

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

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<b>Registration date</b> 09/08/2013	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 31/05/2016	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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 patient's lifestyle, co-morbidities and willingness to change. This can be difficult to do 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**

Adherence to the NICE guidelines; Timepoint(s): The primary outcome is the proportion of overweight or obese patients for which the general practitioner

## **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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**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?
<a href="#">Protocol article</a>	protocol	19/03/2014		Yes	No
<a href="#">Results article</a>	results	27/05/2016		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No