VitD-DPI-OASIS Study
Participant Information Sheet

You are invited to participate in a Research Project that is explained below.
Thank you for taking the time to read this Information Statement.

UCD VitD-DPI-OASIS Study

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 in older adults using a vitamin D-fortified bread. The VitD-DPI-OASIS study is led by researchers at University College Dublin and University College Cork with collaborators in Teagasc Agriculture and Food Development Authority and Aryzta Food Solutions. Aryzta Food Solutions will help to make the bread for the study; however, will have no commercial gain from the study. This project is funded by the Department of Agriculture, Food & Marine, Ireland. Dr Aifric O'Sullivan, Prof Eileen Gibney and Malak Ali are conducting the study in UCD's Institute of Food and Health.

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 adults aged 65 and over to participate in this study.

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

Screening (approx. 20 mins)

If you express an interest in the study, a researcher will explain the 10-week study to you in detail and will send you a copy of the participant information leaflet and consent form. If you wish to continue, you will complete a screening questionnaire online or over the phone with a researcher (depending on your preference) to determine your eligibility to participate. This screening questionnaire will include general questions on medical conditions with tick box answers, if you answer yes to any medical conditions you will be asked to provide some detail

on them. You will not be eligible to participate if you regularly consume a single high dose vitamin D supplement (>10µg/d equivalent), are exposed to factors that may influence vitamin D status, such as winter sun holiday, tanning beds etc. during the course of the study, if you have any known food allergies or are following a medically prescribed diet, have a medical condition or are taking medications that could impact your participation in the study, if you have regular excessive alcohol intake (≥28 units per week), cannot read, write or understand English or are participating in another research study with an intervention or other lifestyle programme that would interfere with the outcomes of the study. If you are eligible and willing to participate you will be asked to sign the VitD-DPI-OASIS study consent form at the beginning of your study visit.

Baseline visit (Week 0 - approx. 1 hour)

If you are eligible based on the screening questionnaire, you will be asked to attend a baseline visit at UCD Institute of Food and Health in the morning following an overnight fast. Before you begin your first visit, a researcher will read the consent form with you and if you are happy to continue, you will sign the informed consent form. Then, you will be randomly allocated to either the fortified bread or the unfortified (control) bread study group, however, to avoid bias you will not know which group you are in. 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. At this visit a researcher will take your height, weight and blood pressure measurements and a nurse will take a blood sample. We will give you a small breakfast after your blood sample collection and then we will ask you to complete Food Frequency Questionnaire (FFQ) with the researcher. The FFQ is a record of food and beverages consumed over the previous month. You will be presented with a list of foods and asked to record the frequency of consumption from the following options: Never in the past month, 1-3 per month, once per week, 2-4 per week, 5-6 per week, once per day, 2-3 per day, 4-5 per day, 6+ per day. This questionnaire will take approximately 25 minutes to complete. We will also ask you to record your diet at home on two different days. We expect each dietary record will take about 20 minutes to complete. You will then be given additional dietary advice, and you will receive your allocated study bread to consume daily for the next 10 weeks.

Checkup (via phone call) (week 2.5 and 7.5 approx. 30 mins)

The researcher will arrange a phone call with you to see how you are getting on with the study at week 2.5 and again at week 7.5. During this phone call, they will ask you questions on if there have been any changes to your health status, medical history, or medication and supplement use. You will also receive diet counselling, reiterating the changes required to your usual diet to ensure you are staying on track.

Endpoint visit (Week 10- approx. 1 hour)

Following the 10-week study period, the study team will schedule your final visit to UCD. At this visit a researcher will complete another Food Frequency Questionnaire with you, and take

the same height, weight and blood pressure measurements, and a nurse will take a fasting blood sample. We will also ask if you would like to complete an optional exit interview.

What are the possible risks of taking part in this research study?

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 taking blood.

You will consume either a vitamin D fortified bread or an unfortified bread. The control bread will contain no vitamin D and the vitamin bread will deliver 10-15µg vitamin D per serving, in the form of either two slices of bread (total weight = 76 g) or a baguette (total weight= 110g). Studies have shown that this is the dose needed to bring older adults' blood vitamin D to the right level. The dietary requirement in Ireland is 15µg of vitamin D daily, and the Institute of Medicine and some other countries have set their recommendations to 15-20µg of vitamin D daily. Our body can store vitamin D, therefore consuming too much can be harmful. Most foods contain very small amounts of vitamin D and during your first visit you will receive diet counselling explaining the changes required to your diet as well as a detailed list of all vitamin D containing foods. It is important that you consume no more than the one serving of study bread (two slices of bread or a baguette) daily. The amount of vitamin D that will be consumed with your diet and the vitamin D bread is small, so it is unlikely that you will consume too much over the course of the study. Daily consumption of any other vitamin D supplements providing >10µg/d may be unsafe. Researchers will check the vitamin D content of any supplements you are taking at the screening visit and will ask you to stop taking any which provide >10µg/d vitamin D for your safety. If you are unable to stop taking a vitamin D supplements of this dose, you will not be able to enrol onto the study. If you have any concerns about the vitamin D content of your diet over the course of the study please contact a member of the research team (contact details below).

What are the benefits of taking part in this research study?

If you decide to take part, you will be contributing to research which is aiming to improve knowledge on vitamin D fortified foods in older adults. You will be provided with bread throughout the study and information on other sources of vitamin D to help you make the recommended changes.

How will my data be used?

By participating in this study, your information will be collected for the purposes outlined in this participant information leaflet. All data collected as part of this study will be identifiable at the point of collection but will be anonymised before being used in analysis. 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 and will include some other measurements to get a picture of your overall health and metabolism (glucose, cholesterol and inflammation). Anonymised blood samples may be sent to 3rd party laboratories for analysis if we do not have the facilities to perform the analysis onsite. 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.

How will your privacy be protected?

Any information collected will be kept completely confidential. Your information will be in an anonymised (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 Patient Information Leaflet (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 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, Dr 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.

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. Please keep all travel receipts so that the costs can be reimbursed.

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.