Universidad de Oviedo

Departamento de Psicología

Programa de Doctorado en Ciencias de la Salud

Tratamiento para dejar de fumar y prevenir la ganancia de peso dirigido a personas con sobrepeso u obesidad

Treatment for smoking cessation and weight gain prevention for individuals with overweight or obesity

Andrea Krotter Díaz

Oviedo, 2024

Universidad de Oviedo

RESUMEN DEL CONTENIDO DE TESIS DOCTORAL

1.- Título de la Tesis	
Español/Otro Idioma: TRATAMIENTO PARA DEJAR DE FUMAR Y PREVENIR LA GANANCIA DE PESO DIRIGIDO A PERSONAS CON SOBREPESO U OBESIDAD	Inglés: TREATMENT FOR SMOKING CESSATION AND WEIGHT GAIN PREVENTION FOR INDIVIDUALS WITH OVERWEIGHT OR OBESITY

2.- Autor	
Nombre: ANDREA KROTTER DÍAZ	
Programa de Doctorado: CIENCIAS DE LA SALUD	
Órgano responsable: CENTRO INTERNACIONAL DE POSTGRADO	

RESUMEN (en español)

Introducción: En la actualidad, el tabaquismo y el exceso de peso corporal son considerados problemas de salud pública. Dejar de fumar está asociado a una ganancia de peso de entre 4 y 5 kilogramos tras doce meses de abstinencia, lo que supone una barrera para abandonar el consumo de tabaco y es potencialmente perjudicial para la salud de las personas con sobrepeso u obesidad. Dado que hasta la fecha escasean las intervenciones que logren eficazmente el mantenimiento de peso tras dejar de fumar, el objetivo general de la presente Tesis Doctoral fue evaluar la efectividad de una terapia psicológica para dejar de fumar y prevenir simultáneamente el incremento de peso corporal dirigida a personas con sobrepeso u obesidad. Los objetivos específicos fueron: 1) analizar la eficacia de las intervenciones conductuales para dejar de fumar y abordar el peso disponibles hasta la fecha; 2) evaluar la factibilidad y la aceptabilidad de una terapia cognitivo-conductual (TCC) para dejar de fumar y prevenir el incremento de peso dirigida a población con sobrepeso u obesidad combinada con un protocolo de manejo de contingencias (MC) para dejar de fumar; 3) analizar la eficacia de la TCC para dejar de fumar y prevenir el incremento de peso en función de las tasas de abstinencia, el cambio de peso, y otras variables secundarias al finalizar la terapia y en seguimientos realizados uno, tres, seis y doce meses después, así como examinar el efecto aditivo del MC para dejar de fumar en las variables anteriormente mencionadas; y 4) analizar los cambios ocurridos durante la terapia en relación a la conducta tabáquica, la conducta alimentaria, el ejercicio y el sueño y su impacto sobre el peso corporal.

Método: El primer objetivo se abordó mediante un estudio de metaanálisis, mientras

que para los tres objetivos restantes se realizó un ensayo controlado aleatorizado en el que un total de 120 personas con sobrepeso u obesidad se asignaron aleatoriamente al grupo TCC (*n* = 60) o al grupo TCC + MC (*n* = 60).

Resultados: Las intervenciones que incluían el abordaje del peso incrementaban significativamente las tasas de abstinencia en el postratamiento, pero no en los seguimientos, y no eran eficaces para prevenir el incremento de peso. La TCC desarrollada resultó factible y aceptable para la población con sobrepeso u obesidad. Además, la TCC fue eficaz para dejar de fumar y para mejorar el estilo de vida de los participantes teniendo en cuenta algunas variables secundarias (e. g., reducción de los niveles de ingesta emocional), aunque no para prevenir el incremento de peso. A pesar de la evidencia acumulada al respecto, el MC no mejoró significativamente las tasas de abstinencia tabáquica ni ninguna de las variables evaluadas durante o al finalizar la terapia, tampoco en los seguimientos. Un mayor peso corporal inicial y una mayor reducción en los niveles de cotinina en orina se asociaron a un mayor incremento de peso, mientras que un menor apetito o un apetito estable y una mayor realización de ejercicio se asociaron con un menor incremento de peso.

Discusión: Los resultados de la presente Tesis Doctoral mostraron que la TCC fue eficaz para ayudar a las personas con exceso de peso corporal a dejar de fumar, pero no para prevenir el incremento de peso. Estos hallazgos, junto con el hecho de que en el metaanálisis no se encontraran intervenciones que previnieran la ganancia de peso eficazmente, muestran la necesidad de seguir investigando sobre cómo facilitar el mantenimiento del peso tras la deshabituación tabáquica. En la población con sobrepeso u obesidad, identificar a las personas con un mayor peso corporal y mayores niveles de cotinina al inicio de la terapia y abordar los cambios en el apetito y el ejercicio durante el transcurso de esta podría facilitar el mantenimiento del peso.

Universidad de Oviedo

RESUMEN (en Inglés)

Introduction: Currently, smoking and excess body weight are considered public health problems. Smoking cessation is associated with a range of weight gain of 4-5 kilograms after twelve months of abstinence, which poses a barrier to quitting smoking and is potentially harmful to the health of individuals with overweight or obesity. Since effective interventions for maintaining weight after smoking cessation are scarce to date, the general objective of this Doctoral Thesis was to evaluate the effectiveness of a psychological therapy for smoking cessation that simultaneously addresses post-cessation weight gain prevention among individuals with overweight or obesity. The specific aims were: 1) to analyze the effectiveness of behavioral interventions for smoking cessation and weight management; 2) to evaluate the feasibility and acceptability of a cognitive-behavioral therapy (CBT) for smoking cessation and weight gain prevention combined with contingency management (CM) for smoking cessation among individuals with overweight or obesity; 3) analyze the effectiveness of CBT for smoking cessation and weight gain prevention in terms of abstinence rates, weight change, and other secondary outcomes at the end of the treatment and during the follow-ups conducted for a period of 12 months; and 4) to analyze changes occurred during the therapy regarding smoking behavior, eating behavior, exercise, and sleep, and their impact on body weight evolution.

Method: The first specific aim was addressed through a meta-analysis study, while for the remaining three specific aims, a randomized controlled trial was conducted in which a total of 120 individuals with overweight or obesity participated in the therapy. Specifically, half were assigned to the CBT group (n = 60) and the other half to the CBT + CM group (n = 60).

Results: Interventions addressing smoking cessation and weight management significantly increased quit rates at post-treatment but not at the follow-ups. These interventions were not found to be effective in preventing weight gain. The CBT was feasible and acceptable for individuals with overweight or obesity. Additionally, CBT was effective for smoking cessation and improving participants' lifestyle, as evidenced by some secondary outcomes (e.g., reduction in emotional eating levels), however, it was not effective for preventing weight gain. Despite the scientific evidence supporting

AGRADECIMIENTOS

A los 14 años ya había decidido que quería ejercer la psicología en el ámbito clínico. Lo que no sabía entonces era que la investigación y la docencia iban a ser los otros dos puntos de apoyo sobre los que querría asentar mi carrera profesional. Esta Tesis Doctoral intenta representar mi vocación por la clínica y mi interés por explorar otros puntos de vista de entender la Psicología. Hoy cierro una etapa, pero no lo hago sola, sino rodeada de varias personas a las que les debo mucho.

En primer lugar, me gustaría expresar mi agradecimiento a mis directores. A Roberto Secades Villa, por haberme abierto las puertas de la UCCA para trabajar como investigadora por primera vez. A Gloria García Fernández, por haber confiado en mi para realizar esta Tesis Doctoral. Durante este tiempo trabajando mano a mano con vosotros he podido aprender cómo deben hacerse las cosas, así que gracias por ello. También quiero mostrar mi agradecimiento a los demás compañeros del Grupo de Investigación en Conductas Adictivas. Gema Aonso Diego y Ángel García Pérez, me emociona un poco mirar atrás y hacer un balance del tiempo compartido. Sois "codirectores" de esta tesis (y ojalá también de muchas de las cosas que estén por venir). Alba González de la Roz y Sara Weidberg López, vuestra constancia es un ejemplo a seguir. Gracias por haber formado parte de este proceso. También quiero agradecer a las últimas incorporaciones al grupo de investigación: Layla Alemán Moussa, Clara Iza Fernández y Nacho Cuesta López. Es un placer finalizar esta etapa con vosotros.

En segundo lugar, y muy especialmente, a mis padres y a mi hermana. Porque hoy soy la persona que soy, tanto a nivel profesional como personal, gracias a vosotros.

Soy muy afortunada por teneros, vuestras palabras y compañía me han dado aliento siempre que lo he necesitado y habéis hecho vuestros mis éxitos profesionales. Os quiero mucho. A Cristian. Por estar siempre, sujetándome la mano, incondicionalmente. Cualquiera que haga una Tesis Doctoral (o cualquiera, en general) debería tener a su lado a una persona como tú. Eres el mejor y estoy muy agradecida por todo lo que hemos construido juntos hasta hoy. También tengo mucho que agradecer a mi familia de Argentina. Especialmente a mi padrino y tío Esteban, porque siempre está presente a pesar de la distancia; y a mi abuela, porque cuando pudo festejó mis avances laborales y porque, aunque ahora su memoria no le permita expresarlo, sé que está muy orgullosa de todo esto. Hay otras personas que, aunque probablemente no lo sepan, también me han ayudado a lo largo de estos años a cruzar esta meta. El tiempo compartido juntos me ha permitido recargar las pilas para que esta Tesis Doctoral sea hoy una realidad. Paula, Ali, Mella, Silvia, Manu, Cris, Moni, Resu… ¡Muchísimas gracias!

Por último, también quiero mostrar mi agradecimiento a todas las personas que acudieron a la Unidad Clínica de Conductas Adictivas de la Facultad de Psicología a dejar de fumar a lo largo de este proyecto de investigación. Sin su confianza hoy no podría estar escribiendo estas palabras.

FINANCIACIÓN

Los estudios incluidos en la presente Tesis Doctoral se han realizado con la financiación de la Agencia Estatal de Investigación del Ministerio de Ciencia, Innovación y Universidades y del Fondo Europeo de Desarrollo Regional dentro del proyecto titulado “Tratamiento del tabaquismo en fumadores con obesidad” (referencia: RTI2018-101465-A-I00) y mediante un contrato predoctoral procedente del Programa “Severo Ochoa” para la Investigación y Docencia del Principado de Asturias (referencia: PA-21-PF-BP20-015).

ÍNDICE

RESUMEN

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TCC + MC (*n* = 60). **Resultados:** Las intervenciones que incluían el abordaje del peso incrementaban significativamente las tasas de abstinencia en el postratamiento, pero no en los seguimientos, y no eran eficaces para prevenir el incremento de peso. La TCC desarrollada resultó factible y aceptable para la población con sobrepeso u obesidad. Además, la TCC fue eficaz para dejar de fumar y para mejorar el estilo de vida de los participantes teniendo en cuenta algunas variables secundarias (e. g., reducción de los niveles de ingesta emocional), aunque no para prevenir el incremento de peso. A pesar de la evidencia acumulada al respecto, el MC no mejoró significativamente las tasas de abstinencia tabáquica ni ninguna de las variables evaluadas durante o al finalizar la terapia, tampoco en los seguimientos. Un mayor peso corporal inicial y una mayor reducción en los niveles de cotinina en orina se asociaron a un mayor incremento de peso, mientras que un menor apetito o un apetito estable y una mayor realización de ejercicio se asociaron con un menor incremento de peso. **Discusión:** Los resultados de la presente Tesis Doctoral mostraron que la TCC fue eficaz para ayudar a las personas con exceso de peso corporal a dejar de fumar, pero no para prevenir el incremento de peso. Estos hallazgos, junto con el hecho de que en el metaanálisis no se encontraran intervenciones que previnieran la ganancia de peso eficazmente, muestran la necesidad de seguir investigando sobre cómo facilitar el mantenimiento del peso tras la deshabituación tabáquica. En la población con sobrepeso u obesidad, identificar a las personas con un mayor peso corporal y mayores niveles de cotinina al inicio de la terapia y abordar los cambios en el apetito y el ejercicio durante el transcurso de esta podría facilitar el mantenimiento del peso.

SUMMARY (BIS)

Introduction: Currently, smoking and excess body weight are considered public health problems. Smoking cessation is associated with a range of weight gain of 4-5 kilograms after twelve months of abstinence, which poses a barrier to quitting smoking and is potentially harmful to the health of individuals with overweight or obesity. Since effective interventions for maintaining weight after smoking cessation are scarce to date, the general objective of this Doctoral Thesis was to evaluate the effectiveness of a psychological therapy for smoking cessation that simultaneously addresses post-cessation weight gain prevention among individuals with overweight or obesity. The specific aims were: 1) to analyze the effectiveness of behavioral interventions for smoking cessation and weight management; 2) to evaluate the feasibility and acceptability of a cognitive-behavioral therapy (CBT) for smoking cessation and weight gain prevention combined with contingency management (CM) for smoking cessation among individuals with overweight or obesity; 3) analyze the effectiveness of CBT for smoking cessation and weight gain prevention in terms of abstinence rates, weight change, and other secondary outcomes at the end of the treatment and during the follow-ups conducted for a period of 12 months; and 4) to analyze changes occurred during the therapy regarding smoking behavior, eating behavior, exercise, and sleep, and their impact on body weight evolution. **Method:** The first specific aim was addressed through a meta-analysis study, while for the remaining three specific aims, a randomized controlled trial was conducted in which a total of 120 individuals with overweight or obesity were assigned to the CBT group (n = 60) or to the CBT + CM group (n = 60). **Results:** Interventions addressing smoking cessation and weight management significantly increased quit rates at post-treatment but not at the follow-ups. These interventions were not found to be effective in preventing

weight gain. The CBT was feasible and acceptable for individuals with overweight or obesity. Additionally, CBT was effective for smoking cessation and improving participants' lifestyle, as evidenced by some secondary outcomes (e.g., reduction in emotional eating levels), however, it was not effective for preventing weight gain. Despite the scientific evidence supporting their efficacy, CM did not significantly improve smoking abstinence rates or any of the evaluated variables during or at the end of the therapy, nor during follow-ups. Finally, higher baseline body weight and greater reduction in urine cotinine levels were associated with greater weight gain, while lower appetite or stable appetite and higher exercise engagement were associated with less weight gain. **Discussion**: The findings of this Doctoral Thesis indicated that CBT was an effective intervention for smoking cessation among individuals with excess body weight. However, it was not effective for preventing post-cessation weight gain. These findings, in conjunction with the absence of efficacious interventions identified in the meta-analysis for the prevention of weight gain, underscore the necessity for further research on the facilitation of weight maintenance following smoking cessation. In population with overweight or obesity, the identification of individuals with higher body weight and higher levels of cotinine at the beginning of the therapy combined with addressing changes in appetite and exercise during the therapy could facilitate the prevention of weight gain.

INTRODUCCIÓN

1. Tabaquismo y exceso de peso corporal

El tabaquismo y el exceso de peso corporal son dos factores de riesgo para el desarrollo de múltiples problemas de salud. El consumo de tabaco es la principal causa de muerte prevenible en el mundo, con de más de ocho millones de fallecimientos cada año (Organización Mundial de la Salud, 2023). Los efectos perjudiciales del consumo de tabaco como el cáncer, las cardiopatías, las enfermedades cerebrovasculares, las enfermedades pulmonares o la diabetes (Centers for Disease Control and Prevention, 2020) son extensamente conocidos en los países occidentales, incluyendo España. Sin embargo, su consumo sigue siendo altamente prevalente en este país, donde el 33,10% de las personas con edades comprendidas entre los 15 y los 64 años fuman a diario (Plan Nacional sobre Drogas, 2022), lo que se traduce en más de 50.000 muertes anuales vinculadas al tabaquismo (Plan Nacional sobre Drogas, 2020). En el Principado de Asturias la prevalencia de consumo diario es similar a la nacional (i.e., 33,20% entre las personas con edades entre los 15 y 64 años) (Plan Nacional sobre Drogas, 2022).

El exceso de peso corporal también es altamente prevalente en los países occidentales. El indicador habitualmente utilizado para evaluar la presencia de exceso de peso es el índice de masa corporal (IMC), que permite categorizar a las personas con sobrepeso cuando su IMC se sitúa entre 25 y 29,99, y con obesidad cuando su IMC es mayor o igual 30. Se estima que, en el año 2022, el 43% de las personas mayores de 18 años cursaban con sobrepeso en el mundo, mientras que el 16% presentaban obesidad (Organización Mundial de la Salud, 2024). El exceso de peso está asociado al desarrollo de múltiples enfermedades como la diabetes, la dislipidemia, la hipertensión o el cáncer

(Karra et al., 2022; Sarma et al., 2021). En el año 2019 se produjeron aproximadamente 5 millones de muertes en el mundo por causas relacionadas con el exceso de peso corporal (Chong et al., 2023). En España, el 16% de la población adulta presenta obesidad, porcentaje que aumenta hasta el 19,10% en el Principado de Asturias (Ministerio de Sanidad, 2020), uno de las más altos del país.

La elevada prevalencia del tabaquismo y el exceso de peso corporal en España se traducen en un elevado coste social, especialmente en términos de gasto sanitario (Comité Nacional para la Prevención del Tabaquismo, 2023; Okunogbe et al., 2021; Organizanización para la Cooperación y el Desarrollo Económico, 2019), por lo que ambos son considerados problemas de salud pública.

1.1. Coexistencia de factores de riesgo

El consumo de tabaco se asocia a la presencia de otros hábitos perjudiciales para la salud como el sedentarismo, los patrones alimentarios inadecuados (e. g., dieta basada en una mayor ingesta de grasas y un menor consumo de frutas o verduras), el uso de otras sustancias o los problemas de sueño (Cassidy et al., 2017; Costa & Esteves, 2018; Dallongeville et al., 1998; Kaufman et al., 2012; Laredo-Aguilera et al., 2019; Masood et al., 2015; Ross MacLean et al., 2018). Como consecuencia, el tabaquismo está estrechamente relacionado con el sobrepeso y la obesidad (Ellison-Barnes et al., 2023; Park et al., 2023; Radmilović et al., 2023), especialmente cuando el consumo de tabaco se mantiene a largo plazo o cuando el nivel de dependencia a la nicotina es elevado (Chatkin et al., 2010, 2015; MacKay et al., 2013; Tuovinen et al., 2016). La coexistencia del tabaquismo y el exceso de peso corporal se han vinculado a un mayor riesgo de mortalidad frente a los fumadores con normopeso y los no fumadores (Freedman et al., 2006; Luijckx et al., 2019). Es por ello que la población fumadora con sobrepeso u obesidad es considerada una población de riesgo para el desarrollo de problemas de salud

(Rupprecht et al., 2015; Townsend & Mehta, 2020), siendo especialmente relevante desarrollar intervenciones eficaces dirigidas tanto al abandono del consumo de tabaco como al control del peso.

1.2. Prevalencia de consumo de tabaco en población con sobrepeso u obesidad

Diversos estudios epidemiológicos realizados en Europa han analizado el consumo de tabaco en personas con sobrepeso u obesidad (y viceversa). Un estudio realizado en Suecia encontró una prevalencia de consumo de tabaco diario del 14,4% en las personas con sobrepeso y del 16% en las personas con obesidad (Munter et al., 2015). En Reino Unido, la prevalencia de consumo de tabaco entre los adultos de mediana edad (i.e., 31 – 69 años) que presentaban obesidad fue menor, concretamente del 7% (Dare et al., 2015). Otro estudio con población finlandesa (Tuovinen et al., 2016) concluyó que, entre las personas que fumaban ocasionalmente o que fumaban menos de 20 cigarros al día, el 12% de los hombres y el 8,4% de las mujeres mostraban sobrepeso u obesidad. Estos porcentajes se reducían al 6,7% de los hombres y el 1,7% de las mujeres entre los participantes que fumaban más de 20 cigarrillos diarios.

Hasta donde se tiene constancia, en España no se han realizado estudios nacionales en este ámbito. Una investigación llevada a cabo en un hospital de Madrid encontró que el 38,78% de las personas con sobrepeso y el 43,63% de las personas con obesidad eran fumadoras (Martín Timón et al., 2007). Sin embargo, las limitaciones metodológicas de esta investigación exigen cautela al interpretar los resultados, concretamente debido al número de participantes ($N = 126$) y a la escasa representatividad de la muestra (i.e., habitantes de Madrid que habían acudido al hospital para recibir consejo dietético).

2. Relación entre el consumo de tabaco y el peso corporal

Las personas que fuman tabaco tienen un menor peso corporal que las no lo fuman (Audrain-Mcgovern & Benowitz, 2011; Jacobs, 2019; Køster-Rasmussen et al., 2015; Schwartz & Bellissimo, 2021). Sin embargo, algunas investigaciones han sugerido que existe una relación con forma de "U" entre el IMC y el número de cigarrillos fumados al día, es decir, que aunque los fumadores muestren un menor peso corporal que los no fumadores, consumir un mayor número de cigarrillos al día incrementa la probabilidad de tener obesidad (Chiolero et al., 2007; Clair et al., 2011; Pan et al., 2020; Raptou & Papastefanou, 2018). Para comprender la compleja interrelación existente entre el consumo de tabaco y el peso corporal se deben tener en cuenta los efectos que el tabaco ejerce sobre el organismo y la tendencia a la utilización del tabaco como método de control del peso.

Por un lado, a nivel fisiológico, la nicotina es una sustancia psicoactiva con propiedades estimulantes que incrementa la tasa metabólica, es decir, el gasto energético por unidad de tiempo (Audrain-Mcgovern & Benowitz, 2011; Chiolero et al., 2008). Por otro, la nicotina ejerce un "efecto anoréxico" sobre las vías neuronales encargadas de regular el apetito en el sistema nervioso central (Jo et al., 2002; Schwartz & Bellissimo, 2021; Seoane-Collazo et al., 2020), lo que se traduce en una reducción en el apetito que repercute en el balance energético de los fumadores. Ambas cuestiones en conjunto permiten explicar que los fumadores presenten un menor peso corporal que los no fumadores. Sin embargo, aunque resulte contraintuitivo, el consumo de nicotina también está relacionado con una mayor probabilidad de ingerir ciertos alimentos, concretamente los conocidos como de alta palatabilidad, que son aquellos con elevadas concentraciones de sal, azúcares y grasas (Fazzino et al., 2019). La ingesta de esos alimentos ejerce un efecto similar al del consumo de sustancias adictivas en el sistema mesolímbico

dopaminérgico, el denominado "sistema de recompensa cerebral" (Criscitelli & Avena, 2016; Ely & Wetherill, 2023). Esto se traduce en mayores niveles de *craving* o deseo de ingerir ese tipo de alimentos en los fumadores frente a los no fumadores (Chao et al., 2017; Pepino et al., 2009) y que un mayor *craving* hacia la comida se relacione significativamente con un mayor *craving* hacia el tabaco (Mahler & de Wit, 2010; Miyoshi et al., 2024; Styn et al., 2013). Por lo tanto, a nivel fisiológico, la nicotina tiene un efecto paradójico: reduce el peso corporal por sus propiedades estimulantes y lo incrementa potenciado las propiedades reforzantes de algunos alimentos (Donny et al., 2011).

Por otro lado, a nivel psicológico, algunos fumadores utilizan el tabaco para controlar su figura corporal, concretamente para reducir el apetito, evitar comer entre horas, eliminar el *craving* hacia la comida, o prevenir la sobreingesta, entre otros motivos (Burr et al., 2020; Fairweather-Schmidt & Wade, 2015; Harris et al., 2016; Kilmurray et al., 2023; Mason, Martinez, et al., 2022; Taleb et al., 2017; White, 2012). Estas conductas de regulación del peso, que son desadaptativas y potencialmente perjudiciales para la salud, podrían englobarse dentro de lo que se conoce como alimentación desordenada. La alimentación desordenada incluye cualquier conducta que denote una relación poco saludable con la comida, el ejercicio, el peso corporal, y la imagen corporal, sin que sea necesario cumplir los criterios diagnósticos de un trastorno alimentario (Pennesi & Wade, 2016). La utilización del tabaco para regular la insatisfacción con el aspecto corporal permite aliviar temporalmente la preocupación por el peso entre los fumadores (Mason, Tackett, et al., 2022). En este sentido, varios metaanálisis han encontrado una elevada prevalencia de consumo de tabaco en personas con trastornos alimentarios, especialmente en el trastorno por atracón (Bahji et al., 2019; Solmi et al., 2016), en el que el exceso de peso corporal es habitual (McCuen-Wurst et al., 2018).

Además, la preocupación por ganar peso tras de dejar de fumar es una barrera habitual para dejar de consumir tabaco (Chao et al., 2019; Clark et al., 2006; Pomerleau et al., 2001), especialmente entre las personas con sobrepeso u obesidad (Aubin et al., 2009; Beebe & Bush, 2015; Levine et al., 2013; Pankova et al., 2023). Aunque la investigación sobre la relación entre la preocupación por la ganancia de peso y la probabilidad de lograr la abstinencia tabáquica o el control del peso no es concluyente (Germeroth & Levine, 2018; Kilmurray et al., 2023; Taleb et al., 2017; Toyon et al., 2024; Tuovinen et al., 2018), los estudios coinciden en señalar que esa preocupación dificulta la búsqueda de tratamiento (Brouwer & Pomerleau, 2000; Pánková et al., 2017; Taleb et al., 2017; Veldheer et al., 2014).

3. Incremento de peso corporal al dejar de fumar

Entre el 80% y el 90% de las personas que dejan de fumar incrementan su peso corporal (Bush et al., 2016). En un metaanálisis que examinó la ganancia de peso tras dejar de fumar en personas que habían recibido intervenciones sin control de peso concluyó que el incremento medio de peso era de 1,12 kilogramos (kg), 2,26 kg, 2,85 kg, 4,23 kg y 4,67 kg en los seguimientos realizados uno, dos, tres, seis y doce meses después de haber alcanzado la abstinencia tabáquica (Aubin et al., 2012). Otras conclusiones destacables de este estudio se relacionan con el periodo en el que se produce un mayor incremento de peso, concretamente los tres primeros meses tras dejar de fumar (cuando se gana aproximadamente 1 kg cada mes), y con la gran heterogeneidad encontrada en el cambio de peso. Específicamente, mientras que a los 12 meses entre el 16% y el 21% de las personas pierden peso, entre el 13% y el 14% de las personas ganan más de 10 kg. Otro metaanálisis que comparó el cambio de peso entre quienes continuaban fumando y quienes habían dejado de fumar (Tian et al., 2015) concluyó que, cinco años después de

haber logrado la abstinencia, las personas incrementaron su peso en 4,1 kg y su IMC en 1,1 kg/m^2, lo que supone un incremento superior al que mostraron quienes continuaban fumando (en total de 2,6 kg o 0,6 kg/m^2 más).

En la población con exceso de peso corporal los resultados son contradictorios. Por un lado, el estudio realizado por Krukowski et al. (2016) encontró que, entre quienes habían dejado de fumar en el último año, las personas con sobrepeso incrementaron una media de 2,2 kg (95% CI: 1,1 – 3,2), mientras que las personas con obesidad mostraron una reducción no significativa de 1,4 kg (95% CI: -2,9 – 0,1). Por el contrario, el estudio de Lycett et al. (2011) mostró que ocho años después de haber dejado de fumar, el incremento de peso fue superior entre las personas con obesidad que entre las personas con sobrepeso, en concreto 19,5 kg frente a 10,2 kg respectivamente. En cualquier caso, un mayor peso corporal al inicio del tratamiento se ha asociado con una mayor ganancia de peso corporal (Scherr et al., 2015). Este incremento de peso puede ser especialmente perjudicial entre las personas que ya tienen exceso de peso antes de dejar de fumar, tal y como se expone en el siguiente epígrafe.

4. Consecuencias del incremento de peso corporal tras dejar de fumar

La literatura científica señala que es más saludable ser exfumador con sobrepeso u obesidad que fumador con normopeso (Bush et al., 2016; Harris et al., 2016; Pistelli et al., 2009; Siahpush et al., 2014), y que ganar peso al dejar de fumar no atenúa los beneficios del abandono del consumo de tabaco (Harris et al., 2016; Hu et al., 2018; K. Kos, 2020; Sahle et al., 2021; Wang et al., 2022). Sin embargo, los estudios sobre las consecuencias del incremento del peso al dejar de fumar han mostrado resultados contradictorios.

Algunas investigaciones señalan que ganar peso tras dejar de fumar no incrementa el riesgo de desarrollar problemas de salud como accidentes cerebrovasculares, diabetes tipo II, cáncer, o síndrome metabólico (Sahle et al., 2021; Song et al., 2015), y que a pesar del incremento de peso los niveles de colesterol en sangre mejoran (Forey et al., 2013; Gepner et al., 2011). En esta línea, un metaanálisis reciente (Wang et al., 2021) concluyó que, aunque se gane peso al dejar de fumar, tanto la probabilidad de desarrollar enfermedades cardiovasculares como el riesgo de mortalidad se reducen.

Por el contrario, otros estudios han encontrado un incremento en el desarrollo de síndrome metabólico (Janzon et al., 2004) o hipertensión (Takayama et al., 2018), siendo mayor el riesgo cuanto mayor sea la ganancia de peso (Ninomiya et al., 2024). Sin embargo, la mayor parte de la evidencia se concentra en torno a la diabetes tipo II, cuya incidencia parece incrementarse al ganar peso tras dejar de fumar. Esta relación se ha encontrado en diversos ensayos clínicos (Choi et al., 2021; Wu et al., 2022) y se ha constatado reiteradamente en revisiones sistemáticas y metaanálisis (Bush et al., 2016; Harris et al., 2016; Wang et al., 2021).

En el caso de la población con exceso de peso corporal se deben destacar varias cuestiones. En primer lugar, el incremento de peso puede desencadenar que las personas superen el rango del sobrepeso y crucen el umbral de la obesidad (Bush et al., 2016; Munter et al., 2015) con el potencial perjuicio para la salud que esto puede suponer (Dikaiou et al., 2021; Kivimäki et al., 2022). En segundo lugar, las personas con obesidad muestran mayor preocupación por ganar peso, menos confianza en mantener su peso corporal sin ingerir nicotina, y menos tolerancia a la ganancia de peso al dejar de fumar frente a las personas con normopeso o sobrepeso (Beebe & Bush, 2015; Levine et al., 2013; Pankova et al., 2023). También se debe tener en cuenta que el riesgo de recaída es mayor entre quienes están más preocupados por ganar peso al dejar de fumar (Salk et al.,

2019), que las preocupaciones por ganar peso se relacionan con una menor autoeficacia percibida para abandonar el consumo de tabaco (Tuovinen et al., 2015), y que el incremento de peso al finalizar el tratamiento aumenta la probabilidad de recaída en el consumo de tabaco meses más tarde (Krotter et al., 2023). Aunque estos tres últimos estudios no incluyen exclusivamente población con sobrepeso u obesidad, sus resultados junto con los de los estudios previamente mencionados con esa población (Beebe & Bush, 2015; Bush et al., 2016; Levine et al., 2013; Munter et al., 2015; Pankova et al., 2023) remarcan la necesidad de intervenir simultáneamente en el tabaquismo y el aumento de peso entre las personas con sobrepeso u obesidad.

5. Intervenciones para dejar de fumar que incluyen simultáneamente un componente dirigido a abordar el peso corporal

5.1. Intervenciones conductuales

Las intervenciones conductuales incluyen tradicionalmente estrategias dirigidas a la ingesta calórica (e. g., dietas hipocalóricas), el gasto calórico (e. g., incremento de las horas de ejercicio) o las actitudes sobre el aspecto corporal (e. g., reducción de la preocupación por el aspecto corporal).

El primer metaanálisis publicado en este campo examinó la eficacia de intervenciones conductuales para dejar de fumar y prevenir el aumento de peso frente a intervenciones conductuales sin ese componente de control del peso (Spring et al., 2009). Encontró un aumento en las tasas de abstinencia a corto plazo (i.e., seguimientos > 3 meses) en las intervenciones dirigidas a ambos objetivos, así como una reducción significativa en la ganancia de peso. Sin embargo, el efecto beneficioso de esas intervenciones no se encontró a largo plazo (i.e., > 6 meses). A pesar de la heterogeneidad

de las intervenciones incluidas (e. g., ejercicio, dieta, preocupación por el aumento de peso…), este estudio no examinó individualmente los efectos de cada tipo de intervención en la abstinencia y el peso.

Otro metaanálisis posterior (Hartmann-Boyce et al., 2021) actualizó la evidencia de dos revisiones sistemáticas de la *Cochrane* previas (Farley et al., 2012; Parsons et al., 2009). Este estudio analizó la eficacia de las intervenciones destinadas al tabaquismo y al manejo del peso y de las intervenciones para dejar de fumar que podían repercutir también en el peso sin dirigirse directamente a controlarlo (e. g., ejercicio para dejar de fumar). No se encontraron intervenciones que, con una certeza al menos moderada, fueran clínicamente eficaces para reducir el aumento de peso a largo plazo. Sin embargo, se indica que las intervenciones conductuales son el pilar fundamental para controlar el peso y que se requieren más estudios para lograr la prevención de la ganancia, así como estudios que analicen su repercusión en la abstinencia. Por ejemplo, se encontró que los programas de control de peso personalizados pueden reducir el aumento de peso, pero únicamente cuando atienden a la idiosincrasia de cada caso. También concluyó que las intervenciones dirigidas a aceptar el aumento de peso, en lugar de a prevenirlo, mostraron resultados mixtos en la abstinencia y el cambio de peso.

Además, este último metaanálisis (Hartmann-Boyce et al., 2021) y dos revisiones sistemáticas previas (Ussher et al., 2012, 2019) analizaron el impacto del ejercicio como intervención para dejar de fumar con potencial efecto en el peso corporal. El metaanálisis concluyó que el ejercicio no previene el aumento de peso al finalizar el tratamiento ni a corto plazo, pero sí a largo plazo (i.e., ≥ 12 meses). Por su parte, las revisiones sistemáticas no encontraron evidencia de que el ejercicio ayude a dejar de fumar, mientras que no analizaron su impacto en el peso.

5.2. Intervenciones farmacológicas

Aunque las intervenciones farmacológicas no sean objeto de la presente Tesis Doctoral, se expone un breve resumen de la evidencia disponible hasta la fecha. El metaanálisis más completo y reciente sobre este tema (Hartmann-Boyce et al., 2021) concluyó que algunos fármacos empleados para controlar el peso (i.e., dexfenfluramina, fenilpropanolamina, naltrexona) reducen la ganancia al finalizar el tratamiento, pero no a medio ni a largo plazo. Al examinar el impacto de otras intervenciones farmacológicas no diseñadas para controlar el peso, este estudio encontró que el bupropion, la fluoxetina, y la terapia sustitutiva de la nicotina (TSN) reducen el incremento ponderal al finalizar el tratamiento, y que la TSN también es eficaz a largo plazo. Además, concluyó que la vareniclina tiene poco efecto sobre el control del peso, tal y como había indicado un metaanálisis anterior (Sun et al., 2018). Por último, otro metaanálisis que examinó el efecto de combinar diferentes intervenciones farmacológicas sobre el peso concluyó que la menor ganancia se produce al combinar TSN con fluoxetina o al prescribir topiramato (Hsieh et al., 2019).

6. Tratamientos para dejar de fumar que abordan simultáneamente el peso corporal dirigidos a personas con sobrepeso u obesidad

Todos los estudios realizados con esta población han abordado el peso corporal junto con la intervención para dejar de fumar (Heggen et al., 2016; Hurt et al., 2017; Love et al., 2011; White et al., 2019; Wilcox et al., 2010). Las intervenciones aplicadas son muy heterogéneas, encontrándose en la Tabla 1 un resumen de sus componentes.

Dos de los estudios fueron ensayos no controlados (Hurt et al., 2017; Wilcox et al., 2010), otro incluyó dos condiciones experimentales con distintas estrategias dietéticas (Heggen et al., 2015), y los dos restantes incluyeron un grupo control con educación para

la salud (White et al., 2019) o sin manejo del peso (Love et al., 2011), siendo este último un estudio cuasiexperimental.

Tabla 1

Resumen de las intervenciones para dejar de fumar y prevenir el aumento de peso aplicadas en población con sobrepeso u obesidad

	Tabaco		**Peso**	
	Psicológico	**Farmacológico**	**Conductual/psicológico**	**Farmacológico**
Heggen et al. (2016)	Consejo breve	Vareniclina	Grupo 1: Dieta individualizada baja en carbohidratos. Grupo 2: Dieta individualizada moderadamente reducida en grasas	-
Hurt et al. (2017)	Consejo breve	Vareniclina	Consejo breve (dieta e incremento de la actividad física)	Lorcaserina [a]
Love et al. (2011)	TCC	TSN	Tratamiento conductual (dieta, aumento de la actividad física y estrategias conductuales para seguir las recomendaciones)	-
White et al. (2019)	TCC	TSN	TCC para la preocupación por el aumento de peso (e. g., no hacer dieta restrictiva, restructuración cognitiva sobre el peso corporal)	-
Wilcox et al. (2011)	Consejo breve	Naltrexona y bupropion	Consejo breve (dieta hipocalórica e incremento del ejercicio)	-

Nota. TCC = terapia cognitivo-conductual; TSN = terapia sustitutiva de la nicotina.
[a] Fármaco retirado del mercado por sus potenciales efectos perjudiciales para la salud.

6.1. Eficacia sobre la conducta tabáquica

Las tasas de abstinencia continuada o prolongada de los estudios disponibles hasta la fecha con población con sobrepeso u obesidad oscilaron entre el 25,9% y el 50% al finalizar el tratamiento y entre el 25,9% y el 40,7% en los seguimientos realizados a los tres meses (Hurt et al., 2017; White et al., 2019; Wilcox et al., 2011). El único estudio que informó del punto de prevalencia de siete días al finalizar el tratamiento encontró una tasa del 71% combinando los resultados de dos intervenciones que solo diferían en la metodología empleada para controlar el peso, es decir, que utilizaban la misma intervención para dejar de fumar (Heggen et al., 2016). En seguimientos realizados a los tres meses se encontraron puntos de prevalencia de siete días del 21,4% (Love et al., 2011) y el 46,3% (Heggen et al., 2016).

6.1.1. Terapia cognitivo-conductual para dejar de fumar

La terapia cognitivo-conductual (TCC) es una terapia con una amplia evidencia científica en el ámbito del tabaquismo (National Institute on Drug Abuse, 2021; Perkins et al., 2008; Sánchez Hervás et al., 2022). Los programas multicomponente basados en la TCC incluyen psicoeducación sobre los efectos del tabaco, contrato conductual, técnicas motivacionales, reducción gradual del consumo de nicotina, análisis bioquímicos para monitorizar el progreso de cada caso, búsqueda de apoyo social, y prevención de recaídas, entre otros.

En España, el programa multicomponente de Becoña (2007) ha mostrado eficacia en el tabaquismo a corto y largo plazo tanto en población general (López-Núñez, Martínez-Loredo, et al., 2016; Secades-Villa et al., 2009) como en poblaciones vulnerables, incluyendo por ejemplo a fumadores con trastornos depresivos (González-Roz et al., 2019; Martínez-Vispo et al., 2019) o que están recibiendo tratamiento por

trastorno por consumo de sustancias (Secades-Villa et al., 2022). Hasta la fecha no se ha aplicado en población con sobrepeso u obesidad.

6.1.2. Manejo de contingencias para dejar de fumar

El manejo de contingencias (MC) es una intervención basada en el análisis de conducta que se fundamenta en el principio básico de que aportar un reforzador positivo contingente a la emisión de una conducta incrementará su frecuencia (Petry, 2011). El MC basado en incentivos, una de las modalidades de MC más extendidas, consiste en entregar incentivos tangibles (e. g., dinero en efectivo, vales canjeables por bienes o servicios) de forma contingente a la realización del cambio de conducta deseado (Pfund et al., 2021). En el contexto del tratamiento del tabaquismo, ese cambio de conducta se corresponde con la reducción en el consumo de tabaco o la abstinencia, aunque también pueden reforzarse otros objetivos terapéuticos como la asistencia a las sesiones (Higgins et al., 2008). El MC suele utilizarse como complemento a otras intervenciones como la TCC o la entrevista motivacional.

La eficacia del MC depende de ciertos parámetros, a saber, la inmediatez con la que se entrega el reforzador, la frecuencia con la que la persona puede obtener el reforzador, o la magnitud del mismo (Davis et al., 2016; Pfund et al., 2021). Por un lado, el periodo transcurrido entre la demostración de la conducta objetivo (i.e., verificación bioquímica de la abstinencia) y la entrega del reforzador debe ser lo más corto posible. Por otro lado, una mayor frecuencia en el número de oportunidades de conseguir el reforzador se relaciona con una mayor eficacia (e. g., vigencia del MC durante un mayor número de sesiones). Finalmente, la magnitud de los incentivos debe ser lo suficientemente cuantiosa como para motivar el cambio de conducta. En este sentido, un incremento del refuerzo asociado al mantenimiento de la conducta (en este caso la abstinencia tabáquica) tendrá un mayor efecto, especialmente si además se reinicia la

magnitud de los incentivos a su valor inicial en caso de que haya alguna analítica con resultado positivo tras un consumo.

La literatura científica ha avalado de forma reiterada la eficacia del MC para dejar de fumar (González-Roz & Secades-Villa, 2022; Kock et al., 2023; Marchal-Mateos et al., 2024; Notley et al., 2019; Secades-Villa et al., 2020; Weidberg et al., 2022). Sin embargo, su aplicación presenta algunas limitaciones que dificultan su utilización en contextos clínicos reales. Una de las críticas más presentes en la literatura hace referencia a su coste económico y de recursos (Petry et al., 2017; Pfund et al., 2021; Rash & DePhilippis, 2019), debido al coste extra que debe sumarse al de las intervenciones habitualmente utilizadas (e. g., compra de incentivos, monitorización de la abstinencia) o a las dificultades para asegurar el suministro económico que permita disponer de incentivos en las clínicas e instituciones. Sin embargo, algunos estudios que han aplicado el MC para dejar de fumar previamente han concluido que es una intervención coste-eficaz (González-Roz et al., 2021; López-Núñez, Alonso-Pérez, et al., 2016). Teniendo en cuenta el beneficio social que implica el MC en el contexto de las adicciones (Petry et al., 2017), las propuestas para resolver esta limitación incluyen la búsqueda de financiación externa o el uso de depósitos económicos por parte de los participantes (Weidberg et al., 2022). Otro de los puntos débiles del MC se relaciona con la reducción en sus efectos a largo plazo, cuando los incentivos ya no están disponibles, sugiriéndose que la utilización de reforzadores externos no necesariamente se traduce en una motivación intrínseca para mantener la abstinencia (Petry et al., 2017). En este sentido, mientras que un metaanálisis ha concluido que el MC para dejar de fumar tiene efectos beneficiosos a largo plazo (Notley et al., 2019) otro indica que sus efectos solo se producen a corto plazo (Secades-Villa et al., 2020).

A pesar de las críticas anteriormente mencionadas, el MC ha mostrado eficacia para facilitar la abstinencia tabáquica en diversos grupos vulnerables (Higgins, 2023), como las mujeres embarazadas o en periodo de postparto (Kock et al., 2023), las personas con depresión (Marchal-Mateos et al., 2024), o las personas a tratamiento por trastorno por consumo de sustancias (Secades-Villa et al., 2020), por lo que también podría facilitar el alcance de la abstinencia tabáquica en población con sobrepeso u obesidad.

6.2. Eficacia sobre el peso corporal

Los estudios con intervenciones dirigidas tanto a dejar de fumar como a controlar el peso en población con sobrepeso u obesidad han presentado los resultados de cambio de peso de forma muy heterogénea (i.e., en todos los participantes o solo en las personas que logran la abstinencia; presentando la media de cambio de peso en kg, en el IMC, o el porcentaje medio de incremento), lo que dificulta la comparación de los resultados. Hurt et al. (2017) encontraron un incremento no significativo de peso entre los que lograron la abstinencia continuada al finalizar el tratamiento (M_{kg} = 1,1; DT = 3,9) y a los tres meses (M_{kg} = 6,4 kg; DT = 10) tras recibir consejo breve sobre dieta y actividad física junto a lorcaserina. Wilcox et al. (2010) reportaron el porcentaje medio de incremento de peso entre los que consiguieron la abstinencia continuada, encontrando una ligera disminución no significativa del peso al finalizar el tratamiento (M = -0,1%; DT = 2,5%) y un incremento no significativo a los tres meses (M = 1,3%; DT = 3,3%) tras recibir consejo breve sobre dieta hipocalórica y ejercicio. Finalmente, Heggen et al. (2016) examinaron el cambio entre quienes cumplieron con siete días de abstinencia a los tres meses, encontrando incrementos no significativos de 3,3 kg (DT = 4,2) en el grupo que realizó la dieta baja en carbohidratos y de 2,8 kg (DT = 3,8) en quienes siguieron la dieta moderadamente reducida en grasas, no habiendo diferencias entre los grupos. White et al. (2019) no informaron del incremento de peso entre los abstinentes (sino entre todos los

participantes), aunque indicaron que los abstinentes del grupo que recibió TCC para la preocupación por la ganancia de peso mostraron un menor incremento de peso que los del grupo control. Finalmente, el estudio de Love et al. (2011) no informó del cambio de peso de los participantes.

6.2.1. Terapia cognitivo-conductual para la prevención de la ganancia de peso corporal

La TCC también cuenta con una extensa evidencia científica que respalda su utilización para intervenir sobre los trastornos alimentarios (Atwood & Friedman, 2019; Hamid, 2024; Öst et al., 2024). La elevada prevalencia de comportamientos alimentarios desordenados en la población con sobrepeso u obesidad (Askari et al., 2020; Heriseanu et al., 2017; Kolay et al., 2021; Ma et al., 2020; Vasileiou & Abbott, 2023) justifica su abordaje a lo largo de la deshabituación tabáquica.

En este contexto, la TCC para los atracones de comida de Fairburn (2017), que incluye técnicas como psicoeducación sobre el efecto de las dietas, autorregistros de comida, pesaje semanal o manejo de los atracones de comida, podría facilitar el control del peso durante la deshabituación tabáquica en población con sobrepeso u obesidad si se adapta para ese fin. El único estudio que empleó esta terapia en personas con exceso de peso corporal que estaban dejando de fumar encontró resultados prometedores, con una menor ganancia de peso entre los abstinentes frente al grupo control, que había recibido un programa de educación para la salud (White et al., 2019).

6.2.2. Terapia dialéctico conductual para la prevención de la ganancia de peso corporal (y para dejar de fumar)

La terapia dialéctico conductual (DBT) (Linehan, 2015), que cuenta con una amplia evidencia para tratar los problemas de desregulación emocional en las personas con trastorno límite de la personalidad, ha ido extendiéndose especialmente al ámbito de los trastornos alimentarios (Ben-Porath et al., 2020; Braden et al., 2022; Cancian et al., 2019) aunque también al de los trastornos adictivos (Dimeff & Linehan, 2008; Warner & Murphy, 2022). Como probablemente el lector esté familiarizado con la naturaleza transdiagnóstica de la terapia, se percatará de que la ubicación de esta sección dentro del componente de abordaje del peso es una mera cuestión estratégica de organización de la información, dado que las habilidades que promueve la terapia repercutirán tanto en la conducta alimentaria como en la tabáquica.

Los problemas de regulación emocional (i.e., dificultades para evaluar las emociones y adaptar las respuestas emocionales con el objetivo de alcanzar una meta) (Thompson, 1991) se asocian a un mayor IMC especialmente debido al efecto de la alimentación emocional, tanto en la población general como en población fumadora (Dakanalis et al., 2023; Guerrini-Usubini et al., 2023; Jones et al., 2019). Además, un incremento en los niveles de desregulación emocional tras alcanzar la abstinencia tabáquica (Mitchell et al., 2019) podría dificultar su mantenimiento (Rogers et al., 2019). Por lo tanto, el entrenamiento en habilidades de regulación emocional (e. g., tolerancia al malestar, acción opuesta) podría ser de utilidad en este contexto terapéutico, tanto para la conducta alimentaria como la tabáquica (Guerrini-Usubini et al., 2023; Rogers et al., 2019). A pesar de que la presente Tesis Doctoral no se destine a examinar la eficacia de un protocolo completo de DBT, la TCC desarrollada incorpora alguna estrategia de intervención basada en la DBT.

7. Mecanismos explicativos de la ganancia de peso al dejar de fumar

Las personas que muestran mayores niveles de dependencia a la nicotina antes de dejar de fumar, es decir, las que más nicotina consumen (Jung et al., 2012; van Overmeire et al., 2016), son las que evidencian un mayor incremento ponderal tras alcanzar la abstinencia (Killi et al., 2020; Kmetova et al., 2014; Komiyama et al., 2013; Prod'hom et al., 2013). El aumento de peso podría explicarse por las consecuencias de la retirada de la nicotina *per se*, pero también está relacionado con otros aspectos, como las características sociodemográficas, los cambios en la conducta alimentaria u otras variables vinculadas al estilo de vida, como el sedentarismo o los hábitos de sueño (Kaufman et al., 2012; Shaikh et al., 2015), por lo que sus mecanismos explicativos son multicausales. También debe tenerse en cuenta que el síndrome de abstinencia a la nicotina incluye, entre otros síntomas, insomnio o e incremento en el apetito (American Psychiatric Association, 2013).

La investigación sobre el efecto de las variables sociodemográficas es escasa. Mientras que algunos estudios encontraron que las mujeres ganan más peso que los hombres (Kmetova et al., 2014; Taleb et al., 2017) otros concluyen lo contrario (Prod'hom et al., 2013). Por otro lado, una menor edad (Swan & Carmelli, 1995), un menor nivel de ingresos mensuales (Aubin et al., 2009; Swan & Carmelli, 1995) y un menor nivel socioeducativo (Scherr et al., 2015) se asocian a un mayor incremento de peso.

Los cambios en la conducta alimentaria son los que más atención han recibido, tanto a través de estudios de laboratorio como clínicos. En primer lugar, los estudios de laboratorio han examinado el efecto que las primeras horas de abstinencia tiene sobre la conducta alimentaria, específicamente tras solicitar a los participantes no fumar durante 12 horas (Betts & Tiffany, 2019; Yannakoulia et al., 2018), 18 horas (Alsene et al., 2003),

24 horas (Anker et al., 2021) o 48 horas (J. Kos et al., 1997; Saules et al., 2004; Spring et al., 2003). Cuatro estudios concluyeron que la abstinencia tabáquica desencadena un incremento en el apetito y en el número de calorías ingeridas (Anker et al., 2021; J. Kos et al., 1997; Spring et al., 2003; Yannakoulia et al., 2018). Sin embargo, un estudio encontró que la ingesta de calorías se mantenía estable (Saules et al., 2004), y otros dos que el *craving* hacia la comida no se incrementaba durante la abstinencia (Alsene et al., 2003; Betts & Tiffany, 2019).

En segundo lugar, los estudios clínicos monitorizaron los cambios en la conducta alimentaria de los participantes que recibieron intervenciones para dejar de fumar. Dos encontraron cambios, y otros dos no. Concretamente, el incremento en los niveles de ingesta externa (i.e., al presenciar estímulos apetecibles, no por hambre), emocional (i.e., ante emociones agradables o desagradables) y restrictiva (i.e., evitar comer para controlar el peso) fue mayor entre quienes tenían una mayor dependencia a la nicotina antes de dejar de fumar (Killi et al., 2020). Además, la cantidad total de calorías ingeridas se incrementó al alcanzar seis meses de abstinencia continuada en otro estudio, aunque el consumo de grasas fue menor que el de los que seguían fumando (Levine et al., 2012). Sin embargo, un estudio no encontró cambios en la capacidad reforzadora de la comida tras una semana de abstinencia tabáquica (Lerman et al., 2004) y otro concluyó que el apetito, los niveles de hambre y la cantidad de calorías ingeridas se mantuvieron estables hasta el seguimiento de los tres meses (Heggen et al., 2016; Svendsen et al., 2021).

En cuanto a las variables relacionadas con el sedentarismo y el gasto calórico, es esperable que mantener escasos niveles de actividad física (i.e., realización de cualquier movimiento corporal que implique un gasto energético como subir escaleras) y ejercicio físico (i.e., actividad física estructurada y planeada dirigida a mejorar el estado físico, como salir a correr) esté relacionado con un mayor incremento de peso al dejar de fumar.

Sin embargo, hasta el momento actual, solo un estudio ha analizado esta cuestión, encontrando que una menor realización de actividad física al inicio del tratamiento se relaciona con un mayor incremento de peso (Kmetova et al., 2014). La mayoría de los estudios publicados en torno al efecto de la actividad física y el ejercicio sobre el peso se han centrado en analizar la eficacia de las intervenciones dirigidas a incrementar la actividad física y/o el ejercicio, cuyos resultados se comentaron en el epígrafe 5.1.

Finalmente, otra variable que potencialmente podría influir en el peso corporal es el cambio en los patrones de sueño. Dejar de fumar suele acompañarse de problemas de sueño (Htoo et al., 2004; Jaehne et al., 2014), y, a su vez, el insomnio está relacionado con un incremento en el apetito y el peso (Rodrigues et al., 2021; Taheri et al., 2004). En la población con sobrepeso u obesidad en concreto, el exceso de peso es un factor de riesgo para tener problemas de sueño (Cassidy et al., 2017; Patel et al., 2008), por lo que podría ser una variable estrechamente relacionada con el incremento de peso al dejar de fumar.

8. Limitaciones de la investigación previa

La investigación en el ámbito de la intervención en el tabaquismo y el control del peso en general, y en particular en población con sobrepeso u obesidad, presenta algunas limitaciones que sustentan los objetivos de la presente Tesis Doctoral.

En primer lugar, los metaanálisis que evaluaron la eficacia de las intervenciones destinadas a dejar de fumar y abordar el peso corporal publicados hasta la fecha (Hartmann-Boyce et al., 2021; Spring et al., 2009), encontraron que el efecto beneficioso de esas intervenciones no se mantiene a largo plazo (a excepción del ejercicio, cuyos resultados son poco intuitivos, dado que a corto plazo no previene el incremento de peso).

Los resultados de esos estudios remarcan la necesidad de seguir investigando con el objetivo de desarrollar intervenciones eficaces, tanto en términos de abstinencia tabáquica como de control de peso, que repercutan en una mejor calidad de vida entre quienes dejan de fumar. Además, ninguno de los dos metaanálisis analizó los moderadores de la eficacia de las intervenciones dirigidas a dejar de fumar y prevenir el incremento de peso. Dado que los moderadores informan sobre qué variables deben considerarse para mejorar los resultados de los tratamientos, esta laguna en la literatura debe ser abordada.

En segundo lugar, los estudios destinados a intervenir sobre la conducta tabáquica y el peso específicamente dirigidos a población con sobrepeso u obesidad (Heggen et al., 2016; Hurt et al., 2017; Love et al., 2011; White et al., 2019; Wilcox et al., 2010), mostraron una elevada heterogeneidad en las tasas de abstinencia alcanzadas. El margen de mejora de los resultados es amplio, dado que no hay tasas de abstinencia continuada, prolongada o de siete días superiores al 50% a los tres meses. Los diseños de las intervenciones aplicadas para dejar de fumar también presentan varias limitaciones. Por un lado, ningún estudio ha aplicado exclusivamente una terapia psicológica para dejar de fumar, ya que todos los estudios combinaron intervenciones psicológicas con farmacológicas (naltrexona, bupropion, vareniclina o TSN). La literatura indica que las intervenciones psicológicas para dejar de fumar son más eficaces cuando se combinan con farmacoterapia (Hartmann-Boyce et al., 2019; Lancaster & Stead, 2017), aunque también son eficaces cuando se utilizan de forma aislada (Nian et al., 2023; Spring et al., 2009). Teniendo en cuenta que la población con exceso de peso suele consumir más medicación que la población con normopeso (Kit et al., 2012; Randhawa et al., 2017), analizar la eficacia de una intervención psicológica no combinada con fármacos es necesario para poder ofrecer una alternativa no farmacológica para dejar de fumar a esta población. En cuanto a los dos únicos estudios que evaluaron la eficacia de la TCC para

dejar de fumar en personas con exceso de peso, ninguno la aplicó presencialmente, sino mediante llamadas de teléfono (Love et al., 2011) o a través de una página web (White et al., 2019).

Otra cuestión relevante es que, a pesar de la evidencia disponible sobre el MC para dejar de fumar (González-Roz & Secades-Villa, 2022; Kock et al., 2023; Marchal-Mateos et al., 2024; Notley et al., 2019; Secades-Villa et al., 2020; Weidberg et al., 2022), este procedimiento no se ha aplicado en personas con exceso de peso corporal. En último lugar, y como limitación destacable, ninguno de los cinco estudios realizados con esta población evaluó los resultados a largo plazo, es decir, en seguimientos realizados más allá de seis meses tras finalizar la terapia. Por lo tanto, es necesario realizar ensayos que analicen los resultados a largo plazo.

En tercer lugar, en cuanto a los resultados de cambio de peso de los cinco estudios llevados a cabo con población con sobrepeso u obesidad, nuevamente debe destacarse la aplicación conjunta con terapia farmacológica para dejar de fumar, que puede repercutir en el cambio peso (Hartmann-Boyce et al., 2021). Como consecuencia, el efecto de las intervenciones puramente conductuales sobre el peso corporal en esta población todavía no está claro. También es importante señalar que las intervenciones empleadas se focalizan mayoritariamente en la realización de dietas restrictivas (4/5; 80%) (Heggen et al., 2016; Hurt et al., 2017; Love et al., 2011; Wilcox et al., 2010), las cuales no están exentas de riesgos, como el "efecto yo-yo" (recuperación del peso tras el cese de la dieta) (van der Valk et al., 2019) o su posible papel como desencadenante de conductas alimentarias desordenadas como los atracones de comida (Habib et al., 2023; Memon et al., 2020). Además, solamente un estudio intervino sobre las preocupaciones por la ganancia de peso (White et al., 2019), muy prevalentes en esta población (Beebe & Bush, 2015; Levine et al., 2013; Pankova et al., 2023). Ese estudio, que aplicó la TCC de

Fairburn (2017), lo hizo en remoto a través de una página web con una muestra de tan solo 27 personas (White et al., 2019), y encontró una menor ganancia de peso entre quienes lograron la abstinencia frente al grupo control, que había recibido un programa de educación para la salud. Sin embargo, para poder obtener conclusiones robustas sobre su eficacia, se necesitan estudios con un mayor tamaño de muestra que analicen su impacto sobre el cambio de peso a largo plazo.

Otra limitación en torno al manejo del peso es que ningún estudio ha combinado componentes dirigidos a modificar el balance energético de los participantes (e. g., alimentación saludable sin restricción e incremento de la actividad física y el ejercicio), por un lado, y a las preocupaciones por la ganancia de peso por otro, incluyendo estrategias destinadas a prevenir o tratar la alimentación desordenada (e. g., atracones de comida, picoteos entre horas), de clara relevancia en esta población. En este sentido, desarrollar intervenciones basadas en la evidencia científica más actualizada sobre los factores clave del manejo ponderal (National Institute for Health and Care Excellence, 2023), como evitar la estigmatización del exceso de peso corporal (Durrer Schutz et al., 2019), promover hábitos de alimentación saludable como desayunar de forma regular, tener acceso a alimentos saludables en casa, incrementar el consumo de vegetales o reducir el de azúcares (Paixão et al., 2020), e implantar hábitos alimentarios basados en la dieta mediterránea (Lotfi et al., 2022; Muscogiuri et al., 2022), podría ayudar a prevenir el incremento de peso en esta población. Ninguna de las intervenciones aplicadas hasta la fecha ha incorporado ni adaptado tal variedad de técnicas para prevenir el incremento de peso. Finalmente, ninguno de los cinco estudios ha intervenido sobre la regulación emocional durante la deshabituación tabáquica, lo que podría podría facilitar el control del peso.

En cuarto lugar, a pesar de la extensa literatura disponible sobre la relación entre el consumo de tabaco y el peso corporal, los mecanismos explicativos de este binomio no están claros (Chao et al., 2019). Con respecto a los cambios en la conducta alimentaria, la evidencia es contradictoria. Si analizamos en conjunto los resultados de los estudios de laboratorio y de los estudios clínicos, mientras que seis estudios encontraron cambios en la conducta alimentaria tras dejar de fumar (e. g., incremento en el número de calorías ingeridas, el apetito, los niveles de alimentación emocional) (Anker et al., 2021; Killi et al., 2020; J. Kos et al., 1997; Levine et al., 2012; Spring et al., 2003; Yannakoulia et al., 2018), otros cinco no encontraron cambios (Alsene et al., 2003; Betts & Tiffany, 2019; Heggen et al., 2016; Lerman et al., 2004; Saules et al., 2004; Svendsen et al., 2021). Ninguno de estos estudios incluyó exclusivamente a población con sobrepeso u obesidad, que se caracteriza por mantener hábitos alimentarios inadecuados, como un mayor consumo de alimentos ultraprocesados (Askari et al., 2020), mayores niveles de ingesta emocional (Vasileiou & Abbott, 2023), saltarse el desayuno (Ma et al., 2020), comer rápido (Kolay et al., 2021), o más picoteos entre las comidas (Heriseanu et al., 2017), entre otros. Por lo tanto, es crucial analizar los cambios en la conducta alimentaria durante la deshabituación tabáquica y examinar el potencial efecto de esos cambios sobre la evolución del peso.

Con respecto al potencial efecto de otras variables, ningún estudio ha monitorizado la realización semanal de ejercicio durante la participación en un programa para dejar de fumar y su efecto en el cambio de peso. Dado que los fumadores con sobrepeso u obesidad realizan menos ejercicio que las personas que no fuman o que están dentro del rango del normopeso (Cassidy et al., 2017; Laredo-Aguilera et al., 2019), incrementar sus niveles de ejercicio y dilucidar su impacto sobre el peso corporal podría arrojar luz sobre cómo prevenir el incremento de peso en este grupo poblacional.

Tampoco hay, hasta donde se tiene constancia, estudios que hayan examinado los cambios en los patrones de sueño durante la deshabituación tabáquica en la población general ni en los individuos con exceso de peso particularmente. Los cambios en esta variable podrían explicar también por qué se produce el incremento de peso tras la cesación tabáquica.

OBJETIVOS

El objetivo general de la presente Tesis Doctoral fue evaluar la efectividad a corto y largo plazo de una terapia psicológica para dejar de fumar con un componente de prevención de la ganancia de peso dirigido a personas con sobrepeso u obesidad, cuyo protocolo puede consultarse en el Anexo situado al final del documento. Los objetivos específicos fueron:

1. Realizar un metaanálisis sobre la eficacia de las intervenciones conductuales para dejar de fumar que incluyen un componente de manejo del peso.
2. Evaluar la factibilidad y aceptabilidad de implementar una terapia psicológica (TCC) para dejar de fumar y prevenir la ganancia de peso dirigida a población con sobrepeso u obesidad combinada con un protocolo MC para dejar de fumar, así como su eficacia preliminar.
3. Analizar la eficacia de una terapia psicológica (TCC) para dejar de fumar y prevenir el incremento de peso dirigida a población con sobrepeso u obesidad en función de las tasas de abstinencia tabáquica, el cambio de peso, y los cambios en variables secundarias relacionadas con los hábitos alimentarios, la actividad física, y el bienestar psicológico al finalizar la terapia y en seguimientos realizados uno, tres, seis y doce meses después, así como examinar el efecto aditivo del MC para dejar de fumar en las variables anteriormente mencionadas.
4. Analizar los cambios en la conducta tabáquica (i.e., cotinina en orina y días de abstinencia continuada), la conducta alimentaria (i.e., picoteos de comida y

apetito), el ejercicio y el sueño ocurridos durante la terapia y su impacto en el cambio de peso.

PUBLICACIONES

La presente Tesis Doctoral se presenta mediante compendio de publicaciones, incluyendo cuatro estudios publicados en revistas internacionales con factor de impacto e indexadas en el *Journal Citation Reports* (JCR).

1. Effectiveness of including weight management in smoking cessation treatments: A meta-analysis of behavioral interventions

Referencia: García-Fernández, G., Krotter, A., González-Roz, A., García-Pérez, Á. y Secades-Villa, R. (2023). Effectiveness of including weight management in smoking cessation treatments: A meta-analysis of behavioral interventions. *Addictive Behaviors*, *140*, Artículo 107606. https://doi.org/10.1016/j.addbeh.2023.107606

Factor de impacto: 4,4; Q1, Substance Abuse (JCR 2022, SSCI).

Introduction: The potential of weight gain after smoking cessation reduces the incentive to quit. This meta-analysis examines the efficacy of behavioral interventions for smoking cessation that also address postcessation weight gain.

Methods: Medline, Web of Science, PsycINFO, and the Cochrane Central Register of Controlled Trials were searched for randomized controlled trials on behavioral treatments targeting both health outcomes. Six separate meta-analyses were undertaken to assess treatment efficacy on smoking abstinence and weight outcomes at end of treatment (EOT), short-term, and long-term follow-up. Individual and treatment moderators were examined as well as methodological quality and publication bias of studies.

Results: A total of 28 studies were included in the meta-analysis. There was a statistically significant positive impact of treatments addressing both targets on smoking outcomes at EOT (RR = 1.279, 95% CI: 1.096, 1.492, p = .002), but not at follow-ups. Age impacted on EOT abstinence rates Q (1) = 4.960, p = .026) while increasing the number of sessions significantly improved EOT abstinence rates (p = .020). There was no statistically significant impact of these treatments on weight at EOT (Hedges' g = - .015, 95% CI: - .164, .135, p = .849) or follow-ups (short term: Hedges' g = .055, 95% CI: - .060, .170, p = .347; long term: Hedges' g = - .320, 95% CI: - .965, .325, p = .331). There were minimal impacts of publication bias, mostly related to sample size, meaning studies including small sample sizes revealed larger effect sizes on abstinence at EOT.

Discussion: Addressing post-cessation weight management in treatments for smoking cessation significantly enhances tobacco abstinence at EOT though it was not found to have a lasting impact after treatment.

Addictive Behaviors 140 (2023) 107606

Contents lists available at ScienceDirect

Addictive Behaviors

journal homepage: www.elsevier.com/locate/addictbeh

Effectiveness of including weight management in smoking cessation treatments: A meta-analysis of behavioral interventions

Gloria García-Fernández *, Andrea Krotter, Alba González-Roz, Ángel García-Pérez, Roberto Secades-Villa

Department of Psychology, Addictive Behaviors Research Group, University of Oviedo, Plaza Feijoo S-N, Oviedo 33003, Spain

ARTICLE INFO

Keywords:
Smoking cessation
Weight gain
Behavioral interventions
Meta-analysis
Moderators

ABSTRACT

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Discussion: Addressing post-cessation weight management in treatments for smoking cessation significantly enhances tobacco abstinence at EOT though it was not found to have a lasting impact after treatment.

1. Introduction

Tobacco is the most commonly used substance worldwide and one of the main risk factors for diseases (World Health Organization, 2020). Though there is variability, extant literature demonstrates that smoking cessation is associated with an average increase of 4–5 kilograms (kg) (Aubin et al., 2012; Tian et al., 2015), and that concerns about potential weight gain are a substantial obstacle to quit attempts that may trigger relapse (Germeroth & Levine, 2018; Salk et al., 2019). Post-cessation weight gain weakens the beneficial effect of giving up smoking by reducing the cardiovascular diseases benefits resulting from quitting within the first year after smoking cessation (Chen et al., 2021). Research also demonstrates that the co-occurrence of smoking and excess weight increases health risks such as the likelihood of developing a chronic health condition (e.g., diabetes or obesity) (Bush et al., 2016; Hasegawa et al., 2019; Kos, 2020; Zhou et al., 2021) or a disability (Townsend & Mehta, 2020).

Weight gain during smoking cessation is thought to be attributed to the elimination of nicotine's ability to decrease appetite and increase metabolic rate (Chiolero et al., 2008; Collins et al., 1996; Jessen et al., 2005; Schmidt et al., 2019). Research also suggests that smoking cessation is associated with increased caloric intake mediated by complex behavioral, hormonal and neural mechanisms, such as shared neurobiological pathways between highly palatable foods and nicotine. These have been shown to underlie the relationship between smoking, eating and weight regulation (Anker et al., 2021; Audrain-McGovern & Benowitz, 2011; Cepeda-Benito, 2020; Chao et al., 2019; Gottfredson & Sokol, 2019). Further studies are needed to examine these mechanisms responsible for smoking cessation-related weight gain. Given the risks associated with post-cessation weight gain, strategies to limit it should

* Corresponding author at: Department of Psychology, University of Oviedo, Plaza Feijoo s/n, 33003 Oviedo, Spain.
E-mail address: garciafgloria@uniovi.es (G. García-Fernández).

https://doi.org/10.1016/j.addbeh.2023.107606
Received 30 March 2022; Received in revised form 29 December 2022; Accepted 3 January 2023
Available online 6 January 2023

be considered as part of any smoking cessation intervention (Chao et al., 2019; Chen et al., 2021; Kos, 2020; Salman & Doherty, 2020).

Meta-analyses that evaluate the effectiveness of interventions for both smoking cessation and weight control are scarce. Two meta-analyses published in 2009 (Spring et al., 2009) and 2012 (Farley et al., 2012) found that treatments that address both health outcomes were promising, however, conclusions were limited by the restricted number of high-quality studies available, the lack of data on long-term efficacy, and mixed results that required further confirmation. Additionally, a meta-analysis of the effectiveness of multiple risk behavior interventions suggested that there is a concern that targeting both health outcomes may undermine quitting (Meader et al., 2017). An update of Farley et al. (2012) meta-analysis, current up to October 2020 (Hartmann-Boyce et al., 2021), concluded that it is not clear which treatments work best to avoid gaining weight when stopping smoking, or how they affect smoking abstinence outcomes. Implications for research of this meta-analysis stressed that behavioral programmes are the mainstay for weight management and further studies are needed to clarify the evidence on whether they limit weight gain and impact on smoking abstinence (e.g., it was found that a personalized weight-management programme may reduce weight gain but a weight-management programme without personalized assessment, planning and feedback may not reduce weight gain, and may reduce the number of people who stop smoking). These findings suggest that focusing on behavioral interventions may help clarify whether targeting both health outcomes increases or decreases treatment outcomes.

However, this recent meta-analysis is not specifically focused on behavioral interventions and does not examine individual and treatment moderators. Moderators of smoking cessation interventions have been examined but the same has not been done yet with the moderators of treatments addressing both tobacco abstinence and post-cessation weight control (Black, Eisma, et al., 2020; Black, Johnston, et al., 2020; Secades-Villa et al., 2020). Black, Eisma, et al. (2020) found that higher smoking cessation rates are predicted by the provision of smoking cessation medication and the delivery of a greater number of behavior change techniques (BCTs). In the same line, Black, Johnston, et al. (2020) found that smoking cessation interventions with more BCTs are more effective than those with fewer BCTs, and three individual BCTs might be particularly effective for person-delivered interventions across populations and settings (prompting commitment, social reward, identity associated with changed behavior). Finally, Secades-Villa et al. (2020) found that the treatment setting moderated post-treatment smoking reduction outcomes among smokers with substance use disorders (SUD). In particular, compared to smokers with SUD undergoing outpatient treatment, those in residential settings attained lower smoking reductions.

By learning more about the active characteristics and individual moderators of smoking cessation treatments, we can provide better guidance on which treatments will result in best outcomes for different individuals. For example, Cepeda-Benito (1993) found that treatment intensity moderated the effectiveness of nicotine gum, particularly at long-term follow-up, and Cepeda-Benito et al. (2004) extended their previous findings by noting that, whereas men and women benefited from nicotine replacement therapy (NRT) at short-term follow-up, only men benefited from NRT at long-term follow-up.

The primary aim of this meta-analysis was to determine the effectiveness of behavioral interventions for both smoking cessation and post-cessation weight control at EOT, short-term follow-up (i.e., from EOT to $\leq$ 6-month follow-up), and long-term follow-up (i.e., $>$ 6 months). The secondary aim was to evaluate the influence of smoker characteristics and intervention-specific characteristics on treatment outcomes.

2. Material and methods

A systematic literature search of randomized controlled trials (RCTs), published before September 2021, was conducted according to PRISMA guidelines (Moher et al., 2009; Rethlefsen et al., 2021). The study was registered in PROSPERO (ref.: CRD42020144777).

2.1. Eligibility criteria and data sources

Multiple inclusion criteria were applied to the systematic search. Firstly, only RCTs on behavioral treatments targeting both smoking cessation and weight management in comparison to control or comparison conditions without weight management tested at both pre- and post-treatment were included. Studies involving behavioral treatments combined with pharmacotherapies (i.e., behavioral and pharmacological) were included only if identical pharmacotherapy was incorporated in both the experimental condition and control/comparison conditions. Secondly, participants had to be daily smokers and neither pregnant nor in the post-partum period. Thirdly, the studies were required to report data on both smoking cessation and weight change outcomes. Finally, English and Spanish language restrictions were used, date limit was not restricted and only studies published in peer review journals were included.

Studies were retrieved using Medical Subject Headings (MeSH) terms [(tobacco OR smok* cessation) AND (obesity OR weight OR overweight OR body mass index OR Quetelet OR waist-hip ratio) AND (management OR training OR treatment OR intervention OR therapy OR prevention)] in Medline, Web of Science, PsycINFO and the Cochrane Central Register of Controlled Trials (CENTRAL). Two authors independently (GGF and AK) conducted the screening of potentially eligible studies by verifying eligibility criteria and screening the title and abstract before completing a full text screen. Discrepancies were discussed with a third reviewer (AGR).

2.2. Meta-analytic approach

2.2.1. Treatment effectiveness

Comprehensive meta-Analysis (v 3.3.070) was used to meta-analyze smoking cessation and weight change. A total of six separate meta-analyses were performed. Three assessed treatment efficacy on smoking abstinence at end of treatment (EOT, $n = 25$), at short-term (i.e., from EOT to $\leq$ 6-month follow-up, $n = 20$; specifically, one at 4-week follow-up, four at 12 weeks, one at 13 weeks, three at 14 weeks, one at 20 weeks, one at 24 weeks, and nine at 26 weeks), and long-term follow-ups (i.e., $>$ 6 months, $n = 17$; two at 39-week follow-up, 13 at 52 weeks, and two at 60 weeks). The remaining three assessed treatment efficacy on weight changes: EOT ($n = 12$), at short ($n = 5$; specifically, one at 14 weeks follow-up, one at 20 weeks, and three at 26 weeks), and long term ($n = 5$; one at 39 weeks, three at 52 weeks, and another one at 60 weeks). Smoking abstinence was measured as either point-prevalence and/or continuous abstinence. Whenever studies provided both measures, continuous abstinence was used. Weight changes were defined as changes in weight at each of the assessed follow-up time points and converted into kg. Studies providing weight in abstinent-only participants were excluded from the meta-analyses to avoid potential bias (Chao et al., 2019).

Effectiveness of interventions on smoking abstinence was examined using the risk ratio (*RR*) with a 95% confidence interval (CI). In circumstances of zero-outcome events in one treatment condition, one unit was added to the corresponding event-count cell only to permit RR calculation in Stata (v14). The non-event-count cell was decreased by one to preserve the total sample size in each arm and avoid distorting results (Möller & Ahrenfeldt, 2021). Treatment effectiveness on weight management was estimated using Hedges' *g* values of 0.20, 0.50, and 0.80 and interpreted as small, medium, and large (Ellis, 2010).

Given the marked heterogeneity in smoking abstinence outcomes and interventions, a random effects model was adopted to meta-analyze outcomes. Cochran's *Q* and I^2 were calculated to characterize heterogeneity (i.e., $p = .10$) and interpreted as per Higgins et al. (2003)

guidelines: $I^2 \leq 25\%$ low heterogeneity, ~50% moderate heterogeneity and $\geq 75\%$ high heterogeneity across studies.

2.2.2. Moderator analyses

Whenever main significant effects emerged, we examined potential moderators at individual (i.e., sex coded as percentage of females; age; BMI; and nicotine dependence coded as continuous variables) and treatment level (i.e., treatment length: number of smoking cessation therapy sessions and total number of both tobacco + weight management sessions; treatment type coded binary: behavioral or cognitive-behavioral treatments [CBT] vs non-CBTs; weight management treatment type defined as categorical: exercise treatment vs those including counseling on diet only vs interventions focused on weight concerns only or addressing both exercise and diet). The *Q* statistic associated with the differences between groups in mixed effects analyses was used to examine systematic differences based on categorical variables. The mixed effects approach is akin to ANOVA and here was used to compare the group mean effects for two or more subgroups (i.e., independent variables). The mixed effects test estimates a mean effect size and standard error for each group. Thus, with k studies grouped into × mutually exclusive categories of the moderator variable, we can estimate the (average) effect size for each level of the moderator - and test for between-group differences. Meta-regressions were implemented for continuous moderators using a two-sided 95% confidence level ($p < .05$). Meta-regression is a statistical technique to examine how characteristics of studies are related to variation in effect sizes across studies. Meta-regression is analogous to regression analysis and, in our study, we used effect sizes (abstinence rates) as our outcomes, and information extracted from studies regarding sex, age, BMI, and nicotine dependence as moderators/predictors.

2.2.3. Methodological quality assessment and publication bias

Two independent reviewers (AK and AGP) assessed the methodological quality of the studies included using the Cochrane risk-of-bias tool RoB 2 (Sterne et al., 2019). Impact of publication bias was evaluated using the interpretation of the following tests as a whole (Begg & Mazumdar, 1994; Duval & Tweedie, 2000; Egger et al., 1997): 1) Egger's test evaluates the asymmetry of the funnel plot and suggests the absence of publication bias when the regression intercept is close to zero; 2) The Begg and Mazumdar rank indicator correlates the standardized effect size and its variance, with deviations from zero suggesting the presence of publication bias; 3) Duval and Tweedie's trim-and-fill aims to trim studies in the opposite direction of missing studies so that the trimmed meta-analysis is less affected by publication bias. For follow-up, we conducted a jackknife analysis by systematically leaving out each observation at a time so as to estimate bias from any particular study (Greenhouse & Iyengar, 1994). We also conducted a series of two-sided 95% confidence level meta-regressions to examine the effects of year of publication and sample size as potential sources of bias.

3. Results

A total of 18,775 articles were examined (see Fig. 1) and a full-text screening of 145 articles was performed. Although a total of 30 studies were initially selected, two of them (Prod'hom et al., 2013; Ussher et al., 2003) involved the same RCT as another two (Bize et al., 2010; Ussher et al., 2007) and, for this reason, were collapsed into two unique studies. Finally, 28 studies were included in the meta-analysis. Table 1 summarizes the studies included.

3.1. Participants' characteristics

The 28 studies involved 8,942 participants and the sample sizes ranged from 20 to 2,540 subjects. Participants were adults (76.54% females) with a mean age of 44.62 ($SD = 10.28$). The average number of cigarettes smoked per day was 21.17 ($SD = 8.67$), mean nicotine dependence was 5.43 ($SD = 2.37$), and mean body mass index (BMI) was 27.71 ($SD = 5.93$). Most of the studies (71.43 %) were aimed at specific populations, such as females (17/28; Albrecht et al., 1998; Bloom, Ramsey et al., 2020; Danielsson et al., 1999; Dunsiger et al., 2021; Kinnunen et al., 2008; Levine et al., 2010; Marcus et al., 1999; Marcus et al., 1991; Marcus et al., 1995; Marcus et al., 2005; Oncken et al., 2020; Perkins et al., 2001; Pirie et al., 1992; Spring et al., 2004; Vickers et al., 2009; Whiteley et al., 2012; Williams et al., 2010), sedentary individuals (10/28; Albrecht et al., 1998; Bize et al., 2010; Kinnunen et al., 2008; Marcus et al., 1991, 1995, 1999, 2005; Vickers et al., 2009; Whiteley et al., 2012; Williams et al., 2010), participants concerned with their weight (6/28; Bloom, Ramsey et al., 2020; Danielsson et al., 1999; Levine et al., 2010; Perkins et al., 2001; Pirie et al., 1992; Spring et al., 2004), participants with excess weight (1/28; White et al., 2019), participants that gained weight in previous quit attempts (1/28; Danielsson et al., 1999), smokers with cardiovascular risk (1/28; Jennings et al., 2014), and individuals with depression (1/28; Vickers et al., 2009).

3.2. Study and treatment characteristics

The majority of studies (75%, 21/28) were conducted in the USA and the remaining in Europe (Bize et al., 2010; Danielsson et al., 1999; Durmaz et al., 2019; Jennings et al., 2014; Leslie et al., 2012; Lycett et al., 2020; Ussher et al., 2007). Most of the studies implemented face-to-face treatments but four studies were conducted either via telephone calls (Bush et al., 2012, 2018), internet (i.e., web-based cognitive behavioral treatment) (White et al., 2019) or WhatsApp® (Durmaz et al., 2019).

Seven studies (25%) exclusively assessed the effect of behavioral interventions on smoking cessation (Albrecht et al., 1998; Hall et al., 1992; Marcus et al., 1991, 1995, 1999; Perkins et al., 2001; Spring et al., 2004) while the remaining 21 studies (75%) combined behavioral interventions with pharmacotherapy.

Strategies for post-cessation weight gain focused on four types of targets. While the majority incorporated physical activity or exercise (75%, 21/28; Albrecht et al., 1998; Bize et al., 2010; Bush et al., 2018; Ciccolo et al., 2011; Dunsiger et al., 2021; Durmaz et al., 2019; Hall et al., 1992; Jennings et al., 2014; Kinnunen et al., 2008; Leslie et al., 2012; Marcus et al., 1991; Marcus et al., 1995; Marcus et al., 1999; Marcus et al., 2005; Oncken et al., 2020; Pirie et al., 1992; Spring et al., 2004; Ussher et al., 2003; Vickers et al., 2009; Whiteley et al., 2012; Williams et al., 2010), some studies provided advice and reduced-fat meal plans meant to foster portion control and healthy eating (39.29%, 11/28; Albrecht et al., 1998; Bush et al., 2018; Danielsson et al., 1999; Durmaz et al., 2019; Hall et al., 1992; Jennings et al., 2014; Leslie et al., 2012; Lycett et al., 2020; Perkins et al., 2001; Pirie et al., 1992; Spring et al., 2004) and others targeted post-cessation weight concerns using CBT to minimize these concerns, encourage acceptance of moderate weight gain, and improve body dissatisfaction (14.29%, 4/28; Bush et al., 2012; Levine et al., 2010; Perkins et al., 2001; White et al., 2019). Finally, one study (3.57%) targeted distress tolerance, appetite awareness and mindful eating to manage weight concerns and emotional eating (Bloom, Ramsey et al., 2020).

Treatment length ranged from one to 53 sessions, with an average of 19.88 sessions in experimental conditions and 17.38 sessions in control or comparison conditions. With regard to follow-ups, three studies had no follow-up beyond EOT (Albrecht et al., 1998; Jennings et al., 2014; Leslie et al., 2012), eight studies had their follow-up sessions the furthest apart, between 4 and 26 weeks (Bloom, Ramsey et al., 2020; Bush et al., 2012; Ciccolo et al., 2011; Durmaz et al., 2019; Lycett et al., 2020; Vickers et al., 2009; White et al., 2019; Williams et al., 2010), while 17 studies had the biggest gap between EOT and follow-up, which took

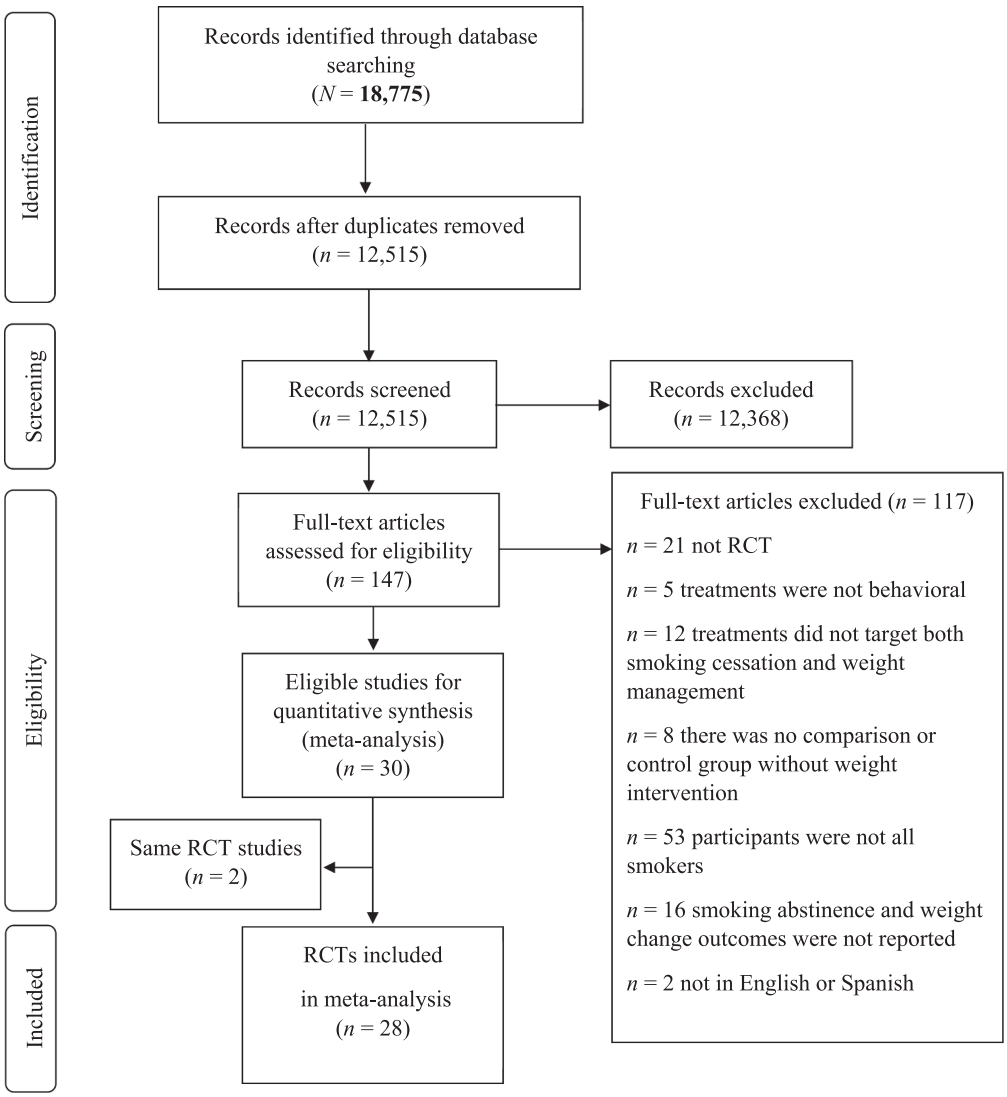

Fig. 1. Literature search procedure. *Note.* RCT = randomized controlled trial.

place between weeks 39 and 60 (Bize et al., 2010; Bush et al., 2018; Danielsson et al., 1999; Dunsiger et al., 2021; Hall et al., 1992; Kinnunen et al., 2008; Levine et al., 2010; Marcus et al., 1991, 1995, 1999, 2005; Oncken et al., 2020; Perkins et al., 2001; Pirie et al., 1992; Spring et al., 2004; Ussher et al., 2007; Whiteley et al., 2012).

3.3. Meta-analysis

3.3.1. Smoking abstinence outcomes

Figs. 2–3 display the forest plots on the treatment efficacy on abstinence outcomes at EOT and follow-ups. The meta-analysis at EOT evidenced a moderate magnitude heterogeneity (I^2 = 66.958%; Q = 72.634; $p < .001$) and the RR was estimated in 1.279 (range: 0.731–7.142) (95% CI: 1.096, 1.492, p = .002). This indicates that treatments that target both smoking cessation and weight management significantly increase the odds of abstinence at EOT (averaged % of abstinence: 33.85) relative to control or comparison conditions (averaged % of abstinence: 28.36).

An analysis by treatment type (n CBT = 14; n non-CBT interventions = 11) revealed no significant differences in the estimated effects (Q [1] = 0.691, p = .406). Interventions based on exercise (n = 12, RR = 1.171, 95% CI: 0.985–1.392, p = .073), weight concerns (n = 2, RR = 1.413, 95% CI: 0.681–2.935, p = .353) or both exercise plus diet (n = 7, RR = 1.250, 95% CI: 0.886–1.764, p = .204) did not reveal a significant impact on smoking abstinence, but those focused on dieting did (n = 2, RR = 1.423, 95% CI: 1.099–1.844, p = .007). Nonetheless, the total between effect was not statistically significant (Q [3] = 1.630, p = .653), which suggests no particular weight-management intervention had a better effect on post-treatment abstinence. Except for age (n = 24; Q [1] = 4.96, p = .026), none of the individual moderators (n female sex = 25, n nicotine dependence = 16, and n BMI = 18) had a statistically significant influence on EOT abstinence rates (all p values > 0.321). Of note is that the number of tobacco sessions did not significantly affect the abstinence rates (p = .547), but the total number of both tobacco and weight management sessions did (p = .021), thus demonstrating that more weight management sessions resulted in higher post-cessation smoking abstinence outcomes.

Meta-analyses at both short- and long-term follow-ups (see Fig. 3) showed no evidence of heterogeneity (short term: I^2 = 34.787%; Q = 29.135; p = .064, long term: I^2 = 26.636%; Q = 21.809, p = .149). Results revealed non-significant effects over time (short term: RR = 1.154, 95% CI: 0.979, 1.360, p = .088; long term: RR = 1.050, 95% CI: 0.899, 1.227, p = .539). Averaged percentage of abstinence in intervention arms was 19.87 at short and 16.89 at long term, respectively. Comparison conditions evidenced 14.80% and 14.72% of abstinence at each time-frame assessment.

Table 1
Study characteristics.

Author (year)	Sample size (% female)	Age Mean ± *SD*	CPD Mean ± *SD*	FTND Mean ± *SD*	BMI Mean ± *SD*	Setting (Country)	Conditions (experimental vs control)	Treatment length (*n* sessions)	Longest follow-up
Albrecht et al. (1998)	109 (100)	41±9	22±9	6±2	26±5	Hospital (USA)	SE + DC vs CC (both with CBTSC)	48	EOT
Bize et al. (2010)	481 (43)	42.2 ±10.1	27±10.2	5.4±2.2	24.49 ±3.98	University (Switzerland)	SE vs HE (both with CBTSC[a])	1	52 weeks
Bloom, Ramsey et al. (2020)	69 (100)	49.6 ±12.4	16.1±6.8	4.81±2.29	31.41 ±6.8	USA	Distress Tolerance + Appetite Awareness + Mindful Eating Skills vs HE (both with CBTSC[a])	9	26 weeks
Bush et al. (2012)	2000 (77)	41.3	At least 5 cigarettes	–	30.4 ±7.2	Helpline (USA)	CBTWC + SCC[a] vs SCC[a]	8 vs 5	26 weeks
Bush et al. (2018)	2540 (65.8)	43.2 ±12.2	20±8.3	–	30 ±7.11	Quit line (USA)	Sequential Weight Talk® (PAC + DC) vs Simultaneous Weight Talk® (PAC + DC) vs CC (all three with SCC[a])	10	52 weeks
Ciccolo et al. (2011)	25 (52)	36.5±12	18±10.1	4 ± 2.6	–	USA	Resistance Training (SE) vs HE (both with SCC[a])	25	26 weeks
Danielsson et al. (1999)	287 (100)	46.8 ±6.9	19.5±7.5	5.8 ± 1.9	26.8 ±2.2	Hospital (Sweden)	Very Low Energy Diet + SCC[a] vs SCC[a]	13 vs 11	52 weeks
Dunsiger et al. (2021)	105 (100)	42.5 ±11.2	17±7.7	–	27.65 ±5.2	USA	SE + SCC vs HE + SCC	36	52 weeks
Durmaz et al. (2019)	132 (39.4)	18–24: 13 25–34: 41 35–44: 32 45–54: 30 +55: 16	<10: 14; 11–20: 64; 11–30: 32; > 30: 22	Low: 14 Medium: 89 High: 29	–	University Clinic and WhatsApp Messenger (Turkey)	WhatsApp Messages (DC + PAC + SC) + SCC vs SCC (both with Motivational Interview[a, b, or c])	1	13 weeks
Hall et al. (1992)	158 (73)	40.3 ±8.8	27.4±11.7	–	–	USA	DC and Diet Plan + EC and Exercise Plan + Eating Self-Management vs Nonspecific Control vs Standard Control (all three with Aversive Therapy + Relapse Prevention)	–	52 weeks
Jennings et al. (2014)	696 (40)	59.9 ±6.7	19.6±8.9	–	–	Hospitals (Italy, Spain, UK, and Netherlands)	Euroaction Plus (DC + PAC + SCC[a or b]) vs Advice and Referral to Local Service	–	EOT
Kinnunen et al. (2008)	182 (100)	38.4 ±9.6	18.5±8.5	4.86±2.33	26.0 ±5.5	Hospital (USA)	SE vs Standard Care Control vs CC (all three with SCC[a])	24	52 weeks
Leslie et al. (2012)	138 (74.5)	50	25.2±11.4	–	28.2 (5.3)	Community-Based Services (UK)	DC + PAC vs Usual Care (both with SCC[a or b])	10 vs 7	EOT
Levine et al. (2010)	349 (100)	42±10.1	20.7±8.4	5.2±2.2	27.3 ±5.5	USA	CBTWC [b] vs CBTWC + Placebo vs CC [b] vs CC + Placebo (all with SCC)	12	39 weeks
Lycett et al. (2020)	76 (60.50)	46.7 ±13.5	–	5.7±2.1	30.4 ±5.3	Primary Care Services (UK)	Slimming World Program (DC) + BSC[a or c] vs BSC[a or c])	18 vs 6	14 weeks
Marcus et al. (1991)	20 (100)	39±8.5	23±9	–	–	USA	SE + BSC vs BSC	53 vs 8	52 weeks
Marcus et al. (1995)	20 (100)	37.5±9	23±9	–	–	USA	SE vs. HE (both with BSC)	53	52 weeks
Marcus et al. (1999)	281 (100)	40.1 ±8.92	22.1±9.3	6.2±1.9	25.4 ±4.9	USA	Supervised Vigorous Exercise vs HE (both with CBTSC)	48	60 weeks
Marcus et al. (2005)	217 (100)	42.7 ±10.3	20.6±9.3	4.8±2.3	26.2 ±5.5	Hospital (USA)	Supervised and Home-Based Moderate-Intensity Exercise Training vs HE (both with CBTSC[a])	16	52 weeks
Oncken et al. (2020)	301 (100)	55.8 ±6.2	18.9±7.5	5.3±1.9	28.5 ±6.4	Universities (USA)	SE vs Relaxation (both with SCC [c])	30	60 weeks
Perkins et al. (2001)	219 (100)	44.5 ±9.9	21.7±9.4	5.0±2.1	25.6 ±4.9	USA	CBTWC vs DC vs CC (all three with CBTSC)	10	52 weeks
Pirie et al. (1992)	417 (100)	43.15	26.2	–	24.1	Clinic (USA)	PAC + DA vs. PAC + DA[a] (both with CBTSC) vs. CBTSC[a] vs. CBTSC	7	52 weeks
Spring et al. (2004)	315 (100)	42.6 ±10.3	20.3±9.4	5.9±1.9	27.4 ±5.4	Universities, Medical School, and Medical Center (USA)	Early Diet (DC + Meal Plan) + PAC vs Late Diet (DC + Meal Plan) + PAC vs CC (all three with CBTSC)	16	39 weeks
Ussher et al. (2007)	299 (62.9)	42.9 ±11.1	21.9±8.9	5.5±2.0	25.5 ±3.6	Clinic (UK)	EC vs HE (both with CBTSC[a])	6	52 weeks
Vickers et al. (2009)	60 (100)	41.3 ±11.9	20.8±7.5	5.9±2.3	–	USA	EC vs HE (both with SCC[a])	10	14 weeks
White et al. (2019)	54 (72.2)	45.9 ±10.5	19.7±8.5	–	33.2 ±6.3	Website (USA)	Online CBTWC vs Online HE (both with Online CBTSC[a])	12	12 weeks
Whiteley et al. (2012)	330 (100)	43.5 ±9.9	17.4±7.1	5.1±2.1	28.2 ±5.8	YMCAs (USA)	SE vs CC (both with CBTSC[a])	16	52 weeks
Williams et al. (2010)	60 (100)	42.3 ±11.5	<10: 14; 11-20: 31; 21-30: 11; > 31: 4	4.8±2.2	–	Research Center (USA)	SE vs HE (both with SCC[a])	25	4 weeks

Note. *SD* = standard deviation; CPD = cigarettes per day; FTND = Fagerström Test for Nicotine Dependence; BMI = body mass index; USA = United States of America; SE = supervised exercise; DC = diet counseling; CC = contact control; CBTSC = cognitive-behavioral therapy for smoking cessation; EOT = end of treatment; HE = health education; CBTWC = cognitive-behavioral therapy for weight concerns; SCC = smoking cessation counseling; PAC = physical activity counseling; EC = exercise counseling; BSC = behavioral smoking cessation treatment; UK = United Kingdom; YMCAs = Young Men's Christian Association.
[a] nicotine replacement therapy, [b] bupropion, [c] varenicline.

3.3.2. Weight change outcomes

There were no statistically significant impacts of smoking cessation treatments plus weight management on weight changes at EOT (Hedges' $g = -0.015$, 95% CI: −.164, 0.135, $p = .849$, see Fig. 4) or follow-ups (short term: Hedges' $g = 0.055$, 95% CI: −.060, 0.170, $p = .347$; long term: Hedges' $g = -0.320$, 95% CI: −.965, 0.325, $p = .331$, see Fig. 5).

Minimal and no heterogeneity was evinced at EOT and short term, respectively (EOT: $I^2 = 33.161\%$; $Q = 16.457$; $p = .125$; short term: $I^2 < 0.001$; $Q = 1.545$; $p = .819$). These latter results contrasted with the markedly high heterogeneity at long term: $I^2 = 96.564\%$; $Q = 116.424$, $p < .001$).

3.3.3. Assessment of methodological quality and publication bias

Nineteen of the 28 studies presented some concerns about the risk of bias and the remaining studies (9/28) presented a high risk of bias (see Table 2).

Table 3 informs on publication bias on the estimated effect sizes by study outcome and time-frame assessment. Overall, there was moderate publication bias for smoking abstinence outcomes and minimal evidence of it for the effect sizes on weight outcomes. In regard to smoking abstinence, none, except for Egger's test for short- and long-term abstinence, were significant. This suggests potentiality of larger effect sizes in smaller studies, which was further confirmed by the significant moderating effects of sample size on short-term abstinence outcomes. As per Tweedie's trim and fill approach, it suggested two potentially missing studies for EOT abstinence effect sizes. However, trimmed estimates did not show any variation in the estimated effects. Year of publication did not impact on smoking abstinence and weight outcomes at any follow-up assessment. A follow-up jackknife analysis revealed the substantial impact of several studies on estimated effect sizes (see Table 4). Jackknife analyses suggested some influential cases for smoking cessation outcomes and lower influence of bias on weight outcomes. For EOT smoking abstinence, changes in estimates between the overall analyses and the jackknife approach were substantial for Jennings et al. (2014) (ES difference = 1.230), Marcus et al. (1991) (ES difference = 5.884), Marcuset al. (1995) (ES difference = 1.727), and White et al. (2019) (ES difference = 1.401). For short-term abstinence, variations in estimates were higher for Marcus et al. (1991) (ES difference = 3.150), Marcus et al. (1995) (ES difference = 1.853), and White et al. (2019) (ES difference = 1.196). At long term, the greatest deviations were observed in Dunsiger et al. (2021) (ES difference = 2.013), Marcus et al. (1991) (ES difference = 1.812), Marcus et al. (1995) (ES difference = 1.957), and Marcus et al. (1999) (ES difference = 1.186). Minimal impacts were detected for weight outcomes, with the only exception being observed in the Marcus et al. (1991) study (ES difference = −1.281).

4. Discussion

Including weight management in smoking cessation treatments did not have an impact on weight change but revealed a more favorable smoking abstinence response at EOT (33.85%) than treatments for quitting smoking without weight management (28.36%). Nonetheless, positive effects reduced over time, revealing an average decrease of 16% in smoking abstinence effects. Despite the short-term effectiveness of smoking cessation treatments with weight management for improving smoking abstinence rates at EOT, results were no longer significant at follow-ups, suggesting no additive effects on smoking abstinence rates after treatment termination.

In line with previous meta-analysis (Farley et al., 2012; Hartmann-Boyce et al., 2021; Spring et al., 2009) but in contrast with others (Meader et al., 2017) concluding that it may not be optimal to target smoking simultaneously with other risk behaviors, the present study found that there was no evidence to suggest that adding a weight management component worsened smoking cessation outcomes. In fact, it seems that adding a weight component to a smoking cessation intervention improves smoking cessation outcomes at EOT, but that such effect is short lived, and likely an artifact of increasing the intensity or attention provided to the individuals in treatment. The maintenance of outcomes following the discontinuation of treatment in tobacco and

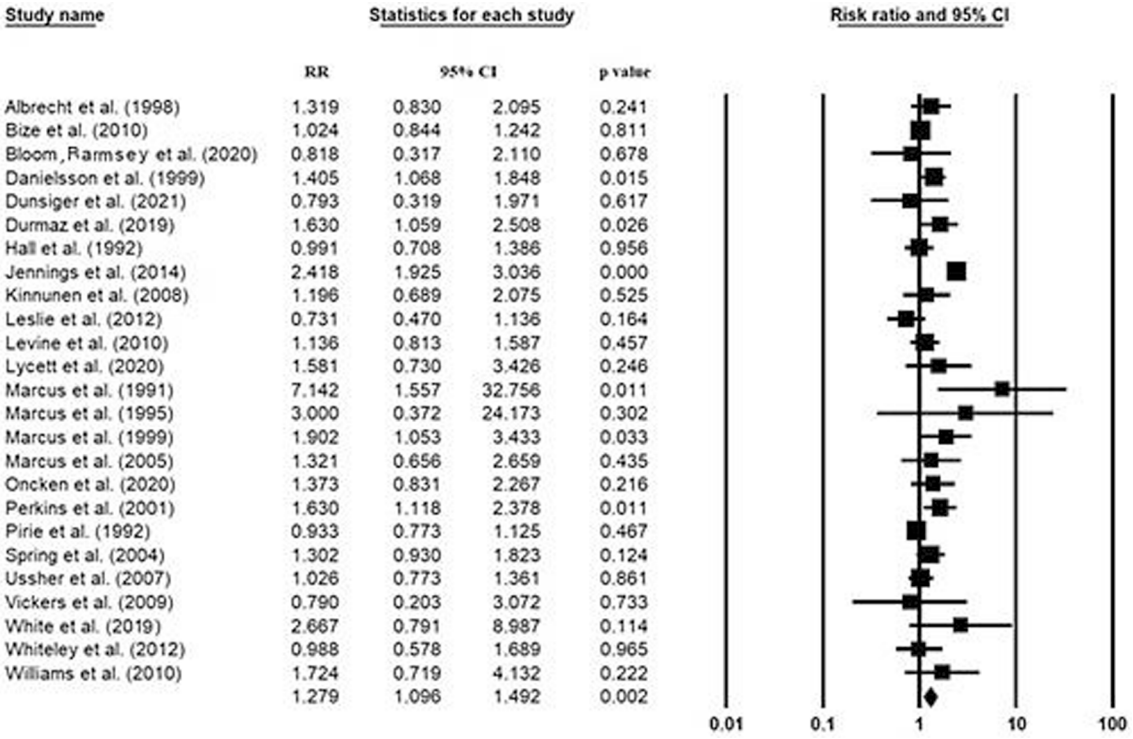

Fig. 2. Forest plots on the efficacy of smoking cessation treatments over smoking abstinence at the end of treatment (EOT). *Note.* RR = Risk ratio.

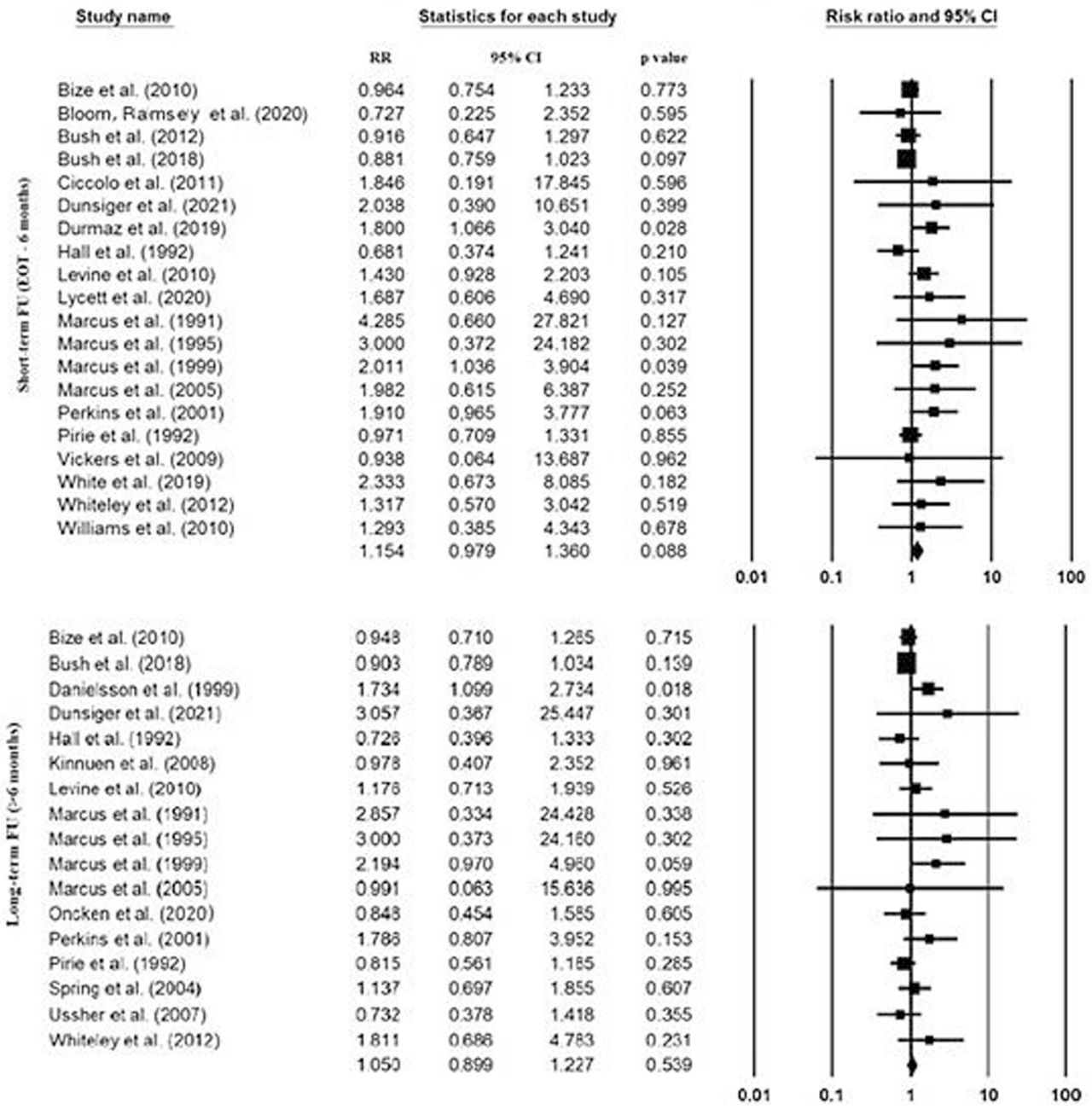

Fig. 3. Forest plots on the efficacy of smoking cessation treatments over smoking abstinence at short- (i.e., from end of treatment to 6 months) and long-term (i.e., from 6 months) follow-ups. *Note.* RR = Risk ratio; FU = follow-up; EOT = end of treatment.

obesity fields is a challenging priority (Paixao et al., 2020). Research highlights the importance of investigating which combinations of techniques lead to higher rates of smoking cessation (Black, Johnston, et al., 2020) and successful weight management (Nordmo et al., 2020; Samdal et al., 2017).

Age was the only individual moderator tested that significantly affected smoking abstinence at EOT, indicating better abstinence outcomes for older individuals. Therefore, the use of treatments targeting both health outcomes seems generalizable among individuals of both sexes, different BMI or nicotine dependence; however, youth-friendly treatments are required to improve quitting among young adults (Dono et al., 2020; Fanshawe et al., 2017; Orsal & Ergun, 2021; Villanti et al., 2020). Further, treatment length was the only moderator tested that significantly impacted smoking abstinence at EOT, showing that an increasing number of treatment sessions led to improved post-treatment smoking abstinence outcomes. It is worth noting that average treatment length was high, with an average of 19.88 sessions in treatments for smoking cessation with weight management and 17.38 sessions in treatments without weight management (de Bruin et al., 2021).

Regarding weight change outcomes, meta-analysis revealed that adding weight management into smoking cessation treatments did not show statistically significant effects. Nevertheless, these results should

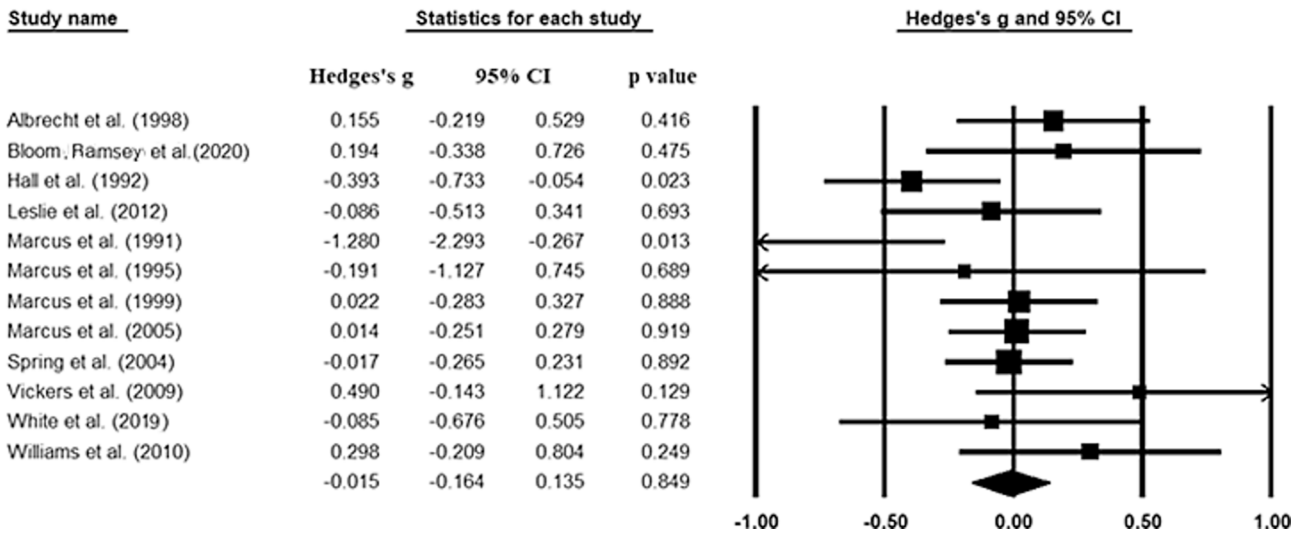

Fig. 4. Forest plots on the efficacy of smoking cessation treatments on weight gain at the end of treatment (EOT).

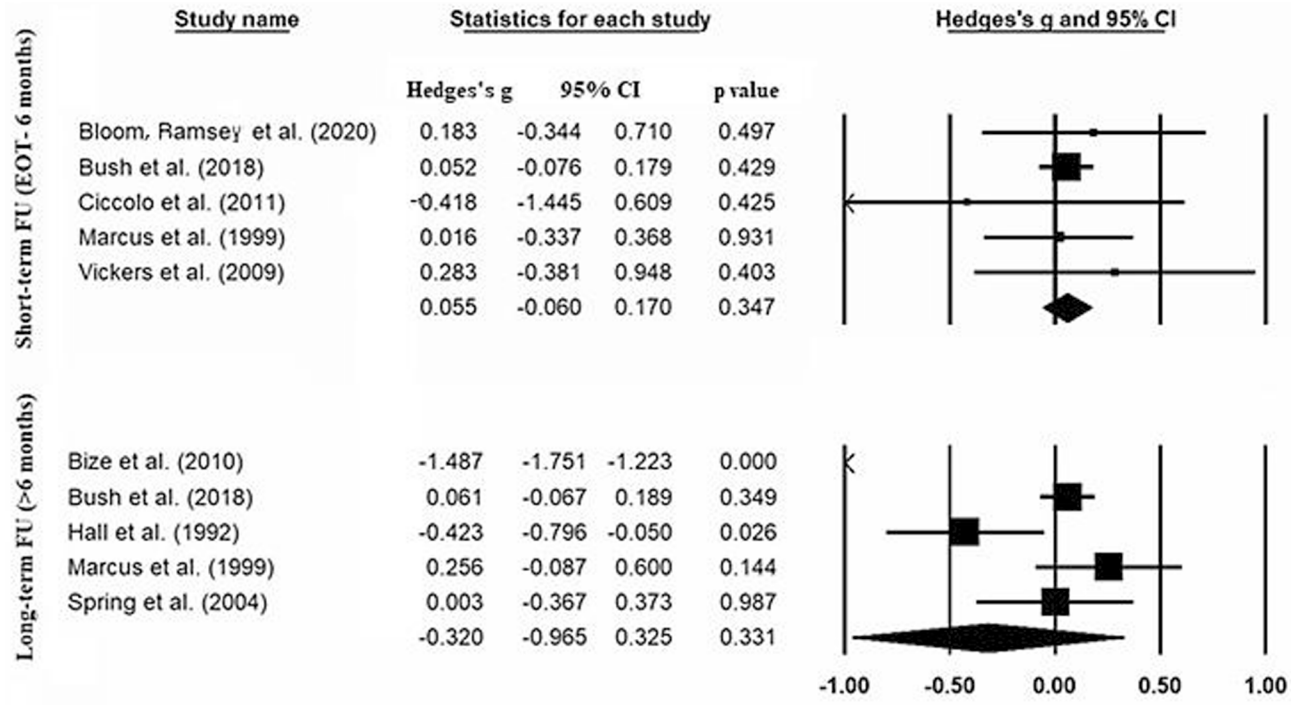

Fig. 5. Forest plots on the efficacy of smoking cessation treatments on weight gain at short- (i.e., from end of treatment to 6 months) and long-term (i.e., from 6 months) follow-ups. *Note.* FU = follow-up; EOT = end of treatment.

Table 2
Methodological quality summary (Cochrane risk-of-bias tool RoB 2).

Author (year)	Randomization process	Deviations from the intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result	Overall risk-of-bias judgement
Albrecht et al. (1998)	Some concerns	High	High	Low	Low	High
Bize et al. (2010)	Low	High	Low	Low	Low	High
Bloom, Ramsey et al. (2020)	Low	Some concerns	Some concerns	Low	Some concerns	Some concerns
Bush et al. (2012)	Low	Low	Some concerns	Low	Low	Some concerns
Bush et al. (2018)	Low	Some concerns	Low	Low	Low	Some concerns
Ciccolo et al. (2011)	Low	Some concerns	Some concerns	Low	Some concerns	Some concerns
Danielsson et al. (1999)	Low	Some concerns	Some concerns	Low	Some concerns	Some concerns
Dunsiger et al. (2021)	Low	Some concerns	Some concerns	Low	Some concerns	Some concerns
Durmaz et al. (2019)	Low	Some concerns	Low	High	Low	High
Hall et al. (1992)	Some concerns	Some concerns	Low	Low	Some concerns	Some concerns
Jennings et al. (2014)	Low	Some concerns	Low	High	Low	High
Kinnunen et al. (2008)	Some concerns	High	Low	Low	Some concerns	High
Leslie et al. (2012)	Low	Some concerns	Some concerns	Low	Some concerns	Some concerns
Levine et al. (2010)	Low	Low	High	Low	Low	High
Lycett et al. (2020)	Low	Some concerns	Some concerns	Low	Low	Some concerns
Marcus et al. (1991)	Some concerns	High	Low	Low	Some concerns	High
Marcus et al. (1995)	Some concerns	Some concerns	Some concerns	Low	Some concerns	Some concerns
Marcus et al. (1999)	Low	Some concerns	Some concerns	Low	Low	Some concerns
Marcus et al. (2005)	Low	Some concerns	Low	Low	Low	Some concerns
Oncken et al. (2020)	Low	Some concerns	Low	Low	Low	Some concerns
Perkins et al. (2001)	Some concerns	Some concerns	High	Low	Some concerns	High
Pirie et al. (1992)	Some concerns	Some concerns	Low	Low	Some concerns	Some concerns
Spring et al. (2004)	Some concerns	Some concerns	Low	Low	Some concerns	Some concerns
Ussher et al. (2007)	Low	Some concerns	High	Low	Some concerns	High
Vickers et al. (2009)	Low	Some concerns	Some concerns	Low	Some concerns	Some concerns
White et al. (2019)	Some concerns	Some concerns	Low	Low	Some concerns	Some concerns
Whiteley et al. (2012)	Low	Some concerns	Low	Low	Low	Some concerns
Williams et al. (2010)	Low	Some concerns	Some concerns	Low	Some concerns	Some concerns

Note. Cochrane risk-of-bias tool RoB 2 comprises five domains and yields an overall risk of bias judgement (low/high/some concerns) regarding reviewers' scores on: 1) the randomization process, 2) deviations from intended interventions, 3) missing outcome data, 4) bias in outcome measurement, and 5) bias in selection of the reported result. Low bias is considered when no bias exists for all of the domains, some concerns are deemed if concerns are raised on at least one domain, but there is no high risk of bias for any domain. High risk of bias is considered when concerns are raised for at least one domain, or if the study is judged to have some concerns for multiple domains.

Table 3
Publication bias outcomes.

Follow-up assessment	Begg-Mazumdar test		Egger's regression analysis			Tweedie's trim and fill approach			Year of publication				Sample size			
	Kendall's τ	*p*	Intercept	95% CI	*p*	N trimmed	ES	95% CI	Coefficient	SE	95 % CI	*p*	Coefficient	SE	95 % CI	*p*
Smoking abstinence																
EOT	0.196	0.168	0.624	-0.798, 2.047	0.373	2	1.253	1.071, 1.465	0.002	0.008	-0.015, 0.019	0.803	0.0003	0.0005	-0.0006, 0.0012	0.512
Short term	0.110	0.495	0.198	0.530, 1.866	**0.001**	NA	NA	NA	0.001	0.009	-0.016, 0.019	0.887	-0.0002	0.0001	-0.0003, <-0.001	**0.010**
Long term	0.272	0.127	0.947	0.164, 1.729	**0.020**	NA	NA	NA	-0.005	0.008	-0.023, 0.011	0.527	-0.001	0.0001	-0.0004, 0.0001	0.228
Weight gain																
EOT	-0.045	0.837	-0.361	-0.253, 1.807	0.718	NA	NA	NA	0.016	0.008	-0.0005, 0.034	0.057	-0.0001	0.0009	-0.0018, 0.0016	0.902
Short term	<0.001	1.00	-0.012	−1.615, 1.590	0.982	NA	NA	NA	0.002	0.009	-0.017, 0.021	0.839	<-0.001	0.0001	-0.0001, 0.0001	0.878
Long term	-0.300	0.462	−3.625	−22.508, 15.256	0.584	NA	NA	NA	-0.008	0.046	-0.098, 0.082	0.861	0.0002	0.0006	-0.001, 0.001	0.740

Note. NA = Not applicable. Note that Tweedie's trim and fill approach was only computed for significant effect sizes as this procedure estimates the number of potentially missing studies that would bring *p* values to non-significant. EOT = end of treatment; Short term = from EOT to 6-month follow up (FU); Long term = > 6-month FU

be interpreted with caution because there is a great heterogeneity in weight interventions and only half of the studies objectively weighed participants. Furthermore, only five studies were included in short- and long-term weight change meta-analyses, and involved follow-ups with heterogeneous temporal points (specifically, one study at 14 weeks, another at 20 weeks, and three studies at 26 weeks at short-term; and one study at 39 weeks, three at 52 weeks, and one at 60 weeks at long-term). Another important limitation is that most of the studies focused on women.

It is worth mentioning that none of the studies in the meta-analysis addressed diet, physical activity, and weight concerns simultaneously, and only one addressed emotional eating (Bloom et al., 2017). Moreover, while one recent study explored dual contingency management (CM) in which both smoking cessation and weight maintenance were incentivized(Bloom, Hunt et al., 2020), no study included in our meta-analysis explored the effect of CM. As CM is a well-established treatment for smoking (Cahill et al., 2015) and a promising approach for weight control (Ellis et al., 2021), the lack of inclusion of studies that used CM leaves out an important part of the picture when looking at treatments for smoking cessation.

Taken together, these results suggest that clinicians should assess and provide weight management strategies regularly while undergoing smoking cessation. Routine assessment of weight (Corbaton Anchuelo et al., 2019), weight concerns (Germeroth & Levine, 2018), diet, physical activity and disordered eating (Durrer Schutz et al., 2019; Paixao et al., 2020; Zhu et al., 2022) before, during and after quitting could be useful. This is especially important for participants who are at risk of health problems if they suffer weight gain (Chen et al., 2021). Just one of the studies included was aimed at participants with excess weight (White et al., 2019) and one focused on those with cardiovascular risk (Jennings et al., 2014). Some recent studies assessing smokers with specific risk profiles include those with diabetes (Martinez et al., 2020) or those attending cardiac rehabilitation (Salman & Doherty, 2020).

Despite this meta-analysis providing a comprehensive assessment of the effectiveness and moderators of behavioral treatments for smoking cessation and post-cessation weight management, the findings should be considered within the context of their limitations. Although 28 studies were included in the meta-analysis, no study was classified as low risk of bias. Further, most of the studies included females (76.8%) and the nature of the smoking cessation and weight management interventions, the time frames of assessments, and the metrics for abstinence and weight were heterogeneous and thus limited the interpretation of the intervention effects (Black, Johnston, et al., 2020). Additionally, several of the moderation analyses comprised a limited set of studies (e.g., two), although the use of large sample sizes across studies warrants sufficient power to detect meaningful effects.

4.1. Conclusions

The results of this study provide evidence on the effectiveness of addressing post-cessation weight gain in smoking cessation treatments for facilitating tobacco abstinence at EOT. However, it is not certain which behavioral interventions specifically work best to achieve smoking abstinence and prevent post-cessation weight gain. Future studies should aim to improve efficacy to stop smoking and limit weight gain for younger individuals and for populations at risk if they gain weight.

5. Author agreement statement

The submitted manuscript contains no data or other material or results that have been published or are in press or submitted elsewhere. All authors have been actively involved in substantive work leading to the report and have approved the final manuscript. No conflicts of interest are declared.

Table 4
Jackknife analyses outcomes.

Follow-up assessment	Range of estimated RR effects (random effects model)	Range of CI 95%		Range of estimated RR effects (jackknife analyses)	Range of CI 95%	
		Lower limit	Upper limit		Lower limit	Upper limit
Smoking abstinence						
EOT	0.731, 7.142	0.203, 1.925	1.125, 32.756	1.188, 1.313	1.060, 1.125	1.331, 1.534
Short term	0.068, 4.285	0.064, 1.066	1.023, 27.821	1.094, 1.214	0.937, 1.018	1.277, 1.471
Long term	0.726, 3.057	0.063, 1.099	1.034, 25.447	0.957, 1.103	0.856, 0.919	1.070, 1.323
Weight gain						
EOT	−1.280, 0.490	−2.293, −0.143	−0.267, 1.122	−0.038, 0.033	−0.195, −0.099	0.107, 164
Short term	−0.418, 0.283	−1.445, −0.076	0.179, 0.948	0.048, 0.069	−0.190, −0.054	0.164, 0.329
Long term	−1.487, 0.256	−1.751, −0.067	−1.223, 0.600	−0.462, −0.005	−1.269, −0.234	0.224, 0.493

Note. RR = risk ratio; EOT = end of treatment; Short term = from EOT to 6 month follow-up (FU) ; Long term = > 6-month FU.

6. Role of funding source

Funding for this study was provided by the Spanish Ministry of Science and Innovation, the State Research Agency and the European Regional Development Fund [Grant number RTI2018-101465-A-100] and a predoctoral grant from the Government of the Principality of Asturias [Grant number PA-21-PF-BP20-015].

CRediT authorship contribution statement

Gloria García-Fernández: Conceptualization, Funding acquisition, Project administration, Investigation, Methodology, Resources, Writing – original draft. **Andrea Krotter:** Investigation, Methodology, Writing – original draft. **Alba González-Roz:** Formal analysis, Methodology, Writing – original draft. **Ángel García-Pérez:** Investigation, Formal analysis. **Roberto Secades-Villa:** Funding acquisition, Supervision.

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

No data was used for the research described in the article.

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

Referencia: García-Fernández, G., Krotter, A., García-Pérez, Á., Aonso-Diego, G. y Secades-Villa, R. (2022). Pilot randomized trial of cognitive-behavioral treatment plus contingency management for quitting smoking and weight gain prevention among smokers with overweight or obesity. *Drug and Alcohol Dependence, 236*, Artículo 109477. https://doi.org/10.1016/j.drugalcdep.2022.109477

Factor de impacto: 4,2; Q2, Substance Abuse (JCR 2022, SSCI).

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_{age} = 52.73, *SD* = 10.91, 56.1% females) with overweight or obesity (M_{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.

Drug and Alcohol Dependence 236 (2022) 109477

Contents lists available at ScienceDirect

Drug and Alcohol Dependence

journal homepage: www.elsevier.com/locate/drugalcdep

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

Gloria García-Fernández *, Andrea Krotter, Ángel García-Pérez, Gema Aonso-Diego, Roberto Secades-Villa

Department of Psychology, Addictive Behaviours Research Group, University of Oviedo, Plaza Feijoo S-N, Oviedo 33003, Spain

ARTICLE INFO

Keywords:
Obesity
Smoking cessation
Weight gain
Cognitive-behavioral treatment
Contingency management
Clinical trial

ABSTRACT

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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

* Correspondence to: Department of Psychology, University of Oviedo, Plaza Feijoo s/n, Oviedo 33003, Spain.
E-mail address: garciafgloria@uniovi.es (G. García-Fernández).

https://doi.org/10.1016/j.drugalcdep.2022.109477
Received 24 January 2022; Received in revised form 20 April 2022; Accepted 21 April 2022
Available online 29 April 2022

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) ≥25.≥ 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 (nº 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 1
Baseline 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 (10.91)	52.18 (6.92)	53.13 (13.17)	.508
Marital status (married, *n*/%)	19 (46.3%)	8 (47.1%)	11 (45.8%)	1
Educational level (≤ 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 (US$)[a]	2885.1 (2200.12)	3436.75 (3301.72)	2517.33 (863.38)	.890
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 smoking[a]	30.31 (10.64)	31.12 (7.31)	29.73 (12.61)	.624
Previous quit attempts[a]	3.02 (2.2)	3.18 (2.7)	2.92 (1.82)	.893
Smoking stage of change (*n*/%)				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 (10.43)	19.88 (13.96)	.397
Cotinine (ng/ml)[a]	2002.55 (1140.74)	2045.43 (1054.23)	1972.18 (1219.68)	.691
Age of excess weight onset[a]	30.75 (12.29)	31 (11.02)	30.56 (13.39)	.679
Years of IMC ≥ 25[a]	23.12 (16.40)	26.85 (21.43)	20.44 (11.51)	.617
Previous diet attempts[a]	4.51 (6.75)	3.53 (5.7)	5.21 (7.44)	.419
Body weight dissatisfaction (*n*/%)	34 (82.9)	14 (82.4)	20 (83.3)	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 (14.12)	87.62 (14.61)	90.44 (13.96)	.751
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 ad-hoc 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 $\leq$ 4 ppm and urine cotinine levels $\leq$ 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 (p*roposals 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

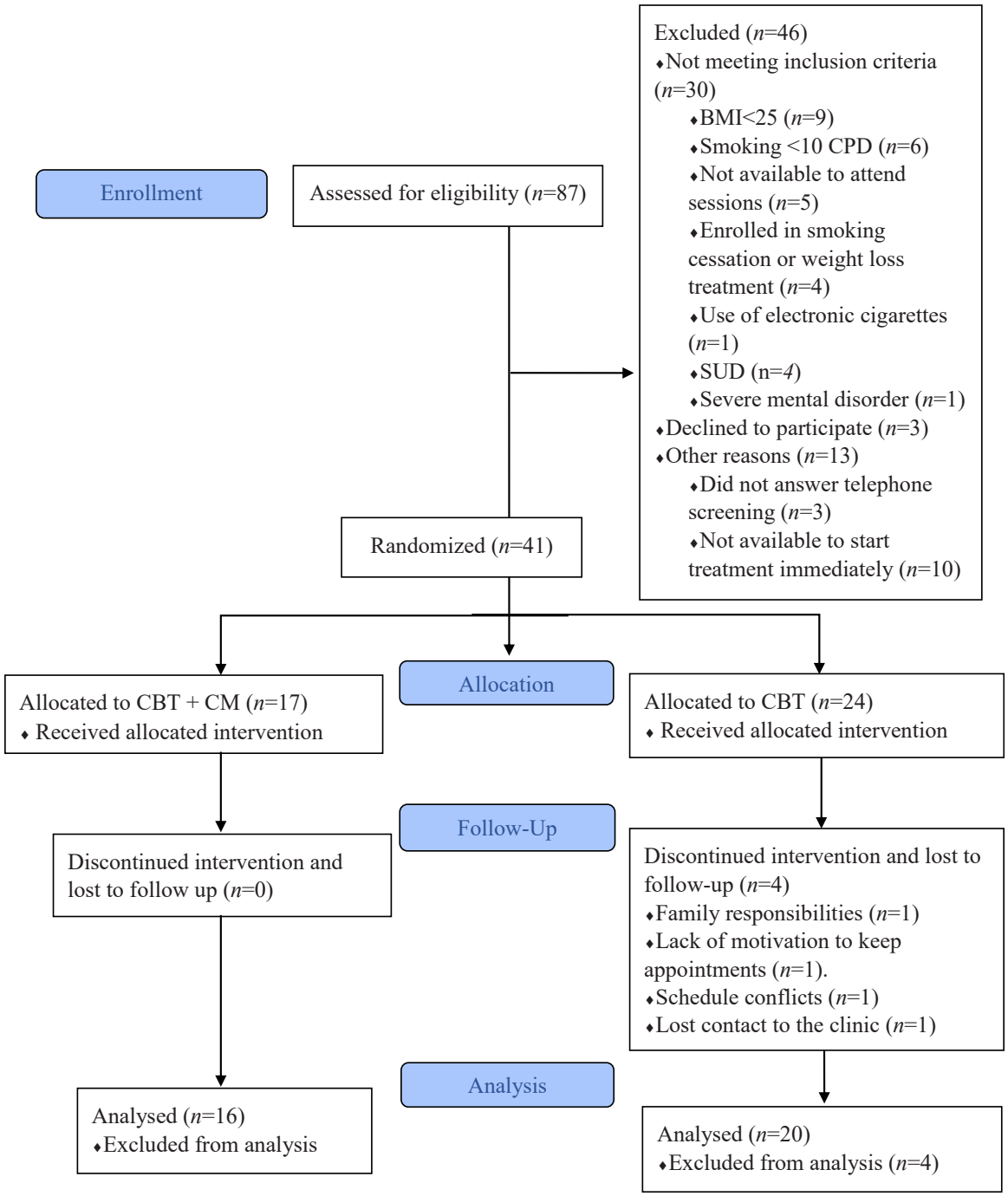

Fig. 1. Participants' flow diagram.

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 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.

Table 2
Acceptability outcomes.

	Completers ($n = 37$)	CBT + CM ($n = 17$)	CBT ($n = 20$)	p
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

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 ($M_{\text{baseline}} = 18.05$; $SD = 6.08$; $M_{\text{EOT}} = 1.32$; $SD_{\text{EOT}} = 3.42$; $p < .001$; $r = 0.88$), CO levels ($M_{\text{baseline}} = 20.08$; $SD = 12.66$; $M_{\text{EOT}} = 3.03$; $SD_{\text{EOT}} = 5.44$; $p < .001$; $r = 0.86$) and urine

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

Based on treatment conditions, participants in CM condition decreased self-reported CPD ($M_{baseline}$ = 18.35; SD = 6.03; M_{EOT} = 0; $p < .001$; $r = 0.88$) and both CO ($M_{baseline}$ = 21.41; SD = 10.43; M_{EOT} = 1.71; SD =0.83; $p < .001$; $r = 0.88$) and cotinine levels ($M_{baseline}$ = 2045.43; SD = 1054.23; M_{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_{EOT} = 2.45; SD = 4.39; $p < .001$; $r = 0.88$), CO readings ($M_{baseline}$ = 18.95; SD = 14.45; M_{EOT} = 4.15; SD = 7.26; $p < .001$; $r = 0.86$), as well as cotinine levels ($M_{baseline}$=2062.16; SD=1320.66; M_{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 ($p = .007$; $\varphi = 0.478$). 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 ($M_{baseline}$ = 88.46; SD = 14.78; M_{EOT} = 89.7; SD = 14.8; $p = .001$; $r = 0.58$). Based on treatment conditions, abstinent individuals enrolled in CBT + CM group significantly increased their body weight ($M_{baseline}$ = 87.62; SD = 14.61; M_{EOT} = 88.91; SD = 14.54; $p = .008$; $r = 0.64$), whereas abstinent participants in CBT group maintained their baseline weight ($M_{baseline}$ = 89.48; SD = 15.48; M_{EOT} = 90.66; SD = 15.61; $p = .059$).

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

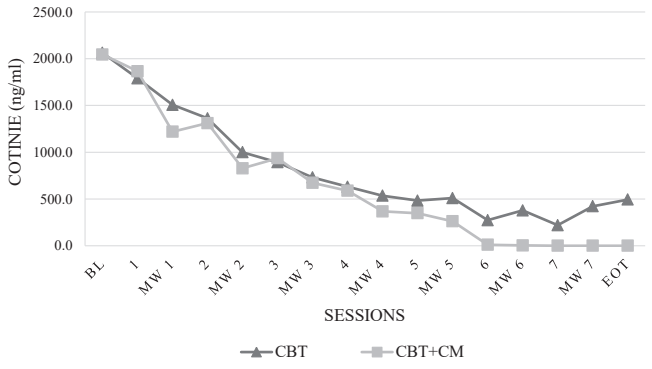

Fig. 2. Reductions in urine cotinine by group throughout treatment. Note. Ng/ml = nanograms per milliliter; BL = baseline; MW = mid-week session; EOT = end of treatment; CBT = cognitive-behavioral treatment; CM = contingency management.

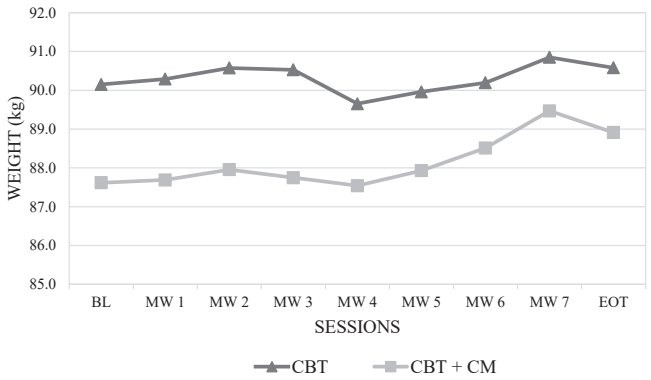

Fig. 3. Weight change during treatment by group. Note. Kg = kilograms; BL = baseline; MW = mid-week session; EOT = end of treatment; CBT = cognitive-behavioral treatment; CM = contingency management.

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 post-cessation 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 post-cessation weight gain prevention.

Role of funding source

This work was supported by the Spanish Ministry of Science and Innovation, the State Research Agency and the European Regional Development Fund [grant number RTI2018-101465-A-100] and a pre-doctoral grant from the Government of the Principality of Asturias [grant number PA-21-PF-BP20-015].

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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3. Contingency management for smoking cessation for individuals with overweight or obesity: A randomized controlled trial

Referencia: Krotter, A., García-Fernández, G., García-Pérez, Á., Aonso-Diego, G. y Weidberg, S. (2024). Contingency management for smoking cessation for individuals with overweight or obesity: A randomized controlled trial. *Drug and Alcohol Dependence, 258*, Artículo 111269. https://doi.org/10.1016/j.drugalcdep.2024.111269

Factor de impacto: 4,2; Q2, Substance Abuse (JCR 2022, SSCI).

Background: Interventions for quitting smoking and weight control among individuals with excess weight are scarce. Our study evaluated the effectiveness of cognitive behavioral therapy (CBT) plus contingency management (CM) in this population, and examined whether CM for smoking cessation improved CBT treatment outcomes at end of treatment (EOT) and at 1-, 3-, 6-, and 12-month follow-ups (FU).

Methods: In an 8-week randomized clinical trial, 120 adults who smoke with overweight or obesity (54.16% females; M_{BMI} = 31.75 ± 4.31) were randomly assigned to CBT for both quitting smoking and weight control (n = 60) or the same treatment plus CM for smoking cessation (n = 60). Outcome variables were compared (i.e., treatment completion, smoking abstinence, weight change and secondary outcomes).

Results: At EOT, the CBT + CM group achieved 78.33% 7-day point-prevalence abstinence rates compared to 61.67% in the CBT group (p = .073), and rates declined over time (12-month FU: 18% vs 12%). Participants who attained abstinence weighed more compared to baseline at EOT (M_{kg} = 1.07; SD = 1.88) and over time (12-month FU: M_{kg} = 4.19; SD = 4.31). No differences were found between the two groups in outcome variables.

Conclusions: Both interventions were effective in promoting abstinence and reducing tobacco use over time. Combining CBT with CM for smoking cessation did not improve treatment outcomes in individuals with overweight or obesity compared to CBT only. Future studies should evaluate whether implementing CM for weight maintenance helps control post-cessation weight gain in this population.

Drug and Alcohol Dependence 258 (2024) 111269

Contents lists available at ScienceDirect

Drug and Alcohol Dependence

journal homepage: www.elsevier.com/locate/drugalcdep

Contingency management for smoking cessation for individuals with overweight or obesity: A randomized controlled trial

Andrea Krotter [a], Gloria García-Fernández [a,*], Ángel García-Pérez [b], Gema Aonso-Diego [a], Sara Weidberg [a]

[a] Department of Psychology, University of Oviedo, Spain
[b] Department of Psychology, Sociology and Philosophy, University of Leon, Spain

ARTICLE INFO

Keywords:
Overweight
Obesity
Smoking cessation
Weight gain
Cognitive behavioral therapy
Contingency management

ABSTRACT

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1. Introduction

Smoking and obesity are significant public health problems priorities as they are among the main causes of preventable morbidity and mortality (He et al., 2022; Luijckx et al., 2019). The prevalence of chronic diseases related to smoking and obesity has increased and one of the objectives pursued by policymakers is to promote evidence-based interventions for quitting smoking, improving healthy eating, and increasing physical activity (Kris-Etherton et al., 2022).

Individuals with overweight or obesity who smoke are a vulnerable population. Tobacco use in this population is high and increases mortality and disability (Luijckx et al., 2019; Rupprecht et al., 2015; Townsend and Mehta, 2020). Excess weight is often a barrier to quitting, especially among women with obesity, since they exhibit more concerns about post-cessation weight gain, lower confidence in their ability to maintain their weight without smoking, and they are less willing to tolerate weight gain after quitting (Levine et al., 2013). Moreover, it is common to gain weight after quitting and this weakens the beneficial effect of tobacco cessation (Hasegawa et al., 2019; Kos, 2020).

Quitting smoking is associated with an average increase of 4–5 kg, although 13% gain more than 10 kg, increasing the risk of continuing smoking (Aubin et al., 2012; Tian et al., 2015). Post-cessation weight gain is related to nicotine's impact, which increases metabolic rate and decreases appetite, and to increased food intake and disordered eating triggered by quitting smoking (Anker et al., 2021; Cepeda-Benito, 2020; Killi et al., 2020). Problematic eating behaviours (e.g., grazing, binge eating) are prevalent in obesity (Catania et al., 2023; McCuen-Wurst et al., 2018; Nightingale and Cassin, 2019). Therefore, providing smoking cessation treatment to people with overweight or obesity is warranted, however interventions have to be adapted to the needs of this population.

Among the general population, there is evidence showing greater

* Correspondence to: Department of Psychology, University of Oviedo, Plaza Feijoo s/n, Oviedo 33003, Spain.
E-mail address: garciafgloria@uniovi.es (G. García-Fernández).

https://doi.org/10.1016/j.drugalcdep.2024.111269
Received 17 January 2024; Received in revised form 9 March 2024; Accepted 10 March 2024
Available online 19 March 2024

smoking cessation rates when smoking cessation treatments also provide weight management (García-Fernández et al., 2023; Hartmann-Boyce et al., 2021). However, few studies have evaluated the effectiveness of interventions for both quitting smoking and weight control for individuals with overweight or obesity (Heggen et al., 2016, 2017; Hurt et al., 2017; Love et al., 2011; Svendsen et al., 2021; White et al., 2019; Wilcox et al., 2010). Although cognitive behavioral therapy (CBT) is considered to be one of the most effective interventions for smoking cessation and obesity (Dalle Grave et al., 2020; Fonseca Pedrero et al., 2021; Hooper et al., 2023) and contingency management (CM) is effective for smoking cessation (Notley et al., 2019), no studies to date have explored the effect of CBT plus CM for smoking cessation for individuals with excess weight. The latest evidence is from a pilot study related to women who smoke with concerns about weight (Bloom et al., 2020), which looked at combined CM for weight loss and smoking cessation. Moreover, individuals with obesity who smoke may value brief, intense, immediate reinforcers more than individuals who smoke without obesity (Bickel et al., 2021). Therefore, CM may be a promising approach for this population.

The present study is an extension of a prior pilot study aimed at examining the feasibility, acceptability and preliminary efficacy of CBT and CBT-plus-CM in individuals who smoke with overweight or obesity (García-Fernández et al., 2022). Given the high recruitment success rate, completion rate, treatment attendance, and satisfaction rating for the treatment, its effectiveness needs to be evaluated with a large randomized controlled clinical trial (RCT). The present study assesses treatment effectiveness at end of the treatment (EOT) and follow-ups (FU) (i.e., 1-, 3-, 6-, and 12-month FU) by examining: 1) treatment outcomes (i.e., treatment completion, smoking abstinence, weight change and improvement in secondary outcomes) of CBT that simultaneously addresses smoking cessation and weight control in individuals with overweight or obesity, and 2) the contribution of CM to CBT.

2. Material and methods

2.1. Participants

Participants were adults wanting to quit smoking recruited in the Principality of Asturias (Spain) through television, radio, newspaper, social media, and poster advertisements between September 2020 and October 2021. Written informed consent was obtained and appropriate data protection and privacy legislation and guidelines were followed.

Inclusion criteria were (1) being ≥ 18 years old, (2) having smoked ≥ 10 cigarettes per day and not used electronic devices over the past year, (3) meeting the diagnostic criteria for tobacco use disorder (American Psychiatric Association, 2013) and (4) having a Body Mass Index (BMI) ≥ 25. Exclusion criteria were (1) being pregnant, breastfeeding or in the six-month postpartum period; (2) being currently (in the previous 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 previous year) severe psychiatric disorder (e.g., active psychotic disorder or suicidal ideation), eating disorder other than binge eating disorder (BED), or substance use disorder (SUD) other than tobacco use disorder; (4) having any health condition requiring a specialized diet or that affected eating (e.g., uncontrolled diabetes); (5) not being able to attend treatment; or (6) taking medication that affects weight.

The participants' baseline characteristics are shown in Table 1. There were no significant differences in any baseline characteristics between participants assigned to the CBT + CM or CBT conditions (all p-values ≥ .096), except in the case of the age variable. In the CBT + CM group, the mean age was 50.65 (SD = 8.24) years, versus 54.43 (SD = 11.85) years in the CBT group (U = 1.305, z = −2.601; p = .009; r = .23).

Table 1
Baseline 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)	.009
Marital status (married, n/%)	67 (55.8)	34 (56.7)	33 (55)	1
Educational level (≤ high school, n/%)	51 (42.5)	22 (36.67)	29 (48.33)	.268
Employed (n/%)	62 (51.67)	32 (53.33)	30 (50)	.855
Monthly income level (US$)[a]	2.119.35 (1.076.81)	2.011.74 (1.224.61)	2.226.96 (907.01)	.096
CPD[a]	21.34 (8.79)	22.75 (9.94)	19.93 (7.27)	.133
Age of smoking onset[a]	15.15 (4.17)	15.15 (3.56)	15.15 (4.75)	.580
Years of regular smoking[a]	30.85 (10.66)	29.29 (8.64)	32.41 (12.23)	.113
Previous quit attempts[a]	2.56 (2.12)	2.65 (2.35)	2.47 (1.87)	.805
Smoking state of change (n/%)				1
Preparation	84 (70)	42 (70)	42 (70)	
Contemplation	36 (30)	18 (30)	18 (30)	
FTCD[a]	5.43 (2.06)	5.53 (2.3)	5.32 (1.8)	.420
CO (ppm)[a]	22.96 (11.27)	23.93 (11.07)	21.98 (11.47)	.295
Cotinine (ng/ml)[a]	2318.25 (1215.54)	2461.75 (1242.91)	2174.76 (1180.43)	.156
Age of excess weight onset[a]	34.73 (14.36)	34.07 (13.04)	35.41 (15.68)	.796
Years of BMI ≥ 25[a]	20.9 (15.52)	22.11 (19.63)	19.81 (10.96)	.875
Previous diet attempts[a]	7.71 (17.37)	7.19 (15.71)	8.22 (18.98)	.85
Body weight dissatisfaction (n/%)	101 (84.17)	50 (83.33)	51 (85)	.803
Reported limitations to exercise (n/%)	27 (22.5)	14 (23.3)	13 (21.7)	1
Diet stage of change (n/%)				.60
Pre-contemplation	23 (19.17)	14 (23.33)	9 (15)	
Contemplation	35 (29.16)	14 (23.33)	21 (35)	
Preparation	26 (21.67)	14 (23.33)	12 (20)	
Action	21 (17.5)	11 (18.34)	10 (16.67)	
Maintenance	15 (12.5)	7 (11.67)	8 (13.33)	
Weight (kg)[a]	88.08 (14.01)	88.25 (14.19)	87.91 (13.94)	.894
BMI[a]	31.75 (4.31)	31.71 (4)	31.78 (4.63)	.709
BMI category (n/%)				.708
Overweight	47 (39.16)	22 (36.67)	25 (41.67)	
Obesity	73 (60.83)	38 (63.33)	35 (58.33)	
Presence of binge eating episodes (n/%)	26 (21.67)	12 (20)	14 (23.33)	.825

Note. [a]Mean (standard deviation). 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/milliliter; BMI = body mass index; kg = kilograms.

2.2. Procedure

Interested individuals who met the preliminary eligibility criteria during a telephone screening were scheduled for an in-person baseline assessment in the Addictive Behaviors Clinical Unit at the University of Oviedo to confirm eligibility and to provide written informed consent. The participant flowchart gives a detailed description (see Fig. 1). From a total of 264 individuals screened, 123 met the inclusion criteria and were enrolled in the study. Participants were randomly assigned to one of the two treatment conditions in accordance with a computer-generated list of random numbers to allocate individuals to interventions in a 1:1 ratio. A total of 120 people were allocated to an intervention: CBT for smoking cessation and weight control (CBT, n = 60), or the same treatment alongside CM for smoking cessation (CBT + CM, n = 60). The trial was pre-registered on clinicaltrials.gov (ID = NCT04332029), and the study protocol was approved by the Research

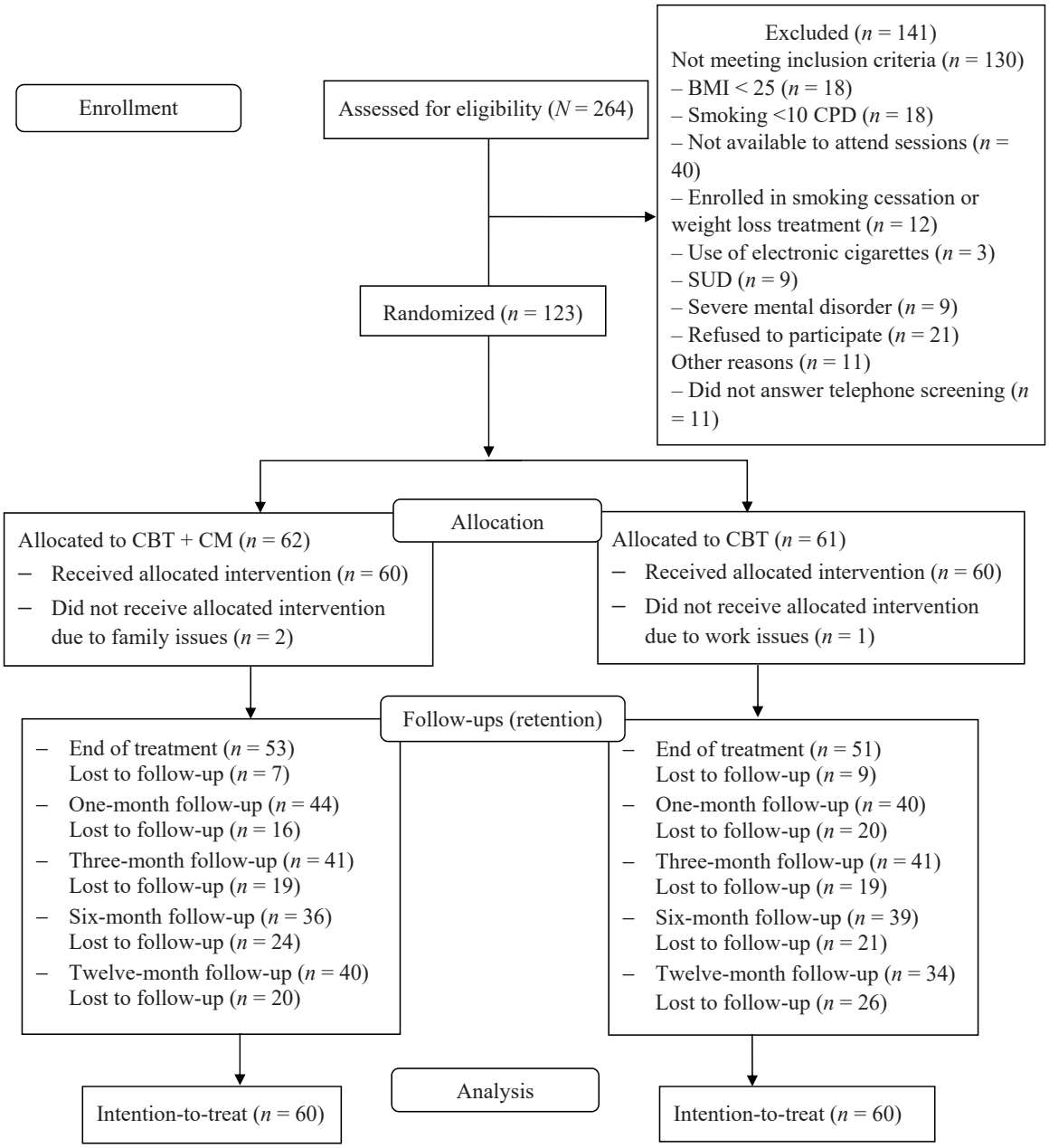

Fig. 1. Consort flow diagram of study participants. Note. BMI = body mass index; CPD = cigarettes per day; SUD = substance use disorder other than tobacco use disorder; CBT = cognitive-behavioral therapy; CM = contingency management; EOT = end of treatment.

Ethics Committee of the Principality of Asturias (nº 329/19).

Due to the COVID-19 pandemic, it is important to specify dates of this RCT to understand where in the pandemic data was collected. Recruitment began in October 2020 and between then and December 2020, 15 out of the 120 participants (12.50%) received interventions under the second stay-at-home order which included curfew and perimeter closures with exceptions for attending health services. Between January 2021 and May 2021 (the date on which the Spanish government decreed the end of the 'state of emergency'), a total of 31.67% (38/120) of the sample received intervention with notable restrictions (i.e., free movement between cities was allowed but leisure facilities such as bars remained closed). The remaining participants (55.83%; 67/120) received the intervention between June 2021 and December 2021 with restrictions such as time limitations for opening leisure venues, social distancing outdoors, use of masks indoors and prohibition of smoking on terraces.

2.3. Assessments and outcomes

2.3.1. Baseline characteristics

Participants were asked to complete a questionnaire including sociodemographic data, variables about tobacco use and variables about weight/eating. The Fagerström Test for Cigarette Dependence (FTCD) (Becoña and Vázquez, 1998) evaluated nicotine dependence establishing five levels: very low (0−2), low (3−4), medium (5), high (6−7) and very high (8−10). Current motivation for weight control was assessed using the S-Weight questionnaire (Andrés et al., 2011).

2.3.2. Primary outcomes and measures

The primary outcome variables were: (1) treatment completion (i.e., participants who started the treatment and completed the EOT assessment); (2) smoking abstinence outcomes at EOT and FU (i.e., 1-, 3-, 6-, and 12-month), in terms of 7-day point-prevalence abstinence rates (i.e.,

percentage of participants who attained abstinence, "not even a puff", for a minimum of seven days prior to assessment), prolonged abstinence rates (i.e., percentage of participants who attained abstinence, "not even a puff", after a grace period of 15 days after the target quit date), and duration of continuous abstinence (i.e., number of consecutive days without smoking, "not even a puff", since participants successfully quit) (Piper et al., 2020); (3) weight change in terms of body weight variation from baseline to EOT and 1-, 3-, 6-, and 12-month FU in those who achieved prolonged abstinence at these time points (Hartmann-Boyce et al., 2021).

Smoking was biochemically assessed through carbon monoxide (CO) and urine cotinine analysis, 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) at baseline, at each session during the intervention, at EOT, and at FU. Abstinence was biochemically confirmed through CO readings ≤ 4 ppm and urine cotinine levels ≤ 80 ng/ml (Benowitz et al., 2020; Ramani et al., 2023).

Participants' height was measured at baseline using a medical stadiometer (SECA Mod.213, 20–205 cm). Body weight was measured, in light clothing and without shoes, using a calibrated medical scale (CL.III 200 kg. SECA Mod. 877) at baseline, weekly during the intervention, EOT and FU. BMI was calculated (BMI = weight [kg]/(height)^2[m]).

2.3.3. Secondary outcomes and measures

Other measures of efficacy were improvements in secondary outcomes (i.e., diet, eating behavior, physical activity, and psychological well-being) assessed with specific instruments completed by participants during the assessments. The scores at EOT and FU were only recorded for participants who completed the assessments.

The PREDIMED-Plus (Álvarez Álvarez et al., 2019) assessed adherence to the Mediterranean diet, and participants were classified as having low (< 7), medium (8−10), and high (≥ 11) adherence. The Spanish version of the Dutch Eating Behavior Questionnaire (DEBQ) (Cebolla et al., 2014) measured three eating styles (i.e., emotional, external, and restrained eating), with higher scores indicating greater agreement with each eating style. The Spanish Regicor Short Physical Activity Questionnaire (REGICOR) (Molina et al., 2017) assessed physical activity intensity (light, moderate, vigorous and total) in metabolic equivalents (METs) per week. The Spanish version of the Depression, Anxiety, and Stress Scales-21 (DASS-21) (Bados et al., 2005) evaluated emotional states (i.e., depression, anxiety, stress).

2.4. Treatment interventions

Participants visited the clinic 15 times over eight weeks. The first visit each week lasted 120 minutes and included a group CBT session (up to four participants) and taking samples for CO and cotinine. A second, midweek group session for each of the first seven weeks lasted 60 min and included sampling for CO and cotinine, a weigh-in, and a progress review. Masters- and doctoral- level psychologists with training in treatment protocols conducted the intervention.

2.4.1. Cognitive behavioral therapy for smoking cessation and weight control (CBT)

A CBT protocol for smoking cessation was used, with additional components for weight control. Participants received coping skills training to quit smoking and a nicotine fading procedure, which consisted of a weekly reduction in nicotine intake of 20% each week based on reductions of tobacco brands and number of daily cigarettes from the first session to 48 hours prior to the sixth session (target quit day). Additional components addressed restructuring post-cessation weight gain concerns, improving diet, increasing physical activity, and reducing problematic eating. Some treatment components were transdiagnostic, both for smoking cessation and weight control (e.g., distress tolerance and emotional regulation skills). A detailed description is provided in the pilot feasibility study (García-Fernández et al., 2022).

2.4.2. CBT plus contingency management for smoking abstinence (CBT + CM)

The CBT + CM condition included the CBT protocol described above plus CM for smoking abstinence. CM consisted of providing vouchers to reinforce abstinence contingent on biochemical breath and urine verification from the sixth session to EOT. Points were provided immediately upon biochemical verification of abstinence at each session and vouchers were exchangeable for a variety of goods, equipment and services, for exercising, cooking, leisure, and entertainment activities, among others. The maximum amount that participants could earn was 320 points (US$ 301.73), with one point equivalent to one euro (US$ 1.19). Vouchers began at 50 points (US$ 47.14) and increased by 5 points (US$ 4.71) for each consecutive negative sample. Participants could additionally receive a bonus of 10 points (US$ 9.43) for two consecutive negative smoking samples. A positive test or missed specimens reset the voucher value back to the initial 50 points, but if two consecutive negative tests were provided, the voucher value was reestablished. The value of the incentives was determined based on previous CM studies for substance use concluding that larger incentives were not associated with higher rates of abstinence (Breen et al., 2020), and that US$ 300 is the standard amount used to reinforce abstinence (Petry et al., 2015).

2.5. Statistical analyses

A power analysis was conducted using G*Power 3.1.9.2 (Faul et al., 2009) to determine sample size. Abstinence rates from a previous study conducted in the clinic comparing CBT + CM vs. CBT for smoking cessation among the general population (López-Núñez et al., 2016) were used to ensure a minimum power of 80% with a 0.05 alpha level. Bivariate analysis were conducted to assess participants' baseline characteristics. The distribution of the data was examined to determine whether to use parametric or nonparametric tests. Differences between groups were examined via *t*-tests or the Mann-Whitney *U* test for continuous variables, and chi-square for categorical variables at EOT and FU. Changes in continuous variables from baseline to EOT and FU were examined using *t*-tests and the Wilcoxon Signed-Rank Test. Effect sizes were calculated by Cohens' *d*, $r = Z / \sqrt{n}$, and the phi coefficient as appropriate. Data was analyzed according to intent-to-treat analysis, in which participants who did not attend assessments were considered as individuals who smoked. No imputation of missing weight data or secondary variables was performed.

Mixed between-within subjects analysis of variance (ANOVA) was conducted to analyze changes in secondary outcomes by treatment group (between-subjects variable) and over time (within-subjects variable). If the assumption of sphericity was violated, the Greenhouse-Geisser or Huynh-Feldt correction methods were used (Blanca et al., 2023). When there were significant group effects, post hoc analysis of covariance was performed to examine whether the significant difference in age between treatment conditions at baseline contributed to the observed differences in secondary outcomes. Simple comparisons were used to compare scores at EOT and FU with baseline scores. Effect size was calculated via partial eta squared (Tabachnick and Fidell, 2014). Confidence levels were set at 95%, and data were analyzed using SPSS package (V.20, Inc., Chicago, IL).

3. Results

3.1. Treatment completion

A total of 86.67% of the participants completed the treatment (104/120) and completion rates did not differ by treatment condition ($p = .788$). Specifically, 88.33% in the CBT + CM condition (53/60) and 85% in the CBT group (51/60) completed the intervention. Participants from

both conditions attended a mean of 13.56 sessions ($SD = 1.68$) with no differences between the groups ($M_{CBT + CM} = 13.87 \pm 1.62$ vs. $M_{CBT} = 13.24 \pm 1.69$; $p = .054$).

3.2. Smoking abstinence outcomes

3.2.1. End of treatment

At EOT, 70% of the total sample (84/120) achieved 7-day point-prevalence smoking abstinence and prolonged abstinence, with no statistically significant differences between the groups (CBT + CM = 78.33% [47/60] vs. CBT = 61.67% [37/60]; $p = .073$; $\varphi = 0.182$). The mean number of days of continuous abstinence for the total sample was 13.46 ($SD = 10.14$), with no statistically significant differences between the groups ($M_{CBT + CM} = 14.53 \pm 8.59$ vs. $M_{CBT} = 12.38 \pm 11.48$; $p = .216$; $r = 0.11$).

3.2.2. Follow-ups

In the full sample, 7-day point-prevalence abstinence rates at 1-, 3-, 6, and 12-month FU were 47.50% (57/120), 36.67% (44/120), 30.83% (37/120), and 25% (30/120). Prolonged abstinence rates at 1-, 3-, 6, and 12-month FU were 40.83% (49/120), 28.33% (34/120), 21.67% (26/120), and 16.67% (20/120) and the mean number of days of continuous abstinence at each FU were 21.57 ± 25.25, 35.41 ± 50.31, 50.67 ± 84.10, and 81.48 ± 150.54.

Table 2 shows smoking abstinence outcomes by group at each FU. There were no statistically significant differences between the groups for smoking abstinence outcomes at any FU (all p-values $\geq .268$)

3.3. Weight change outcomes

Fig. 2 shows weight change in participants who attained abstinence at EOT and FU.

3.3.1. End of treatment

Participants who achieved abstinence from both groups gained weight compared to their baseline ($\Delta_{kg} = 1.07 \pm 1.88$; $p < .001$; $r = .94$). Particularly, participants in the CBT + CM group had significantly increased weight over their baseline ($\Delta_{kg} = .90 \pm 1.90$; $p < .002$; $d = .47$), as did participants in the CBT group ($\Delta_{kg} = 1.29 \pm 1.85$; $p < .001$; $r = .60$). The amount of weight gained was similar in participants who attained abstinence from both groups ($p = .344$).

3.3.2. Follow-ups

Participants who achieved abstinence from both groups had significantly increased weight over their baseline at 1-, 3-, 6, and 12-month FU: 2.31 ± 3.61 ($p < .001$; $r = .61$), 3.03 ± 5.05 kg ($p = .001$; $r = .60$), 3.12 ± 3.48 kg ($p < .001$; $d = .90$), and 4.19 ± 4.31 kg ($p < .001$; $d = .97$).

Mean weight gain of participants who attained abstinence in the CBT + CM condition at 1-, 3-, 6, and 12-month FU was 2.23 ± 3.72 kg ($p = .004$; $r = .72$), 4.08 ± 5.64 kg ($p = .004$; $r = .47$), 3.69 ± 3.36 kg ($p = .003$; $r = .80$), and 4.62 ± 4.97 kg ($p = .016$; $r = .72$). Similarly, participants who attained abstinence in the CBT group significantly gained 2.40 ± 3.58 kg ($p = .004$; $d = .67$), 2.11 ± 4.42 kg ($p = .045$; $r = .47$), 2.48 ± 3.64 kg ($p = .034$; $r = .61$), and 3.67 ± 3.57 kg ($p = .038$; $r = .69$) at 1-, 3-, 6, and 12-month FU. Mean weight gain did not differ by treatment condition at any FU (all p-values $\geq .365$).

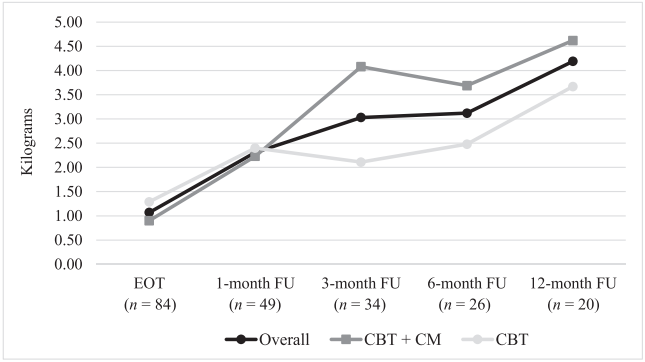

Fig. 2. Mean weight change in abstinent participants at end of treatment and follow-ups. Note. EOT = end of treatment; FU = follow-up; CBT = cognitive-behavioral therapy; CM = contingency management.

3.4. Secondary outcomes

Table 3 shows secondary outcomes at baseline, EOT, and all FU.

There was a significant effect for time in adherence to the Mediterranean diet ($p < .001$; $\eta p^2 = .103$) with improvements in the PREDIMED-Plus scores at EOT and at 1-, 3-, and 6-month FU (all p-values $\leq .008$). The effect for group ($F_{4.449,\ 240.231} = 2.980$; $p = .016$; $\eta p^2 = .052$) disappeared when the covariable age was added to the model ($F_{4.361,\ 231.14} = 1.572$, $p = .177$).

Significant effects for time were also found in emotional eating ($p < .001$; $\eta p^2 = .098$) and external eating ($p < .001$; $\eta p^2 = .258$). Emotional eating (all p-values $\leq .002$) and external eating scores decreased at EOT and all FU (all p-values $< .001$) while restrained eating remained stable ($p = .271$). No effect for treatment group was found in emotional eating ($F_{4.72,\ 254.89} = .895$; $p = .481$) or restrained eating ($F_{5,\ 270} = .352$; $p = .881$), but there was a significant effect for treatment groups in external eating ($F_{3.713,\ 200.496} = 18.758$; $p = .033$; $\eta p^2 = .048$). This effect remained significant ($F_{4.363,\ 231.215} = 3.503$; $p = .007$; $\eta p^2 = .062$) when baseline age was added to the model as a covariate. A larger fall in external eating scores in the CBT group was found at the 3-month FU ($p = .004$) and the 6-month FU ($p = .005$).

Light physical activity ($p = .212$) and moderate physical activity ($p = .242$) did not change, while vigorous physical activity ($p = .004$; $\eta p^2 = .088$) and total physical activity ($p = .005$; $\eta p^2 = .081$) increased at the 3-month FU ($p = .003$). However, in the final, 12-month, FU, participants had significantly lower scores for total physical activity ($p = .030$; $\eta p^2 = .086$). No differences between groups were found in light ($F_{2.177,\ 117.57} = 1.044$; $p = .360$), moderate ($F_{4.193,\ 222.232} = 2.298$; $p = .057$), vigorous ($F_{2.338,\ 126.237} = .840$; $p = .450$), or total physical activity ($F_{2.716,\ 143.950} = 2.045$; $p = .111$).

Finally, there was no effect for time in scores on depression ($p =$

Table 2
Smoking abstinence outcomes at follow-ups.

	PP (n/%)				PA (n/%)				CA (M/SD)			
	CBT + CM ($n = 60$)	CBT ($n = 60$)	p	Effect size[a]	CBT + CM ($n = 60$)	CBT ($n = 60$)	p	Effect size[a]	CBT + CM ($n = 60$)	CBT ($n = 60$)	p	Effect size[b]
1-month FU	30 (50)	27 (45)	.715	0.050	26 (43.33)	23 (38.33)	.710	0.051	22.52 (24.99)	20.62 (25.47)	.770	0.03
3-month FU	20 (33.33)	24 (40)	.570	-0.069	16 (26.67)	18 (30)	.839	0.037	33.45 (49.51)	37.37 (51.45)	.477	0.04
6-month FU	20 (33.33)	17 (28.33)	.693	0.054	14 (23.33)	12 (20)	.825	0.040	33.45 (49.51)	37.37 (51.45)	.610	0.05
12-month FU	18 (30)	12 (20)	.292	0.115	11 (18.33)	9 (15)	.806	0.045	92.27 (155.91)	70.68 (145.47)	.268	0.10

Note. [a] phi coefficient; [b] rank-biserial correlation coefficient. PP = 7-day point-prevalence abstinence rates; PA = prolonged abstinence rates; CA = days of continuous abstinence; M = mean; SD = standard deviation; CBT = cognitive-behavioral therapy; CM = contingency management; FU = follow-up.

Table 3
Secondary outcomes at baseline, end of treatment, and follow-ups ($n = 56$).

	Baseline ($M \pm SD$)	EOT ($M \pm SD$)	1-month FU ($M \pm SD$)	3-month FU ($M \pm SD$)	6-month FU ($M \pm SD$)	12-month FU ($M \pm SD$)	F^a	*df*	*p*	ηp^2
$PREDIMED_{Total}$							6.207	4.449, 240.231	<.001	.103
Overall	9.41 ± 2.90	10.55 ± 2.08	10.73 ± 2.41	11.09 ± 2.31	10.66 ± 2.44	10.05 ± 2.65				
CBT + CM	8.93 ± 2.49	10.77 ± 1.89	10.33 ±2.48	10.43 ± 1.87	10.93 ± 2.39	9.73 ± 2.46				
CBT	9.96 ± 2.74	10.31 ± 1.99	11.19 ± 2.46	11.85 ± 2.56	10.35 ± 2.50	10.42 ± 2.85				
$DEBQ_{Emotional}$							5.896	4.72, 254.89	<.001	.098
Overall	23.71 ± 11.05	21.32 ± 9.57	21.27 ± 9.32	20.21 ± 8.67	20.77 ± 8.82	20.43 ± 9.26				
CBT + CM	25.50 ± 11.59	22.33 ± 9.49	23.53 ± 9.13	22.37 ± 9.50	22.67 ± 9.32	22.60 ± 9.69				
CBT	21.65 ± 10.23	20.15 ± 9.71	18.65 ± 9.00	17.73 ± 6.97	18.58 ± 7.82	17.92 ± 8.21				
$DEBQ_{External}$							18.758	3.713, 200.496	<.001	.258
Overall	26.71 ± 7.44	24.32 ± 7.26	23.48 ± 7.46	22.82 ± 7.51	22.84 ± 7.60	22.52 ± 7.76				
CBT + CM	27.63 ± 6.44	25.37 ± 6.73	25.80 ± 6.49	24.17 ± 6.68	24.97 ± 6.95	24.03 ± 7.81				
CBT	25.65 ± 8.46	23.12 ± 7.77	20.81 ± 7.74	21.27 ± 8.23	20.38 ± 7.71	20.77 ± 7.46				
$DEBQ_{Restrained}$							1.284	5, 270	.271	-
Overall	22.46 ± 7.35	22.29 ±7.63	21.80 ± 8.24	21.57 ±7.49	21.73 ± 8.11	20.88 ± 8.59				
CBT + CM	23.40 ±7.57	23.57 ± 7.73	23.43 ±7.77	23.07±7.39	23.43 ± 7.22	22.20 ± 8.98				
CBT	21.38 ±7.08	20.81 ± 7.39	19.92 ±8.52	19.85±7.37	19.77 ± 8.77	19.35 ±8.01				
$REGICOR_{Light}$							1.565	2.177, 117.57	.212	-
Overall	664.46 ± 928.51	715.02 ± 794.58	507.64 ± 843.60	893.27 ± 1941.10	704.79 ± 947.29	411.45 ± 506.99				
CBT + CM	789.47 ± 1156.08	694.23 ± 761.20	288.33 ± 274.84	996.53 ± 2526.40	759.63 ± 1090.46	408.07 ± 499.65				
CBT	520.23 ± 553.09	739.00 ± 846.01	760.69 ± 1163.49	774.12 ± 926.17	641.50 ± 766.19	415.35 ± 525.23				
$REGICOR_{Moderate}$							1.376	4.193, 222.232	.242	-
Overall	492.60 ± 799.63	419.67 ± 599.33	360.13 ± 746.14	576.07 ± 923.03	439.98 ± 744.76	279.53 ± 384.61				
CBT + CM	534.31 ± 787.02	432.86 ± 526.69	246.28 ± 331.54	824.48 ± 1134.54	548.45 ± 819.49	302.90 ± 383.38				
CBT	446.08 ± 826.52	404.96 ± 681.72	487.12 ± 1023.53	299.00 ± 497.20	319.00 ± 645.81	253.46 ± 391.88				
$REGICOR_{Vigorous}$							5.208	2.338, 126.237	.004	.088
Overall	512.96 ± 1154.53	673.05 ± 1018.24	479.09 ± 808.68	1384.61 ± 2339.36	636.30 ± 1081.97	487.04 ± 713.77				
CBT + CM	564.63 ± 929.31	648.47 ± 691.38	400.43 ± 492.42	1652.90 ± 2711.61	804.30 ± 1384.92	584.47 ± 797.22				
CBT	453.35 ± 1386.99	701.42 ± 1313.37	569.85 ± 1068.39	1075.04 ± 1823.31	442.46 ± 526.89	374.62 ± 599.21				
$REGICOR_{Total}$							4.682	2.716, 143.950	.005	.081
Overall	1691.44 ± 1864.05	1830.22 ± 1669.30	1362.82 ± 1758.85	2894.64 ± 3879.05	1795.36 ± 2211.15	1191.44 ± 1218.89				
CBT + CM	1935.14 ± 1884.59	1816.62 ± 1376.37	955.10 ± 672.41	3564.03 ± 4781.28	2147.31 ± 2752.82	1324.07 ± 1293.67				
CBT	1419.62 ± 1838.93	1845.38 ± 1974.03	1817.58 ± 2401.62	2148.00 ± 2407.93	1402.81 ± 1330.15	1043.50 ± 1136.44				
DASS-21 $_{Depression}$							1.91	4.749, 251.685	.097	-
Overall	9.53 ± 8.87	6.98 ± 7.60	8.18 ± 8.79	8.04 ± 8.65	7.13 ± 6.84	7.27 ± 5.65				
CBT + CM	10.87 ± 8.33	7.93 ± 7.36	9.33 ± 8.36	9.33 ± 8.46	9.13 ± 5.50	8.07 ± 5.13				
CBT	7.92 ± 9.39	5.84 ± 7.87	6.80 ± 9.26	6.48 ± 8.78	4.72 ± 6.60	6.32 ± 6.18				
DASS-21 $_{Anxiety}$							2.199	5, 265	.055	-
Overall	7.24 ± 5.31	5.67 ± 5.61	5.02 ± 5.60	5.75 ± 6.18	4.87 ± 5.16	5.31 ± 5.25				
CBT + CM	7.93 ± 5.52	6.27 ± 6.14	4.60 ± 4.14	5.80 ± 5.52	5.87 ± 5.38	6.60 ± 5.69				
CBT	6.40 ± 5.03	4.96 ± 4.94	5.52 ± 7.03	5.68 ± 7.02	3.68 ± 4.72	3.76 ± 4.29				
DASS-21 $_{Stress}$							1.316	4.634, 245.583	.26	-
Overall	11.02 ± 7.15	9.38 ± 7.00	9.24 ± 8.12	9.20 ± 7.18	8.87 ± 6.72	9.64 ± 6.50				
CBT + CM	12.93 ± 6.78	10.33 ± 6.60	8.93 ± 6.36	10.07 ± 6.57	10.40 ± 5.95	10.33 ± 5.49				
CBT	8.72 ± 7.02	8.24 ± 7.42	9.60 ± 9.95	8.16 ± 7.85	7.04 ± 7.24	8.80 ± 7.57				

Note. [a] Based on mixed between-within subjects' analysis of variance. *F* statistic represents within-subjects effects on time. EOT = end of treatment; *M* = mean; *SD* = standard deviation; FU = follow-up; df = degrees of freedom; CBT = cognitive-behavioral therapy; CM = contingency management; DEBQ = Dutch Eating Behavior Questionnaire; REGICOR = Spanish Register Gironi del Cor (Short Physical Activity Questionnaire); DASS-21 = Depression, Anxiety, and Stress scale.

.097), anxiety ($p = .055$), or stress ($p = .26$), and no effect for group was found in depression ($F_{4.749,\ 251.685} = .451$; $p = .803$), anxiety ($F_{5,\ 265} = 1.432$; $p = .213$), or stress scores ($F_{4.634,\ 245.583}$; $p = .125$).

4. Discussion

This is the first RCT designed to examine the additive effect of CM for smoking cessation to CBT among individuals with overweight or obesity

who want to quit. The main results indicate that adding CM to CBT did not produce a better treatment response than CBT alone in this population. There was no specific benefit from CM for treatment completion, smoking abstinence outcomes, weight control, or improving health related secondary outcomes. Three major findings are highlighted: 1) both CBT + CM and CBT provided similar smoking abstinence outcomes at EOT and all FU; 2) both interventions, when participants successfully quit, similarly led to slight weight gain at EOT and to greater weight gain in the long term; 3) treatment effectiveness in improving secondary outcomes was similar for both interventions with improvements over time in adherence to the Mediterranean diet and reduced emotional and external eating.

The overall smoking abstinence rates at EOT were 78.33% in the CBT + CM group and 61.67% in the CBT group, which are high compared to those reported for smoking cessation interventions with weight management (García-Fernández et al., 2023; Hartmann-Boyce et al., 2021) and to those from studies for quitting smoking among individuals with overweight or obesity (Heggen et al., 2016; White et al., 2019; Wilcox et al., 2010; 71%, 25.9%, and 48.1%, respectively). There are at least three rationales that account for such high cessation rates. Firstly, both treatments for smoking cessation incorporated weight management, which improves smoking cessation rates (García-Fernández et al., 2023; Hartmann-Boyce et al., 2021). Secondly, all participants received CBT adapted to the needs of persons who smoke with overweight or obesity. Post-cessation weight concerns are known to be an important obstacle to quitting smoking in individuals with weight complications (Levine et al., 2013), and addressing diet, physical activity, problematic eating and psychological well-being are important components of interventions in obesity (Durrer Schutz et al., 2019; Pojednic et al., 2022; Spadaccini et al., 2022). Thirdly, treatment completion was high in both conditions (88.33% in CBT + CM vs 85% in CBT), which could have raised smoking cessation rates at EOT (Dorner et al., 2011; Garey et al., 2020).

Tobacco abstinence rates fell over time at 1-, 3-, 6-, and 12-month FU with overall 7-day point prevalence abstinence rates of 47.50%, 36.67%, 30.83%, and 25%. Similarly, prolonged abstinence rates were 40.83%, 28.33%, 21.67%, and 16.67% at 1-, 3-, 6-, and 12-month FU. Our abstinence rates were higher than those reported by Love et al. (2011) with 7-day point prevalence abstinence rates of 21.4% at 6 months, and White et al. (2019) with continuous abstinence rates of 25.9% at 6 months. They were lower than those reported by Heggen et al. (2016), with 7-day point prevalence abstinence rates of 46.3% at 3 months, and Wilcox et al. (2010) with continuous abstinence rates of 40.7% at 3 months. It is worth noting that those latter studies incorporated varenicline or bupropion (Guo et al., 2022).

Overall, both interventions were effective for prompting treatment completion and reducing smoking rates. Despite the CBT + CM group showing a trend towards higher smoking abstinence rates, there were no statistically significant differences between the two groups at EOT or at any FU. These results are not in line with previous research highlighting the effectiveness of CM for smoking cessation (Notley et al., 2019) and for specific populations (González-Roz and Secades-Villa, 2022; Yon et al., 2022). Given the robustness of CM across a range of circumstances and different populations, potential reasons for the lack of effect observed should be discussed. The COVID-19 pandemic, which has been identified as both an obstacle to and facilitator for smoking cessation (Johnston et al., 2023), might have impacted treatment effectiveness. On one hand, the pandemic might have positively affected the motivation to quit smoking and undergo treatment, as well as treatment attendance and completion (Barrington-Trimis et al., 2023), which could explain the high retention and smoking cessation rates at EOT in both groups. On the other hand, the stringent COVID-19 measures in Spain (e.g., movement restrictions, social distancing, bar and restaurant closures, commercial activity and leisure centers limits) might have hindered the effectiveness of CM because participants were unable to use the vouchers freely. Moreover, the post-pandemic normality, with its gradual relaxation of COVID-19 measures, might be a risk factor for smoking and might have affected smoking cessation rates at FU. Finally, another potential basis for the absence of effect could be related to the CM parameters. For example, providing vouchers after EOT may have improved abstinence outcomes in the CBT + CM group (see e.g., González-Roz et al., 2021).

In terms of weight outcomes, both interventions similarly led to a slight weight gain for those successfully quitting smoking at EOT (1.07 kg). This gain was lower than reports from some previous studies (Bize et al., 2010; Levine et al., 2010) but higher than others (Lycett et al., 2020). It is important to note that the treatment target was post-cessation weight control, not weight-loss. At 1-, 3-, 6-, and 12-month FU, post-cessation weight gain among participants who successfully achieved abstinence gradually increased (2.31 kg, 3.03 kg, 3.12 kg, and 4.19 kg), which are higher figures than Ussher et al. (2007) and Audrain-McGovern et al. (2023) but lower than Levine et al. (2010). Finally, there were no statistically significant differences between the two treatments in post-cessation weight gain. It is important to note that CM consisted of providing vouchers to reinforce smoking abstinence and weight control was not incentivized. CM has been used successfully to address several healthy behaviors (Ellis et al., 2021; Giles et al., 2014) and future research is needed to evaluate a dual CM schedule for simultaneously reinforcing smoking abstinence and weight control (Bloom et al., 2020; Van Der Pol et al., 2022). Finally, nicotine replacement therapy (NRT) may attenuate post-cessation weight gain (Farley et al., 2012; Hartmann-Boyce et al., 2021) but its effects on people with overweight or obesity remain unclear and future studies should explore the impact of NRT in this population. To the best of our knowledge, the only study that has used NRT in population with overweight or obesity included NRT in both the experimental and comparison conditions (White et al., 2019).

In secondary outcomes, participants from both groups improved adherence to the Mediterranean diet and reduced emotional and external eating at EOT and FU, as well as increased vigorous and overall physical activity at 3-month FU. There were no significant changes over time in the remaining secondary outcomes (i.e. restrained eating, light and moderate physical activity and emotional states). No statistically significant differences between the two groups were found except for a greater reduction in external eating in the CBT group at 3 and 6-month FU than the CBT + CM group, although the differences disappeared at the 12-month FU. CBT components addressing diet and emotional or external eating may be active factors for this multicomponent program, and this is consistent with previous research (Moraes et al., 2021; Saranapala et al., 2022).

These results must be considered within the limitations of the study. First, not being able to include the participants who did not complete the trial and assessments (e.g., only 61.67% of participants [74/120] attended the 12 month-FU) limits the inferences that can be drawn from the analysis of secondary outcomes, and the lack of data from these participants reduces the reliability of the conclusions. Second, adding a control condition providing the same incentives but not contingent on smoking abstinence would have been a strongest control condition. Third, the effect size observed for differences between groups in 7-day point prevalence rates at EOT is not excessively far from showing a weak association, which suggests that a larger sample might have uncovered significant effects in favor of the CM condition at EOT. Finally, the COVID-19 pandemic might have affected outcomes, and future research is needed to analyze how the pandemic affected smoking cessation, weight and secondary outcomes.

5. Conclusions

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. Participants who attained abstinence showed a slight weight gain at EOT and a greater weight gain over time. There was no benefit from combining

CBT and CM for treatment completion, tobacco abstinence outcomes, weight control, or secondary outcomes. Future research is needed to develop effective smoking abstinence maintenance strategies and post-cessation weight gain control, and to determine which CM parameters may be effective in this specific population group.

Role of Funding source

This work was supported by the Spanish Ministry of Science and Innovation, the State Research Agency and the European Regional Development Fund (grant number RTI2018-101465-A-I00) and a pre-doctoral grant from the Government of the Principality of Asturias (grant number PA-21-PF-BP20–015 to A.K.).

CRediT authorship contribution statement

Sara Weidberg: Resources, Investigation. **Gema Aonso Diego:** Writing – review & editing, Resources, Investigation. **Gloria Garcia-Fernandez:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Investigation, Funding acquisition, Conceptualization. **Andrea Krotter:** Writing – original draft, Investigation, Formal analysis, Data curation. **Ángel García-Pérez:** Writing – review & editing, Software, Resources, Investigation, Data curation.

Declaration of Competing Interest

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

Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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

Referencia: Krotter, A., García-Pérez, Á., Aonso-Diego, G. y García-Fernández, G. (2024). Body weight change during a smoking cessation intervention for individuals with overweight or obesity. *Eating Behaviors, 53,* Artículo 101882. https://doi.org/10.1016/j.eatbeh.2024.101882

Factor de impacto: 2,8; Q2, Clinical Psychology (JCR 2022, SSCI).

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.

Eating Behaviors 53 (2024) 101882

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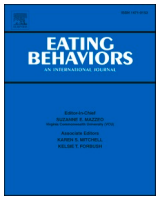

Body weight change during a smoking cessation intervention for individuals with overweight or obesity

Andrea Krotter [a], Ángel García-Pérez [a,b], Gema Aonso-Diego [a], Gloria García-Fernández [a,*]

[a] Department of Psychology, University of Oviedo, Plaza Feijoo s/n, 33003 Oviedo, Spain
[b] Department of Psychology, Sociology and Philosophy, University of Leon, Education Faculty, Vegazana Campus s/n, 24071 Leon, Spain

ARTICLE INFO

Keywords:
Smoking cessation
Post-cessation weight gain
Behavioral changes
Eating
Exercise
Sleep

ABSTRACT

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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

* Corresponding author at: Department of Psychology, University of Oviedo, Plaza Feijoo s/n, 33003 Oviedo, Spain.
E-mail addresses: krotterandrea@uniovi.es (A. Krotter), angap@unileon.es (Á. García-Pérez), aonsogema@uniovi.es (G. Aonso-Diego), garciafgloria@uniovi.es (G. García-Fernández).

https://doi.org/10.1016/j.eatbeh.2024.101882
Received 16 October 2023; Received in revised form 27 April 2024; Accepted 1 May 2024
Available online 6 May 2024

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

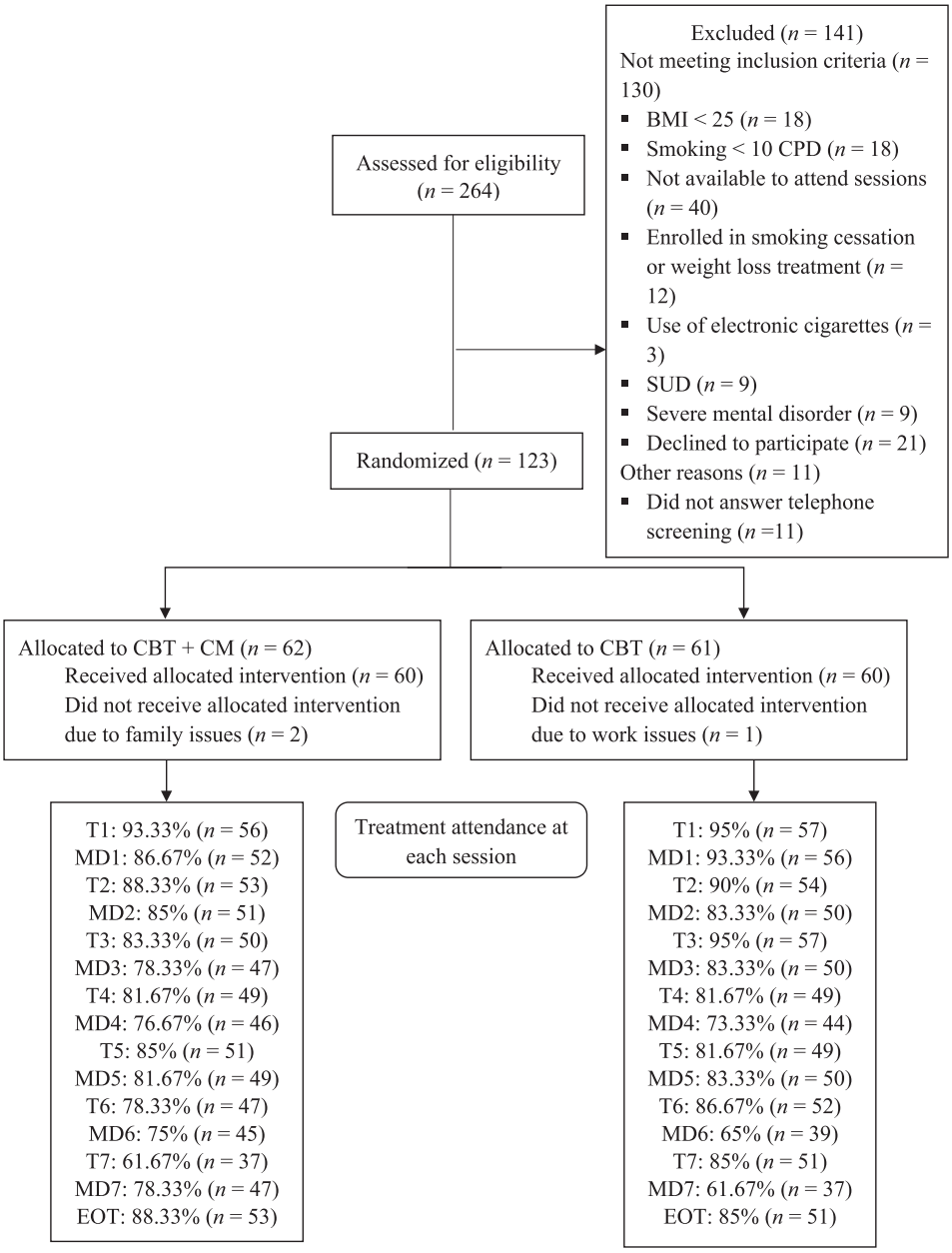

Fig. 1. CONSORT flow diagram. *Note.* BMI = body mass index; CPD = cigarettes per day; SUD = substance use disorder; CBT = cognitive-behavioral therapy; CM = contingency management; T = therapy session; MD = mid-week session; EOT = end-of-treatment.

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).

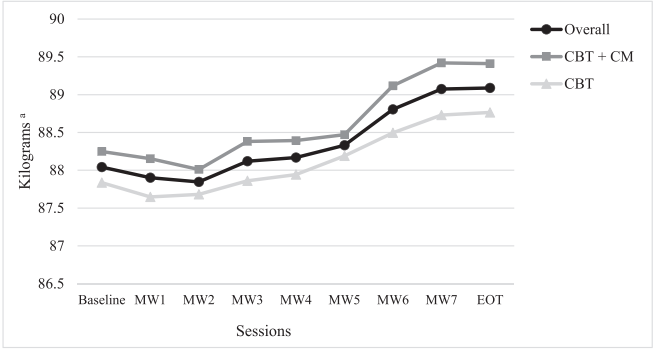

Fig. 2. Weight change throughout the treatment overall and by group. *Note.* CBT = cognitive-behavioral therapy; CM = contingency management; MW = mid-week session; EOT = end of treatment. [a] Multiple imputation of missing data was performed.

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

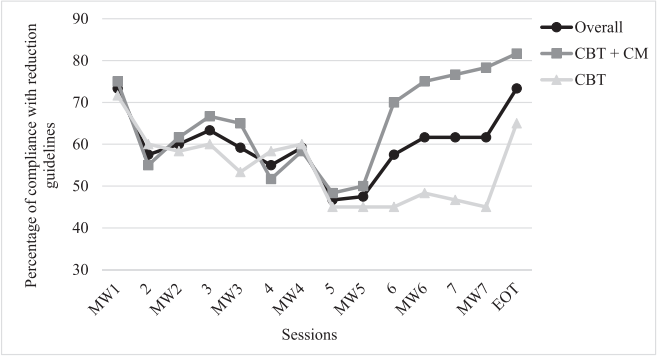

Fig. 3. Adherence to the nicotine fading guidelines throughout the treatment overall and by group. *Note.* CBT = cognitive-behavioral therapy; CM = contingency management; MW = mid-week session; EOT = end of treatment.

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.

Role of funding sources

This work was supported by the Spanish Ministry of Science and Innovation, the State Research Agency and the European Regional Development Fund [grant number RTI2018-101465-A-I00] and a predoctoral grant from the Government of the Principality of Asturias [grant number PA-21-PF-BP20-015]. The funding sources did not participate in the study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the article for publication.

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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DISCUSIÓN

El objetivo principal de la presente Tesis Doctoral fue evaluar la efectividad a corto y largo plazo de una terapia psicológica (TCC) para dejar de fumar y prevenir la ganancia de peso destinada a personas con sobrepeso u obesidad en la que la mitad de los participantes también recibió un protocolo de MC para dejar de fumar (TCC + MC). Se establecieron cuatro objetivos específicos que fueron abordados en las cuatro publicaciones que comprenden la Tesis Doctoral: 1) analizar la eficacia de las intervenciones conductuales para dejar de fumar que abordan simultáneamente el peso corporal; 2) evaluar la factibilidad, la aceptabilidad y la eficacia preliminar de una terapia para dejar de fumar simultáneamente dirigida a prevenir el incremento de peso (TCC) en personas con sobrepeso u obesidad que se combinó con un protocolo de MC para dejar de fumar; 3) examinar los resultados de la TCC en cuanto a las tasas de abstinencia, el cambio de peso, los hábitos alimentarios, la actividad física y el estado de ánimo al término de la terapia y en los seguimientos realizados uno, tres, seis y doce meses después, así como examinar el efecto aditivo de incluir el MC; y 4) analizar los cambios en la conducta tabáquica, la conducta alimentaria, el ejercicio y el sueño ocurridos a lo largo de la terapia, así como su impacto sobre la evolución del peso. En los siguientes apartados se resumen sus principales hallazgos de los estudios incluidos.

1. Eficacia de las intervenciones conductuales para dejar de fumar que abordan simultáneamente el peso corporal

El metaanálisis examinó las tasas de abstinencia y el cambio de peso de un total de 28 ensayos controlados aleatorizados que comparaban las intervenciones conductuales

destinadas abordar tanto el tabaquismo como el peso frente a aquellas dirigidas a abordar exclusivamente el tabaquismo, así como las variables que potencialmente podían moderar su eficacia. Las intervenciones combinadas incrementaron significativamente las tasas de abstinencia al finalizar el tratamiento (33,85% vs. 28,36%) pero no en los seguimientos. Sin embargo, el componente dirigido a prevenir el incremento de peso no tuvo eficacia en ningún punto temporal. El análisis de los moderadores, que no se había realizado en metaanálisis previos, concluyó que al finalizar el tratamiento las tasas de abstinencia eran más elevadas cuando la media de edad era más alta y cuando el número total de sesiones dirigidas al tabaco y al peso era mayor.

La relevancia clínica de estos resultados reside en primer lugar en que intervenir simultáneamente sobre la conducta tabáquica y el peso corporal no solo no perjudica al alcance de la abstinencia tabáquica, tal y como concluyeron metaanálisis previos (Hartmann-Boyce et al., 2021; Spring et al., 2009), sino que incrementa ligeramente las tasas de abstinencia en el postratamiento. Además, dado que la suma total de sesiones dirigidas al tabaco y al peso incrementó las tasas de abstinencia, los profesionales de la salud pueden abordar simultáneamente ambas cuestiones sin que ello suponga un perjuicio para las personas. En segundo lugar, el estudio remarcó la necesidad de desarrollar nuevas intervenciones que alcancen el mantenimiento del peso tras dejar de fumar, también en la línea de las conclusiones de los metaanálisis precedentes (Hartmann-Boyce et al., 2021; Spring et al., 2009). Este punto es de vital importancia teniendo en cuenta los potenciales efectos perjudiciales del incremento de peso, incluyendo el desarrollo de problemas de salud como la diabetes (Bush et al., 2016; Harris et al., 2016; Wang et al., 2021) o el incremento de la probabilidad de recaída (Krotter et al., 2023; Salk et al., 2019; Tuovinen et al., 2015). Dado que ningún estudio había combinado la mejora de los hábitos alimentarios, el incremento de la actividad física y el ejercicio, el abordaje

de las preocupaciones por el incremento de peso y el manejo de las conductas alimentarias desordenadas durante la deshabituación tabáquica, abordar este vacío en la literatura podría arrojar luz sobre cómo prevenir eficazmente la ganancia de peso tras la cesación tabáquica. Esto último unido al hecho de que solamente un estudio de los 28 revisados incluía una muestra de personas con sobrepeso u obesidad desencadenaron los tres objetivos específicos restantes de la presente Tesis Doctoral. Finalmente, una menor edad se asoció a una menor probabilidad de alcanzar la abstinencia tabáquica en el postratamiento. A pesar de que esto pueda sugerir la necesidad de adaptar las intervenciones a la población de menor edad, el rango medio de edad de los estudios incluidos (entre 36,5 ± 12 y 59,9 ± 6,7) excluía a adultos menores de 35 años. Por lo tanto, sería necesario realizar estudios en un rango de edad más amplio para dilucidar el efecto de la edad sobre las tasas de abstinencia en estas intervenciones.

En conclusión, a pesar de las limitaciones del metaanálisis, especialmente vinculadas a la calidad metodológica de los ensayos incluidos (e. g., abstinencia tabáquica y/o peso corporal evaluados mediante autoinforme, muestra mayoritariamente femenina [76,54%]), el estudio enfatizó que intervenir sobre el peso mientras se deja de fumar tiene un impacto positivo en las tasas de abstinencia al finalizar la intervención, a pesar de que no prevenga efectivamente la ganancia de peso. En esa línea, resulta necesario desarrollar nuevas intervenciones que faciliten el mantenimiento del peso tras dejar de fumar a corto y largo plazo.

2. Factibilidad, aceptabilidad y eficacia preliminar de la terapia para dejar de fumar y prevenir el incremento de peso en población con sobrepeso u obesidad

La terapia desarrollada para abordar simultáneamente el tabaquismo y el peso corporal (TCC) resultó factible y aceptable. Con respecto a la factibilidad, la tasa de éxito del reclutamiento fue del 80,39%, y el 90,24% de los participantes finalizó la terapia con una media de asistencia de 13,20 sesiones de las 15 que la conformaban. En cuanto a la aceptabilidad, entre el 70% y el 90% se mostró satisfecho con la intervención recibida en lo referido a la duración y frecuencia de las sesiones, el formato grupal y el día programado para dejar de fumar, entre otros aspectos. La satisfacción con el desempeño de los terapeutas y la utilidad de la terapia también fue elevada, con puntuaciones que oscilaban entre el 8 y el 10. Respecto a la eficacia preliminar, los participantes redujeron significativamente sus niveles de cotinina en orina, y quienes alcanzaron la abstinencia en el postratamiento incrementaron significativamente su peso (M_{kg} = 1,25). La media de asistencia a las sesiones y las tasas de abstinencia al finalizar la terapia fueron significativamente más elevadas en el grupo de TCC + MC que en el grupo de TCC (respectivamente, 14,82 vs. 13,30 y 100% vs. 58,33%). Sin embargo, mientras que el incremento de peso entre los abstinentes del grupo de TCC + MC fue significativo, no lo fue entre los del grupo de TCC (1,29 kg vs. 1,18 kg respectivamente).

Las tasas de reclutamiento fueron similares a las del único ensayo controlado aleatorizado realizado en población con sobrepeso u obesidad (White et al., 2019), y las tasas de finalización también se asemejaron a las encontradas previamente en intervenciones similares con mujeres preocupadas por ganar peso (Bloom et al., 2017; Bloom, Hunt, et al., 2020). La elevada satisfacción de los participantes con la terapia y las tasas de abstinencia alcanzadas, superiores a las de estudios realizados con población

con sobrepeso u obesidad (White et al., 2019; Wilcox et al., 2010), remarcaban la necesidad de examinar la eficacia de la terapia con un mayor número de participantes. Este es el paso posterior a los estudios de factibilidad cuando revelan hallazgos como los aquí encontrados (Eldridge et al., 2016). Los resultados preliminares sobre la eficacia del MC, aunque eran prometedores a pesar de la no consecución del mantenimiento del peso, debían ser interpretados con cautela dado el escaso tamaño de muestra incluido en el estudio ($N = 41$) y la ausencia de un análisis de los resultados a largo plazo.

3. Eficacia de la terapia para dejar de fumar y prevenir el incremento de peso y efecto aditivo del manejo de contingencias para dejar de fumar sobre la abstinencia tabáquica, el peso corporal y otras variables secundarias

Este estudio, destinado a analizar la eficacia de la TCC para dejar de fumar y prevenir el incremento de peso a corto y largo plazo, concluyó que la TCC es eficaz para dejar de fumar, pero no para prevenir el incremento de peso. Al finalizar la terapia, el punto de prevalencia de siete días y la tasa de abstinencia prolongada fueron del 70%. Los porcentajes se redujeron progresivamente con el paso del tiempo hasta el 25% y el 16,67% respectivamente, en el seguimiento de los doce meses. Los participantes que alcanzaron la abstinencia prolongada incrementaron significativamente su peso corporal una media de 1,07 kg al finalizar la terapia y de 4,19 kg a los doce meses. De las variables secundarias analizadas, se produjo una mejora frente a la evaluación inicial en la adherencia a la dieta mediterránea hasta el seguimiento de los seis meses, y se redujeron los niveles de ingesta emocional y externa en todos los seguimientos. Aunque los niveles de actividad física se incrementaron a corto plazo, se redujeron significativamente en el último seguimiento. No hubo cambios en la ingesta restrictiva ni en la sintomatología depresiva, ansiosa y de estrés.

En cuanto al efecto aditivo del MC para dejar de fumar, no se encontraron diferencias estadísticamente significativas en ninguna de las variables analizadas (i.e. tasas de finalización, media de asistencia a las sesiones, punto de prevalencia de siete días, tasas de abstinencia prolongada, días de abstinencia continuada, incremento de peso corporal, y variables secundarias) en ninguno de los puntos temporales (i.e., postratamiento y seguimientos).

Tomado los resultados de los dos grupos en conjunto, las tasas de abstinencia en el postratamiento son más altas que las encontradas en estudios previos con población con exceso de peso (Heggen et al., 2016; White et al., 2019; Wilcox et al., 2010). En los seguimientos, cuando los porcentajes de abstinencia se redujeron considerablemente, las tasas son más elevadas que las de algunos estudios (Love et al., 2011; White et al., 2019) pero más bajas que las de otros (Heggen et al., 2016; Wilcox et al., 2010). Es probable que la eficacia de la TCC a corto plazo esté relacionada con la elevada retención alcanzada al finalizar la terapia (Garey et al., 2020) y a la inclusión del componente dirigido a prevenir el incremento de peso adaptado a las características de la población específica del estudio (Hartmann-Boyce et al., 2021).

El hecho de que el grupo de TCC + MC mostrara una tendencia no significativa a obtener mejores resultados en torno al consumo de tabaco es llamativo si se tiene en cuenta la evidencia que el MC para dejar de fumar acumula (González-Roz & Secades-Villa, 2022; Kock et al., 2023; Marchal-Mateos et al., 2024; Notley et al., 2019; Secades-Villa et al., 2020). Una hipótesis plausible para explicar este fenómeno tiene que ver con la pandemia del COVID-19. El 12,50% de la muestra recibió la intervención entre octubre y diciembre de 2020, estando vigentes medidas muy restrictivas de prevención de la propagación del virus, como el toque de queda y los cierres perimetrales; mientras que el 31,67% la recibió entre enero y mayo de 2021, con medidas como la limitación horaria

de apertura de los locales de ocio hasta que se decretó el fin del estado de alarma. Hasta la fecha, el efecto de la pandemia sobre la conducta tabáquica no está clara, señalándose tanto efectos beneficiosos como perjudiciales (Barrington-Trimis et al., 2023; Johnston et al., 2023). De hecho, en el estudio de factibilidad discutido en el punto anterior, el 40,54% de los participantes señaló que la pandemia facilitó el abandono del consumo de tabaco, el 21,62% afirmó que lo dificultó, y el 8,10% informó motivos en ambos sentidos. Tampoco debe obviarse que las medidas restrictivas de prevención de contagio del COVID-19 dificultaron temporalmente la utilización y disfrute de los incentivos, lo que podría haber reducido su eficacia. Finalmente, otras cuestiones como la retirada de los incentivos durante los seguimientos también podrían haber afectado a los resultados (Davis et al., 2016; Pfund et al., 2021).

En cuanto al cambio de peso, el incremento ponderal fue inferior al encontrado en estudios previos dirigidos a dejar de fumar y a controlar el peso (Bize et al., 2010; Levine et al., 2010), pero superior a otros (Audrain-McGovern et al., 2023; Lycett et al., 2020). La intervención dio lugar a una ganancia ligeramente inferior a los doce meses en comparación con la ganancia mostrada tras dejar de fumar en intervenciones sin manejo del peso (i.e., 0,5 kg menos) (Aubin et al., 2012). La prevención del incremento de peso se llevó a cabo mediante un programa multicomponente. Sin embargo, no se utilizaron técnicas de entrevista motivacional a lo largo de toda la terapia, sino únicamente en la primera y sexta sesión. Estas técnicas han mostrado eficacia para lograr cambios en el estilo de vida en personas con sobrepeso u obesidad (Rodriguez-Cristobal et al., 2017). Dado que no había ningún criterio de inclusión vinculado a la motivación o interés por prevenir el incremento de peso, la utilización de estas técnicas podría haber reforzado la realización de cambios en el estilo de vida que repercutieran en el peso. Su combinación con enfoques más intensivos, como el ejercicio físico supervisado (Marcus et al., 1999),

también podría haber arrojado mejores resultados. Al margen de la no consecución del mantenimiento del peso corporal, el protocolo mejoró temporalmente la adherencia a la dieta mediterránea y la realización actividad física, y logró reducir durante todos los seguimientos la ingesta emocional y externa. Estos cambios son muy beneficiosos para los participantes del estudio.

Las principales limitaciones de esta investigación se relacionan, además de con los potenciales efectos de la pandemia del COVID-19, con la pérdida de datos a lo largo del ensayo (i.e., únicamente el 61,67% de la muestra asistió al seguimiento de los 12 meses). A pesar de ello, los hallazgos destacan que intervenir simultáneamente en el tabaquismo y el peso es efectivo para que las personas con sobrepeso u obesidad dejen de fumar. También pone de manifiesto las dificultades que esta población de riesgo tiene para mantener su peso corporal, y la necesidad de realizar más investigaciones que permitan desarrollar intervenciones eficaces en ese sentido.

4. Cambios en la conducta tabáquica, la conducta alimentaria, el ejercicio y el sueño a lo largo de la terapia y su impacto sobre el peso corporal

En este último estudio dirigido a analizar los cambios ocurridos a lo largo de la terapia y su impacto sobre el peso corporal, tampoco se encontraron diferencias en ninguna de las variables analizadas a lo largo de la terapia entre el grupo de TCC + MC y el grupo de TCC. Considerando los resultados de ambos grupos en conjunto, el número de personas que ganaron peso fue aumentando progresivamente a lo largo de la terapia hasta alcanzar el 17,30% de la muestra en el postratamiento. Esta tendencia también se encontró en otros estudios con diseños similares (Oncken et al., 2020; Prod'hom et al., 2013). Además, en la línea de los resultados de investigaciones previas, un mayor peso

corporal inicial se relacionó con una mayor ganancia de peso (Froom et al., 1999; Lycett et al., 2011).

La adherencia a las pautas de reducción gradual del consumo de nicotina fue casi del 60%, porcentaje inferior al de un estudio previo (López-Núñez, Martínez-Loredo, et al., 2016) pero superior al de otro (Aonso-Diego et al., 2021). El hecho de que una mayor reducción en los niveles de cotinina se relacione con un mayor incremento de peso concuerda con la literatura previa (Killi et al., 2020; Kmetova et al., 2014), e indica que la ganancia de peso se inició antes de que los participantes alcanzaran la abstinencia, es decir, mientras reducían gradualmente el número de cigarrillos que consumían.

El número de participantes que informaron de un incremento en el apetito aumentó progresivamente a lo largo de la terapia. Dado que informar de un apetito reducido o estable se relacionó con una menor ganancia de peso, monitorizar los cambios en el apetito durante la deshabituación tabáquica y utilizar enfoques destinados a la tolerancia al malestar relacionado con el incremento en el apetito (Bloom, Ramsey, et al., 2020) podría mitigar el incremento de peso en esta población. Los picoteos de comida y las horas de sueño se mantuvieron estables a lo largo del tiempo, y no tuvieron efecto sobre el peso corporal. El tiempo de ejercicio se incrementó durante la terapia, y se relacionó significativamente con una menor ganancia de peso. El efecto del ejercicio podría explicarse por el incremento en el gasto calórico y la reducción del *craving* hacia la comida (Oh & Taylor, 2014; Taylor & Oliver, 2009) a lo largo de la deshabituación tabáquica.

Las principales limitaciones de este estudio son el uso de medidas autoinformadas (i.e., conducta alimentaria, sueño y ejercicio) y la no consideración de otras variables relacionadas que podrían haber repercutido en el cambio de peso (e. g., calidad del sueño). A pesar de ello, los resultados tienen implicaciones prácticas relevantes para la

intervención con población con sobrepeso u obesidad, con dificultades para mantener su peso dados los resultados encontrados en el ensayo controlado aleatorizado. Por un lado, las personas con mayor peso corporal y mayores niveles iniciales de cotinina en orina presentan una mayor vulnerabilidad para incrementar su peso durante la deshabituación. Por otro, incrementar los niveles de ejercicio e intervenir sobre los cambios en el apetito podría facilitar el mantenimiento del peso en personas con exceso de peso corporal.

5. Líneas futuras de investigación

A continuación, teniendo en cuenta los resultados de la presente Tesis Doctoral, se sugieren algunas líneas futuras de investigación.

En primer lugar, el protocolo de MC aplicado se destinó a reforzar la abstinencia tabáquica, pero el MC también ha mostrado eficacia para incrementar los niveles de ejercicio o mejorar los hábitos alimentarios (Corepal et al., 2018; de Walque, 2020; Ellis et al., 2021). Un estudio de factibilidad publicado por Bloom, Hunt et al. (2020) examinó un protocolo de MC dual destinado tanto a reforzar la abstinencia tabáquica como al mantenimiento del peso en una muestra de 10 mujeres preocupadas por incrementar de peso tras dejar de fumar, y encontró resultados prometedores. Aunque los hallazgos son preliminares, explorar la eficacia de esta modalidad de MC en población con exceso de peso podría arrojar luz sobre cómo prevenir el incremento de peso tras la cesación tabáquica. También permitiría evaluar si la aplicación del MC con otros parámetros, o a lo largo de un periodo temporal distinto al de la pandemia del COVID-19, es eficaz en esta población.

En segundo lugar, ninguno de los estudios que han examinado los predictores de la ganancia de peso tras dejar de fumar hasta la fecha (John et al., 2006; Killi et al.,

2020; Kmetova et al., 2014; Komiyama et al., 2013; Salk et al., 2019; Taleb et al., 2017) ha incluido exclusivamente a personas con sobrepeso u obesidad. Teniendo en cuenta los resultados de la ganancia de peso encontrados, y que el último artículo incluido sólo examinó las variables asociadas a la ganancia de peso durante el tratamiento, analizar los predictores del incremento de peso a corto y largo plazo, así como de la recaída en el tabaco, podría ser de utilidad para diseñar intervenciones más ajustadas a las necesidades de esta población.

En tercer lugar, enfoques terapéuticos distintos al aplicado en esta Tesis Doctoral, como el de la Terapia de Aceptación y Compromiso (ACT), han mostrado eficacia en diversas revisiones sistemáticas y metaanálisis para dejar de fumar (Krotter et al., 2024; Kwan et al., 2024; Lee et al., 2015) y para abordar el peso corporal e intervenir sobre la conducta alimentaria (Chew et al., 2023; Lillis & Kendra, 2014), también incluyendo específicamente a población con sobrepeso u obesidad (Iturbe et al., 2022; Pitil & Ghazali, 2022). Sería necesario examinar si la ACT dirigida a dejar de fumar y a prevenir el incremento de peso en personas con sobrepeso u obesidad incrementa las tasas de abstinencia y facilita el mantenimiento del peso a largo plazo, algo que hasta la fecha no se ha investigado.

Por último, el IMC es una medida que presenta limitaciones (Buss, 2014; Frankenfield et al., 2001), y asumir que un mayor peso corporal supone necesariamente un peor estado de salud es erróneo, dado que implica omitir que son las variables conductuales como el sedentarismo y los hábitos alimentarios inadecuados las que verdaderamente suponen un perjuicio para la salud (Hunger et al., 2020). Desarrollar estudios en los que se tomen como medidas de resultado exclusivamente variables relacionadas con el estilo de vida, que no enfaticen en la prevención de la ganancia de peso (Khasteganan et al., 2019), podría ser un enfoque útil para la población diana de

este estudio. Algunos ejemplos son las intervenciones basadas en la alimentación intuitiva (Babbott et al., 2023; Linardon et al., 2021) o las conocidas como *Health at Every Size*© (Clarke et al., 2024; Ulian et al., 2018), que no se han aplicado durante la deshabituación tabáquica en esta población hasta la fecha, y que han mostrado eficacia para, por ejemplo, reducir las conductas alimentarias desordenadas o mejorar la apreciación corporal.

CONCLUSIONES

Las conclusiones de la presente Tesis Doctoral son las siguientes:

1) Las intervenciones conductuales que abordan el tabaquismo y el peso corporal incrementan significativamente las tasas de abstinencia en el postratamiento, pero su efecto desaparece a corto y largo plazo. Sin embargo, esas intervenciones no son eficaces para prevenir el incremento de peso.
2) Abordar simultáneamente el tabaquismo y el peso corporal es factible para la población con sobrepeso u obesidad. Los participantes consideraron que la TCC era aceptable, y mostraron una elevada satisfacción con la terapia recibida.
3) La TCC fue eficaz para dejar de fumar, aunque su efecto se redujo progresivamente durante los seguimientos. Sin embargo, no demostró prevenir eficazmente el incremento de peso tras dejar de fumar en ningún punto temporal.
4) A pesar de los resultados preliminares del estudio de factibilidad y de haber una tendencia a favor del MC en el ensayo completo, su combinación con la TCC no mejoró significativamente los resultados relacionados con la conducta tabáquica ni con ninguna de las variables restantes analizadas a lo largo de la terapia, en el postratamiento o en los seguimientos.
5) Las personas con un peso corporal inicial más elevado y con una mayor reducción en los niveles de cotinina en orina durante la terapia mostraron un mayor riesgo de ganar peso. Abordar los cambios en el apetito e incrementar

las horas de ejercicio podría mitigar la ganancia de peso tras dejar de fumar en población con sobrepeso u obesidad.

CONCLUSIONS (BIS)

The conclusions of the present Doctoral Thesis are as follows:

1) Behavioral interventions addressing smoking cessation and body weight management significantly increase abstinence rates at post-treatment, but their effect disappear in the short and long term. Furthermore, these interventions are not effective in preventing weight gain.
2) Addressing simultaneously smoking cessation and weight gain prevention is feasible for individuals with overweight or obesity. Participants found CBT acceptable and reported high satisfaction with the received therapy.
3) CBT has been demonstrated to be an effective intervention for smoking cessation, although its efficacy appears to diminish over time. However, CBT did not demonstrate any significant effect in preventing weight gain among individuals who achieved abstinence during the intervention, at post-treatment, or at any follow-up.
4) Despite the preliminary feasibility study results and a trend favoring CM in the full trial, its combination with CBT did not significantly improve outcomes related to smoking behavior or any of the other variables analyzed throughout the therapy, at post-treatment or at follow-ups.
5) Individuals with a higher baseline body weight and a greater reduction in urine cotinine levels during the therapy showed a higher risk of weight gain. Addressing changes in appetite and increasing exercise hours could mitigate weight gain after smoking cessation in population with overweight or obesity.

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ANEXO: PROTOCOLO

- Objetivo general de la terapia: dejar de fumar y prevenir el aumento de peso mejorando los hábitos saludables. En ningún caso se pretende que las personas realicen una dieta restrictiva para perder peso.
- Objetivos específicos de la terapia relacionados con la prevención de la ganancia de peso:
    - Mejorar la calidad de los hábitos alimentarios (incrementar la adherencia a la dieta mediterránea y comer cinco porciones de frutas/verduras al día).
    - Prevenir la restricción alimentaria, la ingesta emocional y la ingesta externa, así como gestionar adecuadamente los tipos más comunes de sobreingesta (e. g., picoteos de comida, raciones grandes, alimentación en base a alimentos palatables, atracones…).
    - Mejorar el estilo alimentario (e. g., comer entre tres y cinco veces al día, evitar estar más de cuatro horas sin comer, comer con atención plena y con un estilo tranquilo…).
    - Aumentar semanalmente la actividad física y el ejercicio moderadamente intenso.
    - Dormir 7-8 horas al día.
    - Incrementar las actividades gratificantes incompatibles con fumar y comer, así como reducir el tiempo de realización de actividades sedentarias.

- Prevenir la recaída en el tabaquismo y mantener el peso corporal a largo plazo.

– En la siguiente tabla se describen todos los componentes de la terapia (TCC):

Sesión 1A
▪ Autorregistros del consumo de cigarrillos. ▪ Feedback bioquímico del consumo de nicotina mediante monóxido de carbono en aire espirado (CO) y cotinina en orina. ▪ Psicoeducación sobre el consumo de tabaco y la ganancia de peso tras dejar de fumar. ▪ Incremento de la motivación para dejar de fumar y prevenir el aumento de peso. ▪ Análisis funcional de la conducta tabáquica. ▪ Psicoeducación sobre la dieta mediterránea. ▪ Higiene del sueño. ▪ Reducción de la ingesta de nicotina en un 20%.
Sesiones 1B, 2B, 3B, 4B, 5B, 6B, 7B
▪ Feedback bioquímico del consumo de nicotina (CO y cotinina en orina). ▪ Medición del peso corporal. ▪ Seguimiento de las pautas semanales de reducción de consumo de nicotina y mejora de los hábitos de alimentación, la actividad física/ejercicio y el sueño.
Sesión 2A
▪ Autorregistros del consumo de cigarrillos. ▪ Feedback bioquímico del consumo de nicotina (CO y cotinina en orina). ▪ Control estimular de los estímulos relacionados con el tabaquismo y exposición con prevención de respuestas. ▪ Gestión del *craving* del consumo de tabaco mediante aceptación y habilidades de tolerancia al malestar. ▪ Respiración profunda. ▪ Consejo sobre la realización de actividad física y ejercicio mediante una planificación con incremento semanal de ejercicio de intensidad moderada hasta alcanzar 2 horas y media de ejercicio al finalizar la terapia. ▪ Reducción de la ingesta de nicotina en un 20%.
Sesión 3A
▪ Autorregistros del consumo de cigarrillos. ▪ Feedback bioquímico del consumo de nicotina (CO y cotinina en orina). ▪ Psicoeducación sobre las causas de la obesidad, la sobreingesta y la conducta alimentaria desordenada. ▪ Registro de comida. ▪ Incremento de la motivación para hacer 3/5 comidas regulares al día, incrementar el consumo de vegetales, y seguir la dieta mediterránea. ▪ Reducción de la ingesta de nicotina en un 20%.
Sesión 4A
▪ Autorregistros del consumo de cigarrillos. ▪ Feedback bioquímico del consumo de nicotina (CO y cotinina en orina). ▪ Análisis funcional de los episodios de sobreingesta.

▪ Estrategias para mejorar la alimentación y prevenir la conducta alimentaria problemática (restricción alimentaria, picoteos de comida o atracones). o Pautas para evitar la restricción alimentaria realizando ingestas regulares. o Pautas para manejar la ingesta externa mediante el control de estímulos, la exposición y la prevención de respuestas. o Pautas para abordar la ingesta emocional mediante habilidades de aceptación, atención plena, y tolerancia al malestar. ▪ Registro de comida. ▪ Reducción de la ingesta de nicotina en un 20%.
Sesión 5A
▪ Autorregistros del consumo de cigarrillos. ▪ Feedback bioquímico del consumo de nicotina (CO y cotinina en orina). ▪ Solución de problemas. ▪ Habilidades de regulación emocional. ▪ Registro de comida. ▪ Reducción progresiva de los últimos cigarrillos hasta alcanzar la abstinencia 48 antes de la sexta sesión.
Sesión 6A
▪ Incremento de la motivación para dejar de fumar y prevenir la ganancia de peso. ▪ Análisis de las creencias erróneas sobre dejar de fumar y ganar peso. ▪ Manejo del *craving* hacia el tabaco y la comida. ▪ Búsqueda de actividades reforzantes incompatibles con la conducta tabáquica, la sobreingesta y el estilo de vida sedentario. ▪ Registro de comida.
Sesión 7A
▪ Estrategias de prevención de recaídas del tabaquismo y para mantener un estilo de vida saludable. ▪ Registro de comida.
Sesión 8A (postratamiento)
▪ Estrategias de prevención de recaídas del tabaquismo y para mantener un estilo de vida saludable.

– El protocolo de manejo de contingencias aplicado en la mitad de los participantes del ensayo controlado aleatorizado (grupo TCC + MC; $n = 60$) se resume en la siguiente tabla:

	Sesión 6A	Sesión 6B	Sesión 7A	Sesión 7B	Sesión 8A	Total
Puntos [a]	50	55	60	65	70	320
Bonus	0	+10	0	+10	0	

Nota. [a] Un punto equivale a un euro.