Hands up for Max! Hand Hygiene study in Primary Schools

Submission date	Recruitment status No longer recruiting	Prospectively registered		
05/10/2010		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/11/2010	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
22/08/2013	Other			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PB-PG-1207-15212

Study information

Scientific Title

Cluster randomised controlled trial to test the effectiveness of an educational intervention to promote hand washing in reducing absenteeism in primary schools

Study objectives

- 1. Is the Hands up for Max! educational hand washing intervention effective in reducing absenteeism, through reducing the spread of infectious illness, in primary school pupils and staff?
- 2. What percentage pupil and staff absence is due to infectious illness?
- 3. Is there a difference in hand washing behaviour, knowledge and attitudes between pupils and staff in the intervention and control arms of the trial?
- 4. Is the Hands for Max! resource cost effective?
- 5. What can a detailed process evaluation tell us about intervention delivery, hand washing facilities in schools, and pupil and staff hand washing behaviour, knowledge, and attitudes?

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Bristol, Faculty of Medicine and Dentistry Committee for Ethics approved in January 2009 (ref: 080908)

Study design

Pragmatic cluster randomised controlled single centre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

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

Hand hygiene

Interventions

Intervention arm: Hands up for Max! hand washing intervention delivered in primary schools during autumn term 2009 in addition to usual hygiene education.

Control arm: Usual hygiene education continued during autumn term 2009. Hands up for Max! resource offered to schools in autumn term 2010 after all follow-up data for trial completed.

Absence data collected for intervention and control schools for school year 2008/2009 as baseline measure (pre intervention), and absence data for school year 2009/2010 as follow-up data (post intervention).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Pupil and staff absence measured using routine absence data for schools available from the Department for Education. Pupil and staff absence due to infectious illness measured using data collected over 3 months (Jan - April 2010) in a sample of participating schools (sub-study schools, n = 24).

Secondary outcome measures

- 1. Pupil and staff hand washing behaviour, knowledge, and attitudes measured using self-report questionnaires completed in sub-study schools (n = 24) during March May 2010
- 2. Economic evaluation completed using data collected on NHS and wider workforce costs as a result of absence due to illness in sub-study schools (n = 24), collected over 3 months (Jan April 2010)
- 3. Process evaluation including:
- 3.1. Observations of hand washing facilities
- 3.2. Observation of intervention delivery
- 3.3. Exploration of hand washing behaviour
- 3.4. Knowledge and attitudes through interviews with teachers and focus groups with pupils The process evaluation was completed over 3 months: November 2009 January 2010.

Overall study start date

01/09/2009

Completion date

31/08/2011

Eligibility

Key inclusion criteria

- 1. Maintained primary schools (including infant and junior schools) and special schools in the South West of England
- 2. Pupils aged 5 11 years, either sex

Participant type(s)

Patient

Age group

Child

Lower age limit

5 Years

Upper age limit

11 Years

Sex

Both

Target number of participants

176 primary schools (178 recruited)

Key exclusion criteria

Independent primary schools and pupil referral units in the South West of England.

Date of first enrolment

01/09/2009

Date of final enrolment

31/08/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre School of Social and Community Medicine

Bristol United Kingdom BS8 2PS

Sponsor information

Organisation

University of Bristol (UK)

Sponsor details

Research and Enterprise Development (RED) Office 3rd Floor, Senate House Tyndall Avenue Bristol England United Kingdom BS8 1TH

Sponsor type

University/education

Website

http://www.bristol.ac.uk/

ROR

https://ror.org/0524sp257

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme (ref: PB-PG-1207-15212)

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	15/08/2013		Yes	No