

Food choice and changes in body weight and shape in those attempting smoking cessation

Submission date 15/11/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/11/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 17/07/2015	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Good nutrition is vital to good health and while many people do eat well, many make poor food choices leading to poorer health. This is particularly true among the more disadvantaged and vulnerable in the population. Smokers are a well recognised vulnerable group, who are known to make poor food choices and consume a poorer quality diet compared to people who do not smoke. There is a strong link between low income and cigarette smoking, and while there has been an overall fall in the number of people in the population who smoke the fall is less marked among those on low incomes living in poorer areas. Most people gain weight as they get older however there are certain periods of life when the risk of gaining weight is increased. One of these is when stopping smoking and about 80% of people who stop smoking put on around 5-6kg in weight. Many smokers are already overweight or obese and so putting on more weight after stopping smoking has huge implications for their health. The possibility of putting on weight prevents many people from trying to stop smoking. For those who do try to stop, weight gain is frequently a cause of resuming smoking. Stopping smoking improves taste and appetite and snacking is a common replacement activity. Continuation of some of the poor food choices established before trying to stop smoking also encourages weight gain. In Glasgow, Smokefree Services provide a 7-week community-based group behavioural counselling service. Diet and weight issues are routinely raised by people attending these classes but are not formally addressed. It was proposed to provide dietary advice sessions as an add-on to the smoking cessation classes. This setting would allow access to smokers and to people low income groups. Providing dietary advice might help some people stop smoking and so improve health from that point of view but also improve food choice and minimise weight gain. This would have additional benefits to health by lowering further the risk of coronary heart disease. Improved diet quality would lead to better health even in those who fail to stop smoking. The overall aim of this study was to find out if providing a structured programme of advice on diet and physical activity to people trying to stop smoking would help with smoking cessation and so improve health, but also improve food choice and perhaps limit weight gain.

Who can participate?

Adults attempting to stop smoking and attending smoking cessation classes run by Smokefree Services throughout Glasgow were eligible to participate. Participants had to be prepared to attend the add-on sessions being run immediately following the smoking cessation classes.

Smoking Cessation advisors highlighted the study at the first 2 classes of the smoking cessation programme, and distributed written study information. Formal recruitment took place at week 3. All participants were required to give informed consent.

What does the study involve?

Smoking cessation classes were randomly allocated to receive either the additional dietary intervention programme or continue with the usual smoking cessation programme. Classes chosen to receive the dietary intervention commenced a 24-week programme, focussed on improving food choice and minimising weight gain. The intervention was delivered by smoking cessation advisors, who had undergone a 3-day nutrition and behavioural change training programme designed specifically for the study. The programme comprised an initial 6-week programme of nutritional advice with a different aspect of nutrition covered at each add-on group session. This was then followed by 5 additional follow up group sessions for reinforcement of advice, and self monitoring. The format of the dietary intervention was designed to mirror that of the smoking cessation sessions with each session comprising of advice /information, group discussion, sharing of experiences and peer support. Throughout the 24 week programme participants were encouraged to self-monitor their food intakes to promote greater awareness of behaviour, and were also provided with various 'tools' to help them to achieve changes in diet and physical activity.

What are the possible benefits and risks of participating?

There were no known risks to participants.

Where is the study run from?

University of Glasgow (UK).

When is the study starting and how long is it expected to run for?

Recruitment of classes commenced on 1st January 2008 until 31st July 2008. Participant were followed up 6 months and one year post recruitment

Who is funding the study?

This work was funded by the Food Standards Agency UK (FSA) and carried out in collaboration with NHS Greater Glasgow and Clyde Smokefree Services (UK).

Who is the main contact?

Dr Catherine Hankey

Catherine.Hankey@glasgow.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Catherine Hankey

Contact details

College of Medical, Veterinary & Life Sciences

Life-Course Nutrition & Health

School of Medicine

University of Glasgow

4th Floor, Walton Building
Glasgow Royal Infirmary
84 Castle Street
Glasgow
United Kingdom
G4 0SF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NO9025

Study information

Scientific Title

Food choice and changes in body weight and shape in those attempting smoking cessation: a cluster randomised controlled study

Study objectives

To determine if the provision of nutritional advice alongside attempts to stop smoking could assist some in smoking cessation and thus improve health but also improve food choice and perhaps limit the weight gain associated with smoking cessation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West of Scotland Research Ethics Service, 18/09/2007, ref: REC 07/S0709/78

Study design

Cluster randomised controlled study

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Patient information sheet can be found at <http://dl.dropbox.com/u/48057585/fsapatientinfoform.pdf>

Health condition(s) or problem(s) studied

Obesity

Interventions

Smoking cessation classes randomised to intervention commenced a 24-week intervention, focussed on improving food choice and minimising weight gain.

Classes randomised to control received 'usual care'. Randomisation was carried out using an Interactive Voice Response system.

The intervention was delivered by smoking cessation advisors, who had undergone a three day nutrition and behavioural change training programme designed specifically for the study. The intervention comprised an initial 6-week programme of nutritional advice with a different aspect of nutrition covered at each add-on group session. This was followed by five additional follow up group sessions for reinforcement of advice, and self monitoring. Each session comprised of advice/information, group discussion, sharing of experiences and peer support and mirrored the format of smoking cessation sessions.

'Healthy Living Packs' (www.healthscotland.com), were given to provide volunteers with written information. Physical Activity packs and pedometers (SW-200 Digi-Walker, Yamax Corp) were provided to encourage increases in physical activity. Plate models, a tool to assist dietary education, were provided to direct the composition of main meals.

All participants had measurements of body-weight, waist circumference and food choice/intake made at baseline, weeks 6 and 24. Dietary practices were assessed using the Dietary Targets Monitor.

Measurements of exhaled carbon monoxide (CO) were made at weeks 6 and 24 to assess smoking status. A financial incentive (£10 retail voucher) was offered to all participants to encourage attendance at week 6 and week 24 sessions.

Intervention Type

Behavioural

Primary outcome measure

Difference in % weight change at 24 weeks from baseline in the diet intervention group compared to control group

Secondary outcome measures

1. Change in body weight at 24 weeks from baseline
2. Measures of food choice

The study was not powered to detect changes in smoking status

Overall study start date

01/01/2008

Completion date

01/07/2009

Eligibility

Key inclusion criteria

Adults (18 years+) attempting smoking cessation and participating in the smoking cessation programme run by NHS Greater Glasgow and Clyde Smoke Free Services

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

320

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/01/2008

Date of final enrolment

31/07/2008

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre

University of Glasgow

Glasgow

United Kingdom

G4 0SF

Sponsor information

Organisation

Research & Enterprise (UK)

Sponsor details

10 The Square
University of Glasgow
Glasgow
Scotland
United Kingdom
G12 8QQ

Sponsor type

University/education

Website

<http://www.gla.ac.uk/services/researchandenterprise/>

ROR

<https://ror.org/00vtgdb53>

Funder(s)**Funder type**

Government

Funder Name

Food Standards Agency

Alternative Name(s)

The Food Standards Agency, FSA

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

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?
Results article	results	29/05/2012		Yes	No
Results article	participant interview results	03/07/2012		Yes	No