

Obesity intervention delivered by dental teams

Submission date 24/05/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/05/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/11/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Obesity in young people is a major problem in the UK. Being overweight is harmful to young people's health and is linked to serious diseases in later adult life. More research is needed to understand how to help young people avoid becoming overweight. One of the causes of obesity is when young people eat and drink too many sugary items such as fizzy drinks. Cutting down on the amount of sugary foods and drinks is not easy. Dentists and their staff see many young people on a regular basis and their practices could be used to provide advice to young people on their eating habits. Research is needed to assess the impact of dietary advice in dental practices. The aim of this study is to develop and test the effect of providing dietary advice to young people attending dental practices across Islington, Camden and Haringey

Who can participate?

Young people aged 11-16 years, classified as overweight or obese, who consume at least one can of soft drinks per day.

What does the study involve?

Participants will be randomly allocated into one of two groups. One group will receive the standard preventive advice from their dentist. The second group will receive a package of newly developed nutritional advice delivered by a trained researcher. The researchers at the dental surgeries where the dietary advice and support will be delivered will provide this to the young people over four appointments in a one-month period. The researchers providing the advice will be specially trained for this purpose. All young people in the project will have their heights, weights and waist circumference measured and will be asked to provide four dietary records. This information will be collected at the start of the study and then 6 months later.

What are the possible benefits and risks of participating?

Young people receiving the package of newly developed nutritional advice will be given up-to-date dietary information. The young people attending the other dental surgeries will still receive the usual preventive advice from their dentists. All young people will be offered a £10 gift token at the 6-month follow-up appointment as a gesture of thanks for their participation. At the end of the project all the young people and their parents/guardians will be sent a summary of the study findings and a leaflet on nutrition. A disadvantage of being part of this project is the time and hassle involved in being involved. We will make every effort to arrange appointments at a convenient time to minimise any disruptions to participants' busy routines.

Where is the study run from?

This research is being conducted by the Department of Epidemiology and Public Health at University College London.

When is the study starting and how long is it expected to run for?

We will be recruiting participants from April to June 2012 and making follow-up appointments for October to December 2012.

Who is funding the study?

The funding for the research has been provided by a Government agency called the National Institute of Health Research (NIHR).

Who is the main contact?

Professor Richard G Watt

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

8601

Study information

Scientific Title

Preventing obesity in young people attending primary dental care settings: an exploratory randomised controlled trial

Study objectives

Current study hypothesis as of 22/08/2012:

Obesity is a significant public health problem in the UK. Amongst young people obesity rates have risen dramatically in recent years. The health, social and economic consequences of this epidemic are significant. Overweight and obesity is caused by a complex interplay of metabolic, behavioural, social and environmental factors but ultimately results when a sustained energy imbalance occurs. Recent NICE guidance has highlighted the need for effective preventive interventions. Epidemiological and intervention studies have highlighted the important role that sugars consumption, particularly from soft drinks has on the development of obesity. A high proportion of young people attend dentists routinely. This provides a unique opportunity to develop and test an obesity prevention intervention.

Aims and objectives

To develop and test the feasibility of an obesity prevention intervention targeting 11-16 year olds attending general dental services in Islington, Camden and Haringey PCT's

Specific objectives:

1. To assess dental teams' experience, motivation and training needs in providing preventive care for both oral and general health improvement
2. To assess the acceptability to young people and their parents of the proposed intervention
3. To develop a motivational interviewing intervention and training programme specifically designed for dental practices working with young people to prevent obesity
4. To conduct an exploratory randomised controlled trial of the obesity intervention
5. To make recommendations on conducting a definitive randomised controlled trial of the obesity intervention.

More details can be found at <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=8601>

Previous study hypothesis until 22/08/2012:

Aims and objectives

Aim: To develop and test the feasibility of an obesity prevention intervention targeting 12-14 year olds attending general dental services in Islington; Camden; and Haringey PCTs.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London - Camden and Islington, 03/02/2010, ref: 10/H0722/2

Study design

Randomised interventional prevention trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Metabolic & endocrine, obesity

Interventions

SWITCH is an intervention for 11-16 year olds delivered by trained practitioners within dental care settings. The aim of SWITCH is to reduce the participant's consumption of soft drinks and switch to healthier alternatives such as water. Motivational interviewing is the behaviour change method employed in the intervention to strengthen the young person's motivation to reduce their consumption of soft drinks.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Anthropometric measures of BMI and waist circumference measured at baseline and 6 months

Secondary outcome measures

Mean daily consumption of soft drinks measured at baseline and 6 months

Overall study start date

12/07/2011

Completion date

31/03/2013

Eligibility**Key inclusion criteria**

Current inclusion criteria as of 22/08/2012:

1. Young person aged 11-16 years
2. Attending general dental practice
3. Classified as overweight or obese (BMI at or above 85th centile)
4. Full parental and subject consent given
5. Young person consumes at least 1 can of soft drinks per day

Previous inclusion criteria until 22/08/2012

1. Young person aged 12-14 years
3. Classified as overweight (BMI at or above 85th but below 98th centile)

Participant type(s)

Patient

Age group

Child

Lower age limit

11 Years

Upper age limit

16 Years

Sex

Both

Target number of participants

UK Sample Size: 140

Key exclusion criteria

Current exclusion criteria as of 22/08/2012:

1. Young person classified as normal weight (BMI below 85th centile)
2. Has serious underlying medical condition or eating disorder
3. Young person unable to communicate effectively in English
4. On a special prescribed diet

Previous exclusion criteria until 22/08/2012:

1. Young person classified as normal weight or obese (BMI at or above 98th centile)

Date of first enrolment

01/04/2012

Date of final enrolment

01/06/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University College London

London

United Kingdom

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Sponsor information

Organisation

North Central London Research Consortium (UK)

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Sponsor type

Research organisation

Website

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ROR

<https://ror.org/05841h928>

Funder(s)**Funder type**

Government

Funder Name

NIHR Research for Patient Benefit Programme (UK) ref: PB PG 1207-14085

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	01/09/2013		Yes	No