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Slimming World in Stop Smoking Services

Submission date	Recruitment status	[X] Prospectively registered
25/07/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/07/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/03/2021	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12683

Study information

Scientific Title
Slimming World in Stop Smoking Services (SWISSS)

Acronym
SWISSS

Study objectives
Quitting smokers gain weight which puts some off attempting to quit, and seems to increase the risk of developing type 2 diabetes. Dieting is the main way to control weight but may worsen cigarette cravings and undermine cessation. A review of trials showed general healthy eating education does not reduce weight gain in quitting smokers and may hamper smoking cessation. However, planning diets to meet individual requirements, setting and reviewing weight targets does reduce weight gain; but whether this reduces the chance of successfully quitting is uncertain.

Commercial weight management programmes (CWMPs) provide this type of individual dietary support and are available on prescription in most primary care trusts. Clinical trials show CWMPs lead to greater weight loss than other primary care interventions or dieting without support. The aim of this trial is to assess whether referral to a CWMP reduces weight gain on smoking cessation. If so, this would lead to a necessary much larger trial to see whether it did so at the expense of successfully quitting smoking.

We will recruit patients from NHS stop smoking services, they must be smokers over 18 without any condition in which weight loss would be harmful. They will be randomised to either a CWMP during their quit attempt or usual care. All will receive usual stop smoking support and be weighed at the start, end of treatment and at six month follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 29 June 2012 ref:12/SW/0159

Study design
Randomised interventional phase II trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

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
Smoking and weight loss

Interventions
This will be the withdrawal orientated behavioural support provided by NHS stop smoking services which increase the chance of a successful quit attempt four-fold (West, 2010). This consists of weekly behavioural support typically for two weeks before and until four weeks after quit day focusing on key behavioural change techniques and nicotine replacement, varenicline, or bupropion are given to relieve withdrawal symptoms. Participants are encouraged to quit smoking first, before tackling weight; Usual care plus Slimming World, In addition to usual care, participants will be given a referral voucher for Slimming World when they attend their pre-quit visit. They will be booked in to attend weight management sessions from their quit day (or as near to that date as possible). They will attend SW for 12 weeks receiving support to lose or prevent weight gain. The choice of modest weight loss or weight gain prevention will depend upon whether an individual wants to lose weight or not and whether or not s/he is overweight or ; Follow Up Length: 5 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Change in weight from baseline (one week before quit date) to twelve weeks

Secondary outcome measures
No secondary outcome measures

Overall study start date
24/09/2012

Completion date
06/05/2013

Eligibility

Key inclusion criteria
1. Daily smokers with expired CO >10ppm
2. Aged 18 or over
3. Willing to be randomised to either the control or intervention arm and willing and able to comply with the intervention and all study procedures
4. Male & female participants

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 320; Description: We will recruit 320 participants, 160 in each arm. With an alpha error rate of 5% and 90% power this will detect a 2kg (SD=2.5)

Total final enrolment
76

Key exclusion criteria
1. Pregnant smokers
2. BMI<23 kg/m2. Mortality has been shown to be lowest in those with a 22>BMI<25 (Prospective studies collaboration, 2009) so preventing weight gain in those with lower BMIs is may not lead to health gain
3. Any medical condition in which weight loss would be contraindicated e.g. current course of chemotherapy

Date of first enrolment
24/09/2012

Date of final enrolment
06/05/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Primary Care Clinical Sciences School of Health and Population Sciences, Edgbaston
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Behavioural Brain Sciences Centre
Edgbaston

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England
United Kingdom
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Sponsor type
University/education

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

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research [NIHR] - National School for Primary Care Research (UK)

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?
Protocol article	protocol	19/06/2013		Yes	No
Results article	results	26/01/2020	04/03/2021	Yes	No