

Appendix F. Participant Information Documents

MRC Human Nutrition Research & NatCen

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Why have I been chosen to take part?

We select people or households from lists such as the Post Office's list of addresses. To make the results accurate we have to rely on the people chosen for the study – no one else can take their place.

You don't need any special knowledge to take part. Most people who are chosen agree to be interviewed and enjoy the experience.

Who are the interviewers?

NatCen has a team of around 1,000 trained interviewers. For most studies an interviewer will visit you in person to conduct the interview. All our interviewers carry a photo identification card which they will show you. *Always ask for identification from any caller who is not known to you.*

Our responsibility to you

• We guard your privacy

Your answers will be treated in strict confidence in accordance with the Data Protection Act. They are used for statistical research purposes only. Names and addresses are never included with the results.

• We respect your wishes

Your participation in the study is, of course, voluntary. You do not have to answer any particular question if you would prefer not to. At any time in the interview you can withdraw answers you have already given.

• We answer your questions

We will always tell you the purpose of the research and who is funding it.

• We do not pass on addresses

You will not receive any 'junk mail' as a result of taking part. We do not pass addresses on to other organisations for commercial purposes.

NatCen

National Centre for Social Research
35 Northampton Square, London EC1V 0AX
E-mail: info@natcen.ac.uk www.natcen.ac.uk

Scottish Centre for Social Research

5 Leamington Terrace, Edinburgh EH10 4JW
E-mail: info@scotcen.org.uk www.scotcen.org.uk

Operations Department

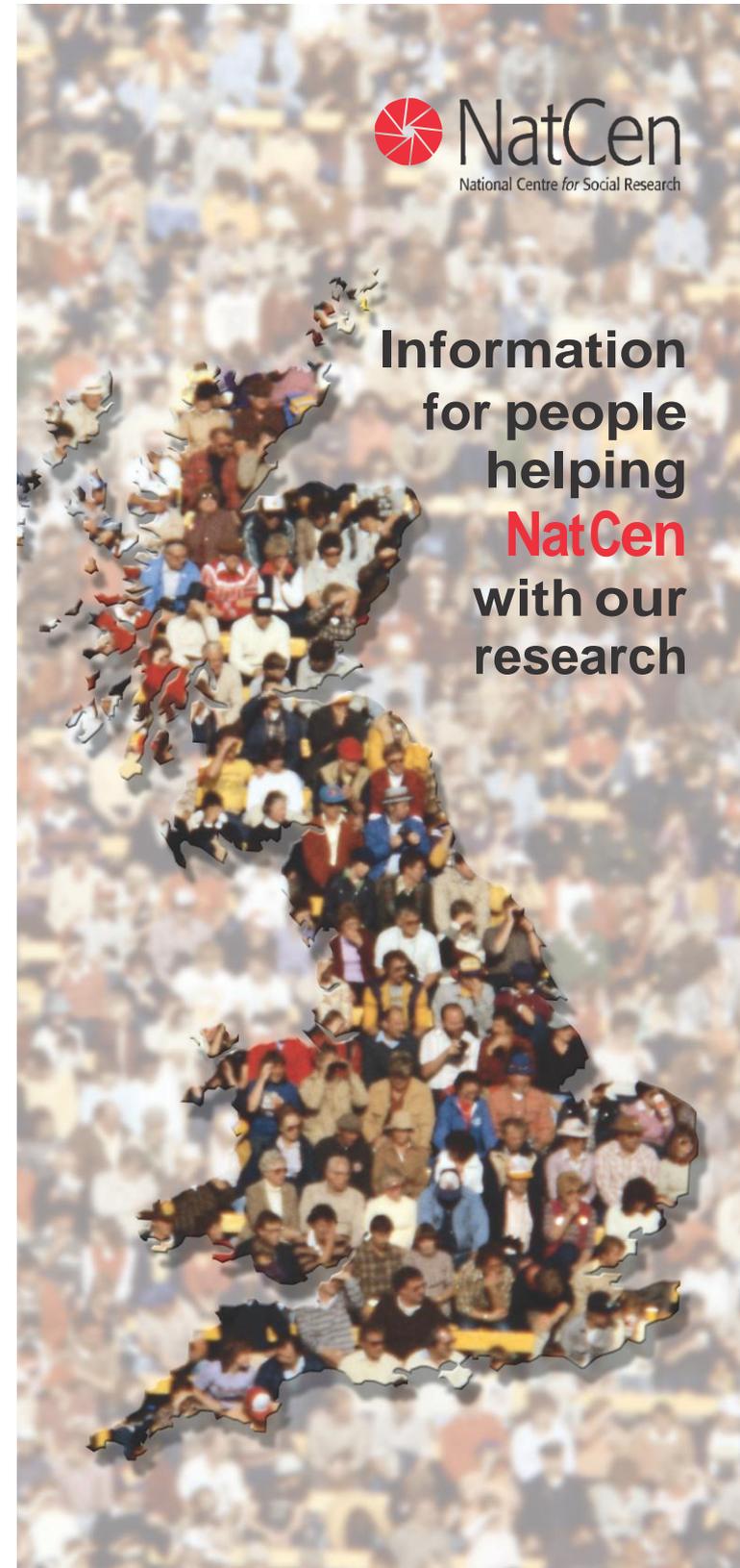
Kings House 101-135 Kings Road, Brentwood
Essex CM14 4LX

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NatCen
National Centre for Social Research



Information
for people
helping
NatCen
with our
research



What is NatCen?

NatCen, the National Centre for Social Research, is Britain's largest independent research organisation studying social policy. It includes the Scottish Centre for Social Research.

Our aim is to make society better informed through high quality social research. We carry out many important national research studies for government departments, research councils and charitable foundations.

The policy areas we study include: health, education, work, childcare, housing and transport. These are some of the studies we undertake:

- **Health Survey for England**
- **Survey of Adult Learning**
- **Workplace Employee Relations Survey**
- **Scottish Social Attitudes**
- **Survey of Parents' Demands for Childcare**
- **Survey of English Housing**
- **National Travel Survey**
- **British Social Attitudes Survey**

We also study the attitudes and values of the population generally and produce research reports such as British Social Attitudes.



Who needs the research?

Government departments and other public bodies such as health and local authorities who need accurate up-to-date statistics to help them plan for people's future needs. They also need to monitor and evaluate schemes and policies which are already in place.

"Well-designed research projects can help the NHS to make important advances in health care."
Dr Brian Jarman, Imperial College School of Medicine

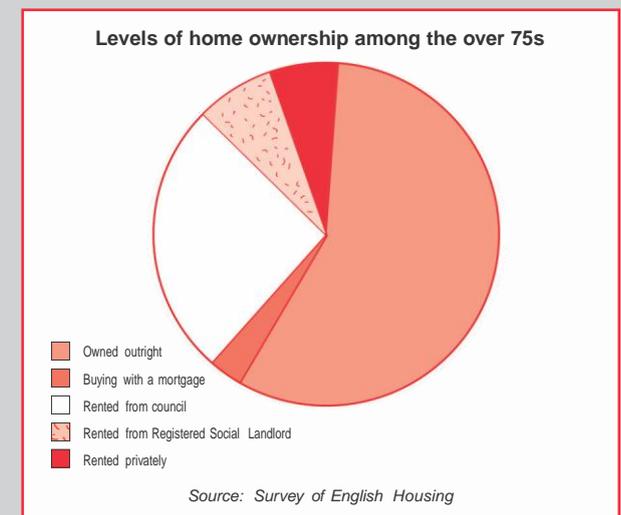
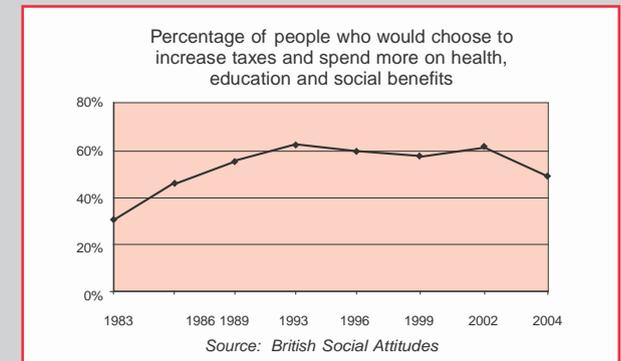
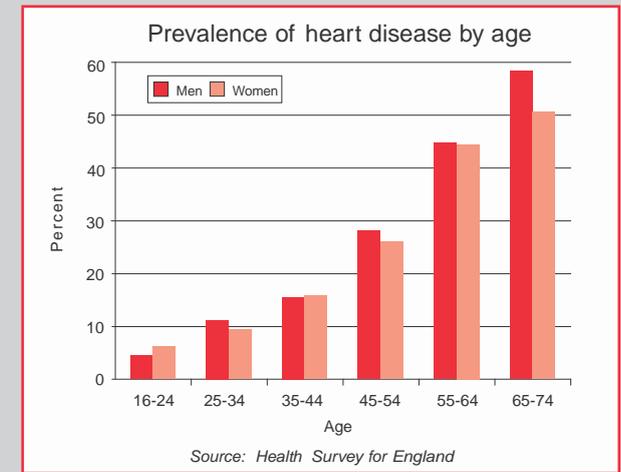
UK charities who frequently use social research to find out more about people's views, circumstances and experiences.

"Being able to make use of this kind of research is very helpful to Age Concern in making recommendations about policy for helping older people."
Evelyn McEwan, Director of Information & Policy, Age Concern

Universities and colleges where academic researchers and students use the findings for independent studies.

"The British Social Attitudes series is essential for understanding society."
Professor Sara Arber, University of Surrey

Here are some examples of findings from our research:



The MRC Collaborative Centre for Human Nutrition Research (HNR) was established in 1998 following the restructuring of the Dunn Nutrition Unit, so as to progress the Medical Research Councils portfolio of strategic and applied nutrition research. HNR was set up with a collaborative remit: to pursue research in partnership with national and international stakeholders.

Importantly, HNR brings together a strong team with specialist expertise in nutrition, dietetics, medicine, physiology, biophysics, analytical chemistry, biochemistry, molecular biology, epidemiology, mathematics and statistics.



Research

MRC Human Nutrition Research works to advance the knowledge of the relationships between diet and its impact on the health of the population. The unit conducts high quality research and provides a national centre of excellence for the measurement and interpretation of dietary, biochemical and functional indicators of nutritional status and health.

Research is organised around 5 sections:

Population Nutrition Research

Investigating diet and health through assessment and analysis of dietary intake and the relationship to biomarkers and disease outcomes.

Nutrition and Health

Studying the role of dietary factors in the prevention and treatment of obesity and related metabolic diseases.

Nutrition and Bone Health

Looking at nutrition and lifestyle factors for the optimisation of peak bone mass and reduction of osteoporosis risk.

Biomineral Research

Investigating the uptake, distribution, cellular handling and functional role of micronutrients.

Bioanalytical Sciences

Discovery and measurement of physiological markers of nutrition, health and disease.

HNR also has a dedicated **Nutrition and Health Communications** team who provide an independent source of authoritative scientific information on nutrition and health, and encourage the translation of scientific knowledge into effective public health policies and practice.

Diet and Health

Over the last ten years, our research has helped to shape the understanding of nutrition science by...

Developing and improving dietary assessment and analysis methods for evaluating the diets of populations and key subgroups like children and the elderly.

Studying the effect of changes in diet on the risk of diabetes, obesity and cardiovascular disease.

Using stable isotope techniques to assess the physical activity levels and energy requirements of people in a wide range of circumstances.

Taking a cross-cultural and international perspective on osteoporosis risk, to provide a better definition of calcium requirements and calcium metabolism in mothers, children, adolescents and older people.

Identifying the functional and quality of life effects of iron deficiency in differing populations, and investigating the influence of the chemical form of iron used in oral supplementation on iron absorption and the potential for side effects.



Surveys

Information gathered from large surveys helps to address current issues of importance to the health of the population. This is achieved by measuring the diet of large numbers of people, all over the UK. HNR is currently involved in 3 major nutrition surveys:

The Infant Diet and Health Study:

funded by the Food Standards Agency and the Department of Health, gathers information on the dietary habits, growth, and nutritional status of infants and young children in the UK.

The National Diet and Nutrition Survey:

funded by the Food Standards Agency and the Department of Health, gathers information on the dietary habits and nutritional status of children and adults in the UK.

The National Study of Health and Development, 1946:

funded by Medical Research Council, has collected information from birth to the current day on the health and life circumstances of five and a half thousand men and women born in one week in 1946.

These national nutrition surveys are the cornerstone of nutrition research in the UK and provide the context for the development of public health policy and help to decide on broader research priorities.



Communicating our science to others

Our work is published in some of the most well respected scientific journals, ensuring that our findings keep the research community informed.

We are also involved in translating science into policy and practice. Many of our researchers sit on advisory boards and expert committees such as the Government's Scientific Advisory Committee on Nutrition.

Our public engagement activities allow nutrition science to reach diverse groups of people of all ages. We are involved in local and national science events and regularly interact with schools within the region to enthuse and inform people about science.

We act as advisors to television and radio programmes on diet and health and provide help to journalists on a range of nutrition and health issues.

We develop resources for health professionals and engage regularly with the food industry to encourage the development of healthier food products.



Get involved in our studies

We are always looking for volunteers; men, women and children to join our nutrition studies. Volunteers gain unique insights into our research and have the opportunity to help shape our understanding of nutrition. They may also benefit from medical tests and in some cases nutrition advice.

If you are interested in joining our volunteer database, why not give one of our staff a call on **01223 437611** or email us at volunteer@mrc-hnr.cam.ac.uk for more information. By calling or emailing us, you are under no obligation to take things any further.

Volunteer feedback

"You get so much from being involved in these trials. Since starting, I've had my cholesterol checked, bone scans... things you wouldn't always get on the NHS! And I've learnt so much from my personal sessions with the dietician - it really makes you think about what you're eating."



Career opportunities at HNR

If you are interested in working at our internationally renowned research centre, or you are interested in applying for a PhD, you can check our website for news of current vacancies at www.mrc-hnr.cam.ac.uk

Further Information

If you would like any more information about the work of the unit, please visit www.mrc-hnr.cam.ac.uk or email communications@mrc-hnr.cam.ac.uk

MRC Human Nutrition Research

Elsie Widdowson Laboratory

120 Fulbourn Road

Cambridge

CB1 9NL

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Medical Research Council

Human Nutrition Research

Conducting Scientific Research into Nutrition and Your Health

National Infant Diet and Health Study

We are writing to ask for your help with an important and unique study. The Department of Health (DH) and the Food Standards Agency (FSA) is funding a study that collects information on the eating habits and health status of young children in the United Kingdom. It involves gathering information about the food young children eat, their general health and development and the household they live in.

This study is being run by a team of independent research organisations led by **MRC Human Nutrition Research (HNR)** and the **National Centre for Social Research (NatCen)**. **NatCen** are carrying out the interviews for this study.

A random sample of parents with children who will be aged between 4 months and 18 months at the time of interview have been selected from Child Benefit records (held by HM Revenue and Customs). It is important we gather information from as many of the families we approach as possible, so we can get an accurate picture of the health and diets of young children across the UK. We hope you will be willing to help us with this important study. The study is optional and you can take part in some parts and not others. We rely on the goodwill of those invited to take part to make the study a success. As a token of our appreciation, everybody who provides information about their child's eating patterns will be **given £30 in High Street Vouchers**.

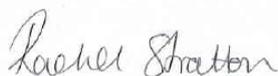
In the next few weeks a NatCen interviewer will visit your address to ask if you are willing to take part in the study. However, if you do not want to be contacted about this study, or if you have any queries, you can call NatCen by [December 23rd 2010/March 25th 2011], on **FREEPHONE: 0800 652 4572**, write to the **FREEPOST** address: National Centre for Social Research, Freepost CL499, 101-135 Kings Road, Brentwood, CM14 4LX, or email: NIDHS@natcen.ac.uk. If you do get in touch, please remember to give your name and the reference number from the top of this letter.

On the back of this letter, we have included more details about the study and the interview, and information about who NatCen and HNR are. You can also visit the National Infant Diet and Health Study website: www.mrc-hnr.cam.ac.uk/working-with-us/national-infant-diet-and-health-study.html. We would like to reassure you that anything you say during the interview will be treated in the strictest of confidence in accordance with the Data Protection Act 1998, and the information will only be used for research purposes and food policy planning.

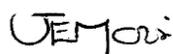
Whether or not you take part will not affect your entitlement to any benefits or tax credits, or any other dealings with Government departments, now or in the future.

Thank you in advance for your help.

Yours sincerely,



Rachel Stratton
Nutrition Science and Delivery
Health and Wellbeing
Department of Health
Wellington House
133-155 Waterloo Road,
London SE1 8UG
E-mail: Rachel.Stratton@dh.gsi.gov.uk



Janice Morris
Operations Department
NatCen
Kings House,
101-135 Kings Road,
Brentwood,
Essex, CM14 4LX
E-mail: NIDHS@natcen.ac.uk



Frequently Asked Questions



Who is carrying out the study?

The study is being funded by the Department of Health (DH) and the Food Standards Agency (FSA) and includes two stages. You do not have to decide until the end of the first stage whether or not you would like to take part in the second stage.

Stage 1: The interview stage is being carried out by the National Centre for Social Research (NatCen), which is Britain's largest independent research institute. They carry out many national studies covering topics such as childcare, health, education, housing and employment. You can find out more about NatCen from their website www.natcen.ac.uk or by writing to: NIDHS, Health & Wellbeing Team, NatCen, 35 Northampton Square, London, EC1V 0AX.

Stage 2: The clinic stage is being organised and carried out by MRC Human Nutrition Research (HNR), who carry out and support nutrition research throughout the UK and internationally. You can find out more about MRC HNR from their website www.mrc-hnr.cam.ac.uk or by writing to: NIDHS, MRC Human Nutrition Research, Elsie Widdowson Laboratory, 120 Fulbourn Road, Cambridge, CB1 9NL.

How was I chosen for the study?

We selected a random sample of parents with children who will be aged between 4 months and 18 months at the time of interview from Child Benefit records provided by HM Revenue and Customs. This ensures that the people who are invited to take part in the survey are representative of parents of children in this age group across the whole country. We would like to reassure you that the research is genuine and the government has approved using the Child Benefit records in this way. If you would like further confirmation of this, you can call Rachel Stratton at the DH on 020 7276 8927 or e-mail: rachel.stratton@foodstandards.gsi.gov.uk. For any other query please contact NatCen using the contact details overleaf.

What will I have to do?

We want to find out about what infants and young children in the UK eat and drink, their health and development and a bit about the households they live in. We would like to talk to the parent or guardian who has most involvement in the everyday feeding of their child. The main interview will take around 40 minutes. We would also like you to complete a food diary over a few days to record what your child eats in that time. If you complete this part of the study we will provide £30 in high street vouchers as a token of our appreciation. If you would like, we can send you feedback on your child's diet. With your permission, the interviewer will also take some physical measurements. The interview will take place in your own home, and your answers will be input on a laptop computer. At the end of this stage, we will ask if you would be interested in visiting a clinic with your child to have some further measurements and tests for the study.

Why should I take part?

We need information from a wide range of families, for example, those with one child and those with more than one child; those who breastfeed their child and those who don't; families with working parents and families with parents who don't work. Otherwise we would not get a true picture of the eating habits and health status of young children in the UK. Ideally everyone who is chosen will take part so that the results are representative of the UK as a whole.

How will the information I provide be used?

Your answers will be used to inform research on what children of this age eat, and help guide government policy on health and nutrition. Your answers to our questions will be treated in the **strictest of confidence**, in accordance with the Data Protection Act 1998. Your name and other personal details will not be quoted in any research findings and no report will ever identify you or your family. Your name and address will be removed from the records of the survey, unless you agree to take part in further research at the end of the interview.

Who will interview me?

One of NatCen's interviewers will get in touch to ask if you would like to take part in the study. The interviewer will show you a NatCen identification card when he or she calls at your house. If the interviewer calls at a time that does not suit you, you can make an appointment for him or her to call back, including during an evening or at the weekend, if that is better for you.

Is the survey compulsory?



No. In all our surveys we rely on voluntary co-operation. The success of the survey depends on the goodwill and co-operation of those asked to take part. The more people who do take part, the more useful the results will be. However, you may take part in some parts of the survey but not others and you are free to withdraw from any part of the study at any time.

Do I get anything from the survey?

If you wish, you may have a record of your measurements and your child's measurements.

Also, if you would like, we can send you feedback on your child's eating habits, which will tell you what he/she eats compared with national recommendations.

If you decide to take part in the clinic visit, we can feedback the results of some of the measurements – such as how much breastmilk your child drinks in a day, and some results form the blood test (such as vitamin D and iron levels).



If I have any other questions?

We hope this leaflet answers the questions you may have, and that it shows the importance of the survey. If you have any other questions, concerns or problems about the study please do not hesitate to ring one of the contacts listed below.

Your co-operation is very much appreciated.

Janice Morris
Project Controller
Operations Department
National Centre for
Social Research
Kings House
101-135 Kings Road
Brentwood
Essex
CM14 4LX

Dr Ken Ong
Survey Doctor
MRC Epidemiology Unit
Institute of Metabolic
Science, Box 285
Addenbrooke's Hospital
Hills Road
Cambridge
CB2 0QQ

Freephone: 0800 652 4572 Tel: 01223 769207

www.mrc-hnr.cam.ac.uk/working-with-us/national-infant-diet-and-health-study.html



Your help with this important survey is very much appreciated!



National Infant Diet and Health Study

Information for parents



This study is being carried out for the Department of Health and the Food Standards Agency, by the National Infant Diet and Health Study team. The team consists of independent research institutes: Medical Research Council (MRC) Human Nutrition Research (HNR) based in Cambridge, National Centre for Social Research (NatCen) based in London, MRC Epidemiology Unit based in Cambridge, and the Human Nutrition Research Centre at Newcastle University.

This leaflet tells you more about the study and why it is being done.



What is it about?



Over the past few years there has been a lot of advice and information provided to parents about how best to feed and wean young children. There has also been a considerable increase in the range of food and drinks available in the shops for babies and toddlers.

The National Infant Diet and Health Study is a large, national study to find out, in detail, about the eating habits of very young children (aged 4 months to 18 months) in the UK.

We would like to talk to the parent or guardian who is most involved in the everyday feeding of your child. The interview will be carried out by one of our trained interviewers and will collect information on your child's eating habits and health, and some basic information about your household.

With your permission, the interviewer will measure your child's length, weight and head circumference, as well as the mother's height and weight.



We would also like to collect information about the day to day eating patterns of your child. If you agree, the interviewer will give you a diary to record information about what your child

eats and drinks over four days, and will arrange to visit you again to collect this and ask a few more questions. Every person who completes this part of the survey will be given **£30 in high street vouchers** as a token of our appreciation.

Second stage of the study – the clinic visit



There is also a second stage to the study, which involves visiting a specialist research clinic with your child. If you agree to take part in this stage of the survey, you will be asked to visit a clinic – all expenses paid, and at a time convenient for you – so that a specially trained nurse can, with your consent, take the following measurements:

- Your child's skinfold thickness
- An assessment of how much breastmilk your child drinks (if breastfed)
- Your child's body composition and fluid intake (if not breastfed)

The nurse will explain in more detail what these involve. The nurse will also ask if you would be willing for your child to provide a small blood sample (less than a teaspoon of blood).

The analysis of these measurements and samples will tell us a lot about the health and nutrition of infants and young children.

All stages of the research are optional, and you can take part in some parts and

not others. If you visit the clinic, you do not have to take part in all of the measurements.

Why have we come to your household?

We selected a random sample of parents with children aged between 4 months and 18 months from Child Benefit records (held by HM Revenue and Customs). This ensures that the people who are invited to take part in the survey are representative of all parents of children in this age group across the whole country.

Some people think that they are not typical enough or are too different from other people to be of any help in the survey. The important thing to remember is that the community consists of a great many different types of people and we need to represent them all in our survey. The results will present a more accurate picture if everyone we approach agrees to take part, and we hope you will.

Is the survey confidential?

Yes. We take very great care to protect the confidentiality of the information we are given. The survey results will not be in a form that can reveal your identity. Your answers will only be used for research purposes. You may be re-contacted about your answers for further research but only if you have given permission to do so.

Remember:

- You can ask for more information either when we call to arrange the appointment or when you are at the clinic.
- At the clinic, the nurse will show you the equipment and explain what will happen before she takes each measurement.
- All of the measurements are optional. If you do not want your child to do one of the parts, just tell the nurse at the clinic. If you do not want to attend the clinic, just let us know.
- All your travel expenses to and from the clinic will be paid, and we can help to arrange transport for you and your child to get to and from the clinic.



Where can I find out more about the Clinic Visit?

If you have any questions you can write to or speak to one of us using the contact details below.

Priti Mistry
Research Assistant
MRC Human Nutrition Research
Elsie Widdowson Laboratory
120 Fulbourn Road
Cambridge
CB1 9NL

Dr Ken Ong
Survey Doctor
MRC Epidemiology Unit
Institute of Metabolic Science
Box 285
Addenbrooke's Hospital
Hills Road
Cambridge, CB2 0QQ

Tel: 0800 6785625

Tel: 01223 769207

Thank you for your help with this survey!



National Infant Diet and Health Study

Information about the clinic visit

Thank you for taking part in the first stage of the National Infant Diet and Health Study. The information that you have provided will help us understand more about the eating habits of infants and young children in the UK.

We would now like to invite you to the next stage of the study, which involves you and your child visiting a research clinic in your area.

This leaflet provides you with some information about what the clinic visit involves. If you and your child decide to attend the clinic, you do not need to have all of the tests and measurements carried out, you can agree to some and not to others. And, of course, you do not have to attend the clinic if you do not want to. If you would like to find out more, with your agreement one of the research team will call you in the next couple of weeks. They will explain more about the clinic visit, and if you are interested in attending they can book an appointment for you and discuss how you can travel to the clinic. All your travel expenses will be paid if you visit the clinic, and we will also give you £10 in high street vouchers as a token of our appreciation.

Who is running the research study?

This study is being carried out for the Department of Health and the Food Standards Agency by the National Infant Diet and Health Study team:

- Medical Research Council Human Nutrition Research (HNR), Cambridge; HNR has overall responsibility for the Study, conducts the research into people's diets and is responsible for the blood analysis. HNR is also responsible for the the Clinic Visit (Stage 2).
- the National Centre for Social Research (NatCen), an independent research institute based in London. NatCen is responsible for the interviews of people in their homes (Stage 1).
- Medical Research Council Epidemiology Unit, also based in Cambridge. Paediatric consultant Dr Ken Ong is the survey doctor.
- Human Nutrition Research Centre at Newcastle University are involved with parts of the work to assess people's diets.

Measurements taken at the clinic

When you visit the clinic, we would like to carry out the following measurements (with your consent):

- **Weight of your child and you**
- **Skinfold thickness** to provide an indication of how much body fat your child has. A trained nurse will use special callipers to measure skinfolds on your child's arm and back.
- **Infant length and head circumference.** Your child may have had these measurements carried out by the interviewer. If not, they can be taken as part of the clinic visit.
- **Assessment of how much breastmilk your child drinks** (if you are breastfeeding). This involves you and your child drinking a dose of special tracer water, and then asking you to collect urine samples for yourself and your child for fourteen days as well as recording your child's breast milk intake in a further diet diary (if you are interested in taking part in this element of the study, the interviewer can explain how to collect urine samples from your child using cotton wool balls in his/her nappy).

We have provided a separate leaflet that gives you more detail on what this involves, so that you can think about whether you are interested in doing this. We also explain what tracer water is on the next page.

If you do agree to this, we will provide you with feedback that shows you how much breastmilk your child is drinking. You will also be given £50 in High Street vouchers as a token of our appreciation.

- **Your child's body composition** (if you are not breastfeeding). This involves your child drinking a dose of special tracer water, and then asking you to collect urine samples from your child for five days.

We have provided a separate leaflet that gives you more detail on what this involves, so that you can think about whether you are interested in doing this. We also explain what tracer water is on the next page.

If you agree to do this, you will be given £30 in High Street vouchers as a token of our appreciation.

- **Taking a small blood sample from your child.** With your consent, a specially trained nurse will take a small blood sample (less than a teaspoon) from your child using specially adapted needles designed for children of this young age. This will allow us to assess important health factors such as the iron status of your child and their vitamin D levels.

We have provided a separate leaflet that tells you more about the blood sample, and why it will be useful for us if you would agree for your child to have a small blood sample taken.

If you do agree for your child to give a blood sample, we will feedback some of the results from that sample (such as blood count, iron store status and vitamin D status) and will give you £30 in high street vouchers as a token of our appreciation.

What is tracer water?

The water in your body already consists of two types: light water and heavy water. Tracer water contains more heavy water than light water. The tracer water is completely safe. We will ask you and your child to drink some tracer water and this will increase the amount of the heavy type that is in your bodies for a short time until you get rid of it naturally. It tastes just like normal water and you cannot tell the difference from ordinary water unless you use a special machine to measure it. It is completely harmless and will not have any effect on you or your child.

The clinics

The clinics we use are either part of children's hospitals, or are based at hospitals or at research institutes. If you live in a very rural area, we aim to offer a specialised mobile clinic that will come to your local area. All of the clinics will have specially trained and experienced staff.

When you are phoned, you will be given the details of your local clinic.

You can also request more information when you are called about the clinic visit, or at the clinic visit itself. Attending a clinic visit does not mean that you have to agree to all of these measurements.

Before you visit the clinic

If you decide that you are interested in the assessment of how much breastmilk your child drinks or your child's body composition, you will need to bring a urine sample from your child (and from yourself if breastfeeding) with you to the clinic.

The interviewer will leave you with the equipment that you need to do this, and will show you what you need to do. The separate leaflet describing these measurements also gives instructions of what you need to do.

Any further questions you have can be answered when you are phoned about the clinic visit, or you can phone Priti Mistry or a member of the National Infant Diet and Health study team on 0800 678562.

National Infant Diet and Health Study



Why provide a blood sample?



Thank you for completing the food and drink diary for your child! The record you provided will help us know about the eating habits of infants and young children in the UK, the calories they consume and their intake of nutrients like fat, protein and carbohydrate, minerals such as iron, calcium and zinc, and vitamins, including B, C, A and E.

However, the amount of vitamins and minerals absorbed varies from child to child depending on the types of foods the nutrient is in, other foods eaten at the same time, and natural variations among people in the way the body works.



Only by measuring vitamins and minerals in a blood sample, can we see if infants and young children in the UK are well supplied with nutrients. For a number of nutrients children are particularly likely to have lower amounts than they should. Also, children may not like and therefore won't eat certain foods. It is especially important that we know if the proportion of infants and young children with low levels of key nutrients is changing. We cannot tell these things from just looking at your child's food and drink diary. We can only tell if we can measure the levels in their blood. On the next page is further information about two of the nutrients we would analyse in your child's blood sample.



We know it is not much fun for children to have blood taken. We understand that. Many children are frightened of needles and think it is going to be very sore. We try to ease this with numbing cream we can apply and by using specialist nurses who take blood from children all the time.

What is the benefit to me and to others?

If you wish to receive them, we will send you the results of your child's blood measurements. Also, with your agreement, we will send these to your GP. Where we feel there may be a potential problem, we will advise you to see your GP, who can follow up what we found. The **overall goal** of our work is to keep track of the nation's diet and nutritional status so that problems can be addressed where necessary to keep the population healthy.

What the blood sample will tell us



Iron is needed for healthy blood and to help carry oxygen around the body. Lack of iron leads to anaemia, causing tiredness, and can affect concentration, intellectual performance and ability to fight infections.

Iron deficiency is the most common nutrient deficiency around the world and children are one of the susceptible groups.

Iron is found in many foods such as cereals and some vegetables but the iron in meat is much better absorbed than iron from other sources. These factors mean that measuring iron in blood is the best way to know if intakes are adequate.



We obtain **vitamin D** from two sources, only one of which is the diet. The other is sunshine, where the ultraviolet light converts vitamin D into an active form in the skin. We need vitamin D for healthy bones.

Low vitamin D levels are relatively common in countries like the UK where there is little ultraviolet light in winter, and also because we are outside less than we used to be in the past.

The only way we know if someone has enough vitamin D for the body's needs is to measure it in the blood. This is a very important measure to assess from the blood sample because the diet tells us so little.



Frequently Asked Questions

Q: How is the tracer water different from tap water?

A: All water is made up of hydrogen and oxygen, but some of the hydrogen and oxygen is slightly heavier than the rest. Tap water is a mixture of light and heavy water. Our tracer waters are just the same as tap water, except that they contain more heavy water than light water.

Q: Is the tracer water harmful?

A: No, all the components are naturally occurring, and consumed every time you drink. Tracer water has been used in humans for over forty years and its reliability, acceptability and safety are well established. It has been used in adults, babies, children and expectant mothers and there are no known risks associated with drinking it.

Q: How long will the tracer water stay in mine and my baby's body?

A: The tracer water is lost from the body at the same rate as any other water, and approximately half will have gone in four days. Losses continue on this basis so that all tracers are gone within about five weeks after starting the test.

Q: What happens if I forget to take the baseline urine samples with me to the clinic when we go to drink the tracer water?

A: We will ask you to obtain them while at the clinic.

Q: What happens if I miss a urine collection after drinking the tracer water?

A: Although we like to have all daily samples of urine for analysis if one or two are missing, the other samples are still useful to us. If you forget to collect a sample but then remember on that day, collect a sample as soon as possible and note down the time. If you forget a day completely then leave the sample tube for that day empty, and continue to collect from the next day forward, as before.

Q: Do I have to store the samples in the fridge?

A: Keeping the samples cold is important so the best place to store them is in the fridge as this is always cold. The bottles are stored in a box, which can be placed in the fridge – the bottles are not visible. You can also put the box in the bag provided. However, if you are very uncomfortable about having the tubes in the fridge you could keep them somewhere else that is cold, such as a shed or unheated garage, but it must be cold all the time.

National Infant Diet and Health Study

How much breast-milk and/or other fluid intake does your baby drink

Information on the measurement of breast milk intake, other fluid intake and body composition of your infant.

The National Infant Diet and Health Study looks at the eating habits of children aged between 4 months and 18 months in the UK. As part of this study we are asking lots of mothers to allow us to measure their baby's daily fluid intake including breast milk, by drinking some tracer water. This will allow us to gather important information relating to the nutrition and growth of UK children.

Tracer water is completely safe and slightly different in composition from normal tap water but it is lost in the same way as normal water in the urine. It also incorporates itself into breast milk and is passed to the baby during feeding. By measuring the fraction of tracer water there is in yours and/or your baby's urine over several days we can determine how much milk your baby has drunk and then relate this to their growth and nutrition.

What is a tracer water?

The water in everyone's body already consists of three types: light water and two sorts of heavy water. Tracer water contains more of the heavy waters than light water. We will ask you (only if a breastfeeding mother), and in all cases your baby to drink some tracer water and this will increase the amount of the heavy types that are in your bodies for a short time, until you get rid of it. The tracer waters are completely safe. They taste just like normal water and you cannot tell it from ordinary water unless you use a special machine to do so. They will not have any effect on you or your baby.

Do I need to do anything before we visit the clinic to drink the tracer waters?

Yes – before you drink the tracer waters, we will ask you, (only if a breastfeeding mother), and your baby (in all cases) to provide a urine sample. This is so we can see how much of the heavy waters there are in your bodies already. Please see the separate document '*Collecting urine samples to take to the clinic*' which explains how to do this.

How will we drink the tracer waters?

We will ask mothers to drink the tracer water out of a bottle through a straw. You will be able to bring your baby's sterilised, favourite empty bottle with you for the baby to drink from. If your baby is

exclusively breast-fed we will give the drink using a sterile, disposable bottle or alternatively a nurse will administer it orally using a syringe.

What will happen after my baby and I have drunk the tracer waters?

If you are a breastfeeding mother and have chosen to participate in this arm of the study, we will ask you to collect a sample of urine every day for the next fourteen days both from yourself and your baby, after drinking the tracer waters. We will also ask you to complete a further diet diary to record your child's breast milk consumption.

Alternatively if you are **not** a breastfeeding mother, you will be asked to collect a urine sample one each day for five days, from your baby after they have drunk the tracer water.

A separate document will be given which explains how to collect these urine samples, and the nurse at the clinic will also be able to provide more information.

Once you complete your urine collections, the interviewer will come to collect them and will send the samples away to have the amount of tracer water in them measured. From this we can tell how fast you and your baby are getting rid of the tracer water and also how much milk and other fluid your baby is actually receiving. We can then use this information to help understand babies' growth and nutritional needs. It takes about five weeks to completely get rid of the tracer water.

How should I store the urine samples?

We will provide special bottles with tight fitting, leak proof lids for the urine samples. The interviewer will leave you with one for you (if breastfeeding) and one for your baby, so that you can collect the urine sample/s to take to the clinic with you. The clinic will then provide you with further bottles to collect the remaining samples after you have drunk the tracer water. The samples need to be kept cold. Ideally they should be kept in the fridge but if you would prefer, they could be kept in an unheated place such as a garage or shed.

What will happen after I have collected all the samples?

The interviewer will arrange an appointment to collect the urine samples. Until then, please continue to keep the samples in a cold place. When the samples are collected, we will send you a voucher as a thank you for taking part in this part of our study.

What if I have any other questions about the tracer water or the study in general?

If you have any additional questions about the tracer water, please call Marilena Leventi or another of the National Infant Diet and Health Study team on 01223 426356. If you have any additional questions about the study in general, please call Jill Sommerville or another member of the National Infant Diet and Health Study team using the same number.

MRC Human Nutrition Research National Infant Diet and Health Study

Breast Milk Volume Assessment – Collecting urine samples to take to the clinic

If you decide to take part in the assessment of how much breast milk your child drinks, you will need to collect a sample of both your and your child's urine to take to the clinic with you. Before we can start the procedure to measure the amount of breast-milk your child drinks we need to know exactly how much heavy water is usually present in both your and your child's urine. This instruction sheet tells you how to collect samples of urine that we can then measure.

Ideally collection of urines should be made up to 3 days before your clinic visit.

You will have been provided with a bag containing the following:

- 1 x bag with labels to complete on collection of your own and your child's urine
- 1 x small glass screw-capped bottle labelled 'Pre M0'
- 1 x disposable plastic cup
- 1 x small glass screw-capped bottle labelled 'Pre B0'
- 1 x disposable syringe (without needle)
- 1 x pair of plastic forceps
- cotton wool

Collecting Mother's Urine

The urine sample which you provide should **not** be from the first urine which you pass in the morning. The urine should be put into the bottle labelled 'Pre M0' with the aid of the plastic cup if desired. Three-quarters fill the bottle, and then put on the cap.

Write down the date and time when you gave the sample on the collection label **and** on the bottle label itself. Dispose of any remaining urine down the toilet and then the empty plastic cup in the household waste.

Collecting Child's Urine

Place the cotton wool into your child's freshly changed nappy. Then every hour or so check the nappy to see if the cotton wool is saturated.

If more than four hours elapse or if the cotton wool gets contaminated with faeces (poo), please discard the cotton wool, and start the collection again.

When the cotton wool is saturated pull the plunger out of the syringe, and transfer the cotton wool into the syringe barrel using the forceps provided. Now by replacing the syringe plunger squeeze the urine out of the cotton wool into the bottle marked 'Pre B0'. Aim to three-quarters fill the bottle, and then put on the cap.

Write the date and time when you collect the sample on the bag's collection label **and** on the bottle label. Also record the time of the nappy change relating to the successful collection period on the bag label too. Dispose of the cotton wool and syringe in the household waste but please wash and dry your forceps as you will be using these again to collect your child's urine samples after drinking the tracer water.

After the collection

After collection ensure that the caps are tightly screwed onto the bottles, and then put the bottles back in all the packaging they came with, and store them somewhere cold, preferably in the fridge. Please do not freeze the samples.

When you attend the clinic for the next stage of the test please bring both urine samples with you, along with your child's usual sterilised feeding bottle, if you have one.

MRC Human Nutrition Research **National Infant Diet and Health Study**

Body Composition and Fluid Intake – Collecting urine samples to take to the clinic

If you decide to take part in the assessment of how much fluid your child drinks and your child's body composition, you will need to collect a sample of your child's urine to take to the clinic with you. Before we can start the procedure to measure the amount of water your child obtains we need to know exactly how much heavy water is usually present in your child's urine. This instruction sheet tells you how to collect a sample of urine that we can then measure.

Ideally collection of urine should be made up to 3 days before your clinic visit.

You will have been provided with a bag containing the following:

- 1 x bag with label to complete on collection of your child's urine
- 1 x small glass screw-capped bottle labelled 'Pre C0'
- 1 x disposable syringe (without needle)
- 1 x pair of disposable forceps
- cotton wool

Collecting Child's Urine

Place the cotton wool into your child's nappy during a nappy change and mentally note the time of changing. Then every hour or so check the nappy to see if the cotton wool is saturated.

If more than four hours elapse or if the cotton wool gets contaminated with faeces (poo) please discard the cotton wool, and start the collection procedure again with clean cotton wool.

When the cotton wool is found saturated pull the plunger out of the syringe, and transfer the cotton wool into the syringe barrel using the forceps provided. Now by replacing the syringe plunger squeeze the urine out of the cotton wool into the bottle marked 'Pre C0'. Aim to three-quarters fill the bottle, and then put on the cap securely.

Write the date and time when you collect the sample on the bag label **and** on the bottle label itself. Also please record the time of the nappy change relating to successful collection period on the bag label. Dispose of the cotton wool and syringe in the household waste but please wash and dry your forceps as this will be used again to collect your child's urine samples after drinking the tracer water.

After the collection

After collection ensure that the cap is tightly screwed onto the bottle, and then put the bottle back in the packaging it came with, and store it somewhere cold, preferably in the fridge. Please do not freeze the sample.

When you attend the clinic for the next stage of the test please bring the urine sample with you, along with the child's usual sterilised feeding bottle.

MRC Human Nutrition Research

National Infant Diet and Health Study

Breast Milk Volume Assessment – How to collect the urine samples

Now that you and your child have drunk the tracer water we need to see how much is in your urine over a fourteen-day period. Therefore we want you to collect a sample of your urine and a sample of your child's urine starting on the day after you drank the water, and then one, every day for two weeks. The samples do not have to be taken at a particular time, but we do need to know the exact time they were collected. Also you will have to complete a diary recording each breast milk feed you give your child. Instructions on how to do this are included in the diary.

You perform the urine collections in exactly the same way as you did for the pre-dose samples. When you leave the clinic you should have been provided with a bag containing:

- these instructions
- urine collection form
- previously collected pre-dose urine samples
- 14 x glass urine collection and storage bottles for post dose daily urine collections labelled Days M1 to M14
- 14 x plastic disposable cups to aid urine collection
- 14 x glass urine collection and storage bottles for post dose daily urine collections labelled Days B1 to B14
- cotton wool
- 15 x syringes (14+1 spare)
- pen
- elastic bands
- 1 spare pair of plastic forceps
- a diary to complete

The boxes containing the empty bottles and pre-dose urine samples should be stored in the fridge if possible and in a cold, dry place if not.

Collecting Mother's Urine

The urine samples that you provide should **not** be from the first urine that you pass in the morning. With the aid of a plastic cup (if desired) put some urine collected from the first calendar day after drinking the tracer water into the bottle marked 'M1' and then do the same on the second day into the bottle labelled 'M2', and so on. It is important to use the bottles in order so we can tell which day they are from. Three-quarters fill the bottle, and then put on the cap. Write the date and time when you give the sample on the collection form **and** on the bottle label itself. Dispose of each day's plastic cup in the household waste, and then store the $\frac{3}{4}$ full capped bottles in their storage containers and in the box provided. You **must** use a clean, dry plastic cup each day you collect a urine sample to stop contamination from the previous days collection. Store the box in the fridge or a suitable cool place (do NOT freeze the urine samples).

Collecting Child's Urine

Your child's urine samples should **not** be from the first urine that is passed in the morning. Place the cotton wool into your child's nappy at a nappy change. Mentally note when you change the nappy. Then every hour or so check the nappy to see if the cotton wool is saturated with urine. If more than four hours elapse or if the cotton wool gets contaminated with faeces (poo) please discard the cotton wool with the nappy, and start the collection procedure again.

When the cotton wool is saturated pull the plunger out of a syringe, and transfer the cotton wool to the syringe barrel using the clean and dry plastic forceps. Now by replacing the syringe plunger squeeze the urine out of the cotton wool into the bottle marked 'B1' for the first day, 'B2' for the second day and so on. Aim to three-quarters fill the bottle, and then put on the cap.

Write the date and time when you actually put the sample in each bottle on the urine collection form **and** on the bottle label itself. Dispose of the cotton wool and syringe in the household waste. The forceps can be washed and dried thoroughly for re-use the next day.

You **must** however use a new, clean, dry syringe each day you collect a urine sample from your child, to stop contamination from a previous days collection.

Never be tempted to re-use the syringe.

If you miss a collection

Do not worry if you accidentally miss a collection. Just leave the bottle for that day empty and make a note in the comments part of the form against that particular day.

After the collections are complete

When you have all thirty, (28 post dose urine samples + 2 pre-dose urine samples), ensure that the caps are tightly screwed onto the bottles, and are back in all the packaging they came with, and store them somewhere cold, preferably in the fridge. The interviewer will come to take the completed samples away, and will send them to HNR for analysis.

MRC Human Nutrition Research National Infant Diet and Health Study

Body Composition and Fluid Intake – How to collect the urine samples

Now that your child has drunk the tracer water we need to see how much is in their urine over a five day period. Therefore we want you to start collecting your child's urine samples on the next calendar day after drinking the water, then one each day, every day for five days in total. The samples do not have to be taken at a particular time, but we do need to know the exact time they were collected.

You perform the urine collections for your child in exactly the same way as you did for the pre-dose sample. When you left the clinic you should have been provided with a bag containing:

- these instructions
- urine collection form
- previously collected urine pre-dose sample
- 5 x glass urine collection and storage bottles for post dose daily urine collections labelled days C1 to C5
- cotton wool
- 6 x syringes (5+1 spare)
- pen
- elastic bands
- 1 spare pair of disposable forceps

The box containing the empty bottles and pre-dose urine sample should be stored in the fridge if possible and in a cold, dry place if not.

Collecting Child's Urine

Your child's urine samples should **not** be from the first urine that is passed in the morning. Place the cotton wool into your child's nappy at a nappy change. Mentally note when you change the nappy. Then every hour or so check the nappy to see if the cotton wool is saturated with urine.

If more than four hours elapse or if the cotton wool gets contaminated with faeces (poo) please discard the cotton wool with the nappy, and start the collection procedure again.

When the cotton wool is saturated pull the plunger out of a syringe, and transfer the cotton wool to the syringe barrel using the clean and dry plastic forceps. Now by replacing the syringe plunger squeeze the urine out of the cotton wool into the bottle marked 'C1' for the first day, 'C2' for the second day and so on. It is important to use the bottles in order so we can tell which day they are from. Aim to three-quarters fill the bottle, and then put on the cap

Write the date and time when you actually put the sample in each bottle on the urine collection form **and** on the bottle label itself. Dispose of the cotton wool and syringe in the household waste. The forceps can be washed and dried thoroughly for re-use the next day.

You **must** however use a new, clean, dry syringe each day you collect a urine sample from your child, to stop contamination from a previous days collection.

Never be tempted to reuse the syringe.

If you miss a collection

Do not worry if you accidentally miss a collection. Just leave the bottle for that day empty and make a note in the comments part of the form against that particular day.

After the collections are complete

When you have all six samples, (5 post dose urine samples + 1 pre-dose urine sample), ensure that the caps are tightly screwed onto the bottles, and are back in all the packaging they came with, and store them somewhere cold, preferably in the fridge. Please do not freeze the samples. The interviewer will come to take the completed samples away, and will send them to HNR for analysis.



NATIONAL INFANT DIET AND HEALTH STUDY

Information for parents about Ametop gel.

If you take part in this study and have consented to your child having a blood sample taken, you can choose to have Ametop gel applied to the skin before the sample is taken.

This leaflet gives you information about what the gel does and how it works.

It is important to remember that you do NOT have to have the gel applied; it is up to you to decide.

- **What is Ametop gel?**

It is a white gel, which, when it is put on the skin and left for a while, makes the skin go numb; this means that the slight scratch when the needle pricks the skin is hardly felt.

- **How long does it take to work?**

The gel works best if it is left on the skin for 20 minutes before the blood sample is taken, and it needs to be kept covered. The nurse will apply the gel and cover it with an adhesive dressing.

Once the blood sample has been taken, the effect of the Ametop will wear off slowly over the next few hours.

- **Can Ametop gel be used on anyone?**

Ametop gel is very safe. If you decide you would like to have the gel applied to your child, the nurse will check with you that it is safe, BEFORE it is applied.

- **Are there any side effects?**

Sometimes the area where the gel has been applied goes pale, and on some children the skin goes a bit red. Occasionally, the area can be a bit itchy, or puff up slightly. None of these effects is serious or harmful and they will wear off as the effect of the Ametop wears off.

Some children have allergies to some types of plaster: if your child is allergic to a particular type of plaster, please tell the nurse, who will make sure that the plaster used to cover the gel is right for you.

Please remember that you do not have to use Ametop gel. It is your choice. If you have any questions about Ametop, or if you are worried about any aspect of the blood sampling procedure, please speak to the nurse before you make up your mind.



NATIONAL INFANT DIET AND HEALTH STUDY

Information for parents about EMLA cream.

If you take part in this study and have consented to your child having a blood sample taken, you can choose to have EMLA cream applied to the skin before the sample is taken. This leaflet gives you information about what the cream does and how it works. It is important to remember that you do NOT have to have the cream applied; it is up to you to decide.

- **What is EMLA cream?**

It is a white cream, which, when it is put on the skin and left for a while, makes the skin go numb; this means that the slight scratch when the needle pricks the skin is hardly felt.

- **How long does it take to work?**

The cream works best if it is left on the skin for 45 minutes to one hour before the blood sample is taken, and it needs to be kept covered. The nurse will apply the cream and cover it with an adhesive dressing.

Once the blood sample has been taken, the effect of the EMLA will wear off slowly over the next few hours.

- **Can EMLA cream be used on anyone?**

EMLA cream is very safe on children aged 3 months and above. If you decide you would like to have the cream applied to your child, the nurse will check with you that it is appropriate to use BEFORE it is applied.

EMLA cream should not be used with children under 12 months of age who are being treated with medicines that can cause a disorder of the red blood cells called methaemoglobinaemia, for example, sulphonamide antibiotics such as sulfamethoxazole.

- **Are there any side effects?**

Sometimes the area where the cream has been applied goes pale, and on some children the skin goes a bit red. Occasionally, the area can be a bit itchy, or puff up slightly. None of these effects is serious or harmful and they will wear off as the effect of the EMLA wears off.

Some children have allergies to some types of plaster: if your child is allergic to a particular type of plaster, please tell the nurse, who will make sure that the plaster used to cover the gel is right for you.

Please remember that you do not have to use EMLA cream. It is your choice. If you have any questions about EMLA, or if you are worried about any aspect of the blood sampling procedure, please speak to the nurse before you make up your mind.



NATIONAL INFANT DIET AND HEALTH STUDY

Information for parents about Ethyl Chloride anaesthetic spray.

If you take part in this study and have consented to your child having a blood sample taken, you can choose to have Ethyl Chloride anaesthetic spray applied to mildly numb your child's the skin before the sample is taken.

This leaflet gives you information about what the spray does and how it works.

It is important to remember that you do NOT have to have the spray applied; it is up to you to decide.

- **What is Ethyl Chloride spray?**

It is a spray, which, when it is applied to the skin and left for a while, makes the skin go numb; this means that the slight scratch when the needle pricks the skin is hardly felt.

- **How long does it take to work?**

The spray works best if it is sprayed onto the skin for 5-10 seconds, until a thin snow film appears. The spray produces a cold sensation. Anaesthesia is produced within a few seconds and lasts for up to a minute to allow the blood sample to be taken.

- **Can Ethyl Chloride spray be used on anyone?**

Ethyl chloride anaesthetic spray is very safe and there are no known contra-indications to its use.

- **Are there any side effects?**

There are no known side-effects. The spray only has a mild numbing effect and sometimes children still feel a little scratch when the blood sample is taken.

Please remember that you do not have to use Ethyl Chloride spray. It is your choice. If you have any questions about Ethyl Chloride spray, or if you are worried about any aspect of the blood sampling procedure, please speak to the nurse before you make up your mind.

Name
Address line 1
Address line 2
Address line 3
Address line 4
Address line 5
Postcode

Dear <Name>,

National Infant Diet and Health Study

A few weeks ago <you/child's name> completed the first part of the National Infant Diet and Health Study – an interview, collection of dietary information and some measurements. Thank you for the time and effort <you/you and child's name> have so far put into this important study, your help is very much appreciated.

In the last few days, <a member of the research team> contacted you to explain more about the second stage and to book a clinic appointment.

Your appointment has been booked as follows:
<clinic name, date and time>



If your child is unwell please phone and cancel your appointment and we can re-arrange it for another time. At your clinic visit, you will be seen by a research nurse, not a physician. All your travel expenses will be paid when you visit the clinic, and we will also give you £10 in high street vouchers as a token of our appreciation.

Please bring your completed expenses claim form to your appointment.

If you have any queries or want further information please contact Priti Mistry at HNR on 01223 426356, email on address below or visit the website:
www.mrc-hnr.cam.ac.uk/working-with-us/national-infant-diet-and-health-study.html

Many thanks in anticipation of your continuing help.

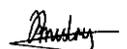
Yours sincerely,

Rachel Stratton

Rachel Stratton

Nutrition Science and Delivery
Health and Wellbeing
Department of Health
Wellington House
133-155 Waterloo Road, London SE1 8UG

Email: Rachel.Stratton@dh.gsi.gov.uk



Priti Mistry

Research Assistant, HNR
MRC Human Nutrition Research
Elsie Widdowson Laboratory
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Why should I take part?

We need information from a wide range of families for example those with one child and those with more than one child; those who breastfeed their child and those who don't; families with working parents and families with parents who don't work. Otherwise we would not get a true picture of the eating habits and health status of young children in the UK. It is important that everyone who is chosen takes part so that the results are representative of the UK as a whole.



What will happen to any information I give?

Any information you give us is treated in strict confidence. The published results of the study will never include any names or addresses. The information collected is used for statistical and research purposes only and will be dealt with according to the principles of the 1998 Data Protection Act.



Why is the information important?

The information already given in stage 1 is very useful, but with the extra information obtained from the clinic visit, it will be even more valuable. For example, only by measuring vitamins and minerals in a blood sample, can we see if infants and young children in the UK are well supplied with nutrients. Therefore it helps to be able to combine the information we collect from your child's food and drink diary with the levels in their blood.



Who is carrying out the study?

The Department of Health and the Food Standards Agency has asked the National Centre for Social Research (NatCen), in collaboration with MRC Human Nutrition Research (HNR), and the Medical Research Council Epidemiology Unit, based in Cambridge and the Human Nutrition Research Centre at Newcastle University.





National Infant Diet and Health Study

Study conduct information for parent/guardian

This sheet gives information on factors such as confidentiality and data protection, communication with your GP, indemnity and compensation, publication etc. It is important that you read and are happy with this along with 'Stage 2 leaflet dated 8 August 2010, version 3.0' before agreeing to take part.

What will happen if I don't want to carry on with the study?

If you decide to withdraw from the study, with your consent, samples and data obtained may be kept and used to contribute to study results or, with your consent, for future studies. However, should you request your samples and data to be destroyed along with any other information relating to you, we will ensure that this takes place.

What if there is a problem?

In the unlikely event that something should go wrong during the study, procedures will be stopped and a clinician will see you. Your involvement in the rest of the study may be stopped. Standard procedures are in place at MRC Human Nutrition Research (MRC HNR) for dealing with any problems should they occur.

If you have any other problems, illnesses or concerns during the study you should discuss these with the principal investigator or a member of staff at MRC HNR on 01223 426356 and ask for Jill Sommerville (Survey Co-ordinator).

Complaints:

Any complaints you have about this study will be fully investigated. If you have a concern about any aspect of this study, you should speak with the principal investigator who will do their best to answer your questions (Alison Lennox *Tel: 01223 426356 email: Alison.Lennox@mrc-hnr.cam.ac.uk*). If you remain unhappy and wish to complain formally, you can contact Polly Page, MRC-HNR Head of Operations: 01223 426356, polly.page@mrc-hnr.cam.ac.uk.

Harm:

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for legal action for compensation against MRC HNR but you may have to pay your legal costs. For research carried out at MRC HNR participants would be in the same position as if public liability insurance had been taken out.

MRC undertakes to give sympathetic consideration, on a case by case basis, to claims of non-negligent harm arising from research carried out at MRC HNR provided the claim does not relate to standard treatment.

Will my taking part in this study be kept confidential?

Any information that is collected about you during the course of the research will be kept strictly confidential and MRC HNR will be the custodian of the data. Any information about you that leaves MRC HNR will have your name and address removed so that you cannot be recognised from it.

HNR has a standard confidentiality procedure for participants involved in research. This stipulates how personal information is collected, used, stored and disposed of during and following completion of research projects.

Any information that is collected about you during the course of the project will be kept strictly confidential and secure in locked filing cabinets and/or electronic files on computers that have restricted access. Each participant is assigned a unique, anonymising code to be used for all data collected during the research. Personal information will be linked only using the anonymised code and will not be published in any results.

Only the specified research team will have access to personal identifying data information. However, with your agreement, your GP will be notified of your study results and copies of these letters will also be provided to you. HNR maintains a central record of all research projects but this does not include personal information on participants. With your agreement we will store data for 20 years. With your consent, and with the appropriate research ethics approval, retained data may be used for future studies.

Who has reviewed the study?

This study has been reviewed by the Scientific Co-ordination Committee of MRC HNR and by *Cambridgeshire 4* Research Ethics Committee.