

Effect of babywearing on the skin (and core?) temperature of a baby

Participant Information Sheet

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What is the purpose of the study?

The purpose of the study is to investigate the effects of babywearing on the temperature of a baby. This research aims to improve our understanding of how warm babies get as a result of being held close to an adult in a sling, and to consider whether the current NHS advice of dressing a baby in one extra layer than the parents is appropriate during babywearing.

Who is doing this research and why?

This study has been designed by the Science Aware Natural Parenting Science Gang (SANP-PSG) with the support of Dr Davide Filingeri. The group is investigating because they are aware that much of the advice given to parents who wish to babywear is the result of common-sense thinking rather than being evidence-based. The group has consulted experts in babywearing and has not been able to find previous studies looking into the effects of babywearing on babies' temperature.

Are there any exclusion criteria?

Inclusion criteria for mother-baby dyads:

- mother and child;
- both in good general health;
- mother experience in using a sling to carry their child;
- mother capable of informed consent;
- mother able to take part in light exercise.

Exclusion criteria for mother-baby dyads:

- baby running a fever;
- mother or baby suffering from neurological diseases, cardiovascular or metabolic disorders;
- mother or baby on medication with a direct effect thermoregulation.

What will I be asked to do?

Your experimental session will take approximately two hours, but in order to ensure the most appropriate timing for your baby, you may spend longer at the lab. When you are not involved in

an experiment, you will be free to do as you wish. During the experiments, data will be collected on your baby's skin and tympanic (ear) temperature, and on your heart rate.

When you arrive at the laboratory you will be asked to fill in the Informed Consent form and a Health questionnaire (about your medical history). Both you and your baby will be weighed and your height measured to help gauge your total skin surface area.

You will be given a long-sleeved cotton t-shirt to wear and a cotton sleepsuit for your baby. With your assistance, 5 thermistors (small wireless temperature sensors) will be placed on your baby and held in place with medical tape.

You and your baby will spend 10 minutes in the lab playing quietly, with your baby on the floor or held on your lap. During this time your temperatures will be recorded, and your baby's tympanic (ear) temperature recorded. You will then put on the provided sling (there will be a babywearing peer-supported there to assist you), and your baby placed inside. Your temperatures will be recorded for another 10 minutes. You will then exercise gently for 10 minutes - walking around the lab, to simulate the sort of exercise that you might do when moving around the house with your baby. Your temperatures will be recorded for another 10 minutes and then you will take off the sling.

After a 10 minute rest period, you will add a vest to your baby's clothing, and the experiment will be repeated.

Once I take part, can I change my mind?

Yes. After you have read this information and asked any questions we will ask you to complete an Informed Consent Form, however if at any time, before, during or after the sessions you wish to withdraw from the study please just contact the main investigator. You can withdraw at any time, for any reason and you will not be asked to explain your reasons for withdrawing.

As your baby is not able to give informed consent, you must consent on his/her behalf. If at any time, before, during or after the sessions you believe that your baby is not happy, you may withdraw from the study on his/her behalf and you will not be asked to explain your reasons for withdrawing.

However, once the results of the study are published (?????), it will not be possible to withdraw your individual data from the research.

Will I be required to attend any sessions and where will these be?

The session mentioned will take place in the Environmental Ergonomics Research Centre, located within the James France building, at Loughborough University.

How long will it take?

Your session, including the whole experiment will take approximately 2 hours. You are invited to spend the whole day at the University so that your session can be scheduled according to the needs of your baby ie when he/she is awake, content and not hungry. Once your experimental session is complete you may leave the campus.

What personal information will be required from me?

You will be asked to complete a Health Screen Questionnaire to identify your medical history.

Are there any risks in participating?

The experiment has been designed to mimic normal conditions that are typical for mothers using slings. The experiments will take place at normal room temperature (around 22°C), use a popular sling, and involve gentle exercise to mimic the type of exercise typically seen when moving around the house.

There is a small risks that you may feel some discomfort while participating. You may feel warmer or cooler than you are used to, but you will be monitored to ensure that your temperature does not rise or fall to such an extent that overheating or overcooling is a risk. At any time point in the study, you will be free to terminate the trial, after which the investigators will provide to warm you up or cool you down if it will be necessary.

There is a small risk that the medical tape that is used to attach the thermistors may irritate your, or your baby's skin slightly. Any irritation is typically mild and should resolve itself over a day.

Will my taking part in this study be kept confidential?

Your taking part in this study will at all times be kept confidential. All data collected will be stored in a password locked folder with access only available to the main researcher. The information will only be kept until the project is completed, after that all your data will be deleted.

I have some more questions; who should I contact?

If you have any queries or questions throughout then please contact Davide on d.filingeri@lboro.ac.uk

What will happen to the results of the study?

The results of the study will be available to SANP-PSG for dissemination.

What if I am not happy with how the research was conducted?

If you are not happy with how the research was conducted, please contact Ms Jackie Green, the Secretary for the University's Ethics Approvals (Human Participants) Sub-Committee:

Ms J Green, Research Office, Hazlerigg Building, Loughborough University, Epinal Way, Loughborough, LE11 3TU. Tel: 01509 222423. Email: J.A.Green@lboro.ac.uk

The University also has a policy relating to Research Misconduct and Whistle Blowing which is available online at

<http://www.lboro.ac.uk/committees/ethics-approvals-human-participants/additionalinformation/codesofpractice/> .

Is there anything I need to do before the sessions?

We kindly ask two things before coming in for a session: you will not have any caffeine or alcohol the day before; and you will not have eaten anything for at least 2 hours before.

Is there anything I need to bring with me?

You do not need to bring anything with you for the experiment. You may wish to bring one or two small toys to help entertain your child.

What type of clothing should I wear?

You should wear a pair of average weight trousers eg jeans and whatever bra you feel comfortable in. You will be provided with a long-sleeved t-shirt on the day.

Your baby will be provided with a sleepsuit and vest to wear during the experiment.

What do I get for participating?

We hope to be able to cover travel expenses to attend the session. If this is a requirement for your attending, please make sure that the project coordinator is aware of this.