

**Participant Information Sheet and Consent Form**

**Interventional Research**

**Title** **The Role of Vitamin D in Controlling and Reducing**

**Diabetes Mellitus Risks**

**Short Title D4D Research**

**Project Sponsor UTS**

**Principal Investigator Associate Professor Christopher Zaslawski**

**Site University of Technology, Sydney**

Protocol Protocol Version IV

Part I – What does my participation in the study involve?

1. Introduction

You are invited to take part in the research: The Role of Vitamin D in Controlling and Reducing Diabetes Mellitus Risks (D4D Research). Before you make your decision, we would like to help you to understand more about this study such as the purpose of the study, what it will involve and how your information will be used. Please take time to carefully read the following information. One of our research staffs will help you to go through this information sheet and answer any questions you may have.

1. What is the purpose of this research?

The D4D research is designed as a multi-centre, single-blinded, randomised study aims to evaluate the possible association between vitamin D and Type II Diabetes, and to see if the corrected vitamin D status could benefit patients with Type II Diabetes.

1. Why have I been chosen?

You have been chosen as a potential participant because you fulfil the following selection criteria:

1) You are older than 18 years; 2) you have been diagnosed with Type II Diabetes in the past 12 months, and not on diabetic medication or insulin treatment; 3) Your vitamin D level from your recent blood test is between 28 nmol/l and 85 nmol/l and not on vitamin D supplements or any relevant medications *(please note serum vitamin D 28-49 nmol/l is classified as vitamin D mild deficiency; 49 to 85 nmol/l is classified as vitamin D sufficient but will still be chosen for the reason of study sensitivity)*; 4) You do not have thyroid disease, liver disease, kidney disease, cancer, osteoporosis, dementia, mental disease or taking relevant medications; 5) You are not pregnant or breastfeeding.

You would not be eligible for the current trial if you are:

1) Unable to give written informed consent form or follow the research instructions; 2) Currently using a vitamin D supplement; 3) Have thyroid disease, liver disease, kidney disease, cancer, osteoporosis, dementia, mental health disorder or taking relevant medications; 4) Women who are pregnant or breastfeeding; 5) Vegan and cannot ingest any animal product.

1. Do I have to take part in the research?

The participation in the D4D research is completely voluntary. If you do decide to participate, you will be given this **Participant Information Sheet** & **Consent Form (PICF)** to sign, and given a copy to keep. You can change your mind later and withdraw from the study at any stage, for any reason.

1. Other relevant information

There will be a total of 20 to 140 participants involved in this study. Recruitment and assessment will be conducted in Earlwood Medical Centre and Bangor Medical Centre. A NATA (National Association of Testing Authorities, Australia) accredited pathology laboratory will conduct the blood test of vitamin D level and Diabetes biomarkers every three to six months. Data will be analysed in the University of Technology, Sydney.

We strongly recommend that you inform your family doctor of your participation in this study. You can take your regular medicine as long as it was checked and approved by the research team. If you are having any diabetes-related medication or vitamin D supplements (including calcium and Vitamin D supplements) during the study period, please let out research team know and you may be excluded from the current study. If you would like to know more information, please visit our website www.d4dresearch.com or talk to our research team.

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

Once you make the decision, you will need to sign the **Patient Information and Consent Form (PICF)** and it has to be completed prior to any assessments being performed.

Secondly, you will be randomly assigned to one of four treatment groups as: vitamin D supplement group, dietary intervention group, sun exposure group or wait-list control group. You would be known for which treatment you are receiving during the trial but the research staffs including the statisticians are blind to the treatment allocation i.e. which treatment group you are in and hence which treatment you are receiving.

To be specific, if you are in the vitamin D supplement group, you will be given oral vitamin D supplementation with a dosage of 500 IU per day. If you are in the diet group, you will be required to follow a dietary plan with help of an Accredited Practicing Dietitian to obtain 10-15 µg/d of vitamin D. If you are in the sun exposure group, you will be asked to expose about 15% of the body surface to obtain approximately 12.5 µg/d of vitamin D per day. No intervention will be given to the wait list control group.

The total time of your attendance in this study is 9 months. You are required to attend the initial baseline assessment, and the follow-up assessment on a monthly basis. Information collection would be conducted in each monthly assessment but the blood test will be only conducted at the baseline, 3rd month, and 9th month assessment.

Please feel free to contact the research team if you experience any discomfort or an upsetting symptom, we would assess the problem and if necessary, cease your participation immediately and provide you with medical treatment if required.

There are no additional costs associated with participating in this study, nor will you be paid. All tests and medical care required as part of the study will be provided to you free of charge. However, you may be reimbursed $25 voucher for any reasonable travel, parking, meals and other expenses associated with the study visit.

1. What do I have to do?

As we mentioned before:

* If you are in the vitamin D supplement group, you will need to take one tablet of vitamin D (500IU) per morning and you should keep a written record of supplement taken for the monthly assessment.
* If you are in the dietary intervention group, please follow the dietary plan designed by the Accredited Practising Dietitian to obtain 10-15 µg/d of vitamin D from food and keep a dietary diary for the monthly assessment. Dietary diary could be recorded in paper form or through the smart phone application.
* If you are in the sun exposure group, you will be required to expose approximately 15% of your body surface (i.e. hands, face and arms) in sunlight for 3-11 minutes every day and to keep a sun exposure dairy for the monthly assessment.

You are required to attend the initial baseline assessment, and the follow-up assessment on a monthly basis for 9 months. Information collection would be conducted in each monthly assessment but the blood test will be only conducted at the baseline, 3rd month, and 9th month assessment.

Please note it is your responsibility and commitment for taking the research supplements, or following the dietary plan or sun exposure time; and attending the monthly assessment including a necessary blood test, in accord with the instructions provided.

1. What will happen to my test samples?

Your test sample including your data and blood sample will be collected in monthly assessment in Earlwood Medical Centre or Bangor Medical Centre. All information will be de-identified with a code to maintain the privacy or confidentiality and will later be analysed by research staff in University of Technology, Sydney.

1. What are the possible benefits of taking part?

Some possible benefits may include a corrected vitamin D level and a healthier lifestyle of diet and exercise, however we cannot guarantee or promise that you will receive any benefits from the D4D research.

1. What are the side effects of the study medications?

You may worry about the dosage of vitamin D used in the current D4D study. However the daily vitamin D dosage (500 IU/d) used in the study is set following the Adequate Intake (AI) of vitamin D in Australia and is considered as a safe level. Hence it is unlike to cause any side effects or symptoms by having this dosage through sun exposure, dietary change or supplementary intake.

Participants in dietary intervention group may experience food allergy or intolerance by adding seafood or eggs into the daily meals, even if you are cleared from the allergy history at the initial screening. Please inform our research team if you experience any severe allergic reaction or food intolerance, we will assess the condition and provide allergy test or medical treatment if necessary, and will exclude you from the current study.

1. What are the possible disadvantages and risks in taking part?

If you have thyroid diseases, liver impairment, renal failure (eGFR <50 ml/min), cancer, osteoporosis, dementia or mental diseases and are taking any relevant medications, study staff will exclude you from the study as they may interfere with diabetes and blood glucose control.

If you become upset or distressed as a result of your participation in the research, the study staff is able to arrange the supportive counselling service or other appropriate support if necessary.

**FOR FEMALE PARTICIPANTS:** Although vitamin D changes in the current study would not harmful to an embryo or foetus, you must not participate in this study if you are pregnant, or trying to become pregnant, or breastfeeding. If you do become pregnant whilst participating in this study you should advise your study doctor immediately. The research staff may withdraw you from the study and advise on further medical attention should this be necessary.

1. What if new information becomes available?

The study team will inform you if any new information becomes available and discuss with you whether you want to continue in the study. If you decide to withdraw, our study team will assist you on that and if you decide to continue with the study, you will be asked to sign an updated consent form.

1. Can I have other treatments during this study project?

Whilst you are participating in this study project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell the research staff about any treatments or medications you are undertaking and going to take, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments.

You should also tell the research staff about any changes of these conditions or treatment during your participation in the research. The study staff will also advise you if the treatments or medications need to be stopped or advise your family doctor during the period you are in the study.

1. What do I do if I wish to withdraw from the research?

If you wish to withdraw from this study please advise the research team. You will be asked to sign a **Withdrawal of Consent Form** and your will be provided a copy of this form including the information sheet .

The research staff will stop to collect additional information from you. **A consent or arrangement of using your data** will be sought from you. With the agreement from you; the data collected up to the time of withdrawing will be included in the study results. However you have your right to have your existed data removed, please contact the research team if you want to do so.

1. Could this study be stopped unexpectedly?

This study may be stopped unexpectedly for a variety of reasons including unacceptable side effects or decisions made in the interests by local regulatory/health authorities.

1. What happens when the study ends?

You don't need to follow the treatments i.e. vitamin D supplements, sun exposure time and meal plan when the study is finished. A study result summary can be provided upon the request once the study is completed, please contact the research team if you would like to have a copy of result summary.

It is suggested to consult with your family doctor about the appropriate future treatment plan for your Diabetes condition after the study.

Part II – How is the study being conducted?

1. What will happen to information about me?

By signing the consent form, you consent to the relevant research staff of collecting and using personal information about you for the D4D study.

All information and documentations will be identified by a code ID number only, to maintain your privacy and confidentiality. All local databases will be securely encrypted and password protected in an independent hard disk, which is only accessed by principal investigators. The hard disk will be backed up twice a month for data security. Study staff will be required to sign agreements to preserve the confidentiality of all participants. Your information will only be used for the purpose of this study project and it will only be disclosed with your permission, except as required by law.

Participant files will be maintained in storage for a period of 7 years after completion of the study. At the end of the period, research data and primary materials will be disposal of either permanently by achieving or destroying. For any type of studies including sub-studies, ancillary studies or any research outside of the D4D, which is using data or samples collected by the D4D, it will require a review and agreement from current principal investigator committee.

For the purpose of this research, information about you may be obtained from your health records held at this and other health services. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in D4D study. Your health records and any information collected and stored by the study staff during the study may be reviewed (for the purpose of verifying the procedures and the data) by the UTS human research ethics committee, regulatory authorities, or as required by law. By signing the consent form, you authorise the release of, or access to, this confidential information as noted above. Information about your participation in this study may be recorded in your health records.

The study results will be released to the participating physicians, referring physicians, and participants. It is anticipated that the results of this study will be published and or presented in a variety of public or professional forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission.

In accord with relevant Australian and/or NSW privacy and other relevant laws, you have the right to request access to your personal information collected and stored by the study team. You also have the right to request any information with which you disagree be corrected. Please contact the research team named at the end of this document if you would like to access your information.

1. What if something goes wrong?

Please contact our research team immediately if you suffer any side effects or complications including distress or psychological injury as a result of this study. Our research team will assist you for assessment and in arranging appropriate medical treatment if necessary.

1. Who is organising and funding the research?

This study is being mainly conducted by Ms Fay YU as part of her PhD study at the University of Technology, Sydney under the supervision of Associate Professor Christopher Zaslawsi and Adjunct Professor Danforn Lim. This study is being funded by the Australian Traditional Medicine Society (ATMS), which is a not-to-profit company.

1. Who has reviewed the study?

This study has been reviewed and given approval by the UTS Human Research Ethics Committee. The conduct of this study at UTS and data collected from Earlwood Medical Centre and Bangor Medical Centre has been authorised by the UTS Human Research Ethics Committee.

1. Further information and who to contact

Please contact our research team if you would like any further information on this study .

If you would like to talk to someone not directly involved with the study for any further information regarding your rights or should you wish to make a complaint to people independent of the study team, you may contact the UTS Ethics Secretariat on 02/9514 9772 and quote the HREC reference number: ET16-0640.

| **Question** | **Who to contact** | **Phone / Facsimile** |
| --- | --- | --- |
| General questions or concerns during the study | Study Coordinator  Principal Investigators | Ms. Fay YU (Dietitian)  02 9554 7788 [contact@D4Dresearch.com](mailto:contact@D4Dresearch.com)  A/Prof Chris Zaslawski  02 9514 7856 or  chris.zaslawski@uts.edu.au  Adj Prof Danforn Lim  02 9554 7788 |
| Questions about the way the research is being conducted | Principal Investigators  Institutional Research Governance Officer | A/Prof Chris Zaslawski  02 9514 7856 or [chris.zaslawski@uts.edu.au](mailto:chris.zaslawski@uts.edu.au)  Adj Prof Danforn Lim  02 9554 7788 |
| Questions regarding side effects | Ms. Fay YU | Ms. Fay YU (Dietitian)  02 9554 7788 or  [contact@D4Dresearch.com](mailto:contact@D4Dresearch.com) |



**PARTICIPANT CONSENT FORM**

**Title The Role of Vitamin D in Controlling and Reducing**

**Diabetes Mellitus Risks**

**Short Title D4D study**

**Project Sponsor UTS**

**Principal Investigator Associate Professor Christopher Zaslawski**

**Site University of Technology, Sydney**

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1. I have read the attached Participant Information Sheet outlining the nature and purpose of the research study and I understand what I am being asked to do.
2. I have discussed my participation in this study with a member of the study team named below. I have had the opportunity to ask questions and I am satisfied with the answers I have received.
3. I have been informed about the possible risks of taking part in this study.
4. I consent to medical practitioners, other health professionals, hospitals or laboratories outside this institution releasing information concerning my condition and treatment which is needed for this study and understand that such information will remain confidential.
5. I freely consent to participate in the research project as described in the attached Participant Information Sheet.
6. I understand that my participation is voluntary and that I am free to withdraw at any time during the study without affecting my future health care.
7. I understand that if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, the investigator/sponsor will request my permission to access my medical records for collection of follow-up information for research and analysis.

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| --- | --- | --- | --- | --- |
| Name of Participant |  | Signature of Participant |  | Date |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Witness to Participant’s Signature |  | Signature of Witness |  | Date |

\*Witness is not to be the Investigator or member of the study team nor their delegate

\* Please note that in the event that an Interpreter is used, the Interpreter is not a witness to the consent process

**All witnesses must be over 18 years of age**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Witness to consent process (GCP Guidelines 4.8.9) |  | Signature of Witness |  | Date |

\*Witness is not to be the Investigator or member of the study team nor their delegate

\* Please note that in the event that an Interpreter is used, the Interpreter is not a witness to the consent process

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Investigator |  | Signature of Investigator |  | Date |



*Participant will be provided with a copy of the Participant Information Sheet and this Consent Form*

*All parties signing the Consent Form must date their own signature*

**WITHDRAWAL OF PARTICIPATION**

**Title The Role of Vitamin D in Controlling and Reducing**

**Diabetes Mellitus Risks**

**Short Title D4D study**

**Project Sponsor UTS:**

**Principal Investigator Associate Professor Christopher Zaslawski**

**Site University of Technology, Sydney**

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I hereby wish to WITHDRAW my intent to participate further in the above research project and understand that such withdrawal will not jeopardise my future health care*.*

|  |  |  |
| --- | --- | --- |
| Participant’s Name (printed) |  |  |
| Signature |  |  |
| Date |  |  |

In the event the participant decided to withdraw verbally, please give a description of the circumstances. Coordinating Investigator to provide further information here:

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| --- |
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|  |  |  |
| --- | --- | --- |
| Participant’s Name (printed) |  |  |
| Signature of Investigator |  |  |
| Date |  |  |

Coordinating Investigator to sign the withdrawal of consent form on behalf of a participant if verbal withdrawal has been given:

*Participant will be provided with a copy of this Withdrawal of Consent Form*