

INFORMED CONSENT FORM

I. GENERAL INFORMATION:

Study title: **“Evaluate the Results of Fall Prevention in Older Adults With Type 2 Diabetes Mellitus.”**

ICF Version: 1.0. October 11, 2023

Principal investigator: Dinh Trung Hoa

Site: National Geriatric Hospital

Sponsors: None

Timeline: From January 2024 to December 2025

Official site: National Geriatric Hospital

Participant's code:

II. INTRODUCTION

Dear sir/madam, I would like to thank you for taking the time for this interview.

My name is **DINH TRUNG HOA**

I am investigator of this study, I am working at National Hospital of Endocrinology

I am doing a research with its title: Evaluate the Results of Fall Prevention in Older Adults With Type 2 Diabetes Mellitus

Two objectives of the study:

1. Describe the current situation of falls, the risk of falls, and some related factors in elderly type 2 diabetic patients

2. Evaluate the results of fall prevention and related factors in the study population..

I have been thoroughly trained in the research implementation process, ensuring compliance with ethical aspects of research and good clinical practice.

I am communicating with you about this study to invite you OR your guardian to participate in this study with us.

You are invited to participate in the study because you has type 2 diabetes diagnosed according to the American Diabetes Association (ADA) 2022 criteria, age > 60 who is at risk of fall

You have the right to participate or not participate in the research, you can stop participating in the research whenever you want. Your failure to participate or stop participating in the study will not affect your medical care and treatment and other benefits you are currently having.

I will provide you with full information about this research. During the process of providing information, if you have any questions, you can ask me to answer immediately to ensure you clearly understand the research.

III. RESEARCH INFORMATION

1. Why should this research be done?

Falls and related injuries are a problem that cannot be overlooked because they cause an increase in post-fall complications such as disability, hospitalization due to injury, and even death. In high-income countries, approximately 1% of healthcare expenditures are fall-related expenditures. The cause of falls is often multifactorial, and in many studies, diabetes mellitus (DM) has been shown to be closely related to an increased risk of falls. Therefore, it is essential to evaluate risk factors and prevent falls for elderly diabetic patients.

2. What do I OR my child/grandchild/guardian need to do if I agree to participate in this research?

Sign the consent form to participate in the study

If you agree to participate in this research, we will ask you to do the following activities:

- Outpatient examination at the National Geriatrics hospital
- Take blood for testing (basic biochemical parameters) three times at the first visit and again after 3 and 6 months.
- Measure parameters such as Times Up and Go (TUG), Berg Balance Scale (BBS), and Functional Reach Test (FRT) to assess the risk of fall
- Receive instructions on basic diet and exercise and prescribe medications as recommended
- You will be given exercise equipment, instructions on how to follow Otago training program, and several exercise supervisions at home

3. How many people will participate in this study like me OR my child/grandchild/guardian?

For 1st objective, expected sample size of 323 elderly type 2 diabetes patients coming for examination at the National Geriatric Hospital.

For 2nd objective, patients will be screened and assessed for fall risk after recruitment in the first objective. Patients with an average and high risk of falling will be recruited, and the expected sample size is 80.

4. What risks/disadvantages may I OR my child/grandchild/ guardian face by participating in the study?

Studies conducted worldwide on fall prevention through the Otago exercise program have not recorded any incidents during exercise. Besides, the Otago program is specifically designed to practice at home to prevent falls for the elderly, so it is very safe for patients participating in the study.

5. If there is a direct risk/disadvantage to my health, how will I OR my child/grandchild/guardian be cared for?

Me, other investigators, doctors and nurses at the National Geriatric hospital or when medical staff supervise patients exercising at home, they will directly give support care and treatment.

6. What benefits can I OR my child/grandchild/parent could get by participating in research?

Patients participating in the study will receive:

- Comprehensive geriatric evaluation examination by specialists
- Consulting on treatment and prescribing medications as recommended
- Applying new methods to treat diseases (Otago training program)
- Monitor and evaluate treatment outcomes periodically

7. If I do not participate in this study, will my condition be treated differently?
DO NOT APPLY

8. Will I be informed about test results from this study? How I could receive results?

Results of tests and examinations during the research process will be notified directly to research participants. The method of informing results ensures the confidentiality and accuracy of test results.

Do you OR the research participant's legal guardian wish to receive the test results?

_____ YES

_____ NO

9. What are the security measures for information/records relating to me personally OR my guardian?

All research participant information is carefully protected to maintain privacy and sensitive patient information could not leak out.

10. Which individuals/organizations can inspect my personal records?

The National Geriatric Hospital is the official site of study and has agreed to allow the implementation of the research questionnaire, as well as the collection of research data. Hanoi Medical University is the code issuer and the ethics council is the governing and managing unit of the project.

11. In case I have further questions about this study, who should I contact?

- About the research: Contact directly with principal investigator Dinh Trung Hoa - Phone number: +84858038888
- In case of injury related to research: Contact principal investigator Dinh Trung Hoa directly - Phone number: +84858038888
- Regarding the rights of research subjects : Contact the Ethics Council of Hanoi Medical University - Phone number: 02438523798

Thank you very much for participating in the discussion!

Day month year.....

Information provider

(Sign and write full name)

Day month year.....

Person to whom information is provided

(Sign and write full name)

VOLUNTEER APPLICATION TO PARTICIPATE IN RESEARCH

I,

Declaire that

- I have read the information given for the study " **“Evaluate the Results of Fall Prevention in Older Adults With Type 2 Diabetes Mellitus.”**" at the National Geriatric Hospital, ICF version [Digital version 1.0 on October 10, 2023,], and the research staff explained to me about this study and the procedures for registering to participate in the study.
- I had the opportunity to ask questions about this study and I was satisfied with the answers and explanations given.
- I have had the time and opportunity to consider participating in this study.
- I have understood that I have the right to access the data described in the information leaflet by responsible persons.
- I understand that I have the right to withdraw from the study at any time for any reason.

I agree that my primary care physicians (if any) will be notified of my participation in this study.

Check the appropriate box (this decision will not affect your ability to participate in the study):

I

Do

Do not

agree to participate in this study

Signed by participant OR guardian (<i>for research on participants who are children or the elderly who does not have decision-making capacity</i>)	Day/month/year
In necessary,	
* Signature of witness	Day/month/year
* Write the name of the witness	
Signature of the investigator	Day/month/year
Write the name of the investigator:	

