

Participant 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 take part in a research study that is being carried out by researchers at Queen's University Belfast (QUB) and the University of Surrey and involves other research teams from across Europe as part of a wider study. This study aims to improve awareness of iodine deficiency in young women (18-24 years old). The study includes an intervention where participants will receive information on iodine and what the current recommendations are and a control group who will receive general UK dietary advice.

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 and friends 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 female between the age of 18-24 years old.

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). There will be approximately 260 other similar volunteers across the UK taking part in this study. 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 express an interest in taking part, a researcher will send you an information sheet and contact you via telephone/email to arrange a screening appointment, which should last no longer than 10-15 minutes; a screening appointment is where we ask questions to assess if you are eligible to take part in this study. At this stage, the researcher will ask you some questions about your age, your health (whether or not you have a thyroid disease) and if you are or could potentially be pregnant. You will be asked to self-report at screening and during the study (if you are eligible) that you are not pregnant. If you are pregnant on the screening call you will not be eligible to participate in the study. If you are pregnant at the 2nd or 3rd follow up study appointments, you will be withdrawn from the study. There is no risk to the developing baby if you get pregnant during the study, but it may affect the results of the study.
- If you are eligible to take part, you will be asked to read and sign an online consent form. You will be given a unique study ID number and randomly assigned to a study group. You will be randomly allocated to one of two study groups. The groups are selected by a computer which has no information about the individual – i.e., participants are randomised into the groups by chance. The 2 study groups are:
 - **Group 1. Iodine intervention** – you will be given information on iodine nutrition.
 - **Group 2. Control** – you will be given general healthy eating advice.
- After you have been randomised into either Group 1 or Group 2, you will be asked to provide a urine sample. You will be provided with a urine sample kit including instructions. You can either post your urine sample to researchers at CPH, QUB (postage will be pre-paid) or drop off at a pre-arranged location.
- We will then contact you to arrange an online appointment which will last approximately 20-30 minutes. If you are randomised to Group 1 (intervention group), you will be asked to complete a questionnaire and the QUB researcher will speak to you about iodine. If you are randomised to Group 2 (Control group), we will ask you to complete a questionnaire and you will be provided with a nutrition fact sheet but will receive the iodine information at the end of the study.

- At the end of this appointment, we will schedule two follow up appointments which will take place at 2-4 weeks and 6-8 months after your first appointment. You will also be asked to provide a urine sample at both follow up appointments (three urine samples in total). Your sample will be stored at QUB until the end of the study when all samples will be sent to the central EUthyroid2 laboratory at the Institute of Marine Research, Norway.
- At the 2-4 week follow-up appointment, you will be asked to complete a questionnaire on how you felt about the study procedures and your experience of being in the study.
- There is also the opportunity to be involved in an optional online interview to help us evaluate the study after your final study visit (i.e. 6-8 months). If you consent to this and are randomly chosen to be involved in the interview, this will be conducted by researchers from the University and will last approximately 60-90 minutes. The interview will be completed online and with your permission, it will be audio-recorded, but deleted after the interview has been transcribed. The information recorded will be confidential, and only the EUthyroid2 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. key identifiers such as your name will be removed). If you do not consent to the interview, you may still take part in the study provided you are eligible after screening.

As thanks for taking part, the following incentives are available:

- £5 voucher after providing first urine sample and completing the first online questionnaire.
- £5 voucher after providing second urine sample and completing the follow up questionnaire at 2-4 weeks.
- £10 voucher after providing the third urine sample and completing the follow-up questionnaire at 6-8 months.
- With your consent (which is optional), any remaining urine sample at the end of the study may be used for future nutrition and health focused analysis.

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?

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. EUthyroid2 aims to serve our societies by conducting research to improve public health.

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 at QUB who can be contacted at EUthyroid2@qub.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@qub.ac.uk. Should you remain unhappy and wish to make a formal complaint, you can contact the Research Governance Team at Queen's University Belfast (Telephone: 028 9097 2529; Email: researchgovernance@qub.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 the 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, 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. Only QUB and Surrey researchers will have access to any personal data.
- Study data includes all the answers to the questionnaires, and the results of the urine samples. Study data will be collected via LimeSurvey software which is hosted by UMG, Germany, who are coordinating the study. Further information on LimeSurvey 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 and samples already taken can be retained, but no further data or samples will be collected.
- The EUthyroid2 study data will only be processed and analysed by EUthyroid2 research team members at the University Medicine Greifswald (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.

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

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. A summary of the overall study results will be sent to those taking part. 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

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 _____

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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 and without my legal rights being affected.
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 and samples already taken can be retained, but no further data or samples will be collected.

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8. I agree to gift my urine samples to Queen’s University Belfast. I consent to the storage of my urine sample at Queen’s University Belfast and transfer to the central EUthyroid2 laboratory at the Institute of Marine Research, Norway. I understand that I will not benefit financially from any research.
9. **Optional:** I consent to the use of my urine sample for future nutrition and health focused analysis.
10. **Optional:** I agree to take part in the process evaluation interview if chosen to participate and I understand that the interviews will be digitally recorded and transcribed verbatim and there is a possibility of direct quotation being used in publications, but no identifiable information.
11. **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 contact details:
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