

Participant information sheet

Using nicotine replacement therapy to create a smoke-free home

You are being invited to take part in a research study run by the University of Stirling. This information sheet describes the study and explains what will be involved if you would like to take part.

What is the study trying to find out? It can be difficult to keep your home smoke-free. We would like to see if using nicotine replacement therapy (NRT) indoors - instead of smoking indoors - helps to reduce children's exposure to second-hand smoke in the home. In this study, we will post NRT products (inhalators, spray, gum etc) to your home free of charge so you can try this out. There is no pressure on you to stop smoking completely.

Who can take part? We are looking for 100 parents/carers/relatives who smoke in the home in Lanarkshire to take part. More than one adult per household can take part. You can take part if you:

- sometimes smoke in the home
- are aged 18 or over
- care for one or more children in the home aged between 0–16 years, at least 1 day per week

Are NRT products (gum, inhalator, lozenge, mouthspray) safe to use?

Using NRT indoors is much safer than smoking in the home. Mild side effects of NRT can occur in some cases, including a sore throat, mouth irritation, hiccups or heartburn. You can change the type of NRT product you use in this study, if your first choice doesn't suit you.

We don't want to introduce risks of using NRT, and so you will not be able to take part if:

- You take any of the following medicines - Theophylline or Aminophylline, Clozapine, Erlotinib, Olanzapine, Riociguat, Chlorpromazine, Flecainide, Methadone or Warfarin
- You are pregnant or breastfeeding
- You have a hypersensitivity to nicotine or any of the NRT product ingredients

What will happen if I want to take part?

- We will call you at least 2 days after you've read this information sheet, if you have said you might like to take part. With your permission, we'll ask you some questions about smoking in your home the age of the child you care for, and whether you are the child's parent or legal guardian. If you are eligible, we will then arrange a convenient time for our researcher to visit you. Depending on your household arrangements, there is the option of helping us understand the changes to smoking in your home through the use of an air quality monitor, or by measuring a chemical in your child's saliva. You can choose one or both of these options depending on your circumstances and preference. We will not take samples of saliva if your oldest child is under the age of 5 or if you are not the child's parent or legal guardian. If you choose to help us measure second-hand smoke levels through the use of air quality monitoring then the monitor will be left in the living room of your home for 1 week.

- **Please make sure that you've spoken with other household members about the study before taking part - including the child who would be providing saliva samples - as they need to be aware of and agree to these measures being taken.**
- After 1 week, we'll call you to discuss which of the two study groups you are in. We need to compare findings from both groups to see if using NRT in the home makes a difference.

GROUP A: receives free NRT posted to home to use indoors, and fortnightly telephone support, for 12 weeks.

GROUP B: receives online advice on creating a smoke-free home. After 12 weeks, has the option to receive a free 12 week supply of NRT posted to home, to use indoors.

- You will be asked to take part in two short telephone calls – at the end of week 6 and week 12 - so we can learn more about your experience of taking part.
- You may also be invited to take part in a telephone interview (up to 1 hour) to explore these experiences in more detail.

Will I be able to continue using NRT once I finish using my 12-week supply? You will be able to receive a further 12-week supply of free NRT posted to your home with support of the NHS Lanarkshire Quit Your Way Service.

What if I decide to quit smoking during the study? You would be supported to set a quit date and offered support from NHS Lanarkshire's specialist stop smoking service, alongside 12 weeks free nicotine replacement therapy.

I smoke in the home, and sometimes use an e-cigarette in the home too. Can I keep using the e-cigarette indoors if I take part in the study? Using an e-cigarette in the home will impact a little on the air quality and/or the saliva measurements we make. This may make it harder for us to study whether using NRT indoors reduces children's exposure to second-hand smoke. Ideally, we would ask that you don't vape indoors on this basis.

Does the air quality monitor use electricity? The monitor uses very little electricity. We estimate this will cost you less than 80p if you take part. We will post you 2 x £25 supermarket vouchers of your choice to thank you for taking part and to acknowledge the electricity costs of having the monitor on in your home.

What happens to any information that I give you? If you take part, a few members of the research team will need to know your name and contact details so they can contact you as part of the study. Most of the research team will not see this information, as we will remove your name from the research data and replace it with a code number. We will keep all information about you safe and secure. If you were to lose capacity during participation in the study, we would keep your data up to the point of removing you from the study.

If you agree to help us by providing a sample of your child's saliva for measurement of a chemical that shows how much nicotine they have breathed in, then your child's saliva samples will be sent to ACM Laboratory in York for analysis. They must follow our rules

about keeping the samples safe. Each sample will be anonymised when it is obtained. Saliva samples will only be analysed to get a sense of how much nicotine is in your child's body. Samples will not be used for genetic testing or any other purposes.

Once we have spoken with everyone taking part, we will see if there are any clear messages about whether NRT can be used in the home in this way. We will write up a report and talk to professionals about what we find. Hopefully this will result in better support for parents in the future. We can't provide individual feedback on air quality and salivary cotinine levels, but we can provide you with a summary of overall study findings.

What are my choices about how my information is used? You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means we won't be able to let you see/change the data we hold about you.

Where can I find out more about how my information is used? You can find out more about how your information is used in our Data Privacy Notice. This is available from Laura Sinclair and Tracy Henderson using either email address or telephone number at the end of this sheet.

How will we store your data? We take data security very seriously. All electronic data will be stored on a password protected University computer. Any paper copies will be kept in a locked filing cabinet. All digital recordings will be destroyed after completion of the project. Research data from the study will be stored securely at the University of Stirling for 10 years. Data related to the administration of the project (e.g. your consent form) will be stored for at least 6 years. Personal data will be handled in accordance with the UK Data Protection Act (1998).

What are the possible benefits and risks of taking part? There will be no immediate benefits for you, but by taking part in this study you can help us better understand ways to help households to create a smoke-free home. You may also learn new ways to protect your family from second-hand smoke in the home. There are no known risks if you take part.

Do I have to take part? It is completely up to you. If you don't want to take part, or choose to leave the study at any point, this will have no effect on the services that are available to you through NHS Lanarkshire. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you decide to stop taking part, or have any questions, please contact Tracy or Laura using the contact details below. If you have any concerns about any aspect of the study, please contact Dr Rachel O'Donnell:

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