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A cluster randomised controlled trial of a tailored intervention to improve the management of obesity/overweight in primary care

Submission date
09/08/2013

Recruitment status
No longer recruiting

Registration date
09/08/2013

Overall study status
Completed

Last Edited
31/05/2016

Condition category
Nutritional, Metabolic, Endocrine

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

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
15046

Study information

Scientific Title
A cluster randomised controlled trial of a tailored intervention to improve the management of obesity/overweight in primary care

Acronym
TIGO - A tailored cluster RCT intervention

Study objectives
The aim of our study is to improve the quality of obesity care delivered by primary healthcare teams. Traditional interventions such as educational sessions for healthcare professionals related to NICE guidelines on obesity have only limited effectiveness. We have developed valid, feasible and efficient methods of tailoring implementation to the treatment of obesity. Tailoring involves designing an intervention to overcome the specific limiting factors or barriers experienced by a particular group of health care professionals to providing improved health care, which in this case is care in accordance with the NICE guidelines for Obesity. This study has developed and will examine a tailored intervention of improving the implementation of the NICE guidelines for Obesity in primary care practices.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/LO/1157

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

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
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Assessment of lifestyle, determinants addressed:
1. Ways to assess willingness to change
2. Resources to motivate and inform patients

In order for a weight loss intervention to be successful the patient needs to be ready and willing to make changes to their lifestyle. If the patient is not ready and willing to do so, it is likely the intervention will fail. The NICE guidelines recommend that health care professionals assess a patients lifestyle, co-morbidities and willingness to change. This can be difficult to as; Determining overweight/obesity, Determinants addressed:
1. Acceptable ways to raise and discuss the issue of weight with patients
2. How to effectively measure waist circumference

The issue of raising weight with patients is complex, and if raised inappropriately patients are often resistant to discuss their weight or follow a proposed weight loss intervention. Our previous study found that health care professionals found it difficult to find acceptable ways to raise the issue of weight with patients. The intervention aims; Management, Determinants addressed:
1. Lack of prescriptive information
2. Lack of knowledge

Many patients felt that they were aware of the concept of healthy eating, and the need to reduce their calorie intake in order to lose weight. But they felt more prescriptive advice would be of benefit. Patients interviewed in study 2 felt that the advice provided by commercial slimming clubs on portion sizes and guidance on a more prescriptive diet would be beneficial. The intervention will provide health care professionals;

Ongoing support, We will also offer intervention teams monthly telephone calls with the obesity lead and provide practices with a closed list of contacts to enable them to create a support network with other intervention teams.; Referral, Determinants addressed:
1. Lack of information on referral pathways

There are many community run programmes and initiatives in primary care to improve health and assist weight loss. Some of these programmes are available for patients to self-refer into, while others require a referral from a health care professional. Study 2 found that many health care professionals were not aware of the services on offer and how to refer patients to them. The intervention aims to provide health care professionals; Follow Up Length: 9 month(s); Study Entry : Registration and One or More Randomisations

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Adherance to the NICE guidelines; Timepoint(s): The primary outcome is the proportion of overweight or obese patients for which the general practiti

Secondary outcome measures

1. Lifestyle assessment: The proportion of patients with a record of lifestyle assessment
2. Percentage weight loss: The percentage of obese patients who change weight (lost or gained) over the intervention period
3. Referral: Referral to external weight loss services
4. Weight change: The mean weight change per patient over the intervention period

Overall study start date
02/09/2013

Completion date
01/11/2013

Eligibility

Key inclusion criteria
All general practices in EMSY net will be invited to participate in the study. Primary care teams must have an up-to-date knowledge of obesity and be aware of the NICE recommendations for the treatment of overweight and obesity in adults.
Target Gender: Male & Female; Upper Age Limit 85 years ; Lower Age Limit 16 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 28; UK Sample Size: 28

Key exclusion criteria
General practices outside EMSY net will be excluded.

Date of first enrolment
02/09/2013

Date of final enrolment
01/11/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Health Sciences
Leicester
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Sponsor information

Organisation
University of Leicester (UK)

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Gwendolen Road
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Sponsor type
University/education

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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	19/03/2014		Yes	No
Results article	results	27/05/2016		Yes	No
HRA research summary			28/06/2023	No	No