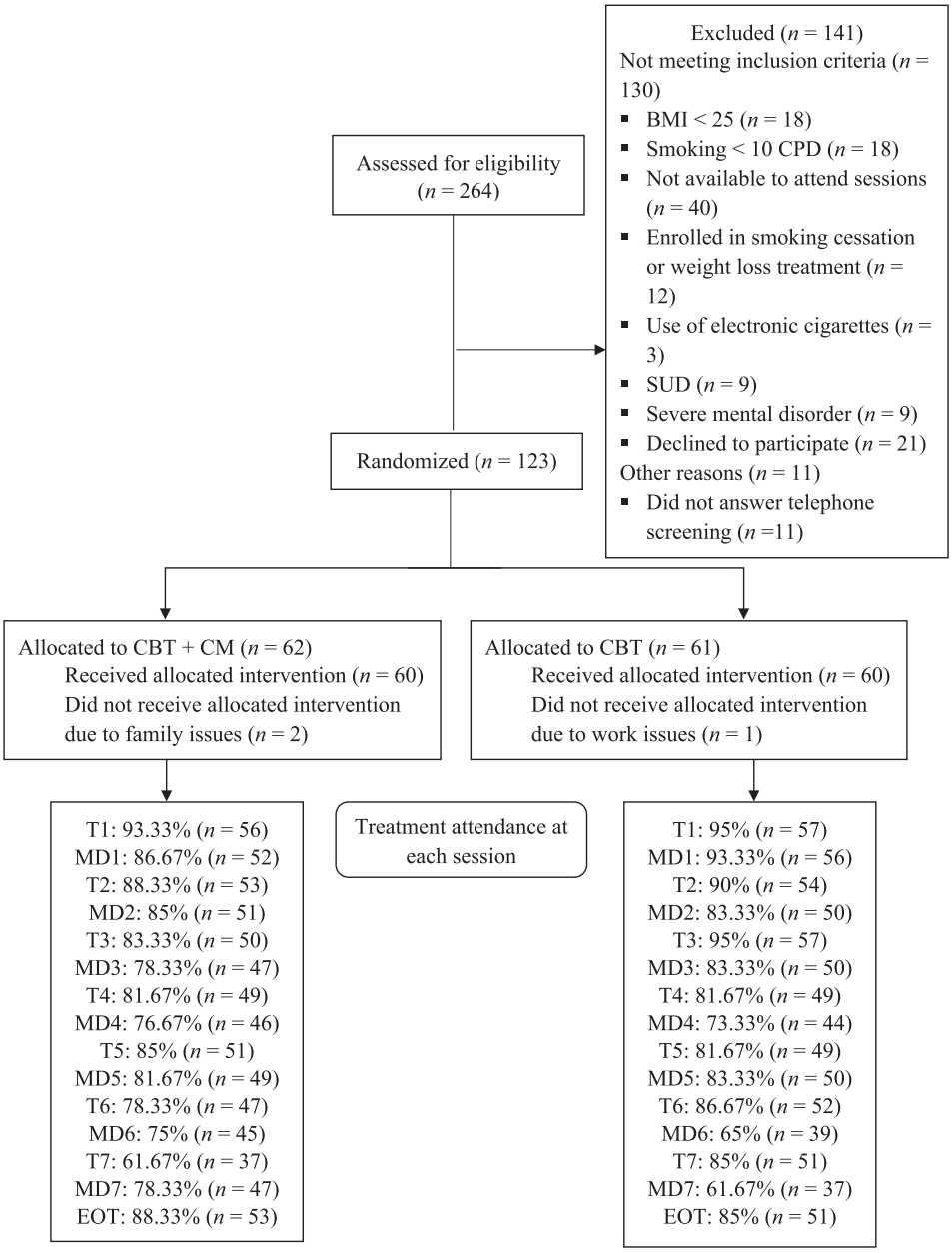

Fig. 1. CONSORT flow diagram. *Note.* BMI = body mass index; CPD = cigarettes per day; SUD = substance use disorder; CBT = cognitive-behavioral therapy; CM = contingency management; T = therapy session; MD = mid-week session; EOT = end-of-treatment.

120 min in length) of group-based CBT (≤4 participants) for smoking cessation and weight control over eight weeks, and seven additional mid-week sessions (each mid-week session was 60 min long). All sessions were carried out face-to-face by masters- and doctoral-level psychologists, trained in the specific treatment protocols, with prior experience in smoking cessation interventions. For a detailed description of the intervention protocols, please see García-Fernández et al. (2022).

A nicotine fading procedure was implemented for achieving smoking cessation through the reduction of the number of daily cigarettes and the change to tobacco brands with lower nicotine. Specifically, participants reduced their nicotine intake by 20 % weekly from the first week to 48 h prior to the session scheduled on the sixth week (i.e., the programmed quit day). At each session, participants received biochemical feedback about tobacco consumption through carbon monoxide (CO) in exhaled air and urine cotinine analysis. Cognitive-behavioral techniques such as stimulus control, problem-solving skills, or relapse prevention were used. The intervention for weight control entailed weekly individually weight monitoring (i.e., private in-person weigh-in during group mid-week sessions supervised by the therapist as part of the intervention) and guidelines to improve exercise, sleep hygiene, psychoeducation regarding the Mediterranean diet, recording meals, and decreasing disordered eating (e.g., emotional eating). Some components were transdiagnostic, for both smoking cessation and weight control (e.g., emotional regulation skills).

Participants allocated to CBT + CM received vouchers when their abstinence status was biochemically confirmed. The maximum value of incentives was 320 points, where one point equated one euro (a total of US$ 341.06). Vouchers were initially issued on achieving 50 points (US$ 53.29) in the sixth therapy session (first abstinence session following the protocol) and increased by 5 points (US$ 5.33) at each consecutive session when the participant maintained smoking abstinence, up to a value of 70 points (US$ 74.60) at the EOT (i.e., the eighth therapy session). When participants achieved two consecutive negative samples,

Table 1
Baseline participants' characteristics.

	Overall ($N = 120$)	CBT + CM ($n = 60$)	CBT ($n = 60$)	p
Sex (female, *n*/%)	65 (54.16)	33 (55)	32 (53.33)	1
Age (years)[a]	52.54 (10.34)	50.65 (8.24)	54.43 (11.85)	0.009
Marital status (married, *n*/%)	67 (55.8)	34 (56.7)	33 (55)	1
Employed (*n*/%)	62 (51.67)	32 (53.33)	30 (50)	0.855
CPD[a]	21.34 (8.79)	22.75 (9.94)	19.93 (7.27)	0.133
Age of smoking onset[a]	15.15 (4.17)	15.15 (3.56)	15.15 (4.75)	0.580
Years of regular smoking[a]	30.85 (10.66)	29.29 (8.64)	32.41 (12.23)	0.113
Previous quit attempts[a]	2.56 (2.12)	2.65 (2.35)	2.47 (1.87)	0.805
FTCD[a]	5.43 (2.06)	5.53 (2.3)	5.32 (1.8)	0.420
CO (ppm)[a]	22.96 (11.27)	23.93 (11.07)	21.98 (11.47)	0.295
Cotinine (ng/ml)[a]	2318.25 (1215.54)	2461.75 (1242.91)	2174.76 (1180.43)	0.156
Weight gained in previous quit attempts[a]	4.58 (6.63)	3.90 (7.90)	5.25 (6.14)	0.092
Weight (kg)[a]	88.08 (14.01)	88.25 (14.19)	87.91 (13.94)	0.894
BMI[a]	31.75 (4.31)	31.71 (4)	31.78 (4.63)	0.709
BMI category (*n*/%)				0.708
Overweight	47 (39.16)	22 (36.67)	25 (41.67)	
Obesity	73 (60.83)	38 (63.33)	35 (58.33)	
Age of excess weight onset[a]	34.73 (14.36)	34.07 (13.04)	35.41 (15.68)	0.796
Years of BMI $\geq$ 25[a]	20.9 (15.52)	22.11 (19.63)	19.81 (10.96)	0.875
Previous diet attempts[a]	7.71 (17.37)	7.19 (15.71)	8.22 (18.98)	0.850
Concerned about post-cessation weight gain (*n*/%)	82 (68.33)	42 (70)	40 (66.67)	0.844
Hours of exercise per week[a]	2.46 (3.25)	2.59 (3.20)	2.34 (3.34)	0.604
Grazing episodes per day[a]	3.95 (7.48)	4.32 (7.92)	3.58 (7.06)	0.646
Hours of sleep per day[a]	7.02 (1.08)	6.95 (1.03)	7.10 (1.13)	0.713

Note. CBT = cognitive-behavioral therapy; CM = contingency management; CPD = cigarettes per day; FTCD = Fagerström Test for Cigarette Dependence; CO (ppm) = carbon monoxide in parts per million; ng/ml = nanograms per milliliter; BMI = body mass index.
[a] Mean (standard deviation).

regardless of whether negative samples were obtained during therapy sessions or mid-week sessions, they received a bonus of 10 points (US$ 10.66). A positive test or missed specimens reset the voucher value back to the initial 50 points, although the value was restored to the one given before the reset if the participant then produced two consecutive negative tests. No incentives were provided to participants allocated to the CBT group.

2.3. Assessment

Participants completed a questionnaire prior to initiating the treatment, in which they provided sociodemographic data (i.e., sex, age, marital status, and employment status), smoking-related characteristics (i.e., number of cigarettes smoked per day, age of smoking onset, years of regular smoking, and previous quit attempts), and weight-related characteristics (i.e., mean of kg gained in previous quit attempts, age of excess weight onset, years of having BMI $\geq$ 25, number of previous diet attempts, and concern about post-cessation weight gain). The Fagerström Test for Cigarette Dependence (FTCD; Becoña & Vázquez, 1998) was used to assess nicotine dependence at baseline, which was categorized into five levels based on total score: very low (0–2), low (3–4), medium (5), high (6–7) and very high ($\geq$8).

Body weight was measured at baseline, at mid-week sessions, and at EOT using a calibrated medical scale (CL.III 200 kg. SECA Mod. 877). Participants' height was assessed with a medical stadiometer (SECA Mod.213, 20–205 cm) for BMI calculation; in such a way, participants were categorized as individuals within the overweight range (BMI ranged from 25 to 29.99) or obesity range (BMI $\geq$ 30).

Tobacco consumption was biochemically assessed through CO (measured using a piCO Smokerlyzer: Bedfont Scientific Ltd, Rochester, UK), and urine cotinine (analyzed by the BS-120 chemistry analyzer: Shenzhen Mindray Bio-Medical Electronics Co. Ltd., Shenzhen, P. R., China) both at baseline, at mid-week sessions, and at EOT.

During mid-week sessions, the assessment of other health-related variables was conducted. Participants self-reported changes on appetite (i.e., 'during the past week, have you felt changes on your appetite compared to the previous week?': 'my appetite is equal to the previous week', 'I felt less appetite than the previous week', or 'I felt greater appetite than the previous week'), number of grazing episodes (i.e., 'how many times per day during the past week have you grazed between meals, that is to say, repeatedly ate small quantities of food outside the five meals recommended by the treatment?'), hours of exercise undertaken ('how many hours have you exercised during the past week?'), and hours of sleep ('how many hours per day have you slept on average during the past week?').

2.4. Measures and outcomes

Weekly weight change was analyzed at every mid-week session and at the EOT, considering the percentage of participants who met weight gain criteria, defined as an increase of $\geq$3 % baseline body weight (Stevens et al., 2006).

In-treatment smoking-related variables were analyzed according to four measures, specifically: 1) Treatment adherence to nicotine fading (i.e., percentage of sessions in which patients met cotinine criteria according to the 20 % weekly reduction); 2) participants' quit day (i.e., following the program schedule of 48 h before the sixth session, earlier, later, or never quitting); 3) cotinine level changes, and 4) number of days of continuous abstinence (i.e., number of days without smoking not even a puff, biochemically confirmed by CO $\leq$ 4 parts per million [ppm] and urine cotinine $\leq$80 nanograms per milliliter [ng/ml]) (Benowitz et al., 2020; Karelitz et al., 2021) at each mid-week session and EOT. Priority for biochemical verification was given when self-reported abstinence and biochemical verification (i.e., carbon monoxide and urine cotinine) were inconsistent to ensure the validity of the data (Benowitz et al., 2020; Scheuermann et al., 2017).

In-treatment changes in other health-related variables, particularly eating behavior (appetite, grazing episodes), exercise and sleep, were examined at each mid-week session. Measures and data collection procedures were identical in both groups.

2.5. Data analyses

Univariate descriptive statistics (i.e., means and frequencies) were used to characterize the study sample (i.e., sociodemographic, smoking-, and weight-related characteristics). Data distribution was analyzed to determine the adequacy of parametric or non-parametric tests. Differences between groups were analyzed using *t*-tests or Mann-Whitney *U* tests for continuous variables (e.g., adherence to nicotine reduction guidelines), and chi-square for categorical ones (e.g., time point in which participants quitted smoking). Effect sizes were calculated, as appropriate, by Cohens' d (Cohen, 1988), $r = Z/\sqrt{n}$ (Rosenthal, 1994), phi coefficient (Fleiss, 1994), and Cramer's V (Cramér, 1946).

Due to missing data of weight registration during the treatment (see Fig. 1 to find the missing data for each session), a multiple imputation procedure was performed to replace missing weight data and elaborate an interpretable weight change graph (i.e., the weight change graph without multiple imputation was imprecise and unstable because of missing data from participants whose weight was not within the sample mean). A total of five imputed datasets were created, which has been

evidenced to be sufficient according to statistical theoretical grounds (Allison, 2000). Following prior recommendations (Elobeid et al., 2009; Sterne et al., 2009), the selection of imputation variables were age, sex, baseline weight, baseline BMI and treatment group. Multiple imputation data was used solely to elaborate the graph, using pooled results of weight at each session across the five datasets.

A mixed between-within subjects analysis of variance (ANOVA) was conducted to analyze changes in cotinine levels, days of continuous abstinence, grazing episodes, hours of exercise, hours of sleep during treatment and by group. Between-subjects variable was the treatment group. Only data from individuals who attended all mid-week control sessions ($n = 55$) was analyzed in the ANOVA. Missing data was not imputed because there were no statistically significant differences between those who attended all mid-week sessions ($n = 55$) and those who did not ($n = 65$) in terms of sex, age, treatment condition, baseline BMI, baseline cotinine levels, and baseline FTCD scores (all $p \geq .064$). If sphericity was violated, the Greenhouse-Geisser correction method was applied to avoid bias. Simple contrasts were used to compare the measure at each session with the first mid-week control session as reference category. Effect size was calculated through a partial eta square (Tabachnick & Fidell, 2014).

Finally, mixed-effects model repeated measures (MMRM) analysis with restricted maximum likelihood was performed to explore whether body weight changes over time were due to group treatment, sex, baseline weight, and BMI category (overweight or obesity), and behavioral changes during treatment (i.e., cotinine levels, days of continuous abstinence, appetite changes, number of grazing episodes, and hours of exercise and sleep). This analysis included an unstructured modeling of frequencies at each visit and within-subject error correlation structure. Cotinine, days of continuous abstinence, appetite changes, grazing episodes, exercise, and sleep were treated as time-varying covariates, while baseline weight was treated as a time-invariant variable. MMRM controls for missing data by utilizing all available data to estimate parameters via restricted maximum likelihood (see e.g., Detry & Ma, 2016; Pugh et al., 2022) but MMRM requires that each participant has attended at least two mid-week sessions to estimate the parameters. Six participants among the total sample did not attend at least two mid-week sessions. Only data from individuals who attended at least two mid-week sessions ($n = 114$) were included in the MMRM models and missing data was not imputed. The model A examined the main effects of the mentioned variables. The model B examined the main effects and the interaction between the cotinine variable and sex, grazing episodes, exercise, and sleep. Finally, the model C analyzed the same variables as model B and included the interaction of sex and changes in appetite, exercise, and grazing episodes. The MMRM method is adequate to estimate models despite missing data in longitudinal studies (Vallejo et al., 2011) and particularly in studies with weight outcomes (Elobeid et al., 2009).

The statistical package used was the SPSS (version 24, Inc., Chicago, IL), and the analytic plan was pre-specified and discussed prior to analysis. All data analysis included participants regardless of their nicotine reduction or abstinence status.

3. Results

3.1. Weight changes

Weight change during treatment is displayed in Fig. 2. During the first three weeks, no participants met criteria for weight gain (i.e., ≥3 % of baseline weight). Weight increased from the fourth week to EOT. Specifically, two attendants gained weight at fourth and fifth week (2.22 % and 2.02 %, respectively), six at sixth week (7.14 % of attendants), 11 at seventh (13 % of attendants), and 18 individuals at EOT (17.30 % of attendants). There were no differences between the CBT + CM group and the CBT group in the percentage of individuals who gained weight at any time point (all p-values ≥ .381).

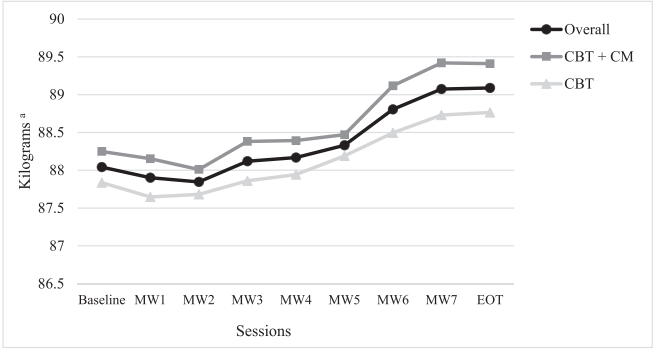

Fig. 2. Weight change throughout the treatment overall and by group. *Note.* CBT = cognitive-behavioral therapy; CM = contingency management; MW = mid-week session; EOT = end of treatment. [a] Multiple imputation of missing data was performed.

3.2. Smoking changes

Adherence to nicotine fading guidelines (i.e., percentage of samples meeting the 20 % nicotine reduction per week) was 59.82 % (SD = 31.97) (see Fig. 3). Regarding the quit day, almost half of the sample (n = 52, 43.33 %) achieved 48-hour smoking abstinence prior to the sixth session (i.e., the programmed quit day). A total of 39 individuals (32.50 %) achieved abstinence before the programmed quit day, seven (5.83 %) after the programed quit day, and 22 participants did not quit smoking (18.33 %, of which 14 were dropouts). Cotinine levels decreased ($F_{3.050,\ 146.419} = 64.332$; $p < .001$; $\eta_p^2 = 0.573$) every week compared to the first week (all p-values ≤ .001). Number of days of continuous abstinence increased during the intervention ($F_{1.360,\ 159.065} = 172.541$; $p > .001$; $\eta_p^2 = 0.596$) and there were significant differences in the number of days of continuous abstinence at each session compared to the first session (all p-values ≤ .001).

No differences between the CBT + CM group and the CBT group were found in any smoking-related variables: nicotine fading adherence (U = 1436; p = .055), quit day (χ^2 (3) = 4.167; p = .244), cotinine levels ($F_{3.050,\ 146.419} = 1.294$; p = .279), and number of days of continuous abstinence ($F_{1.360,\ 159.065} = 2.575$; p = .099).

3.3. Other health-related changes (eating, exercise, and sleep)

The percentage of individuals who reported increased appetite among those who attended the sessions changed from 9.26 % during the first week to 34.52 % in the seventh week. The number of grazing episodes remained stable during treatment ($F_{2.957,\ 130.095} = 2.057$, p = .110). No differences between the CBT + CM group and the CBT group

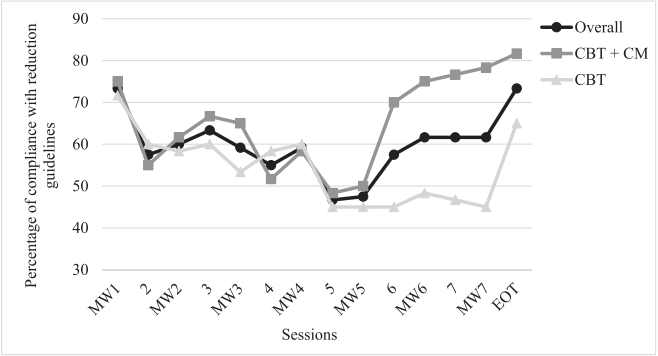

Fig. 3. Adherence to the nicotine fading guidelines throughout the treatment overall and by group. *Note.* CBT = cognitive-behavioral therapy; CM = contingency management; MW = mid-week session; EOT = end of treatment.

on appetite changes (all p-values $\geq$ .19) and grazing episodes ($F_{2.957,\ 130.095} = 0.658$, $p = .577$) were found.

Exercise performance increased during treatment ($F_{3.374,\ 151.847} = 3.873$, $p = .008$) without differences between treatment groups ($F_{3.374,\ 151.847} = 1.803$, $p = .142$). Specifically, compared to the first week, there was a significant increase in the fourth ($p = .006$), fifth ($p = .007$) and sixth mid-week sessions ($p = .007$).

Finally, hours of sleep remained stable during treatment ($F_{3.781,\ 177.705} = 0.473$, $p = .745$) and there were no significant differences between groups ($F_{3.781,\ 177.705} = 3.781$, $p = .193$).

3.4. Effect of in-treatment changes on body weight evolution

Table 2 depicts a detailed description of in-treatment variables introduced in the MMRM. Model A provides a better fit than Models B and C (see Table 3). Participants with higher baseline body weight (Model A: $\beta_2 = 0.9925$; $p < .001$) and greater reduction in cotinine levels (Model A: $\beta_2 = -0.0001$; $p = .021$) gained more weight during the treatment. Reporting no appetite changes (Model A: $\beta_2 = -0.2210$, $p = .003$), having less appetite (Model A: $\beta_2 = -0.7193$; $p < .001$), and exercising for more hours (Model A: $\beta_2 = -0.0339$; $p = .003$) were associated with less weight gain during the treatment. Time variable was significant as well (Model A: $p = .009$), indicating that time passing was associated with weight gain. The MMRM revealed that treatment group, sex, baseline BMI category (i.e., overweight vs. obesity), days of continuous abstinence, average of grazing episodes per week, and mean hours of sleep were not significantly related to weight change over treatment (all p-values $> .088$).

4. Discussion

This is the first study evaluating in-treatment changes in smoking, eating, exercise, and sleep through a smoking cessation treatment for individuals with overweight or obesity, as well as examining the effects of these in-treatment behaviors on weight change. The following main findings are highlighted: 1) The percentage of individuals with weight gain increased gradually from the fourth week; 2) the adherence to smoking cessation treatment was high and most participants progressively achieved smoking cessation; 3) there was a tendency to increase appetite and exercise time, while grazing episodes and sleeping hours remained stable; and 4) higher baseline weight, greater cotinine reduction during the intervention, and time, were related to a greater weight gain, whereas stable or reduced appetite feelings and more hours of exercise during treatment were associated to a lower weight gain.

It is worth mentioning that no participant met the criteria for weight gain during the first three weeks, and the percentage of individuals who gained weight (i.e., $\geq$3 % baseline weight) increased progressively from 2.22 % in the fourth week to 17.30 % at the EOT. According to the treatment protocol, which included a nicotine fading procedure, participants had reduced their cigarette consumption by at least 80 % by the fourth week. Thus, weight increase is evidenced when participants drastically reduced their tobacco use. This trend of progressive weight gain is in line with previous studies for smoking cessation and weight control among sedentary individuals (Prod'hom et al., 2013) and post-menopausal women (Oncken et al., 2020).

The adherence to nicotine reduction guidelines was high, and most of the participants attained abstinence on the scheduled quit day. Nicotine reduction was lower compared to previous studies with similar nicotine fading procedures among individuals from the general population (López-Núñez et al., 2016) and higher than among individuals with substance use disorders (Aonso-Diego et al., 2021). The only study that used a nicotine fading procedure among population with overweight and obesity did not report in-treatment tobacco changes (Love et al., 2011).

Given that treatment included a gradual reduction of tobacco use, not an abrupt quit procedure, we have analyzed the effect on weight change of both smoking abstinence and nicotine intake reduction. It was found that greater cotinine reduction, but not the number of days of continuous abstinence, led to higher weight gain. It is noteworthy that the increase in weight occurs before achieving smoking abstinence, while the participants were reducing their nicotine intake. Notably, individuals with higher nicotine dependence have greater levels of cotinine (Jung et al., 2012; Van Overmeire et al., 2016), and greater post-cessation weight gain (Killi et al., 2020; Kmetova et al., 2014; Komiyama et al., 2013). Considering that nicotine intake raises energy expenditure (Audrain-Mcgovern & Benowitz, 2011; Stojakovic et al., 2017), individuals with higher cotinine levels may be more affected by the removal of nicotine's metabolic effects and, therefore, may demonstrate greater weight gain (Audrain-Mcgovern & Benowitz, 2011; Stamford et al., 1986).

Regarding eating behaviors, to our knowledge, this is the first study analyzing weekly changes on grazing episodes and appetite over a smoking cessation treatment. Grazing episodes remained stable during treatment, in line with a prior study that did not find changes in caloric intake after a smoking cessation intervention with post-cessation weight gain prevention (Audrain-McGovern et al., 2023), and they were not related to weight change. On the other hand, even though most participants informed of no changes in appetite, the number of participants reporting higher appetite increased gradually over treatment, and stable or reduced appetite feelings were associated with less weight gain. This increase of appetite is highly reported among individuals that achieve tobacco abstinence, given that nicotine use reduces appetite (Audrain-Mcgovern & Benowitz, 2011; Schwartz & Bellissimo, 2021; Stojakovic et al., 2017) and a common symptom of nicotine withdrawal is increased appetite (Pankova et al., 2018; Pomerleau et al., 2001).

In terms of exercise, participants increased the number of hours they exercised per week during the treatment, and more time exercising was associated with less weight gain. Available literature indicates that exercise increases caloric expenditure and reduces food craving during smoking cessation (Oh & Taylor, 2014; Taylor & Oliver, 2009). Our

Table 2
Variables included in the mixed-effects model repeated measures by total sample.

Variables	MW 1 ($n = 108$)	MW 2 ($n = 101$)	MW 3 ($n = 98$)	MW 4 ($n = 90$)	MW 5 ($n = 99$)	MW 6 ($n = 84$)	MW 7 ($n = 84$)
Weight (kg)[a]	88.13 (14.14)	88.34 (14.27)	87.92 (13.47)	87.36 (13.80)	87.58 (12.80)	88.82 (13.21)	88.37 (12.64)
Cotinine[a]	1547.50 (830.92)	1101.82 (708.17)	788.69 (673.31)	492.28 (463.82)	473.97 (580.73)	143.10 (449.24)	135.82 (518.28)
Continuous abstinence[a]	0.02 (0.19)	0.13 (0.94)	0.49 (2.15)	0.99 (3.61)	1.97 (4.43)	6.51 (5.85)	11.71 (7.72)
Grazing episodes per day[a]	2.71 (5.35)	2.77 (5.80)	3.29 (7. 09)	3.86 (7.59)	2.90 (6.18)	3.78 (7.41)	3.58 (7.77)
Appetite (n/%)							
Stable	95 (87.96)	76 (75.25)	62 (63.27)	61 (67.78)	62 (62.63)	52 (61.90)	49 (58.33)
Greater	10 (9.26)	21 (20.79)	29 (29.59)	26 (28.89)	32 (32.32)	28 (33.33)	29 (34.52)
Less	3 (2.78)	4 (3.96)	7 (7.14)	3 (3.33)	5 (5.05)	4 (4.76)	6 (1.19)
Hours of exercise per week[a]	2.39 (4.06)	2.38 (3.33)	2.57 (3.10)	3.50 (3.70)	3.18 (3.71)	3.50 (3.85)	3.36 (3.88)
Hours of sleep per day[a]	7.07 (1.50)	7.02 (1.39)	7.17 (1.14)	7 (1.50)	7.13 (1.59)	7.13 (1.30)	7.15 (1.20)

Note. MW = mid-week session; kg = kilograms.
[a] Mean (standard deviation).

Table 3
Results of fitting taxonomy of Mixed-effects Model Repeated Measures to weight change ($n = 114$).

	Model A[a]				Model B				Model C			
	df_N	df_D	F	Pr > F	df_N	df_D	F	Pr > F	df_N	df_D	F	Pr > F
Baseline kg (β_1)	1	102.120	22,317.755	<0.001	1	97.579	21,844.891	<0.001	1	97.508	22,082.652	<0.001
Time (β_2)	6	93.371	3.052	0.009	6	94.080	3.116	0.008	6	92.193	3.057	0.009
Time × sex (β_3)									6	85.624	0.984	0.441
Group (β_4)	1	105.239	0.035	0.852	1	103.126	0.002	0.968	1	102.951	0.013	0.910
Sex (β_5)	1	107.205	0.013	0.908	1	173.844	0.000	0.993	1	206.222	0.004	0.947
Sex × cotinine (β_6)					1	267.393	0.084	0.772	1	278.877	0.342	0.559
Sex × appetite change(β_7)									2	330.828	3.063	0.048
Sex × exercise (β_8)									1	309.236	2.305	0.130
Sex × grazing (β_9)									1	263.157	0.517	0.473
Baseline BMI category (β_{10})	1	103.972	0.338	0.562	1	100.059	0.335	0.564	1	101.070	0.121	0.729
Cotinine (β_{11})	1	278.216	5.425	0.021	1	238.688	5.851	0.016	1	238.295	7.670	0.006
Continuous abstinence (β_{12})	1	195.610	2.932	0.088	1	198.594	3.690	0.056	1	199.667	2.965	0.087
Grazing (β_{13})	1	291.299	0.347	0.556	1	316.260	0.582	0.446	1	307.917	0.710	0.400
Grazing × cotinine (β_{14})					1	295.388	0.268	0.605	1	283.924	0.138	0.711
Appetite change (β_{15})	2	339.876	14.452	<0.001	2	338.040	13.918	<0.001	2	330.445	14.113	0.000
Exercise (β_{16})	1	344.972	8.716	0.003	1	379.276	7.852	0.005	1	372.674	6.952	0.009
Exercise × cotinine (β_{17})					1	268.526	0.914	0.340	1	260.890	0.966	0.327
Sleep (β_{18})	1	309.660	2.525	0.113	1	340.865	5.519	0.019	1	343.493	6.692	0.010
Sleep × cotinine (β_{19})					1	226.995	3.270	0.072	1	221.923	4.430	0.036
Goodness-on-fit (AIC/BIC/parameters)	1401.5/1521.8/46				1475.9/1596/50				1487.4/1607/60			

Note. df_N = numerator degrees of freedom; df_D = denominator degrees of freedom; AIC = Akaike information criterion; BIC = Bayesian information criterion.
[a] Information criteria allow us to conclude that model A provides a better fit than models B and C.

intervention consisted of exercise counseling with an incremental planning of moderately intense exercise to reach an activity time of 2 h 30 min per week, without supervised exercise, and monitoring the amount of time spent exercising, but without monitoring the intensity. Finally, participants' sleep time did not change during treatment, and was not significantly related to weight increase, as previous research has found (Kmetova et al., 2014).

It should be noted that participants with higher baseline weight showed greater weight gain, in line with some previous studies (Froom et al., 1999; Lycett et al., 2011; Swan et al., 1997) and in contrast to others (Bush et al., 2014; Pankova et al., 2018). Higher body weight is linked with unhealthy lifestyle habits, such as sedentarism (Agrawal et al., 2013; Mortensen et al., 2006) and poor eating habits (Heriseanu et al., 2017; Kolay et al., 2021). Thus, the implementation of general weight control strategies in our intervention (e.g., psychoeducation on the Mediterranean diet, strategies to improve eating behaviors and prevent problematic eating, exercise counseling) may not have been effective enough to achieve weight maintenance among those with higher baseline weight. According to the results, when conducting treatments on smoking cessation with individuals with overweight or obesity, it is crucial to identify those with a higher baseline weight before starting the intervention. Additionally, it is important to evaluate the effectiveness of personalized weight management strategies (e.g., individualized dietary guidelines or supervised exercise) for preventing weight gain, especially in those with higher baseline body weight.

Time was also significantly related to weight gain during the analyzed period comprising seven weeks. This could suggest that weight gain is related to other variables that were not included in the MMRM, such as types of food that are being eaten, food portions, or sleep quality. Finally, it should be mentioned that sex and baseline BMI were not associated with weight change. Male sex was related to weight gain in one study (Prod'hom et al., 2013), but female sex was in another (Kmetova et al., 2014). Although these studies included long-term analysis (one-year follow-up), more research within this field is required to elucidate the impact of sex on post-cessation weight gain. Regarding BMI, a prior study evidenced that participants in the overweight range (i.e., BMI between 25 and 29.99) gained less weight than those in the obesity range (BMI $\geq$ 30) at the eight-year follow-up (Lycett et al., 2011). Differences could be due to the period analyzed (during eight weeks of intervention in our study vs. 8-year follow-up in the aforementioned study).

Finally, it appears that the CM condition did not impact smoking during the intervention period and both treatment conditions showed similar results in all in-treatment variables. This is not surprising for weight, eating behaviors, exercise, and sleep variables, because CM consisted of providing vouchers to reinforce smoking abstinence, but it is surprising for smoking variables. The lack of advantage of CM for smoking cessation is not in line with previous studies that have found that CM procedures improved in-treatment behaviors (i.e., abstinence during treatment, and weekly reduction in nicotine levels) (Aonso-Diego et al., 2021; López-Núñez et al., 2016). Considering that recruitment for the study started in September 2020, the new context and lifestyle due to the COVID-19 pandemic could have affected in-treatment outcomes and CM efficacy (e.g., not being able to use the reinforcing vouchers because of national restrictions and health rules). Future research is needed to analyze how the pandemic impacted smoking cessation, weight, and health-related in-treatment outcomes (Brown, 2021; Veldhuizen et al., 2021).

Altogether, this study provides evidence of the targets in which health professionals may focus to prevent post-cessation weight gain among individuals with overweight and obesity who smoke. Individuals with higher baseline weight are a vulnerable group that needs more intensive and personalized treatment for smoking cessation and weight control. Appetite should be regularly assessed during smoking cessation treatments. There is a need for conducting studies examining the triggering mechanisms of appetite changes upon smoking cessation, as well as developing interventions to address appetite variations during the smoking cessation. In this vein, distress tolerance-based interventions targeting eating behavior during smoking cessation (Bloom et al., 2020), which have not been implemented among individuals with excessive body weight who smoke, could help this population cope with appetite changes. On the other hand, adding personalized exercise training (e.g., supervised exercise; Oncken et al., 2020) could also be effective.

This study should be interpreted considering several limitations. Firstly, weight and tobacco-related variables were objectively measured but appetite, grazing, sleep, and exercise were self-reported and may produce bias due to the lack of validated measures. Secondly, eating behaviors and sleep include a broad spectrum of variables that were not all considered in this study (e.g., weekly consumption of highly palatable food, sleep quality). Thirdly, the protocol required a gradual reduction in nicotine intake with abstinence not expected until week six of eight so it is important to interpret findings (e.g., rate of weight gain,

levels of abstinence, changes in other health behaviors) in this context, which may limit the generalizability of results when individuals are not participating in a nicotine fading procedure (e.g., abrupt smoking cessation interventions) and patterns of behavior may differ considerably. Fourthly, modeling baseline BMI as a multicategorical variable (e.g., overweight, obesity class I, class II, and class III) rather than as a dichotomous variable could have revealed more nuanced results, as individuals with higher baseline weight evidenced greater weight increase. Lastly, the sample was comprised by Spanish adults, who have particular daily life habits (e.g., specific dietary patterns that are widespread in Mediterranean countries), hindering the extrapolation of the results to diverse populations with overweight and obesity from different countries.

5. Conclusion

To our understanding, this study provided the first evidence of changes in weight, smoking behavior, eating behavior, exercise, and sleep along a smoking cessation treatment with weight gain prevention, and the effect of these in-treatment changes on weight evolution among individuals with overweight and obesity. Our results suggest that individuals with greater baseline weight and greater cotinine reduction during the intervention may be vulnerable to gain more weight. Exercise performance and not presenting appetite changes or feeling less appetite may be associated with less weight gain in this population. Assessing and addressing weight, eating behavior, and exercise in smoking cessation interventions may be promising to improve weight outcomes.

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CRediT authorship contribution statement

Andrea Krotter: Writing – original draft, Formal analysis, Data curation, Conceptualization. **Ángel García-Pérez:** Writing – review & editing, Formal analysis, Data curation, Conceptualization. **Gema Aonso-Diego:** Writing – review & editing, Formal analysis, Data curation. **Gloria García-Fernández:** Writing – review & editing, Supervision, Project administration, Funding acquisition, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

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