



NORTHPOP
Barns hälsa i Västerbotten

A study about children's health in Västerbotten

– Invitation to you as a parent-to-be



The focus of the **Northpop** study is to identify risk and health factors for common children's diseases. All parents-to-be in Västerbotten are invited to participate. Each family's contribution is valuable. The project is being implemented by researchers at Umeå University and staff at Västerbotten County Council. All the research done in the study has been approved by an ethics review board.

WHAT IS THE AIM OF THE NORTHPOP STUDY?

Our goal is that children are healthy and thrive. In recent decades, asthma, allergies, excess weight and behavioural problems have increased among children and youth. We know that the foundation for future health is laid early on in life and we are still lacking important pieces of the jigsaw puzzle of knowledge about how heredity and environment interact during pregnancy and childhood. To understand how early risk factors affect health later on in life, we need to follow children throughout their growing-up period.



WHAT WILL BE INVESTIGATED?

We intend to investigate the health and lifestyle of parents-to-be during pregnancy, and how the child is affected by pharmaceuticals, eating habits and environment after the birth and during the growing-up period. We will also study the significance of the bacteria that are always present in the mouth and bowel and which are important for the immune system, metabolism and the normal development of the body. We are also interested in hereditary factors.

Supplementary information relating to the mother's, partner's and child's health and living conditions will be gathered. All the gathering of information has been approved

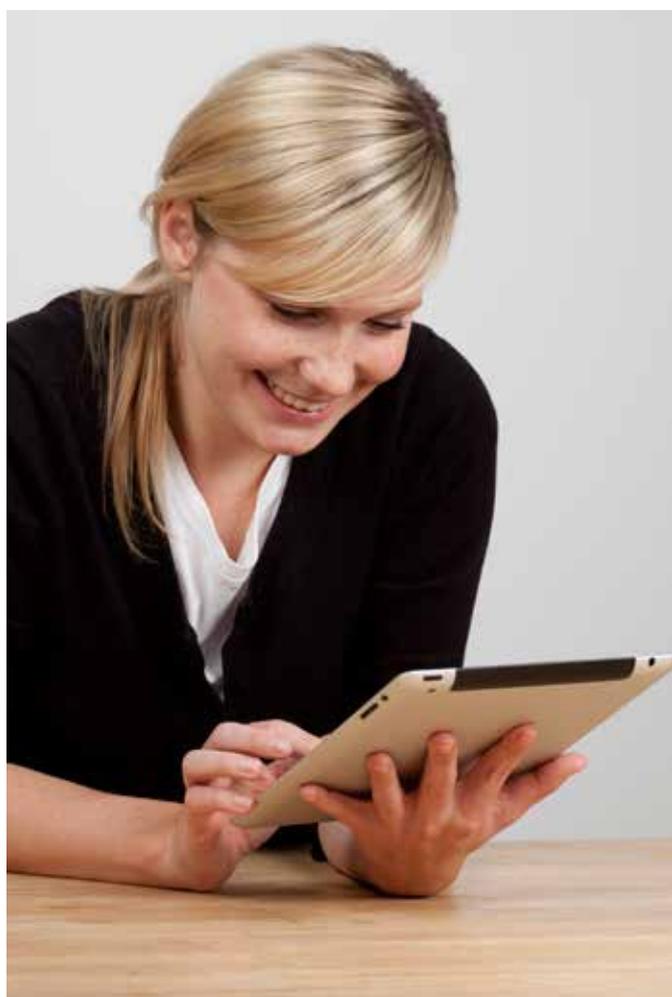


ved by an ethics review board and it will not be possible to identify participants in published research findings. Information will be gathered from medical files of mothers, partners and children from hospitals, maternity clinics, child healthcare centres, school health services and from national quality registers (Pregnancy Register, Swedish Neonatal Quality Register, child healthcare and school healthcare quality register) at Statistics Sweden (civil registry data and information about education and employment etcetera) and the National Board of Health and Welfare (Medical Birth Register, the National Board of Health and Welfare's Patient Register and the Pharmaceuticals Register).

HOW WILL THE STUDY WILL DONE?

We will follow your child's development from inside the mother's womb up to the age of 7 years. After that, further follow-ups may be done if the ethics review board gives its approval. When the children have turned 18, they choose for themselves whether they want to continue taking part in any follow-up studies.

Participation is voluntary and you can drop out at any time and without any special reason. In that case, no research will be done on the gathered materials. If you break off your participation, that will of course not have any effect on your or your child's future treatment or care by the health and medical care services.



WHAT WE ASK THE MOTHER TO DO

You will be asked to answer a questionnaire on the internet on a number of occasions about your and your child's health, illnesses, eating habits and other habits. The questionnaire also has questions about your child's development and behaviour.

During pregnancy, you will be asked to fill in three questionnaires and an extra blood sample (10 ml) will be taken in conjunction with the routine blood test done in week 28 of pregnancy at the maternity care clinic. This blood sample will be used to investigate indicators for diet and environmental factors that can affect the baby during pregnancy. Then you will be given a questionnaire when the child is 3 months, 9 months, 18 months, 3 years and 7 years old. One month after giving birth, you will be asked to provide a sample of breast milk (20 ml) in order to examine the composition of bacteria and environmental factors. All samples are voluntary but of great significance for the study.

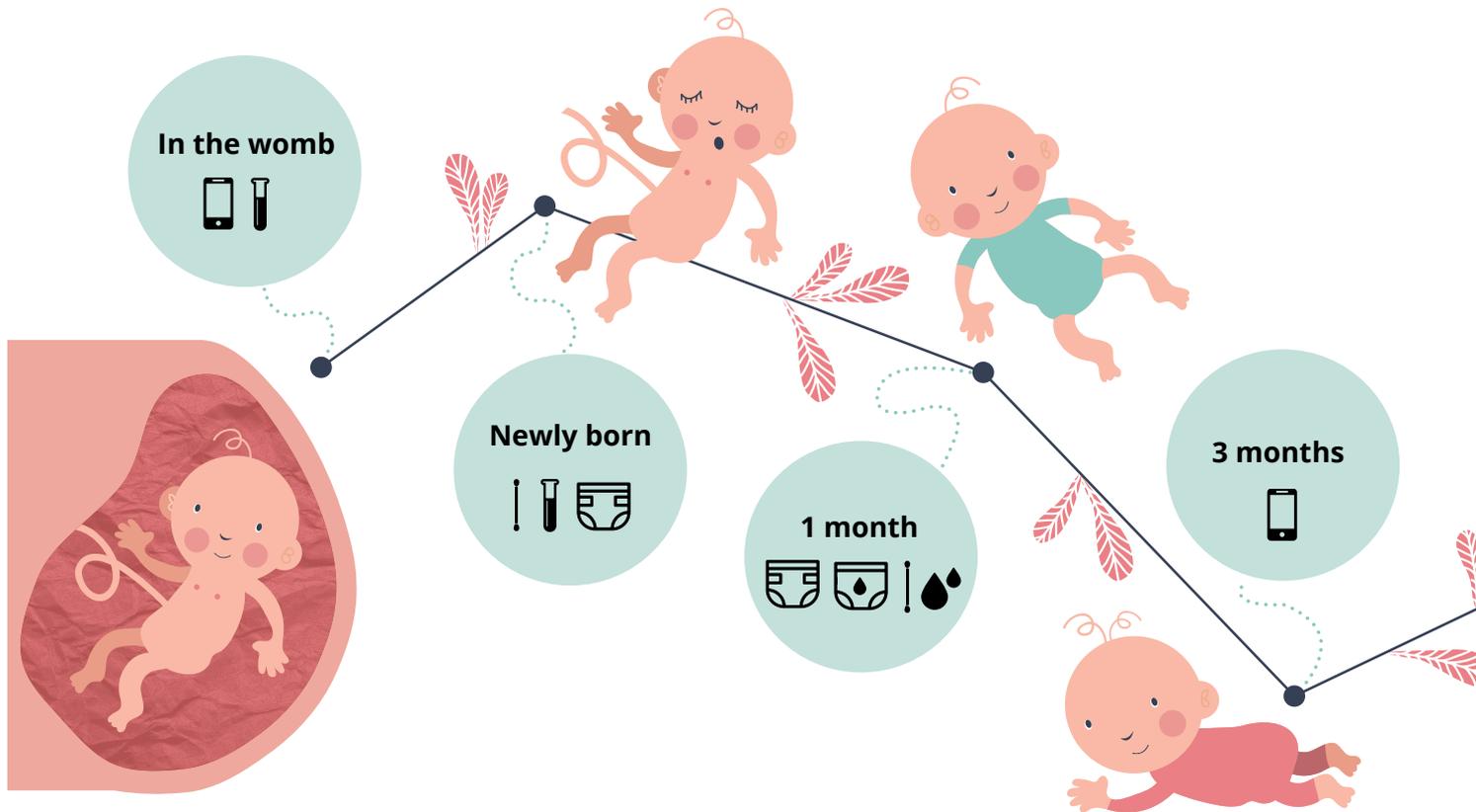
WHAT WE ASK THE FATHER/PARTNER TO DO

During your partner's pregnancy, you will be asked to fill in three questionnaires on the internet about health, illnesses, eating habits and other habits.

FILLING IN THE QUESTIONNAIRE

The questionnaire can be filled in using a computer, tablet or mobile phone. You can also be given a paper version if you prefer that.

Time line for the gathering of samples and questionnaires in Northpop.



 Saliva sample	 Blood sample	 Breast milk sample	 Faeces sample (child)
 Questionnaire	 Allergy "dot test"	 Urine sample (child)	 Faeces sample (child)

SAMPLES AND EXAMINATIONS OF THE CHILD

After the birth, a blood sample is taken (10 ml, about 2 teaspoons) from the umbilical cord. This is completely painless for both mother and baby and is done in conjunction with other routine samples being taken from the umbilical cord.

This blood sample will be used to investigate indicators for environmental factors that may have influenced the baby during pregnancy. We will also investigate variations in specific genes that are linked to the risk of developing the illnesses that are being studied.

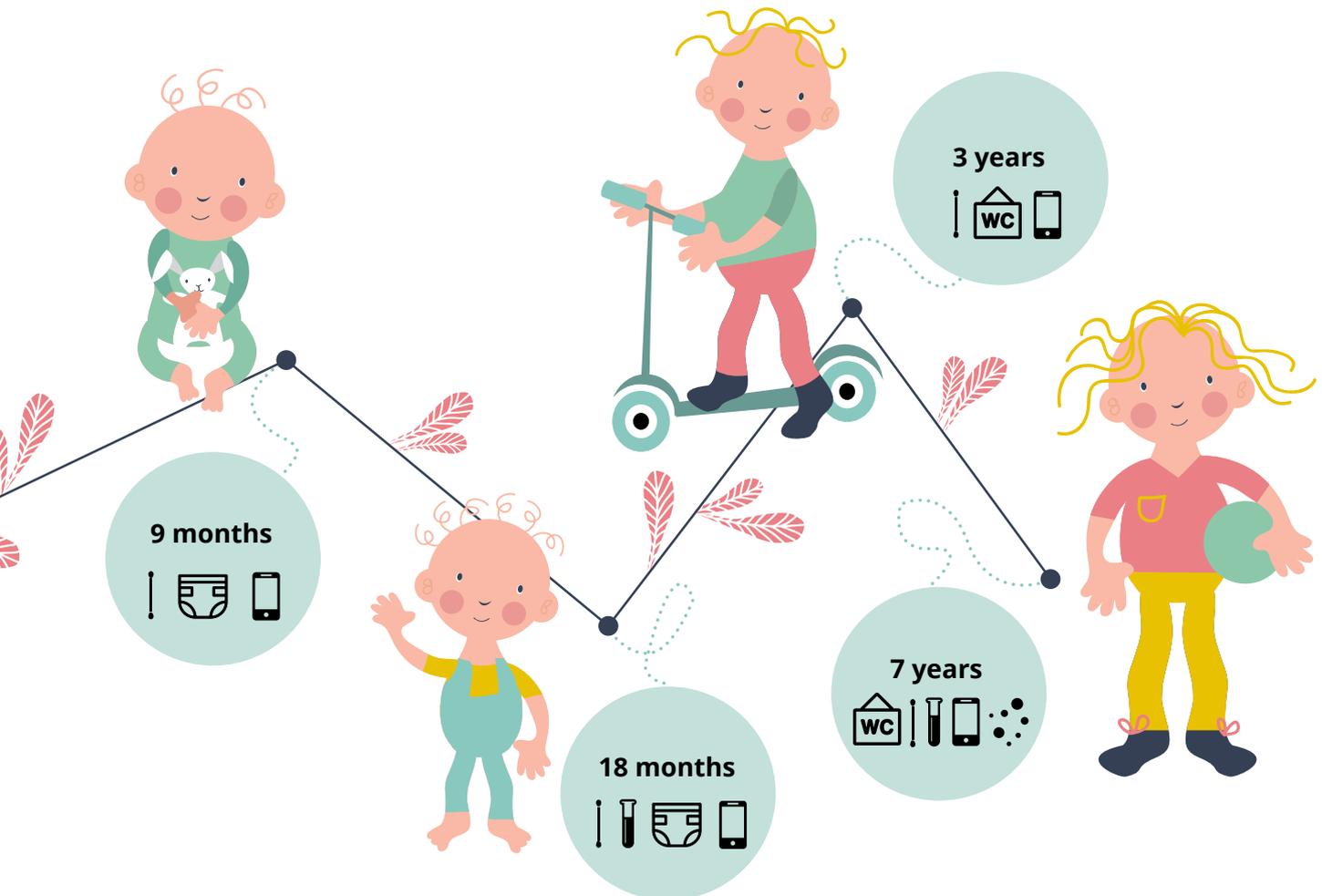
Saliva and faeces samples will be taken from the baby before the mother leaves the maternity ward and again at the age of 1, 9 and 18 months and 3 and 7 years of age. These samples will be used to examine how the immune system and bacteria composition are developing. When the

baby is 1 month old, a urine sample will be taken from the baby to investigate environmental factors. The staff at the labour ward or maternity hospital will demonstrate how the samples will be taken before the mother leaves the maternity hospital.

This information is also available on **Northpop's** website www.northpop.se. The other samples that are taken when the child is older are taken in the home by the parents and handed in to a child healthcare centre in conjunction with a routine visit there.

Information about environmental factors and the child's diet, health, growth and development is gathered via the questionnaire that the parent fills in.

To find out if the child is developing some form of allergy illness, you will be asked for a voluntary blood sample from



the child at the age of 18 months and then 7 years. When the child is 7 years old, you will be offered the opportunity to have an allergy "dot test" on the child's skin. With these examinations, we will investigate if the child reacts to common allergy-triggering substances. Some of the children will be asked to measure how much they move about during some short periods of time using a sort of pedometer.

THE HANDLING OF SAMPLES

Samples will be frozen and stored in a biobank located at the University Hospital of Umeå. The samples are saved after being encoded and the encryption key is stored so that only authorised staff have access to it. The samples may only be used for the purposes approved by the ethics review board.





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THE HANDLING OF PERSONAL DATA AND SECRECY

All the answers and results of the study, known as personal data, will be handled so that only authorised staff have access to them. The personal data that have been collected will be kept for as long as necessary in order to achieve the goal of the research project. After that, they will be destroyed. Samples and encoded data and samples for analysis may be sent to collaborating researchers within and beyond the EU/EEA in collaboration projects. This will be done after the collaboration partner in question has shown they have integrity protection that corresponds to that stipulated in Sweden's Personal Data Act (SFS 1998:204).

RESEARCH ETHICAL REVIEW

The regional ethics review board has inspected and approved this project. The collected samples and data may be used for other health-related research, in which case a new ethical review will be done. The regional ethics review board assesses whether you must be contacted again to give consent to such a research project. As already explained, all participation is voluntary.

INFORMATION ABOUT THE RESULTS AND THE RIGHT TO EXTRACTS FROM REGISTERS

On the project's website www.northpop.se you will be able to log in and see a graphic presentation of your child's growth and development and the results of allergy tests. News about the study and new research results will be presented on the website. There you will also find advice about your child's diet and how you can support your child's development. Other analysis results will not be supplied in

a routine way. Instead, results will be published in scholarly journals in such a way that no individuals can be identified. If we detect any abnormal sample results, the study doctor will decide in each individual case whether an investigation is required.

Once a year, you can submit a written request for an extract from the register, free of charge, showing the data that is stored there about you and your child and a general description of what research has been done. Under the Personal Data Act, you are also entitled to request that any incorrect information is rectified.

ARE THERE ANY RISKS?

We do not expect any particular risks to arise. Before blood samples are taken, the child's skin will be anaesthetised with a cream in order to minimise any pain and the sample will be taken by an experienced research nurse. The allergy "dot test" done on the skin when the child is 7 years old exposes the child to minimal unpleasantness.

ARE THERE ANY BENEFITS?

There will be no benefits for the individual child but in a larger perspective, the investigation will give important information about how we can prevent, diagnose and treat asthma, allergies, obesity, excess weight and behavioural problems (e.g. ADHD).

INSURANCE AND REIMBURSEMENT

The child is insured through patient injury insurance of the same kind as that used within the medical care services. The study will not imply any additional costs for you. Travel costs may possibly be reimbursed when you visit the research clinic.

RESPONSIBILITY AND CONTACT DETAILS

The researchers in charge of the project are Professor Magnus Domellöf, docent/senior consultant Christina West, Professor Ingrid Mogren, docent/senior consultant Sven-Arne Silfverdal and PhD/dietician specialising in paediatrics Inger Öhlund, all of whom work at Västerbotten County Council and the Department of Clinical Sciences, Umeå University.

FOR MORE INFORMATION, PLEASE CONTACT

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Västerbotten County Council is the body in charge of sampling and the storing of samples and is responsible for personal data.

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Umeå University is the body in charge and is responsible for personal data in conjunction with research carried out by university researchers.

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