

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/07/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/07/2024	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Study design

Randomized controlled trial nested within a longitudinal birth cohort

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Safety

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

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 ($>21^{\circ}\text{C}$), fine ($16-21^{\circ}\text{C}$) or cold ($<16^{\circ}\text{C}$). They then record the ambient temperature twice per week over a year.

Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Simple card wall thermometer

Primary outcome measure

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.

Secondary outcome measures

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

Overall study start date

01/01/1992

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

Age group

Child

Lower age limit

1 Weeks

Upper age limit

52 Weeks

Sex

Both

Target number of participants

5,000

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

England

United Kingdom

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

United Kingdom

BS8 1QU

Sponsor information

Organisation

University of Bristol

Sponsor details

Avon Longitudinal Study of Parents and Children (ALSPAC) Ethics and Law Committee, Oakfield House, Oakfield Grove, Clifton

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+44 (0)117 331 0010

ethics@childrenofthe90s.ac.uk

Sponsor type

University/education

Website

<https://www.bristol.ac.uk/alspac/researchers/research-ethics/>

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, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

University of Bristol

Alternative Name(s)

Universitas Bristolensis, 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

Publication and dissemination plan

Planned publication in a peer-review journal; paper to be submitted June 2024

Intention to publish date

25/06/2024

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