UCD Fam-D-Bread Study

Participant Information Leaflet (Adults 18+)

Researchers at the University College Dublin (UCD) Institute of Food and Health, and University College Cork Centre for Vitamin D and Nutrition Research are conducting a study which aims to improve wintertime vitamin D status among young families in Ireland using a vitamin D-fortified bread. The Fam-D-Bread study is led by researchers at University College Dublin (Prof Aifric O'Sullivan and Prof Eileen Gibney) and University College Cork (Prof Mairead Kiely) with collaborators in Teagasc, the Food Development Agency and Bretzel Bakery. Bretzel Bakery will help to make the bread for the study; however, they will have no commercial gain from the study. This project is funded by the Department of Agriculture, Food & Marine, Ireland.

What is this research about and why are we doing it?

Vitamin D is an essential nutrient that has several health benefits. We can make vitamin D in our skin when the sun shines or we can get vitamin D from certain foods. In Ireland, we don't get enough sunshine, particularly from October to March, and most people are not eating enough foods that contain vitamin D to meet their requirements and so a large proportion of the population are at risk of low vitamin D status. For this reason, it is important for us to look at ways to increase our vitamin D intake from foods and therefore improve our year-round vitamin D status. This study will examine if we can improve vitamin D intake and prevent low vitamin D status in wintertime using a vitamin D fortified bread. We expect that outcomes from this research will inform policy and recommendations to improve vitamin D intake in Ireland.

Why have you been invited to take part in this research study?

We are seeking healthy families with at least one parent/guardian and one child/adolescent (aged 5-18 years) to take part in this research.

What will happen if you decide to take part in this research study?

Screening (approx. 10 mins)

If your family wishes to take part in our study, we will first invite an adult to fill in an online screening questionnaire via Qualtrics on behalf of the family. This screening questionnaire will include general questions related to the size and age distribution of your family. The questionnaire will also ask about medical conditions, medication use, supplement use, dietary intake, and sun exposure (like upcoming holidays or use of tanning beds) within the family. Individuals are not eligible to participate if they are regularly consuming a single high dose vitamin D supplement (>10µg/d equivalent) or if exposed to factors that may influence vitamin D status (winter sun holiday, tanning beds, etc.) during the course of the study. Individuals may be unable to take part if food allergies, dietary restrictions, medical conditions or medications could impact your participation in the study and study outcomes. Researchers from UCD will contact the lead participant (the family member who completed the screening questionnaire) via phone or email to discuss next steps.

If your family is eligible based on the screening questionnaire and decide to take part, all participating family members will be asked to attend a UCD research centre on two occasions, 8 weeks apart. Please note that not all family members have to take part in this research as long as the participating family members meet the study's inclusion criteria (i.e. one parent/guardian and one child/dependent). A study visit will take up to 2 hours to complete; however, if it is more convenient for you, we can complete some

of these questionnaires at a home visit. You will still need to attend two study visits at a UCD research centre, but the length of the visit would be roughly 30 minutes.

Baseline visit with full data collection (Week 0 - approx. 2 hours)
If your family decides to attend a full study visit at our research centre at a UCD research centre, all participating family members will be asked to consent to participation in the study. First, a researcher will inform you about the study procedures, review the participant information leaflet with you, and you will have the opportunity to ask any questions or request further information. Adults (aged 18 years or over) will be asked to provide written informed consent. Parents/guardians will be asked to provide informed parental consent for their child/dependent. Children (under the age of 18 years) will be asked to assent to their participation in the study. Dependents over the age of 18 years wishing to participate with their parent/guardian or family will be asked to sign informed consent. Your family will be randomly allocated to either the fortified bread or the unfortified (control) bread study group, however, to avoid bias neither the researchers not participants will know which group families are allocated to.

During the full study visit, the following assessments will be completed,

- Body measurements (weight, height, waist and hip circumference) (all family members)
- Blood pressure (adults only)
- Demographics and lifestyle questionnaire (1 per family)
- Food frequency questionnaire related to the family's diet over the past month (1 per family)
- A small blood sample will be collected by a trained and experienced research nurse (all family members). These samples will be frozen and analysed for nutrients and other health related markers.

We will give you a small snack after your blood sample collection and provide dietary advice for a healthy, balanced diet. You will receive your allocated study bread to start consuming daily.

OR

Baseline data collection (at home, Week -1, approx. 1.5 hours)
If your family decides to opt for a home visit for data collection, a researcher will schedule a home visit at a time of your choosing. The data collection procedure will be the same with the exception of blood sampling. A researcher will discuss study procedures with participating family members and ensure the appropriate consent/assent forms have been signed.

The following data will be collected during your home visit,

- Body measurements (weight, height, waist and hip circumference) (all family members)
- Demographics and lifestyle questionnaire (1 per family)
- Food frequency questionnaire related to the family's diet over the past month (1 per family)

Baseline data collection (onsite blood sampling, Week 0, approx. 30 mins)
Once your family has completed a home visit, we will schedule a short visit to a UCD research centre blood sampling. Small blood sample will be collected by a trained experienced research nurse. These samples will be frozen and analysed for nutrients and other health related markers. Blood pressure readings will be recorded from adult participants. We will give you a snack after your blood sample

collection and provide dietary advice for healthy, balanced diets. You will receive your allocated study bread to start consuming daily.

Checkup (via phone call) (Week 2 and 6 approx. 10 mins)
The researcher will arrange a phone call with a parent or guardian of the family to see how you are getting on with the study at weeks 2 and 6. During this phone call, they will ask you questions on if there have been any changes to health status, medical history, or medication and supplement use within the family.

Endpoint data collection (Week 8)
At the end of the 8-week study, you will be asked to return to a research centre for follow-up data collection. As described above, your family will have the option for a home visit from a researcher or to have all data collected during a full study visit at a research centre. The following will be collected either at home or at a research centre,

- Body measurements (weight, height, waist and hip circumference)
- Food frequency questionnaire related to the family's diet over the past month
- Acceptability/exit questionnaire

A small blood sample will be collected from all participating family members onsite at a research centre. Blood pressure readings will be collected from adult participants. A snack will be provided following blood sampling.

<u>What are the possible risks of taking part in this research study?</u>
The risks to you are negligible. However, there are some risks when giving blood, including discomfort, fainting, minor bruising, or superficial inflammation. To ensure this risk is kept to a minimum, all samples will be collected by a nurse who is trained and experienced in collecting blood samples. A standard protocol will be followed to ensure safe blood collection. If for any reason you do not consent or wish to take part in blood sampling, you do not have to take part in this research.

<u>What are the benefits of taking part in this research study?</u>
If you decide to take part, you will be contributing to research which is aiming to improve knowledge on vitamin D fortified foods among children, adolescents and adults in Ireland. You will be provided with bread throughout the 8-week study and information on other sources of vitamin D to help you make the recommended changes.

<u>What are the benefits to the researcher if I take part in this research study?</u>
With this research, researchers aim to inform national policy to solve vitamin D deficiency in Ireland. If you decide to take part, the researchers can gather evidence to support this policy. This research project supports postgraduate students who will be able to analyse the anonymised data to answer research questions as part of their research degree theses and can then publish the analysis in academic papers in peer-reviewed journals. The investigators of this research will achieve the aims and objectives provided to the project's funder (the Department of Agriculture, Food and the Marine).

<u>How will my data be used?</u>
By participating in this study, your information will be collected for the purposes outlined in this Participant Information Leaflet (PIL). If you provide informed consent, you will be assigned a study code number, and this code will be used to input the data generated from the study. During the data collection phase of the study your study code number will be linked to your name and contact details in a separate

file and stored safely on a secure password protected database. Once data collection is complete, the file linking your name and contact details to your study code number will be destroyed and your data will be anonymised. We will use your blood sample to measure your vitamin D. The anonymised data will be used in one or more scientific papers and reports and will be available for use by the study collaborators for future nutrition/vitamin D research projects. Archived data may be used by other researchers in future upon request from the lead researcher named above. We will retain anonymous coded data records and any remaining blood samples for 10 years or 5 years post publication at which point they will be safely destroyed.

How will my privacy be protected?

Any information collected will be kept completely confidential. Your information will be in a pseudonymised (coded) format and stored using a study number. Any personal data which you provide to the University will be treated with the highest standards of security and confidentiality, in accordance with Irish and European Data Protection Legislation. By consenting to participate, means that your data will be used for the purposes outlined in this participant information leaflet. All data will be stored securely on Multi-Factor Authentication protected files and your data and any remaining blood samples will be retained for 10 years. Some findings from the study will be presented and published at a later date, but these will describe the study population as a whole and not refer to individual people.

What is the legal basis for processing my data? Or why are you processing my data?

Any data you provide to us during the course of this study will be processed fairly and lawfully. The General Data Protection Regulation (GDPR) allows us to process your data because the research is of substantial public interest (Articles 6(1) (e) and 9(2) (g) of the GDPR). Signing the Informed Consent Form means that your data and biological samples will be used for the purposes outlined in this PIL.

How will you find out what happens with this study?

On completion of the study, the researchers involved in the study will put together a summary of the study results. We will not be able to provide individual data as all analysis will be done using coded samples and data only. If you decide to take part in the study, you will sign a consent form. The consent form will include a statement that will give you the opt-in option to allow us to save your email or postal address so that we can share the summary report with you when complete.

Can you change your mind at any stage and withdraw from the study?

Your decision to take part in this study is entirely voluntary. You are able to ask questions or withdraw from the study at any time without having to provide an explanation. If you decide to withdraw from the study early, your coded data collected from when you signed the consent form will be used for statistical analysis unless you also withdraw your consent for them to be used in this way. If a member of your family wishes to withdraw from the study, your remaining family members may choose to continue their participation if your family still meets study inclusion criteria (i.e. at least one parent/guardian and at least one child/dependent). If you withdraw your consent and request for your data to be removed, your data will be destroyed. However, this can only be done if you withdraw during the data collection period (after signing consent until your final onsite visit to UCD), as your data will be anonymised once data collection is complete. This means that we will use only a study code to save your data and therefore we will not be able to identify you. Following your withdrawal, no new data will be collected.

Who do I contact if I have any concerns about the protection of my data?

If you require further information regarding your data, please firstly contact the study's principal investigator, Prof Aifric O'Sullivan at aifric.osullivan@ucd.ie. If you feel you require further assistance, you

can contact the UCD Data Protection Officer Office of the DPO, Roebuck Castle, UCD, Belfield, Dublin 4, by email at gdpr@ucd.ie or phone on 01 716 8704. Alternatively, I understand I can direct complaints to a party independent to this study at foodandhealth@ucd.ie.

Will I be reimbursed for travel expenses?

Yes, reasonable travel expenses will be reimbursed; however, you will need to discuss this with the researcher before you travel as all travel claims need to be approved. If travel is approved, you will need to keep all travel receipts so that the costs can be reimbursed. Compensation will not be provided for time or participation.

Contact details and further information:

Please feel free to ask for further information before deciding if you will take part. If you want further information, you can contact the researchers at vitamind@ucd.ie or 01 716 2467.

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