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Pilot randomized trial of cognitive-behavioral treatment plus contingency management for quitting smoking and weight gain prevention among smokers with overweight or obesity

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ABSTRACT

Background: Post-cessation weight gain is a risk factor for relapse among quitters. The primary study aim was to evaluate, among smokers with overweight or obesity, the feasibility and acceptability of a cognitive-behavioral treatment (CBT) plus contingency management (CM) for quitting smoking and weight control. The secondary aim was to examine preliminary tobacco abstinence and weight change outcomes.

Methods: In an 8-week pilot randomized clinical trial, 41 participants ($M_{\rm age} = 52.73$, SD = 10.91, 56.1% females) with overweight or obesity ($M_{\rm BMI} = 31.86$, SD = 4.7) received a CBT for both quitting smoking and weight gain prevention (n = 24) or the same treatment plus CM (n = 17), consisting of providing incentives contingent upon smoking abstinence biochemically verified.

Results: Recruitment success rate was 80.39% (41/51), completion rate was 90.24% (37/41), and mean number of sessions attended (out of 15 possible) was 13.20 (SD=3.1). Mean satisfaction rating for the treatment (1–10 likert-type scale with 10 being most satisfactory) was 9.73 (SD=61). Preliminary efficacy data indicated that the CM group achieved higher abstinence rates compared with the CBT condition (100% vs. 58.33%, p=.007). Abstinent participants increased 1.25 kg (SD=1.79) their baseline body weight at the end of treatment (p=.001).

Conclusions: Providing weight gain prevention strategies and CM within a smoking cessation treatment seems feasible and acceptable. Preliminary data indicated that including CM facilitates tobacco abstinence rates, nevertheless no advantage for CM was found for weight control.

1. Introduction

Smoking and obesity are relevant public health problems and main causes of preventable morbidity and mortality worldwide, with 1.3 billion adults smoking tobacco and 39% presenting overweight and 13% obesity (World Health Organization, 2021a, 2021b). Moreover, rates of smoking among those with overweight or obesity remain quite high compared to general population (Bahji et al., 2019; LaRowe et al., 2009; Solmi et al., 2016; Stefanovics et al., 2020; Zawertailo et al., 2020) and the co-occurrence of smoking and excess weight increases mortality risk (Luijckx et al., 2019; Zhou et al., 2021) and disability (e.g., limitations on activities of daily living) (Townsend and Mehta, 2020).

Post-cessation weight gain weakens the beneficial effect of quitting, increasing the risk of diabetes and cardiovascular or cardiometabolic

diseases, especially among individuals with obesity (Bush et al., 2016; Chen et al., 2021; Hasegawa et al., 2019; Kos, 2020). Concerns on potential post-cessation weight gain are a substantial barrier when trying to quit and post-cessation weight gain is a risk factor for relapse among quitters (Germeroth and Levine, 2018). Moreover, smoking cessation may trigger disordered eating during the quitting process (Killi et al., 2020; Salk et al., 2019) and disordered eating (e.g., grazing, binge eating, loss-of-control eating, emotional eating) is already prevalent among individuals with excess weight (McCuen-Wurst et al., 2018; Nightingale and Cassin, 2019). Interventions to effectively address post-cessation weight gain-related behaviors might be warranted specially for smokers with obesity.

Despite this, studies that evaluate the effectiveness of interventions for quitting smoking and weight control among smokers with

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overweight or obesity are scarce. Love et al. (2011) found that offering a weight management program to overweight and obese weight-concerned smokers improved tobacco treatment outcomes and White et al. (2019) showed that the use of a web-based cognitive behavioral smoking treatment had promising results for maintaining weight and smoking abstinence among smokers with overweight or obesity. Studies including pharmacotherapies for smokers with obesity such as Wilcox et al. (2010) found that naltrexone/bupropion combination therapy with behavioral counseling was associated with decreased nicotine use, limited nicotine withdrawal symptoms, and no significant weight gaining. Hurt et al. (2017) in a clinical pilot study suggested that using combination varenicline and lorcaserin warrants further research and other recent studies found that smoking cessation treatment including varenicline and dietary counseling improved cardiometabolic risk (Heggen et al., 2016, 2017; Svendsen et al., 2021).

To our knowledge, no study has evaluated a specific CBT for weight gain prevention while quitting smoking that comprehensively targeted post-cessation weight concerns, diet, activity and disordered eating among smokers with overweight or obesity (Hartmann-Boyce et al., 2021), which are key factors in the obesity field (Durrer Schutz et al., 2019; Paixao et al., 2020). In addition, no study to date has explored the effect of CM for smoking cessation among smokers with overweight or obesity. CM is a well-established treatment across a wide range of substance use disorders (SUD) including smoking (Krist et al., 2021; Ziser et al., 2018) and a promising approach for other medical conditions (Ellis et al., 2021). CM-based interventions for smoking cessation have proved effective among specific populations such as adults with SUD (Dingemans et al., 2017; Secades-Villa et al., 2020), women who are pregnant and postpartum (Washio et al., 2021) or individuals with psychotic disorders and SUD (Destoop et al., 2021). Moreover, it is worth reflecting on the recent contribution of a pilot study for combined CM for weight loss/smoking cessation in women smokers with weight-concerns (Bloom et al., 2020).

The present study addressed this gap in the literature by analyzing: (1) the feasibility (i.e., recruitment rate success, treatment completion rate and the frequency of session attendance of the participants) and acceptability (i.e., post-treatment satisfaction) of a CBT that simultaneously addresses quitting smoking and weight gain prevention and CM in individuals with overweight and obesity, and (2) the preliminary effectiveness of these protocols on smoking abstinence and weight change outcomes at post-treatment.

2. Methods

2.1. Participants and setting

The study sample comprised adult smokers with overweight and obesity recruited in Spain from the local community through newspaper, radio, television, poster, and social media advertisements posted around the community between September 2020 and February 2021.

Inclusion criteria were (1) being aged 18 years old or over, (2) having smoked 10 or more cigarettes per day within the last year and not using electronic devices, (3) meeting the diagnostic criteria for nicotine dependence according to the Diagnostic and Statistical Manual of Mental Disorders-5th ed. (American Psychiatric Association, 2013) and, (4) having a body mass index (BMI) \geq 25. \geq 25. Exclusion criteria were (1) being pregnant, breastfeeding or in the six-month postpartum period, (2) being currently (in the last 30 days) in receipt of other treatment for smoking cessation or weight control (either behavioral or pharmacological), (3) being diagnosed with a current (during the last year) severe psychiatric disorder (e.g., active psychotic disorder or suicidal ideation), eating disorder other than Binge-Eating Disorder, or SUD other than tobacco use disorder, (4) having any health condition that requires a specialized diet or affected eating (e.g., uncontrolled diabetes), (5) not being able to attend the entire treatment or (6) taking medication that impacts on weight.

Interested individuals who met preliminary eligibility criteria during a telephone screening were scheduled for an in-person 120-min baseline assessment at the Clinical Unit of Addictive Behaviors of the University of Oviedo to confirm eligibility and register baseline data. Written informed consent was obtained from all participants and the privacy rights of participants were observed. The study protocol was approved by the local Ethical Committee of Research of the Principality of Asturias (n° 329/19) and was registered in the ClinicalTrials.gov database (identifier: NCT04332029).

Participants' baseline characteristics are shown in Table 1. There were no significant differences between treatment conditions in any baseline characteristics (all p-values ≥ 0.258).

2.2. Design and treatment allocation

Participants were randomly assigned to two treatment conditions: CBT for tobacco abstinence and weight gain prevention (n=24), or the same treatment alongside CM for smoking abstinence (n=17). A computer-generated list of random numbers was used to allocate the participants to interventions in a 1:1 ratio.

Table 1Baseline characteristics.

	Overall $(N = 41)$	CBT + CM $(n = 17)$	CBT $(n=24)$	p
Sex (female, n/%)	23 (56.1%)	9 (52.9%)	14 (58.3%)	.981
Age (years) ^a	52.73	52.18 (6.92)	53.13	.508
0- ())	(10.91)	()	(13.17)	
Marital status (married,	19 (46.3%)	8 (47.1%)	11 (45.8%)	1
$n/\%$) Educational level (\leq high school, $n/\%$)	15 (36.6%)	4 (23.5%)	11 (45.8%)	.258
Employed (n/%)	23 (56.1%)	11 (64.7%)	12 (50%)	.538
Monthly income level	2885.1	3436.75	2517.33	.890
(US\$)a	(2200.12)	(3301.72)	(863.38)	
CPD ^a	18.73 (6.34)	18.35 (6.03)	19 (6.67)	.807
Age of smoking onset ^a	14.63 (3.22)	14.23 (2.41)	14. 92 (3.71)	.697
Years of regular	30.31	31.12 (7.31)	29.73	.624
smoking ^a	(10.64)		(12.61)	
Previous quit attempts ^a	3.02 (2.2)	3.18 (2.7)	2.92 (1.82)	.893
Smoking stage of change (n/%)	()	0.10 (2.,)	_,,_ (=,,=,,	1
Preparation	27 (65.9)	11 (64.7)	16 (66.7)	
Contemplation	14 (34.1)	6 (35.3)	8 (33.3)	
FTND ^a	4.95 (2.04)	5 (2.5)	4.92 (1.69)	.779
CO (ppm) ^a	20.51 (12.5)	21.41	19.88	.397
	,	(10.43)	(13.96)	
Cotinine (ng/ml) ^a	2002.55	2045.43	1972.18	.691
	(1140.74)	(1054.23)	(1219.68)	
Age of excess weight	30.75	31 (11.02)	30.56	.679
onset ^a	(12.29)	01 (11.02)	(13.39)	.0, ,
Years of IMC ≥ 25 ^a	23.12	26.85	20.44	.617
rears of five ≥ 25	(16.40)	(21.43)	(11.51)	.017
Previous diet attempts ^a	4.51 (6.75)	3.53 (5.7)	5.21 (7.44)	.419
Body weight	34 (82.9)	14 (82.4)	20 (83.3)	1
dissatisfaction $(n/\%)$	34 (82.9)	14 (62.4)	20 (63.3)	1
Diet stage of change (n/%)				.964
Pre-contemplation	8 (19.5)	4 (23.5)	4 (16.7)	
Contemplation	14 (34.1)	5 (29.4)	9 (37.5)	
Preparation	5 (12.2)	2 (11.8)	3 (12.5)	
Action	11 (26.8)	5 (29.4)	6 (25)	
Maintenance	3 (7.3)	1 (5.9)	2 (8.3)	
Weight (kg) ^a	89.27	87.62	90.44	.751
	(14.12)	(14.61)	(13.96)	
BMI ^a	31.86 (4.7)	31.37 (4.44)	32.22 (4.94)	.597
BMI category (n/%)	, ,		• •	1
Overweight	16 (39%)	7 (41.2%)	9 (37.5%)	
Obesity	25 (61%)	10 (58.8%)	15 (62.5%)	

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

Participants were required to visit the clinic 15 times over 8 weeks. The first visit each week lasted 120 min and included a group CBT session (up to 4 participants) with a lab session to provide samples of carbon monoxide (CO), cotinine, and weight samples. A second midweek session, for each of the first seven weeks, lasted 60 min and included the samples and the review of progress and difficulties since the previous session.

Masters- and doctoral-level psychologists with previous experience in smoking cessation treatments and with previous training in specific protocols conducted the treatment. All sessions were audio-recorded and reviewed to ensure compliance with the study protocol.

2.3. Assessment

During the intake session, participants were asked to complete an adhoc questionnaire which collected sociodemographic data (i.e., sex, age, education level, marital status, employment status and monthly income), tobacco use-related variables and weight/eating-related variables.

Smoking-related variables were number of cigarettes smoked per day (CPD), age of smoking onset, years of regular smoking, number of previous quit attempts and current motivation to quit. Regarding weight and eating related variables, participants were asked about age of excess weight onset (IMC \geq 25), years of excess weight (IMC \geq 25), number of previous diet attempts, body weight dissatisfaction and current motivation for weight control using the S-Weight questionnaire (Andrés et al., 2011).

The Fagerström Test for Nicotine Dependence (FTND) (Heatherton et al., 1991) was used to evaluate nicotine dependence. FTND established five levels based on scores: very low (0-2), low (3-4), medium (5), high (6-7) and very high (8-10) (Fagerström et al., 1990). Tobacco use was also biochemically assessed through CO and urine cotinine analysis at the time of the intake assessment, and at each session using a piCO Smokerlyzer (Bedfont Scientific Ltd, Rochester, UK) and the BS-120 chemistry analyzer (Shenzhen Mindray Bio-Medical Electronics Co. Ltd., Shenzhen, P.R. China) respectively. Tobacco abstinence was verified through CO readings ≤ 4 ppm and urine cotinine levels ≤ 80 ng/ml (Benowitz et al., 2020; Karelitz et al., 2021).

Participants' height was measured at baseline using a medical stadiometer (SECA Mod.213, 20–205 cm). Body weight was measured using a calibrated medical scale (CL.III 200 kg. SECA Mod.877) in light clothing and without shoes at baseline, weekly during the intervention, and at end-of-treatment (EOT). Height and weight measurements were used to calculate BMI (BMI = weight [kg]/(height)² [m]).

2.4. Treatment interventions

2.4.1. Cognitive-behavioral treatment (CBT)

Becoña's (2007) CBT protocol for smoking cessation was used, with additional material added to address overweight and obesity. Per the original protocol, participants received coping skills training to quit smoking consisting on information about tobacco, behavioral contract through which participants pledged to attend the sessions, self-monitoring and graphical representation of cigarette smoking, analysis of the antecedents and consequences of smoking behavior to facilitate stimulus control and the progressive selection of situations in which participants will stop smoking, strategies for coping with nicotine withdrawal symptoms, physiological feedback consumption measured by CO and cotinine, training in alternative behaviors, social reinforcement of objectives completion and abstinence, and relapse prevention strategies. A nicotine fading procedure was used, which consisted of a weekly reduction in nicotine intake of 20% each week based on reductions on both tobacco brands and number of daily cigarettes from the first session to 48-hours prior to the sixth session (quit day).

Additional components added to the protocol specifically addressed post-cessation weight gain concerns, nutrition, physical activity, and disordered/problematic eating (i.e., restrained eating, external eating, emotional eating, grazing and binge eating), based on the latest evidence-based weight management guidelines for the maintenance of body weight (Durrer Schutz et al., 2019; Paixao et al., 2020) and evidence-based CBT and third wave acceptance-based dialectical behavioral therapy (DBT) for disordered eating/binge eating, in which participants also learnt self-regulation skills (for example, how to deal with cravings) (Atwood and Friedman, 2020; Ben-Porath et al., 2020). Some treatment components were transdiagnostic both for smoking cessation and weight gain prevention. Description of the treatment protocol is shown in supplementary Table S1.

2.4.2. CBT plus contingency management (CM)

CM consisted of providing vouchers to reinforce abstinence contingent on biochemical breath and urine verification. The schedule incorporated an increasing magnitude of reinforcement. Participants received points (one point was equivalent to US\$ 1.19) contingent upon biochemical confirmation of tobacco abstinence from the sixth session to the eighth session. Smoking abstinence was defined as breath CO equal to or less than 4 parts per million (ppm) (Karelitz et al., 2021) and cotinine equal to or less than 80 nanograms per milliliter (ng/ml), according to prior recommendations (Benowitz et al., 2020). Vouchers began at 50 points (US\$ 59.30) and escalated by 5 points (US\$ 5.93) for each consecutive negative sample. Participants could additionally receive a bonus of 10 points (US\$ 11.86) for achieving two consecutive negative smoking samples. Including both escalating reinforcers and bonuses has shown a positive impact on treatment outcomes (Businelle et al., 2009; Halpern et al., 2015). A positive test or missed specimens reset the voucher value back to the initial 50 points (US\$ 59.30), but if they provided two consecutive negative tests, the vouchers value was reestablished to the one given before the reset. The maximum amount that participants could earn at the EOT was US\$ 379.50.

2.5. Outcomes

Treatment feasibility was analyzed based on three criteria: (1) recruitment success (percentage of individuals completing baseline out of the total of participants who met the inclusion criteria), (2) rates of treatment completion (patients who attended at least five sessions and completed post-treatment assessment), and (3) session attendance (average of therapy and mid-week sessions attended).

Treatment acceptability was examined based on participant's ratings on several treatment parameters: (1) overall helpfulness, comprehension and how easy it was to follow, (2) length and structure, (3) helpfulness of individual treatment components, and (4) satisfaction with treatment and therapists, willingness to recommend the program and perceived usefulness. An individual semi-structured phone-based interview was carried out by an external research assistant at the EOT. It comprised five parts providing participants a 10-point rating scale (from totally disagree to totally agree) except for the second part, which consisted of a three-option answer choice (it is adequate, I prefer more, or I prefer less) and the last part, that consisted of open questions.

The interviewer first asked participants for treatment ratings on helpfulness (how helpful they perceived the treatment for quitting smoking and weight control), comprehension (how well they understood the treatment contents) and how easy it was to follow (how easy it was to follow the treatment assignments). During the second part, the interviewer asked for the participants' satisfaction with treatment length, program's structure, including the duration and frequency of sessions, group format, proportion of content dedicated to smoking cessation and weight control strategies, schedules of target quit day and meals self-monitoring. During the third part, the interviewer asked for the participants' ratings on the individual treatment components helpfulness (most and least useful contents-skills-activities). During the fourth part, the interviewer asked for the participants' satisfaction with the therapist (style and skill) and treatment, willingness to recommend the program to other smokers and

perceived applicability of the content of the program beyond smoking and weight (if participants have learnt skills useful for their everyday life). Finally, the interviewer asked open questions for the participants' spontaneous reactions about treatment (proposals for improvement and their general personal experience) and COVID-19 impact on treatment (whether the pandemic situation benefited or made it difficult to quit smoking and maintain weight).

Smoking abstinence outcomes were assessed in terms of reduction in self-reported CPD, CO levels and urinary cotinine concentrations. Smoking abstinence outcomes at EOT were analyzed considering 48-hour point-prevalence. Weight change outcomes were assessed in terms of body weight and BMI change from baseline to EOT.

2.6. Statistical analyses

We conducted descriptive statistics and frequencies analyses to assess participants' baseline characteristics and provide data on feasibility and acceptability outcomes. Non-parametric statistical methods were carried out, given the non-normality of variables. We performed comparisons between groups with the chi-square test for categorical variables and the Mann-Whitney U test for continuous variables. Finally, the Wilcoxon Signed-Rank test was used to assess changes in continuous variables from baseline to post-treatment. Effect sizes were calculated as follows: using phi coefficient in categorical variables (Fleiss, 1994) and using $r = Z / \sqrt{n}$ (Rosenthal, 1994) in continuous variables, with > 0.10 being small, > 0.30 medium, and > 0.50 large (Field, 2013). Confidence

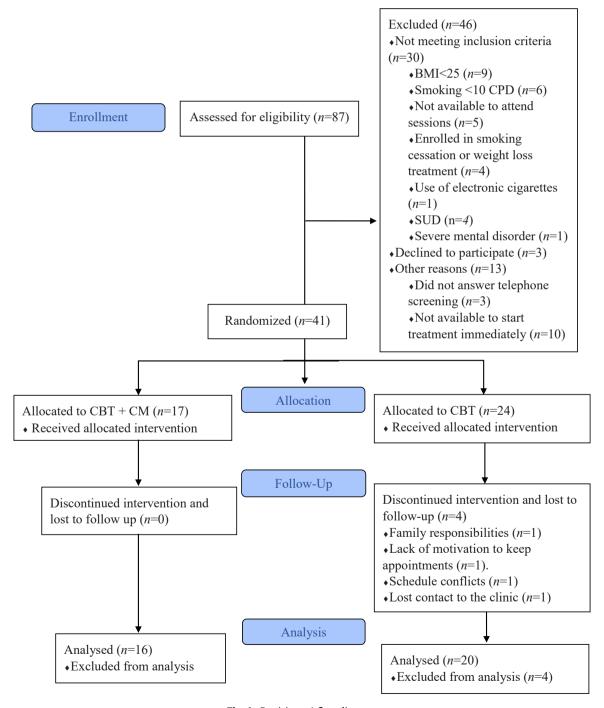


Fig. 1. Participants' flow diagram.

level was 95% and all statistical analyses were conducted using the SPSS package (V.20, Inc., Chicago, IL).

3. Results

3.1. Feasibility outcomes

Fig. 1 shows participants' flowchart. From the 87 telephone calls and e-mails received from interested individuals, 84 individuals completed the initial telephone screening, 33 participants did not meet inclusion criteria, and 10 were not available to start the treatment immediately. In the end, 41 smokers completed the baseline assessment and initiated treatment. A total of 24 individuals were randomly assigned to CBT while 17 were allocated to CBT + CM intervention. Therefore, recruitment success rate was 80.39% (41/51).

A total of 90.24% of the participants completed the treatment (37/41) and completion rates did not differ by treatment condition. Specifically, all the participants in the CBT + CM condition completed the intervention (17/17), and 20/24 participants in the CBT group did too (p=.080). One participant dropped out after the first mid-week session, one dropped out at the second mid-week session, another dropped out after the fifth mid-week session and the last one after the sixth therapy session. Participants who dropped out of treatment had a lower educational level (p=.013), smoked significantly more cigarettes per day at baseline (p=.048) and had been smoking for fewer years than completers (p=.019).

The mean number of sessions attended among all enrolled participants (out of 15 possible) was 13.20 (SD=3.1). Completers attended a mean number of 14 sessions (SD=1.16), with significant differences by treatment group (CBT + CM: 14.82 ± 0.39 ; CBT: 13.30 ± 1.92 ; p=.002; r=0.52). Similarly, when comparing treatment conditions, there were significant differences both in therapy sessions attended (CBT + CM: 7.94 ± 0.24 ; CBT = 7.10 ± 0.97 ; p=.001, r=0.56), and attendance of mid-week sessions (CBT + CM: 6.88 ± 0.33 ; CBT: 6.20 ± 1.32 ; p=.042, r=0.33).

3.2. Acceptability outcomes

Satisfaction ratings were high for both conditions without significant differences between groups in any acceptability variables analyzed (all p-values ≥ 0.165) (Table 2).

Participants' treatment ratings related to treatment helpfulness, comprehension and ease to follow were high, with scores ranging from 8 to 10. Most participants (70–90%) were satisfied with treatment length, duration and frequency of sessions, group format, the proportion of content dedicated to smoking cessation and weight control, the schedules of target quit day and the start of meals self-monitoring. Moreover, ratings for helpfulness of treatment components were high with equal or higher than 8 mean ratings for all of them. Specifically, incentives received an average score of 9.35 (SD=0.99) for helpfulness. Finally, participants gave very high scores (9–10) when rating their satisfaction with the intervention and the therapists, learning skills beyond smoking and weight and whether they would recommend the treatment to other smokers.

Regarding the final open questions of the interview, most participants reported a positive general balance of treatment and mainly highlighted some aspects of the program (e.g., gradual reduction of nicotine intake, biochemical monitoring, program organization, the professionalism and warmth of the therapists, and targeting simultaneously quitting smoking and weight gain prevention). Finally, regarding the question of whether the COVID situation had benefited or made it difficult to quit smoking or maintain weight, 40.54% (n=15) considered that the situation helped (e.g., fewer social activities, mobility restrictions, restaurants closed, less contact with smokers, use of masks, restrictions on smoking in the street, social rejection of smoking or concerns about having COVID which helped to smoke less

Table 2
Acceptability outcomes.

	Completers	CBT + CM	CBT	p
	(n = 37)	(n = 17)	(n = 20)	
Treatment helpfulness ^a	9.19 (1.2)	9.12 (0.33)	9.25 (0.24)	.812
Content comprehension ^a	9.24 (1.01)	9.29 (0.24)	9.2 (0.24)	.88
Ease guidelines ^a	8.53 (1.48)	8.53 (0.344)	8.53 (0.36)	.934
Treatment length $(n/\%)$,	()	.772
Adequate	26 (70.3)	11 (64.7)	15 (75)	
Longer	7 (18.9)	4 (23.5)	3 (15)	
Shorter	4 (10.8)	2 (11.8)	2 (10)	
Session's length $(n/\%)$.288
Adequate	34 (91.9)	17 (100)	17 (85)	
Longer	0	0	0	
Shorter	3 (8.1)	0	3 (15)	
Sessions' frequency $(n/\%)$.288
Adequate	35 (94.6)	15 (88.2)	20 (100)	
More sessions	1 (2.7)	1 (5.9)	0	
Less sessions	1 (2.7)	1 (5.9)	0	
Group format $(n/\%)$.644
Adequate	32 (86.5)	14 (82.2)	18 (90)	
Preferred individual	0	0	0	
Preferred individual and group	5 (13.5)	3 (17.6)	2 (10)	
Proportion of content dedicated to smoking and weight (n/%)				.165
Adequate	29 (78.4)	11 (64.7)	18 (90)	
More time on tobacco cessation	3 (8.1)	2 (11.8)	1 (5)	
More time on weight control	5 (13.5)	4 (23.5)	1 (5)	
Target quit day schedule (n/%)	, ,	, ,		.321
Adequate	24 (64.9)	9 (52.9)	15 (75)	
Preferred before	9 (24.3)	6 (35.3)	3 (15)	
Preferred after	4 (10.8)	2 (11.8)	2 (10)	
Meals self-monitoring schedule $(n/\%)$.639
Adequate	30 (81.1)	14 (82.4)	16 (80)	
Preferred before	6 (16.2)	3 (17.6)	3 (15)	
Preferred after	1 (2.7)	0	0	
Satisfaction with the intervention ^a	9.73 (0.61)	9.76 (0.11)	9.70 (0.16)	.704
Satisfaction with the therapists ^a	9.89 (0.39)	9.94 (0.06)	9.85 (0.11)	.629
Treatment recommendation ^a	9.89 (0.39)	9.88 (0.08)	9.9 (0.1)	.499
Useful skills learning ^a	9.09 (1.28)	8.94 (0.35)	9.20 (0.26)	.574

Note. ^a Mean (standard deviation) scored on 1–10 Likert-type scale; CBT = cognitive-behavioral treatment; CM = contingency management

and reduce social eating), 21.62% (n=8) believed that it made it difficult (e.g., increased stress, anxiety and depressive symptoms due to uncertainty about the pandemic evolution, spending more time at home, boredom and being unable to plan outdoor activities, which triggered smoking, overeating and physical inactivity), 16.21% (n=6) reported no influence, 8.10% (n=3) gave reasons both in favor and against, 5.40% (n=2) provided positive comments about COVID-protection during the program (e.g., use of masks, ventilation, small groups) and another 8.10% (n=3) did not provide additional comments. Participants' spontaneous reactions about COVID-19 impact on treatment goals are shown in supplementary Table S2.

3.3. Smoking abstinence and weight change outcomes

There was a statistically significant reduction in self-reported CPD and smoking biochemical measures in both groups. Participants decreased self-reported CPD (M baseline = 18.05; SD = 6.08; M EOT = 1.32; SD EOT = 3.42; p < .001; r = 0.88), CO levels (M baseline = 20.08; SD = 12.66; M EOT = 3.03; SD EOT = 5.44; p < .001; r = 0.86) and urine

cotinine ($M_{\text{baseline}} = 2054.47$; SD = 1189.35; $M_{\text{EOT}} = 239.02$; $SD_{\text{EOT}} = 649.19$; p < .001; r = 0.86).

Based on treatment conditions, participants in CM condition decreased self-reported CPD ($M_{\rm baseline}=18.35; SD=6.03; M_{\rm EOT}=0; p<.001; r=0.88$) and both CO ($M_{\rm baseline}=21.41; SD=10.43; M_{\rm EOT}=1.71; SD=0.83; p<.001; r=0.88$) and cotinine levels ($M_{\rm baseline}=2045.43; SD=1054.23; M_{\rm EOT}=0.771; SD=3.17 p<.001; r=0.88$). All the participants (17/17) achieved tobacco abstinence biochemically verified.

Similarly, individuals in the CBT group reduced CPD (M baseline = 17.8; SD=6.27; M $_{\rm EOT}=2.45$; SD=4.39; p<.001; r=0.88), CO readings (M baseline = 18.95; SD=14.45; M $_{\rm EOT}=4.15$; SD=7.26; p<.001; r=0.86), as well as cotinine levels (M baseline=2062.16; SD=1320.66; M $_{\rm EOT}=441.53$; SD=839.38; p<.001; r=0.83). In this case, 58.33% (14/24) reached tobacco abstinence, and there were significant differences in abstinence rates at EOT between groups in favor of CM group (p=.007; $\phi=0.478$). Fig. 2 shows change in urine cotinine during treatment.

Regarding weight change outcomes among participants from both groups, abstinent participants increased their baseline body weight by a mean of 1.25 kg (SD=1.79) at EOT ($M_{\rm baseline}=88.46; SD=14.78; M_{\rm EOT}=89.7; SD=14.8; <math>p=.001; r=0.58$). Based on treatment conditions, abstinent individuals enrolled in CBT + CM group significantly increased their body weight ($M_{\rm baseline}=87.62; SD=14.61; M_{\rm EOT}=88.91; SD=14.54; <math>p=.008; r=0.64$), whereas abstinent participants in CBT group maintained their baseline weight ($M_{\rm baseline}=89.48; SD=15.48; M_{\rm EOT}=90.66; SD=15.61; <math>p=.059$).

4. Discussion

This is the first study to assess the feasibility, acceptability and preliminary effectiveness of a CBT for both smoking cessation and weight gain prevention plus CM specifically among smokers with overweight and obesity. Three results are highlighted: (1) CBT and CM for smokers with overweight and obesity seems to be feasible and acceptable; (2) both treatments showed preliminary effectiveness for achieving tobacco abstinence and for weight gain prevention; and (3) including a CM component facilitates session attendance and tobacco abstinence rates more than CBT alone but it does not benefit weight change outcomes.

Treatment was feasible according to the high rates of successful recruitment, treatment completion and frequency of session attendance. It is worth to note as a study strength that attendance rates were high in both groups without compensations. The 80.39% recruitment rate is similar to general population rates (Lopez-Nunez et al., 2016) and to population with overweight or obesity (White et al., 2019). Also, completion rate (90.24%) and treatment attendance rate, with

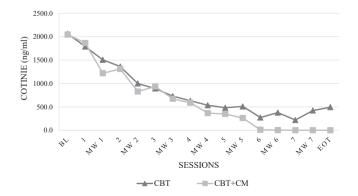


Fig. 2. Reductions in urine cotinine by group throughout treatment. Note. Ng/ml = nanograms per milliliter; BL = baseline; MW = mid-week session; EOT = end of treatment; CBT = cognitive-behavioral treatment; CM = contingency management.

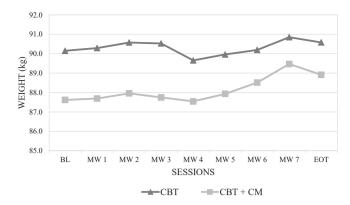


Fig. 3. Weight change during treatment by group. Note. Kg = kilograms; BL = baseline; MW = mid-week session; EOT = end of treatment; CBT = cognitive-behavioral treatment; CM = contingency management.

completers attending a mean of 14 sessions out of 15 sessions, are similar to those found in previous feasibility studies for smoking cessation among weight-concerned women (Bloom et al., 2020, 2017).

Participants rated treatment conditions as acceptable regarding several parameters, e.g., treatment length, duration and frequency of sessions, high utility and ease of understanding, satisfaction with the program and the therapists, and perceived usefulness of the program. Previous studies showed similar results based on the high recommendation of the program and on the high perceived utility of the components (Bloom et al., 2020, 2017; Labbe et al., 2019; Minami et al., 2018).

Both treatment conditions showed preliminary effectiveness for achieving smoking abstinence and for weight gain prevention. Smoking cessation rates were higher compared to those found in previous studies for smoking cessation among smokers with overweight or obesity (White et al., 2019; Wilcox et al., 2010). Regarding weight change outcomes, it is important to bear in mind that the treatment target was post-cessation weight gain prevention. Although a pre-post treatment weight gain change was observed (+1.25 kg), it was less than seen in previous studies (Tian et al., 2015).

There were no differences between treatment conditions in completion rates or post-treatment satisfaction rates, but session attendance and abstinence rates were higher in the CM group while weight maintenance among quitters was higher in the CBT condition. Other studies have also found that CM procedures improve intra-treatment behaviors (i.e., retention rates, abstinence during treatment, and weekly reduction in nicotine levels) (Aonso-Diego et al., 2021; Lopez-Nunez et al., 2016) and promote adherence to substance use disorder treatments (Stitzer et al., 2021) and for other medical conditions (Ellis et al., 2021). Regarding weight change outcomes, it is worth to note that CM consisted of providing vouchers to reinforce smoking abstinence but weight maintenance was not incentivized, and a dual CM schedule for promoting smoking abstinence and weight control seems promising (Bloom et al., 2020). Future research is needed to determine which CM parameters could be more effective in this specific population group in the short and long term.

These findings should be interpreted with caution due to several limitations. The COVID-19 pandemic situation could affect outcomes and future research is needed to deeply analyze how the pandemic impacted treatment attendance (e.g., factors associated to the high attendance rates), smoking cessation and weight outcomes (e.g., factors associated to those participants who increased baseline weight) at short and long term. The majority of the participants reported that it was easier to achieve treatment goals during the pandemic but recent studies have shown that COVID-19 had a deleterious impact on substance use, mental health and weight-related behaviors in individuals with obesity (Almandoz et al., 2021). Further, the small sample size that characterizes feasibility studies may have led us to obtain insufficient statistical

power to detect significant differences to be yielded. Therefore, it requires that a larger randomized controlled trial be conducted to yield definite conclusions on CBT and CM effectiveness for quitting smoking and post-cessation weight control.

4.1. Conclusions

The study found that addressing smoking cessation and postcessation weight gain prevention simultaneously and including CM for smoking cessation was feasible and acceptable among individuals with overweight and obesity. Future large-scale clinical trials should evaluate whether the implementation of CM for weight maintenance or for increasing physical exercise facilitates smoking abstinence and postcessation weight gain prevention.

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CRediT authorship contribution statement

Gloria García-Fernández: Conceptualization, Funding acquisition, Project administration, Supervision, Data collection, Writing – original draft. Andrea Kotter: data collection, Formal analyses, Writing – original draft. Ángel García-Pérez: Software and Data collection. Gema-Aonso Diego: Data collection and Formal analysis. Roberto Secades-Villa: Conceptualization, Funding acquisition and Supervision. All authors have approved the final article.

Conflict of interest

The authors declare that they have no competing interests regarding this paper.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.drugalcdep.2022.109477.

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