



## **Information for those taking part in research study**

### **A community-based stop-smoking programme for women**

We are inviting you to take part in a research study. Before you decide if you want to take part, it is important for you to understand why it is being done and what it will involve. Please take your time to read the information in this leaflet before deciding to take part. If you have any questions or do not understand the information, you can ask the research team. Their details are at the end of this leaflet.

#### **What is the aim of this research?**

The aim of this research is to compare a community-based programme to the face-to-face stop-smoking service offered by the HSE. We will carry out the research in different areas and aim to find out which one works best for women. The HSE supports both programmes.

We will give women from eight areas the opportunity to take part. We will give four of the areas the 'We Can Quit' programme and four the HSE programme. Your area cannot choose which one to test.

At the end of the study, everyone will be offered the chance to take part in the new 'We Can Quit' programme.

#### **Who is organising the research?**

The study is led by Professor Catherine Hayes, Principal Investigator, at Trinity College Dublin in partnership with the Irish Cancer Society, HSE staff and UK researchers. This study is funded by the Health Research Board Ireland.

#### **Can I take part in this study?**

We are looking for women aged 18 or over who smoke every day, but would like to try to stop smoking. If you live in one of the selected study areas you may be able to take part.

To get the most from the programme, it is important that you understand and speak English.

You must also be willing to stay in the programme and attend a follow-up appointment after six months.

If you are pregnant now we cannot accept you into the research programme. If you become pregnant during the study, you can continue the programme but your data will not be included in the research.

### **Do I have to take part?**

No, it is up to you to decide whether or not you would like to take part.

If you agree to take part, you are still free to leave the study at any time without explaining why. You may also refuse to answer any of the questions or opt out of part of the study if you choose. If you choose to leave the study, you will still be able to access standard stop-smoking programmes and your standard of care and legal rights will not be affected.

### **How many people will take part in the research?**

About 200 women across eight areas will take part in the study. We need you to take part for the duration of the programme and for six months after so we can follow up with you.

### **What will happen if I take part?**

If you decide to take part in the research, we will ask you to sign the consent form. We will then ask you to answer questions about:

- yourself
- your smoking
- your general health and well-being.

This should take about 20 minutes. We will then assign you to the programme that we have chosen for your area. We will ask you to attend for the duration of the programme.

### **The programmes**

If you are part of the 'We Can Quit' programme, we will invite you to attend weekly group sessions over 12 weeks. The group sessions will take place in your area, and each session will last about 1.5 hours.

If you are part of the standard programme, we will invite you to attend the HSE stop-smoking programme. It involves attending individual sessions with a Stop Smoking Office (usually 6-7 sessions). The sessions will take place in your area, and each session will last about 30 to 60 minutes.

Three months after the programme begins, we will ask you to fill in a follow-up questionnaire. This will take 15 minutes at most. We will also ask you to fill in a questionnaire after six months, which will take 10 minutes at most. These questions will ask about the programme and your health. We will use them to learn more about the programmes and measure the health benefits of stopping smoking. If you need help completing the questionnaire, please feel free to ask the research team.

To measure whether or not the programmes have helped you to stop smoking, we will test saliva samples for signs of smoking. We will do this by collecting saliva samples at the end of the programme sessions and six months after the programme finishes. We will send these samples to a company (ABS Laboratories) in the UK. Your name or personal details will not appear on any of the samples that we send for analysis.

### **Short interview**

We would like to get a sense of your experience of the programme. To do this, we will ask participants who have taken part in the 'We Can Quit' programme to do a short interview with one of the research team:

- at the end of the programme, and
- six months after the research is finished.

This will help us to get a full picture of what the programme was like and how we may improve it in the future. We will record the interview with a voice recorder. The recording will be sent to a transcriber who will put it into writing word for word without your name, and the voice recording will then be destroyed. You may ask for the text of the interview if you wish. The interview will take no longer than one hour.

### **Breathing test**

We are also interested in the effects on your health when you stop smoking. To measure this, we may ask you to do a simple breathing test at the start, middle and end of the programme. These tests only take a few minutes and there is no risk.

### **What are the risks of taking part?**

There are no major risks to taking part in this study. However, you may experience withdrawal symptoms, such as cravings to smoke, or minor side effects from nicotine replacement therapy. Your Programme Facilitator, Stop Smoking Officer or pharmacist will provide you with a full list of these symptoms and advise you on how to deal with them.

## **What are the advantages of taking part?**

If you succeed in stopping smoking:

- your health and wellbeing will improve
- your breathing may get better as well as your ability to exercise
- you will be off cigarettes
- you may be better off financially
- your skin and hair may improve
- you will lower your risk of heart disease, stroke and cancer
- you may increase your life expectancy.

You will also help researchers and healthcare staff to learn how to best support and encourage women to quit smoking. This may help to shape stop smoking services for women in Ireland.

## **What will happen to the information that I provide?**

We will not share any information that identifies you (like your name and address) outside of the research team. We will keep all your information confidential. We will replace your name with a code and store your name separately from your other information (data). Only the researcher will hold the key to the code. The researcher will enter the information that you provide on a password-protected computer using your code. The data will be sent to our research partners in the UK where they will be analysed. Trinity College Dublin is the Data Controller. This means that the College controls and is responsible for the keeping and use of your personal information. Our research partners in the UK are Data Processors, that is they process your data. They must only process your data on the instructions of the Data Controller. The responsibilities of the Data Processor include the necessity to keep personal data secure from unauthorised access, disclosure, destruction or accidental loss. The company to which we send your saliva samples is also a Data Processor. The company will destroy the samples after analysis. The person who will put the recording of the interview into writing word for word without your name is also a Data Processor. She will destroy the voice recording when it is transcribed. Your data will not be used in future unconnected research without your consent. If you would like to have more information about how your data are protected, please ask for Privacy Notice. You can get a copy of the WCQ2 Privacy Notice from the Research Assistant Emma Burke (see contact details below).

In keeping with national and Trinity College guidelines, we will keep your study data in a safe and secure place for ten years. Only the research team will have access to this. Your information will be destroyed securely after that time.

To make sure that the information collected during the study is correct and that the study was performed correctly, your records may be checked by the researchers, members of a steering committee or the Research Ethics Committee. They will keep your information confidential.

If you need to make a complaint, you can contact the Data Protection Officer at [dataprotection@tcd.ie](mailto:dataprotection@tcd.ie).

### **What will happen to the study results?**

The study results will be used to guide researchers and clinical staff on how best to organise stop-smoking services for women. The results of the study may be used for publication in a medical journal and for discussion at a health conference. You will not be identified in any presentation or publication.

### **Will I be paid for being part of this study?**

You will be eligible for a €20 shopping voucher, if you complete follow-up questionnaires.

### **Has this study been approved?**

The study has been approved by the Research Ethics Committee of the School of Medicine at Trinity College Dublin.

### **Where can I get more information?**

If you would like to have more information about the study or if you have any questions, please contact:

- The Research Assistant, Emma Burke, at 01-896 1643 (email [wqc2@irishcancer.ie](mailto:wqc2@irishcancer.ie)).