Information for the participant and Informed consent form

Title of the study: Stay Healthy-Cardiovascular Risk Prevention-Young50

Acronym: YOUNG50

Funded by : European Union and Directorate of Health / Ministry of Health Luxembourg

Project coordination: Directorate of Health and Luxembourg Institute of Health

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1 INTRODUCTION

You have been invited to participate in a pilot study about the screening and prevention of cardiovascular risks. The purpose of this document is to provide you with some information on the study to help you decide whether or not you would like to take part. Your participation is voluntary. If you decide to take part, you may withdraw at any time without having to give any reason. Similarly, should your general practitioner deem your state of health unsuitable at any point, he/she will ask you to withdraw from the study. This study received a favorable opinion from the National Research Ethics Committee on 06/07/2022. However, you should not take this latter information as an incentive to participate in this study.

YOUNG50 is a program co-funded by the European Union's Health Programme (2014-2020) and the Directorate of Health of Luxembourg. The Luxembourg Institute of Health (LIH) works along with the Directorate of Health to conduct the study.

2 WHAT IS THE PURPOSE OF THE STUDY YOUNG50?

YOUNG50 is a study for screening and prevention of cardiovascular disease (CVD) risk factors. Cardiovascular risk is the probability of developing a cardiovascular or neurovascular disease or accident (myocardial infarction or stroke). Cardiovascular diseases result from the deposit of fat on the walls of the arteries. These deposits form atheromatous plaques, which can block the arteries and end up interfering with the blood flow. These atherosclerotic plaques can form blood clots, which can break off at any time. Blood circulation can then be reduced in all organs and in particular vital organs such as the brain or the heart. This is called atherosclerosis.

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There are eight major CVD risk factors considered for the YOUNG50 study, falling into two groups:

- behavioural risk factors (diet, low physical activity, smoking, alcohol use);
- medical risk factors (high systolic blood pressure, high total cholesterol, high fasting plasma sugar, and high body mass index (BMI)).

YOUNG50 main objective is to transfer and adapt an Italian public health program called CARDIO50 for screening and prevention of CVD risks factors among 50-years-old, in three European countries: Lithuania, Romania, and Luxembourg.

In Luxembourg, YOUNG50 is part of the upcoming national plan on cardio-neuro-vascular diseases in Luxembourg. Beyond screening in people aged 50, the project aims to:

- activate an integrated model of assistance to help modify or reduce risk factors among healthy subjects
- promote interventions to modify unhealthy lifestyles
- identify problems or issues and areas for improvement of the program.

Your participation in YOUNG50 will enable us to provide preliminary results that will be very useful for setting up an effective national plan against cardio-neurovascular diseases in Luxembourg.

This study aims to enrol 50 to 100 participants in Luxembourg.

3 HOW DID YOU GET MY CONTACT DETAILS?

You have been invited to take part because you were selected from the patient records of your general practitioner.
After you have been selected, your general practitioner contacted you about sharing your details with the LIH in order to invite you to this study.
If you did not object, your doctor has shared a limited amount of your personal data so the LIH could invite you to take part in this survey. This data includes your name, address and gender.
No medical or health information has been shared. This information remains strictly confidential between you and your general practitioner.

We will keep your personal data confidential and will only use your contact details to invite you to take part in the study.

If you agree to participate in the study, your contact details will be destroyed two months after the end of the study.
If you refuse to participate in the study, your contact details will be destroyed two months after the end of the recruitment period of the study.

4 HOW DO I TAKE PART?

The study is composed of several steps (see **Error! Reference source not found.**):

1. Read carefully the **invitation letter**
2. Use the **link** in the invitation letter and the personal **token** to access an online questionnaire
3. Fill the **consent** form
4. Complete the **questionnaire** to assess your lifestyle habits. It should take you around 15 minutes to complete.

5. Do a medical **check-up visit**.
    - Plan your **blood test** (dosing of cholesterols and blood sugar levels, an average total of 10 mL will be necessary for the analyses) in a medical laboratory of your choice using the prescription attached.
    - **Please contact LIH** (+352 26970-747 (MON-FRI, 9 AM – 1 PM) or email young50@lih.lu) to schedule an appointment with your **general practitioner** (GP).This appointment will be related to the YOUNG50 study only.
6. During your appointment, please bring the results of your blood test. Your GP will measure your arterial pressure, your body mass index and waist circumference.
   Your GP will have access to a report of your answers to the questionnaire. Depending of all this information, your **cardiovascular risk level** will be calculated:

    - If you have an exclusion criteria or if you have no or low risk, the study ends.
    - If you have moderate or high risk, your GP will give you some **recommendations and information** about the more suitable actions to reduce your risk level. You will choose **one objective.**

7. A follow up visit with your GP will be organised 6 months after the first appointment. A reminder letter will be sent to you one month before the date of your **follow up visit**. LIH will contact you to schedule an appointment with your **general practitioner**. For the follow up visit, you will answer the same online questionnaire on young50.lu, do the same blood test and visit your GP.

After each visit, you will be invited by letter to answer a satisfaction questionnaire about the study. The satisfaction survey is very important for us to get your feedback and improve the future national program. Please feel free to add any comment you might have in the satisfaction survey. As the rest of the data of the study, your answers will remain anonymous when analysed.

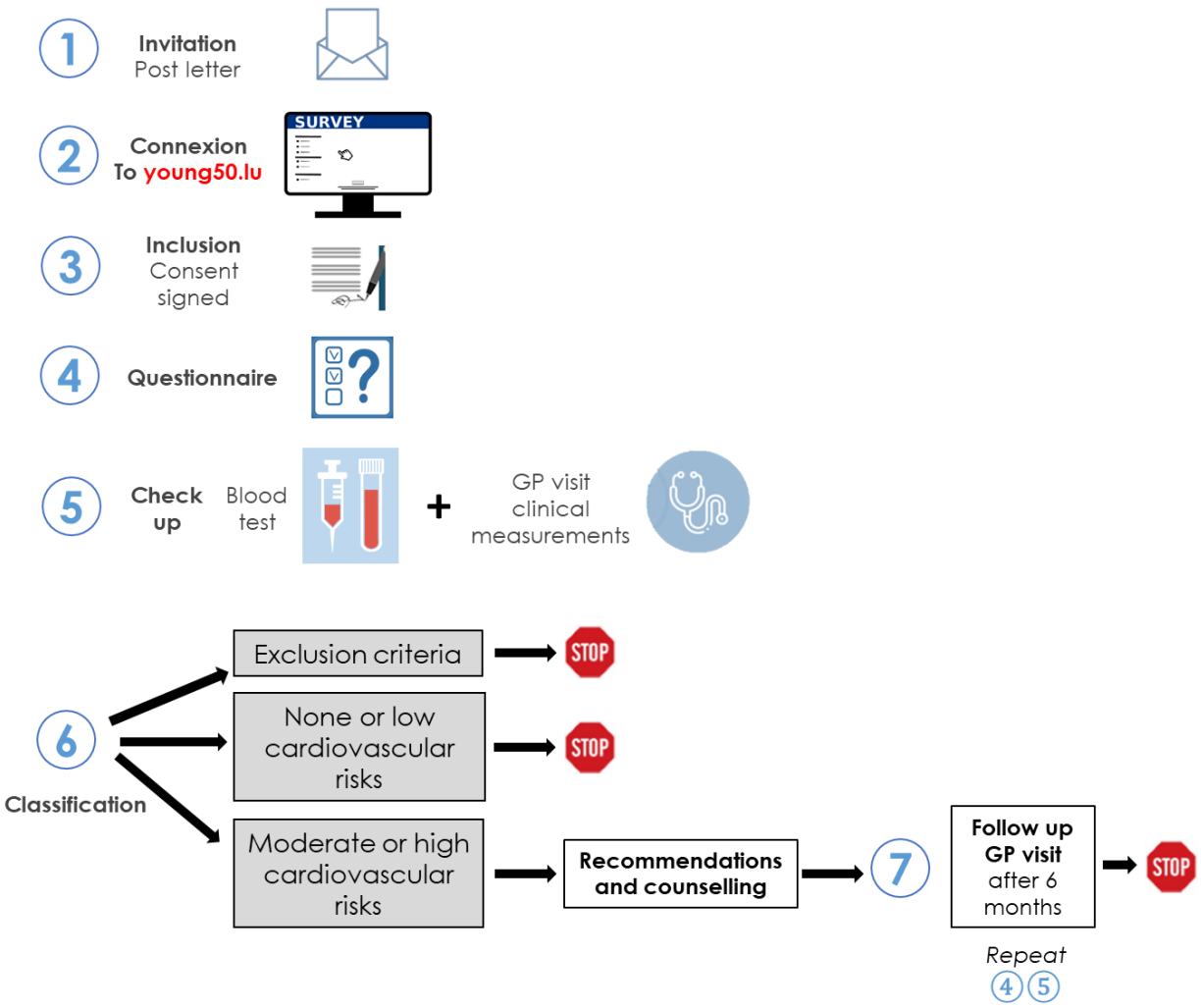

Figure 1 - Steps of the study

Your name will not be attributed or attached to the health information collected in the study. Instead, a number code will be assigned to each person participating in the study. This number is only known by the Medical Investigators and her delegates, of the LIH study team.

5 USE OF MY SAMPLE

As the samples for the measure of cholesterols and blood sugar levels will be analysed in the private medical laboratory of your choice, no sample will be kept for the use of the YOUNG50 study.

6 WHAT ARE THE POSSIBLE RISKS?

The blood test for this study will involve a minimal risk similar to that of giving an equivalent amount of blood for other medical tests. There is a small risk of discomfort, bleeding or bruising from the blood drawing.

No other risk is associated with the procedures specific to the study.

If you decide to withdraw from the study, your GP will ensure that you continue to be offered the very best medical care.

7 WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?

By participating in this study, you will benefit from a cardiovascular risk check-up and personalised recommendations from your GP. Your participation is voluntary. You will receive no form of compensation for your involvement or for any subsequent developments resulting from the study.
However, your participation is important to us, as you will be able to provide the information we need to improve research on cardiovascular risk prevention. It will allow evaluating the effectiveness of this project on a national level. It will provide preliminary results that will be very useful to identify problems and potential improvement areas for the program. It will be used to set up an effective national plan against cardio-neuro-vascular diseases in Luxembourg.

8 WHAT IS THE PURPOSE OF STORING MY DATA AND ITS FINAL USE?

If you choose to participate in the study, we will collect your personal data (contact information, health information, lifestyle habits, socio-demographic data, satisfaction) from electronic questionnaires, blood test results and a clinical assessment by your doctor.
The participants' data will be used to evaluate this screening and prevention study and to identify problems and areas for improvement. The results will be included in a final study report.

9 CONFIDENTIALITY AND PROTECTION OF PERSONAL DATA

Your data will be treated as strictly confidential. It will also be pseudonymised, meaning that your name will be replaced by a confidential reference code. This code alone will not directly identify you and will only be used to process your data for scientific purposes. Your identity will never be disclosed in any document produced for the public or for other institutions. Apart from your GP, only the principal medical investigator and the LIH administrative assistant will have access to your identity in a confidential and secure manner.
If you agree to participate in the study, your contact details will be destroyed two months after the end of the study. Your pseudonymised data will be stored at LIH, in accordance with the applicable legal provisions, for a period of 2 years following the end of the data collection.
If you refuse to participate in the study, your contact details will be destroyed two months after the end of the recruitment period of the study.
For more details on the personal data protection, please read the information document describing how we will process your personal data as part of this study (see Data Protection Notice).

10 COSTS ASSOCIATED WITH YOUR PARTICIPATION

The sponsor has arranged to compensate your GP for the time that he devotes to the study and for all associated consultations and scheduled examinations. If you decide to take part, neither you nor your insurance company will be entitled to any form of remuneration. The screening visits with your general practitioner will be covered as part of this study. You will only be invoiced for the standard medical services you receive to treat your clinical condition. However, you will be reimbursed in accordance with the currently applicable legal provisions.

11 INSURANCE

The insurance policy taken out by LIH will cover its liability in this study.

12 YOUR DECISION TO TAKE PART

Your decision to accept or decline to take part in this study will in no way influence the quality of the care you are given. If you choose to take part, you may withdraw at any time without giving a reason.

Before you take part in the study, you will need to provide your consent by completing the form, at the beginning of the questionnaire.

If you would like further information on the study, please contact our helpline number at LIH on +352 26970-747 (MON-FRI, 9 AM – 1 PM) or email young50@lih.lu .

Informed consent form

- I declare that I have read and understood the information provided in the information notice.
- I have had enough time to consider my involvement in the study and to discuss it with a person of my choice, such as my general practitioner or a member of my family. I have had the opportunity to ask all of the questions that have occurred to me in relation to the study and I have received satisfactory responses to each of them.
- I am aware of what is expected of me as a participant in this study.
- I am aware that my participation in this study is entirely voluntary and that I am free to withdraw at any time without giving a reason for my decision and without being held liable for any material or non-material damages. I will only need to inform my GP or the study team of my decision.
- I am aware that there will be no secondary use of my data.
- I accept that the results from this study may be disclosed and reported in scientific publications. The way in which these results are presented will in no way enable me to be identified, either directly or indirectly.
- As described in the information document on the processing of my personal data as part of this study, I understand that any personal information gathered in relation to this study will be treated as strictly confidential, in accordance with the General Data Protection Regulation (EU) 2016/679 of 27 April 2016 (known as the GDPR) and all subsequent texts replacing or supplementing this Regulation (in particular, Luxembourg's law of 1 August 2018 on the organisation of its National Commission for Data Protection and the implementation of the GDPR).
- I have received information explaining how my personal data will be processed as part of this study (see Data Protection Notice).

	YES	NO
I willingly agree to take part in this study under the terms set out on the information notice.	☐	☐

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