

Participant Information Leaflet

Version 1: Date: August 2024

Study title: COMMunity PARTICipation for Stop Smoking in Ireland: COMPASS

Principal investigator's name: Prof. Frank Doyle

Principal investigator's title: Associate Professor, Department of Health Psychology, RCSI University of Medicine and Health Sciences

Principal investigator's contact details: FDoyl4@rcsi.ie , +353-1-402-2718

Co-Principal Co-Investigator's name: Dr Paul Kavanagh

Co-Principal investigators title: Consultant in Public Health Medicine, HSE National Health Intelligence Unit

Co-Principal investigator's contact details: paul.kavanagh@hse.ie

Co-investigators:

- Professor Linda Bauld – Co-director of the Centre for Population Health Science at the University of Edinburgh
- Ms. Martina Blake – Lead for the HSE Tobacco Free Ireland Programme
- Professor Sara Burke – Associate Professor and the Director of the Centre for Health Policy and Management at Trinity College Dublin
- Professor Molly Byrne – Professor of Health Psychology at University of Galway
- Dr Rikke Siersbaek – Research Fellow in Clinical Medicine at Trinity College Dublin
- Professor Susan Smith – Professor in the Department of General Practice at RCSI
- Professor Jan Sorensen – Director of the Health Care Outcomes Research Centre at RCSI
- Professor Deborah Stanistreet – Head of Department of Public Health and Epidemiology at RCSI
- Professor Ken Ward – Professor and Assistant Dean of Affairs, UNM College of Population Health
- Mrs. Pauline Williams – Public-Patient Involvement representative

Funder: Health Research Board Ireland Project Grant

Data Controller's Identity: Prof. Frank Doyle

Data Controller's Contact Details: FDoyl4@rcsi.ie , +353-1-402-2718

Data Protection Officer's Identity: Dónall King

Data Protection Officer's Contact Details: donallking@rcsi.ie/dataprotection@rcsi.ie

Irish Data Commission Office:

1800 437 737/ dpo@dataprotection.ie

Why is this study being done?

You are being invited to take part in a research study that aims to test the acceptability of a co-designed financial Incentive scheme to stop smoking, that can be used by stop smoking services across Ireland.

Before you decide whether or not you wish to take part, you should read the information provided below carefully. Take time to ask questions if needed. Please do not feel rushed or pressured to make an immediate decision. It is important that you clearly understand the risks and benefits of taking part in this study, so that you can make an informed decision that is right for you. You are not obligated to participate in this study, it is completely voluntary, and a decision not to take part will not affect you, or your involvement in stop smoking services in the future. If you agree to take part, you are entitled to withdraw from the study, without questions asked, at any time before the write-up and publication stages. You can do this by contacting the study research assistants, Brian Doyle, Reham Lasheen or Cheyenne Downey, using the details below.

Mr. Brian Doyle

Email: briandoyle@rcsi.ie

OR

Ms. Reham Lasheen

Email: rehamlasheen23@rcsi.ie

OR

Ms. Cheyenne Downey

Email: cheyennedowney@rcsi.ie

Ph: +353(0) 86 030 2408

This study will help the Health Service Executive (Tobacco Free Ireland Programme) to understand the impact of financial incentives on stop smoking services in Ireland. Financial incentives will be used to improve smoking cessation rates long-term. This research aims to establish whether financial incentives improved smoking cessation care.

Who is organising and funding this study?
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This study is being organised by researchers from the RCSI School of Population Health in collaboration with the Health Service Executive Tobacco Free Ireland Programme. This research was funded by the Health Research Board in Ireland.

Why am I being asked to take part?

You are being asked to take part in this study because you have experience with stop smoking services in Ireland. The research team would like to gather your experiences and views of stop smoking services and any perceived barriers or facilitators of providing financial incentives within the services.

What will happen to me if I agree to take part?

If you agree to take part, you can choose to take part in all or any of the three participatory aspects of the study, depending on your preference.

Part 1: This involves taking part in an anonymous electronic survey, either online or via text message.

You do not have to take part in all aspects of the study. You can participate in a part that is most interesting to you.

Part 2: You may also be invited to participate in a semi-structured interview with a member of the research team. You will be asked questions about your experience with stop smoking services, your role in stop smoking services (e.g. service manager or service user etc.), your age, and your opinions of FISS, including perceived barriers and facilitators of national implementation. Any information you share is confidential and you will not be identified. You can also decide to engage in the interview in person or online via Microsoft Teams, and the discussion will last approximately 40 minutes. With your consent, the interview will be audio-recorded to generate a written transcript for analysis.

Part 1: Survey information

Your responses to the survey will be confidential and only accessible by the RCSI research team. Any details that may make you identifiable to others will be removed. Information will be securely stored in RCSI's OneDrive, which can only be accessed by members of the study team. Your information will not be stored by any external organisation or persons.

Part 2: Audio Recordings of interviews

The semi-structured interviews and workshops will be audio-recorded for transcription, and field work notes may be taken by a member of the research team, so that your responses can be collected and later analysed. The audio file from the interviews will be transcribed and any details that may make you identifiable to others will be removed. Transcription will be conducted by one of the study research assistants, Cheyenne Downey or Brian Doyle, or the PhD student, Reham Lasheen. Prof. Frank Doyle will review these transcripts to ensure sensitive or potentially identifiable information has been removed. The audio files will be securely stored in RCSI's OneDrive and will only be accessible to members of the study team. You will have the opportunity to review and edit the transcribed

document on request or withdraw all or parts of your data before it is used for analysis. Your information will not be managed or stored by anyone outside of the RCSI research team.

What are the benefits?

The aim of this study is to help improve stop smoking services in Ireland by including financial incentives to stop smoking and evaluating the impact of this. If the financial incentive used in this study receives a positive response, this study can highlight the value of offering financial incentives to those interested in using stop smoking services.

What are the risks?

There are no risks for taking part in this study. You do not have to finish the survey and you can take breaks or withdraw from the workshop(s) or pause or terminate your semi-structured interview if desired.

How will my information be kept confidential? What will happen to my data?

The research team have put in place several steps to make sure the study is confidential. Only the Principal Investigator (Prof. Frank Doyle) and study research assistants and PhD student (Reham Lasheen, Cheyenne Downey and Brian Doyle) will know your identity or be able to match your name with the information you provided. Any information that might make you identifiable to others will be removed before the data is shared with the rest of the research team for analysis. You will not be identifiable by your personal information.

The data collected (survey information, audio, and transcribed information) will not be stored with your name on it. If you choose to take part in an interview and after you provide informed consent, we will assign a number to you, e.g. 'Participant 1', and this will be used to name all files to ensure the data is stored anonymously.

All your information will be encrypted and stored in RCSI's OneDrive secure cloud platform. Access will be managed by the Principal Investigator (Prof. Frank Doyle) to ensure that your identity and data are protected. Any publications arising from this project will not identify you in any way.

Once any publications arising from this research have been accepted for publication, all data relating to the study will be deleted from the secure folders by the PI. The period for which the data will be retained will not exceed 5 years.

Data Protection

1. We will be using the information you provide in our research to help develop supportive services for people living with kidney failure. These services may be available to you in the future.

2. We will be processing your data for scientific research purposes under Article 6 (Lawfulness of Processing) and Article 9 (Processing of special categories of personal data) of the General Data Protection Regulation 2016: <https://gdpr-info.eu/>
3. Only the PI (Frank Doyle) and the study researcher assistants and PhD students (Reham Lasheen, Cheyenne Downey and Brian Doyle) will have access to the information with your name on it. The wider research team will only have access to the information which has any identifiers removed.
4. The data you provide will be encrypted and stored in dedicated secure restricted RCSI OneDrive folders. The data will be retained until the publications arising from this research has been accepted. After this has happened, the data will be deleted. This period will not exceed 5 years.
5. The data collected will be managed carefully as described in line with General Data Protection Regulations (GDPR) requirements. As the data will not contain any personal details, impact of any breach is not expected to cause you any harm.
6. You are entitled to change your mind about taking part in this research. If you wish to withdraw consent you can contact the Lead Investigator, Frank Doyle (FDoyle4@rcsi.ie / 01 402 2718) Brian Doyle (briandoyle@rcsi.ie) , Reham Lasheen (rehamlasheen23@rcsi.ie) OR Cheyenne Downey (cheyennedowney@rcsi.ie / 086 030 2408)
7. As a participant in this study, you have a right to lodge a complaint with the Data Protection Commissioner in Ireland if you are not happy with how your data is managed. Contact details are available on the first page of this leaflet.
8. You can request access to your information and for a copy of it to be provided to you if you wish. This will be possible until the identifiable data has been removed.
9. You can request that your data is not processed for analysis until the point that the identifiable data has been removed.
10. There will be no automated processing of data/decision making as part of this research.
11. The data from this study will not be used for any purpose other than in the completion of this research.
12. In order to complete this research, the transcripts which have any identifiable data removed will be shared securely with researchers in RCSI Dublin. In order to protect your data, only the de-identified data will be shared. It will be shared as encrypted files in a secure restricted folder on RCSI's OneDrive. Access to the study folder will be granted by the PI to named research team members via their RCSI account. Logging in to their RCSI account requires an individual password and dual-factor authentication.
13. Data will remain with the project team at RCSI. Transcription will be conducted within the RCSI by the research assistants, Reham Lasheen, Cheyenne Downey and Brian Doyle.

Where can I get further information?

If you have any further questions about the study, now or at any time in the future, please contact:

Name: Professor Frank Doyle, Associate Professor,
Department of Health Psychology,
RCSI University of Medicine and Health Sciences,
123 St Stephen's Green, Dublin 2, Ireland

E-mail Address: FDoyle4@rcsi.ie

Phone Number: +353-1-402-2718

Name: Ms Cheyenne Downey, Research Assistant,
Department of Health Psychology,
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Name: Mr Brian Doyle
Department of Health Psychology,
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123 St Stephen's Green, Dublin 2, Ireland
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Name: Ms Reham Lasheen
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123 St Stephen's Green, Dublin 2, Ireland
Email Address: rehamlasheen23@rcsi.ie

PARTICIPANT CONSENT FORM

Study title: COMMunity Participation for Stop Smoking services in Ireland: COMPASS

I have read and understood the information about this research project. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I understand that I don't have to take part in this study and that I can opt out at any time. I understand that I don't have to give a reason for opting out and I understand that opting out won't affect me in any way or affect my current or future service use in any way.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I am aware of the potential risks, benefits and alternatives of this research study.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I have been assured that no identifiable information will be collected about me, and all the data I share will be kept private, confidential and used for research purposes only.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I understand that I can request a copy of this completed consent form for my records.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I give informed explicit consent to have my data processed as part of this research study.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I understand that any data collected for this study will be stored securely in a dedicated encrypted and password-protected folder for no longer than 5 years.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I consent to take part in this research project, having been fully informed of the risks and benefits.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I consent to be contacted by researchers as part of this research study.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I give permission for material/data to be stored for <u>possible future research related</u> to the current study <u>without further consent being required</u> but only if the research is approved by a Research Ethics Committee.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I give permission for material/data to be stored for <u>possible future research unrelated</u> to the current study <u>without further consent</u> being required but only if the research is approved by a Research Ethics Committee.	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Patient/Participant Name (Block Capitals)

Patient/Participant Signature

Date

