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

Submission date	Recruitment status	[_] Prospectively registered
14/03/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/03/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/11/2015	Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Anne-Marie Glenny

Contact details
School of Dentistry
The University of Manchester
Higher Cambridge Street
Manchester
United Kingdom
M15 6FH
+44 (0)161 275 7811
anne-marie.glenny@manchester.ac.uk

Additional identifiers

Protocol serial number
TPCS/ethics/07140

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

Primary study design
Interventional

Study design
Cluster randomised controlled trial

Study type(s)
Other

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 childs 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 childs 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 childs 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 childs parent /guardian via the child. No further contact will be made.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
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.

Key secondary outcome(s)
The cost of each intervention compared with the control group. This will completed once the study fieldwork is completed.

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

Healthy volunteers allowed

No

Age group
Child

Lower age limit
5 Years

Upper age limit
5 Years

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
The University of Manchester (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

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