ISRCTN83865809 https://doi.org/10.1186/ISRCTN83865809

Very low calorie diet, modest dietary restriction and sequential behavioural programme in overweight smokers stopping smoking

Submission date	Recruitment status	[X] Prospectively registered
22/12/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/10/2018	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Paul Aveyard

Contact details
UK Centre for Tobacco Control Studies: a UKCRC Centre of Excellence in Public Health Research
Primary Care Clinical Sciences
University of Birmingham
Birmingham
United Kingdom
B15 2TT
+44 (0)121 414 8529
p.n.aveyard@bham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RG_08-166

Study information

Scientific Title
Randomised controlled trial of very low calorie diet, modest dietary restriction and sequential behavioural programme to effect hunger, urges to smoke, abstinence and weight gain in overweight smokers stopping smoking

Study objectives
This is a study to test the hypothesis that a very low calorie diet (VLCD) can reduce urges to smoke, alleviate hunger and manage obesity in those on a smoking cessation programme. Participants will be screened for suitability to take part in the project. The sample population will be smokers who are already overweight (body mass index [BMI] greater than 25). Participants will be randomised into an open label 429 - 559 kcal/day VLCD, 'low fat, energy restricted' or control group. Compliance to dietary advice will be verified by the presence or absence of urinary ketones for those on the VLCD and by 7-day food intake diaries for the other groups. Urges to smoke, hunger and withdrawal will be measured using the Mood and Physical Symptoms Scale (MPSS) recorded daily in a diary. Seven day point prevalence abstinence will be assessed weekly in the clinic and 4-week prolonged abstinence assessed by the Russell Standard. Weight and waist circumference will be measured and analysed in prolonged abstinent smokers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
In progress, submission via IRAS to NHS REC, NHS/HSC R&D, Portfolio Adoption

Study design
Multicentre randomised controlled open label trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Healthy, overweight smokers

Interventions

Smoking cessation interventions for all patients:
All participants will have identical treatment to support smoking cessation. This consists of weekly behavioural support using withdrawal orientated therapy of approximately 60 minutes per occasion. In addition, participants will be given a 25 mg nicotine patch e.g. Nicorette 25 mg transdermal 16 hour patch provided by South Birmingham PCT. This will be used for 8 weeks commencing on the evening of the quit day session, following rapid smoking to quit. Combination NRT will not be provided to avoid the possibility that use of acute form of NRT would differ by group if they experienced more urges to smoke or which might be used to satiate hunger.

Participants will be weaned off the patches with a lower dose patch (Nicorette 15 mg, then 10 mg transdermal 16 hour patch) provided every two weeks after that. Behavioural support and provision of NRT will be given only by therapists trained as NHS Stop Smoking Service providers.

Step by step (SBS):
Standard smoking cessation interventions include aspects of dietary advice. Even detailed dietary advice has not been shown to affect weight gain. However, standard smoking cessation advice includes the following:
1. Avoid hunger, which leads to urges to smoke, and can make lapsing more likely. Eat breakfast if this is normally missed (as it often is in smokers).
2. To satiate hunger and avoid excess weight gain, avoid highly calorie dense high glycaemic index foods, such as Mars bars. Instead prepare for increased hunger by using grapes, or carrot sticks and other immediately available sources of food. There is evidence that glucose tablets satiate urges to smoke within minutes, so these can be used.
3. Avoid excess alcohol and consider avoiding all alcohol for the immediate post-cessation period. This is to avoid lapsing due to disinhibition and the 'cue' which alcohol provides, rather than to avoid calories.
4. Drink lots of water which helps fill the stomach and satisfies 'oral cravings'
The SBS group will receive this advice and be told that they will receive the diet intervention at 3 months.

Individually-tailored dietary advice (ITDA):
Energy prescriptions used in previous studies of smoking cessation have varied. These include energy requirement minus 150 to 300 kcal/day (which is considered to equate to metabolic slowing upon nicotine withdrawal; the amount depends on number of cigarettes smoked), or a 500 kcal deficit tailored to individual requirements, a 500 kcal deficit tailored to individual requirements should weight increase by 1 kg, or a 1600 kcal diet.

Individually tailored dietary advice in this study will be based on conventional dietetic practice. An appropriate number of portions from each of the food groups that make up a healthy diet will be advised. It will be low in fat and restricted in alcohol studies have shown that these significantly increase in the diets of smokers when they quit. The energy prescription will be based on the NICE 2006 guidelines for the management of obesity. It will provide a 600 kcal deficit of energy requirement, (up to a maximum intake of 1800 kcal, which has been considered to work best in clinical practice).

Very low calorie diet (VLCD):
Lipotrim (Howard Foundation Research Ltd) will be provided for the study at cost price from Howard Foundation Research Ltd purchased by the PCT and provided free to participants. Subjects will take three shakes each day. Female formula totals 425 kcal, male formula totals 559 kcal and is complete in all essential nutrients. This will be provided weekly for 4 weeks. After

4 weeks subjects will be advised to return to eating food but continue to lose weight on an individually tailored calorie controlled diet, identical to that provided to the ITDA group.

All dietary interventions will be supervised by a registered dietician who is proficient in VLCD use and has been trained in smoking cessation. Treatment will be provided in a two-hour group setting, with measures taken and energy prescribed on an individual basis at the end of the group sessions. Any significant changes in clinical condition of individual subjects, as measured on a weekly basis, will be discussed with the supervising GP and action taken, e.g. clinically significant fall in blood pressure in subjects on the VLCD taking anti-hypertensives will require adjustment of anti-hypertensive medication. The subject's own GP will be kept informed.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The combined urge to smoke score from the MPSS (MPSS-C): expecting to see pairwise differences between the VLCD and the other arms in mean MPSS-C score measured at the end of one week of attempted abstinence in abstinent smokers defined as exhaled CO less than 10 ppm. It is standard practice to compare withdrawal scores only in those who are abstinent or largely abstinent
2. A difference in the proportion of quitters between the trial arms as measured by 7-day point prevalence abstinence at visit 4 (1-week after quit day) and prolonged smoking abstinence defined according to the Russell standard at visit 7 (end of week 4)
3. Weight gain defined as difference in weight between visits 2 and 11 (8 weeks after quit day) in participants who achieve prolonged abstinence defined according to the Russell standard
4. Measure of hunger and perceived food craving, using a hunger and craving score (HCS), and examine the association with urges to smoke during the first week after quitting in each of the arms. We will also examine the association between hunger score and weight gain in abstinent smokers.

Secondary outcome measures
Weight gain defined as difference in weight between visit 2 and visit 7 (4 weeks after quit day) in participants who achieve prolonged abstinence defined according to the Russell standard.

Tertiary outcome measures:
1. Systolic and diastolic blood pressure (BP) measured weekly
2. Heart rate measured weekly
3. Fasting lipids and glucose measured at visits 11 (8 weeks after quit day), 26 weeks and 52 weeks after quit day
4. Change in weight, waist to hip ratio and % body fat composition measured at each visit
5. Change in lung function measured at visits 11 (8 weeks after quit day), 26 weeks and 52 weeks after quit day
6. Nutritional analysis showing mean change in dietary intake before and after intervention and compared by trial arm. This will be broken down by nutrient, i.e. energy in calories, percentage energy from simple and complex carbohydrates, percentage energy from total, saturated, monounsaturated and polyunsaturated fat, percentage energy from alcohol and amount of

protein and micronutrient and trace elements in grams, milligrams and micrograms respectively
7. Comparison of nutrient intake to craving scores at the end of the first week of quitting in the ITDA and SBS group

Overall study start date
02/03/2009

Completion date
30/11/2010

Eligibility

Key inclusion criteria
1. Aged over 18 years, either sex
2. Daily cigarette smoker with an exhaled carbon monoxide (CO) of at least 10 ppm at least 15 minutes after last smoking
3. BMI of at least 25 kg/m^2
4. Not on a diet or weight loss programme
5. Willing to be randomised to any of the three arms and willing and able to comply with the intervention and all study procedures

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. If subjects have any of the absolute or relative contra-indications to VLCD use (e.g. recent myocardial infarctions [MI], pregnant, lactose intolerance)
2. Type 2 diabetics on oral hypoglycaemic agents or insulin (diet controlled type 2 diabetics may be included)
3. Previous adverse reaction to nicotine patches (which would preclude their future use)
4. Currently using smoking cessation medication or medication, e.g. nortriptyline that is known to help smokers quit
5. Those already actively losing weight on a diet, currently using sibutramine or orlistat, or scheduled for bariatric surgery
6. Suspected abuse of alcohol or other drug
7. Use of any smokeless tobacco
8. Currently participating in other therapeutic clinical trials

Date of first enrolment
02/03/2009

Date of final enrolment
30/11/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UK Centre for Tobacco Control Studies: a UKCRC Centre of Excellence in Public Health Research
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
c/o Dr Brendan W. Laverty
Assistant Director
Research & Commercial Services
Aitchison Building
Edgbaston
Birmingham
England
United Kingdom
B15 2TT
+44 (0)121 414 7618
b.w.laverty@bham.ac.uk

Sponsor type
University/education

Website
http://www.bham.ac.uk/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
University/education

Funder Name
University of Birmingham (UK) - UKCRC Centre of Excellence in Public Health Research Award

Results and Publications

Publication and dissemination plan
Not provided at time of registration

2012 results published in thesis http://etheses.bham.ac.uk/3254/

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/10/2010		Yes	No