

Strategies for maximising consent rates for child dental health surveys: a cluster randomised controlled trial

Submission date 14/03/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/03/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/11/2015	Condition category Oral Health	<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

Study information

Scientific Title

Strategies for maximising consent rates for child dental health surveys: a cluster randomised controlled trial

Acronym

Consent trial

Study objectives

Working hypothesis:

To test the null hypothesis that there is no difference in consent rates between strategies used for recruiting participants to child dental health surveys, against the alternative working hypothesis of a difference.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Manchester Ethics Committee, 05/10/2007, ref: TPCS/ethics/07140

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Other

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

Child dental health

Interventions

Financial incentive one and postage:

Each school will be provided with stamped, named envelopes, containing a standard information leaflet and standard consent form, to be addressed by the school and posted to the parents of the selected children. The parents will be asked to return the consent form to the school. In each

school the person responsible for the management of the consent letters will receive a £50 Marks and Spencers (M&S) voucher if the school achieve a consent rate of 75% or above.

Financial incentive two:

Named envelopes, containing the standard consent form and standard information leaflet for each child selected to be surveyed, will be distributed by the school and sent to the child's parent /guardian via the child. Each school will be given £4.00 for each selected child whose parents consent to the survey.

Additional information:

The head of each school will be provided with information about the importance of oral health and the dental survey, to be presented at a school assembly. In addition each parent will be given a glossy leaflet about the importance of oral health along with the standard consent form and standard information leaflet, to be distributed via the children.

Multiple letters:

Named envelopes, containing the standard consent form and standard information leaflet for each child selected to be surveyed, will be distributed by the school and sent to the child's parent /guardian via the child. Two weeks after the consent forms are sent the school will be contacted to find out how many have been returned. A second letter will be prepared for non-responders and sent to the school for distribution. This letter is again in an envelope and addressed to the child's parent/guardian. One to two weeks later the school will be contacted again to find out how many forms have been returned and get the names of the non-responders. Local advice from the school will be taken with regard to the remaining non-responders.

Control arm:

Named envelopes, containing the standard consent form and standard information leaflet for each child selected to be surveyed, will be distributed by the school and sent to the child's parent /guardian via the child. No further contact will be made.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The main outcome of interest will be the consent rate, by school, on the day of dental examination, measured once the dental examination is completed. A health economic evaluation will also be undertaken.

Secondary outcome measures

The cost of each intervention compared with the control group. This will be completed once the study fieldwork is completed.

Overall study start date

15/09/2007

Completion date

31/07/2008

Eligibility

Key inclusion criteria

The inclusion criteria for the randomised controlled trial (RCT) will be any school, with 20 or more five year old children selected for the annual British Association for the Study of Community Dentistry (BASCD) survey in the following Primary Care Trusts (PCTs):

1. Halton and St Helens PCT
2. Warrington PCT
3. Western Cheshire PCT
4. Knowsley PCT
5. Liverpool PCT
6. Blackburn and Darwen Teaching PCT

Participant type(s)

Patient

Age group

Child

Lower age limit

5 Years

Upper age limit

5 Years

Sex

Both

Target number of participants

42 schools collecting information from 20 children in each arm, therefore a minimum of 840 children

Key exclusion criteria

Any child whose parent/legal guardian does not give written informed consent

Date of first enrolment

15/09/2007

Date of final enrolment

31/07/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
The University of Manchester
Manchester
United Kingdom
M15 6FH

Sponsor information

Organisation
The University of Manchester (UK)

Sponsor details
University Research Office
Oxford Road
Manchester
England
United Kingdom
M13 9PL

Sponsor type
University/education

Website
<http://www.manchester.ac.uk>

ROR
<https://ror.org/027m9bs27>

Funder(s)

Funder type
University/education

Funder Name
The University of Manchester (UK) - Oral Health Unit

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?
Results article	results	04/09/2013		Yes	No