

Winter Weight Watch Study: Efficacy of a brief public health intervention to prevent weight gain during the Christmas holiday period

Submission date 10/08/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/08/2016	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/12/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Being obese (very overweight) can increase significantly the risk of serious diseases such as diabetes, heart disease, cancer and stroke. Studies show that many people gain weight over the Christmas period (average gain 0.5-1.0 kg per holiday) which is then not lost again once the holidays are over. This could mean that a person gains an extra 5-10kg over a ten year period. Whilst there is much publicity about holiday weight gain in the press, few studies address this problem. Many people gain weight over the holiday period because they typically eat a lot of high fat, high calorie food, snack a lot, are less physically active, drink more alcohol, eat more snacks, eat for longer periods and have easy access to food. People often feel holiday periods are a time where they can eat what they choose. There is a need therefore to investigate the effectiveness of simple, low-cost strategies to prevent people from gaining weight. The aims of this study are to assess whether a leaflet can prevent weight gain over the Christmas holiday period; to identify who is most likely to gain weight over Christmas; and to explore what causes people to gain weight.

Who can participate?

Healthy adults aged at least 18 with a BMI of 20.0 kg/m² or more

What does the study involve?

Participants are randomly allocated to either the intervention (test) group or the usual care group. Those in the usual care group are given a standard information leaflet about healthy lifestyles. Those in the intervention group are given a leaflet that outlines key facts about gaining weight over Christmas and offers top tips to prevent it. This is not a study about dieting over Christmas, as this is unlikely to be acceptable to the public; rather, it is focused on raising awareness about the potential for holiday weight gain and suggests simple ways in which people can ensure a reasonable balance between calories consumed (eaten) and calories burned. The goal is for participants to gain no more than 0.5 kg. Participants are weighed before and after Christmas. Up to 20 participants from the intervention group are also interviewed about their experiences of the study to gain detailed feedback on the strategies used to maintain their weight over Christmas and any barriers they have experienced.

What are the possible benefits and risks of participating?
Potential benefits include prevention of weight gain during Christmas. There are no known risks.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
September 2016 to August 2019

Who is funding the study?
University of Birmingham (UK)

Who is the main contact?
Frances Mason

Contact information

Type(s)
Public

Contact name
Mrs Frances Mason

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
160673

Study information

Scientific Title
Efficacy of a brief public health intervention to prevent weight gain during the Christmas holiday period: randomised controlled trial and nested qualitative study

Acronym
WWW

Study objectives

The research has several aims:

1. To assess whether a brief low cost intervention can prevent weight gain over the Christmas holiday period
2. To identify who is most susceptible to weight gain over Christmas
3. Explore determinants of weight gain through a secondary analysis of the trial data
4. Understand participants' experiences and thoughts about conscious energy restraint and energy expenditure at Christmas through semi structured interviews

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Birmingham Science, Technology, Engineering and Mathematics Ethical Review Committee, 28/07/2016, ref: ERN_16_0673

Study design

Randomised controlled trial and a qualitative study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Obesity and overweight

Interventions

Participants will be recruited from community pharmacies, schools (parents) and supermarkets prior to Christmas. They will be randomised to either the intervention or the usual care group.

1. Intervention group: receive a leaflet that outlines key facts about Christmas holiday weight gain and offers top tips ('Ten Top Tips' leaflet) to prevent weight gain on holiday. The top ten tips leaflet has already been shown to be effective in community settings and needs minor amendments for use here.
2. Control group: receive an information leaflet about healthy lifestyles.

This is not a study about dieting over Christmas, which would be very unlikely to be acceptable to the public; rather, it is focused on raising awareness about the potential for holiday weight

gain and will suggest simple ways in which people can ensure reasonable energy balance, given many never lose the weight gained over Christmas.

The behavioural goal will be for participants to gain no more than 0.5kg of their baseline weight. The primary outcome is change in weight. Participants will be weighed before and after Christmas (follow up). 284 participants will provide 80% power to detect 0.75kg (SD=2.0) difference in weight change between the groups.

Up to 20 participants from the intervention group will be interviewed about their experiences of the study to gain detailed feedback on the behavioural/cognitive strategies used to maintain their weight over Christmas and any barriers they may experienced.

Intervention Type

Behavioural

Primary outcome measure

Change in weight from baseline (mid-late November) to follow up (mid-January – early February)

Secondary outcome measures

1. Proportion of participants in both groups who have gained ≤ 0.5 kg at follow up
2. Frequency of self-weighing in the previous two weeks using a single-item measure
3. Change in percentage body fat, measured by bioelectrical impedance at baseline and follow up

Added 01/11/2018:

4. Difference between groups in cognitive restraint, emotional eating and uncontrolled eating as measured by the three factor eating questionnaire at baseline and follow up

Overall study start date

26/09/2016

Completion date

01/08/2019

Eligibility

Key inclusion criteria

1. Aged 18 years or more
2. BMI 20.0 kg/m² or more

Participant type(s)

All

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

284

Key exclusion criteria

1. Unable to understand English sufficiently to provide written informed consent
2. Women who are known to be pregnant or intending to become pregnant during the study period
3. Women who are breastfeeding

Date of first enrolment

01/10/2016

Date of final enrolment

14/12/2018

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**University of Birmingham**

Department of Primary Care Clinical Sciences

College of Medical and Dental Sciences

Birmingham

United Kingdom

B15 2TT

Sponsor information**Organisation**

University of Birmingham

Sponsor details

Dept. of Primary Care Clinical Sciences

College of Medical and Dental Sciences

Birmingham

England

United Kingdom

B15 2TT

Sponsor type

University/education

ROR

<https://ror.org/03angcq70>

Funder(s)

Funder type

University/education

Funder Name

School of Medicine, PhD Studentship award, University of Birmingham

Results and Publications

Publication and dissemination plan

To be confirmed at a later date

Intention to publish date

01/08/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan		15/05/2018	15/05/2018	No	No
Results article	results	10/12/2018		Yes	No