

Who will receive the information collected, and what will happen to the information?

Dr Niina Kolehmainen, the lead researcher at Newcastle University, will receive the information. The information will be held securely in Newcastle University for ten years. Niina is a senior researcher and an NHS children's therapist. She is bound by a professional code of conduct and the University rules on confidentiality, and is responsible to ensuring that your data is handled appropriately and kept confidential.

Will the information be confidential?

Yes, all information will be strictly confidential. The research team have signed a confidentiality agreement.

How will you publish the study findings?

We plan to publish the findings to parents and children, policy makers, children's healthcare providers, and other researchers. In the publications, we will not involve any information that could be used to identify you or your child. We will not make details about you or your child public at any point. If you would like to receive alerts about any publications, please let us know. We can add you on the study mailing list.

Who is paying for and conducting the research?

This study is funded by the National Institute for Health Research, the UK NHS "research arm". It is carried out by Newcastle University in collaboration with your local NHS Trust as well as other Trusts in England.

Is there an NHS Research Ethics Committee approval?

The study has an approval from North East - Newcastle & North Tyneside 2 Research Ethics Committee (Ref: 17/NE/0051, IRAS 218313) and it has been approved by the local NHS organisation.

What if I want more information, or if there is a problem?

Please contact me, Niina Kolehmainen. You can call me on 07964329630 or by email niina.kolehmainen@newcastle.ac.uk.

Thank you!



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Movement & Activity in Children with Developmental Concerns

ActiveCHILD 3-year study

What is the purpose of the project?

To find out how children's movements and activity change from birth to age 5 years. **At the moment we are particularly looking for children with difficulties in movement or with concerns about physical development.**

Why have my child and I been invited for the study?

Your local NHS children's service is involved in this research. We are looking for a wide range of children and families to participate.

We are inviting children and families to take part if the child is around 9-26 months old.

What will happen to me and my child as part of the research?

The study runs for three years. We will ask information from you and your child six times during that three years.

The next page tells you about the different types of information.

BASIC INFORMATION about your family and child. This would involve:

- you completing a 5-minute online questionnaire; and
- us obtaining basic health information about your child from your NHS professional. This includes any medical diagnoses and any concerns about your child's development. For details, please see an example attached, titled "THERAPIST FORM".

DATA ABOUT YOUR CHILD'S ACTIVITY and YOUR FAMILY LIFE

This would involve:

- your child wearing a tiny 'mini-computer' a size of a watch (an "accelerometer"). This records the child's movements. Your child would wear it during the day, for six times over 3 years, up to 7-days at each time.
- you completing a brief, daily activity log for the days when your child wears the mini-computer.
- you completing a set of brief questionnaires (total 15-20min). This is easy tick-boxes.

MORE IN-DEPTH INFORMATION ABOUT YOUR FAMILY ROUTINES

There is much that we do not yet know about active play and physical activity in very young children. To understand things better, we would like to approach a small proportion of parents to be interviewed once. This is an optional part, and you can still do the study without doing the interview. If you decide to take part in the main study, you will receive more information and can then make a separate decision about the interview.

Will me or my child be tested for an intervention?

No. This study will not test any interventions. This study seeks to understand children's movement and activity in order to develop better interventions.

Can I refuse my and my child's participation?

Yes, absolutely. You are free to say either yes or no. Your decision will not affect you or your child in any way, and we will not contact you further.

I am interested in this project – what should I do next?

Please contact the lead researcher, Dr Niina Kolehmainen. For details, please see cover letter or the back of this leaflet.

What are the possible risks and burdens?

We do not think that this study will have risks to you or your child. The study does not involve intrusive treatments or interventions. The study does not involve denying any treatment or advice from your or your child. The data collection does not address sensitive topics.

Reminding your child to wear the mini-computer and complete the brief questions in the evenings can feel tough. We will work with you to make this as easy as possible.

What are the possible benefits?

You will help NHS services to understand how children with movement concerns develop. This will enable better treatments and better ways to support families.

Young children, especially children with developmental problems, do not often get to take part in research. This means treatments for them do not develop as fast as treatments for other children and adults. It is important that children with developmental concerns are involved in research, and treatments for them can be improved.

As part of the research, you will get feedback on your child's movement and activity. You and your child will also receive small fun rewards (e.g. activity toys, parent resources), and will have early access to the study results.

What information will be held about me, my child and my family?

At the moment, we do not hold any information about you or your child. If you will take part, we will hold the information collected from you and your child, and the data the health professional passes to us.