

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

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<b>Registration date</b> 05/07/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/07/2024	<b>Condition category</b> 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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## Contact information

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Public, Scientific, Principal investigator

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### 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

### Study design

Randomized controlled trial nested within a longitudinal birth cohort

### Primary study design

Interventional

### 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 (>21°C), fine (16-21°C) or cold (<16°C). 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

United Kingdom

BS8 1QU

## 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](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](mailto:alspac-data@bristol.ac.uk) (data) or [bbl-info@bristol.ac.uk](mailto: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