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Does the use of a bedroom thermometer in infancy reduce the incidence of respiratory ill-health, particularly infections and coughs

Submission date
07/06/2024

Recruitment status
No longer recruiting

Registration date
05/07/2024

Overall study status
Ongoing

Last Edited
05/07/2024

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Children's health depends partly on protection from temperature extremes, in particular, there is an association with overheating in cases of cot deaths. As part of the Back-to-Sleep campaign (to reduce cot deaths), 30 years ago, it was suggested that a thermometer in the room where the infant slept would ensure that temperature extremes were recognised, and action taken to keep infants safe. This study was designed to test whether having such a thermometer resulted in subsequent ill-health in young children, particularly respiratory problems.

Who can participate?
Mothers enrolled in the Avon Longitudinal Study of Parents & Children (ALSPAC) with an expected delivery date between 1st May and 31st December 1992.

What does the study involve?
Half the mothers were sent a simple thermometer to keep in their child's bedroom. This indicated whether the room was too hot, too cold or just right. Twice a week, the mother was asked to note down the date and temperature on a chart supplied by the study.

What are the possible benefits and risks of participating?
There are no particular benefits except for a free thermometer for the intervention arm. Participating in ALSPAC relies on altruism. A possible risk is exposing infants to external air from windows being opened to regulate the bedroom temperature which may contain environmental pollutants and allergens. Possible anxiety to parents if they struggle to control the temperature of the room.

Where is the study run from?
The ALSPAC offices (Bristol)

When is the study starting and how long is it expected to run for?
The intervention started on 1st May 1992 and data collection is ongoing. We stopped collecting data on the temperature monitoring approx 31/12/1993. However, we used data collected on

the ALSPAC cohort up to age 18 years to examine allergies and respiratory problems in the cases and controls within this RCT. The ALSPAC cohort continues to this day.

Who is funding the study?
The thermometers were kindly donated by the South Western Electricity Board (SWEB), the postage and printing by HTV West (the local television station in 1992) and the funds for linkage and statistical analysis by Cot Death Research (now the Lullaby Trust). The UK Medical Research Council and Wellcome (grant ref: 217065/Z/19/Z) and the University of Bristol have provided core support for ALSPAC since 2000 and continue to do so. A full list of ALSPAC funding is available here: https://www.bristol.ac.uk/alspac/external/documents/grant-acknowledgements.pdf

Who is the main contact?
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Additional identifiers

Protocol serial number
B4469, WT 217065/Z/19/Z, 102215/2/13/2

Study information

Scientific Title
Long-term respiratory health benefits of using a bedroom thermometer in infancy: a randomised controlled trial nested within the ALSPAC pre-birth cohort

Study objectives
To evaluate any health risks and benefits associated with the provision of a bedroom thermometer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval for the ALSPAC study was obtained from the ALSPAC Ethics and Law Committee (ALEC; IRB00003312) and the Local NHS Research Ethics Committees: Bristol & Weston Health Authority: E1808 Children of the Nineties: Avon Longitudinal Study of Pregnancy and Childhood (ALSPAC) 28/11/1989); Southmead Health Authority: 49/89 Children of the Nineties – "ALSPAC", 05/04/1990); Frenchay Health Authority: 90/8 Children of the Nineties, 28.06.1990. Children in Focus: Southmead Health Services: 48/89: ALSPAC – “The 10% Club”, 25 /08/1992

Primary study design
Interventional

Study design
Randomized controlled trial nested within a longitudinal birth cohort

Study type(s)
Safety

Health condition(s) or problem(s) studied
Respiratory symptoms

Interventions
During pregnancy (or shortly after delivery) women are randomly selected (by odd or even date of birth) to receive a simple thermometer to put on the wall of the room in which their baby sleeps, to identify temperatures labelled as hot (>21oC), fine (16-21oC) or cold (<16oC). They then record the ambient temperature twice per week over a year.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Simple card wall thermometer

Primary outcome(s)
Respiratory signs and symptoms measured using data reported by the mother (and later the child) at 6, 18, 30, 42 months, 4, 5, 6, 7, 8, 10, 13, 14, 16 and 18 years of age.

Key secondary outcome(s)
1. Respiratory infections [a cold, influenza, tonsillitis or laryngitis, chest infection] measured using self-completion questionnaires at 6, 18, 30, 42 months, 4, 5, 6, 7, 8, 10, 13, 14, and 16 years of age
2. Cough [cough, cough lasting at least two days, cough medication given] measured using self-completion questionnaires at 6, 18, 30, 42 months, 4, 5, 6, 7, 8, 10, 13, 14 and 16 years of age
3. Ear infections [earache, ear infection, pus discharge from ear(s), grommets inserted] measured using self-completion questionnaires at 6, 18, 30, 42 months, 4, 5, 6, 7, 8, 10, 13, 14 and 16 years of age
4. Respiratory conditions with likely allergic aetiology [wheeze, asthma, hay fever (allergic rhinitis)] measured using self-completion questionnaires at 6, 18, 30, 42 months, 4, 5, 6, 7, 8, 10, 13, 14, 16 and 18 years of age

Completion date
31/12/2050

Eligibility

Key inclusion criteria
1. Mother enrolled in the Avon Longitudinal Study of Parents & Children study
2. Expected date of delivery between 1st May and 31st December 1992
3. Gestation at birth >32 weeks
4. Live birth

Participant type(s)
Healthy volunteer, Resident, Population

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 Weeks

Upper age limit
52 Weeks

Sex
All

Total final enrolment
5243

Key exclusion criteria
1. Preterm births <32 weeks gestation
2. Participant refusing ALSPAC

Date of first enrolment
31/05/1992

Date of final enrolment
31/12/1992

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Bristol
Administrative Centre: University of Bristol, Beacon House, Queens Road, Bristol BS8 1QU. The ALSPAC study was based (at the time of this trial) at the Institute of Child Health, Tyndall Avenue.
Bristol
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Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type

Research council

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
University of Bristol

Alternative Name(s)
Universitas Bristolliensis, bristoluniversity, bristoluni

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Lullaby Trust

Alternative Name(s)
The Lullaby Trust, The Foundation for the Study of Infant Deaths, The Lullaby Trust Sales Limited, FSID

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
ALSPAC data access is through a system of managed open access. The steps below highlight how to apply for access to the data included in this paper and all other ALSPAC data. Note that variable names are included in the tables within this paper. Please read the ALSPAC access policy (http://www.bristol.ac.uk/media-library/sites/alspac/documents/researchers/data-access /ALSPAC_Access_Policy.pdf) which describes the process of accessing the data and biological samples in detail, and outlines the costs associated with doing so.
1. You may also find it useful to browse our fully searchable research proposals database (https://proposals.epi.bristol.ac.uk/), which lists all research projects that have been approved since April 2011.
2. Please submit your research proposal (https://proposals.epi.bristol.ac.uk/) for consideration by the ALSPAC Executive Committee using the online process. You will receive a response within 10 working days to advise whether your proposal has been approved.
If you have any questions about accessing data, please email alspac-data@bristol.ac.uk (data) or bbl-info@bristol.ac.uk (samples).
The ALSPAC data management plan (http://www.bristol.ac.uk/media-library/sites/alspac /documents/researchers/data-access/alspac-data-management-plan.pdf) describes in detail the policy regarding data sharing, which is through a system of managed open access.

Detailed information on how the confidentiality of the cohort is maintained may be found on the study website: http://www.bristol.ac.uk/alspac/researchers/research-ethics/. All methods were conducted following the relevant guidelines and regulations. Informed consent for the use of data collected via questionnaires was assumed from participants following the recommendations of the ALSPAC Ethics and Law Committee at the time. Signed informed consent was obtained from the parent for face-to-face examinations before the child was old enough to consent him/herself.

IPD sharing plan summary
Available on request