

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 26/03/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/11/2015	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## 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

## **Study design**

Cluster randomised controlled trial

## **Primary study design**

Interventional

## **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 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(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 be 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?
<a href="#">Results article</a>	results	04/09/2013		Yes	No