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Short-term effects of standard weight management advice and of the 5-2 diet delivered in self-help or group support format

Submission date
19/07/2016

Recruitment status
No longer recruiting

Registration date
21/07/2016

Overall study status
Completed

Last Edited
30/08/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
The 5:2 diet consists of limiting food intake to 500 calories in women and 600 calories in men on two non-consecutive days per week. The diet became popular with extensive reports of success on social media, but there is no scientific evidence so far on whether it works. A number of clients at our weight clinic have reported their experience with the 5:2 diet and we have now also tested it in clinical practice. This identified some barriers such as finding suitable foods and planning meals for the fasting days, but the main hurdle to carrying out the 5:2 diet is the hunger and discomfort on the fasting days. Our experience confirms that people who stick with the programme typically learn to cope with the fasting days well, especially once they see the positive results. We now believe that the diet can be effective with some clients even in its usual self-help format, but that it is likely to work better if group support is included to help people stick with the plan over the first few weeks. This is because after this initial period, the diet should get much easier to maintain without further external support. The aim of this study is to assess the initial effects of the 5:2 diet compared to state-of-the-art standard brief advice, and also to assess the effects of the 5:2 diet when delivered in self-help format and when accompanied by group support. Apart from assessing effects on weight, the study will also provide information on effects the 5:2 diet has on exercise levels and healthy eating.

Who can participate?
Patients aged 18 and over who are overweight or obese (BMI ≥30kg/m2, or BMI≥28kg/m2 with other illnesses [comorbidities])

What does the study involve?
Participants are randomly allocated to one of three groups.
The first group receive a 20-minute session on the 5-2 plan and a written guide on how to use it with recommendations for internet resources along with a leaflet listing local resources for exercise. Participants are encouraged to purchase and use pedometers to increase their exercise levels and to assess their weight weekly. Participants are asked to reduce their energy intake on two non-consecutive days per week to 500 calories for women and 600 calories for men.
The second group receive a brief explanation of the 5:2 plan and are booked for six weekly

group support sessions. The sessions focus on helping clients to adhere to 5:2, share coping and fasting strategies and maintain motivation. Each session lasts for about one hour and groups comprise of 10-20 participants. Participants also receive a leaflet listing local resources for exercise and are encouraged to purchase and use pedometers to increase their exercise levels and to assess their weight weekly. Participants are asked to reduce their energy intake on two non-consecutive days per week to 500 calories for women and 600 calories for men.
The third group receive a 20-minute session with an advisor focusing on healthy eating and physical activity and instructions on using the 'Facts not Fads' and the 'Get Active, Stay Active' British Heart Foundation self-help guides, supplemented by the NHS Change 4 Life series of booklets and a leaflet listing local resources for exercise. Participants are encouraged to use pedometers to increase their exercise levels and to assess their weight weekly.

What are the possible benefits and risks of participating?
The main benefit to the participant is the chance to try a treatment that could enhance the likelihood of achieving and maintaining a beneficial amount of weight loss. We do not forsee any potential risks to participants.

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
November 2015 to January 2018

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Sarrah Peerbux
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
n/a

Study information

Scientific Title
Short-term effects of standard weight management advice and of the 5-2 diet delivered in self-help or group support format

Acronym
5-2 Study

Study objectives
The study will evaluate whether the 5-2 diet combined with multi-session behavioural support results in greater weight loss compared to the 5-2 diet delivered in a self-help format and standard advice on diet and physical activity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - City Road & Hampstead Research Ethics Committee, 29/02/2016, ref: 16/LO/0073

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Obesity

Interventions
Randomisation would be computer-generated by the study statistician, using envelopes to reveal the randomisation allocation.

5-2 self-help (5-2 SH) arm would receive a 20-minute session on the 5-2 plan and a written guide on how to use it with recommendations for internet resources along with a leaflet listing local resources for exercise. Participants will be encouraged to purchase and use pedometers to increase their exercise levels and to assess their weight weekly. In both 5-2 arms, participants will be asked to reduce their energy intake on two non-consecutive days per week to 500 calories for women and 600 calories for men. Participants will be seen by Research Health Psychologists.

5-2 plus group support (5-2 GS) arm would receive a brief explanation of the 5-2 plan and will be booked for six weekly group support sessions. Participants would also receive a leaflet listing local resources for exercise and will be encouraged to purchase and use pedometers to increase their exercise levels and to assess their weight weekly. The sessions will focus on helping clients to adhere to 5-2, share coping and fasting strategies and maintain motivation. Each session would last for approximately one hour and groups will comprise of 10-20 participants. Research Health Psychologists will run the groups.

Standard advice self-help (SH) arm would receive a 20-minute session with an advisor focusing on healthy eating and physical activity and instructions on using the 'Facts not Fads' and the 'Get Active, Stay Active' British Heart Foundation self-help guides, supplemented by the NHS Change 4 Life series of booklets and a leaflet listing local resources for exercise. Participants will be encouraged to use pedometers to increase their exercise levels and to assess their weight weekly. Participants will be seen by Research Health Psychologists.

Intervention Type
Behavioural

Primary outcome measure
Weight loss at 6 months

Secondary outcome measures
1. Changes in weight, blood pressure, dietary habits (measured by the Fat and Fiber related Diet Behaviour Questionnaire), exercise levels (measured by the International Physical Activity Questionnaire) and proportion of participants losing at least 5% of their body weight at 6 weeks and 6 months and the self-reported change in weight at 3 months. Dietary habits and exercise levels will be assessed at baseline, 6 weeks and 6 months only
2. Adherence to the three interventions, determinants of adherence, and barriers and facilitators to adherence at 6 weeks, 3 and 6 months

Overall study start date
01/11/2015

Completion date
30/01/2018

Eligibility

Key inclusion criteria
1. Age 18 years and older
2. BMI≥30kg/m2, or BMI≥28kg/m2 with comorbidities

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300 participants

Total final enrolment
300

Key exclusion criteria
1. Women who are pregnant, breastfeeding or planning to conceive in the next 6 months
2. History of eating disorders
3. Currently involved in another research project
4. Currently using 5:2 diet
5. Non English speakers
6. Unavailable for 6 month follow-up
7. BMI>45kg/m2
8. Lost more than 5% of their body weight in the last 6 months
9. Taking medication prescribed by a psychiatrist (these medications can affect weight and psychiatric illness makes adherence to long-term programs difficult)
10. Diabetics who require insulin

Date of first enrolment
27/06/2016

Date of final enrolment
01/06/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Queen Mary University of London
Wolfson Institute of Preventive Medicine
Health and Lifestyle Research Unit
2 Stayner's Road
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E1 4AH

Sponsor information

Organisation
Queen Mary University of London (UK)

Sponsor details
Joint Research Management Office
Queen Mary Innovation Centre
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Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Study results will be published in a peer-reviewed journal and may be presented at scientific conferences.

Intention to publish date
01/01/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/11/2021	18/11/2021	Yes	No
HRA research summary			28/06/2023	No	No
Dataset	SSPS file	17/11/2021	30/08/2023	No	No
Protocol file	version 2.6	26/05/2017	30/08/2023	No	No