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Habit-based advice for weight control in general practice

Submission date
26/07/2011

Recruitment status
No longer recruiting

Registration date
26/07/2011

Overall study status
Completed

Last Edited
23/10/2019

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?
Over 60% of adults in the UK are overweight or obese. Obesity increases the risk of developing several conditions including heart disease, diabetes and some types of cancer. Achieving a healthy weight not only reduces health risks, but can also improve wellbeing and quality of life. The government identified Primary Care (General Practice) as the first port of call for advice about weight management, creating an urgent need for simple, effective interventions that can be delivered in this setting. Ten Top Tips (10TT) is a simple, leaflet-based intervention using a habit-based model to make healthy behaviours easier. It recommends ten behaviours to help with weight management, alongside advice on how to turn the behaviours into habits. Habits are formed when we repeat an action many times, in a similar place or at a similar time of day (for example brushing teeth before going to bed). Once behaviours have become habitual, they occur without much thought, making it easier to keep doing them. By repeating and monitoring healthy eating and activity behaviours, it is possible to form healthy habits that can help with weight management. A pilot study has already shown that use of the Ten Top Tips was associated with habit development and weight loss. This study will look at whether this simple weight control intervention based on habit-formation theory will achieve a clinically significant loss in body weight over 3 months compared with usual care in obese primary care patients. The secondary research objectives are: i) to examine whether the effects are maintained over at least 12 months, and whether benefits persist up to 24 months; ii) to explore whether the intervention leads to improvements in, and increased automaticity of, diet and physical activity behaviours, alongside improvements in clinical markers for potential co morbidities (blood pressure, total cholesterol/LDL and blood glucose); and iii) to undertake a full economic evaluation to establish cost-efficacy in the NHS context. We are also measuring quality of life (which includes a measure of anxiety/depression), dietary restraint (which measures how confident a person is that they can control their eating in certain situations/moods), weight efficacy (how much a person believes that he/she is capable of performing weight management behaviours), weight-related self-regulation (how much control a person feels they have over their weight and eating behaviours) and social support for engaging in physical activity and healthy eating.

Who can participate?
500 obese adults (BMI ≥ 30; age ≥ 18).

What does the study involve?
Participants will be randomly allocated to a treatment group (intervention group 10TT) or to a usual care group (control group). Participants in the intervention group will meet the practice nurse for baseline measurements of weight and height, waist circumference, blood pressure and a small blood sample will be taken (5-10ml). They will be asked to complete a questionnaire on eating habits, activity levels, quality of life and other psychological measures. They will then be given the 10TT leaflet with additional brief information on forming healthy habits. They will also be given simple diary sheets to record whether they have been able to stick to the tips for the first 3 months, and they will be asked to return completed sheets to the researchers. They may also be invited to take part in a recorded telephone interview describing their experience of 10TT: things they liked and things they found difficult. Over the next two years, the nurse will arrange to meet with them to measure their weight and waist circumference five times, and on each occasion they will also complete a questionnaire. Each appointment will last between 30 and 60 minutes. At the second appointment (3 months after the first assessment), they will have a second blood test and blood pressure measurement. Participants allocated to the control group will meet the practice nurse for baseline measurements of weight and height, waist circumference, blood pressure and a small blood sample (5-10ml), but will not be given the leaflet. They will be offered the usual care for weight management provided by their GP surgery. Over the next two years, the nurse will arrange to meet with them to measure their weight and waist circumference five times, and on each occasion they will also complete a questionnaire. Each appointment will last between 30 and 60 minutes. At the second appointment, 3 months after their first assessment, they will also have a second blood test and blood pressure measurement. The results from the two groups will be analysed at the end of the study to see how the 10TT intervention compares to usual care.

What are the possible benefits and risks of participating?
While additional primary care appointments for intervention/baseline assessment and follow-up may be an inconvenience for participants, appointments will be organised at convenient times whenever possible. Patients taking part in this study will have access to support to initiate and maintain lifestyle changes that might improve their health.

Where is the study run from?
Participants will be recruited from 14 GP surgeries from across England.

When is the study starting and how long is it expected to run for?
The study will start around July 2011 and will run for 24 months in total.

Who is funding the study?
The study is funded by the MRC National Prevention Research Initiative.

Who is the main contact?
Dr Rebecca Beeken
r.beeken@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Rebecca Beeken

Contact details
Health Behaviour Research Centre
Department of Epidemiology and Public Health
University College London
1-19 Torrington Place
London
United Kingdom
WC1E 6BT
-
r.beeken@ucl.ac.uk

Additional identifiers

Protocol serial number
10330

Study information

Scientific Title
Randomised controlled trial of habit-based advice for weight control in general practice (10TT Trial)

Acronym
10TT

Study objectives
The principal research objective of the Ten Top Tips Trial (10TT) is to test the hypothesis that this simple weight control intervention based on habit-formation theory will achieve clinically significant loss in body weight over 3 months in obese primary care patients, compared with patients placed receiving usual care.

Our secondary research objectives are:
1. To examine whether the effects will be maintained over at least 12 months, and whether benefits persist up to 24 months
2. To explore whether the intervention leads to improvements in, and increased automaticity of, diet and physical activity behaviours, alongside improvements in clinical markers for potential co morbidities [blood pressure, total cholesterol / low density lipoprotein (LDL) and blood glucose] and
3. To undertake a full economic evaluation to establish cost-efficacy in the NHS context

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East London REC 2, 23/08/2010, ref: 10/H0802/59

Study design
Randomised; Interventional; Design type: Prevention, Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Ten Top Tips (10TT) is a self-guided leaflet for weight management focusing on making simple diet and exercise behaviours habitual. It represents the first behaviour change intervention of which we are aware that has been explicitly based on habit-formation theory. The component behaviours in the 10TT leaflet reflect the consensus among researchers, clinicians and policy makers on healthy diet and lifestyle and were developed with input from these groups.

Follow Up Length: 24 month(s); Study Entry : Single Randomisation only

Intervention Type
Behavioural

Primary outcome(s)
Body weight; Timepoint(s): Baseline, 3 months, 6 months, 12 months, 18 months, 24 months

Key secondary outcome(s))
1. Automaticity of target behaviours; Timepoint(s): Baseline, 3 months, 6 months, 12 months, 18 months, 24 months
2. Blood cholesterol/low density lipoprotein (LDL)/glucose levels; Timepoint(s): Baseline, 3 months
3. Blood pressure; Timepoint(s): Baseline, 3 months
4. Waist circumference; Timepoint(s): Baseline, 3 months, 6 months, 12 months, 18 months, 24 months
5. Diet; Timepoint(s): Baseline, 3 months, 6 months, 12 months, 18 months, 24 months
6. Dietary restraint; Timepoint(s): Baseline, 3 months, 6 months, 12 months, 18 months, 24 months
7. Health-related quality of life; Timepoint(s): Baseline, 3 months, 6 months, 12 months, 18 months, 24 months
8. Physical activity; Timepoint(s): Baseline, 3 months, 6 months, 12 months, 18 months, 24 months
9. Self-regulation of eating behaviour; Timepoint(s): Baseline, 3 months, 6 months, 12 months, 18 months, 24 months
10. Social support for healthy eating and physical activity; Timepoint(s): Baseline, 3 months, 6 months, 12 months, 18 months, 24 months
11. Weight self efficacy; Timepoint(s): Baseline, 3 months, 6 months, 12 months, 18 months, 24 months

Completion date
18/01/2015

Eligibility

Key inclusion criteria
1. Adults aged more than or equal to 18
2. Body mass index (BMI) more than or equal to 30
Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
537

Key exclusion criteria
1. Inability to provide informed consent due to mental incapacity or active psychotic illness
2. Pregnancy
3. Terminal illness

Date of first enrolment
02/08/2011

Date of final enrolment
31/10/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London
London
United Kingdom
WC1E 6BT

Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) - National Prevention Research Initiative (NPRI) (UK), Grant Codes: G080202

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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?
Results article	results	01/02/2017		Yes	No
Protocol article	protocol	16/08/2012		Yes	No

Other publications	economic evaluation	13/08/2018	23/10/2019	Yes	No