



**QUEEN'S
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EUthyroid2 Personnel Information Sheet

Title of study: EUthyroid2 – The next step towards the elimination of iodine deficiency and preventable iodine-related disorders in Europe: Targeting young women (18-24 years).

1. Invitation

You are invited to help facilitate a cluster-randomised controlled trial being carried out by researchers at Queen's University Belfast (QUB) and the University of Surrey. The study involves other research teams from across the globe as part of a wider EUthyroid2 study. This study aims to improve awareness of iodine deficiency in young women (18-24 years old). The study aims to recruit approximately 130 young women across Northern Ireland and includes an intervention where participants will receive information on iodine and what the current recommendations are and a control group.

Before you decide to take part, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your family, friends and colleagues if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

2. What is the purpose of the study?

This study aims to improve low awareness of iodine deficiency and iodine-deficiency disorders (IDD) and highlight the importance of iodine nutrition among young adults. This is important because the human body needs constant small amounts of iodine for metabolism and brain development, but normal diets in most countries do not contain enough iodine, resulting in iodine deficiency, the world's largest cause of preventable mental impairment. While the health of all population groups can be affected, pregnant women and children are especially at risk. It is also a cause of thyroid diseases.

3. Why have I been chosen?

You have been selected for this study as you are currently employed in a healthcare, research or education setting or are working towards a healthcare-related qualification. If you are a student working towards a healthcare-related qualification, you are required to have completed two years of undergraduate study.

4. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be asked to keep this information sheet and to sign a consent form (you will also keep a copy of the consent form). If you decide to take part, you are free to withdraw at any time and without giving a reason.

5. What will happen to me if I take part?

If you are interested in being involved, your role in the study would be to deliver the necessary educational materials to participants in Group 1 (Iodine Intervention) at QUB. There is no specific time commitment involved; we will work around your timetable to identify times that suit you and the study participants. You may also be asked to participate in an interview to evaluate the study processes. Further detail is provided below.

Key tasks of your role:

- Participants in the Intervention group will receive an iodine education session. You will be trained to deliver this education session and will be given all required materials, including a factsheet and access to a link/QR code for a video on iodine.

- To evaluate the implementation of this study, you will also be asked to participate in surveys and/or an interview. The surveys will be conducted at three timepoints:
 - At the beginning of the study (before you are educated on the study procedures and intervention).
 - After being educated, and;
 - When 50% of the intervention sample have been recruited.

You will be asked about your knowledge on iodine, your opinion on the intervention materials, and your experiences during the study period.

- A small sample of EUthyroid2 study personnel will be contacted, if you consent, by a representative of the EUthyroid2 research team to ask if you would like to participate in an interview (approximately 30-60 minute long). Participation is voluntary and you can withdraw at any time. The aim of the interview is to gain insight into your experiences during the study and assess study implementation. For example, this could include questions on your opinion on the information materials, what processes are useful for the implementation of the intervention or what you believe should have been done differently. The interview will be completed online and with your permission, it will be audio-recorded. The information recorded will be confidential, and only the research team will have access to the information documented during your interview. The recorded file or the transcription of the audio file will be pseudonymised (i.e. your name will be removed). If you do not consent to the interview, you may still take part in the delivery of the education to the intervention study group.

6. What are the possible risks or disadvantages of taking part?

Participation in this study will require your time and commitment. However, it is not expected that taking part in this research study will cause any discomfort or harm to you.

7. What are the possible benefits of taking part?

There will be no direct benefit to you, but your participation may increase your knowledge about the importance of iodine in your diet and will help us find out more about how to prevent iodine deficiency and iodine-related disorders. By participating in the study, you will gain valuable experience and may contribute to finding best-practice models and increase knowledge and awareness of iodine and iodine-related diseases in the UK. EUthyroid2 aims to serve our societies by conducting research to improve public health. You will receive a certificate at the end of the study period to confirm your involvement in the study.

8. What if something goes wrong?

Complaints: If you have a concern about any aspect of this study, you should ask to speak to the researchers. QUB research staff are available at EUthyroid2@gub.ac.uk. They will do their best to answer your questions. If a suitable explanation is not provided by a researcher, then you should contact the Chief Investigator Professor Jayne Woodside, Centre for Public Health j.woodside@gub.ac.uk. Should you remain unhappy and wish to make a formal complaint, you can contact the Research Governance Team at QUB (Telephone: 028 9097 2529; Email: researchgovernance@gub.ac.uk).

9. Will my taking part in this study be kept confidential?

- If you agree to take part in this research study, the information you provide will be securely stored by the research team. Data will be collected and stored according to relevant UK data protection legislation. As this study is part of a larger international study, the study data (your answers to the questionnaires) will be transferred in an encrypted form via a secure internet connection to a server operated by the University Medicine Greifswald (UMG), Germany for analysis.
- In case of personal data, we distinguish between personal contact data and collected study data. Personal contact data includes all the data that allow us to identify you as a person: for example, first name/last name, address, date of birth. Your personal data will be stored at QUB in password protected software. QUB and Surrey researchers will have access to any personal data.
- Study data includes all the answers to the questionnaires. Study data will be collected via LimeSurvey software which is hosted by UMG, Germany, who are coordinating the study. Further information on Lime Survey data privacy can be found at <https://www.limesurvey.org/privacy-notice>.
- The data collected during the interviews and the examinations will not be stored with any name and address but will be coded with a number (pseudonymisation). All the scientific analyses will be carried out with pseudonymised data. The transfer of study data from the study centre to other scientific groups will also be pseudonymised.

- Researchers at QUB/Surrey will not see responses to the questionnaires if it is completed via LimeSurvey. However, if questionnaires are completed using a paper copy, study data will be required to be entered onto LimeSurvey software by the research team. As mentioned above, this data will be coded with a number, so there is no personally identifiable information on LimeSurvey.
- If you decide to withdraw consent (or lose capacity to consent) during the study, any data already taken can be retained, but no further data will be collected.
- The EUthyroid2 study data will only be processed and analysed by EUthyroid2 research team members at UMG who will have access to pseudonymised data only (i.e. your name will be removed).
- The audio file and the transcript of the Process Evaluation Interviews will be transmitted in an encrypted form via a secure internet connection to a server operated by the University of Greifswald, Germany. The Heinrich Heine University of Düsseldorf, Germany is an official partner of the EUthyroid2 project and the involved researchers will perform the analyses of the interview data. The audio recordings are to facilitate the interview data and will be deleted after the interview has been transcribed. The transcripts of the audio files will be used for data analysis and will be stored for 10 years.
- In some instances, inspectors from regulatory authorities may need to access data for checking the quality of the research. Study documentation will be kept for 10 years from when the study has been completed to allow for full and final publication of the research results and will be held securely by the Chief Investigator. At the end of this period, data that are no longer required will be securely destroyed.

10. What will happen to the results of the research?

You will receive a summary of the overall study results. The results will help researchers to make recommendations on how to improve young women's (18-24 years old) understanding of iodine and iodine deficiency-related disorders. Results will be presented at scientific and patient conferences as well as events for the public and professionals working in this area; they will also be published in scientific journals. You will not be identified in any publication or presentation.

11. Who is organising and funding the research?

The EUthyroid2 project is funded by the European Union and the UK Research and Innovation as part of the Horizon Europe Framework Programme to reduce the risk of non-communicable diseases in adolescents and young people.

12. Who has reviewed the study?

This study in Northern Ireland has been reviewed by the Faculty of Medicine, Health and Life Sciences Research Ethics Committee, Queen's University Belfast.

13. Contact for Further Information

Version 3, date 11/11/2024

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We would like to thank you for taking the time to read this information sheet.

If you have any queries, concerns or complaints about the way this research project is being conducted, you can contact a member of the study team whose details are listed below:

Chief Investigator: Professor Jayne Woodside Centre for Public Health School of Medicine, Dentistry and Biomedical Sciences Institute of Clinical Sciences Grosvenor Road Belfast BT12 6BJ Email: j.woodside@qub.ac.uk Tel: +44(0)2890 978942	QUB research team: Dr Danielle Logan / Sinead O'Hagan Centre for Public Health School of Medicine, Dentistry and Biomedical Sciences Institute of Clinical Sciences Grosvenor Road Belfast BT12 6BJ Email: EUthyroid2@qub.ac.uk Tel: 07385968725
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This research will be conducted in compliance with data protection legislation. For more information about how we look after your information, how to access your rights and who to contact if you have any queries or concerns about data protection please visit the Queen's University Belfast website - www.qub.ac.uk/privacynotice/Research/ListofResearchPrivacyNotices/PrivacyNoticeforResearchParticipants

Thank you for your interest in this study and for taking the time to read through this information sheet.

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CONSENT FORM

Participant ID _____

Title of Project:	EUthyroid2 – The next step towards the elimination of iodine deficiency and preventable iodine-related disorders in Europe: Targeting young women (18-24 years)
Chief Investigator:	Professor Jayne Woodside
Study Number:	

Please initial box

1. I confirm that I have read, or had read to me, and understand the information sheet dated 11/11/2024, version 3 for the above study. I have had the opportunity to ask questions and these have been answered fully.
2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason.
3. I understand the study is being conducted by researchers from Queen's University Belfast and that my personal information will be held securely on University premises and handled in compliance with relevant data protection legislation.
4. I understand that data collected as part of this study will be processed by authorised individuals from Queen's University Belfast and University Medicine Greifswald where it is relevant to my taking part in this research.
5. I agree to take part in the above study inclusive of all the procedures mentioned in the participant information sheet.
6. I understand that the information I provide may be published as a report. Confidentiality and anonymity will be maintained and it will not be possible to identify me from any publications.
7. I understand that if I withdraw (or lose capacity to consent) during the trial, I agree that data already taken can be retained.

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8 **Optional:** I agree to take part in the process evaluation interview and I understand that interviews will be digitally recorded and transcribed verbatim and there is a possibility of direct quotation being used in publications, but no identifiable information.

9. **Optional:** I agree to being contacted at a later date and invited to take part in future studies of a similar nature. I understand that I am only agreeing to receive information and I am under no obligation to take part in any future studies.

*If you decide not to consent to being contacted in the future it will not have any influence on your involvement in this particular research study.

Name of Participant (please print)

Signature

Date

Name of Person Taking Consent
(please print)

Signature

Date

Chief Investigator or Researcher Contact details:

Professor Jayne Woodside
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School of Medicine, Dentistry and Biomedical Sciences
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