Title of the study:

Health and Lifestyle in the Maas-Rhine Region and the effects of a physical activity program: the Interreg Maas-Rhine Blue Zone project.

Sponsor:

Hasselt University (Martelarenlaan 42, 3500 Hasselt, Belgium)

Research institute*:*

- Hasselt University – Faculty of Health and Life Sciences - Biomedical Research Institute (BIOMED, Agoralaan, Gebouw C, Diepenbeek, België)

- Université de Liège – Faculté de Médecine, Département des Sciences de l'activité physique et de la réadaptation - Research Unit for a life-Course perspective on Health and Education (RUCHE), Intervention et gestion en activités physiques et sportives - Bât. B21 Quartier Blanc Gravier, allée des Sports 2, 4000 Liège 1, Belgique

Medical Ethics Committee:

- Central Committee : Comité d'Éthique Hospitalo-Facultaire Universitaire de Liège

- Local Committee : Commissie Medische Ethiek, Universiteit Hasselt

Local researchers:

- Dr. Ine Nieste (physiotherapist and researcher Hasselt University) (ine.nieste@uhasselt.be)

- Dr. Aude Aguilaniu (physiotherapist and researcher Université de Liège) (aude.aguilaniu@uliege.be)

- Dr. Chiel Hex (physician and researcher Hasselt University)

- Dr. Laetitia Buret (médecin et chercheur Université de Liège)

Additional researchers :

- Hasselt University: Prof. Dr. Bert Op 't Eijnde, Prof. Dr. Chris Burtin, Prof. Dr. Hanne Kindermans, Prof. Dr. Katleen Bogaerts, Dr. An Voets, Dr. Kim Pannemans, Dr. Wouter Franssen, Drs. Jen Vanherle, Drs. Lena Fonteyn.

- Université de Liège: Prof. Dr. Alexandre Mouton

I Necessary information for your decision to participate

Introduction: What does the study involve?

You are invited to participate in a study on the health and lifestyle of people in the Maas-Rhine region, an area that spans Belgian Limburg, Dutch Limburg, Liège, and Aachen. Previous studies have shown significant differences in life expectancy between people in these areas, despite the fact that they are close to each other and share a common history.

The goal of this study is to understand how the health of people in these regions differs. We will do this by measuring two key pillars of health: physical health, such as cardiovascular health, and mental health. Additionally, we will examine various lifestyle factors that influence these pillars of health, such as physical activity, diet, sleep quality, stress levels, social interactions, and the use of harmful substances like alcohol and cigarettes. Finally, we want to investigate the effect of a physical activity program on these health pillars and lifestyle factors.

This study provides insights that can help policymakers work more effectively towards improving health and lifestyle in these regions.

Before you decide whether to participate in this study, we would like to provide you with more information about what this entails organisationally, as well as the potential benefits and risks. This will enable you to make an informed decision. This is referred to as "informed consent." We kindly ask you to read the following pages of information carefully. If you have any questions, you can contact the researchers via the mail address IMRbluezone@uhasselt.be. This document consists of three sections: (I) essential information you need to make your decision, (II) your written consent, and (III) appendices with more details about specific aspects of the basic information.

If you participate in this clinical study, you should know the following:

- This clinical study is initiated after evaluation by multiple ethical committees.
- Your participation is voluntary; there can be no form of coercion. Your signed consent is required for participation. Even after you have signed, you can inform the researcher if you wish to withdraw from the study at any time.
- The data collected as part of your participation will be kept confidential. Your anonymity will be ensured when results are disclosed and published.
- You will not be charged for any specific actions, visits, or examinations related to this study.
- Insurance has been arranged in case you experience any harm during your participation in this clinical study.
- If you require additional information, you can always contact the researcher or a member of her team.

Additional information on "Rights of the Participant in a Clinical Study" can be found in Appendix III.

Objective and Description of the Study

Research shows significant differences in life expectancy between people in different areas of the Maas-Rhine region. Lifestyle differences may play a role, but little cross-border research has been done on both lifestyle factors and objective physical and mental health in this region. Often, research is conducted per country, resulting in a lack of broader comparison across the entire Maas-Rhine region. Therefore, this study focuses on the following questions:

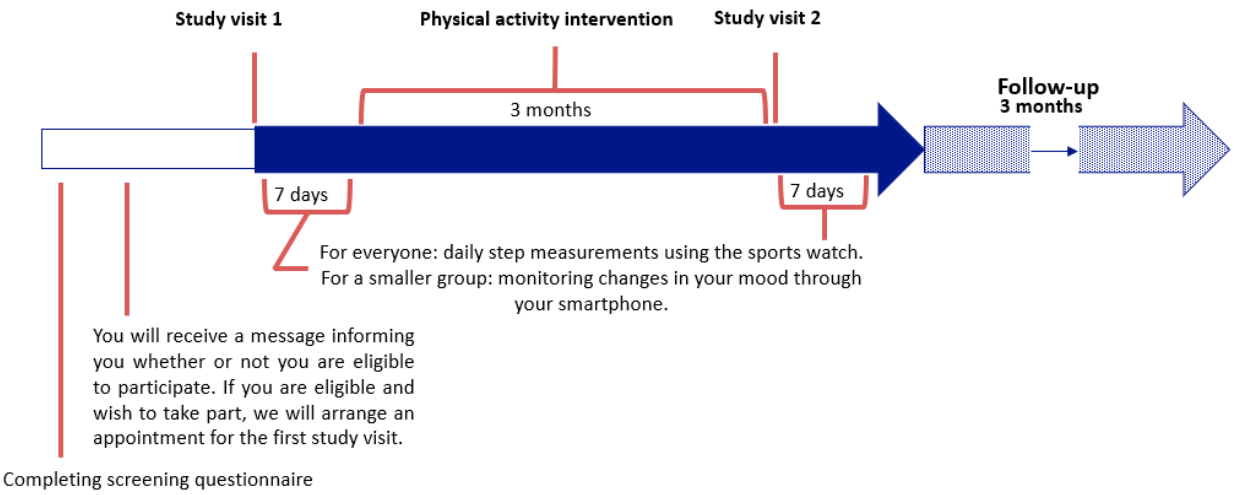
1. Are there differences in physical and mental health between people in different areas of the Maas-Rhine region?
2. Are there differences in lifestyle factors between these groups?
3. What is the effect of a physical activity intervention on physical and mental health and lifestyle factors, and do these effects differ by area?

The results will help policymakers improve health and lifestyle across the region through cross-border initiatives.

A total of 1,000 participants will be recruited for this study in the Maas-Rhine region, with 250 participants per region (Belgium-Limburg, Netherlands-Limburg, Liège, and Aachen). Additionally, a smaller group of 75 participants per region will also be asked to answer a few questions at 8 different times throughout the day using a smartphone, aiming to assess how they feel physically and emotionally at that moment. This is to gain an understanding of how physical and emotional well-being changes over the course of the days.

How will the study proceed?

Based on the screening questionnaire you completed, it has been determined whether you are eligible to participate. For this, your educational level was also taken into account, as it influences health and lifestyle factors. This is why we aim to select a representative group from the Maas-Rhine region. This means that a maximum of 25% of participants may have completed an education beyond secondary school or vocational training, such as a university or higher education. If you are eligible and choose to participate, you will be invited for two study visits: one before the start of the physical activity intervention, and one after its completion. For participants from Belgian Limburg, these study visits will take place in Genk (address on page 15). For participants from Liège, these study visits will take place in different locations (see page 15). The physical activity intervention lasts 3 months between the two study visits. After the second study visit, you will continue to be monitored for 3 more months via the watch. The following figure shows an overview of the study procedure.



Study visit 1 (before the physical activity intervention)

- During the first study visit, we will explain everything about the study and you will be able to ask any questions. If you decide to participate, we will sign the consent form together, which you can find on page 10-12.
- You will need to fill out some questionnaires about your health and lifestyle factors. This will be done on the computer, and someone will be present to assist you if necessary. Afterward, your blood pressure, height, weight, hip and waist circumference will be measured, and a blood sample will be taken (2 small tubes).
- You will receive the sports watch needed for the exercise programme, and we will assist you in connecting the watch to your smartphone.
- If you are selected to answer a few questions at various times throughout the day about how you feel physically and emotionally at that moment, you will be given instructions on how to use the app for this purpose. You will then receive 8 notifications per day on your smartphone for 7 days to indicate how you feel.
- Study visit 1 lasts approximately 1.5 hours.

- After the first visit, we will measure how many steps you take on average per day for 7 days using the sport watch. We will use this to create a personalised physical activity intervention for you. It is important that you continue to take your usual amount of steps, as you are accustomed to.

Physical activity intervention (3 months)

- After we have measured how many steps you take on average per day, you will receive a personalised goal via email to increase your steps. After 3 weeks, we will check if you have met the goal, and based on that, you will receive a new goal. This will be repeated 4 times in total (at the start of the intervention, and after 3, 6, and 9 weeks).
- If you reach your goal, you will receive a new one. If you do not reach the goal, we will try to motivate you to achieve it in the next period.
- It is important that you connect the sport watch to your smartphone weekly, so your data is automatically sent to the research team. We will explain how to do this during study visit 1.
- In every email we send you, you will find a link to a video with tips on how to increase your daily steps.
- After the study, you may keep the sport watch.

Study visit 2 (after the physical activity intervention)

- During the second study visit, we will repeat the same measurements as during the first visit. This will also take approximately 1.5 hours.
- If you are selected to answer a few questions at different times throughout the day about how you feel at that moment, you will again receive 8 notifications per day for 7 days after study visit 2 to indicate how you feel.

Follow-up (3 months)

- After the second study visit, we will measure how many steps you take per day for another 3 months. All you need to do is connect the sports watch to your smartphone weekly.
- You will not receive any new goals from us.
- After the 3 months, you will receive a few questionnaires about your mental health and lifestyle via email. You will not need to come to the research centre anymore.

Important information for your study visit

- Please do **not drink alcohol** on the day of your study visit. Apart from that, you can eat and drink as you normally would.
- We kindly ask you to wear light clothing so the measurements can be carried out smoothly. If possible, try to wear similar clothing during both study visits.

What are the possible risks and discomforts of participating in the study?

The measurements and physical activity intervention in this study do not involve major risks, but some minor discomforts may occur. These include:

- The blood sample (2 small tubes, 15 ml in total) may cause slight irritation or bruising, and rarely an infection may occur. The needle prick may feel uncomfortable but will be done by an experienced nurse or doctor.
- Wearing the sports watch may cause light skin irritation at the wrist. This is completely normal, not dangerous, and temporary.
- A smaller group of participants will be asked to complete short questionnaires daily via their smartphone about how they feel physically and emotionally, which can sometimes be challenging as it interrupts their daily life. However, these questions are very short and need to be completed for just 7 consecutive days, both before and after the intervention. You do not need to respond if it would be unsafe to look at your phone (e.g., when driving). Negative emotions may be raised during the questionnaire, which could be uncomfortable. Participants selected for this will be chosen randomly, but you can choose not to participate without affecting the rest of your study involvement.
- During the physical activity intervention, you will be asked to increase your daily steps. You may experience mild muscle stiffness during the first few days, which is completely normal, not dangerous, and temporary.

You cannot participate in this study if you are pregnant, as it could affect your blood results. If you later discover that you were pregnant during your participation, you can inform the research team (IMRbluezone@uhasselt.be). In this case, your blood results will be removed. Participation in the study will not have any negative effects on your health or the health of your (unborn) child.

What are the benefits for me if I participate in the study?

- Insight into your physical health, mental health, and lifestyle: you will gain insights into your own health, such as your blood pressure and other important measurements. At the end of the study, you can choose to receive a comprehensive overview of all your personally measured results, including advice on how to improve your health or lifestyle where necessary.
- Personalised physical activity intervention: you will receive a customised physical activity intervention to help you increase your daily steps, which can improve your overall health and help you feel fitter.
- Contribution to scientific research: by participating, you will contribute to valuable scientific research. The findings can help improve health and lifestyle in the Maas-Rhine region and assist policymakers in making better decisions for the region.

What happens to all the data from my tests?

All data collected during your participation will be stored. All data will be stored in an encrypted format, ensuring they remain pseudonymous. This means that they cannot be directly linked to your identity

without access to a separate encryption key, which is managed solely by the authorised researcher (Dr. Ine Nieste). The coding will consist of a combination of letters and numbers (e.g., BZ-UHa-001).

All data collected during the study, including measurements taken during study visits, data from the sport watch, and information from the app for recording mood fluctuations, will be stored on secure data platforms. These platforms meet the stringent privacy and security standards set forth by European privacy legislation (the General Data Protection Regulation, or GDPR). Your data will be fully protected, and only the responsible researchers will have access to the encrypted data. After 25 years, all data will be permanently destroyed.

The blood samples collected during this study will be analysed in the laboratory of the University Hospital of Aachen (Laboratory Diagnostic Center of RWTH University Hospital Aachen). The study will examine various substances in the blood, such as sugar levels, fat levels, inflammatory markers, and kidney function. These substances, known as biomarkers, provide insight into your physical health. The blood samples will be registered and stored according to the guidelines of the Limburg University Biobank (UbiLim) and Aachen (RWTH Centralized Biomaterial Bank, RWTH cBMB).

After the analyses, the remaining blood samples and their associated coded information will be stored for 10 years at the Biobank of the University Hospital of Aachen (RWTH cBMB). These samples may be made available to researchers for medical advancements, but only with approval from a scientific and ethical committee. You will not be notified or informed about this, but general information on how samples are being used in other projects will be made available on our website (www.IMRbluezone.eu), along with the overall study results once they become available. Research using blood samples can help improve understanding of how diseases develop and how they can be prevented. It is possible that your blood samples may be used for genetic research. Additionally, they may contribute to research on chronic conditions such as diabetes and cardiovascular diseases. Your blood samples will be used solely for scientific research and will not be sold. If you agree to this, you do not need to take any further action. If you do not wish for your samples to be used this way, you can indicate this on the consent form.

Confidentiality

The research team guarantees that both your personal data and all research results derived from this study will be processed confidentially and encoded, in compliance with the General Data Protection Regulation (GDPR, law of 30/07/2018). The research findings from this study will be shared with policymakers in the Maas-Rhine region and presented at conferences and published in scientific journals, without revealing your identity.

If mildly abnormal results are found in the mental health questionnaire or in the blood results as part of this study (see details in part III of this consent form), we will only share these with your general practitioner if you give your consent on page 11. We strongly recommend giving consent to share this information so that your general practitioner can properly monitor your health. If necessary, the researcher and/or your general practitioner will provide advice on possible next steps.

If significantly abnormal blood results are found, we are legally required under Belgian law to share this information with your general practitioner (Belgian Law of 7 May 2004 on Experiments on the Human Person). Page 14 explains what we consider to be 'mildly' and 'significantly' abnormal.

Can my participation in the study end early?

Your participation in the study is entirely voluntary. If you choose not to participate, you do not need to sign anything or provide a reason, and there will be no consequences. If you decide to participate, you are free to stop at any time, even during the study. You do not need to provide a reason for stopping, but it may help the researchers understand if you discontinue because the physical activity programme is too difficult. Stopping early will not pose any health risks.

The researcher can also decide to stop the study, for example, if unexpected issues arise (such as a serious illness) or if you do not follow the participation requirements. If you agree to have your blood samples stored for future research now, you can withdraw this consent at any time. You can contact the lead researcher (Dr. Ine Nieste) to revoke your consent, and all remaining blood samples will be destroyed.

Use of the sports watch

As part of the intervention, you will receive a sports watch, which you can keep after the study concludes. In return, you are expected to regularly sync the watch with your smartphone via the study account set up for you during the first study visit.

If, during the exercise programme or follow-up period, you decide not to share your activity data with the research team anymore, you must return the watch and will not be allowed to keep it. Additionally, if it is found that you have stopped syncing the watch without a valid reason and have been reminded multiple times, you will be asked to return the watch.

In the event of a defect, the sports watch will be replaced once during the study, provided that you return the defective one. If the watch is lost, it will not be replaced, and your participation in the study will end.

If you participate in this study, we ask that you:

- Fully cooperate to ensure the study runs smoothly.
- Do not withhold any information regarding your health, medications, or symptoms you may be experiencing.
- Do not participate in another clinical study involving an experimental treatment—whether it be a study drug, medical device, or procedure—while participating in the current study.

You also need to know that:

It is recommended that you inform your general practitioner about your participation in this study. You and your general practitioner will be notified if any mildly abnormal results arise from the tests, provided you give your consent. Significantly abnormal blood results will always be shared, as described on page 8 in the confidentiality paragraph.

Approval of this study

This study has been approved by the Medical Ethics Committees of Hasselt University and the University of Liège. After reading this information, you may contact us for any questions or further details. Once you have had sufficient time to consider, you will be asked to decide whether to participate in this study. If you agree to participate, you will need to sign the consent form. You will receive a copy of this information and the signed consent form.

Contact

If you require additional information, or in case of any issues or concerns, you may contact the researcher (Ine Nieste) or a member of her study team (telephone number +32(0)11 26 93 50, email address IMRbluezone@uhasselt.be).

Title of the study: **Health and Lifestyle in the Maas-Rhine Region and the effects of a physical activity program: the Interreg Maas-Rhine Blue Zone project.**

II Informed consent

Participant

- I declare that I have been informed about the nature, purpose, duration, potential benefits, and risks of the study and that I understand what is expected of me. I have read the information document and its appendices.
- I have had sufficient time to consider my participation and to discuss it with a person of my choice, such as my general practitioner or a family member.
- I have had the opportunity to ask any questions that came to mind and have received clear answers to my questions.
- I understand that my participation in this study is voluntary and that I am free to withdraw at any time.
- I understand that I must return the sports watch if I stop sharing my activity data or if I fail to connect it without a valid reason, and I agree to this condition.
- I understand that data about me will be collected during my participation in this study and that the researcher and the sponsor will ensure the confidentiality of these data in accordance with Belgian legislation.
- I consent to the processing of my personal data according to the terms described in the section on confidentiality. I also give permission for the transfer and processing of my coded data by researchers (possibly in countries other than Belgium) collaborating on this study.
- I agree that the study data collected for this study may later be processed, provided that such processing remains limited to the context of this study for a better understanding of disease and its treatment.
- I have received a copy of the participant information sheet and the informed consent form.

Name and first name of participant:	
Date:	
Signature participant:	

- Complete as desired:
  - I agree that the blood samples collected during the study will be stored for 10 years in the Biobank of the University Hospital of Aachen (RWTH cBMB) and may be used for future research without requiring additional consent, provided that such research is approved by the appropriate authorities:

    ☐ yes ☐ no. This does not affect my participation in the study. If you do not agree, the blood samples will be destroyed immediately after analysis for the current study.
  - If I wish to receive my personal study results after the study is completed (i.e. after the follow-up period), I agree that these results are also shared directly with my general practitioner if one or more mildly abnormal results are found (as defined in Part III of this consent form):

    ☐ yes ☐ no. This does not affect my participation in the study.
  - I agree that incidental findings (as described in Part III of this consent form) that may be relevant to my health or the health of my blood relatives will be shared with me (directly or through my treating physician):

    ☐ yes ☐ no. This decision does not affect my participation in the study.
  - If I am selected to indicate how I feel physically and emotionally throughout the day via an app on my smartphone for 7 days before and after the physical activity intervention, I confirm that I have been fully informed about this and agree to participate:

    ☐ yes ☐ no ☐ not applicable. This does not affect my participation in the study.
  - I agree to be contacted again in 5 years by phone for follow-up questions related to this project, provided that the follow-up study has been approved by the relevant authorities.

    ☐ yes ☐ no.

Name and first name of participant:	
Date:	
Signature participant:	

Researcher

I, **Ine Nieste**, the undersigned researcher, declare that I have provided the necessary information regarding this study orally and have also provided the participant with a copy of the information document. I confirm that no pressure has been exerted on the participant to obtain their consent for participation in the study, and I am willing to answer any additional questions. I confirm that I operate in accordance with the ethical principles outlined in the latest version of the "Declaration of Helsinki," "Good Clinical Practice," and the Belgian law of 7 May 2004 on experiments involving human subjects.

Name, first name, date and signature of the representative of the researcher	Name, first name, date and signature of de researcher

Title of the study: **Health and Lifestyle in the Maas-Rhine Region and the effects of a physical activity program: the Interreg Maas-Rhine Blue Zone project.**

III Additional information

1: Additional information about the organisation of the study

Here you will find detailed information about the course of the study, the planned study visits, and the specific measurements that will take place during the study. Previously, you completed a secure digital questionnaire about your personal details, which was used to determine whether you were eligible to participate in the study. If you have been selected, an appointment for the first study visit has been scheduled. It is possible that you may not be able to start immediately, as participants will be enrolled throughout the year. If this is the case, we will discuss together what is most suitable for you. This is important to ensure that participants start in every season, so we can be certain that the effects of the physical activity program are not caused by seasonal influences.

Each study visit will last approximately 1.5 hours. During Study Visit 1, upon arrival at the research centre, you will watch a video explaining the entire study. You may watch this video as many times as you like. Afterwards, you will have the opportunity to ask questions and, if you decide to participate, you will sign the consent form together with the researcher.

Measurements

After signing the consent form, you will complete several **questionnaires** on a computer, which will take approximately 45 minutes. The questionnaires will cover the following topics:

- **Additional personal information:** family situation, religious beliefs, whether or not feeling that you belong to a minority, employment status, motivation for study participation, medical background (health issues, experienced burden, and medication use), health literacy, and contact details of your general practitioner
- **Mental health**: symptoms of anxiety and depression.
- **Health-related quality of life.**
- **Lifestyle**: physical activity, eating habits, sleep quality, stress levels, social contacts, and the use of harmful substances such as alcohol and cigarettes.

Next, your **blood pressure, height, weight, hip, and waist circumference** will be measured. It is important to **dress lightly** so that you can keep your clothes on during the measurements without affecting the results. These measurements will take about 10 minutes. Afterward**, blood will be taken** in two small tubes by an experienced nurse or doctor (15ml in total). This will also take about 10 minutes. In your blood sample, we will measure your cholesterol, blood sugar, inflammation markers, and kidney function.

Based on these results, we calculate the percentage risk that you may develop a serious heart or blood vessel condition, such as a heart attack or stroke, in the next 10 years. This calculation takes into account your age, sex, smoking status, and whether you have diabetes or an existing heart or vascular condition. It is important to know that this is only an estimate of your risk. It does not take into account all personal factors, such as your lifestyle, family history, or other health conditions. Therefore, it is not an exact prediction, but rather a tool to help you better understand your heart health.

Results of the measurements

During the second study visit, you will be asked whether you would like to receive your personal study results. If you choose to do so, your results will be sent to you by email after the 3-month follow-up period, along with an explanation and general advice. We strongly recommend that you discuss these results with your general practitioner, who is best positioned to interpret them in the context of your overall health. If you agree on page 11, we will also share your results with your general practitioner in case of one or more mildly abnormal findings, based on the following criteria:

- **Blood sugar:**
    - **For people without a diabetes diagnosis:** HbA1c values between 5.7-7%, which indicate prediabetes, a risk factor for developing type 2 diabetes. Within this range, there are generally no immediate health risks, but long-term risks do exist, making medical follow-up advisable.
    - **For people with a diabetes diagnosis:** HbA1c values between 7-8.5%.
- **Lipid concentrations**: Total cholesterol levels higher than 190 mg/dL, which is an important risk factor for the development of cardiovascular diseases.
- **Kidney function**: Creatinine levels between 1.3 - 1.9mg/dL for men and between 1.1 - 1.6 mg/dL for women, which may indicate reduced kidney function and requires further follow-up.
- **Mental health**: A score of 11/21 or higher on one of the subscales of the questionnaire on symptoms of anxiety and depression. This may indicate symptoms that require further evaluation.

The following thresholds are considered significantly abnormal and will always be shared with you and your general practitioner, as they represent a serious health risk:

- **Blood pressure:** If your upper (systolic) value is 180 mm Hg or higher and/or the lower (diastolic) value is 120 mm Hg or higher, this may pose a possible acute health risk and requires medical follow-up. This will be shared with your general practitioner immediately after your study visit.
- **Blood sugar:**
    - **For people without a diabetes diagnosis:** HbA1c values higher than 7%, which indicates a diagnosis of diabetes and may be associated with increased short-term health risks and requires medical follow-up.

  - **For people with a diabetes diagnosis:** HbA1c values higher than 8.5% indicate a severely dysregulated diabetes. This may be associated with increased short-term health risks and requires medical follow-up.
- **Kidney function:** Creatinine values above 1.9mg/dL for men and above 1.6mg/dL for women, which may suggest acute kidney failure and requires medical follow-up.

The blood results will be analysed as soon as possible and shared with you and your general practitioner no later than 4 months after collection.

Sports watch

At the end of Study Visit 1, you will receive the **sports watch** and assistance with pairing it to your smartphone. Once you wear the sports watch, your physical activity and data will be transmitted to the research team. It is important that you maintain your usual activity level, as your personal physical activity intervention will be based on what you normally do. You do not need to be more or less active; **simply continue doing what you normally do**. The following data will be transmitted to the research team:

- Steps per day
- Time spent sitting and physical activity of low, moderate, and high intensity.
- Exercise data: you can start an exercise session on the sports watch. The type of sport, duration, and your heart rate will then be transmitted.

To get the most accurate picture of your activity level, it is important to wear the watch daily as much as possible. You can also keep it on while showering, swimming, and sleeping. If you go to the sauna, it is better to remove the watch. If you experience any discomfort while sleeping, you can remove the watch. If you do not experience discomfort while sleeping, you may keep the watch on, as it provides us with valuable information on your sleeping times. If you develop skin irritation on the wrist where you wear the watch, it is better to regularly switch wrists to prevent discomfort. You should pair the sports watch with your smartphone approximately once a week. If you forget to do this once and do it a little later, it is not a problem. You will receive instructions on how to do this during Study Visit 1. It is important to know that no information about your health condition is measured or transmitted. If you experience any discomfort or do not feel well, please contact your general practitioner.

Changes in your physical and emotional well-being throughout the day

If you are selected and agree to answer some questions throughout the day about how you feel physically and mentally, you will receive instructions on how to use the app (M-Path). You will then receive 8 notifications per day on your smartphone for 7 days to indicate how you feel.

Physical activity intervention

After the first study visit, the physical activity measurements will begin. You will receive a personal step goal and further information via email about when the intervention will start for you. The program will last a total of 3 months. The **goal of the intervention** is to motivate you to take more steps daily. At the

end of the intervention, you will be invited for Study Visit 2, during which the same measurements as in Study Visit 1 will be repeated.

Follow-up

After Study Visit 2, your sports watch will remain connected to the research platform for an additional 3 months so that we can monitor how active you remain after the physical activity program. It is important to **continue wearing the watch and regularly pair it with your smartphone**. During this period, you will not receive new goals to increase your daily steps. After 3 months, the connection between the watch and the research platform will be disconnected, and the research team will no longer have access to your data. You can then create a personal account if you wish. If you need assistance with this, you can contact the research team. After these 3 months, you will receive several questionnaires via email (the same ones as during the study visits). Once you have completed them, your participation in the study will be finished.

Practical information

For the two study visits, you will need to come to the research centre at a time of your choosing. The addresses are as follows:

- The address for carticipants from Belgian Limburg:
  Polikliniek Solidaris Genk, Winterslagstraat 55, bus 2.1, 3600 Genk
- The address for participants from Liège will be communicated personally.

2: Additional information on the protection and rights of participants in a clinical study

Ethical committees

This study was evaluated by two independent ethical committees (the Medical Ethics Committee of Hasselt University and the University of Liège), which provided a favourable opinion. The ethical committees are responsible for protecting individuals participating in clinical studies. They ensure that your rights as a patient and study participant are respected, that, based on current knowledge, the balance between risks and benefits is favourable for participants, and that the study is scientifically relevant and ethically justified. The ethical committees provide their advice in accordance with the Belgian law of 7 May 2004. You should not consider the positive opinion of the Ethical Committees as an encouragement to participate in this study.

Voluntary participation

Feel free to ask any questions that come to mind before signing. Take the time to discuss it with a trusted person if you wish. You have the right not to participate in this study or to stop your participation at any time, without needing to provide a reason, even if you previously agreed to participate. Your decision will in no way affect your relationship with the researcher.

If you decide to withdraw your consent, you can simply notify the study team by sending an email to: IMRbluezone@uhasselt.be. No new data will be collected or shared after your withdrawal. However,

any data collected before your withdrawal will be retained in coded form to ensure the scientific validity of the study, in accordance with European data protection legislation (GDPR).

If you agree to participate in this study, you will sign the consent form. The researcher will also sign the form, confirming that they have provided you with the necessary information about the study. You will receive your own copy. It is recommended that you inform the researcher if you decide to stop your participation in the study.

Costs related to your participation

If you decide to participate in this study, there will be no additional costs for you or your insurance company. The visits and procedures related to this study, as described in the study process, will be paid for by the sponsor.

Furthermore, all participants will receive a free sports watch, valued at €160, to track their daily steps and assist them in meeting their physical activity goals. You may keep the sports watch after the study ends.

Confidentiality guarantee

- Your participation in the study means that you agree for the researcher to collect data about you and for the study sponsor to use this data for research and in the context of scientific and medical publications.
- Your data will be processed in accordance with the European General Data Protection Regulation (GDPR) and Belgian legislation on the protection of natural persons with regard to the processing of personal data. Hasselt University is the data controller for your data. The processing of your personal data is based on your explicit consent, which you provide by signing this information form and participating in the study.
- You have the right to ask the researcher what data has been collected about you and for what purpose in the context of the study. You have the right to access this data and request corrections if any of it is inaccurate.
- The researcher is obliged to treat the collected data confidentially. This means they will not disclose your name, e.g., in publications or at conferences, and they will pseudonymise your data (replace your identity with an identification code in the study) before passing it on to the database manager.
- The researcher and their team will be the only individuals who can link the transferred data to your medical record throughout the study.
- The transferred personal data will not include a combination of elements that could identify you.
- The designated data manager appointed by the sponsor will not be able to identify you based on the transferred data. This person is responsible for collecting the data gathered by all researchers involved in the study and for processing and safeguarding this data in accordance with Belgian privacy laws.
- For quality control purposes of the study, your medical record may be reviewed by individuals bound by professional confidentiality, such as representatives of the ethical committees, the

study sponsor, or an external audit firm. This can only occur under strict conditions, under the responsibility of the researcher, and under their or their team's supervision.

- The (pseudonymised) research data may be transferred to Belgian or other regulatory bodies, to the involved ethical committees, and to other doctors or institutions collaborating with the sponsor.
- It may also be shared with other sites of the sponsor in the Belgium and in other countries where data protection standards may differ or be less strict. This will always occur in pseudonymised form as explained above.
- Your consent to participate in this study also means that you agree for your coded medical data to be used for the purposes described in this information sheet and transferred to the above-mentioned individuals and/or institutions.
- The sponsor will use the collected data for the study you are participating in.
- If you withdraw your consent to participate in the study, the pseudonymised data already collected before your withdrawal will be retained. This ensures the validity of the study. No new data will be provided to the sponsor.

If you have any questions about how we use your data, you can always contact the researchers via the mail address IMRbluezone@uhasselt.be. You can also contact our Data Protection Officer (DPO) for questions or concerns about the processing of your personal data via the email address dpo@uhasselt.be.

If you have a complaint about the processing of your data, you can contact the Belgian supervisory authority responsible for ensuring compliance with the fundamental principles of data protection:
The Belgian supervisory authority is called:
Data Protection Authority (GBA)
Drukpersstraat 35,
1000 Brussels
Tel. +32 2 274 48 00
Email: contact(at)apd-gba.be
Website: www.gegevensbeschermingsautoriteit.be

Blood samples taken as part of this study

For the samples taken as part of this study, a coding procedure is also used, similar to the one used for your study data. The samples transferred to the sponsor are only identified by a code in the context of this clinical study. The sponsor is responsible for ensuring the traceability of your biological samples. The manager of these samples (RWTH Centralized Biomaterial Bank, RWTH cBMB, or the University Hospital Aachen) commits to using the samples solely as described in this section and to destroy them after the prescribed storage period. The biological material is considered a "donation," and you should be aware that, in principle, you will not receive any financial benefit (royalties) related to the development of new therapies resulting from the use of the biological material you have donated, which may have commercial value. If you withdraw your consent to participate in the study, you may request that any

unused portion of your sample(s) be destroyed or returned. To do this, please contact the researcher. The results obtained from your sample(s) before withdrawing your consent remain the property of the sponsor.

Within this field, there is continuous technical progress. Therefore, if you agree, we would like to store your biological samples for 10 years for future research. This research will remain within the context of the current clinical study and is focused on gaining a better understanding of the disease, its treatment, and the response to this treatment. Any research outside the context described in this document can only take place after approval by an ethics committee.

Incidental findings

A result that is found incidentally during the study, beyond the primary objectives, is referred to as an incidental finding. If this result could be important for your health or the health of your family members, the sponsor will inform the researcher. With your consent, the researcher will inform you and your treating physician about the results and their potential consequences. If necessary, the researcher and/or your treating physician will provide guidance on the steps you should take.

Insurance

Every participation in a study involves some level of risk, however small. The sponsor is responsible for any harm that the participant, or in the case of death, their beneficiaries, may suffer, which is directly or indirectly related to their participation in the study, even if there is no fault. You do not need to prove fault. The sponsor has taken out insurance for this liability. Therefore, we ask you to report any new health issues to the researcher. If the researcher believes that there may be a connection with the study (there is no connection with the study in the case of damage resulting from the natural course of your disease or known side effects of your standard treatment), they will inform the sponsor of the study, who will initiate the claims process with the insurance company. The insurance company may appoint an expert to assess the link between your new health issues and the study. In the case of disagreement with the researcher or the expert appointed by the insurance company, and whenever you find it necessary, you or your beneficiaries in case of death can directly sue the insurer in Belgium (Ethias, Flanders Office, Department 2154, Prins-Bisschopssingel 73, 3500 Hasselt, Tel. +32 (0) 1128 21 11; policy number 45.235.577). The law provides that the lawsuit can be filed either with the court where the damaging event occurred, or with the court of your place of residence, or with the court of the insurer's registered office.