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CLASS Trial: Evaluation of a school-based intervention to protect children from second-hand smoke

Submission date	Recruitment status	[ ] Prospectively registered
25/10/2010	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/02/2011	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/05/2012	Respiratory	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Kamran Siddiqi

Contact details
North West House
West Park Ring Road
Leeds
United Kingdom
LS16 6QD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
09/3000/05

Study information

Scientific Title
CLASS Trial (Children Learning About Second-hand Smoke): Evaluation of a school-based intervention (Smoke Free Homes) to protect children from second-hand smoke

Acronym
CLASS (Children Learning About Second-hand Smoke)

Study objectives
Aim:
To investigate the potential effectiveness and cost-effectiveness of a school-based intervention, 'Smoke Free Homes' (SFH), in protecting children from second-hand smoke (SHS) at home, reducing uptake of smoking in young people, and improving smoking quit rates.

Objectives:
1. To estimate the effectiveness of SFH in:
1.1. Reducing children's exposure to SHS
1.2. Discouraging them to take up smoking in their teenage years (11 - 15 years), and
1.3. Encouraging adult smokers in their households to quit smoking
2. To estimate the effectiveness of SFH in encouraging families to impose and sustain smoking restrictions at home
3. To assess the integrity and fidelity of the implementation process and other contextual factors that might contribute to the variation in outcomes
4. To estimate the cost-effectiveness and understand the budgetary implications of SFH in obtaining its intended outcomes

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Yorkshire Research Ethics Committee approved on the 7th Janaury 2011 (ref: 10/H1310 /91)

Study design
Single-centre cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Children's exposure to second-hand smoke

Interventions
It is planned that schools in the intervention arm will receive SFH at the beginning of the autumn term 2011 (September 2011) by which time participating children will be in Years 5 and 6.

SFH is a school-based intervention to encourage families to implement smoking restrictions in their homes and, as a consequence, to protect children and non-smokers from SHS. A trained SFH project worker will visit each school and take Years 5 and 6 children (on two separate occasions) through a series of educational activities using a SFH toolkit. Children from the same year are grouped together for the SFH session. Children, whose parents specifically ask for their children to be withdrawn from the SFH activities, will continue to attend their regular classes or appropriate provision will be made.

The SFH activities consist of a class-room presentation, quiz, games, role play, posters and a speech bubble competition lasting approximately one and a half hours. Children will be given a promise form which contains pictorial and written messages on the hazards of SHS, a pictorial step-guide for families to make their homes smoke free, a puzzle to help families learn about the benefits of a smoke free home and a tear-off slip to make a commitment to impose smoking restrictions at home. Children are expected to bring this slip back to school and receive a SFH Gold certificate should their home be totally smoke free. These activities are designed to raise awareness among children about the hazards of SHS and empower them to negotiate smoking restrictions with other family members at home. Families are encouraged to "sign-up" to a voluntary contract not to allow smoking inside their houses and in front of children. In addition:
1. School teachers will receive a training session on SFH to help them in reinforcing SFH messages
2. A brief session on SFH for all children will be provided through a whole school assembly, and
3. School-based family events could be supported by the SFH co-ordinator at the schools request

Schools randomly allocated to the control group will not receive the SFH activities immediately. Children will of course continue with normal teaching. If SFH is shown to be effective, schools in the control arm will be offered the SFH activities after 24 months when all participating children have left the primary schools and moved to secondary schools.

There will be two baseline data collection points. There will be seven follow points:
Follow up 1: 3 months
Follow up 2: 6 months
Follow up 3: 15 months
Follow up 4: 27 months
Follow up 5: 39 months
Follow up 6: 51 months
Follow up 7: 63 months

The sample of children selected to be followed up will be followed up for 5 years and 3 months in total. The parents/carers of the children being followed up will be followed up initially for 6 months (this may be extended).

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Salivary cotinine levels among participating children (with a detectable level of cotinine at baseline) at first follow up (approximately three months post intervention). We will measure salivary cotinine levels of all children at baseline before the intervention in both arms of the trial. At the first follow up point (3 months), after the intervention, we will measure salivary cotinine levels of children in both arms of the trial, who remain in the trial (90% of children who test positive for cotinine at baseline and 10% of children who test negative for cotinine at baseline). We will look to see if there is a difference in cotinine levels between the intervention and control groups following the intervention.

Salivary cotinine measurement is a widely recognised method for detecting both active and passive smoking. The children will be asked to collect saliva in the mouth and blow it into a plastic container through a straw. The samples are subsequently analysed and a gas-liquid chromatography technique can detect cotinine levels as low as 0.1 ng/ml. Based on cotinine measurements taken as part of the national household survey, various thresholds for active and passive smoking have been defined for different age groups.

Secondary outcome measures
1. Proportion of children whose cotinine levels are zero at baseline
2. Smoking restrictions at home assessed through surveys completed by parents/carers at baseline, 1st follow up and through surveys completed by children at baseline and follow up 1 and follow up 3 to 7
3. Children's attitude and behaviours towards smoking and intention to start smoking assessed through surveys completed by children at baseline and follow up 1 and follow up 3 to 7
4. Smoking status of adults and their intention to quit assessed through surveys completed by parents/carers at baseline and follow up 1
5. School attendance, we will collect data on school attendance of participating children from school registers at baseline, during the intervention and at follow up 1 and follow up 3 to 7
6. Children's quality of life measured using a short quality of life questionnaire (PedsQL) completed by children at baseline and follow up 1 and follow up 3 to 7
7. Use of healthcare resources by the families of participating children assessed through Health Service Use surveys completed by parents/carers at baseline, baseline 2, 1st and 2nd follow up
8. Proportion of children whose self reported smoking status and exposure to secondhand smoke is validated by results of salivary cotinine levels at baseline and all follow up points measured by comparing salivary cotinine results with self reported smoking status. Cotinine levels will be assessed in a random sample of children who remain in the trial at all follow points. The size of the random sample will be determined by how well the baseline cotinine tests validate the self reported information provided in the children's baseline surveys.
9. Difference in parent survey response rate (defined as the proportion of surveys returned by participants) when participants are sent electronic reminders on the day they receive the survey
10. Difference in time to parent response (defined as the number of days which elapses, between the survey being sent out to participants and the survey being recorded as returned to York Trials Unit)
11. Difference in parent survey response rate (defined as the proportion of surveys returned by participants) when participants are sent electronic reminders or letter reminders if they have

not returned the survey after two weeks
12. Difference in time to parent response (defined as the number of days which elapses, between an electronic reminder or letter reminder being sent out to participants (after two weeks of the survey originally being sent out) and the survey being recorded as returned to York Trials Unit)

Overall study start date
01/12/2010

Completion date
01/03/2017

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Schools:
1. Primary schools in Yorkshire from neighbourhoods with high deprivation, initially from the lowest 10% super output areas (this could be increased to 20% if required)
2. Schools in neighbourhoods which have above average smoking prevalence rates. The current average is 21%.
3. All secondary schools who have primary schools participating in the CLASS trial in their catchment area, or secondary schools identified by participating primary schools, will be invited to take part in the trial in order that participating children can be followed up.

Participants:
1. Within these schools all children (and their parents/carers) in years 4 and 5 in the 2010/2011 school academic year will be eligible for the CLASS trial (children will be aged 8 - 10 years at the time of recruitment).
2. Parents/carers will have to give informed consent for their own participation and their child /childrens participation in the trial
3. After baseline data has been collected only a sample of children and parents/carers will be followed up for the remainder of the trial. This sample will include 90% of children (and their parents/carers) who test positive for cotinine at baseline and 10% of children (and their parents /carers) who test negative for cotinine at baseline.

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
50 primary schools; 2200 children and their parents/carers

Key exclusion criteria
1. Primary schools where SFH or any similar activities have taken place in the last two years and where children in Years 4 and 5 in the 2010/2011 school academic year were involved in the activities
2. Primary schools already participating in a similar research study
3. Children and their parents/carers if informed consent cannot be given by the parent/carer

Date of first enrolment
01/12/2010

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North West House
Leeds
United Kingdom
LS16 6QD

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
c/o Clare Skinner
Faculty of Medicine and Health Research Office
Level 10, Room 10.110
Worsley Building
Clarendon Way
Leeds
England
United Kingdom
LS2 9NL

Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Public Health Research (PHR) programme (ref: 09/3000/05)

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