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Weight loss Referrals for Adults in Primary care (WRAP)

Submission date
04/09/2012

Recruitment status
No longer recruiting

Registration date
15/10/2012

Overall study status
Completed

Last Edited
08/07/2022

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Overweight and obese adults are now more common, and this is associated with diseases such as diabetes, heart disease and cancer, which puts increased pressure on the National Health Service (NHS). There is urgent need for weight loss programmes that are effective, affordable and can be delivered on a large scale via GP surgeries. Recent studies have demonstrated the short tem effectiveness of GP referral to a commercial weight loss provider. The NHS now needs information on the longer term outcomes of these programmes and the length of treatment that is most effective and gives best value for money.

Who can participate?
Men and women, aged 18 and over, who have a Body Mass Index (BMI) of 28 kg/m2 and who have been identified by a participating GP practice as likely to benefit from weight loss. Participants must be willing and able to participate in the weight loss group they are assigned to, and to attend measurement appointments with the research team.

What does the study involve?
Participants will be randomly assigned to one of three treatment programmes:
1. Referral to Weight Watchers for 12 weeks, free of charge.
2. Referral to Weight Watchers for 12 months, free of charge.
3. Standard information with periodic weighing and feedback, delivered by the research team.
Participants will attend 4 appointments over the 2 years, during which measures including weight,
body composition, waist circumference and blood pressure will be taken. Participants will also be asked to complete questionnaires measuring psychological factors, quality of life, and health care usage. The research team will also ask the participants if they are willing to provide additional blood samples at the initial visit and at 1 year measure risk factors for diabetes and cardiovascular disease.

What are the possible benefits and risks of participating?
Free advice and support will be given to assist in following a healthy diet and losing weight. There is little risk in taking part in this trial. If blood is taken, there may be minor discomfort or bruising, but this will be monitored carefully by trained professionals.

Where is the study run from?
MRC Human Nutrition Research, Cambridge, in collaboration with University of Oxford, University of Liverpool, University of East Anglia, University of Cambridge, and the National Heart Forum.

When is the study starting and how long is it expected to run for?
Recruitment will take place between October 2012 and October 2013. All participants will be followed up for 2 years from their initial assessment.

Who is funding the study?
National Prevention Research Initiative grant and Weight Watchers International as part of an MRC Industrial Collaboration Award.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MR/J000493/1

Study information

Scientific Title
A randomised controlled trial to test the clinical and cost-effectiveness of primary care referral to a commercial weight loss provider

Acronym
WRAP

Study objectives

Aim

To evaluate the clinical and cost effectiveness of 3 weight loss interventions that can be delivered in primary care:

1. Referral to a commercial provider for 12 weeks (CP12)
2. Referral for 52 weeks (CP52)
3. A brief intervention (BI)

Primary Objectives

The primary research question is whether the CP interventions achieve significantly greater weight loss from baseline to 12 months than BI, and whether CP52 achieves significantly greater weight loss from baseline to 12 months than CP12.

Secondary Objectives

1. Clinical Effectiveness

We will examine differences between the three interventions in weight, waist circumference, body composition, and blood pressure at 3, 12 and 24 months and differences in biochemical measures (blood glucose, total cholesterol, HDL cholesterol, LDL cholesterol, and HbA1c) at 12 months. Specifically we will test the following hypotheses:

1.1. Both CP interventions achieve significantly greater weight loss than BI from baseline to 3 months and baseline to 24 months and CP52 produces significantly greater weight loss than CP12 from baseline to 24 months.

1.2. Both CP interventions achieve significantly greater improvements in waist circumference, body composition and blood pressure than BI between baseline and 3, 12 and 24 months.

1.3. CP52 achieves significantly greater improvements in waist circumference, body composition and blood pressure than CP12 between baseline and 3, 12 and 24 months.

1.4. Both CP interventions achieve significantly greater improvements in biochemical measures than BI between baseline and 12 months, and CP52 achieves significantly greater improvements than CP12.

2. Cost-effectiveness

We will also examine the cost-effectiveness of each of these interventions. The following hypotheses will be tested:

2.1. CP52 is more cost-effective than CP12, as assessed by both within trial cost effectiveness and long term cost-effectiveness analyses.

2.2. Both CP12 and CP52 are more cost-effective than BI.

3. Participant Experience

A qualitative workstream will explore the attitudes of participants and health care professionals to primary care referrals to commercial providers for weight loss, and also their wider experiences of weight management. It will specifically examine:

3.1. The extent to which being overweight or obese is considered a medical issue by participants and primary care health professionals

3.2. The extent to which participants feel that the referral to a CP is part of NHS health care provision and the importance of this in motivating participants and adherence to the programme.

3.3. The extent to which the weekly weigh in and the sense of peer support, are experienced to be key aspects of the CP.

4. Psychosocial factors
This study will also examine psychosocial factors that are associated with completion of the intervention, weight loss and weight loss maintenance, to enable greater understanding of who benefits from these interventions and to inform development of new interventions.

5. Biological Sampling
This study will collect blood samples in order to examine changes in markers of risk of CVD and diabetes (fasting lipids, glucose and glycosylated haemoglobin). DNA will be collected for subsequent analyses of how genetic variation effects response to the interventions.

Updated 21/02/2014: recruitment for this trial has now closed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East of England - Cambridge East, 26/08/2012, ref: 12/EE/0363

Study design
Multi-centre randomised controlled trial with a parallel design

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Referral to a Commercial Provider
Participants who are assigned to the two commercial referral arms will receive vouchers to attend Weight Watchers sessions and asked to attend a local meeting that is convenient for them. They will be asked not to mention their participation in the trial to the group leader or other members, to make their experience as representative as possible. They will also be given access to the Weight Watchers website for the duration of their intervention. Adherence to the intervention will be monitored both through self-report at assessment appointments and data collected by WW at weekly meetings (which can be provided, with consent, through the WW NHS referral database and tracked using NHS referral ID) and these data will be controlled for in sensitivity analyses and explored in the qualitative data to further understand the impact of the interventions.

CP12: Participants allocated to the 12 week referral will receive free vouchers to attend 12 Weight Watchers sessions and access to their internet resources for 16 weeks. This is the package currently used in the WW NHS Referral Scheme and currently costs the NHS £55+VAT.

CP52: Participants allocated to the 52 week referral will receive free membership of Weight Watchers and access to their internet resources for 12 months. This packages is estimated to cost the NHS £190+VAT

Brief Intervention
The control intervention is a standardised brief intervention: recognition of the problem by the GP, basic written information on weight loss strategies and regular weighing (to coincide with outcome measurements). This will allow us to control for the impact of the GP recommending weight loss intervention and trial participation on weight loss.

Intervention Type
Behavioural

Primary outcome(s)
Group differences in change in body weight (kg) from 0 to 12 months.

Key secondary outcome(s))
1. Anthropometric measures:
Participants will be asked to remove shoes and heavy clothing items. Height will be measured in cm by stadiometer. Waist circumference will be measured in cm using a tape measure. Weight and fat mass will be measured in kg using a Tanita segmental body composition analyser, which measures fat mass by bioelectrical impedance. Fat mass is more closely related to health risks than BMI at an individual level and this is a measure that could be used in routine clinical practice. Blood pressure will be measured using standardised methods.

2. Economic evaluation:
The incremental cost-effectiveness ratio (ICER) of the intervention is the main outcome of the economic evaluation and will be expressed as incremental costs per incremental change in weight/BMI for the within-trial evaluation. NICE generally accepts that an intervention is cost effective if it has an incremental cost-effectiveness ratio of less than £20,000 per Quality Adjusted Life Year (QALY), and there should be increasingly strong reasons for accepting as cost effective interventions with an incremental cost-effectiveness ratio of over £30,000 per QALY. Primary care providers (in collaboration with the PCRN and with appropriate consent) will provide research staff with access to patient records to collect data at 12 and 24 months on all recorded health care usage, including any changes in medication. Participants will also complete a self-report measure of Quality of Life (EQ5D) and a resource use questionnaire covering health service attendances and any weight loss treatment for the previous 3 months. These data will be combined with data on medication and health care usage obtained from the primary care provider.

3. Psychosocial Factors:
Demographic data on age, gender, ethnic group, and SES (occupation, highest level of education) will be self- reported. WW attendance, website usage and weights measured at WW will be recorded by the WW NHS Referral Scheme database and with consent these data can be provided to research staff and matched to participant data using the referral ID. These data will be used for sensitivity analyses. Participants will also complete a small number of validated self-report questionnaires to examine predictors of attrition, weight loss, and post-treatment weight maintenance: [Three Factor Eating Questionnaire, Self Determination Theory Packet; Rosenberg Self Esteem; Life Satisfaction Questionnaire, Self Report Habit Index; Hospital Anxiety and Depression Scale]. Selected questionnaires have either demonstrated an association in previous studies, or represent constructs identified as potentially important in recent reviews[19-21].

4. Biological Sampling:
12 month changes in fasting glucose, HbA1c and lipid profile. We will also explore how genetic variation effects treatment response.

5. Patient Experience:
The qualitative workstream will be based on semi-structured interviews following general topic guides that will be refined by the research team and piloted with a subset. Ten participating GPs and up to 30 participating patients (10 from each arm) will be recruited once the trial is underway. Patient participants will be selected purposefully to ensure a broad general sample is achieved according to basic demographic variables within each cohort, including age, gender, ethnicity, rural/urban. A subset will complete interviews after each assessment appointment. Though a relatively small sample, key to this aspect of the project will be to build up a longitudinal account of their experiences. The dedicated RA will build up a detailed picture of participants' expectations and experiences of the interventions and the views of health professionals concerning their use of commercial weight loss services.

Completion date
30/03/2016

Eligibility

Key inclusion criteria
1. BMI ≥28 kg/m2
2. Aged ≥18 years
3. Willing and able to comply with the study procedures

For simplicity, we will not vary the BMI criteria by ethnic group.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
1267

Key exclusion criteria
1. Planned or current pregnancy in the next two years
2. Previous or planned bariatric surgery

GPs will be allowed to define any additional inclusion/exclusion criteria to meet local practice and will be asked to provide details on these for the reporting of the study. No further criteria will be imposed, thus capturing the population that would typically be referred to these treatments. Participants receiving other weight loss treatments, e.g. Orlistat, will not be

excluded as such participants would still be eligible for commercial referrals in standard practice, but this will be adjusted for in the analyses. Participants will be randomised to intervention arms, and thus those receiving additional treatment should be evenly spread across the interventions and these treatments will be accounted for in the cost-effectiveness analyses.

Date of first enrolment
18/10/2012

Date of final enrolment
01/10/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Medical Research Council
Cambridge
United Kingdom
CB1 9NL

Sponsor information

Organisation
Medical Research Council (UK)

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Government

Funder Name
National Prevention Research Initiative (UK) ref: MR/J000493/1

Funder Name
Weight Watchers International - MRC Industrial Collaboration Award (UK)

Funder Name
[The Funding Partners relevant to this award are (in alphabetical order): Alzheimer's Research Trust; Alzheimer's Society; Biotechnology and Biological Sciences Research Council; British Heart Foundation; Cancer Research UK; Chief Scientist Office, Scottish Government Health Directorate; Department of Health; Diabetes UK; Economic and Social Research Council; Health and Social Care Research and Development Division of the Public Health Agency (HSC R&D Division); Medical Research Council; The Stroke Association; Wellcome Trust; Welsh Assembly Government; and World Cancer Research Fund.]

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	03/06/2017		Yes	No
Results article	secondary analysis	07/11/2021	10/11/2021	Yes	No
Results article	Relationship between BMI and quality of life	07/07/2022	08/07/2022	Yes	No
Protocol article	protocol	18/06/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes