IRB NUMBER: 20688031815

LOYOLA UNIVERSITY CHICAGO
HEALTH SCIENCES DIVISION
MAYWOOD, ILLINOIS
DEPARTMENT OF SCHOOL OF NURSING

INFORMED CONSENT

Participant's Name: _____

Medical Record Number: _____

PROJECT TITLE: Can Vitamin D3 Improve Cognitive Function in Individuals with Type 2 Diabetes? (THINK-D)

THE APPROVAL FOR THIS PROJECT EXPIRES ON 02/21/2019.

Participant Information

PRINCIPLES CONCERNING RESEARCH: You are being asked to take part in a research project. It is important that you read and understand the principles that apply to all individuals who agree to participate in the research project described below:

1. Taking part in the research is entirely voluntary.

2. We do not know if you will benefit from taking part in the research but the knowledge obtained may help others.

3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.

4. If during your participation in the research project new information becomes available which would affect your being in the research project (such as better treatments or the side effects of the treatments), your doctor will discuss this new information with you and will help you make a decision about your continuing in the research.

The purpose of the research, how it is to be done, and what your part in the research will be is described below. Also described are the risks, inconveniences, discomforts and other important information which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions you have about this research with the staff members.

PURPOSE OF RESEARCH: You are being asked to participate in this study because you have type 2 diabetes and may have episodes where you have trouble thinking, remembering, and concentrating. There is research evidence that people with diabetes are more likely to have

problems with cognition which refers to "thinking" which is associated with difficulty in understanding, learning, remembering, and paying attention.

This purpose of this study is to determine if vitamin D supplementation can improve cognition.

This research is sponsored by Mary A. Byrn, PhD, Assistant Professor at Loyola University Chicago Marcella Niehoff School of Nursing through a grant provided by The University of Chicago.

Bio Tech Paramacal, Inc. will be supplying the vitamin D3.

Approximately 80 people will participate in this research.

DESCRIPTION AND EXPLANATION OF PROCEDURES: If you agree to participate in this study, you will be randomly assigned, like the flip of a coin, to receive either 50,000 IUs of vitamin D3 weekly or 5000 IUs of vitamin D3 weekly. You will not be told which dose of the vitamin D you will receive and you will not be able to choose which group you will be assigned to. The 50,000 IUs of vitamin D3 weekly is the study dose and 5000 IUs approximates the standard dose of vitamin D3 currently recommended by the Institute of Medicine in a given week.

Neither you nor your doctor will be able to choose which dose of vitamin D3 you receive. Your chances of being assigned to either of the vitamin D3 doses is equal. You have a 50/50 chance of receiving 50,000 IUs of vitamin D3 or 5,000 IUs of vitamin D3.

If you agree to participate, you will be asked to complete the following research activities over 3 months.

Visit One (Baseline Eligibility Enrollment)

- This visit should take approximately three hours or less to complete
- We will review this consent document with you and answer any questions you may have about the study.
- We will review your medical history and medication use. If you are taking medications, we will review your medications with you.
- Vital signs (blood pressure and heart rate), body weight and height will be measured.
- You will have a blood sample (about 2 tablespoons) taken from a vein in your arm to tell us your vitamin D and factors that impact your vitamin D (calcium). We will also assess your inflammatory markers, and kidney and liver function.
- We will assess your diabetes by doing a finger stick to measure your HbA1c.
- A meal or snack will be provided to you following the blood draw.
- You will be asked to complete paper/pencil tests and verbal tests that assess your thinking abilities and problem solving skills. You will also be asked to complete a questionnaire booklet that asks about your social support, functioning abilities, and factors that can impact your vitamin D level like sun exposure, diet, and sleep.
- You will have a nursing physical assessment.

Your HbA1c will be measured by a fingerstick in our office. The other labs will be measured in a laboratory. The results from the lab work will provide us with information about your eligibility in the study. If you are not eligible to continue participation in the study, we will notify you by phone and provide you with the reason as to why you are not eligible. If you are eligible to continue participation in this study, we will ask you to return to Loyola in two weeks for another visit.

Visit Two (Pick-Up Vitamin D)

- This visit should take approximately two hours or less to complete
- Vital signs (blood pressure and heart rate) will be measured
- You will also be asked to complete the same verbal tests that you completed on your first visit.
- You will pick up your vitamin D3 supplement prepared by the pharmacist. You will take this supplement every week for three months.
- You will receive a message (phone, text, or email) to remind you to take your capsule every week and to call use if any questions or concerns.

Phone Call (approximately 4 weeks following the start of the vitamin D supplement)

- This should take approximately 15 to 30 minutes to complete
- You will be asked to report any side affects you have experience since starting the vitamin D3 supplementation
- You will be asked to complete two thinking tests over the phone.

Visit Three (Final Visit)

- This visit should take approximately three hours or less to complete.

You will complete all the activities that you did on your baseline visit which includes: Vital signs (blood pressure and heart rate), measurement of height and weight, collection of blood specimens, questionnaires and verbal tests previously done, and a nursing physical assessment
Unscheduled visits (can occur at any time)

If you are unable to tolerate the vitamin D3 supplement or have any side effects, please call us immediately. If this occurs, you may be asked to return to Loyola for an unscheduled visit. At this visit, you may be asked to temporarily or permanently stop the vitamin D3 supplement. At these visits, we may take a blood sample, measure your blood pressure and heart rate, review other medications you are taking and review side effects you have been experiencing.

Telephone calls from you

While you participate in this study, we ask that you call us immediately if:

- You are admitted to a hospital
- You plan to participate in any other research studies
- You are prescribed any new medications

- You are unable to understand the activities of the study
- You become pregnant

A description of this clinical trial will be available at *http://www.ClinicalTrials.gov,* as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

RISKS/DISCOMFORTS: It will be important that you do not take other vitamin D3 supplements while in the study as you may be taking 50,000 IU of D3 weekly. Published reports suggest that 50,000 IUs per day of vitamin D (note that the proposed study dose is 50,000 IU **per week**) can increase vitamin D and cause high calcium levels, this is called hypercalcemia. We will be checking your calcium level at the blood draw visits to evaluate if you have hypercalcemia.

The dose at which the Vitamin D is being administered has minimal side effects. Side effects most commonly reported include: bone pain, constipation, dry mouth, headache, nausea, and vomiting. Since vitamin D may increase serum calcium, there is the potential to develop kidney stones. If you are unsure if you should participate in the study, you should speak with your doctor first. We will be monitoring for side effects upon your study visits and with phone calls.

It is important that you understand that if you need assistance with the management of your emotions such as medication or counseling, you should talk to your health care provider about this. If we assess that you have thoughts of harming yourself during the study, we will contact a psychiatrist at Loyola University Medical Center. Signing this consent document will give us permission to contact a psychiatrist if that situation should arise.

You may experience a slight discomfort when the blood is drawn for lab tests.

In addition to the risks mentioned above, there may be unknown or unanticipated risks associated with participating in this study.

REPRODUCTIVE AND SEXUAL ACTIVITY INFORMATION: The intervention in this study could affect a developing baby. Therefore, you cannot participate in this research project if you are pregnant or breast feeding.

If you are a woman of childbearing potential, a pregnancy test will be done to make certain that you are not pregnant before beginning the study.

Both men and women who are able to have children must use an effective method of preventing pregnancy while participating in this study.

In addition, as study medications may remain in the body for a period beyond their administration, you will be asked to continue to employ an effective method of preventing pregnancy for 90 days after you have finished taking the study medication. You are encouraged to discuss your preferred method with Dr. Mary Byrn. She will answer any questions you have

regarding effective methods of preventing pregnancy. It is important that you consult with your physician because some study medications may affect the effectiveness of various methods of preventing pregnancy.

If you become pregnant, suspect that you have become pregnant, or you have fathered a child during the study, notify Dr. Byrn immediately.

BENEFITS: We do not know if you will benefit from participating in this study. However, in the future, other people may benefit from this study because of the knowledge gained.

ALTERNATIVE TREATMENTS: You do not have to participate in this research project to receive care and treatment at Loyola University Medical Center.

You can choose the treatments in this project without participating in the project.
Your doctor has discussed other options with you along with their risks and benefits.

FINANCIAL INFORMATION: Neither you nor your insurance provider will be billed for any procedures that are performed exclusively for this research study. The vitamin D3 supplementation will be provided free of charge. You will be responsible for any usual out-of-pocket expenses such as co-pays, coinsurance or deductibles for standard visits to your health care provider.

You will receive compensation for your participation in the study. Parking will be provided for each in-person visit. Also, you will receive $20.00 for completing Visit one, $25.00 for completing Visit two, and $30.00 for completing Visit three. If you receive payment for participating in this research, personal information about you, including your name, address, and Social Security number, will be released to the Loyola University Chicago Accounting Office for the purpose of recording the payment and for tax reporting to the United States Internal Revenue Service (IRS). You will need to complete a W-9 form. This form will be provided to you. If you choose not to complete the W-9, you will not receive reimbursement.

RESEARCH RELATED INJURY: In the event that you are injured or have side effects as a result of participating in this research project, your doctor will take the necessary steps to treat the problem. There are no funds available from Loyola University Medical Center, Loyola University Health System or Loyola University Chicago to pay for the cost of care of the problem. You will be financially responsible for the cost of care of any problems. By signing this form, you are not giving up any legal rights to seek to obtain compensation of injury.

WITHDRAWAL OF CONSENT: Your consent to use and disclose your medical information for the purpose of this research study is completely voluntary. You can withdraw your consent for LUMC to use and disclose your information and your consent to participate in this study at any time without affecting your ability to receive care and treatment at LUMC unrelated to the research study. Withdrawal means that all study procedures and follow-up will stop and we will not send any more information about you to the sponsor of this research or its designees. However, information already used and disclosed to the research sponsor prior to the time of

your withdrawal from this study may continue to be used and disclosed by LUMC and the sponsor.

For your safety, we may ask that you return to clinic one more time for an unscheduled visit. We will also ask that you return any unused study medication. If you withdraw from the study, you will need to contact your physician(s) to discuss what other options may be available.

If you withdraw from the study, we will ask that you sign the form attached to this consent and send it to Mary Byrn, PhD, RN or give it to the study staff. Your withdrawal from the study will not have any affect on any actions by LUMC taken before the attached form is received by LUMC.

The study investigator, the Institutional Review Board, the regulatory authorities, or the sponsor, may terminate the study at any time with or without your consent.

The research team may choose to take you out of the study because of unexpected or serious side effects, treatment non-compliance, or because you are not taking the medication as you were instructed. You may also be removed from the study if the research team feels that you are not benefiting from the study treatment.

CONSENT

I have fully explained to _____ the nature and purpose of the above-described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability. I may be reached at 773-508-8973 .

_____Date:____/_____/____
Signature

Mary Byrn, PhD, RN, the principal investigator for this study, or her associates will be available to answer any questions you may have. Mary Byrn can be reached at: 773-508-8973.

If you ever feel that you have been injured by participating in this study or if you have any questions concerning your rights as a research participant, you may contact either Kenneth Micetich, MD, Chair of the Institutional Review Board for the Protection of Human Subjects-Loyola University Chicago Health Sciences Division, at 708-216-2633 or the Director of the Human Research Subjects Protection Program at 708-216-4608.

Although you have the right to revoke this authorization, you accept that such revocation will not apply to any uses and disclosures of your information that are described in the Loyola University Health System Notice of Privacy Practices or otherwise allowable under any Federal or State laws.

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

_____Date:____/_____/____
Signature: Participant

_____Date:____/_____/____
Signature: Witness

PROJECT TITLE:

REVOCATION OF AUTHORIZATION TO
RELEASE PROTECTED HEALTH INFORMATION (PHI)

I, _____, hereby revoke my consent to participate in the study titled, "Can Vitamin D3 Improve Cognitive Function in Individuals with Type 2 Diabetes? (THINK-D)", at Loyola University Medical Center ("LUMC"). I also revoke my consent to release information I provided to LUMC that allowed LUMC to use and disclose my medical information to as outlined on the consent form, which I signed on ____/_____/____ (INSERT DATE CONSENT WAS SIGNED ORIGINALLY). I understand that this revocation does not apply to any action LUMC has taken in reliance on the consent I signed earlier.

_____Date:____/_____/____
Signature: Participant

Please return this form to:

Mary Byrn, PhD, RN
School of Nursing
Loyola University Medical Center
2160 South First Avenue
Maywood, Illinois 60153